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Contents

[1] Text with EEA relevance.

EN

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

The titles of all other acts are printed in bold type and preceded by an asterisk.

([1]) Text with EEA relevance.

Corrigenda

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2022/2343 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 November 2022

laying down management, conservation and control measures applicable in the Indian Ocean Tuna Commission (IOTC) Area of Competence, amending Council Regulations (EC) No 1936/2001, (EC) No 1984/2003 and (EC) No 520/2007

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee ([1]),

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

Whereas:

(1) The objective of the Common Fisheries Policy (CFP), as set out in Regulation (EU) No 1380/2013 of the European Parliament and of the Council ([3]), is to ensure the exploitation of marine biological resources in a way that contributes to long-term environmental, economic and social sustainability.

(2) The Union has, by means of Council Decision 98/392/EC ([4]), approved the United Nations Convention of 10 December 1982 on the Law of the Sea. By means of Council Decision 98/414/EC ([5]), the Union has approved the Agreement for the Implementation of that Convention relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, which contains principles and rules with regard to the conservation and management of the living resources of the sea. In the framework of its wider international obligations, the Union participates in efforts made in international waters to conserve fish stocks.

([1]) OJ C 341, 24.8.2021, p. 106.

([2]) Position of the European Parliament of 4 October 2022 (not yet published in the Official Journal) and decision of the Council of 24 October 2022.

([3]) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

([4]) Council Decision 98/392/EC of 23 March 1998 concerning the conclusion by the European Community of the United Nations Convention of 10 December 1982 on the Law of the Sea and the Agreement of 28 July 1994 relating to the implementation of Part XI thereof (OJ L 179, 23.6.1998, p. 1).

([5]) Council Decision 98/414/EC of 8 June 1998 on the ratification by the European Community of the Agreement for the implementing of the provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the conservation and management of straddling stocks and highly migratory fish stocks (OJ L 189, 3.7.1998, p. 14).

(3) Pursuant to Council Decision 95/399/EC ([6]), the Union is a contracting party to the Agreement for the establishment of the Indian Ocean Tuna Commission (IOTC).

(4) The IOTC adopts annual conservation and management measures (CMMs) by way of resolutions that are binding on contracting parties and on cooperating non-contracting parties to the IOTC, including on the Union. This Regulation implements resolutions of the IOTC, adopted between 2000 and 2021, except for measures which already form part of Union law.

(5) To ensure compliance with Regulation (EU) No 1380/2013, Union legislation has been adopted to establish a system of control, inspection and enforcement, which includes the fight against illegal, unreported and unregulated (IUU) fishing. In particular, Council Regulation (EC) No 1224/2009 ([7]) establishes a Union system for control, inspection and enforcement with a global and integrated approach so as to ensure compliance with all the rules of the CFP. Council Regulation (EC) No 1005/2008 ([8]) establishes a Community system to prevent, deter and eliminate IUU fishing. Those Regulations already include provisions covering a number of the measures laid down in IOTC resolutions. It is therefore not necessary to include those provisions in this Regulation.

(6) In accordance with Article 4 of Regulation (EU) 2019/473 of the European Parliament and of the Council ([9]), the European Fisheries Control Agency (EFCA) should, at the Commission's request, assist the Union and the Member States in their relations with third countries and regional international fisheries organisations of which the Union is a member. When needed for the implementation of Union obligations, EFCA should, at the Commission's request, coordinate control and inspection activities by Member States on the basis of international control and inspection programmes, which may include programmes implemented in IOTC CMMs, in accordance with Article 9 of Regulation (EU) 2019/473. EFCA may draw up, in concert with the Member States concerned, joint operational inspection and surveillance programmes for that purpose by establishing joint deployment plans. It is therefore appropriate to adopt provisions that include EFCA, when so designated by the Commission, as the body designated by the Commission that receives from Member States and transmits to the IOTC Secretariat information relating to control and inspection, such as at sea inspection reports and notifications of the control observers scheme.

(7) Taking into account the situation of fish stocks and the need to ensure effective control activities and a level-playing field for all operators in the IOTC area, and pursuant to Articles 28 and 29 of Regulation (EU) No 1380/2013, Union actions in international fisheries organisations are to be based on the best available scientific advice so as to ensure that fishery resources are managed in accordance with the objectives laid down in Article 2 of that Regulation, and the Union is to ensure that Union fishing activities outside Union waters are based on the same principles and standards as those applicable under Union law, including those relating to control of fishing activities, while promoting a level-playing field for Union operators vis-à-vis third-country operators.

(8) The IOTC Rules of Procedure establish English and French as its official languages. In order to permit operators to effectively carry out their activities falling within the scope of this Regulation and to avoid obstacles in communication with the competent port authorities, the transhipment declaration should be submitted in one of the official languages of the IOTC.

([6]) Council Decision 95/399/EC of 18 September 1995 on the accession of the Community to the Agreement for the establishment of the Indian Ocean Tuna Commission (OJ L 236, 5.10.1995, p. 24).

([7]) Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 (OJ L 343, 22.12.2009, p. 1).

([8]) Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 (OJ L 286, 29.10.2008, p. 1).

([9]) Regulation (EU) 2019/473 of the European Parliament and of the Council of 19 March 2019 on the European Fisheries Control Agency (OJ L 83, 25.3.2019, p. 18).

(9) When Member States and the Commission conduct research on certain species in the IOTC area, such as oceanic whitetip sharks, thresher sharks and blue sharks, they should also consider the impact of climate change on their abundance.

(10) 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 formal comments on 23 May 2022. Personal data processed in the framework of this Regulation is to be treated in accordance with the applicable provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council ([11]) and Regulation (EU) 2018/1725. In order to ensure effective enforcement of this Regulation, it is necessary to store those personal data for a period of 10 years. In the event that the personal data in question are needed in order to follow up an infringement, inspection or judicial or administrative procedures, it should be possible for those data to be stored for a period exceeding 10 years, but no longer than 20 years.

(11) In order to swiftly implement into Union law future IOTC resolutions amending or supplementing the ones established in this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending provisions concerning the use of non-entangling and biodegradable fish aggregating devices (FADs), ports designated under the IOTC rules, information per vessel for the list of active vessels for tuna and swordfish, the percentage of observer coverage and field samplers coverage for artisanal fisheries, conditions of chartering, the percentage of inspections for port landings, reporting deadlines and Annexes 1 to 10 to this Regulation that cover IOTC requirements for catch reporting, birds mitigation measures, data collections and FADs, chartering requirements, transhipment declaration and certain bigeye tuna statistical programme documents, as well as references to IOTC conservation and management measures that relate to principles for design and deployment of FADs to reduce entanglement, FAD reporting, marking and identification of vessels, IUU reporting documents, bigeye tuna statistical programme documents, port state entry notifications, minimum standard port Member State inspection procedures, reporting forms for infringements and catch and fishing measures reporting templates. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([12]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(12) As this Regulation provides a new and comprehensive set of rules, the provisions concerning IOTC CMMs laid down in Council Regulations (EC) No 1936/2001 ([13]), (EC) No 1984/2003 ([14]) and (EC) No 520/2007 ([15]) should be deleted. Those Regulations should therefore be amended accordingly,

([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) 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).

([12]) OJ L 123, 12.5.2016, p. 1.

([13]) Council Regulation (EC) No 1936/2001 of 27 September 2001 laying down control measures applicable to fishing for certain stocks of highly migratory fish (OJ L 263, 3.10.2001, p. 1).

([14]) Council Regulation (EC) No 1984/2003 of 8 April 2003 introducing a system for the statistical monitoring of trade in bluefin tuna, swordfish and bigeye tuna within the Community (OJ L 295, 13.11.2003, p. 1).

([15]) Council Regulation (EC) No 520/2007 of 7 May 2007 laying down technical measures for the conservation of certain stocks of highly migratory species and repealing Regulation (EC) No 973/2001 (OJ L 123, 12.5.2007, p. 3).

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation implements into Union law management, conservation and control measures established by the Indian Ocean Tuna Commission (IOTC) that are binding on the Union.

Article 2

Scope

This Regulation shall apply to:

(a) Union fishing vessels which operate in the Area;

(b) Union fishing vessels in the case of transhipments and landings of IOTC species outside the Area; and

(c) third-country fishing vessels making use of ports in Member States and which carry IOTC species or fishery products originating from such species.

Article 3

Definitions

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

(1) 'the Agreement' means the Agreement for the establishment of the Indian Ocean Tuna Commission;

(2) 'the Area' means those parts of the Indian Ocean as defined in Article II of and Annex A to the Agreement;

(3) 'Union fishing vessel' means any vessel of any size flying the flag of a Member State, equipped for commercial exploitation of marine biological resources, including support vessels, fish processing vessels, vessels engaged in transhipment and carrier vessels equipped for the transportation of fishery products, except container vessels;

(4) 'IOTC species' means tuna and tuna-like species and sharks listed in Annex B to the Agreement, and other species caught in association with those species;

(5) 'contracting parties and cooperating non-contracting parties' or 'CPCs' means contracting parties to the Agreement or cooperating non-contracting parties;

(6) 'conservation and management measure' or 'CMM' means an applicable conservation and management measure adopted by the IOTC pursuant to Articles V(2)(c) and IX(1) of the Agreement;

(7) 'unfit for human consumption' means a fish that is meshed or crushed in the purse seine, or is damaged due to depredation, or has died and spoiled in the net where a gear failure has prevented both the normal retrieval of the net and catch, and efforts to release the fish alive without including a fish that is considered undesirable in terms of size, marketability or species composition, or a fish that is spoiled or contaminated as the result of an act or omission of the crew of the Union fishing vessel;

(8) 'fish aggregating device' or 'FAD' means a permanent, semi-permanent or temporary object, structure or device of any material, man-made or natural, which is deployed and/or tracked for the purpose of aggregating target tuna species for consequent capture;

(9) 'drifting FAD' or 'DFAD' means a FAD not tethered to the bottom of the ocean;

(10) 'anchored FAD' or 'AFAD' means a FAD tethered to the bottom of the ocean;

(11) 'data buoys' means floating devices, either drifting or anchored, that are deployed by governmental or recognised scientific organisations or entities for the purpose of electronically collecting and measuring environmental data, and not for the purpose of fishing activities;

(12) 'IOTC transhipment declaration' means the document set out in Annex 7;

(13) 'IMO number' means a 7-digit number, which is assigned to a vessel under the authority of the International Maritime Organization (IMO);

(14) 'chartering' means an agreement or an arrangement by which a fishing vessel flying the flag of a CPC is contracted for a defined period of time by an operator in another CPC without a change of flag; the 'chartering CPC' refers to the CPC that holds the quota allocation or fishing possibilities and the 'flag CPC' refers to the CPC in which the chartered vessel is registered;

(15) 'carrier vessel' means a support vessel engaged in transhipment and receiving IOTC species from another vessel;

(16) 'e-Port State Measures application' or 'e-PSM application' means the web-based application designed and developed to facilitate and assist a CPC to implement the IOTC resolutions related to port State measures;

(17) 'illegal, unreported and unregulated fishing' or 'IUU fishing' means fishing activities as defined in Article 2, points (1) to (4), of Regulation (EC) No 1005/2008.

CHAPTER II

MANAGEMENT AND CONSERVATION

SECTION 1

Tropical Tunas

Article 4

Discard ban

1. Union purse seine vessels shall retain on board and land all catches of tropical tunas (bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*) and skipjack tuna (*Katsuwonus pelamis*)), except where the master of the vessel determines that:

(a) fish are unfit for human consumption, or

(b) there is insufficient storage capacity to accommodate tropical tuna and the non-targeted species caught during the final set of a trip.

2. Fish referred to in paragraph 1, point (b), may only be discarded if the master and crew attempt to release the tropical tuna and the non-targeted species alive as soon as possible, while taking into consideration the safety of the crew, and no further fishing is undertaken after the discard until the tropical tuna and the non-targeted species on board the vessel have been landed or transhipped.

3. The master of a Union fishing vessel shall record the exceptions referred to in paragraph 1, points (a) and (b), in the relevant logbook, including estimated tonnage and species composition of discarded fish, and estimated tonnage and species composition of retained fish from that set.

4. For the purposes of this Article, non-targeted species includes non-targeted tuna species, as well as rainbow runner (*Elagatis bipinnulata*), dolphinfish (*Coryphaena hippurus*), triggerfish (family *Balistidae*), billfish (families *Xyphiidae* and *Istiophoridae*), wahoo (*Acanthocybium solandri*) and barracuda (family *Sphyraenidae*).

Article 5

Prohibition of fishing on data buoys

1. Union fishing vessels shall not intentionally fish within one nautical mile of a data buoy or interact with a data buoy in the Area, in particular by:

(a) encircling the buoy with fishing gear;

(b) tying up to or attaching the vessel, or any fishing gear, part or portion of the vessel, to a data buoy or its mooring; or

(c) cutting a data buoy anchor line.

2. By way of derogation from paragraph 1, Union fishing vessels may operate within one nautical mile of data buoys provided that they operate under scientific research programmes of Member States notified to the IOTC and they do not interact with those data buoys.

3. Union fishing vessels shall not take on board a data buoy in the Area, unless the owner responsible for that buoy has explicitly authorised or requested them to do so.

4. Union fishing vessels operating in the Area shall keep watch for moored data buoys at sea and shall take all reasonable measures to avoid fishing gear entanglement or directly interacting in any way with those data buoys. When a Union fishing vessel's gear becomes entangled with a data buoy, it shall remove the entangled fishing gear with as little damage to the data buoy as possible.

5. Union fishing vessels shall report to their flag Member States any data buoy that they have observed to be damaged or otherwise inoperable, along with the details of observation, the buoy's location, and any discernible identifying information on it. Member States shall send such reports, and information on the location of data buoys assets that they have deployed throughout the Area to the Commission, in accordance with Article 51(5).

SECTION 2

Billfishes

Article 6

Billfishes

1. Union fishing vessels shall not retain on board, tranship, or land, any specimens of striped marlin (*Tetrapturus audax*), black marlin (*Istiompax indica*), blue marlin (*Makaira nigricans*) or Indo-pacific sailfish (*Istiophorus platypterus*) with a lower jaw fork length of less than 60 cm. If they catch such fish, they shall return them immediately to the sea, in a manner that maximises post-release survival potential without compromising the safety of the crew.

2. Union fishing vessels catching striped marlin, black marlin, blue marlin or Indo-pacific sailfish shall record the relevant catch and effort data in accordance with Annex 1.

3. Member States shall implement a data collection programme to ensure accurate reporting of striped marlin, black marlin, blue marlin or Indo-pacific sailfish catches in accordance with Article 51(1).

4. Member States shall report on actions taken to monitor catches and to manage fisheries for the sustainable exploitation and conservation of striped marlin, black marlin, blue marlin and Indo-pacific sailfish in their national scientific report in accordance with Article 51(6).

SECTION 3

Blue Sharks

Article 7

Blue sharks

1. Catches of blue shark (*Prionace glauca*) by Union fishing vessels shall be recorded in the logbook in accordance with Article 14 of Regulation (EC) No 1224/2009.

2. Member States shall implement data collection programmes to ensure improved reporting of accurate blue shark catch, effort, size and discard data. Member States shall report data on catches of blue sharks in accordance with Article 51(1).

3. Member States shall include in their implementation report information on the actions taken to monitor catches of blue sharks in accordance with Article 51(5).

4. Member States are encouraged to undertake scientific research on blue shark that would provide information on key biological, ecological, behavioural characteristics, life-history, migrations, post-release survival and guidelines for safe release and identification of nursery grounds, as well as improving fishing practices. Such information shall be included in the reports that are sent to the Commission in accordance with Article 51(6).

SECTION 4

Fishing using aircraft, FADs and artificial lights

Article 8

Prohibition of the use of aircraft to catch fish

1. Union fishing vessels, including support and supply vessels, shall not use aircraft or unmanned aerial vehicles as fishing aids. Any occurrence of a fishing operation undertaken in the Area with the aid of aircraft or an unmanned aerial vehicle shall be immediately reported to the flag Member State, the Commission or a body designated by it. The Commission, or a body designated by it, shall inform the IOTC Secretariat thereof without delay.

2. Aircraft and unmanned aerial vehicles may be used for scientific, monitoring, control and surveillance purposes.

Article 9

Fish aggregating devices

1. Union fishing vessels shall record fishing activities in association with drifting FADs and anchored FADs, separately, using the specific data elements set out in Annex 2. Member States shall send that information to the Commission in accordance with Article 51.

2. Daily information on all active FADs shall be transmitted to the Commission containing the following information: date, instrumented buoy identification and assigned vessel and daily position, compiled at monthly intervals and submitted not earlier than 60 days but no later than 90 days after the monthly compilation of the information concerned. The Commission shall send that information to the IOTC Secretariat.

3. Member States shall draw up national management plans for the use of drifting FADs by their purse seine vessels. Those management plans shall:

(a) as a minimum follow the guidelines set out in Annex II to CMM 19/02;

(b) include initiatives or surveys to investigate, and to the extent possible, minimise the capture of small bigeye and yellowfin tuna and non-target species associated with FADs; and

(c) include guidelines to prevent, to the extent possible, the loss or abandonment of FADs.

4. No later than 75 days before the IOTC annual meeting, Member States shall submit to the Commission, in accordance with Article 51(5), a report on the progress of the management plans of FADs, including reviews of the initially submitted management plans and reviews of the application of the principles of Annex V to CMM 19/02. The Commission shall send that information to the IOTC Secretariat no later than 60 days before the IOTC annual meeting.

Article 10

Non-entangling and biodegradable FADs

1. Union fishing vessels shall use non-entangling designs and materials for the construction of FADs ensuring that the surface structure of the FAD is not covered or is covered only with non-meshed material. If a sub-surface component is used, it shall not be made from netting but from non-meshed materials, such as ropes or canvas sheets.

2. Union fishing vessels shall endeavour to transition to the use of biodegradable FADs in all circumstances except for materials used for the instrumented buoys.

3. Operators shall endeavour to conduct trials using biodegradable materials to facilitate the transition to the use of only biodegradable material for drifting FADs construction by their fleets.

Article 11

Prohibition of the use of artificial lights to attract fish

1. Union fishing vessels shall not use, install or operate surface or submerged artificial lights for the purpose of aggregating tuna and tuna-like species beyond territorial waters.

2. The use of lights on drifting FADs is prohibited.

3. Where Union fishing vessels encounter drifting FADs equipped with artificial lights in the Area, they shall immediately remove them and bring them back to port.

4. Union fishing vessels shall not conduct fishing activities around or near any vessel or drifting FAD equipped with artificial lights for the purpose of attracting tuna and tuna-like species in the Area.

5. Navigation lights and lights necessary to ensure safe working conditions shall not be subject to the prohibition laid down in paragraph 1.

SECTION 5

Transhipments in port

Article 12

Transhipment

All transhipment operations of IOTC species shall take place in ports designated in accordance with Article 5 of Regulation (EC) No 1005/2008, or in ports designated and publicised for that purpose by a CPC and communicated to the IOTC Secretariat.

Article 13

Transhipment operations

1. Transhipment operations in port may only be undertaken in accordance with the following procedure:

(a) prior to transhipping, the master of a Union fishing vessel shall notify the following information to the port state authorities, at least 48 hours in advance:

— the name of the fishing vessel and its number in the IOTC record of fishing vessels;

— the name of the carrier vessel, and the product to be transhipped;

— the tonnage by product to be transhipped;

— the date and location of transhipment;

— the major fishing grounds of the tuna and tuna-like species and sharks catches;

(b) the master of a Union fishing vessel shall record and transmit by electronic means a transhipment declaration in accordance with Article 22 of Regulation (EC) No 1224/2009.

2. No later than 15 days after the transhipment, the master of a Union fishing vessel concerned shall complete the IOTC transhipment declaration and transmit it to its flag Member State in one of the official languages of the IOTC, along with the vessel's number in the IOTC record of fishing vessels. The master of a Union carrier vessel shall also, within 24 hours after the transhipment, complete and transmit to the competent port state authorities the IOTC transhipment declaration in one of the official languages of the IOTC.

Article 14

Landing of transhipped catches by Union carrier vessels

1. By way of derogation from Article 17(1) of Regulation (EC) No 1224/2009, the period for prior notification shall be at least 48 hours before the estimated time of arrival at the port.

2. Member States where transhipped catches are landed shall take the appropriate measures to verify the accuracy of the information received and shall cooperate with the flag Member State of the carrier vessel, the port State where the transhipment took place and the flag states of the catching fishing vessels involved to ensure that landings are consistent with the catch amount reported for each fishing vessel. That verification shall be carried out in such a way that the carrier vessel suffers the minimum interference and inconvenience and that degradation of the fish is avoided.

3. The master of a Union carrier vessel landing in a third country shall, at least 48 hours before entry into port and in addition to the prior notification referred to in paragraph 1, give prior notification in accordance with the national legislation of the third country in whose port the vessel intends to land transhipped catches. The master shall also send the IOTC transhipment declaration in one of the official languages of the IOTC to the competent authorities of the State in which transhipped catches are to be landed and shall not land before being authorised to do so.

4. Where landings take place in a third country, the master of the carrier vessel shall cooperate with the port state authorities.

5. Flag Member States of the Union fishing vessels shall include details on the transhipments by its vessels in their reports in accordance with Article 51(5).

CHAPTER III

PROTECTION OF CERTAIN MARINE SPECIES

SECTION 1

Elasmobranchs

Article 15

General conservation measures for sharks

1. Union fishing vessels shall take all reasonable steps to apply the IOTC identification guides and handling practices.

2. Union fishing vessels shall, to the extent possible, promptly release unharmed unwanted shark species caught alive on board of vessels, with the exception of blue sharks. Such catches shall be reported in the logbook in accordance with Article 14 of Regulation (EC) No 1224/2009, including the status on release (dead or alive).

3. Member States shall report data on all catches of sharks, including all available historical data, estimates and life status of discards and release (dead or alive) and size frequencies of sharks caught by their fishing vessels to the Commission, in accordance with Article 51(1).

Article 16

Oceanic whitetip sharks

1. Union fishing vessels shall not retain on board, tranship, land, store, sell or offer for sale any part or whole carcass of oceanic whitetip sharks (*Carcharhinus longimanus*).

2. By way of derogation from paragraph 1, scientific observers shall be allowed to collect biological samples from oceanic whitetip sharks taken in the Area that are dead at haul back, provided that the samples are a part of a research project approved by the IOTC Scientific Committee or the IOTC Working Party on Ecosystems and Bycatch.

3. Where possible, Member States and the Commission shall endeavour to conduct research on oceanic whitetip sharks taken in the Area, in order to identify potential nursery areas.

Article 17

Thresher sharks

1. Union fishing vessels shall not retain on board, tranship, land, store, sell or offer for sale any part or whole carcass of thresher sharks of all species of the family *Alopiidae*.

2. By way of derogation from paragraph 1, scientific observers shall be allowed to collect biological samples from thresher sharks taken in the Area that are dead at haul back, provided that the samples are a part of a research project approved by the IOTC Scientific Committee or the IOTC Working Party on Ecosystems and Bycatch.

3. Recreational and sport fishers shall release all thresher sharks alive. Under no circumstances shall they retain them on board, tranship, land, store, sell or offer them for sale. Member States shall ensure that recreational and sport fishers carrying out fishing with risk of catching thresher sharks are equipped with instruments suitable for releasing the animals alive.

4. Member States and the Commission shall endeavour to conduct research on thresher sharks taken in the Area, in order to identify potential nursery areas.

Article 18

Mobulid rays

1. Union fishing vessels shall be prohibited from intentionally setting any gear type around a mobulid ray (species of the genus *Mobula*) if the animal is sighted prior to commencement of the set.

2. Union fishing vessels shall not retain on board, tranship, land, store, sell or offer for sale any part or whole carcass of a mobulid ray.

3. Union fishing vessels shall promptly release alive and unharmed, to the extent practicable, mobulid rays caught unintentionally as soon as they are seen in the net, on the hook, or on the deck, in a manner that will result in the least possible harm to the individual rays captured. They shall take all reasonable steps to apply handling procedures for mobulid rays, while taking into consideration the safety of the crew.

4. Notwithstanding paragraph 3, where a Union purse seine vessel unintentionally catches and freezes a mobulid ray in the course of its operations, it shall surrender the whole mobulid ray to the responsible governmental authorities, or other competent authority, or discard it at the point of landing. Mobulid rays surrendered in that manner may not be sold or bartered but may be donated for the purposes of domestic human consumption.

5. Union fishing vessels shall use proper mitigation, identification, handling and releasing techniques and keep on board all necessary equipment to release mobulid rays.

Article 19

Whale sharks

1. Union fishing vessels shall be prohibited from intentionally setting a purse seine net around a whale shark (*Rhincodon typus*) in the Area, if it is sighted prior to the commencement of the set.

2. Where a whale shark is unintentionally encircled or entangled in the fishing gear, Union fishing vessels shall:

(a) take all reasonable steps to ensure its safe release, in line with available IOTC Scientific Committee's best practice guidelines for the safe release and handling of whale sharks, while taking into consideration the safety of the crew;

(b) report the incident to the vessel's flag Member State, with the following information:

— the number of individuals;

— a short description of the interaction, including details of how and why the interaction occurred, if possible;

— the location of the encirclement;

— the steps taken to ensure safe release; and

— an assessment of the life status of the whale shark on release, including whether it was released alive but subsequently died.

SECTION 2

Other Species

Article 20

Cetaceans

1. Union fishing vessels shall be prohibited from intentionally setting a purse seine net around a cetacean in the Area, if it is sighted prior to the commencement of the set.

2. Where a cetacean is unintentionally encircled in a purse seine net, or caught by other gear types fishing for tuna and tuna-like species associated with cetaceans, Union fishing vessels shall:

(a) take all the reasonable steps to ensure its safe release, in line with the IOTC Scientific Committee's available best practice guidelines for the safe release and handling of cetaceans, while taking into consideration the safety of the crew;

(b) report the incident to the vessel's flag Member State, with the following information:

— the species (if known);

— the number of individuals;

— a short description of the interaction, including details of how and why the interaction occurred, if possible;

— the location of the encirclement;

— the steps taken to ensure safe release; and

— an assessment of the life status of the animal on release, including whether the cetacean was released alive but subsequently died.

3. Member States shall report the information referred to in paragraph 2, point (b), of this Article through logbooks in accordance with Article 14 of Regulation (EC) No 1224/2009 including the status upon release (dead or alive), or when an observer is on board through observer programmes and send it to the Commission, in accordance with Article 51(1) and (5).

Article 21

Marine turtles

1. Union fishing vessels shall apply the following mitigation measures:

(a) longline vessels shall carry line cutters and de-hookers in order to facilitate the appropriate handling and prompt release of marine turtles (species of families *Cheloniidae* and *Dermochelyidae*) that have been caught or entangled, taking all reasonable steps to ensure safe release and handling following the IOTC handling guidelines;

(b) purse seine vessels shall, to the extent practicable:

— avoid encirclement of marine turtles, and if a marine turtle is encircled or entangled, take practicable measures to safely release the turtle in accordance with the IOTC handling guidelines;

— release all marine turtles found entangled in FADs or fishing gear;

— where a marine turtle is entangled in the net, stop the net roll as soon as the turtle comes out of the water; before resuming the net roll, the operator shall disentangle the turtle without injuring it, and assist its recovery before returning it to the water; and

— carry and employ dip nets, when appropriate, to handle marine turtles.

2. Union fishing vessels shall bring aboard, if practicable, any captured marine turtle that is comatose or inactive as soon as possible and foster its recovery, including aiding in its resuscitation, before safely returning it to the water.

3. Member States shall ensure that Union fishing vessels use proper mitigation, identification, handling and de-hooking techniques and keep on board all necessary equipment for the release of marine turtles, taking all reasonable steps in accordance with handling guidelines in the IOTC Marine Turtle Identification Cards provided in IOTC handling guidelines referred to in paragraph 1, point (a).

4. Member States shall report on the implementation of the Guidelines of the Food and Agriculture Organization of the United Nations (FAO) to Reduce Sea Turtle Mortality in Fishing Operations.

5. Member States shall send all data on their vessels interactions with marine turtles to the Commission, in accordance with Article 51(1). Those data shall include the level of logbook or observer coverage and an estimate of total mortality of marine turtles incidentally caught in their fisheries.

6. Union fishing vessels shall record all incidents involving marine turtles during fishing operations, including status on release (dead or alive) in the logbooks in accordance with Article 14 of Regulation (EC) No 1224/2009. They shall report such incidents to their flag Member States with information, where possible, on the species, location of capture, conditions, actions taken on board and location of release. Member States shall send that information to the Commission, in accordance with Article 51(1).

Article 22

Seabirds

1. Union fishing vessels shall use mitigation measures to reduce in levels of seabird bycatch across all fishing areas, seasons and fisheries. In the area south of 25 degrees South latitude, all longline vessels shall use at least two of the three mitigation measures set out in Annex 4 and shall comply with the minimum standards for those measures. The design and deployment of bird scaring lines shall comply with the additional specifications set out in Annex 5.

2. Union fishing vessels shall record data on incidental seabird bycatch by species, in particular through the Regional Observer Scheme referred to in Article 30, and report them to the Commission in accordance with Article 51(1). Observers shall, to the extent possible, take photographs of seabirds caught by Union fishing vessels and transmit them to national seabird experts or the IOTC Secretariat for confirmation of identification.

3. Member States shall inform the Commission, or a body designated by it, as to how the Regional Observer Scheme referred to in Article 30 is implemented, in accordance with Article 51(5).

CHAPTER IV

CONTROL MEASURES

SECTION 1

General conditions

Article 23

Documentation on board Union fishing vessels

1. Union fishing vessels shall maintain fishing logbooks in accordance with this Regulation. The original recording contained in the fishing logbooks shall be kept on board the fishing vessel for at least 12 months.

2. Union fishing vessels shall carry on board valid documents issued by the competent authority of the flag Member State including:

(a) licence, permit or authorisation to fish and terms and conditions attached to the licence, permit or authorisation;

(b) vessel's name;

(c) port in which the vessel is registered and the registration number(s);

(d) international call sign;

(e) names and addresses of the owner(s) and, if applicable, the charterer;

(f) overall length; and

(g) engine power, in kw/horsepower, where appropriate.

3. Member States shall verify the validity of the documents to be carried on board fishing vessels regularly, and at least once a year.

4. Member States shall ensure that all documents carried on board and any further amendments to them are issued and certified by the competent authority and that fishing vessels are marked in such a way that they can be readily identified with generally accepted international standards, such as the FAO Standard Specification for the Marking and Identification of Fishing Vessels.

SECTION 2

Record of vessels

Article 24

Record of authorised fishing vessels

1. The following Union fishing vessels shall be registered in the IOTC record of fishing vessels:

(a) vessels of 24 metres or more in overall length;

(b) vessels of less than 24 metres in overall length, if they fish outside the exclusive economic zone (EEZ) of a Member State.

2. Union fishing vessels that are not registered in the IOTC record referred to in paragraph 1 shall not be authorised to fish for, retain on board, tranship or land IOTC species or support any fishing activity or set DFADs in the Area.

This paragraph shall not apply to vessels of less than 24 metres in overall length operating in the EEZ of a Member State.

3. Member States shall submit to the Commission the list of vessels complying with the requirements of paragraph 1 which are authorised to operate in the Area. That list shall include the following information for each vessel:

(a) name of vessel(s), register number(s);

(b) IMO number;

(c) previous name(s) (if any) or indication of its non-availability;

(d) previous flag(s) (if any) or indication of its non-availability;

(e) details of previous deletion from other registries (if any) or indication of their non-availability;

(f) international radio call sign(s) (if any) or indication of its non-availability;

(g) port of registration;

(h) type of vessel(s), overall length (m) and gross tonnage (GT);

(i) total volume of fish hold(s) in cubic metres;

(j) name and address of owner(s) and operator(s);

(k) name and address of beneficial owner(s), if known and different from vessel owner/operator, or indication of their non-availability;

(l) name, address and registration number of company operating the vessel (if any);

(m) gear used;

(n) time period(s) authorised for fishing and/or transhipping;

(o) colour photographs of the vessel showing:

— the starboard and portsides, each showing the whole structure;

— the bow;

(p) at least one colour photograph clearly showing at least one of the external markings specified in point (a).

4. Member States shall promptly notify the Commission of any addition to, deletion from, or amendment of the IOTC record. The Commission shall send that information to the IOTC Secretariat without delay.

5. During each year, the Commission shall, if necessary, provide the IOTC Secretariat with updated information on Union fishing vessels registered in the IOTC record referred to in paragraph 1.

Article 25

Communication of information

The information to be notified by Member States to the Commission in accordance with Article 24 of this Regulation shall be submitted in an electronic format in accordance with Article 39 of Regulation (EU) 2017/2403 of the European Parliament and of the Council ([16]).

Article 26

Authorisation of fishing vessels

1. Member States shall issue an authorisation to fish for IOTC species for fishing vessels flying their flag in accordance with Article 21 of Regulation (EU) 2017/2403.

2. Member States shall submit to the Commission an updated template of the official authorisation to fish outside national jurisdictions, and update the information in the template whenever necessary. The Commission shall send this information to the IOTC Secretariat without delay. The template shall include the following information:

(a) name of the competent authority;

(b) name and contact of personnel of the competent authority;

(c) signature of the personnel of the competent authority; and

(d) official stamp of the competent authority.

3. The template referred to in paragraph 2 shall be used exclusively for monitoring, control and surveillance purposes. A difference between the template and the authorisation carried onboard the vessel shall not constitute an infringement, but shall prompt the controlling State to clarify the issue with the identified competent authority of the flag State of the vessel in question.

([16]) Regulation (EU) 2017/2403 of the European Parliament and of the Council of 12 December 2017 on the sustainable management of external fishing fleets, and repealing Council Regulation (EC) No 1006/2008 (OJ L 347, 28.12.2017, p. 81).

Article 27

Obligations for Member States issuing fishing authorisations

1. Member States shall:

(a) authorise their vessels to operate in the Area only if they are able to fulfil the requirements and responsibilities under the IOTC Agreement, this Regulation and CMMs;

(b) take the necessary measures to ensure that their fishing vessels comply with this Regulation and CMMs;

(c) take the necessary measures to ensure that their auxiliary fishing vessels keep on board valid certificates of vessel registration and valid authorisations to fish or tranship;

(d) ensure that their authorised fishing vessels have no history of IUU fishing activities or that, if a vessel has such a history, the new owner has provided sufficient evidence demonstrating that:

— the previous owners and operators have no legal, beneficial or financial interest in, or control over that vessel;

— the parties involved in the IUU incident have officially resolved the matter and sanctions have been completed; and

— having taken into account all relevant facts, their auxiliary fishing vessels are not engaged in or associated with IUU fishing;

(e) ensure, to the extent possible under national legislation, that the owners and operators of their auxiliary fishing vessels are not engaged in or associated with tuna fishing activities conducted by vessels not registered in the IOTC record referred to in Article 24(1); and

(f) take the necessary measures to ensure, to the extent possible under national legislation, that the owners of auxiliary fishing vessels registered in the IOTC record referred to in Article 24(1) are citizens of, or legal entities in, the flag Member State, so that any control or punitive action can be taken against them where required.

2. Member States shall report the results of the review of the actions and measures taken pursuant to paragraph 1 of this Article to the Commission, or to a body designated by it, in accordance with Article 51(5).

3. Member States which issue licences to their authorised fishing vessels shall report annually to the Commission, or to a body designated by it, all measures taken in accordance with Annex I to CMM 05/07, using the format set out in Annex II to CMM 05/07, and in accordance with Article 51 of this Regulation.

Article 28

Measures against vessels not registered in the IOTC record of vessels

1. Union fishing vessels not registered in the IOTC record referred to in Article 24(1) shall not fish for, retain on board, tranship or land IOTC species in the Area.

2. To ensure the effectiveness of this Regulation with regard to species covered by statistical document programmes, Member States shall:

(a) validate statistical documents only for Union vessels registered in the IOTC record;

(b) require that, when imported into the territory of a CPC, the species covered by statistical document programmes caught by Union fishing vessels in the Area shall be accompanied by statistical documents; and

(c) cooperate, when importing catch of species covered by statistical document programmes, with the flag Member States of vessels catching those species to ensure that statistical documents are not forged or do not contain misinformation.

3. Member States shall notify the Commission, or a body designated by it, of any factual information showing that there are reasonable grounds for suspecting that vessels not registered in the IOTC record are engaged in fishing for or transhipment of IOTC species in the Area. The Commission, or a body designated by it, shall notify the IOTC Secretariat of that information immediately.

Article 29

Record of active vessels fishing for tuna and swordfish

1. Member States with vessels fishing for tunas and swordfish in the Area shall, using the appropriate IOTC report template, submit to the Commission by 1 February of each year a list of fishing vessels flying their flag that were active in the Area during the previous year and that:

(a) are 24 metres in overall length or above, or

(b) in the case of vessels shorter than 24 metres in overall length, operated in waters outside the EEZ of their Member State.

2. Member States with vessels fishing for yellowfin tunas in the Area shall, using the appropriate IOTC report template, submit to the Commission by 1 February of each year a list of all fishing vessels flying their flag which have fished for yellowfin tuna in the Area during the previous year.

3. The Commission shall forward the information referred to in paragraphs 1 and 2 to the IOTC Secretariat before 15 February of each year.

4. The list of vessels referred to in paragraph 1 shall contain the following information for each vessel:

(a) the IOTC number;

(b) name and registration number;

(c) IMO number, if available;

(d) previous flag (if any);

(e) international radio call sign (if any);

(f) vessel type, length and gross tonnage (GT);

(g) name and address of owner, charterer or operator (where relevant);

(h) main target species; and

(i) period of authorisation.

SECTION 3

Regional Observer Scheme

Article 30

Regional Observer Scheme

1. In order to improve the collection of scientific data, Union fishing vessels of 24 metres in overall length and above, and those under 24 metres fishing outside the EEZ of a Member State, shall ensure that at least 5 % of the number of operations or sets for each gear type while fishing in the Area are covered by observers endorsed by the Regional Observer Scheme.

2. When purse seine vessels are carrying an observer as referred to in paragraph 1, that observer shall also monitor the catches at landing to identify the composition of bigeye tuna catches.

3. Paragraph 2 shall not apply to Member States that already have a sampling scheme the coverage of which fulfil requirements set out in paragraph 1.

Article 31

Observers' obligations

1. Observers on board Union fishing vessels shall:

(a) record and report their fishing activities and verify positions of the vessel;

(b) observe and estimate catches as far as possible with a view to identifying catch composition and monitoring discards, by-catches and size frequency;

(c) record gear type, mesh size and attachments employed by the master;

(d) collect information to enable the cross-checking of entries recorded in the logbooks (species composition and quantities, live and processed weight and location, where available); and

(e) carry out scientific work as requested by the IOTC Scientific Committee.

2. The observer shall, within 30 days of completion of each trip, provide a report to the flag Member State. The report shall be provided by area of 1°latitude by 1°longitude. Member States shall send each report to the Commission, or to a body designated by it, within 140 days from reception, and shall ensure that the reports from the observer placed on the longline fleet are sent regularly throughout the year. The Commission, or the body designated by it, shall forward the reports to the IOTC Secretariat within 10 days of their receipt.

Article 32

Field samplers

1. Field samplers shall monitor the number of landings by Union artisanal fishing vessels at the landing place. As regards artisanal fishing vessels, the samplers should cover at least 5 % of the total number of fishing trips by such vessels or of the total number of active fishing vessels.

2. Field samplers shall collect information on land during unloading of fishing vessels. Field sampling programmes can be used for quantifying catch, retained bycatch and collecting tag returns.

3. Field samplers shall monitor catches at the landing place with a view to estimating catch-at-size by type of boat, gear and species, or carry out such scientific work as requested by the IOTC Scientific Committee.

Article 33

Member States obligations

1. Member States shall recruit qualified observers to place on board vessels flying their flag.

2. Member States shall:

(a) take the necessary measures to ensure that observers are able to carry out their duties in a competent and safe manner;

(b) ensure that observers alternate vessels between their assignments;

(c) ensure that the vessel on which an observer is placed provides suitable food and lodging during the observer's deployment of the same level as that of the officers on board, where possible;

(d) ensure that the master of a vessel cooperates with observers in order for them to carry out their duties safely including providing access, as required, to the retained catch, and catch which is intended to be discarded; and

(e) bear the cost of the observer scheme.

3. Member States shall report the number of vessels monitored and the coverage achieved by gear type to the Commission, in accordance with Article 51(6).

SECTION 4

Monitoring and surveillance

Article 34

Vessel monitoring system (VMS)

1. Member States shall, no later than two working days following detection or notification of technical failure or non-functioning of the vessel monitoring device on board a Union fishing vessel, forward the geographical position of the vessel to the IOTC Secretariat, or shall ensure that these positions are forwarded to the IOTC Secretariat by the master or the owner of the vessel, or their representative.

2. Where a Member State suspects that one or more vessel monitoring devices on board the vessel of another flag Member State or another CPC do not meet required operational conditions, or have been tampered with, it shall immediately notify the Commission, or a body designated by it. The Commission, or the body designated by it, shall forward the notification to the IOTC Secretariat and the vessel's flag State.

Article 35

Chartering

1. Chartering shall be subject to the following conditions:

(a) the flag CPC has consented in writing to the chartering agreement;

(b) the duration of the fishing operation under the chartering agreement does not exceed 12 months in any calendar year;

(c) fishing vessels to be chartered shall be registered with the responsible CPC which shall explicitly agree to comply with the CMMs and enforce them on their vessels; all flag CPCs shall effectively fulfil their duty to control their fishing vessels to ensure compliance with CMMs;

(d) fishing vessels to be chartered shall be registered in the IOTC record referred to in Article 24 and shall be authorised to operate in the Area;

(e) if the chartered vessel is allowed by the chartering CPC to operate in the high seas, the flag CPC shall be responsible for controlling the high seas fishing conducted pursuant to the chartering arrangement;

(f) chartered vessels shall report VMS and catch data to both the chartering CPC and flag CPC, and to the IOTC Secretariat, as provided in the Charter Notification Scheme set out in Annex 6;

(g) all catches, including bycatches and discards, taken pursuant to the chartering agreement shall be counted against quota or fishing possibilities of the chartering CPC; the observer coverage on board such chartered vessels shall be counted against the coverage rate of the chartering CPC for the duration of its fishing activity under the chartering agreement;

(h) the chartering CPC shall report to the IOTC all catches, including bycatches and discards, and other information required by the IOTC;

(i) chartered vessels shall be duly equipped with VMS, and fishing gear shall be marked for effective fishery management;

(j) observer coverage of at least 5 % of fishing effort;

(k) chartered vessels shall have a fishing licence issued by the chartering CPC and shall not be on the IOTC IUU vessel list, that of any other regional fisheries management organisation (RFMO), or on the Union IUU vessel list;

(l) chartered vessels shall not be authorised to use the quota of the flag CPC, and under no circumstances shall chartered vessels be authorised to fish under more than one chartering agreement at the same time;

(m) landing shall take place in the ports of the CPC, or under the direct supervision of CPC, in order to ensure that the activities of the chartered vessels do not undermine CMMs.

Article 36

Chartering notification scheme

1. The chartering Member State shall notify the Commission of any vessel to be identified as chartered in accordance with this Article without delay within 15 days and no later than 72 hours before commencement of fishing activities under a chartering agreement, by submitting electronically the following information with respect to each chartered vessel:

(a) the name (in both original registration language and Latin alphabets), registration number of the chartered vessel, and IMO number;

(b) the name and contact address of the beneficial owner of the vessel;

(c) the description of the vessel, including the overall length, type of vessel and the type of fishing method(s) to be used under the chartering agreement;

(d) a copy of the chartering agreement and any fishing authorisation or licence it has issued to the vessel, including the quota allocation or fishing possibility assigned to the vessel, and the duration of the chartering arrangement;

(e) its consent to the chartering agreement; and

(f) the measures adopted to implement the provisions included in the chartering agreement.

2. The flag Member State shall notify the Commission of any vessel to be identified as chartered in accordance with this Article, without delay within 17 days and no later than 96 hours before commencement of fishing activities under a chartering agreement by submitting electronically the information with respect to each chartered vessel referred to in paragraph 1.

3. Upon receiving the information from Member States set out in paragraph 1 or 2, the Commission shall forward the following information to the IOTC Secretariat:

(a) its consent to the chartering agreement;

(b) the measures adopted to implement the provisions included in the chartering agreement; and

(c) its agreement to comply with CMMs.

4. Member States referred to in paragraphs 1 and 2 shall immediately inform the Commission of the start, suspension, resumption and termination of the fishing operations under the chartering agreement.

5. Member States chartering fishing vessels shall report to the Commission by 10 February of each year the particulars of chartering agreements made in the previous calendar year, including information on catches taken and fishing effort deployed by the chartered vessels as well as the level of observer coverage achieved on the chartered vessels in accordance with Article 35(1), point (j). The Commission shall forward that information to the IOTC Secretariat by 28 February of each year.

Article 37

Vessels with no nationality

Where a Member State's vessel or aircraft makes any sighting of fishing vessels that are suspected of, or confirmed as, being without nationality that may be fishing in the high seas of the Area, that Member State shall report the sighting to the Commission, or to a body designated by it. The Commission, or the body designated by it, shall forward the information to the IOTC Secretariat immediately.

Article 38

Fishing vessels with flags of convenience

Member States shall, as regards large scale tuna longline vessels with flags of convenience (FOCs):

(a) refuse landing and transhipment by flag of convenience vessels which are engaged in fishing activities diminishing the effectiveness of the measures laid down in this Regulation or measures adopted by the IOTC;

(b) take every possible action to urge their importers, transporters and other operators concerned to refrain from transacting in and transhipping tunas and tuna-like species caught by vessels carrying out flag of convenience fishing activities;

(c) inform their general public of fishing activities which are carried out by large scale tuna longline vessels with FOCs and which diminish the effectiveness of IOTC conservation and management measures, and urge their general public not to purchase fish harvested by such vessels;

(d) urge their manufacturers and other business people concerned to prevent their vessels and equipment or devices from being used for flag of convenience longline fishing operations; and

(e) monitor and exchange information concerning flag of convenience fishing vessels activities, including the port sampling activities conducted by the IOTC Secretariat.

CHAPTER V

CATCH DATA

Article 39

Record of catch and effort data

1. Union fishing vessels shall keep an electronic logbook to record data that includes, as minimum requirements, the information and data set out in Annex 1.

2. The logbook shall be completed by the master of the fishing vessel and be submitted to the flag Member State, as well as to the coastal State in whose EEZ the Union fishing vessel has fished. Only the part of the logbook corresponding to the activity deployed in the coastal State EEZ shall be provided to the coastal State.

3. Member States shall report to the Commission all the data for any given year on an aggregated basis in their annual reports, in accordance with Article 51(1).

Article 40

Bigeye tuna catch certificate

1. All bigeye tuna imported into the territory of a Member State shall be accompanied by an IOTC Bigeye Tuna Statistical Document, as provided for in Annex 8, or an IOTC bigeye tuna re-export certificate which meets the requirements of Annex 9.

2. By way of derogation from paragraph 1, bigeye tuna caught by purse seine vessel or pole and line (bait) vessels and destined principally for the canneries in the Area are not subject to this statistical requirement.

3. The documents referred to in paragraph 1 shall be validated in accordance with the format set out in Annex IV to CMM 03/03 and the following rules:

(a) the IOTC bigeye tuna statistical document shall be validated by the flag Member State of the vessel that caught the tuna, or if the vessel is operating under a chartering arrangement, by the State that exported the tuna;

(b) the IOTC bigeye tuna re-export certificate shall be validated by the State that re-exported the tuna;

(c) statistical documents for bigeye tuna caught by Union vessels may be validated by the Member State where the products are landed, provided the corresponding quantities of bigeye tuna are exported outside the Union from the territory of the Member States of landing.

4. By 15 March of each year, for the period from 1 July to 31 December of the previous year, and by 15 September of each year, for the period from 1 January to 30 June of the current year, Member States that import bigeye tuna shall report to the Commission the data collected under the bigeye tuna statistical document programme, using the format set out in Annex III to CMM 03/03. The Commission shall examine the information and shall transmit it to the IOTC Secretariat by 1 April and 1 October, respectively.

5. Member States which export bigeye tuna shall examine export data upon receiving the import data referred to in paragraph 4 of this Article, and shall report the results to the Commission annually, in accordance with Article 51(5).

CHAPTER VI

PORT STATE MEASURES, INSPECTION, ENFORCEMENT AND IUU

SECTION 1

Port state measures

Article 41

Points of contact and designated ports

1. A Member State wishing to grant access to its ports to third-country fishing vessels carrying IOTC species caught in the Area or fishery products originating from IOTC species that have not been previously landed or transhipped shall:

(a) designate the port to which third-country fishing vessels may request entry pursuant to Article 5 of Regulation (EC) No 1005/2008;

(b) designate a point of contact for the purposes of receiving prior notice pursuant to Article 6 of Regulation (EC) No 1005/2008;

(c) designate a point of contact for the purposes of receiving inspection reports pursuant to Article 11(3) of Regulation (EC) No 1005/2008.

2. Member States shall transmit any changes to the list of designated points of contact and designated ports to the Commission, or to a body designated by it, at least 30 days before the changes take effect. The Commission, or the body designated by it, shall forward that information to the IOTC Secretariat at least 15 days before the changes take effect.

Article 42

Prior notice

1. By way of derogation from Article 6(1) of Regulation (EC) No 1005/2008, the period for prior notification shall be at least 24 hours before the estimated time of arrival at the port or immediately after the end of the fishing operations, if the time distance to the port is less than 24 hours.

2. By way of derogation from Article 6(1) of Regulation (EC) No 1005/2008, the information to be provided by masters of third country fishing vessels or their representatives shall be that required under Annex 10 to this Regulation which shall be accompanied by a catch certificate validated in accordance with Chapter III of Regulation (EC) No 1005/2008 if those third-country fishing vessels carry on board IOTC fishery products.

3. The prior notice referred to in Article 6 of Regulation (EC) No 1005/2008 and the information required under paragraph 2 of this Article may be transmitted electronically through e-PSM application.

4. Port Member States may request any additional information in order to determine whether the fishing vessels referred to in paragraph 1 have engaged in IUU fishing or related activities.

Article 43

Authorisation to enter, land and tranship in ports

1. After receiving the relevant information pursuant to Article 42, a port Member State shall decide whether to authorise or deny the third-country fishing vessel entry into and use of its ports. Where a third-country fishing vessel has been denied entry, the port Member State shall inform the flag State of the vessel and the Commission, or a body designated by it. The Commission, or the body designated by it, shall forward the information to the IOTC Secretariat without delay. Port Member States shall deny entry to fishing vessels included in the IOTC IUU vessel list, that of any other RFMO or the Union IUU vessel list.

2. Where a prior notice has been received through e-PSM application, the port Member State shall communicate its decision to authorise or deny entry into port through the same application.

3. Pursuant to Article 8(1) of Regulation (EC) No 1005/2008, in the case of carrier vessels, the IOTC transhipment declaration is required and shall be submitted at least 48 hours prior to the intended time of landing. In order to ensure that landings are consistent with the reported catch amount of each catching fishing vessel, the Member States where transhipped catches are to be landed shall take the appropriate measures to verify the accuracy of the information received and shall cooperate with the flag State of the carrier vessel, any port State involved in the transhipments to be landed and the flag states of the catching fishing vessels involved. That verification shall be carried out in such a way that the carrier vessel suffers the minimum interference and inconvenience and that degradation of the fish is avoided.

4. Where a landing or transhipment declaration is received by the port Member State from a catching fishing vessel pursuant to Article 8(1) of Regulation (EC) No 1005/2008, the port Member States shall take appropriate measures to verify the accuracy of the information received and shall cooperate with the flag CPC to ensure that landings and/or transhipments are consistent with the amount of catches reported for each catching vessel.

5. Each port Member State shall submit to the Commission by 15 June of each year the list of fishing vessels that are not flagged to that port Member State and which have landed in its ports tuna and tuna-like species caught in the Area in the preceding calendar year. That information shall be included in the appropriate IOTC report template and shall detail the catch composition by weight and species landed. The Commission shall examine such reports and transmit them to the IOTC Secretariat by 30 June of each year.

SECTION 2

Inspection

Article 44

Port inspection

1. Each year, each port Member State shall inspect in its designated ports at least 5 % of all landings or transhipments related to IOTC species made by fishing vessels that are not flagged to that port Member State.

2. Inspections shall involve the monitoring of the entire landing or transhipment and include a cross-check between the quantities, by species, recorded in the prior notice and the quantities by species actually landed or transhipped. When the landing or transhipment is completed, the inspector shall verify and note the quantities by species of fish remaining on board.

Article 45

Inspection procedure

1. This Article shall apply in addition to the rules on the inspection procedure laid down in Article 10 of Regulation (EC) No 1005/2008.

2. Inspectors from port Member States shall be properly qualified inspectors authorised for that purpose, and shall carry a valid document of identity that they shall present to the master of the vessel to be inspected.

3. As a minimum standard, port Member States shall ensure that their inspectors carry out the tasks set out in Annex II to CMM 16/11. Port Member States, in carrying out inspections in their ports, shall require the master of the vessel to give inspectors all necessary assistance and information, and to present relevant material and documents as may be required, or certified copies thereof.

4. In the written report of the results of each inspection, each port Member State shall, as a minimum, include the information set out in Annex III to CMM 16/11. Within three working days of the completion of the inspection, the port Member State shall transmit a copy of the inspection report and, upon request, an original or certified copy thereof, to the master of the inspected vessel, to the flag State, to the Commission, or to a body designated by it. The Commission, or the body designated by it, shall forward the report to the IOTC Secretariat.

5. By 15 June of each year, each port Member State shall submit to the Commission the list of fishing vessels not flagged to that port Member State which have landed in its ports tuna and tuna-like species caught in the IOTC area the preceding calendar year. That information shall detail the catch composition by weight and species landed. The Commission shall forward that information to the IOTC Secretariat by 1 July of each year.

SECTION 3

Enforcement

Article 46

Procedure in the case of evidence of infringements of IOTC measures during port inspections

1. If the information collected during the inspection provides evidence that a fishing vessel has committed a breach of the IOTC measures, this Article shall apply in addition to Article 11 of Regulation (EC) No 1005/2008.

2. The competent authorities of the port Member State shall forward a copy of the inspection report to the Commission, or to a body designated by it, as soon as possible and in any case within three working days. The Commission, or the body designated by it, shall transmit that report to the IOTC Secretariat and to the flag CPC point of contact without delay.

3. Port Member States shall promptly notify the action taken in the event of infringements to the competent authority of the flag CPC and to the Commission, or to a body designated by it. The Commission, or the body designated by it, shall transmit that information to the IOTC Secretariat.

Article 47

Alleged infringements reported by Member States

1. Member States shall submit to the Commission, using the reporting form of Annex I to CMM 18/03, any documented information that indicates possible instances of non-compliance by any fishing vessel with IOTC conservation and management measures in the Area over the past two years at least 80 days in advance of the annual meeting of the IOTC. The Commission shall examine that information and, if appropriate, forward it to the IOTC Secretariat at least 70 days in advance of the compliance committee meeting.

2. The documented information referred to in paragraph 1 shall be accompanied by the information concerning the IUU fishing activity of each of the listed vessels, including:

(a) reports regarding the alleged IUU fishing activity relating to CMMs in force;

(b) trade information obtained on the basis of relevant trade statistics such as those from statistical documents and other verifiable national or international statistics;

(c) any information obtained from other sources or gathered from fishing grounds, such as:

— information gathered from inspections undertaken in port or at sea;

— information from coastal states including VMS transponder or Automatic Identification System (AIS) data, surveillance data from satellites or airborne or seaborne assets;

— IOTC programmes, except where such a programme stipulates that information gathered is to be kept confidential; or

— information and intelligence collected by third parties.

Article 48

Alleged infringements reported by CPC and the IOTC Secretariat

1. Where the Commission receives from a CPC or the IOTC Secretariat any information indicating alleged IUU fishing activities by a Union fishing vessel, it shall transmit that information to the Member State concerned without delay.

2. The Member State concerned shall provide the Commission with the findings of any investigation undertaken in relation to the allegations of non-compliance by fishing vessels flying its flag, and any actions taken to address compliance concerns, at least 45 days in advance of the annual meeting of the IOTC. The Commission shall forward that information to the IOTC at least 15 days in advance of the annual meeting.

Article 49

Draft IOTC IUU vessel list

1. If the Commission receives official notification of the inclusion of a Union fishing vessel in the draft IOTC IUU vessel list from the IOTC Secretariat, it shall transmit that notification, including the supporting evidence and any other documented information provided by the IOTC Secretariat, to the flag Member State concerned.

2. The Member State concerned shall provide comments no later than 30 days in advance of the annual meeting of the IOTC Compliance Committee. The Commission shall examine and forward that information to the IOTC Secretariat at least 15 days in advance of the annual meeting of the Compliance Committee.

3. Once notified by the Commission, the authorities of the flag Member State concerned shall:

(a) notify the owner and the operators of the fishing vessel of its inclusion in the draft IOTC IUU vessel list and of the possible consequences that may result from that inclusion being confirmed in the IUU vessel list adopted by the IOTC; and

(b) closely monitor the vessels included in the draft IOTC IUU vessel list, in order to determine their activities and detect possible changes of name, flag, or registered owner of those vessels.

Article 50

Provisional IOTC IUU vessel list

1. In order to prevent a Union fishing vessel included in the draft IOTC IUU vessel list, as referred to in Article 49, from being included in the provisional IOTC IUU vessel list, the flag Member State shall provide the following information to the Commission demonstrating that:

(a) the vessel has, at all relevant times, complied with the conditions of its authorisation and:

— conducted fishing activities in a manner consistent with the CMMs,

— conducted fishing activities within the waters under the jurisdiction of a coastal State in a manner consistent with the laws and regulations of that coastal State, or

— fished exclusively for species not covered by the Agreement; or

(b) effective punitive action has been taken in response to the IUU fishing activities in question, including prosecution and imposition of sanctions of adequate severity to be effective in securing compliance and deterring further infringements.

2. The Commission shall examine the information referred to in paragraph 1 and transmit it to the IOTC Secretariat without delay.

CHAPTER VII

FINAL PROVISIONS

Article 51

Data reporting

1. No later than 15 June of each year, Member States shall submit to the Commission, using the table set out in Annex II to CMM 18/07, the information for the preceding calendar year, concerning the following elements:

(a) estimates of the total catch by species and gear, if possible quarterly, separated, whenever possible, by retained catches in live weight and by discards in live weight or numbers, for all species under the IOTC mandate as well as the most commonly caught elasmobranch species according to records of catches and incidents;

(b) total catch data concerning cetaceans, marine turtles and seabirds data as referred to in Articles 20, 21 and 22, respectively;

(c) for purse seine and pole and line fisheries, data on catch and effort stratified by fishing mode and extrapolated to the total national monthly catches for each gear; documents describing the extrapolation procedures shall also be submitted routinely;

(d) for longline fisheries, data on catches by species, in numbers or weight, and effort as the number of hooks deployed, provided by 5° grid area and monthly strata; documents describing the extrapolation procedures shall also be submitted routinely;

(e) a summary of the most recent yellowfin tuna catches in accordance with Article 39;

(f) zero catches, that shall be reported using the table set out in Annex II to CMM 18/07.

2. In addition to the information referred to in paragraph 1, Member States shall include the following fishing effort data by the purse seiners fleet using supply vessels and FADs:

(a) the number and characteristics of purse seine supply vessels, operating under their flag, or assisting purse seine vessels operating under their flag, or licensed to operate in their EEZ, which have been operated in the Area;

(b) number and days at sea by purse seine vessels and purse seine supply vessels by 1° grid area and month to be reported by the flag Member State of the supply vessel;

(c) the positions, dates and the time of setting, FAD identifier and type, and FAD design characteristics of each FAD.

3. The information referred to in paragraph 1, for type of vessels and in regard to provisional and final data, shall be submitted to the Commission on the following dates:

(a) provisional data for longline fleets operating on the high seas for the previous year shall be submitted no later than 15 June of each year; final data shall be submitted no later than 15 December of each year;

(b) final data for all other fleets, including supply vessels, shall be submitted no later than 15 June each year.

4. The Commission shall analyse the information, and send it to the IOTC Secretariat by the specific deadlines provided for in this Regulation.

5. Member States shall submit to the Commission 75 days before the annual meeting of the IOTC information for the preceding calendar year, containing the information on actions taken to implement their reporting obligations for all IOTC fisheries, including shark species caught in association with IOTC fisheries, in particular the steps taken to improve their data collection for direct and incidental catches. The Commission shall compile the information in a Union implementation report and send it to the IOTC Secretariat.

6. Flag Member States shall send annually to the Commission a national scientific report, no later than 45 days before the session of the IOTC Scientific Committee, at a date communicated by the Commission, containing the following information:

(a) general fisheries statistics;

(b) report on the implementation of Committee recommendations;

(c) the progress achieved undertaking research as provided in Article 15(3), Article 16(3), Article 17(4) and Article 18(5); and

(d) other relevant information related to fishing activities for IOTC species as well as sharks, other byproduct and bycatch species.

7. The report referred to in paragraph 6 shall be drawn up in accordance with the template prescribed by the Scientific Committee of the IOTC. The Commission shall send to the flag Member States the required template. The Commission shall analyse the information in the report, compile it in a Union report and send it to the IOTC Secretariat.

Article 52

Confidentiality and data protection

1. Data collected and exchanged in the framework of this Regulation shall be treated in accordance with the applicable rules on confidentiality pursuant to Articles 112 and 113 of Regulation (EC) No 1224/2009.

2. The collection, transfer, storage or other processing of any data pursuant to this Regulation shall be in accordance with Regulations (EU) 2016/679 and (EU) 2018/1725.

3. Personal data processed under this Regulation shall not be stored for a period longer than 10 years, except if the personal data are necessary to enable the follow-up of an infringement, an inspection, or judicial or administrative procedures. In those cases, the personal data may be stored for 20 years. If personal data are retained for a longer period, those data shall be anonymised.

Article 53

Guidelines

The Commission shall provide Member States which have fishing opportunities in the fisheries managed by the IOTC with any guidelines developed by the IOTC, in particular with regard to:

(a) identification guides and handling practices for sharks;

(b) handling procedures for mobulid rays;

(c) the IOTC Scientific Committee's best practice guidelines for the safe release and handling of whale sharks;

(d) the IOTC Scientific Committee's best practice guidelines for the safe release and handling of cetaceans; and

(e) handling guidelines on marine turtles.

The Member States concerned shall ensure that those guidelines are provided to the masters of their vessels engaged in the fisheries concerned. Those masters shall take all reasonable steps to apply such guidelines.

Article 54

Procedure for amendments

1. Where necessary in order to implement into Union law amendments or supplements to the existing IOTC resolutions which become binding on the Union, and insofar as amendments to Union law do not go beyond the IOTC resolutions, the Commission is empowered to adopt delegated acts in accordance with Article 55 for the purpose of amending:

(a) description of FADs in Article 10;

(b) CPC ports to be used for transhipment in Article 12;

(c) information per vessel for the list of active vessels for tuna and swordfish, set out in Article 24(3);

(d) percentage of observer coverage set out in Article 30(1);

(e) field samplers coverage for artisanal fisheries set out in Article 32(1);

(f) conditions of chartering set out in Article 35(1);

(g) percentage of inspections for port landings set out in Article 44(1);

(h) reporting deadlines set out in Article 29(1) and (3), Article 45(5) and Article 51;

(i) Annexes 1 to 10;

(j) references to international acts set out in Article 9(3), point (a), Article 9(4), Article 21(4), Article 23(4), Article 27(3), Article 40(3) and (4), Article 42(3), Article 45(3) and (4), Article 47(1) and Article 51(1).

2. Any amendments adopted in accordance with paragraph 1 shall be strictly limited to the implementation into Union law of amendments and supplements to the IOTC resolutions concerned that are binding on the Union.

Article 55

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 54 shall be conferred on the Commission for a period of five years from 22 December 2022. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 54 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 54 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 56

Amendments to Regulations (EC) No 1936/2001, (EC) No 1984/2003, and (EC) No 520/2007

1. Article 2, point (b) and Articles 20 to 21a of Regulation (EC) No 1936/2001 are deleted.

2. Article 1, point (b), Article 8, point (b), and Annexes VII, XII, XIV, and XVIII to Regulation (EC) No 1984/2003 are deleted.

3. Article 4(2) and Articles 18 to 20 of Regulation (EC) No 520/2007 are deleted.

Article 57

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 all Member States.

Done at Strasbourg, 23 November 2022.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	M. BEK

ANNEX 1

Record once per set/shot/operation

Note: for all gears in this Annex use the follow format for date and time

For date: when recording date of the set/shot/operation: record the YYYY/MM/DD

For time: record 24hr time as either the local time, GMT or national time and clearly specify which time has been used.

OPERATION

For longline:

Date of set

Position in latitude and longitude: either position at noon or position of start of gear or area code of operation (e.g. Seychelles EEZ, high seas, etc.) may be optionally used

Time of starting setting and, when possible, retrieving the gear

Number of hooks between floats: if there are different hooks counts between floats in a single set then record the most representative (average) number

Total number of hooks used in the set

Number of light–sticks used in the set

Type of bait used in the set: e.g. fish, squid, etc.

Optionally, sea surface temperature at noon with one decimal point (XX.X°C)

For purse seine:

Date of set

Type of event: fishing set or deployment of a new fish aggregating device (FAD)

Position in latitude and longitude and time of event, or if no event during the day, at noon

If fishing set: specify if the set was successful, its duration, the hold utilised, type of school (free swimming school or FAD associated. If FAD associated, specify the type (e.g. log or other natural object, drifting FAD, anchored FAD, etc.). Refer to the CMM 18/08

> Procedures on a FADs management plan, including a limitation on the number of FADs, more detailed specification of catch reporting from FAD sets, and the development of improved FAD designs to reduce the incidence of entanglement of non-target species (or any subsequent superseding Resolution)

Optionally, sea surface temperature at noon with one decimal point (XX.X°C)

For gillnet:

Date of set: record the date for each set or day at sea (for days without sets)

Total length of net (meters): floatline length used for each set in meters

Start fishing time: record the time when starting each set and, when possible, gear retrieving

Start and end position in latitude and longitude: record start and end latitude and longitude that represent the area that your gear is set between or, if no set, record the latitude and longitude at noon for days without sets

Depth at which net is set (meters): approximate depth at which the gillnet is set

For Pole and Line:

Fishing effort information in logbooks shall be recorded by day. Catch information in logbooks shall be recorded by trip or, when possible, by fishing day.

Date of operation: record the day or date

Position in latitude and longitude at noon

Number of fishing poles used during that day

Start fishing time (record the time immediately after bait fishing is complete and the vessel heads to the ocean for fishing. For multiple days, the time at which search starts should be recorded) and end fishing time (record the time immediately after fishing is complete from the last school; on multiple days this is the time fishing stopped from the last school). For multiple days number of fishing days should be recorded.

Type of school: FAD associated and/or free school

CATCH

Catch weight (kg) or number by species per set/shot/fishing event for each of the species and form of processing in section 'Species' below:

For longline by number and weight

For purse seine by weight

For gillnet by weight

For pole and line by weight or number

SPECIES

For longline:

Primary Species	FAO code	Other Species	FAO code
Southern bluefin tuna (*Thunnus maccoyii*)	SBF	Shortbill spearfish (*Tetrapturus angustirostris*)	SSP
Albacore (*Thunnus alalunga*)	ALB	Blue shark (*Prionace glauca*)	BSH
Bigeye tuna (*Thunnus obesus*)	BET	Mako sharks (*Isurus* spp.)	MAK
Yellowfin tuna (*Thunnus albacares*)	YFT	Porbeagle shark (*Lamna nasus*)	POR
Skipjack tuna (*Katsuwonus pelamis*)	SKJ	Hammerhead sharks (*Sphyrna* spp.)	SPN
Swordfish (*Xiphias gladius*)	SWO	Silky shark (*Carcharhinus falciformis*)	FAL
Striped marlin (*Tetrapturus audax*)	MLS	Other bony fishes	MZZ
Blue marlin (*Makaira nigricans*)	BUM	Other sharks	SKH
Black marlin (*Istiompax indica*)	BLM	Seabirds (in number) ([1])	
Indo–Pacific sailfish (*Istiophorus platypterus*)	SFA	Marine Mammals (in number)	MAM

		Marine turtles (in number)	TTX
		Thresher sharks (*Alopias* spp.)	THR
		Oceanic whitetip shark (*Carcharhinus longimanus*)	OCS
		Optional species to be recorded	
		Tiger shark (*Galeocerdo cuvier*)	TIG
		Crocodile shark (*Pseudocarcharias kamoharai*)	PSK
		Great white shark (*Carcharodon carcharias*)	WSH
		Mantas and devil rays (*Mobulidae*)	MAN
		Pelagic stingray (*Pteroplatytrygon violacea*)	PLS
		Other rays	

([1]) When a CPC is fully implementing the observer program the provision of seabird data is optional

For purse seine:

Primary Species	FAO code	Other species	FAO code
Albacore (*Thunnus alalunga*)	ALB	Marine turtles (in number)	TTX
Bigeye tuna (*Thunnus obesus*)	BET	Marine mammals (in number)	MAM
Yellowfin tuna (*Thunnus albacares*)	YFT	Whale sharks (*Rhincodon typus*) (in number)	RHN
Skipjack tuna (*Katsuwonus pelamis*)	SKJ	Thresher sharks (*Alopias* spp.)	THR
Other IOTC species		Oceanic whitetip shark (*Carcharhinus longimanus*)	OCS
		Silky sharks (*Carcharhinus falciformis*)	FAL
		Optional species to be recorded	FAO code
		Mantas and devil rays (*Mobulidae*)	MAN
		Other sharks	SKH
		Other rays	
		Other bony fish	MZZ

For gillnet:

Primary Species	FAO code	Other Species	FAO code
Albacore (*Thunnus alalunga*)	ALB	Shortbill spearfish (*Tetrapturus angustirostris*)	SSP
Bigeye tuna (*Thunnus obesus*)	BET	Blue shark (*Prionace glauca*)	BSH
Yellowfin tuna (*Thunnus albacares*)	YFT	Mako sharks (*Isurus* spp.)	MAK
Skipjack tuna (*Katsuwonus pelamis*)	SKJ	Porbeagle shark (*Lamna nasus*)	POR

Longtail tuna (*Thunnus tonggol*)	LOT	Hammerhead sharks (*Sphyrna* spp.)	SPN
Frigate tuna (*Auxis thazard*)	FRI	Other sharks	SKH
Bullet tuna (*Auxis rochei*)	BLT	Other bony fish	MZZ
Kawakawa (*Euthynnus affinis*)	KAW	Marine turtles (in number)	TTX
Narrow barred Spanish mackerel (*Scomberomorus commerson*)	COM	Marine mammals (in number)	MAM
Indo–Pacific king mackerel (*Scomberomorus guttatus*)	GUT	Whale sharks (*Rhincodon typus*) (in number)	RHN
Swordfish (*Xiphias gladius*)	SWO	Seabirds (in number) ([1])	
Indo–Pacific sailfish (*Istiophorus platypterus*)	SFA	Thresher sharks (*Alopias* spp.)	THR
Marlins (*Tetrapturus* spp., *Makaira* spp.)	BIL	Oceanic whitetip shark (*Carcharhinus longimanus*)	OCS
Southern bluefin tuna (*Thunnus maccoyii*)	SBF	Optional species to be recorded	
		Tiger shark (*Galeocerdo cuvier*)	TIG
		Crocodile shark (*Pseudocarcharias kamoharai*)	PSK
		Mantas and devil rays (*Mobulidae*)	MAN
		Pelagic stingray (*Pteroplatytrygon violacea*)	PLS
		Other rays	

([1]) When a CPC is fully implementing the observer program the provision of seabird data is optional

For pole and line:

Primary Species	FAO code	Other Species	FAO code
Albacore (*Thunnus alalunga*)	ALB	Other bony fish	MZZ
Bigeye tuna (*Thunnus obesus*)	BET	Sharks	SKH
Yellowfin tuna (*Thunnus albacares*)	YFT	Rays	
Skipjack tuna (*Katsuwonus pelamis*)	SKJ	Marine turtles (in number)	TTX
Frigate and bullet tuna (*Auxis* spp.)	FRZ		
Kawakawa (*Euthynnus affinis*)	KAW		
Longtail tuna (*Thunnus tonggol*)	LOT		
Narrow barred Spanish mackerel (*Scomberomorus commerson*)	COM		
Other IOTC species			

REMARKS

Discard of tuna, tuna-like fish and sharks to be recorded by species in weight (kg) or number for all gears should be recorded in the remarks.

Any interactions with whale sharks (*Rhincodon typus*), marine mammals, and seabirds should be recorded in the remarks.

Other information should also be written in the remarks.

Note: The species included in the logbooks are regarded as minimum requirement. Optionally other frequently caught shark and/or fish species should be added as required across different areas and fisheries.

ANNEX 2

Guidelines for preparation of drifting fish aggregating device (DFAD) management plans

To support obligations in respect of the DFAD management plan (DFAD–MP) to be submitted to the Commission by Member States with fleets fishing in the IOTC area of competence, associated to DFADs, DFAD–MP should include:

1. An objective

2. Scope

   Description of its application with respect to:

   vessel-types and support and tender vessels

   DFAD numbers and DFAD beacon numbers to be deployed

   reporting procedures for DFAD deployment

   incidental bycatch reduction and utilisation policy

   consideration of interaction with other gear types

   plans for monitoring and retrieval of lost DFADs

   statement or policy on 'DFAD ownership'

3. Institutional arrangements for management of the DFAD–MPs:

   institutional responsibilities

   application processes for DFAD and/or DFAD beacons deployment approval

   obligations of vessel owners and masters in respect of DFAD and/or DFAD beacons deployment and use

   DFAD and/or DFAD beacons replacement policy

   reporting obligations

4. DFAD construction specifications and requirements:

   DFAD design characteristics (a description)

   DFAD markings and identifiers, including DFAD beacons

   lighting requirements

   radar reflectors

   visible distance

   radio buoys (requirement for serial numbers)

   satellite transceivers (requirement for serial numbers)

5. Applicable areas:

   details of any closed areas or periods e.g. territorial waters, shipping lanes, proximity to artisanal fisheries, etc.

6. Applicable period for the DFAD–MP.

7. Means for monitoring and reviewing implementation of the DFAD–MP.

8. DFAD logbook template (data to be collected specified in Annex 3).

Guidelines for preparation of anchored fish aggregating device (AFAD) management plans

To support obligations in respect of the AFAD management plan (AFAD–MP) to be submitted to the IOTC Secretariat by CPCs with fleets fishing in the IOTC area of competence, associated to AFADs, AFAD–MP should include:

1. An objective

2. Scope:

   Description of its application with respect to:

   a) vessel types

   b) AFAD numbers and/or AFAD beacons numbers to be deployed (per AFAD type)

   c) reporting procedures for AFAD deployment

   d) distances between AFADs

   e) incidental bycatch reduction and utilisation policy

   f) consideration of interaction with other gear types

   g) the establishment of inventories of the AFADs deployed, detailing AFAD identifiers, characteristics and equipment of each AFAD as laid down in point 4 of this Annex, coordinates of the AFAD's mooring sites, date of set, lost and reset

   h) plans for monitoring and retrieval of lost AFADs

   i) statement or policy on 'AFAD ownership'

3. Institutional arrangements for management of the AFAD–MP:

   a) institutional responsibilities

   b) regulations applicable to the setting and use of AFADs

   c) AFAD repairs, maintenance rules and replacement policy

   d) data collection system

   e) reporting obligations

4. AFAD construction specifications and requirements:

   a) AFAD design characteristics (a description of both the floating structure and the underwater structure, with special emphasis on any netting materials used)

   b) anchorage used for mooring

   c) AFAD markings and identifiers, including AFAD beacons if any

   d) lighting requirements, if any

   e) radar reflectors

   f) visible distance

   g) radio buoys, if any (requirement for serial numbers)

   h) satellite transceivers (requirement for serial numbers)

   i) echo sounder

5. Applicable areas:
   a) coordinates of mooring sites, if applicable
   b) details of any closed areas e.g., shipping lanes, Marine Protected Areas, reserves etc.

6. Means for monitoring and reviewing implementation of the AFAD–MP.

7. AFAD logbook template (data to be collected specified in Annex IV).

ANNEX 3

Data collection for drifting fish aggregating devices (DFADs) and anchored fish aggregating devices (AFADs)

DATA COLLECTION FOR DFADs

a) For each activity on a DFAD, whether followed by a set or not, each fishing, support and supply vessel to report the following information:

   i. Vessel (name and registration number of the fishing, support or supply vessel)

   ii. Position (as the geographic location of the event (Latitude and Longitude) in degrees and minutes)

   iii. Date (as DD/MM/YYYY, day/month/year)

   iv. DFAD identifier (DFAD or beacon ID)

   v. DFAD type (drifting natural FAD, drifting artificial FAD)

   vi. DFAD design characteristics

   Dimension and material of the floating part and of the underwater hanging structure

   vii. Type of the activity (visit, deployment, hauling, retrieving, loss, intervention to service electronic equipment).

b) If the visit is followed by a set, the results of the set in terms of catch and bycatch, whether retained or discarded dead or alive. CPCs to report this data aggregated per vessel at 1*1 degree (where applicable) and monthly to the Secretariat

DATA COLLECTION FOR AFADs

a) Any activity around an AFAD.

b) For each activity on an AFAD (repair, intervention, consolidation, etc.), whether followed or not by a set or other fishing activities:

   i. Position (as the geographic location of the event (Latitude and Longitude) in degrees and minutes)

   ii. Date (as DD/MM/YYYY, day/month/year)

   iii. AFAD identifier (i.e. AFAD marking or beacon ID or any information allowing to identify the owner).

c) If the visit is followed by a set or other fishing activities, the results of the set in terms of catch and bycatch, whether retained or discarded dead or alive.

ANNEX 4

Mitigation measures for seabirds in longline fisheries

Mitigation	Description	Specification
Night setting with minimum deck lighting	No setting between nautical dawn and before nautical dusk. Deck lighting to be kept to a minimum.	Nautical dusk and nautical dawn are defined as set out in the Nautical Almanac tables for relevant latitude, local time and date. Minimum deck lighting should not breach minimum standards for safety and navigation.
Bird-scaring lines (Tori lines)	Bird-scaring lines shall be deployed during the entire longline setting to deter birds from approaching the branch line.	For vessels greater than or equal to 35 m: — Deploy at least 1 bird-scaring line. Where practical, vessels are encouraged to use a second tori pole and bird scaring line at times of high bird abundance or activity; both tori lines should be deployed simultaneously, one on each side of the line being set. — Aerial extent of bird-scaring lines must be greater than or equal to 100 m. — Long streamers of sufficient length to reach the sea surface in calm conditions must be used. — Long streamers must be at intervals of no more than 5 m.
		For vessels less than 35 m: — Deploy at least 1 bird-scaring line. — Aerial extent must be greater than or equal to 75 m. — Long and/or short (but greater than 1 m in length) streamers must be used and placed at intervals as follows: — Short: intervals of no more than 2 m. — Long: intervals of no more than 5 m for the first 55 m of bird scaring line. Additional design and deployment guidelines for bird-scaring lines are provided in Annex 5 to this Regulation.
Line weighting	Line weights to be deployed on the snood prior to setting.	Greater than a total of 45 g attached within 1 m of the hook or; Greater than a total of 60 g attached within 3,5 m of the hook or; Greater than a total of 98 g weight attached within 4 m of the hook.

ANNEX 5

Supplemental Guidelines for Design and Deployment of Tori Lines

Preamble

Minimum technical standards for deployment of tori lines are found in Annex 4 to this Regulation, and are not repeated here. These supplemental guidelines are designed to assist in the preparation and implementation of tori line regulations for longline vessels. While these guidelines are relatively explicit, improvement in tori line effectiveness through experimentation is encouraged, within the requirements of Annex 4 to the Regulation. The guidelines take into account environmental and operational variables such as weather conditions, setting speed and ship size, all of which influence tori line performance and design in protecting baits from birds. Tori line design and use may change to take account of these variables provided that line performance is not compromised. On-going improvement in tori line design is envisaged and consequently review of these guidelines should be undertaken in the future.

Tori line design (see Figure 1)

1. An appropriate towed device on the section of the tori line in the water can improve the aerial extension.

2. The above water section of the line should be sufficiently light that its movement is unpredictable to avoid habituation by birds and sufficiently heavy to avoid deflection of the line by wind.

3. The line is best attached to the vessel with a robust barrel swivel to reduce tangling of the line.

4. The streamers should be made of material that is conspicuous and produces an unpredictable lively action (e.g. strong fine line sheathed in red polyurethane tubing) suspended from a robust three-way swivel (that again reduces tangles) attached to the tori line.

5. Each streamer should consist of two or more strands.

6. Each streamer pair should be detachable by means of a clip so that line stowage is more efficient.

Deployment of tori lines

1. The line should be suspended from a pole affixed to the vessel. The tori pole should be set as high as possible so that the line protects bait a good distance astern of the vessel and will not tangle with fishing gear. Greater pole height provides greater bait protection. For example, a height of around 7 m above the water line can give about 100 m of bait protection.

2. If vessels use only one tori line it should be set to windward of sinking baits. If baited hooks are set outboard of the wake, the streamer line attachment point to the vessel should be positioned several meters outboard of the side of the vessel that baits are deployed. If vessels use two tori lines, baited hooks should be deployed within the area bounded by the two tori lines.

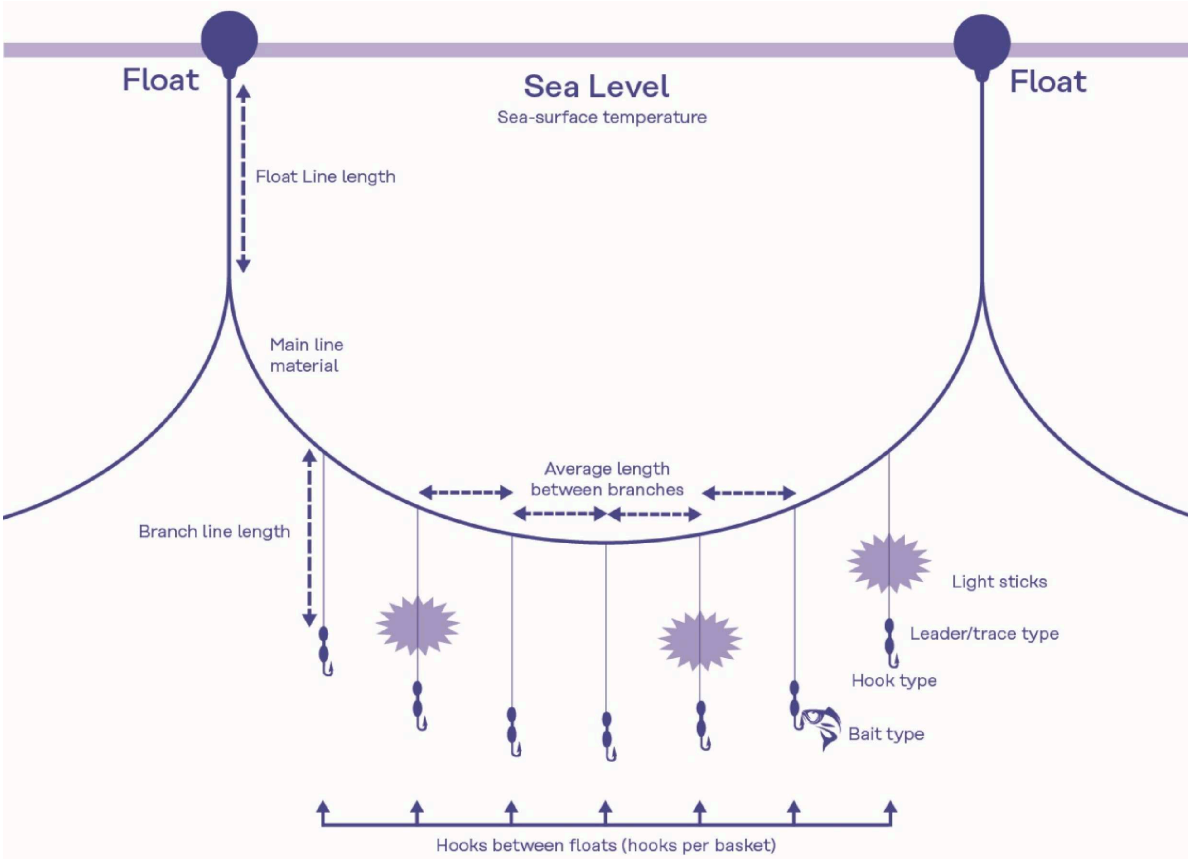
3. Deployment of multiple tori lines is encouraged to provide even greater protection of baits from birds.

4. Because there is the potential for line breakage and tangling, spare tori lines should be carried onboard to replace damaged lines and to ensure fishing operations can continue uninterrupted. Breakaways can be incorporated into the tori line to minimize safety and operational problems should a longline float foul or tangle with the in-water extent of a streamer line.

5. When fishers use a bait casting machine (BCM), they must ensure coordination of tori line and machine by: i) ensuring the BCM throws directly under the tori line protection, and ii) when using a BCM (or multiple BCMs) that allows throwing to both port and starboard, two tori lines should be used.

6. When casting branchline by hand, fishers should ensure that the baited hooks and coiled branchline sections are cast under the tori line protection, avoiding the propeller turbulence which may slow the sink rate.

7. Fishers are encouraged to install manual, electric or hydraulic winches to improve ease of deployment and retrieval of tori lines.



Longline (Gear Configuration): Average branch line length (meters): straight length in meters between snap and hook.

Translation:

Float

Sea level

Sea-surface temperature

Float line length

Main line material

Average length between branches

Branch line length

Light sticks

Leader/trace type

Hook type

Bait type

Hooks between floats (hooks per basket)

ANNEX 6

General provisions of chartering agreement

The chartering agreement shall contain the following conditions:

The flag CPC has consented in writing to the chartering agreement;

The duration of the fishing operations under the chartering agreement does not exceed 12 months in any calendar year.

Fishing vessels to be chartered shall be registered to responsible contracting parties and cooperating non-contracting parties, which explicitly agree to apply IOTC conservation and management measures and enforce them on their vessels. All flag contracting parties or cooperating non-contracting parties, concerned shall effectively exercise their duty to control their fishing vessels to ensure compliance with IOTC conservation and management measures.

Fishing vessels to be chartered shall be on the IOTC record of vessels authorized to operate in the IOTC Area of Competence.

Without prejudice to the duties of the chartering CPC, the flag CPC shall ensure that the chartered vessel complies with both the legislation of the chartering CPC and of the flag CPCs and shall ensure compliance by chartered vessels with relevant Conservation and Management Measures established by IOTC, in accordance with their rights, obligations and jurisdiction under international law. If the chartered vessel is allowed by the chartering CPC to go and fish in the high seas, the flag CPC is then responsible for controlling the high seas fishing conducted pursuant to the charter arrangement. The chartered vessel shall report VMS and catch data to both the CPCs (chartering and flag) and to the IOTC Secretariat.

All catches (historical and current/future), including bycatch and discards, taken pursuant to the chartering agreement, shall be counted against the quota or fishing possibilities of the chartering CPC. The observer coverage (historical, current/future) on board such vessels shall also be counted against the coverage rate of the chartering CPC for the duration that the vessel fishes under the Charter Agreement.

The chartering CPC shall report to the IOTC all catches, including bycatch and discards, and other information required by the IOTC, and as per the Charter Notification Scheme detailed in Part IV of CMM 19/07.

Vessel Monitoring Systems (VMS) and, as appropriate, tools for differentiation of fishing areas, such as fish tags or marks, shall be used, according to the relevant IOTC Conservation and Management Measures, for effective fishery management.

There shall be observer coverage of at least 5 % of fishing effort.

The chartered vessels shall have a fishing license issued by the chartering CPC, and shall not be on the IOTC IUU list, and/or IUU list of other Regional Fisheries Management Organisations.

When operating under charter agreements, the chartered vessels shall not, to the extent possible, be authorized to use the quota (if any) or entitlement of the flag Contracting Parties or Cooperating Non-Contracting Parties. In no case shall the vessel be authorized to fish under more than one chartering agreement at the same time.

Unless specifically provided in the chartering agreement, and consistent with relevant domestic law and regulation, the catches of the chartered vessels shall be unloaded exclusively in the Ports of the chartering Contracting Party or under its direct supervision in order to assure that the activities of the chartered vessels do not undermine IOTC Conservation and Management Measures.

The chartered vessel shall at all times carry a copy of the charter documentation.

ANNEX 7

IOTC Transhipment Declaration

Carrier Vessel	Fishing Vessel
Name of the Vessel and Radio Call Sign: Flag:	Name of the Vessel and Radio Call Sign: Flag:
Flag State license number:	Flag State license number:
National Register Number, if available: IOTC Register Number, if available:	National Register Number, if available: IOTC Register Number, if available:

	Day	Month	Hour	Year	Agent's name:	Master's name of LSTV:	Master's name of Carrier:
Departure				from			
Return				to	Signature:	Signature:	Signature:
Transhipment							

Indicate the weight in kilograms or the unit used (e.g. box, basket) and the landed weight in kilograms of this unit: _____kilograms

LOCATION OF TRANSHIPMENT

Species	Port		Sea	Type of product							
				Whole	Gutted	Headed	Filleted				

If transhipment effected at sea, IOTC Observer Name and Signature:

ANNEX 8

IOTC Bigeye Tuna Statistical Document

DOCUMENT NUMBER	IOTC BIGEYE TUNA STATISTICAL DOCUMENT
EXPORT SECTION 1. FLAG OF COUNTRY/ENTITY/FISHING ENTITY	
2. DESCRIPTION OF VESSEL AND REGISTRATION NUMBER (if applicable) Vessel Name ..... Registration Number..... LOA (m) ..... IOTC Record No. (if applicable):	
3. TRAPS (if applicable)	
4. POINT OF EXPORT (City, State/Province, Country/Entity/Fishing Entity)	
5. AREA OF CATCH (check one of the following) (a) Indian (b) Pacific (c) Atlantic * In case of (b) or (c) checked, the item 6 and 7 below do not need to be filled out.	

6. DESCRIPTION OF FISH

Product Type (*1) F/FR	D/GG/DR/FL/OT	Time of Harvest (mm/yy)	Gear Code (*2)	Net Weight (Kg)

*1 = F=Fresh, FR = Frozen, RD = Round, GG = Gilled and Gutted, DR = Dressed, FL = Fillet

OT = Other, describe the type of product

*2 = When the Gear Code is OT, describe the type of gear,

7. EXPORTER CERTIFICATION I certify that the above information is complete, true, and correct to the best of my knowledge and belief.

Name:..... Company name: ..... Address: ..... Signature: ..... Date: ..... License Number (if applicable): .....

8. GOVERNMENT VALIDATION I validate that information listed above is complete, true, and correct to the best of my knowledge and belief.

Total weight of the shipment: Kg

Name& Title ..... Signature: ..... Date: ..... Government Seal.....

IMPORT SECTION:

9. IMPORTER CERTIFICATION I certify that the above information is complete, true, and correct to the best of my knowledge and belief.

Importer Certification (Intermediate Country/Entity/Fishing Entity)

Name ..... Address: ..... Signature: ..... Date: ..... License # (if applicable): .....

Importer Certification (Intermediate Country/Entity/Fishing Entity)

Name: ..... Address: ..... Signature: ..... Date: ..... License # (if applicable): .....

Final Point of Import

City: ..... State/Province: ..... Country/Entity/Fishing Entity: .....

NOTE: If a language other than English or French is used in completing this form, please add an English translation of this document.

INSTRUCTIONS:

DOCUMENT NUMBER: Block for the issuing Country to designate a country coded Document Number.

(1) FLAG COUNTRY/ENTITIES/FISHING ENTITIES: Fill in the name of the country of the vessel that harvested the Bigeye tuna in the shipment and issued this Document. According to the Recommendation, only the flag state of the vessel that harvested the Bigeye tuna in the shipment or, if the vessel is operating under a charter arrangement, the exporting state can issue this Document.

(2) DESCRIPTION OF VESSEL (if applicable): Fill in the name and registration number, length overall(LOA) and IOTC Record number of the vessel that harvested the Bigeye tuna in the shipment.

(3) TRAPS (if applicable): Fill in the name of the trap that harvested the Bigeye tuna in the shipment.

(4) POINT OF EXPORT: Identify the City, State or Province, and Country from which the Bigeye tuna was exported.

(5) AREA OF CATCH: Check the area of catch. (If (b) or (c) checked, items 6 and 7 below do not need to be filled out.)

(6) DESCRIPTION OF FISH: The exporter must provide, to the highest degree of accuracy, the following information.

NOTE: One row should describe one product type

(1) Product Type: Identify the type of product being shipped as either FRESH or FROZEN, and in ROUND, GILLED AND GUTTED, DRESSED, FILLET or OTHER form. For OTHER, describe the type of products in the shipment.

(2) Time of Harvest: Fill in the time of harvest (in month and year) of the Bigeye tuna in the shipment

(3) Gear Code: Identify the gear type which was used to harvest the Bigeye tuna using the list below. For OTHER TYPE, describe the type of gear, including farming.

(4) Net product weight: in kilograms.

(5) EXPORTER CERTIFICATION: The person or company exporting the Bigeye tuna shipment must provide his/her name, company name, address, signature, date the shipment was exported, and dealer license number (if applicable).

(6) GOVERNMENT VALIDATION: Fill in the name and full title of the official signing the Document. The official must be employed by a competent authority of the flag state government of the vessel that harvested the Bigeye tuna appearing on the Document or other individual or institution authorised by the flag state. When appropriate, this requirement is waived according validation of the document by a government official, or if the vessel is operating under a charter arrangement, by a government official or other authorised individual or institution of the exporting state. The total weight of the shipment shall also be specified in this block.

(7) IMPORTER CERTIFICATION: The person or company that imports Bigeye tuna must provide his/her name, address, signature, date the Bigeye tuna was imported, license number (if applicable), and final point of import. This includes imports into intermediate countries/entities/fishing entities. For fresh and chilled products, the signature of the importer may be substituted by a person of a customs clearance company when the authority for signature is properly accredited to it by the importer.

GEAR CODE:

GEAR CODE	GEAR TYPE,
BB	BAITBOAT
GILL	GILLNET
HAND	HANDLINE
HARP	HARPOON
LL	LONGLINE
MWT	MID-WATER TRAWL
PS	PURSE SEINE
RR	ROD AND REEL
SPHL	SPORT HANDLINE
SPOR	SPORT FISHERIES UNCLASSIFIED
SURF	SURFACE FISHERIES UNCLASSIFIED
TL	TENDED LINE
TRAP	TRAP
TROL	TROLL
UNCL	UNSPECIFIED METHODS
OT	OTHER TYPE

RETURN A COPY OF COMPLETED DOCUMENT TO: (the name of the office of the competent authority of the flag state).

ANNEX 9

IOTC bigeye tuna re-export certificate

<table>
<tr><td colspan="2">DOCUMENT NUMBER</td><td colspan="3">IOTC BIGEYE TUNA RE-EXPORT CERTIFICATE</td></tr>
<tr><td colspan="5">RE-EXPORT SECTION:
1. RE-EXPORTING COUNTRY/ENTITY/FISHING ENTITY</td></tr>
<tr><td colspan="5">2. POINT OF RE-EXPORT</td></tr>
<tr><td colspan="5">3. DESCRIPTION OF IMPORTED FISH</td></tr>
<tr><td colspan="2">Product Type(*)
F/FR RD/GG/DR/FL/OT</td><td>Net Weight (Kg)</td><td>Flag country/Entity/ Fishing Entity</td><td>Date of Import</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">4. DESCRIPTION OF FISH FOR RE-EXPORT</td></tr>
<tr><td colspan="2">Product Type(*)
F/FR RD/GG/DR/FL/OT</td><td>Net Weight (Kg)</td><td colspan="2"></td></tr>
<tr><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td colspan="5">*F = FRESH, FR = Frozen, RD = Round, GG = Gilled and Gutted, DR = Dressed, FL = Fillet
OT = Other(Describe the type of product)</td></tr>
<tr><td colspan="5">5. RE-EXPORTER CERTIFICATION: I certify that the above information is complete, true and correct to the best of my knowledge and belief.
Name/Company Name …… Address…… Signature …… Date …… License Number (if applicable) ……</td></tr>
<tr><td colspan="5">6. GOVERNMENT VALIDATION: I validate that the above information is complete, true and correct to the best of my knowledge and belief.
Name & Title…… Signature…… Date …… Government Seal ……</td></tr>
</table>

IMPORT SECTION:

7. IMPORTER CERTIFICATION: I certify that the above information is complete, true and correct to the best of my knowledge and belief.

Importer Certification (Intermediate Country/Entity/Fishing Entity)

Name: …… Address: …… Signature: …… Date: …… License # (if applicable) ……
Importer Certification (Intermediate Country/Entity/Fishing Entity)

Name: …… Address: …… Signature: …… Date: …… License # (if applicable) ……
Importer Certification (Intermediate Country/Entity/Fishing Entity)

Name: …… Address: …… Signature: …… Date: …… License # (if applicable) ……
Final Point of Import

City: …… State/Province: …… Country/Entity/Fishing Entity: ……

NOTE: If a language other than English or French is used in completing this form, please add the English translation of this document.

INSTRUCTIONS

DOCUMENT NUMBER: Block for the issuing Country/Entity/Fishing Entity to designate a Country/Entity/Fishing Entity coded document number.

(1) RE-EXPORTING COUNTRY/ENTITY/FISHING ENTITY

Fill in the name of the Country/Entity/Fishing Entity which re-exports the Bigeye tuna in the shipment and issued this Certificate. According to the Recommendation, only the re-exporting Country/Entity/Fishing Entity can issue this Certificate.

(2) POINT OF RE-EXPORT

Identify the City/State Province and Country/Entity/Fishing Entity from which the Bigeye tuna was re-exported.

(3) DESCRIPTION OF IMPORTED FISH

The exporter must provide, to the highest degree of accuracy, the following information: NOTE: One row should describe one product type. (1)Product type: Identify the type of product being shipped as either FRESH or FROZEN, and in ROUND, GILLED AND GUTTED, DRESSED, FILLET or OTHER form. For OTHER, describe the type of products in the shipment. (2) Net weight: Net product weight in kilograms. (3) Flag Country/Entity/Fishing Entity: the name of the Country/Entity/Fishing Entity of the vessel that harvested the Bigeye tuna in the shipment. (4) Date of import: Imported date.

(4) DESCRIPTION OF FISH FOR RE-EXPORT

The exported must provide, to the highest degree of accuracy, the following information: NOTE: One row should describe one product type. (1) Product type: Identify the type of product being shipped as either FRESH or FROZEN, and in ROUND, GILLED AND GUTTED, DRESSED FILLET or OTHER form. For OTHER, describe the type of products in the shipment. (2) Net weight: Net product weight in kilograms.

(5) RE-EXPORTER CERTIFICATION

The person or company re-exporting the Bigeye tuna shipment must provide his/her name, address, signature, date the shipment was re-exported, and re-exporter's license number (if applicable).

(6) GOVERNMENT VALIDATION

Fill in the name and full title of the official signing the Certificate. The official must be employed by a competent government authority of the re-exporting Country/Entity/Fishing Entity appearing on the Certificate, or other individual or institution authorised to validate such certificates by the competent government authority.

(7) IMPORTER CERTIFICATION

The person or company that imports Bigeye tuna must provide his/her name, address, signature, date the Bigeye tuna was imported, license number (if applicable) and re-exported final point of import. This includes imports into intermediate Countries/Entities/Fishing Entities. For fresh and chilled products, the signature of the importer may be substituted by a person of a customs clearance company when the authority for signature is properly accredited to it by the importer.

RETURN A COPY OF THE COMPLETED CERTIFICATE TO: (the name of the office of the competent authority of the re-exporting Country/Entity/Fishing Entity).

ANNEX 10

Information to be provided in advance by vessels requesting port entry

1. Intended port of call							
2. Port State							
3. Estimated date and time of arrival							
4. Purpose(s)							
5. Port and date of last port call							
6. Name of the vessel							
7. Flag State							
8. Type of vessel							
9. International Radio Call Sign							
10. Vessel contact information							
11. Vessel owner(s)							
12. Certificate of registry ID							
13. IMO ship ID, if available							
14. External ID, if available							
15. IOTC ID							
16. VMS	No	Yes: National		Yes: RFMO(s)		Type:	
17. Vessel dimensions	Length			Beam		Draft	
18. Vessel master name and nationality							

19. Relevant fishing authorization(s)

Identifier	Issued by	Validity	Fishing area(s)	Species	Gear

20. Relevant transhipment authorization(s)

Identifier		Issued by		Validity	
Identifier		Issued by		Validity	

21. Transhipment information concerning donor vessels

Date	Location	Name	Flag State	ID number	Species	Product form	Catch area	Quantity

22. Total catch onboard				23. Catch to be offloaded
Species	Product form	Catch area	Quantity	Quantity

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2344

of 29 November 2022

on the reimbursement, in accordance with Article 17(3) of Regulation (EU) 2021/2116 of the European Parliament and of the Council, of the appropriations carried over from financial year 2022

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/2116 of the European Parliament and of the Council of 2 December 2021 on the financing, management and monitoring of the common agricultural policy and repealing Regulation (EU) No 1306/2013 ([1]), and in particular Article 17(3), second subparagraph, thereof,

After consulting the Committee on the Agricultural Funds,

Whereas:

(1) In accordance with Article 12(2), first subparagraph, point (d), of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ([2]), non-committed appropriations relating to the actions financed by the European Agricultural Guarantee Fund (EAGF) as referred to in Article 4(1) of Regulation (EU) No 1306/2013 of the European Parliament and of the Council ([3]) may be carried over to the following financial year. Such carryover is limited to 2 % of the initial appropriations voted by the European Parliament and by the Council and to the amount of the adjustment of direct payments as referred to in Article 8 of Regulation (EU) No 1307/2013 of the European Parliament and of the Council ([4]) which was applied during the preceding financial year.

(2) In accordance with Article 17(3), second subparagraph, of Regulation (EU) 2021/2116, for financial year 2022, appropriations carried over in accordance with Article 12(2), first subparagraph, point (d), of Regulation (EU, Euratom) 2018/1046 remain available and the overall amount of non-committed appropriations available for reimbursement represents more than 0,2 % of the annual ceiling for EAGF expenditure.

([1]) OJ L 435, 6.12.2021, p. 187.

([2]) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

([3]) Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

([4]) Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

(3) In accordance with Article 17(4) of Regulation (EU) 2021/2116, the reimbursement only applies to final beneficiaries in those Member States where financial discipline applied ([5]) in the preceding financial year.

(4) In accordance with Article 1(1) of Commission Implementing Regulation (EU) 2021/951 ([6]), financial discipline is applied to direct payments in respect of calendar year 2021 to establish the crisis reserve. The crisis reserve has been partially called on in financial year 2022 for an amount of EUR 350 million by Commission Delegated Regulation (EU) 2022/467 ([7]), leaving EUR 147,3 million available. Moreover, on the basis of the execution of 2022 EAGF appropriations under shared management for the period from 16 October 2021 to 15 October 2022 and an estimated execution under direct management from 1 January 2022 to 31 December 2022, additional non-committed appropriations will remain in the 2022 EAGF budget.

(5) On the basis of the Member States' declarations of expenditure for the period from 16 October 2021 to 15 October 2022, the financial discipline reduction effectively applied by the Member States in the financial year 2022 amounts to EUR 495,6 million.

(6) Of this amount of financial discipline applied in financial year 2022, EUR 485,2 million of unused appropriations, which remains within the limit of 2 % of the initial appropriations relating to the actions referred to in Article 4(1) of Regulation (EU) No 1306/2013, can be carried over to financial year 2023 following a decision of the Commission in accordance with Article 12(3) of Regulation (EU, Euratom) 2018/1046.

(7) In order to ensure that the reimbursement to the final recipients of unused appropriations as a result of the application of financial discipline remains proportionate to the amount of the financial discipline adjustment, it is appropriate that the Commission determines the amounts available to the Member States for the reimbursement.

(8) The amounts established by this Regulation are definitive and apply, without prejudice to the application of reductions in accordance with Article 41 of Regulation (EU) No 1306/2013, to any other corrections taken into account in the monthly payment decision concerning the expenditure effected by the paying agencies of the Member States for October 2022, in accordance with Article 18(3) of Regulation (EU) No 1306/2013 and to any deductions and supplementary payments to be made in accordance with Article 18(4) of that Regulation or to any decisions which will be taken within the framework of the clearance of accounts procedure.

(9) In accordance with the introductory phrase of Article 12(2) of Regulation (EU, Euratom) 2018/1046, the non-committed appropriations may be carried over to the following financial year only. It is therefore appropriate for the Commission to determine eligibility dates for the expenditure of the Member States in relation to the reimbursement in accordance with Article 17(3) of Regulation (EU) 2021/2116, taking into account the agricultural financial year as defined in Article 35 of that Regulation.

(10) Regulation (EU) 2021/2116 is to apply from 1 January 2023 as set out in Article 106 of that Regulation. Therefore, this Regulation should apply as of the same date,

HAS ADOPTED THIS REGULATION:

Article 1

The amounts of the appropriations that will be carried over from financial year 2022 in accordance with Article 12(2), first subparagraph, point (d), and Article 12(2), third subparagraph, of Regulation (EU, Euratom) 2018/1046 and that in accordance with Article 17(3) of Regulation (EU) 2021/2116 are made available to the Member States for the reimbursement to the final beneficiaries, are laid down in the Annex to this Regulation.

([5]) Financial discipline does not apply in financial year 2022 in Croatia in accordance with Article 8(2) of Regulation (EU) No 1307/2013.

([6]) Commission Implementing Regulation (EU) 2021/951 of 11 June 2021 fixing the adjustment rate for direct payments pursuant to Regulation (EU) No 1306/2013 of the European Parliament and of the Council in respect of the calendar year 2021 (OJ L 209, 14.6.2021, p. 93).

([7]) Commission Delegated Regulation (EU) 2022/467 of 23 March 2022 providing for exceptional adjustment aid to producers in the agricultural sectors (OJ L 96, 24.3.2022, p. 4).

The amounts that will be carried over are subject to the carryover decision of the Commission in accordance with Article 12(3) of Regulation (EU, Euratom) 2018/1046.

Article 2

Member States' expenditure in relation to the reimbursement of the appropriations carried over shall only be eligible for Union financing if the relevant amounts have been paid to the beneficiaries before 16 October 2023.

Article 3

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

It shall apply from 1 January 2023.

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

Done at Brussels, 29 November 2022.

For the Commission,
On behalf of the President,
Wolfgang BURTSCHER
Director-General
Directorate-General for Agriculture and Rural Development

ANNEX

Amounts available for reimbursement of appropriations carried over

(amounts in EUR)

Belgium	7 097 289
Bulgaria	11 255 446
Czechia	12 925 229
Denmark	11 696 658
Germany	65 935 967
Estonia	2 749 659
Ireland	15 643 791
Greece	18 069 199
Spain	66 186 860
France	99 836 686
Italy	42 101 124
Cyprus	412 283
Latvia	4 020 097
Lithuania	6 763 226
Luxembourg	481 848
Hungary	17 623 016
Malta	42 930
Netherlands	9 351 194
Austria	8 115 108
Poland	30 712 998
Portugal	9 178 262
Romania	21 215 691
Slovenia	1 049 202
Slovakia	6 377 030
Finland	6 987 416
Sweden	9 419 153

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2345

of 1 December 2022

correcting the Swedish language version of Implementing Regulation (EU) 2017/373 laying down common requirements for providers of air traffic management/air navigation services and other air traffic management network functions and their oversight, repealing Regulation (EC) No 482/2008, Implementing Regulations (EU) No 1034/2011, (EU) No 1035/2011 and (EU) 2016/1377 and amending Regulation (EU) No 677/2011

(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 Article 43(1), points (a) and (f) thereof,

Whereas:

(1) The Swedish language version of Commission Implementing Regulation (EU) 2017/373 ([2]) contains an error in Subpart B, Section 4, point ATS.TR.400, point (b), of Annex IV as regards alerting service. That error alters the meaning of the provision.

(2) The Swedish language version of Implementing Regulation (EU) 2017/373 should therefore be corrected accordingly. The other language versions are not affected.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 127 of Regulation (EU) 2018/1139, delivered on 6 January 2020,

HAS ADOPTED THIS REGULATION:

Article 1

(Does not concern the English language)

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*.

([1]) OJ L 212, 22.8.2018, p. 1.

([2]) Commission Implementing Regulation (EU) 2017/373 of 1 March 2017 laying down common requirements for providers of air traffic management/air navigation services and other air traffic management network functions and their oversight, repealing Regulation (EC) No 482/2008, Implementing Regulations (EU) No 1034/2011, (EU) No 1035/2011 and (EU) 2016/1377 and amending Regulation (EU) No 677/2011 (OJ L 62, 8.3.2017, p. 1).

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

Done at Brussels, 1 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2346

of 1 December 2022

laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 1(2), in conjunction with Article 9(1), thereof,

Whereas:

(1) Regulation (EU) 2017/745 lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. Regulation (EU) 2017/745 further requires the Commission to adopt for groups of products without an intended medical purpose listed in its Annex XVI, common specifications addressing, at least, application of risk management as set out in the general safety and performance requirements laid down in Annex I to that Regulation and, where necessary, clinical evaluation regarding safety.

(2) From the date of application of the common specifications, Regulation (EU) 2017/745 is to apply also to those groups of products without an intended medical purpose.

(3) In order for manufacturers to be able to demonstrate the conformity of products without an intended medical purpose with regard to application of risk management, the common specifications should cover the application of risk management as set out in the second sentence of Section 1 and in sections from 2 to 5, 8 and 9 of Annex I to Regulation (EU) 2017/745. Consequently, in accordance with Article 9(2) of Regulation (EU) 2017/745, products without an intended medical purpose that are in conformity with the common specifications are to be presumed to be in conformity with the requirements set out in those provisions.

(4) The common specifications should in principle be laid down for all groups of products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745. However, as Regulation (EU) 2017/745 regulates the placing on the market, making available on the market or putting into service in the Union, common specifications are not needed for products for which there is no information available about them being marketed in the Union. For example, there is no information on the following products being marketed in the Union: contact lenses containing tools, such as antenna or microchip, contact lenses which are active devices; active implantable products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixing a part of the body; active devices intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction; active implantable equipment intended to be used to reduce, remove or destroy adipose tissue. In addition, for some products the information available is not sufficient to allow the Commission to draw up common specifications. That is for example the case for some other items intended to be introduced into or onto the eye.

(5) Sunbeds and equipment using infrared optical radiation to warm the body or parts of the body intended for treatment of tissues or parts of the body under the skin should not be considered products for skin treatment for the purposes of Annex XVI to Regulation (EU) 2017/745. Consequently, they should not be covered by this Regulation.

[1] OJ L 117, 5.5.2017, p. 1.

(6) The group of products listed in point 6 of Annex XVI to Regulation (EU) 2017/745 is intended for brain stimulation where only electrical currents or magnetic or electromagnetic fields penetrate the cranium. Invasive devices intended for brain stimulation, such as electrodes or sensors that are partially or totally introduced into the human body, should not be covered by this Regulation.

(7) Regulation (EU) 2017/745 requires a product without a medical purpose listed in Annex XVI to that Regulation, when used under the conditions and for the purposes intended, to present no risks at all or present a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

(8) The groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 cover a wide variety of devices for different applications and intended uses. A common methodology for risk management should be drawn up to ensure a harmonised approach by manufacturers of different groups of devices and to facilitate a coherent implementation of the common specifications.

(9) In order to ensure appropriate risk management, it is necessary to identify specific risk factors to be analysed and minimised and to identify specific risk control measures to be implemented with respect to each group of products listed in Annex XVI to Regulation (EU) 2017/745.

(10) In order to facilitate the implementation of risk management by manufacturers of both medical devices and products without an intended medical purpose risk management for both groups of products should be based on the same harmonised principles and the requirements should be compatible. The rules on the application of risk management should therefore be in line with well-established international guidance in the field, including the international standard ISO 14971:2019 on application of risk management to medical devices.

(11) Regulation (EU) 2017/745 provides that the clinical evaluation of products without an intended medical purpose are to be based on relevant clinical data concerning performance and safety. Such data are to include information from post-market surveillance, post-market clinical follow-up, and, where applicable, specific clinical investigation. As in general it is not possible to demonstrate equivalence between a medical device and a product without an intended medical purpose, where all available results on clinical investigations relate to medical devices only, clinical investigations should be performed for products without an intended medical purpose.

(12) Where clinical investigations are performed to confirm the conformity with the relevant general safety and performance requirements, it is not possible to complete the clinical investigations and the conformity assessment within six months. For such cases transitional arrangements should be laid down.

(13) Where a notified body has to be involved in the conformity assessment procedure, it is not possible for the manufacturer to complete the conformity assessment within 6 months. For such cases transitional arrangements should be laid down.

(14) Transitional provisions should be laid down also for products covered by Annex XVI to Regulation (EU) 2017/745 for which notified bodies have issued certificates in accordance with Council Directive 93/42/EEC ([2]). Also for those products, it is not possible for the manufacturer to complete clinical investigations and the conformity assessment within 6 months.

(15) In order to ensure the product safety during the transitional period, it should be allowed to continue to place the products on the market and to make them available on the market or put them into service, provided that the products in question were already lawfully marketed in the Union before the date of application of this Regulation, that they continue to comply with the requirements of Union and national law applicable before the date of application of this Regulation and that their design and intended purpose are not significantly changed. As the purpose of putting in place the transitional arrangements is to allow the manufacturers enough time to conduct the required clinical investigations and conformity assessment procedures, the transitional arrangements should cease where manufacturers do not proceed with the clinical investigations or conformity assessment procedure, as applicable, within a reasonable timeframe.

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

(16) The Medical Device Coordination Group has been consulted.

(17) The application date of this Regulation should be deferred as provided for in Regulation (EU) 2017/745.

(18) 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

Common specifications

1. This Regulation lays down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745.

Annex I lays down common specifications for all those groups of products without an intended medical purpose.

Annex II lays down common specifications for contact lenses as specified in Section 1 of that Annex.

Annex III lays down common specifications for products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy, with the exception of tattooing products and piercings, as specified in Section 1 of that Annex.

Annex IV lays down common specifications for substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing, as specified in Section 1 of that Annex.

Annex V lays down common specifications for equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty as specified in Section 1 of that Annex.

Annex VI lays down common specifications for high intensity electromagnetic radiation (for example, infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment as specified in Section 1 of that Annex.

Annex VII lays down common specifications for equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as specified in Section 1 of that Annex.

2. The common specifications laid down in this Regulation cover the requirements set out in the second sentence of Section 1 and in Sections 2 to 5, 8 and 9 of Annex I to Regulation (EU) 2017/745.

Article 2

Transitional provisions

1. A product for which the manufacturer intends to perform, or is performing, a clinical investigation to generate clinical data for the clinical evaluation in order to confirm the conformity with the relevant general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745 and the common specifications set out in this Regulation, and in the conformity assessment of which a notified body has to be involved in accordance with Article 52 of that Regulation, may be placed on the market or put into service until 22 June 2028, provided that the following conditions are met:

(a) the product was already lawfully marketed in the Union before 22 June 2023 and continues to comply with the requirements of Union and national law that were applicable to it before 22 June 2023;

(b) there are no significant changes in the design and intended purpose of the product.

By way of derogation from the first subparagraph of this paragraph, from 22 June 2024 until 22 December 2024, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if the sponsor has received from the Member State concerned a notification, in accordance with Article 70(1) or (3) of Regulation (EU) 2017/745, confirming that the application for the clinical investigation of the product is complete and that the clinical investigation falls within the scope of the Regulation (EU) 2017/745.

By way of derogation from the first subparagraph, from 23 December 2024 until 22 June 2026, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if the sponsor has started the clinical investigation.

By way of derogation from the first subparagraph, from 23 June 2026 until 22 June 2028, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer.

2. A product for which the manufacturer does not intend to perform a clinical investigation, but in the conformity assessment of which a notified body has to be involved in accordance with Article 52 of that Regulation, may be placed on the market or put into service until 22 June 2025, provided that the following conditions are met:

(a) the product was already lawfully marketed in the Union before 22 June 2023 and continues to comply with the requirements of Union and national law that were applicable to it before 22 June 2023;

(b) there are no significant changes in the design and intended purpose of the product.

By way of derogation from the first subparagraph, from 22 September 2023 until 22 June 2025, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer.

3. A product to which this Regulation applies and which is covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC may be placed on the market or put into service until the dates laid down in paragraph 1, first subparagraph, and paragraph 2, first subparagraph, as applicable, also after the expiry date of such certificate, provided that the following conditions are met:

(a) the product was already lawfully marketed in the Union before 22 June 2023 and continues to comply with the requirements of Directive 93/42/EEC, except for the requirement to be covered by a valid certificate issued by a notified body where the certificate expires after 26 May 2021;

(b) there are no significant changes in the design and intended purpose of the product;

(c) after the expiry date of the certificate issued by a notified body in accordance with Directive 93/42/EEC, the appropriate surveillance of the compliance with the conditions referred to in points (a) and (b) of this paragraph is ensured by way of a written agreement signed by the notified body that has issued the certificate in accordance with Directive 93/42/EEC or a notified body designated in accordance with Regulation (EU) 2017/745 and the manufacturer.

Article 3

Entry into force and date of application

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

2. It shall apply from 22 June 2023. However, Article 2(3) shall apply from 22 December 2022.

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

Done at Brussels, 1 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Scope

1. This Annex applies to all the devices covered by Annexes II to VII.

Risk Management

2. General requirements

2.1. Manufacturers shall establish and document responsibilities, operative modalities and criteria for the execution of the following steps of the risk management process:

(a) risk management planning;

(b) identification of hazards and risk analysis;

(c) risk evaluation;

(d) risk control and evaluation of residual risks;

(e) risk management review;

(f) production and post-production activities.

2.2. Top-level management of the manufacturers shall ensure that adequate resources are allocated and that competent personnel is assigned for risk management. Top-level management shall define and document a policy for establishing criteria for risk acceptability. Such policy shall take into account the generally acknowledged state of the art, known concerns related to safety expressed by interested parties and shall include the principle that risks are to be eliminated or reduced as far as possible by means of control measures without adversely affecting the overall residual risk. Top-level management shall ensure that the risk management process is executed and shall review its effectiveness and suitability at planned intervals.

2.3. The personnel responsible for performing risk management tasks shall be appropriately qualified. They shall have, where that is needed for the performance of tasks, proven and documented knowledge of and experience in using the particular device, equivalent devices without an intended medical purpose or analogous devices with a medical purpose, as well as knowledge of the technologies involved and risk management techniques. Evidence of qualification and competences of personnel, such as education, training, skills and experience, shall be documented.

An analogous device with a medical purpose shall be understood as the same device with a medical purpose or a medical device for which equivalence to the same device with a medical purpose has been demonstrated by the manufacturer in accordance with Section 3 of Annex XIV to Regulation (EU) 2017/745 of the European Parliament and of the Council ([1]).

2.4. The results of the risk management activities, including the reference to the device, the reference to the persons who carried out the activities and the dates of execution of such activities, shall be recorded. For every identified hazard, the records shall provide traceability to the results of risk analysis, risk evaluation, risk control and evaluation of residual risks.

2.5. Based on the results of the risk management process, manufacturers shall define the categories of users and consumers that are to be excluded from the use of the device or for which special conditions of use have to be applied. A consumer shall be understood as a natural person on whom a product without an intended medical purpose is intended to be used.

([1]) 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 (OJ L 117 5.5.2017, p. 1).

2.6. Throughout the entire lifecycle of a device, the manufacturer shall establish a system to ensure a continuous systematic update of the risk management process in relation to that device.

3. Risk management planning

3.1. Risk management planning documents shall include:

(a) references and description of the device, including its parts and components;

(b) a list of the activities to be performed in each step of the risk management process, their scope and the actions for the verification of completion and effectiveness of the risk control measures;

(c) a specification of the life cycle phases of the device covered by each activity included in the plan;

(d) a specification of responsibilities and authorities for the execution of the activities, for the approvals of the results and for the risk management review;

(e) a specification of criteria for risk acceptability based on the policy referred to in Section 2.2;

(f) a specification of criteria for the collection of relevant information from the production and from the post production phases and for the use of such information to review and update, if necessary, the risk management results.

3.2. The criteria for risk acceptability shall include the description of the criterion for the acceptability of the overall residual risk. The method for the evaluation of the overall residual risk shall be defined and documented.

3.3. In defining the criteria for risk acceptability in accordance with the principles established by the policy referred to in Section 2.2, manufacturers shall consider that all risks, including those related to surgical intervention, are to be eliminated or reduced as far as possible. If the undesirable side-effects are of transient nature and do not require medical or surgical intervention to prevent life-threatening illness or permanent impairment of a body function or permanent damage to a body structure, residual risks may be considered as being acceptable. If one or more of the conditions laid down in this Section is not met, the manufacturer shall provide a justification explaining the reasons for the acceptability of the risks.

4. Identification of hazards and risk analysis

4.1. Documents for the identification of hazards and risk analysis shall:

(a) include a description of the device, its intended use and the reasonably foreseeable misuse;

(b) list the qualitative and quantitative characteristics that could affect the safety of the device;

(c) list the known and the foreseeable hazards associated with the device, its intended use, its characteristics and its reasonably foreseeable misuse, when used in both normal and fault conditions;

(d) list the hazardous situations resulting from the consideration of the foreseeable events for each identified hazard;

(e) include the qualitative or quantitative terms and descriptions, or the categorization, for the estimation of the severity and the probability of occurrence of harms.

(f) for each hazardous situation, list the estimated severity and probability of occurrence of harms and the resulting estimation of risks.

4.2. The description of the intended use of the device shall include information on the part of the human body or type of tissue interacted with, the categories of users and consumers, the use environment and the treatment procedure.

4.3. In the risk analysis manufacturers shall take into account the specificities of various user and consumer groups. This includes considering whether the user is a healthcare professional or a lay person. In the case of a lay person distinction shall be made between a person without qualification for the use of the device and a person who uses a device in the context of his or her professional activities, and who, although not being a healthcare professional, has a proven qualification for the use of the device. It shall be presumed by the manufacturer that all those user and consumer groups have access to the device unless the device is only sold directly to healthcare professionals.

4.4. Manufacturers shall consider clinical data as one of the sources of information for the risk analysis and for the estimation of the severity and the probability of occurrence of harms.

4.5. Where due to the nature of the devices or for ethical reasons data on the probability of occurrence of harm cannot be generated, manufacturers shall estimate the risk on the basis of the nature of the harm and a worst case estimate of the probability of the harm occurring. In the technical documentation manufacturers shall provide evidence justifying the reason for not providing data on the probability of occurrence of harm.

4.6. The description of the scope for the risk analysis shall be recorded.

5. Risk evaluation

5.1. For any hazardous situation, manufacturers shall evaluate the estimated risks and determine whether the risks are acceptable in accordance with the criteria referred to in Section 3.1, point (e).

5.2. Where the risk is not acceptable, risk control shall be performed.

5.3. Where the risk is acceptable, risk control is not needed and the final estimated risk shall be considered as a residual risk.

6. Risk control and evaluation of residual risks

6.1. Documents for risk control and evaluation of residual risks shall include:

(a) a list of the implemented risk control measures and the evaluation of their effectiveness;

(b) a list of the residual risks after completed implementation of the risk control measures;

(c) the evaluation of acceptability for residual risks and for the overall residual risk, in accordance with the criteria referred to in Section 3.1, point (e);

(d) the verification of the effects of the risk control measures.

6.2. Risk control measures to be implemented by the manufacturer shall be selected from the following categories of risk control options:

(a) inherent safety ensured by design;

(b) inherent safety ensured by manufacturing;

(c) protective measures in the device or in the manufacturing process;

(d) information for safety and, where appropriate, user training.

Manufacturers shall select risk control measures in the priority order from points (a) to (d). Measures from a risk control option shall not be implemented unless the measures from the previous option cannot be implemented or, where implemented, have not resulted in the risk acceptability.

6.3. Manufacturers shall ensure that the information for safety is not limited to the instruction for use or to the label, but also available by other means. Information integrated in the device itself that the user cannot disregard and public information easily accessible to the user shall be considered. Where appropriate, user training shall be considered. The information shall be presented taking into account the degree of understanding of users and consumers as referred to in Section 9.

6.4. Risk control measures shall be taken even if the performance of the device is thereby reduced as long as the main function of the device is maintained.

6.5. When deciding on risk control measures, manufacturers shall verify whether the risk control measures generate new harm, hazards or hazardous situations and whether the estimated risks for previously identified hazardous situations are affected by those measures. The reduction of a risk shall not increase one or several other risks so that the overall residual risk could be increased.

7. Risk management review

7.1. Documents for risk management review shall include a review before the release for commercialisation of the device. The review shall ensure that:

(a) the risk management process has been carried out in accordance with the risk management planning documents referred to in Section 3.1;

(b) the overall residual risk is acceptable and the risks have been eliminated or reduced as far as possible;

(c) the system to collect and review information on the device from the production and the post-production phases is implemented.

8. Production and post-production activities

8.1. Documents for production and post production activities shall:

(a) specify the system to collect and review information on the device from the production and the post-production phases;

(b) list the sources of publicly available information on the device, on equivalent devices without an intended medical purpose or on analogous devices with a medical purpose;

(c) specify the criteria to evaluate the impact of the information collected on the results of previous risk management activities and the consequent actions on the device.

As part of the system to collect and review information on the device from the post-production phases, manufacturers shall consider clinical data from the post market surveillance, and, where applicable, clinical data from the summary of safety and clinical performance referred to in Article 32 of Regulation (EU) 2017/745 or the post-market clinical follow-up referred to in Part B of Annex XIV to that Regulation.

8.2. For the specification of the criteria to evaluate the impact of the information collected, the manufacturer shall consider:

(a) hazards or hazardous situations that have not been identified previously;

(b) hazardous situations for which the risk is no longer acceptable;

(c) whether the overall residual risk is no longer acceptable.

Any impact of the information collected affecting the effectiveness and suitability of the risk management process shall be considered as an input for the top-level management review referred to in Section 2.2.

8.3. For the specification of the consequent actions on the results of previous risk management activities, manufacturers shall consider an update of the former results of the risk management activities to:

(a) include new hazards or hazardous situations and evaluate the related risks;

(b) re-evaluate hazardous situations, residual risks and the overall residual risk no longer acceptable;

(c) establish the need for actions in relation to the devices already made available on the market.

8.4. Manufacturers shall take account of any changes in risks identification, analysis and evaluation which could arise from new data or changes in device use environment.

Information for safety

9. When providing information for safety referred to in Section 6.2, point (d), and on the risks linked to the use of the device referred to in Sections 11.2, point (c) and 12.1, point (c), manufacturers shall take into account:

(a) the different degree of understanding of users and consumers, with particular emphasis on devices intended to be used by lay persons;

(b) the work environment where the device is intended to be used, especially in case of use outside a medical or otherwise professionally controlled work environment.

10. If the device is intended by the manufacturer only for a non-medical purpose, information supplied with the device shall not bear any clinical benefit claim or statement. If the device is intended by the manufacturer for a medical and non-medical purpose, information provided for the non-medical purpose shall not bear any clinical benefit claim or statement.

11. Label

11.1. The label shall bear the words “non-medical purpose:” followed by a description of that non-medical purpose.

11.2. If feasible, manufacturers shall specify on the label:

(a) the information regarding the categories of users and consumers referred to in Section 2.5;

(b) the expected performance of the device;

(c) the risks arising from the use of the device.

12. Instructions for use

12.1. The instructions for use shall include:

(a) the information regarding the categories of users and consumers referred to in Section 2.5;

(b) a description of the expected performance of the device, in such a way so that the user and the consumer understands which non-medical effect can be expected from the use of the device;

(c) a description of the residual risks of the device, including their control measures, presented in a clear and easily understandable way so that the consumer can make an informed decision on whether to be treated with it, have it implanted or otherwise use it;

(d) the expected lifetime or the expected resorption period of the device and any necessary follow-up;

(e) reference to any harmonised standard and common specifications applied.

ANNEX II

Scope

1. This Annex applies to contact lenses listed in Section 1 of Annex XVI to Regulation (EU) 2017/745. Contact lenses containing tools, such as antenna or microchip, contact lenses which are active devices and other items intended to be introduced into or onto the eye are not covered by this Annex.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. Manufacturers shall analyse and eliminate or reduce as far as possible the risks linked to the following aspects:

Design and manufacturing

(a) the shape of the device, in particular in view of avoiding irritation by edges or sharps, disconnection or dislocation from the cornea, wrinkling or folding, unequal pressure on the cornea related to positioning;

(b) the selection of raw materials for lens, for surface treatments and, if relevant, for lens storage solutions in view of biological safety, biocompatibility, chemical and biological contaminants as well as permeability of oxygen and compatibility with lens storage solutions;

(c) biological safety and biocompatibility of the final product, with its packaging and storage solution, including consideration of at least the aspects of cytotoxicity, sensitization, irritation, acute systemic toxicity, subacute toxicity, implantation, sterilization residues and degradation products, extractable and leachable substances. Where the cumulative contact duration is expected to exceed 30 days, aspects of subchronic toxicity, chronic toxicity and genotoxicity shall also be considered;

(d) microbiological properties, including bioburden, microbiological contamination of the final device, residual bacterial endotoxins, sterility, contact lens disinfection and preservation;

(e) appropriateness of the primary packaging in terms of keeping the lens sterile, permanently covered by storage fluid and avoiding degradation of the product, for example by leaching of container or cover materials, by intrusion of microbial contaminations;

(f) the effect of long-term storage and the conditions of storage on the stability and properties of the lens;

Distribution chain

(a) lack of pre-use testing of suitability of lens wearing performed by ophthalmologist, optometrist, specialised optician or qualified contact lens specialist;

(b) lack of expertise of distributors outside the classic optician distribution chain with regard to both the selection of appropriate lenses and their use, storage and safe transport;

(c) lack of expertise of distributors outside the classic optician distribution chain with regard to safety or handling advice to the users;

User-related hazards/risks

(a) lack of experience with and training on the use of contact lenses of certain uses;

(b) identification of contra-indications under which contact lenses shall not be used;

(c) possible reduced availability to the cornea of tear film and oxygen;

(d) lack of hygiene, such as failure to wash and dry hands prior to users placing, using and removing lenses resulting in possible infection, severe inflammation or other diseases of the eye;

(e) possible vision hindrance and reduced transmission of light;

(f) any possible factors that could cause deterioration of eye sight such as coloration, lack of precise fitting to the eye's surface and lack of correction;

(g) identification of any non-medical conditions under which contact lenses are not be used. Conditions to be considered shall include driving, piloting or operating heavy machinery and water-based activities such as showering, bathing and swimming;

(h) increased risk of eye damage if the lenses are worn extensively (for example for long periods, consecutive multiple use);

(i) increased risk of eye damage if lenses are still worn when eye redness and irritation occur;

(j) the effect of duration of use on any of the risks mentioned above;

(k) possible misuse of the primary packaging as containment for storage between several uses;

(l) for multiple use contact lenses, risks linked to re-use and irregular re-use by the same consumer;

(m) lack of familiarity of consumers with emergency measures in case of any undesirable side-effects.

4. Specific risk control measures

(a) The field of vision shall not be reduced by the lens, including in case of reasonably foreseeable dislocation or imprecise placing. The lens shall permit transmission of sufficient light for adequate visibility under any condition of use.

(b) All materials of the lens and the inner side of its primary packaging, including its storage solution, shall be biocompatible, non-irritating and non-toxic. In addition, the substances used for colouring of or printing on the contact lenses shall not leach under the intended conditions of use.

(c) Lenses and the inner side of their primary packaging, including its storage solution shall be sterile and non-pyrogenic. If in contact with the eye, the storage liquid shall not injure the cornea, eye and the surrounding tissue.

(d) Lenses shall be designed so as not to compromise the health of the cornea, eye and surrounding tissue. Lens features such as low oxygen permeability, imprecise placing, dislocation, sharp edges, abrasion, unequal mechanical pressure distribution shall be considered.

(e) As regards lenses for multiple use, the manufacturer shall either provide effective maintenance liquids and means for cleaning and disinfecting together with the lens sufficient for the entire lifetime of the lens, or indicate the required maintenance liquids and means for cleaning and disinfecting. The manufacturer shall also either provide or indicate any other equipment or tools for the maintenance and cleaning of the lenses for multiple use.

(f) As regards lenses for multiple use, the manufacturer shall validate the maximum number of re-uses and maximum duration of use (for example in hours per day and/or number of days).

(g) Manufacturers shall consider whether eye drops need to be used to compensate for dryness. Where such eye-drops are needed, manufacturers shall define criteria to demonstrate their suitability;

(h) Manufacturers shall establish a procedure for the identification of any undesirable side-effects by the user and how to deal with them, including reporting to the manufacturer of such undesirable side-effects;

(i) The instructions for use and the label shall be designed and written in a manner so that they can be understandable by a lay person and that enables a lay person to use the device safely.

Information for safety

5. Label

5.1. The outer packaging intended to be provided to users shall contain the following indications:

(a) where devices are intended for single use, in addition to the internationally recognized symbol, in bold font of largest used size on the label the text "Do not re-use";

(b) indication of the dimensions of the lens (outer diameter of the lens and base curve radius);

(c) the recommendation to read the instructions for use.

6. Instructions for use

6.1. The instructions for use shall contain:

(a) in bold font of largest used size in the instructions the text: "Do not re-use", in addition to the internationally recognized symbol, where devices are intended for single use;

(b) a warning "Used lenses shall not be used by other persons";

(c) the indication of the dimensions of the lens (outer diameter of the lens and base curve radius);

(d) the indication of the materials of the lens, including its surface and colouring pigments;

(e) the indication of water content and oxygen permeability;

(f) an indication of the possible effect of incorrect storage conditions on the quality of the product and maximum storage time;

(g) instructions on what to do in case of displacement;

(h) hygiene measures prior to use (for example washing and drying hands), during use and after use;

(i) a warning "Do not contaminate lenses with make-up or aerosols.";

(j) a warning "Do not clean lenses with tap water.";

(k) for multiple use lenses, a detailed description of the cleaning and disinfection procedure, including the description of the necessary equipment, tools and solutions, which shall be named in detail; a description of required storage conditions;

(l) for multiple use lenses, the maximum number of re-uses and maximum duration of use(s) (for example in hours per day and/or number of days);

(m) where the use of eye drops is recommended, a description of suitable eye drops and the description on how to use them;

(n) listing of contraindications under which contact lenses are not to be used. Such a list shall include: dry eyes (inadequate tear fluid), use of eye medication, allergies, inflammation or redness in or around the eye, poor health affecting the eye such as cold and flu, previous medical intervention which may adversely affect the use of the device, any other systemic illness affecting the eye;

(o) a warning: "Do not use whilst participating in traffic-related situations (for example driving, riding a bike), operating machinery or whilst undertaking water-related activities such as showering, bathing and swimming.";

(p) a warning: "Avoid activities where possible vision hindrance and reduced transmission of light create a risk.";

(q) a statement regarding increased risk of eye damage in case of continuous wear when eye redness and irritation occur;

(r) a warning “Do not use after date of expiry.”;

(s) a clear indication of the maximum wearing time;

(t) a warning “Do not use lenses beyond maximum wearing time.”;

(u) a warning “Do not use lenses during sleeping periods”;

(v) a statement on the increased risk of eye damage if the lenses are worn extensively (for example multiple re-uses);

(w) a warning “Do not use in excessively dry or dusty environments.”;

(x) a warning “Do not re-use the primary packaging as containment for storage between uses.”, where primary packaging is not intended by the manufacturer for such use;

(y) a warning: “Do not re-use the storage solution.”;

(z) a list of risks linked to ocular health associated with lens wear, as identified by risk analysis, including, if applicable, reduced availability to the cornea of water and oxygen (oxygen transmissibility);

(aa) a list of possible undesirable side-effects, their probability of occurrence and their indicators;

(bb) instructions on how to deal with complications, including emergency measures;

(cc) an instruction “Remove the lens immediately in case of:

— irritation or eye pain such as stinging, burning, itching, foreign body sensation;

— reduced comfort when compared with previous wearing of an identical lens;

— unusual secretions or excessive tear-flow,

— redness of the eye,

— severe or persistent dryness,

— reduced or blurred vision linked to the use of the lens.

If any of these symptoms continue after removal of the lens, contact a qualified healthcare professional, such as an ophthalmologist, or an optometrist, authorised by national law to treat such symptoms. The continuation of these symptoms might indicate a more serious condition.”;

(dd) information on when and how to report undesirable side-effects to the manufacturer.

ANNEX III

Scope

1. This Annex applies to products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy, listed in Section 2 of Annex XVI to Regulation (EU) 2017/745. Tattooing products, piercings and products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of fixation of body parts are not covered by this Annex. This Annex does not apply to active implantable devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

   The risk analysis shall include a section on risks that are related to the specific non-medical intended purpose of introducing the device into the human body through surgically invasive means, taking into account specific characteristics of potential users and consumers of the device.

3. Specific risks

3.1. Manufacturers shall take into account the following aspects and related risks:

   (a) physical and chemical characteristics and full composition of the implant;

   (b) the selection of raw materials in view of biological safety, biocompatibility and chemical and biological additives or contaminants;

   (c) for resorbable devices, resorption and life-time in the body, indicating the half-life and the end of the resorption;

   (d) biological safety and biocompatibility of the final product, including consideration of at least the aspects of cytotoxicity, sensitisation, irritation, material mediated pyrogenicity, acute systemic toxicity, subacute toxicity, subchronic toxicity, chronic toxicity, genotoxicity, carcinogenicity, implantation, sterilisation residues and degradation products, extractable and leachable substances;

   (e) microbiological properties, including bioburden, microbiological contamination of the final device, residual bacterial endotoxins and sterility;

   (f) the specific anatomical location for which clinical and other data support the use of the device;

   (g) consumer specific factors (for example previous accidents, special conditions, age restrictions);

   (h) potential interactions with magnetic field, (for example heating related to magnetic resonance imaging);

   (i) use of accessories (for example delivery instruments designed to be specifically used with the device for the implantation procedure) and their compatibility with the implant;

   (j) time interval between implantations, where applicable.

3.2. Where appropriate, manufacturers shall in particular analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

   (a) microbiological contamination;

   (b) presence of manufacturing debris;

   (c) implantation procedure related aspects (including use errors);

(d) implant failure (for example rupture, unintended degradation);

(e) implant dislodgement and migration;

(f) asymmetry;

(g) implant visibility through the skin;

(h) implant deflation and wrinkling;

(i) gel bleeding and leakage;

(j) sweating and silicone migration;

(k) local inflammation and swelling;

(l) regional swelling or lymphadenopathy;

(m) capsule formation and contracture;

(n) discomfort or pain;

(o) hematoma;

(p) infection and inflammation;

(q) superficial wound;

(r) wound dehiscence;

(s) extrusion of implant and interruption of wound healing;

(t) scarring and scar hyperpigmentation and hypertrophy;

(u) nerve injury;

(v) seroma;

(w) compartment pressure problems and compartment syndrome;

(x) limitation in cancer diagnosis;

(y) over-sized implants;

(z) vascular damage;

(aa) breast implant associated anaplastic large cell lymphoma (BIA-ALCL);

(bb) granuloma, including siliconoma where applicable;

(cc) necrosis.

4. Specific risk control measures

(a) Devices shall be sterile and non-pyrogenic. Where implants are supplied non-sterile with the intention to be sterilised before use, adequate instruction for sterilisation shall be provided.

(b) The safe use of the device shall be supported by clinical and other data considering the anatomical location.

(c) Long-term data shall be collected to evaluate the presence of non-degradable substances originating from the devices.

(d) Presence of substances referred to in Section 10.4.1, points (a) and (b), of Annex I to Regulation (EU) 2017/745 shall be evaluated independently of their concentration.

(e) Manufacturers shall provide training on the implantation and safe use of the device. That training shall be accessible to users.

Information for safety

5. Label

5.1. The label shall contain:

(a) in bold font of largest used size on the label the text: “Only to be implanted in an appropriate medical environment by appropriately trained medical doctors who are qualified or accredited in accordance with national law.”;

(b) a clear indication that devices are not to be used in persons who are less than 18 years old;

(c) the overall qualitative composition of the product.

6. Instructions for use

6.1. The instructions for use shall contain:

(a) on top in bold fonts of largest used size in the instructions of use the text: "Only to be implanted in an appropriate medical environment by appropriately trained medical doctors who are qualified or accredited in accordance with national law.";

(b) a clear indication that devices are not to be used in persons who are less than 18 years old;

(c) the recommendation for the user to consider any previous procedures, accidents, conditions, medications or other simultaneous treatments of the consumer that may affect the procedure (for example skin diseases, traumas and auto-immune diseases);

(d) the instruction for the user to consider any specific risks that may be applicable to activities of the consumer (for example profession, sports or other activities regularly performed by the consumer);

(e) a comprehensive list of contra-indications. This list shall include keloid scars;

(f) the overall qualitative and quantitative composition of the product;

(g) the recommendation for the user on a post-implantation monitoring time in order to identify any potential undesirable side-effects;

(h) an indication of the appropriate time interval between treatments, where applicable;

(i) a requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.2 before the consumer is treated with the device.

6.2. The instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a) to (e), of Annex I;

(b) a list of all residual risks and potential side-effects, including those commonly related to surgery such as bleeding, potential drug interactions and the risks associated with anaesthesia, in a clear way;

(c) information on when and how to report undesirable side-effects to the manufacturer, information on device removal, information on when to contact a healthcare professional;

(d) details on volume and size of the device;

(e) the statement "The users received appropriate training on how to safely use the device.", where relevant.

ANNEX IV

Scope

1. This Annex applies to substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing, listed in Section 3 of Annex XVI to Regulation (EU) 2017/745. This Annex only applies to the means for introduction into the body, for example syringes and dermarollers, where they are prefilled with the substances, combinations of substances or other items listed in Section 3 of Annex XVI to Regulation (EU) 2017/745. This Annex does not apply to active devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. Manufacturers shall take into account the following aspects and related risks:

(a) physical and chemical characteristics of the device;

(b) the selection of raw materials in view of biological safety, biocompatibility and chemical and biological additives or contaminants;

(c) biological safety and biocompatibility of the final product, including consideration of at least the aspects of cytotoxicity, sensitisation, irritation, material mediated pyrogenicity, acute systemic toxicity, subacute toxicity, subchronic toxicity, chronic toxicity, genotoxicity, carcinogenicity, implantation, sterilisation residues and degradation products, extractable and leachable substances;

(d) resorption and life-time in the body, indicating the half-life and the end of the resorption, including the possibility of metabolisation (for example enzymatic degradation of the filler material such as hyaluronidase for hyaluronic acid fillers);

(e) microbiological properties, bioburden, microbiological contamination of the final device, residual bacterial endotoxins and sterility;

(f) the specific anatomical location of injection or introduction;

(g) consumer specific factors (for example previous and current treatments (medical and surgical), age restrictions, pregnancy, breast-feeding);

(h) if applicable, risks related to the use of local anaesthetic, either as part of the product or stand-alone;

(i) for non-resorbable devices, the risk associated with the removal of the device;

(j) aspects associated with the use of the device, including:

— injection technique;

— means of injection (for example rollers, catheters or needles);

— maximum quantity injected depending on location and applied technique;

— possible repeated injections;

— force required to administer the product;

— product temperature;

— transfer of the product (for example from a vial to a syringe).

3.2. Where appropriate, manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) microbiological contamination;

(b) presence of manufacturing debris;

(c) hazards associated with the procedure to inject or otherwise introduce the device (including use errors);

(d) migration of the device;

(e) device visibility through the skin;

(f) unintended local inflammation and swelling;

(g) regional swelling or lymphadenopathy;

(h) capsule formation and contracture;

(i) discomfort or pain;

(j) hematoma;

(k) infection and inflammation;

(l) superficial wound;

(m) interruption of wound healing;

(n) scarring and scar hyperpigmentation and hypertrophy;

(o) nerve injury;

(p) seroma;

(q) compartment pressure problems and compartment syndrome;

(r) granuloma, including siliconoma where applicable;

(s) edema;

(t) vascular damage;

(u) severe allergic reactions;

(v) blindness;

(w) necrosis.

4. Specific risk control measures

(a) Devices shall be sterile non-pyrogenic and intended for single use.

(b) The safe use of the device shall be supported by clinical and other data considering the anatomical location.

(c) Long-term data shall be collected to evaluate the presence of non-degradable substances originating from the devices.

(d) Manufacturers shall provide training on the administration and safe use of the device. That training shall be accessible to users.

(e) Presence of substances referred to in Section 10.4.1, points (a) and (b), of Annex I to Regulation (EU) 2017/745 shall be evaluated independently of their concentration.

Information for safety

5. Label

5.1. The label shall contain:

(a) in bold fonts of largest used size on the label the text: "Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law".

(b) a clear indication that devices are not to be used in persons who are less than 18 years old.

6. Instructions for use

6.1. The instructions for use shall contain:

(a) on top in bold font of largest used size in the instructions for use the text: "Only to be administered by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law.";

(b) a clear indication that devices are not to be used in persons who are less than 18 years old;

(c) precise and detailed technical information for a good administering practice;

(d) description of treatment of the most common side-effects, such as overdosing, swelling, hardening, nodules and immune responses, with the instruction to consult a medical professional if needed;

(e) instructions for users as to how and when new injections can be placed at previously injected locations;

(f) a list of constituents, which specifies:

— all constituents responsible for the intended action with specification of their concentration and, where applicable, their molecular weight range, their particle size and their degree of cross-linking, together with the method used for its determination;

— other constituents such as cross-linking agents, solvents, anaesthetics and preservatives, with specification of their concentration;

(g) the recommendation for the user to consider any previous procedures, accidents, conditions, medications or other simultaneous treatments of the consumer that may affect the procedure (for example skin diseases, traumas and auto-immune diseases);

(h) the recommendation for the user of a post-administration monitoring time in order to identify any potential undesirable side-effects;

(i) a requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.2 before the consumer is treated with the device.

6.2. The instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a) to (e), of Annex I;

(b) all residual risks and potential undesirable side-effects listed in a clear way and described in a language commonly understood by lay persons. This includes a clear declaration on the presence of any substances referred to in Section 10.4.1 of Annex I to Regulation (EU) 2017/745, heavy metals or other contaminants;

(c) information on when and how to report undesirable side-effects to the manufacturer;

(d) information on when to contact healthcare professional;

(e) any contra-indications to the procedure;

(f) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant.

In addition, a specific part of the annex shall be designed to record information on the location, the number and the volume of the injections, for each consumer. The manufacturer shall recommend the healthcare professional to fill in this specific part.

ANNEX V

Scope

1. This Annex applies to equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty, listed in Section 4 of Annex XVI to Regulation (EU) 2017/745. This Annex does not apply to active implantable devices.

Definitions

2. For the purpose of this Annex, the following definitions apply:

   (1) "liposuction" means the surgical removal of localised subcutaneous fat deposits by aspiration;

   (2) "liposuction devices" means devices intended by the manufacturer to be used for the purpose of liposuction;

   (3) "lipolysis" means the localised destruction of fat deposit;

   (4) "lipolysis devices" means devices intended by the manufacturer to be used for the purpose of lipolysis;

   (5) "lipoplasty" means the modification of body contours by removal of excess fat;

   (6) "lipoplasty devices" means devices intended by the manufacturer to be used for the purpose of lipoplasty.

Risk management

3. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 4 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 5 of this Annex.

4. Specific risks

4.1. Where relevant as regards the device in question, manufacturers shall take into account the following aspects and related risks:

   (a) the volume of adipose tissue which may be removed or, in the case of lipolysis, destroyed and the expected metabolic effect, including the metabolisation of released tissue components, taking into account the probable different characteristics of the person undergoing treatment;

   (b) the minimum time lapse between subsequent procedures;

   (c) the anatomical location of the use of the device;

   (d) the cannula type, for example the diameter and nature of the tip of the cannula;

   (e) the amount of suction which will be applied;

   (f) the use and subsequent metabolisation of infiltrative fluid with a justification for the choice of fluid and its composition;

   (g) the type of liposuction which the device is intended to provide, for example dry or wet, and the type of anaesthetic;

   (h) whether the device is a simple liposuction device, i.e. blunt cannula suction, or whether it incorporates any other mechanism of action, for example the use of laser energy or ultrasound;

   (i) the age distribution, gender and body-mass-index of the population to which the clinical data or other sources of data relate;

   (j) the way in which energy is emitted.

4.2. Where relevant as regards the device in question, manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) post-operative seroma;

(b) tissue injury, organ perforation and bleeding;

(c) post-operative ecchymosis and edema;

(d) interference with active implantable or active body-worn medical devices and with metallic passive medical devices or other metallic objects present on or inside the body;

(e) thermal injury;

(f) mechanical injuries, including those caused by unintended cavitation, and corresponding side-effects;

(g) inflammation.

4.3. For liposuction devices, in addition to the risks listed in Section 4.2, manufacturers shall analyse, eliminate or reduce as far as possible the following risks:

(a) haemorrhage;

(b) perforation of abdominal viscera, thorax or peritoneum;

(c) pulmonary embolism;

(d) bacterial infections such as necrotizing fasciitis, gas gangrene and sepsis;

(e) hypovolemic shock;

(f) thrombophlebitis;

(g) seizures;

(h) risks related to local anaesthetic use: consideration should be given to lidocaine-induced cardiotoxicity or lidocaine-related drug interactions for tumescent liposuction.

4.4. For lipolysis devices, in addition to those risks listed in Section 4.2, manufacturers shall in particular analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) burns to incision sites and overlying tissue;

(b) other harmful effects of the internal or external local discharge of energy;

(c) over-exposure;

(d) neurovascular and local tissue injury, including reduction in cutaneous sensory nerve function;

(e) remodelling of collagen that may lead to neoformations;

(f) reorganisation of the dermis, with reference to reticular dermis;

(g) body deformity or similar poor aesthetic outcome causing the need for medical intervention;

(h) for lipolysis devices that are surgically invasive, the hazards linked to the types and sizes of incision.

When complying with requirements of this section, manufacturers shall take account of the nature of the tissue and its hydration status.

5. Specific risk control measures

5.1. All materials coming into contact with the body shall be biocompatible, non-irritating, and non-toxic when used in accordance with the instructions for use.

5.2. Invasive parts of the devices shall be sterile and pyrogen-free before use.

5.3. Lipolysis devices shall include controls for the application time, the waveform, the energy applied and the temperature reached on or in the body. The controls shall include simultaneous visual and audible automatic alarms for cases where a critical value is reached for one parameter (for example temperature, energy and pressure level and duration of use) or for a combination of parameters.

5.4. Where applicable, manufacturers shall make sure the devices have the following functions: low energy preset, emergency stop function (for example emergency stop switch), automatic deactivation in case of over-exposure or excessive liposuction, respectively.

5.5. Liposuction devices, lipolysis devices and lipoplasty devices shall not be used in private environments by lay persons.

5.6. Manufacturers shall provide training to users on safe and effective use of the device.

Information for safety

6. Instruction for use

6.1. The instructions for use shall contain a comprehensive list of contra-indications for the consumer. It shall include the following contra-indications:

(a) coagulant disorders, being treated with anticoagulant medications;

(b) uncontrolled hypertension;

(c) diabetes mellitus;

(d) phlebitis and vasculitis;

(e) cancer or tumours;

(f) extreme obesity (body mass index above 40);

(g) pregnancy;

(h) vascular fragility;

(i) recent surgery (6 weeks);

(j) skin infections and open lesions;

(k) varicose veins in the area of treatment;

(l) medical conditions, such as heart, lung, or circulatory system disease;

(m) age less than 18;

(n) incapability to understand the consequences, implications and risks of the medical procedures (for example liposuction, lipolysis, lipoplasty) where the devices are used;

(o) elevated body temperature (pyrexia).

In addition to the contra-indications listed in the first subparagraph, for lipolysis devices employing radiofrequency electric currents or electromagnetic fields, the list shall contain the following:

(a) any metallic passive medical device or other metallic object present on or inside the body;

(b) any active implantable or active body-worn medical device.

6.2. The instructions for use shall list the body parts on which the device cannot be used.

6.3. The instructions for use shall contain a comprehensive list of adverse effects for the consumer. This list shall include the following adverse effects:

(a) hyper- or hypovolaemia;

(b) bradycardia;

(c) venous thromboembolism;

(d) fat embolism;

(e) infection;

(f) fluid accumulation;

(g) skin erythema or panniculitis;

(h) contour irregularities.

6.4. The instructions for use shall contain a comprehensive list of warnings. This list shall include the following warning:

"Liposuction, lipolysis and lipoplasty are not reliable methods for weight reduction. Consideration should be given to exercise and dietary as well as lifestyle modification, both as alternatives to liposuction and lipolysis and in order to maintain any reduction in adipose tissue which these procedures may achieve. Devices have not been validated for the treatment of clinically diagnosed obesity and therefore should not be used for such purposes.".

6.4.1. In addition to the warning referred to in Section 6.4, for liposuction devices, the instructions for use shall contain the following warning:

"The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and the consumer's safety. The capacity of providing adequate, timely fluid management is essential for the consumer's safety.".

6.4.2. In addition to the warnings referred to in Sections 6.4 and 6.4.1, for liposuction devices that may use a tumescent fluid, the instructions for use shall contain the following warnings:

(a) "Careful consideration shall be given to consumer suitability with respect to medication which has the potential to cause bradycardia or hypotension as this has been reported as the cause of death in a number of consumers undergoing tumescent liposuction. Consumers taking drugs such as beta-adrenergic antagonists, non-dihydropyridine calcium-channel blockers, cardiac glycosides, and centrally acting alpha-adrenergic agonists shall be subject to very careful consideration as deaths have been reported due to bradycardia and hypotension. The procedure has to be preceded by a medical consultation which has to be documented and during which chronic disease and drugs taken by patient need to be considered.";

(b) "Consumers shall be warned that they may experience extended post-operative analgesia (for example for 24 hours or more) which may result in reduced sensation in the areas infiltrated and therefore consumers shall be warned to protect themselves from injury.".

6.4.3. In addition to the warning referred to in Section 6.4, for lipolysis devices, the instructions for use shall contain the following warning:

"Liver or cardiovascular dysfunction, such that the transient release of glycerol or free fatty acid, may be associated with increased risk.".

6.5. For liposuction and lipolysis devices, the instructions for use shall contain the following warning:

"Devices intended for invasive use shall only be used in an appropriate medical environment by appropriately trained medical doctors who are qualified or accredited in accordance with national law. The medical doctor who carries out the procedure shall be assisted by at least one medical doctor or allied health professional who is qualified or accredited in accordance with national law.

All staff involved in the procedure shall be trained and shall keep their knowledge of basic cardiac life support and in the checking of equipment and emergency drugs used for resuscitation purposes up-to-date. Medical doctors performing the procedure shall also be trained in advanced cardiac life support.

The medical doctor or allied health professional responsible for anaesthetic management shall ensure appropriate monitoring of the consumer both during the procedure and after it. With respect to tumescent liposuction, appropriate post-procedure monitoring shall be in place as lidocaine levels have been found to rise for up to 16 hours post-delivery.".

6.6. The instructions for use shall contain the requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.7 before the consumer is treated with the device.

6.7. The instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a), (b) and (c), of Annex I;

(b) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant;

(c) information on when and how to report undesirable side-effects to the manufacturer;

(d) a recommendation to undergo a medical consultation, including a diagnostic examination, of the areas intended for the treatment.

ANNEX VI

Scope

1. This Annex applies to high intensity electromagnetic radiation (for example infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment, listed in Section 5 of Annex XVI to Regulation (EU) 2017/745.

   For the purposes of this Annex, skin resurfacing includes skin rejuvenation.

   For the purposes of this Annex, tattoo removal includes removal of permanent make-up.

   For the purposes of this Annex, other skin treatments include non-medical treatment of nevi flammei, haemangioma, teleangiectasia, pigmented skin areas, and scars that are not injury within the meaning of Article 2, point (1), second indent, of Regulation (EU) 2017/745. For example, this Annex applies to devices intended to treat acne scars, but it does not apply to devices for other acne treatment.

   This Annex does not apply to equipment using infrared optical radiation to warm the body or parts of the body and to sunbeds.

Definitions

2. For the purpose of this Annex, the following definitions apply:

   (1) "device for professional use" means a device that is intended to be used in a healthcare environment or otherwise controlled professional environment by professionals having proven qualification in the safe and effective use of the device;

   (2) "device for home use" means a device that is intended to be used in private environments, not in a controlled professional environment, by lay persons.

Risk management

3. When carrying out the risk management process provided for in Annex I to this Regulation, as part of the analysis of risks associated with the device, manufacturers shall consider the specific risks listed in Section 4 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 5 of this Annex.

4. Specific risks

4.1. Manufacturers shall take into account the following aspects and related risks:

   (a) various skin types and the degree of tanning of the skin;

   (b) presence of any skin abnormality (for example relief, texture or colour) or disease affecting the skin;

   (c) age of the consumers;

   (d) possibility of concurrent medical treatments or drug misuse;

   (e) use of photosensitising medicines or cosmetics;

   (f) reduced reaction to harm caused by local or systemic anaesthesia;

   (g) exposure to other light sources.

4.2. Manufacturers shall analyse, eliminate or reduce as far as possible the following risks:

   (a) burns;

   (b) formation of scars and keloids;

   (c) hypopigmentation and hyperpigmentation;

   (d) accelerated aging of skin;

(e) allergic/chemical skin reaction (for example to colour pigments of tattoos or make-up);

(f) formations of skin cancers;

(g) alteration of skin cancers, skin diseases, nevi, herpes, possible delay of disease diagnoses (for example melanoma, endocrine diseases);

(h) reactions in case of possible drug intake or use of cosmetics;

(i) possible reactions to sun or sunbed exposure;

(j) possible photosensitive dermatosis;

(k) vitiligo;

(l) erythema, mostly temporary and occasionally persistent;

(m) purpura resulting from bleeding from small blood vessels;

(n) crusting;

(o) edema;

(p) blistering;

(q) inflammation, folliculitis, skin infection;

(r) eye damage, including damage to retina and cornea;

(s) prickling or feeling of heat;

(t) dry skin and itching due to shaving or combination of shaving and light treatment;

(u) excessive pain;

(v) paradoxical hypertrichosis (increased growth of hair after treatment);

(w) overexposure;

(x) unintended release of radiation;

(y) ignition, explosion or production of fumes.

5. Specific risk control measures

5.1. Manufacturers shall apply the following safety measures as regards devices for professional use:

(a) avoidance of unauthorized access to or unintended use of the devices (for example by means of key switch or code or dual control of energy emission);

(b) display of the characteristics of the emitted optical radiation for the purpose of permanent surveillance and recording of the emission through the device in addition to the requirements of Section 16.2 of Annex I to Regulation (EU) 2017/745;

(c) continuous contact controls and an interlock system ensuring that the device works only in case of suitable skin contact with the emitting area of the device;

(d) avoidance of overexposure for each session of the treatment by particular measures;

(e) where the wavelength of the radiation emitted is less than 1 200 nm, instruments or methods to assess the skin pigmentation to ensure proper settings for the treatment;

(f) measures to avoid overexposure by repeated treatment sessions or repeated treatments;

(g) low energy preset;

(h) optimised limitation of pulse energy and pulse duration (exposure time on tissue) and a combination of these two parameters with the wavelength range;

(i) optimized limitation of treatment areas (spot sizes) also taking into account the parameters referred to in point (h);

(j) minimisation of scattered radiation;

(k) minimisation of the risk of accidental emission;

(l) emergency stop function (for example emergency stop switch);

(m) for devices for hair removal: minimisation of ultraviolet radiation (to be achieved for example by using appropriate high quality band edge filter);

(n) devices intended to deliver a permanent change of the appearance shall not be used on persons who are less than 18 years old;

(o) information for the user on the correct functioning of the device and the actual mode of operation by means of acoustic or optical means in standby mode, in operating mode and in case of loss of skin contact during the procedure;

(p) instruction of the user to protect nevi or lesions during the procedure.

5.2. Devices for home use shall not emit radiation outside the wavelength range between 400 nm and 1 200 nm. Without prejudice to Section 4, a tolerance for the emitted energy on wavelengths above 1 200 nm is permitted up to maximum 15 % of the total emitted energy.

5.3. Devices for home use may only be used for the purpose of hair removal.

5.4. Manufacturers of devices for home use shall implement the risk control measures listed in Section 5.1 unless otherwise provided in this Regulation. In addition, manufacturers of devices for home use shall:

(a) set limits for the duration of exposure and include automatic deactivation to avoid risk of overexposure;

(b) include continuous contact controls and an interlock system ensuring that the device works only in case of full skin contact with the emitting area of the device, instead of applying the requirements laid down in point (c) of Section 5.1;

(c) include an integrated skin tone sensor assessing the skin patch of or near to the area to be treated and allowing emission output only if skin pigmentation is suited for treatment and if there is continuous full skin contact after skin tone analysis, instead of applying the requirements laid down in point (e) of Section 5.1.

Manufacturers of devices for home use shall also make available on the internet, videos with instructions on how to safely use the device.

5.5. Together with the device manufacturers shall provide appropriate eye protection for users, consumers and any other person likely to be exposed to the radiation due to reflection, misuse or mishandling of the emitting device. The eye protection for the user has to ensure that the eyes are protected from intense pulsed light or laser light whilst not impairing accurate and safe treatment.

5.6. If the eye protection is intended to be used several times, it must be ensured that the protection level is not negatively impacted by necessary cleaning or disinfecting procedures during the whole lifetime of the device. Necessary cleaning and disinfecting instructions shall be provided.

5.7. Manufacturers shall provide training accessible to users. Such training shall cover the conditions for safe and effective use of the device, the management of any associated incidents and the identification and subsequent processing of reportable incidents. For devices for home use, videos with instructions shall be considered as training accessible to users.

Information for safety

6. Instructions for use

6.1. The instructions for use shall contain:

(a) the minimum radiation intensity, duration and frequency of use necessary to trigger the desired effect;

(b) the maximum and the recommended radiation intensity, duration and frequency of use;

(c) the minimum interval between several applications at the same location;

(d) the risks arising from excessive use;

(e) the radiation intensity, duration and frequency which triggers a sharp increase of risks, if any;

(f) the radiation intensity, duration and frequency beyond which there is no more additional performance;

(g) the pulse energy, fluence, wavelength range [nm], pulse duration [ms], pulse profile(s);

(h) the maximum admissible treatment spot size [cm^2];

(i) description of the minimum homogeneity of the treatment spot;

(j) description of requirements for the spatial distribution of the treatments spots, taking into account that overlapping treated areas shall not lead to overexposure;

(k) safety features of the device;

(l) the expected lifetime of the device;

(m) the expected stability of performance;

(n) cosmetics and drugs interacting or expected to interact with the treatment and their description;

(o) other sources of radiation, such as prolonged exposure to sun light or sunbeds, that might increase the risks;

(p) for devices for professional use, a requirement for the user to provide the consumer with a copy of the annex provided for in Section 6.11 before the consumer is treated with the device.

6.2. With the exemption of devices for hair removal where excessive hair is not attributed to a medical condition, the manufacturer shall advise the users and the consumers to undergo a medical consultation including a diagnostic examination of the skin areas intended for the treatment. Manufacturers shall advise users not to treat any consumers prior to obtaining documentation from such consultation.

6.3. The instructions for use shall clearly describe requirements for cleaning and maintenance. For devices intended for professional use, the instructions for use shall include the measurement of light energy density and required safety measures, performed at least annually.

For devices for professional use, the manufacturer shall also instruct on how to ensure constant performance and recommend at least an annual electrical safety test and maintenance.

6.4. The instructions for use shall clearly describe the operating environment and the conditions in which the devices can be operated safely. For devices for professional use, the instructions for use shall also include:

(a) the description or a listing of appropriate accessories or conditions of other products used in the procedure;

(b) the safety precautions to be taken, which include the use of non-reflective instruments (no mirrors shall be used), the use of absorbing or diffusing surfaces of tools as well as the avoidance of inflammable products and substances and, where applicable, the need to provide adequate room ventilation;

(c) an adequate warning notice outside the procedure room.

6.5. The instructions for use shall highlight the need:

(a) to avoid at all times exposure of eyes to emitted light;

(b) for users, consumers and any other person likely to be exposed to the radiation due to reflection, misuse or mishandling of the emitting device to wear appropriate eye protection during treatments with intense pulsed light or laser devices, especially when these devices are to be used close to the face.

6.6. The instructions for use shall clearly indicate for which consumers, on which parts of the skin, on which types of skin and for which conditions of skin the device shall not be used.

6.7. The instructions for use shall clearly indicate that the device is not to be used on skin parts which have an increased likelihood of skin cancer, open wounds or rashes, or swollen, red, irritated, infected, or inflamed areas or skin eruptions. In addition, the instructions for use shall give information about further contra-indications such as photosensitive epilepsy, diabetes or pregnancy, if applicable.

6.8. For devices intended to deliver a permanent change of the appearance, the instructions for use shall indicate that they shall not be used on persons who are less than 18 years old.

6.9. For devices for professional use, the manufacturer shall ensure that all appropriate information is made available to the healthcare professional or service provider in order for them to be able to ensure that professional users are evaluating consumers. This includes consumers' suitability for treatment with devices and counselling them appropriately and adequately with respect to risks and potential outcomes of the procedure, taking into account the consumers' health history and the medications they take.

6.10. For devices for home use, the instructions for use shall contain the internet address where the videos with instructions made available in accordance with Section 5.4. can be found.

6.11. The instructions for use of devices for professional use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) information listed in Section 12.1, points (a), (b) and (c), of Annex I;

(b) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant;

(c) information on when and how to report undesirable side-effects to the manufacturer;

(d) a recommendation to undergo a medical consultation, including a diagnostic examination, of the skin areas intended for the treatment.

ANNEX VII

Scope

1. This Annex applies to equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as listed in Section 6 of Annex XVI to Regulation (EU) 2017/745. Such equipment includes devices for transcranial alternating current stimulation, transcranial direct current stimulation, transcranial magnetic stimulation and transcranial random noise stimulation. This Annex does not apply to invasive devices.

Risk management

2. When carrying out the risk management process provided for in Annex I to this Regulation, among risks associated with the device, manufacturers shall consider the specific risks listed in Section 3 of this Annex and, where relevant to the device, adopt the specific risk control measures listed in Section 4 of this Annex.

3. Specific risks

3.1. When carrying out the risk management process, special care shall be taken as to the placement of the electrodes and the strength, waveform, duration and other parameters of the electrical current and magnetic fields.

3.2. Manufacturers shall take into account the following aspects and related risks:

(a) the incorrect placement of electrodes and coils may result in failed performance, enhanced electrical currents in tissue or unintended neural responses;

(b) brain stimulation may have very different neural responses and thus unintended effects on different groups of persons. Some groups may be particularly vulnerable: persons who are less than 18 years old, young adults, pregnant women, psychiatric patients, persons with psychological disorders or medical conditions affecting the central nervous system, alcohol addicts, users of addictive substances and other substances that modify a person's natural perception;

(c) the presence of active implantable or body-worn medical devices and/or metallic passive medical devices or other metallic objects present on or inside the body may give rise to specific risks arising from the application of electrical energy and magnetic fields;

(d) excessive, frequent and cumulative long-term use may result in unforeseen neural effects which in some cases might result in structural changes in the brain.

3.3. Manufacturers shall analyse, eliminate or reduce as far as possible risks related to the following hazards or harms:

(a) psychological risks;

(b) neural and neuro-toxicity risks;

(c) short-term, medium-term and long-term cognitive side-effects, such as compensatory trade-offs (for example the decline or sub-serving of brain regions which are not stimulated);

(d) transient auditory threshold shift or tinnitus;

(e) long-term side-effect changes of the brain functioning;

(f) hazards linked to the long-term effects of repeated stimulation;

(g) hazards linked to the use of the device in certain environments highly stimulating or attention demanding;

(h) atypical or other idiosyncratic effects;

(i) specific hazards arising at the interface between electrodes and skin;

(j) electromagnetic interference or injury caused by interaction with active implants (for example pacemakers, implanted cardioverter-defibrillators, cochlear implants, neural implants), active devices (for example neural stimulation devices, medication infusion devices), non-active metallic implants (for example metallic dental implants) or body-worn devices (for example biosensors);

(k) hazards associated with device usage after intake of alcohol and/or soft-drugs and/or central nervous system stimulating substances/pharmaceuticals;

(l) hazards associated with possible potentiating effects of combined use (usage of few/several devices in the same time targeting same person or different person) and reasonable foreseeable misuse.

4. Specific risk control measures

4.1. When applying Section 4.2 of Annex I, unless there is specific evidence for safe use, the following categories of consumers shall be excluded:

(a) persons with a history of epilepsy;

(b) persons undergoing pharmaceutical treatment for conditions related to the central nervous system;

(c) persons undergoing therapeutic treatment which change the excitability of the central nervous system;

(d) users of illicit substances or other substances that modify a person's natural perception regardless of whether those are commonly understood as therapeutic drugs;

(e) persons who have a tumour in the central nervous system;

(f) persons who have vascular, traumatic, infectious or metabolic lesions or diseases of the brain;

(g) persons who suffer from sleep disorders, drug dependency or alcoholism;

(h) persons who are less than 18 years old;

(i) pregnant women.

4.2. Manufacturers shall apply the following safety measures where relevant:

(a) avoidance of unauthorised access to the device (for example by means of key switch or code) and unintended use of the device (for example by means of dual control of energy emission);

(b) minimisation of stray magnetic fields;

(c) minimisation of the risk of accidental emission;

(d) emergency stop function (for example emergency stop switch);

(e) automatic deactivation where maximum acceptable output is reached;

(f) automatic deactivation where maximum acceptable duration of exposure is reached;

(g) automatic deactivation in case of overexposure due to a combination of output and duration;

(h) videos with instructions on how to safely use the device made available on the internet;

(i) provision of appropriate training accessible to users on safe and effective use of the device;

(j) information for the user on the correct functioning of the device and the actual mode of operation through acoustic or optical means in standby mode, in operating mode and in case of loss of full skin contact during the procedure.

4.3. Devices shall contain controls for the application time, the waveform and the energy applied. They shall contain automatic alarms for cases where a critical value is reached for one parameter (for example energy level, duration of use) or for combination of parameters. Critical values shall be set below the maximum acceptable values.

Information for safety

5. The instructions for use and, if possible, the label, shall indicate the performance that the consumer can expect from the use of the device as well as the risks arising from its use. The intended performance shall be described in such a way that the consumer understands which non-medical effects can be expected from the use of the device (for example enhanced intelligence or improvement in mathematical ability).

6. Information on warnings, precautions and side-effects shall cover:

   (a) specific risks for persons listed in Section 4.1;

   (b) risks for persons with active implantable or active body-worn medical devices;

   (c) risks for persons with metallic passive medical devices or other metallic objects present on or inside the body;

   (d) information about how to deal with over-exposure to energy;

   (e) information on how to deal with psychological disturbances.

7. Instructions for use

7.1. The instructions for use shall indicate clearly how electrodes and magnetic coils are to be placed on the head. If the exact placement cannot be indicated, the instructions for use shall be specific enough to allow correct placement. The risks arising from a wrong placement of electrodes and coils shall be explained as well as potential negative effects on performance.

7.2. The instructions for use shall provide information on:

   (a) the duration, intensity and frequency of stimulation and all risks arising from use, including from excessive use;

   (b) the energy delivered, brain area targeted, wave forms and pulse characteristics.

   Unless there is specific evidence for safe use, as provided for in Section 4.1, the instructions for use shall clearly indicate that the device is not to be used on or by the categories of consumers listed in Section 4.1.

7.3. The instructions for use shall also clearly indicate that the device is not to be used in case of open wounds or rashes, or swollen, red, irritated, infected, or inflamed areas or skin eruptions, where components of the device will come into contact with these areas.

7.4. The instructions for use shall list all possible direct and indirect risks to the consumer undergoing brain stimulation and to the user by interaction of the electric currents, magnetic fields or electromagnetic fields generated by the brain stimulation device with metallic passive implanted medical devices and other metallic objects present on or inside the body as well as with active implantable medical devices (for example pacemakers, implanted cardioverter-defibrillators, cochlear implants and neural implants) and active body-worn medical devices (for example neural stimulation devices and medication infusion devices). This shall include information on conduction of electric current, reinforcement of internal electric fields, heating or displacement of metallic implants such as electrodes, stents, clips, pins, plates, screws, braces, or other metallic objects such as shrapnel or jewellery.

7.5. Where the device is intended or expected to be applied on the consumer by a professional user, the instructions for use shall contain a requirement for the user to provide the consumer with a copy of the annex provided for in Section 7.7 before the consumer is treated with the device;

7.6. The instructions for use shall contain the internet address where the videos with instructions made available in accordance with Section 4.2, point (h) can be found.

7.7. Where the device is intended or expected to be applied on the consumer by a professional user, the instructions for use shall contain an annex, written in a language commonly understood by lay persons and in the form that is easy to be handed over to all the consumers. The annex shall contain:

(a) the information listed in Section 12.1, points (a), (b) and (c), of Annex I;

(b) the statement "The users received appropriate training on the conditions to safely use the device.", where relevant;

(c) information on when and how to report undesirable side-effects to the manufacturer.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2347

of 1 December 2022

laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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 51(3), point (b), thereof,

Whereas:

(1) The classification rules 9 and 10 on active devices in Sections 6.1. and 6.2. of Annex VIII to Regulation (EU) 2017/745 refer to an intended medical purpose, respectively for therapy and diagnosis, and thus cannot be applied to active products without an intended medical purpose referred to in Article 1(2) of that Regulation. Such products are therefore to be classified as class I in accordance with rule 13 in Section 6.5. of Annex VIII to Regulation (EU) 2017/745.

(2) By letter of 28 July 2022, certain Member States jointly requested the reclassification of several active products without an intended medical purpose by way of derogation from Annex VIII to Regulation (EU) 2017/745, in order to ensure an appropriate conformity assessment of those active products that is consistent with their inherent risks before their placing on the market.

(3) According to available scientific evidence on equipment that emits high intensity electromagnetic radiation, as referred to in Section 5 of Annex XVI to Regulation (EU) 2017/745, intended for use on the human body, such as lasers and intense pulsed light ('IPL') equipment, the use of such equipment may cause side effects, for example, superficial burns, inflammation, pain, pigmentation change, erythema, hypertrophic scarring and blisters. Side effects are often indicated as transient, for example, inflammations, but important and long-lasting effects are also reported, such as skin pigmentation changes.

(4) High intensity electromagnetic radiation emitting equipment without an intended medical purpose, intended for use on the human body for hair removal, such as lasers and IPL equipmentthat administer energy to or exchange energy with the human body or supply energy that will be absorbed by the human body, should therefore be classified as class IIa. Such classification also corresponds to classification of analogous active devices that have an intended medical purpose and whose functioning and risks profile are similar to those of the equipment without an intended medical purpose in question.

(5) High intensity electromagnetic radiation emitting equipment without an intended medical purpose, intended for the use on the human body for skin treatment, such as laser or IPL equipment for skin resurfacing, for scar removal, for tattoo removal, or for treatment of nevi flammei, haemangioma, telangiectasia and pigmented skin areas that administer energy to or exchange energy with the human body or supply energy that will be absorbed by the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, should therefore be classified as class IIb. Such classification also corresponds to classification of analogous active devices that have an intended medical purpose and whose functioning and risks profile are similar to those of the equipment without an intended medical purpose in question.

([1]) OJ L 117, 5.5.2017, p. 1.

(6) According to available scientific evidence on equipment intended to be used to reduce, remove or destroy adipose tissue, as referred to in Section 4 of Annex XVI to Regulation (EU) 2017/745, such as equipment for liposuction, radiofrequency lipolysis, ultrasound lipolysis, cryolipolyisis, laser lipolysis, infrared and electrical stimulation lipolysis, acoustic shockwave therapy or lipoplasty, the use of such products may cause side effects, for example, local inflammation, erythema, bruising and swelling. Side effects are often indicated as transient, but important and long-lasting effects are also reported, such as paradoxical adipose hyperplasia after cryolipolysis treatment. Those products should therefore be classified as class IIb. Such classification also corresponds to classification of active therapeutic devices whose functioning and risks profile are similar to those of the equipment without an intended medical purpose in question, intended to administer energy to or exchange energy with the human body or supply energy that will be absorbed by the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy.

(7) According to available scientific evidence on equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as referred to in Section 6 of Annex XVI to Regulation (EU) 2017/745, such as those for transcranial magnetic stimulation or transcranial electric stimulation, the use of such products may cause side effects, for example, atypical brain development, abnormal patterns of brain activity, increase metabolic consumption, fatigue, anxiety, irritability, headaches, muscle twitches, tics, seizures, vertigo and skin irritation at the electrode site. While such equipment is not surgically invasive, the electrical currents or magnetic or electromagnetic fields do penetrate the cranium to modify neuronal activity in the brain. Such modifications can have long-lasting effects and any unintended effects may be difficult to reverse. Such products should therefore be classified as Class III.

(8) As a result of reclassification under this Regulation, in accordance with Article 52 of Regulation (EU) 2017/745, a notified body is to be involved in the conformity assessment of the products concerned, to assess and confirm that, among the relevant general safety and performance requirements, the product achieves the intended performance and that the risks posed by the product have been eliminated or reduced as far as possible.

(9) The Medical Device Coordination Group has been consulted.

(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

By way of derogation from Section 6.5 of Annex VIII to Regulation (EU) 2017/745, the following groups of active products without an intended medical purpose listed in Annex XVI to that Regulation are reclassified as follows:

(a) high intensity electromagnetic radiation emitting equipment as referred to in Section 5 of Annex XVI to Regulation (EU) 2017/745 that is intended for the use on the human body for skin treatment is reclassified as class IIb, unless it is intended for hair removal only in which case it is reclassified as class IIa;

(b) equipment intended to be used to reduce, remove or destroy adipose tissue as referred to in Section 4 of Annex XVI to Regulation (EU) 2017/745, is reclassified as class IIb;

(c) equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain as referred to in Section 6 of Annex XVI to Regulation (EU) 2017/745is reclassified as class III.

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*.

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

Done at Brussels, 1 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2348

of 1 December 2022

amending Annex I to Implementing Regulation (EU) 2021/605 laying down special control measures for African swine fever

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ([1]), and in particular Article 71(3) thereof,

Whereas:

(1) African swine fever is an infectious viral disease affecting kept and wild porcine animals and can have a severe impact on the concerned animal population and the profitability of farming causing disturbance to movements of consignments of those animals and products thereof within the Union and exports to third countries.

(2) Commission Implementing Regulation (EU) 2021/605 ([2]) was adopted within the framework of Regulation (EU) 2016/429, and it lays down special disease control measures regarding African swine fever to be applied for a limited period of time by the Member States listed in Annex I thereto (the Member States concerned), in restricted zones I, II and III listed in that Annex.

(3) The areas listed as restricted zones I, II and III in Annex I to Implementing Regulation (EU) 2021/605 are based on the epidemiological situation of African swine fever in the Union. Annex I to Implementing Regulation (EU) 2021/605 was last amended by Commission Implementing Regulation (EU) 2022/2204 ([3]) following changes in the epidemiological situation as regards that disease in Germany and Lithuania. Since the date of adoption of that Implementing Regulation, the epidemiological situation as regards that disease in certain Member States concerned has evolved.

(4) Any amendments to restricted zones I, II and III in Annex I to Implementing Regulation (EU) 2021/605 should be based on the epidemiological situation as regards African swine fever in the areas affected by that disease and the overall epidemiological situation of African swine fever in the Member State concerned, the level of risk for the further spread of that disease, as well as scientifically based principles and criteria for geographically defining zoning due to African swine fever and the Union's guidelines agreed with the Member States at the Standing Committee on Plants, Animals, Food and Feed and publicly available on the Commission's website ([4]). Such amendments should also take account of international standards, such as the Terrestrial Animal Health Code ([5]) of the World Organisation for Animal Health (WOAH) and justifications for zoning provided by the competent authorities of the Member States concerned.

(5) Since the date of adoption of Implementing Regulation (EU) 2022/2204 the epidemiological situation in certain zones listed as restricted zones III in Latvia and Slovakia has improved as regard kept porcine animals, due to the disease control measures being applied by those Member States in accordance with Union legislation.

([1]) OJ L 84, 31.3.2016, p. 1.

([2]) Commission Implementing Regulation (EU) 2021/605 of 7 April 2021 laying down special control measures for African swine fever (OJ L 129, 15.4.2021, p. 1).

([3]) Commission Implementing Regulation (EU) 2022/2204 of 11 November 2022 amending Annex I to Implementing Regulation (EU) 2021/605 laying down special control measures for African swine fever (OJ L 293, 14.11.2022, p. 5).

([4]) Working Document SANTE/7112/2015/Rev. 3 'Principles and criteria for geographically defining ASF regionalisation'. https://ec.europa.eu/food/animals/animal-diseases/control-measures/asf_en

([5]) OIE Terrestrial Animal Health Code, 29th Edition, 2021. Volumes I and II ISBN 978-92-95115-40-8; https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/

(6) Taking into account the effectiveness of the disease control measures for African swine fever for kept porcine animals in certain restricted zones III listed in Annex I to Implementing Regulation (EU) 2021/605 being applied in Latvia in accordance with Commission Delegated Regulation (EU) 2020/687 ([6]), and in particular those laid down in Articles 22, 25 and 40 thereof, and in line with the risk mitigation measures for African swine fever set out in the WOAH Code, certain areas in the Ventspils, Balvu and Rēzeknes counties in Latvia, currently listed as restricted zones III in Annex I to Implementing Regulation (EU) 2021/605 should now be listed as restricted zones II in that Annex, due to the absence of outbreaks of African swine fever in kept porcine animals in those restricted zones III for the past three months, while the disease is still present in wild porcine animals. Those restricted zones III should now be listed as restricted zones II taking account of the current African swine fever epidemiological situation.

(7) Also, taking into account the effectiveness of the disease control measures for African swine fever for kept porcine animals in certain restricted zones III listed in Annex I to Implementing Regulation (EU) 2021/605 being applied in Slovakia in accordance with Delegated Regulation (EU) 2020/687, and in particular those laid down in Articles 22, 25 and 40 thereof, and in line with the risk mitigation measures for African swine fever set out in the WOAH Code, certain areas in the Rimavská Sobota district in Slovakia, currently listed as restricted zones III in Annex I to Implementing Regulation (EU) 2021/605 should now be listed as restricted zones II in that Annex, due to the absence of outbreaks of African swine fever in kept porcine animals in those restricted zones III for the past twelve months, while the disease is still present in wild porcine animals. Those restricted zones III should now be listed as restricted zones II taking account of the current African swine fever epidemiological situation.

(8) In order to take account of the recent developments in the epidemiological situation of African swine fever in the Union, and in order to combat the risks associated with the spread of that disease in a proactive manner new restricted zones of a sufficient size should be demarcated for Latvia and Slovakia, and listed as restricted zones II in Annex I to Implementing Regulation (EU) 2021/605. As the situation as regards African swine fever is very dynamic in the Union, when demarcating those new restricted zones, account has been taken of the epidemiological situation in the surrounding areas.

(9) Given the urgency of the epidemiological situation in the Union as regards the spread of African swine fever, it is important that the amendments to be made to Annex I to Implementing Regulation (EU) 2021/605 by this Implementing Regulation take effect as soon as possible.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Implementing Regulation (EU) 2021/605 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

([6]) Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

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

Done at Brussels, 1 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex I to Implementing Regulation (EU) 2021/605 is replaced by the following:

'ANNEX I

RESTRICTED ZONES

PART I

1. **Germany**

The following restricted zones I in Germany:

Bundesland Brandenburg:

— Landkreis Dahme-Spreewald:

  — Gemeinde Alt Zauche-Wußwerk,

  — Gemeinde Byhleguhre-Byhlen,

  — Gemeinde Märkische Heide, mit den Gemarkungen Alt Schadow, Neu Schadow, Pretschen, Plattkow, Wittmannsdorf, Schuhlen-Wiese, Bückchen, Kuschkow, Gröditsch, Groß Leuthen, Leibchel, Glietz, Groß Leine, Dollgen, Krugau, Dürrenhofe, Biebersdorf und Klein Leine,

  — Gemeinde Neu Zauche,

  — Gemeinde Schwielochsee mit den Gemarkungen Groß Liebitz, Guhlen, Mochow und Siegadel,

  — Gemeinde Spreewaldheide,

  — Gemeinde Straupitz,

— Landkreis Märkisch-Oderland:

  — Gemeinde Müncheberg mit den Gemarkungen Müncheberg, Eggersdorf bei Müncheberg und Hoppegarten bei Müncheberg,

  — Gemeinde Bliesdorf mit den Gemarkungen Kunersdorf - westlich der B167 und Bliesdorf - westlich der B167

  — Gemeinde Märkische Höhe mit den Gemarkungen Reichenberg und Batzlow,

  — Gemeinde Wriezen mit den Gemarkungen Haselberg, Frankenfelde, Schulzendorf, Lüdersdorf Biesdorf, Rathsdorf - westlich der B 167 und Wriezen - westlich der B167

  — Gemeinde Buckow (Märkische Schweiz),

  — Gemeinde Strausberg mit den Gemarkungen Hohenstein und Ruhlsdorf,

  — Gemeine Garzau-Garzin,

  — Gemeinde Waldsieversdorf,

  — Gemeinde Rehfelde mit der Gemarkung Werder,

  — Gemeinde Reichenow-Mögelin,

  — Gemeinde Prötzel mit den Gemarkungen Harnekop, Sternebeck und Prötzel östlich der B 168 und der L35,

  — Gemeinde Oberbarnim,

  — Gemeinde Bad Freienwalde mit der Gemarkung Sonnenburg,

  — Gemeinde Falkenberg mit den Gemarkungen Dannenberg, Falkenberg westlich der L 35, Gersdorf und Kruge,

  — Gemeinde Höhenland mit den Gemarkungen Steinbeck, Wollenberg und Wölsickendorf,

— Landkreis Barnim:

  — Gemeinde Joachimsthal östlich der L220 (Eberswalder Straße), östlich der L23 (Töpferstraße und Templiner Straße), östlich der L239 (Glambecker Straße) und Schorfheide (JO) östlich der L238,

  — Gemeinde Friedrichswalde mit der Gemarkung Glambeck östlich der L 239,

  — Gemeinde Althüttendorf,

  — Gemeinde Ziethen mit den Gemarkungen Groß Ziethen und Klein Ziethen westlich der B198,

  — Gemeinde Chorin mit den Gemarkungen Golzow, Senftenhütte, Buchholz, Schorfheide (Ch), Chorin westlich der L200 und Sandkrug nördlich der L200,

  — Gemeinde Britz,

  — Gemeinde Schorfheide mit den Gemarkungen Altenhof, Werbellin, Lichterfelde und Finowfurt,

  — Gemeinde (Stadt) Eberswalde mit der Gemarkungen Finow und Spechthausen und der Gemarkung Eberswalde südlich der B167 und westlich der L200,

  — Gemeinde Breydin,

  — Gemeinde Melchow,

  — Gemeinde Sydower Fließ mit der Gemarkung Grüntal nördlich der K6006 (Landstraße nach Tuchen), östlich der Schönholzer Straße und östlich Am Postweg,

  — Hohenfinow südlich der B167,

— Landkreis Uckermark:

  — Gemeinde Passow mit den Gemarkungen Briest, Passow und Schönow,

  — Gemeinde Mark Landin mit den Gemarkungen Landin nördlich der B2, Grünow und Schönermark,

  — Gemeinde Angermünde mit den Gemarkungen Frauenhagen, Mürow, Angermünde nördlich und nordwestlich der B2, Dobberzin nördlich der B2, Kerkow, Welsow, Bruchhagen, Greiffenberg, Günterberg, Biesenbrow, Görlsdorf, Wolletz und Altkünkendorf,

  — Gemeinde Zichow,

  — Gemeinde Casekow mit den Gemarkungen Blumberg, Wartin, Luckow-Petershagen und den Gemarkungen Biesendahlshof und Casekow westlich der L272 und nördlich der L27,

  — Gemeinde Hohenselchow-Groß Pinnow mit der Gemarkung Hohenselchow nördlich der L27,

  — Gemeinde Tantow,

  — Gemeinde Mescherin mit der Gemarkung Radekow, der Gemarkung Rosow südlich der K 7311 und der Gemarkung Neurochlitz westlich der B2,

  — Gemeinde Gartz (Oder) mit der Gemarkung Geesow westlich der B2 sowie den Gemarkungen Gartz und Hohenreinkendorf nördlich der L27 und der B2 bis zur Kastanienallee, dort links abbiegend dem Schülerweg folgend bis Höhe Bahnhof, von hier in östlicher Richtung den Salveybach kreuzend bis zum Tantower Weg, diesen in nördlicher Richtung bis zu Stettiner Straße, diese weiter folgend bis zur B2, dieser in nördlicher Richtung folgend,

  — Gemeinde Pinnow nördlich und westlich der B2,

— Landkreis Oder-Spree:

  — Gemeinde Storkow (Mark),

  — Gemeinde Spreenhagen mit den Gemarkungen Braunsdorf, Markgrafpieske, Lebbin und Spreenhagen,

— Gemeinde Grünheide (Mark) mit den Gemarkungen Kagel, Kienbaum und Hangelsberg,

— Gemeinde Fürstenwalde westlich der B 168 und nördlich der L 36,

— Gemeinde Rauen,

— Gemeinde Wendisch Rietz bis zur östlichen Uferzone des Scharmützelsees und von der südlichen Spitze des Scharmützelsees südlich der B246,

— Gemeinde Reichenwalde,

— Gemeinde Bad Saarow mit der Gemarkung Petersdorf und der Gemarkung Bad Saarow-Pieskow westlich der östlichen Uferzone des Scharmützelsees und ab nördlicher Spitze westlich der L35,

— Gemeinde Tauche mit der Gemarkung Werder,

— Gemeinde Steinhöfel mit den Gemarkungen Jänickendorf, Schönfelde, Beerfelde, Gölsdorf, Buchholz, Tempelberg und den Gemarkungen Steinhöfel, Hasenfelde und Heinersdorf westlich der L36 und der Gemarkung Neuendorf im Sande nördlich der L36,

— Landkreis Spree-Neiße:

— Gemeinde Turnow-Preilack mit der Gemarkung Turnow,

— Gemeinde Drachhausen,

— Gemeinde Schmogrow-Fehrow,

— Gemeinde Drehnow,

— Gemeinde Teichland mit den Gemarkungen Maust und Neuendorf,

— Gemeinde Guhrow,

— Gemeinde Werben,

— Gemeinde Dissen-Striesow,

— Gemeinde Briesen,

— Gemeinde Kolkwitz mit den Gemarkungen Klein Gaglow, Hähnchen, Kolkwitz, Glinzig und Krieschow nördl. der BAB 15, Gulben, Papitz, Babow, Eichow, Limberg und Milkersdorf,

— Gemeinde Burg (Spreewald)

— Kreisfreie Stadt Cottbus außer den Gemarkungen Kahren, Gallinchen, Groß Gaglow und der Gemarkung Kiekebusch südlich der BAB,

— Landkreis Oberspreewald-Lausitz:

— Gemeinde Lauchhammer,

— Gemeinde Schwarzheide,

— Gemeinde Schipkau,

— Gemeinde Senftenberg mit den Gemarkungen Brieske, Niemtsch, Senftenberg und Reppist,

— die Gemeinde Schwarzbach mit der Gemarkung Biehlen,

— Gemeinde Großräschen mit den Gemarkungen Wormlage, Saalhausen, Barzig, Freienhufen, Großräschen,

— Gemeinde Vetschau/Spreewald mit den Gemarkungen: Naundorf, Fleißdorf, Suschow, Stradow, Göritz, Koßwig, Vetschau, Repten, Tornitz, Missen und Orgosen,

— Gemeinde Calau mit den Gemarkungen: Kalkwitz, Mlode, Saßleben, Reuden, Bolschwitz, Säritz, Calau, Kemmen, Werchow und Gollmitz,

— Gemeinde Luckaitztal,

— Gemeinde Bronkow,

— Gemeinde Altdöbern mit der Gemarkung Altdöbern westlich der Bahnlinie,

— Gemeinde Tettau,

— Landkreis Elbe-Elster:

— Gemeinde Großthiemig,

— Gemeinde Hirschfeld,

— Gemeinde Gröden,

— Gemeinde Schraden,

— Gemeinde Merzdorf,

— Gemeinde Röderland mit der Gemarkung Wainsdorf, Prösen, Stolzenhain a.d. Röder,

— Gemeinde Plessa mit der Gemarkung Plessa,

— Landkreis Prignitz:

— Gemeinde Groß Pankow mit den Gemarkungen Baek, Tangendorf, Tacken, Hohenvier, Strigleben, Steinberg und Gulow,

— Gemeinde Perleberg mit der Gemarkung Schönfeld,

— Gemeinde Karstädt mit den Gemarkungen Postlin, Strehlen, Blüthen, Klockow, Premslin, Glövzin, Waterloo, Karstädt, Dargardt, Garlin und die Gemarkungen Groß Warnow, Klein Warnow, Reckenzin, Streesow und Dallmin westlich der Bahnstrecke Berlin/Spandau-Hamburg/Altona,

— Gemeinde Gülitz-Reetz,

— Gemeinde Putlitz mit den Gemarkungen Lockstädt, Mansfeld und Laaske,

— Gemeinde Triglitz,

— Gemeinde Marienfließ mit der Gemarkung Frehne,

— Gemeinde Kümmernitztal mit der Gemarkungen Buckow, Preddöhl und Grabow,

— Gemeinde Gerdshagen mit der Gemarkung Gerdshagen,

— Gemeinde Meyenburg,

— Gemeinde Pritzwalk mit der Gemarkung Steffenshagen,

Bundesland Sachsen:

— Stadt Dresden:

— Stadtgebiet, sofern nicht bereits Teil der Sperrzone II,

— Landkreis Meißen:

— Gemeinde Diera-Zehren, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Glaubitz, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Hirschstein,

— Gemeinde Käbschütztal,

— Gemeinde Klipphausen, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Niederau, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Nünchritz, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Röderaue, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Stadt Gröditz, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Stadt Lommatzsch,

— Gemeinde Stadt Meißen, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Stadt Nossen,

— Gemeinde Stadt Riesa,

— Gemeinde Stadt Strehla,

— Gemeinde Stauchitz,

— Gemeinde Wülknitz, sofern nicht bereits Teil der Sperrzone II,

— Gemeinde Zeithain,

— Landkreis Mittelsachsen:

— Gemeinde Großweitzschen mit den Ortsteilen Döschütz, Gadewitz, Niederranschütz, Redemitz,

— Gemeinde Ostrau mit den Ortsteilen Auerschütz, Beutig, Binnewitz, Clanzschwitz, Delmschütz, Döhlen, Jahna, Kattnitz, Kiebitz, Merschütz, Münchhof, Niederlützschera, Noschkowitz, Oberlützschera, Obersteina, Ostrau, Pulsitz, Rittmitz, Schlagwitz, Schmorren, Schrebitz, Sömnitz, Trebanitz, Zschochau,

— Gemeinde Reinsberg,

— Gemeinde Stadt Döbeln mit den Ortsteilen Beicha, Bormitz, Choren, Döbeln, Dreißig, Geleitshäuser, Gertitzsch, Gödelitz, Großsteinbach, Juchhöh, Kleinmockritz, Leschen, Lüttewitz, Maltitz, Markritz, Meila, Mochau, Nelkanitz, Oberranschütz, Petersberg, Präbschütz, Prüfern, Schallhausen, Schweimnitz, Simselwitz, Theeschütz, Zschackwitz, Zschäschütz,

— Gemeinde Stadt Großschirma mit den Ortsteilen Obergruna, Siebenlehn,

— Gemeinde Stadt Roßwein mit den Ortsteilen Gleisberg, Haßlau, Klinge, Naußlitz, Neuseifersdorf, Niederforst, Ossig, Roßwein, Seifersdorf, Wettersdorf, Wetterwitz,

— Gemeinde Striegistal mit den Ortsteilen Gersdorf, Kummersheim, Marbach,

— Gemeinde Zschaitz-Ottewig,

— Landkreis Nordsachsen:

— Gemeinde Arzberg mit den Ortsteilen Stehla, Tauschwitz,

— Gemeinde Cavertitz mit den Ortsteilen Außig, Cavertitz, Klingenhain, Schirmenitz, Treptitz,

— Gemeinde Liebschützberg mit den Ortsteilen Borna, Bornitz, Clanzschwitz, Ganzig, Kleinragewitz, Laas, Leckwitz, Liebschütz, Sahlassan, Schönnewitz, Terpitz östlich der Querung am Käferberg, Wadewitz, Zaußwitz,

— Gemeinde Naundorf mit den Ortsteilen Casabra, Gastewitz, Haage, Hof, Hohenwussen, Kreina, Nasenberg, Raitzen, Reppen, Salbitz, Stennschütz, Zeicha,

— Gemeinde Stadt Belgern-Schildau mit den Ortsteilen Ammelgoßwitz, Dröschkau, Liebersee östlich der B182, Oelzschau, Seydewitz, Staritz, Wohlau,

— Gemeinde Stadt Mügeln mit den Ortsteilen Mahris, Schweta südlich der K8908, Zschannewitz,

— Gemeinde Stadt Oschatz mit den Ortsteilen Lonnewitz östlich des Sandbaches und nördlich der B6, Oschatz östlich des Schmorkauer Wegs und nördlich der S28, Rechau, Schmorkau, Zöschau,

— Landkreis Sächsische Schweiz-Osterzgebirge:

— Gemeinde Bannewitz,

— Gemeinde Dürröhrsdorf-Dittersbach,

— Gemeinde Kreischa,

— Gemeinde Lohmen,

— Gemeinde Müglitztal,

— Gemeinde Stadt Dohna,

— Gemeinde Stadt Freital,

— Gemeinde Stadt Heidenau,

— Gemeinde Stadt Hohnstein,

— Gemeinde Stadt Neustadt i. Sa.,

— Gemeinde Stadt Pirna,

— Gemeinde Stadt Rabenau mit den Ortsteilen Lübau, Obernaundorf, Oelsa, Rabenau und Spechtritz,

— Gemeinde Stadt Stolpen,

— Gemeinde Stadt Tharandt mit den Ortsteilen Fördergersdorf, Großopitz, Kurort Hartha, Pohrsdorf und Spechtshausen,

— Gemeinde Stadt Wilsdruff, sofern nicht bereits Teil der Sperrzone II,

Bundesland Mecklenburg-Vorpommern:

— Landkreis Vorpommern Greifswald

— Gemeinde Penkun,

— Gemeinde Nadrensee,

— Gemeinde Krackow,

— Gemeinde Glasow,

— Gemeinde Grambow,

— Landkreis Ludwigslust-Parchim:

— Gemeinde Barkhagen mit den Ortsteilen und Ortslagen: Altenlinden, Kolonie Lalchow, Plauerhagen, Zarchlin, Barkow-Ausbau, Barkow,

— Gemeinde Blievenstorf mit dem Ortsteil: Blievenstorf,

— Gemeinde Brenz mit den Ortsteilen und Ortslagen: Neu Brenz, Alt Brenz,

— Gemeinde Domsühl mit den Ortsteilen und Ortslagen: Severin, Bergrade Hof, Bergrade Dorf, Zieslübbe, Alt Dammerow, Schlieven, Domsühl, Domsühl-Ausbau, Neu Schlieven,

— Gemeinde Gallin-Kuppentin mit den Ortsteilen und Ortslagen: Kuppentin, Kuppentin-Ausbau, Daschow, Zahren, Gallin, Penzlin,

— Gemeinde Ganzlin mit den Ortsteilen und Ortslagen: Dresenow, Dresenower Mühle, Twietfort, Ganzlin, Tönchow, Wendisch Priborn, Liebhof, Gnevsdorf,

— Gemeinde Granzin mit den Ortsteilen und Ortslagen: Lindenbeck, Greven, Beckendorf, Bahlenrade, Granzin,

— Gemeinde Grabow mit den Ortsteilen und Ortslagen: Fresenbrügge, Grabow, Griemoor, Heidehof, Kaltehof, Winkelmoor,

— Gemeinde Groß Laasch mit den Ortsteilen und Ortslagen: Groß Laasch,

— Gemeinde Kremmin mit den Ortsteilen und Ortslagen: Beckentin, Kremmin,

— Gemeinde Kritzow mit den Ortsteilen und Ortslagen: Schlemmin, Kritzow,

— Gemeinde Lewitzrand mit dem Ortsteil und Ortslage: Matzlow-Garwitz (teilweise),

— Gemeinde Lübz mit den Ortsteilen und Ortslagen: Bobzin, Broock, Broock Ausbau, Hof Gischow, Lübz, Lutheran, Lutheran Ausbau, Riederfelde, Ruthen, Wessentin, Wessentin Ausbau,

— Gemeinde Neustadt-Glewe mit den Ortsteilen und Ortslagen: Hohes Feld, Kiez, Klein Laasch, Liebs Siedlung, Neustadt-Glewe, Tuckhude, Wabel,

— Gemeinde Obere Warnow mit den Ortsteilen und Ortslagen: Grebbin und Wozinkel, Gemarkung Kossebade teilweise, Gemarkung Herzberg mit dem Waldgebiet Bahlenholz bis an die östliche Gemeindegrenze, Gemarkung Woeten unmittelbar östlich und westlich der L16,

— Gemeinde Parchim mit den Ortsteilen und Ortslagen: Dargelütz, Neuhof, Kiekindemark, Neu Klockow, Möderitz, Malchow, Damm, Parchim, Voigtsdorf, Neu Matzlow,

— Gemeinde Passow mit den Ortsteilen und Ortslagen: Unterbrüz, Brüz, Welzin, Neu Brüz, Weisin, Charlottenhof, Passow,

— Gemeinde Plau am See mit den Ortsteilen und Ortslagen: Reppentin, Gaarz, Silbermühle, Appelburg, Seelust, Plau-Am See, Plötzenhöhe, Klebe, Lalchow, Quetzin, Heidekrug,

— Gemeinde Rom mit den Ortsteilen und Ortslagen: Lancken, Stralendorf, Rom, Darze, Paarsch,

— Gemeinde Spornitz mit den Ortsteilen und Ortslagen: Dütschow, Primark, Steinbeck, Spornitz,

— Gemeinde Werder mit den Ortsteilen und Ortslagen: Neu Benthen, Benthen, Tannenhof, Werder.

2. **Estonia**

The following restricted zones I in Estonia:

— Hiiu maakond.

3. **Greece**

The following restricted zones I in Greece:

— in the regional unit of Drama:

  — the community departments of Sidironero and Skaloti and the municipal departments of Livadero and Ksiropotamo (in Drama municipality),

  — the municipal department of Paranesti (in Paranesti municipality),

  — the municipal departments of Kokkinogeia, Mikropoli, Panorama, Pyrgoi (in Prosotsani municipality),

  — the municipal departments of Kato Nevrokopi, Chrysokefalo, Achladea, Vathytopos, Volakas, Granitis, Dasotos, Eksohi, Katafyto, Lefkogeia, Mikrokleisoura, Mikromilea, Ochyro, Pagoneri, Perithorio, Kato Vrontou and Potamoi (in Kato Nevrokopi municipality),

— in the regional unit of Xanthi:

  — the municipal departments of Kimmerion, Stavroupoli, Gerakas, Dafnonas, Komnina, Kariofyto and Neochori (in Xanthi municipality),

  — the community departments of Satres, Thermes, Kotyli, and the municipal departments of Myki, Echinos and Oraio and (in Myki municipality),

  — the community department of Selero and the municipal department of Sounio (in Avdira municipality),

— in the regional unit of Rodopi:

  — the municipal departments of Komotini, Anthochorio, Gratini, Thrylorio, Kalhas, Karydia, Kikidio, Kosmio, Pandrosos, Aigeiros, Kallisti, Meleti, Neo Sidirochori and Mega Doukato (in Komotini municipality),

  — the municipal departments of Ipio, Arriana, Darmeni, Archontika, Fillyra, Ano Drosini, Aratos and the Community Departments Kehros and Organi (in Arriana municipality),

— the municipal departments of Iasmos, Sostis, Asomatoi, Polyanthos and Amvrosia and the community department of Amaxades (in Iasmos municipality),

— the municipal department of Amaranta (in Maroneia Sapon municipality),

— in the regional unit of Evros:

— the municipal departments of Kyriaki, Mandra, Mavrokklisi, Mikro Dereio, Protokklisi, Roussa, Goniko, Geriko, Sidirochori, Megalo Derio, Sidiro, Giannouli, Agriani and Petrolofos (in Soufli municipality),

— the municipal departments of Dikaia, Arzos, Elaia, Therapio, Komara, Marasia, Ormenio, Pentalofos, Petrota, Plati, Ptelea, Kyprinos, Zoni, Fulakio, Spilaio, Nea Vyssa, Kavili, Kastanies, Rizia, Sterna, Ampelakia, Valtos, Megali Doxipara, Neochori and Chandras (in Orestiada municipality),

— the municipal departments of Asvestades, Ellinochori, Karoti, Koufovouno, Kiani, Mani, Sitochori, Alepochori, Asproneri, Metaxades, Vrysika, Doksa, Elafoxori, Ladi, Paliouri and Poimeniko (in Didymoteixo municipality),

— in the regional unit of Serres:

— the municipal departments of Kerkini, Livadia, Makrynitsa, Neochori, Platanakia, Petritsi, Akritochori, Vyroneia, Gonimo, Mandraki, Megalochori, Rodopoli, Ano Poroia, Katw Poroia, Sidirokastro, Vamvakophyto, Promahonas, Kamaroto, Strymonochori, Charopo, Kastanousi and Chortero and the community departments of Achladochori, Agkistro and Kapnophyto (in Sintiki municipality),

— the municipal departments of Serres, Elaionas and Oinoussa and the community departments of Orini and Ano Vrontou (in Serres municipality),

— the municipal departments of Dasochoriou, Irakleia, Valtero, Karperi, Koimisi, Lithotopos, Limnochori, Podismeno and Chrysochorafa (in Irakleia municipality).

4. **Latvia**

The following restricted zones I in Latvia:

— Dienvidkurzemes novada, Grobiņas pagasts, Nīcas pagasta daļa uz ziemeļiem no apdzīvotas vietas Bernāti, autoceļa V1232, A11, V1222, Bārtas upes, Otaņķu pagasts, Grobiņas pilsēta,

— Ropažu novada Stopiņu pagasta daļa, kas atrodas uz rietumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes.

5. **Lithuania**

The following restricted zones I in Lithuania:

— Kalvarijos savivaldybė,

— Klaipėdos rajono savivaldybė: Agluonėnų, Dovilų, Gargždų, Priekulės, Vėžaičių, Kretingalės ir Dauparų-Kvietinių seniūnijos,

— Marijampolės savivaldybė išskyrus Šumskų ir Sasnavos seniūnijos,

— Palangos miesto savivaldybė,

— Vilkaviškio rajono savivaldybė: Bartninkų, Gražiškių, Keturvalakių, Pajevonio, Virbalio, Vištyčio seniūnijos.

6. **Hungary**

The following restricted zones I in Hungary:

— Békés megye 950950, 950960, 950970, 951950, 952050, 952750, 952850, 952950, 953050, 953150, 953650, 953660, 953750, 953850, 953960, 954250, 954260, 954350, 954450, 954550, 954650, 954750, 954850, 954860, 954950, 955050, 955150, 955250, 955260, 955270, 955350, 955450, 955510, 955650, 955750, 955760, 955850, 955950, 956050, 956060, 956150 és 956160 kódszámú vadgazdálkodási egységeinek teljes területe,

— Bács-Kiskun megye 600150, 600850, 601550, 601650, 601660, 601750, 601850, 601950, 602050, 603250, 603750 és 603850 kódszámú vadgazdálkodási egységeinek teljes területe,

— Budapest 1 kódszámú, vadgazdálkodási tevékenységre nem alkalmas területe,

— Csongrád-Csanád megye 800150, 800160, 800250, 802220, 802260, 802310 és 802450 kódszámú vadgazdálkodási egységeinek teljes területe,

— Fejér megye 400150, 400250, 400351, 400352, 400450, 400550, 401150, 401250, 401350, 402050, 402350, 402360, 402850, 402950, 403050, 403450, 403550, 403650, 403750, 403950, 403960, 403970, 404650, 404750, 404850, 404950, 404960, 405050, 405750, 405850, 405950,

— 406050, 406150, 406550, 406650 és 406750 kódszámú vadgazdálkodási egységeinek teljes területe,

— Győr-Moson-Sopron megye 100550, 100650, 100950, 101050, 101350, 101450, 101550, 101560 és 102150 kódszámú vadgazdálkodási egységeinek teljes területe,

— Jász-Nagykun-Szolnok megye 750150, 750160, 750260, 750350, 750450, 750460, 754450, 754550, 754560, 754570, 754650, 754750, 754950, 755050, 755150, 755250, 755350 és 755450 kódszámú vadgazdálkodási egységeinek teljes területe,

— Komárom-Esztergom megye 250150, 250250, 250450, 250460, 250550, 250650, 250750, 251050, 251150, 251250, 251350, 251360, 251650, 251750, 251850, 252250, kódszámú vadgazdálkodási egységeinek teljes területe,

— Pest megye 571550, 572150, 572250, 572350, 572550, 572650, 572750, 572850, 572950, 573150, 573250, 573260, 573350, 573360, 573450, 573850, 573950, 573960, 574050, 574150, 574350, 574360, 574550, 574650, 574750, 574850, 574860, 574950, 575050, 575150, 575250, 575350, 575550, 575650, 575750, 575850, 575950, 576050, 576150, 576250, 576350, 576450, 576650, 576750, 576850, 576950, 577050, 577150, 577350, 577450, 577650, 577850, 577950, 578050, 578150, 578250, 578350, 578360, 578450, 578550, 578560, 578650, 578850, 578950, 579050, 579150, 579250, 579350, 579450, 579460, 579550, 579650, 579750, 580250 és 580450 kódszámú vadgazdálkodási egységeinek teljes területe.

7. **Poland**

The following restricted zones I in Poland:

w województwie kujawsko - pomorskim:

— powiat rypiński,

— powiat brodnicki,

— powiat grudziądzki,

— powiat miejski Grudziądz,

— powiat wąbrzeski,

w województwie warmińsko-mazurskim:

— gminy Wielbark i Rozogi w powiecie szczycieńskim,

w województwie podlaskim:

— gminy Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew i część gminy Kulesze Kościelne położona na południe od linii wyznaczonej przez linię kolejową w powiecie wysokomazowieckim,

— gminy Miastkowo, Nowogród, Śniadowo i Zbójna w powiecie łomżyńskim,

— gminy Szumowo, Zambrów z miastem Zambrów i część gminy Kołaki Kościelne położona na południe od linii wyznaczonej przez linię kolejową w powiecie zambrowskim,

— gminy Grabowo, Kolno i miasto Kolno, Turośl w powiecie kolneńskim,

w województwie mazowieckim:

— powiat ostrołęcki,

— powiat miejski Ostrołęka,

— gminy Bielsk, Brudzeń Duży, Bulkowo, Drobin, Gąbin, Łąck, Nowy Duninów, Radzanowo, Słupno, Staroźreby i Stara Biała w powiecie płockim,

— powiat miejski Płock,

— powiat ciechanowski,

— gminy Baboszewo, Dzierzążnia, Joniec, Nowe Miasto, Płońsk i miasto Płońsk, Raciąż i miasto Raciąż, Sochocin w powiecie płońskim,

— powiat sierpecki,

— gmina Bieżuń, Lutocin, Siemiątkowo i Żuromin w powiecie żuromińskim,

— część powiatu ostrowskiego niewymieniona w części II załącznika I,

— gminy Dzieżgowo, Lipowiec Kościelny, Mława, Radzanów, Strzegowo, Stupsk, Szreńsk, Szydłowo, Wiśniewo w powiecie mławskim,

— powiat przasnyski,

— powiat makowski,

— powiat pułtuski,

— część powiatu wyszkowskiego niewymieniona w części II załącznika I,

— część powiatu węgrowskiego niewymieniona w części II załącznika I,

— część powiatu wołomińskiego niewymieniona w części II załącznika I,

— gminy Mokobody i Suchożebry w powiecie siedleckim,

— gminy Dobre, Jakubów, Kałuszyn, Stanisławów w powiecie mińskim,

— gminy Bielany i gmina wiejska Sokołów Podlaski w powiecie sokołowskim,

— powiat gostyniński,

w województwie podkarpackim:

— gmina Krempna w powiecie jasielskim,

— część powiatu ropczycko – sędziszowskiego niewymieniona w części II załącznika I,

— gminy Pruchnik, Rokietnica, Roźwienica, w powiecie jarosławskim,

— gminy Fredropol, Krasiczyn, Krzywcza, Przemyśl, część gminy Orły położona na zachód od linii wyznaczonej przez drogę nr 77, część gminy Żurawica na zachód od linii wyznaczonej przez drogę nr 77 w powiecie przemyskim,

— powiat miejski Przemyśl,

— gminy Gać, Jawornik Polski, Kańczuga, część gminy Zarzecze położona na południe od linii wyznaczonej przez rzekę Mleczka w powiecie przeworskim,

— powiat łańcucki,

— gminy Trzebownisko, Głogów Małopolski, część gminy Świlcza położona na północ od linii wyznaczonej przez drogę nr 94 i część gminy Sokołów Małopolski położona na południe od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,

— gmina Raniżów w powiecie kolbuszowskim,

— część powiatu dębickiego niewymieniona w części II załącznika I,

w województwie świętokrzyskim:

— gminy Nowy Korczyn, Solec–Zdrój, Wiślica, Stopnica, Tuczępy, Busko Zdrój w powiecie buskim,

— powiat kazimierski,

— powiat skarżyski,

— część powiatu opatowskiego niewymieniona w części II załącznika I,

— część powiatu sandomierskiego niewymieniona w części II załącznika I,

— gminy Bogoria, Osiek, Staszów i część gminy Rytwiany położona na wschód od linii wyznaczonej przez drogę nr 764, część gminy Szydłów położona na wschód od linii wyznaczonej przez drogę nr 756 w powiecie staszowskim,

— gminy Pawłów, Wąchock, część gminy Brody położona na zachód od linii wyznaczonej przez drogę nr 9 oraz na południowy - zachód od linii wyznaczonej przez drogi: nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie, drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy i część gminy Mirzec położona na zachód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno - wschodnim do granicy gminy w powiecie starachowickim,

— powiat ostrowiecki,

— gminy Fałków, Ruda Maleniecka, Radoszyce, Smyków, Słupia Konecka, część gminy Końskie położona na zachód od linii kolejowej, część gminy Stąporków położona na południe od linii kolejowej w powiecie koneckim,

— gminy Bodzentyn, Bieliny, Łagów, Morawica, Nowa Słupia, część gminy Raków położona na wschód od linii wyznaczonej przez drogi nr 756 i 764, część gminy Chęciny położona na południe od linii wyznaczonej przez drogę nr 762, część gminy Górno położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy łączącą miejscowości Leszczyna – Cedzyna oraz na południe od linii wyznaczonej przez ul. Kielecką w miejscowości Cedzyna biegnącą do wschodniej granicy gminy, część gminy Daleszyce położona na północ od linii wyznaczonej przez drogę nr 764 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą łączącą miejscowości Daleszyce – Słopiec – Borków, dalej na północ od linii wyznaczonej przez tę drogę biegnącą od skrzyżowania z drogą nr 764 do przecięcia z linią rzeki Belnianka, następnie na północ od linii wyznaczonej przez rzeki Belnianka i Czarna Nida biegnącej do zachodniej granicy gminy w powiecie kieleckim,

— gminy Działoszyce, Michałów, Pińczów, Złota w powiecie pińczowskim,

— gminy Imielno, Jędrzejów, Nagłowice, Sędziszów, Słupia, Sobków, Wodzisław w powiecie jędrzejowskim,

— gminy Moskorzew, Radków, Secemin, część gminy Włoszczowa położona na zachód od linii wyznaczonej przez drogę nr 742 biegnącą od północnej granicy gminy do miejscowości Konieczno i dalej na zachód od linii wyznaczonej przez drogę łączącą miejscowości Konieczno – Rogienice – Dąbie – Podłazie, część gminy Kluczewsko położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy i łączącą miejscowości Krogulec – Nowiny - Komorniki do przecięcia z linią rzeki Czarna, następnie na północ od linii wyznaczonej przez rzekę Czarna biegnącą do przecięcia z linią wyznaczoną przez drogę nr 742 i dalej na zachód od linii wyznaczonej przez drogę nr 742 biegnącą od przecięcia z linią rzeki Czarna do południowej granicy gminy w powiecie włoszczowskim,

w województwie łódzkim:

— gminy Łyszkowice, Kocierzew Południowy, Kiernozia, Chąśno, Nieborów, część gminy wiejskiej Łowicz położona na północ od linii wyznaczonej przez drogę nr 92 biegnącej od granicy miasta Łowicz do zachodniej granicy gminy oraz część gminy wiejskiej Łowicz położona na wschód od granicy miasta Łowicz i na północ od granicy gminy Nieborów w powiecie łowickim,

— gminy Cielądz, Rawa Mazowiecka z miastem Rawa Mazowiecka w powiecie rawskim,

— gminy Bolimów, Głuchów, Godzianów, Lipce Reymontowskie, Maków, Nowy Kawęczyn, Skierniewice, Słupia w powiecie skierniewickim,

— powiat miejski Skierniewice,

— gminy Mniszków, Paradyż, Sławno i Żarnów w powiecie opoczyńskim,

— gminy Czerniewice, Inowłódz, Lubochnia, Rzeczyca, Tomaszów Mazowiecki z miastem Tomaszów Mazowiecki, Żelechlinek w powiecie tomaszowskim,

gmina Przedbórz w powiecie radomszczańskim, w województwie pomorskim:

— gminy Ostaszewo, miasto Krynica Morska oraz część gminy Nowy Dwór Gdański położona na południowy - zachód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,

— gminy Lichnowy, Miłoradz, Malbork z miastem Malbork, część gminy Nowy Staw położna na zachód od linii wyznaczonej przez drogę nr 55 w powiecie malborskim,

— gminy Mikołajki Pomorskie, Stary Targ i Sztum w powiecie sztumskim,

— powiat gdański,

— Miasto Gdańsk,

— powiat tczewski,

— powiat kwidzyński,

w województwie lubuskim:

— gmina Lubiszyn w powiecie gorzowskim,

— gmina Dobiegniew w powiecie strzelecko – drezdeneckim,

w województwie dolnośląskim:

— gminy Dziadowa Kłoda, Międzybórz, Syców, Twardogóra, część gminy wiejskiej Oleśnica położona na północ od linii wyznaczonej przez drogę nr S8, część gminy Dobroszyce położona na wschód od linii wyznaczonej przez linię kolejową biegnącą od północnej do południowej granicy gminy w powiecie oleśnickim,

— gminy Jordanów Śląski, Kobierzyce, Mietków, Sobótka, część gminy Żórawina położona na zachód od linii wyznaczonej przez autostradę A4, część gminy Kąty Wrocławskie położona na południe od linii wyznaczonej przez autostradę A4 w powiecie wrocławskim,

— część gminy Domaniów położona na południowy zachód od linii wyznaczonej przez autostradę A4 w powiecie oławskim,

— gmina Wiązów w powiecie strzelińskim,

— część powiatu średzkiego niewymieniona w części II załącznika I,

— miasto Świeradów - Zdrój w powiecie lubańskim,

— gminy Pielgrzymka, miasto Złotoryja, część gminy wiejskiej Złotoryja położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w miejscowości Nowa Wieś Złotoryjska do granicy miasta Złotoryja oraz na południe od linii wyznaczonej przez drogę nr 382 biegnącą od granicy miasta Złotoryja do wschodniej granicy gminy w powiecie złotoryjskim,

— gmina Mirsk w powiecie lwóweckim,

— gminy Janowice Wielkie, Mysłakowice, Stara Kamienica w powiecie karkonoskim,

— część powiatu miejskiego Jelenia Góra położona na północ od linii wyznaczonej przez drogę nr 366,

— gminy Bolków, Męcinka, Mściwojów, Paszowice, miasto Jawor w powiecie jaworskim,

— gminy Dobromierz, Jaworzyna Śląska, Marcinowice, Strzegom, Żarów w powiecie świdnickim,

— gminy Dzierżoniów, Pieszyce, miasto Bielawa, miasto Dzierżoniów w powiecie dzierżoniowskim,

— gminy Głuszyca, Mieroszów w powiecie wałbrzyskim,

— gmina Nowa Ruda i miasto Nowa Ruda w powiecie kłodzkim,

— gminy Kamienna Góra, Marciszów i miasto Kamienna Góra w powiecie kamiennogórskim,

w województwie wielkopolskim:

— gminy Koźmin Wielkopolski, Rozdrażew, miasto Sulmierzyce, część gminy Krotoszyn położona na wschód od linii wyznaczonej przez drogi: nr 15 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 36, nr 36 biegnącą od skrzyżowania z drogą nr 15 do skrzyżowana z drogą nr 444, nr 444 biegnącą od skrzyżowania z drogą nr 36 do południowej granicy gminy w powiecie krotoszyńskim,

— gminy Brodnica, część gminy Dolsk położona na wschód od linii wyznaczonej przez drogę nr 434 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 437, a następnie na wschód od drogi nr 437 biegnącej od skrzyżowania z drogąnr 434 do południowej granicy gminy, część gminy Śrem położóna na wschód od linii wyznaczonej przez drogę nr 310 biegnącą od zachodniej granicy gminy do miejscowości Śrem, następnie na wschód od drogi nr 432 w miejscowości Śrem oraz na wschód od drogi nr 434 biegnącej od skrzyżowania z drogą nr 432 do południowej granicy gminy w powiecie śremskim,

— gminy Borek Wielkopolski, Piaski, Pogorzela, w powiecie gostyńskim,

— gmina Grodzisk Wielkopolski i część gminy Kamieniec położona na wschód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,

— gmina Czempiń w powiecie kościańskim,

— gminy Kleszczewo, Kostrzyn, Kórnik, Pobiedziska, Mosina, miasto Puszczykowo, część gminy wiejskiej Murowana Goślina położona na południe od linii kolejowej biegnącej od północnej granicy miasta Murowana Goślina do północno-wschodniej granicy gminy w powiecie poznańskim,

— gmina Kiszkowo i część gminy Kłecko położona na zachód od rzeki Mała Wełna w powiecie gnieźnieńskim,

— powiat czarnkowsko-trzcianecki,

— część gminy Wronki położona na północ od linii wyznaczonej przez rzekę Wartę biegnącą od zachodniej granicy gminy do przecięcia z droga nr 182, a następnie na wschód od linii wyznaczonej przez drogi nr 182 oraz 184 biegnącą od skrzyżowania z drogą nr 182 do południowej granicy gminy w powiecie szamotulskim,

— gmina Budzyń w powiecie chodzieskim,

— gminy Mieścisko, Skoki i Wągrowiec z miastem Wągrowiec w powiecie wągrowieckim,

— powiat pleszewski,

— gmina Zagórów w powiecie słupeckim,

— gmina Pyzdry w powiecie wrzesińskim,

— gminy Kotlin, Żerków i część gminy Jarocin położona na wschód od linii wyznaczonej przez drogi nr S11 i 15 w powiecie jarocińskim,

— powiat ostrowski,

— powiat miejski Kalisz,

— powiat kaliski,

— powiat turecki,

— gminy Rzgów, Grodziec, Krzymów, Stare Miasto, Rychwał w powiecie konińskim,

— powiat kępiński,

— powiat ostrzeszowski,

w województwie opolskim:

— gminy Domaszowice, Pokój, część gminy Namysłów położona na północ od linii wyznaczonej przez linię kolejową biegnącą od wschodniej do zachodniej granicy gminy w powiecie namysłowskim,

— gminy Wołczyn, Kluczbork, Byczyna w powiecie kluczborskim,

— gminy Praszka, Gorzów Śląski część gminy Rudniki położona na północ od linii wyznaczonej przez drogę nr 42 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 43 i na zachód od linii wyznaczonej przez drogę nr 43 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 42 w powiecie oleskim,

— gmina Grodkówww powiecie brzeskim,

— gminy Komprachcice, Łubniany, Murów, Niemodlin, Tułowice w powiecie opolskim,

— powiat miejski Opole,

w województwie zachodniopomorskim:

— gminy Nowogródek Pomorski, Barlinek, Myślibórz, część gminy Dębno położona na wschód od linii wyznaczonej przez drogę nr 126 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 23 w miejscowości Dębno, następnie na wschód od linii wyznaczonej przez drogę nr 23 do skrzyżowania z ul. Jana Pawła II w miejscowości Cychry, następnie na północ od ul. Jana Pawła II do skrzyżowania z ul. Ogrodową i dalej na północ od linii wyznaczonej przez ul. Ogrodową, której przedłużenie biegnie do wschodniej granicy gminy w powiecie myśliborskim,

— gmina Stare Czarnowo w powiecie gryfińskim,

— gmina Bielice, Kozielice, Pyrzyce w powiecie pyrzyckim,

— gminy Bierzwnik, Krzęcin, Pełczyce w powiecie choszczeńskim,

— część powiatu miejskiego Szczecin położona na zachód od linii wyznaczonej przez rzekę Odra Zachodnia biegnącą od północnej granicy gminy do przecięcia z drogą nr 10, następnie na południe od linii wyznaczonej przez drogę nr 10 biegnącą od przecięcia z linią wyznaczoną przez rzekę Odra Zachodnia do wschodniej granicy gminy,

— gminy Dobra (Szczecińska), Police w powiecie polickim,

w województwie małopolskim:

— powiat brzeski,

— powiat gorlicki,

— powiat proszowicki,

— część powiatu nowosądeckiego niewymieniona w części II załącznika I,

— gminy Czorsztyn, Krościenko nad Dunajcem, Ochotnica Dolna w powiecie nowotarskim,

— powiat miejski Nowy Sącz,

— powiat tarnowski,

— powiat miejski Tarnów,

— część powiatu dąbrowskiego niewymieniona w części III załącznika I.

8. **Slovakia**

The following restricted zones I in Slovakia:

— in the district of Nové Zámky, Sikenička, Pavlová, Bíňa, Kamenín, Kamenný Most, Malá nad Hronom, Belá, Ľubá, Šarkan, Gbelce, Bruty, Mužla, Obid, Štúrovo, Nána, Kamenica nad Hronom, Chľaba, Leľa, Bajtava, Salka, Malé Kosihy,

— in the district of Veľký Krtíš, the municipalities of Ipeľské Predmostie, Veľká nad Ipľom, Hrušov, Kleňany, Sečianky,

— in the district of Levice, the municipalities of Keť, Čata, Pohronský Ruskov, Hronovce, Želiezovce, Zalaba, Malé Ludince, Šalov, Sikenica, Pastovce, Bielovce, Ipeľský Sokolec, Lontov, Kubáňovo, Sazdice, Demandice, Dolné Semerovce, Vyškovce nad Ipľom, Preseľany nad Ipľom, Hrkovce, Tupá, Horné Semerovce, Hokovce, Slatina, Horné Turovce, Veľké Turovce, Šahy, Tešmak, Plášťovce, Ipeľské Uľany, Bátovce, Pečenice, Jabloňovce, Bohunice, Pukanec, Uhliská,

— in the district of Krupina, the municipalities of Dudince, Terany, Hontianske Moravce, Sudince, Súdovce, Lišov,

— the whole district of Ružomberok,

— in the region of Turčianske Teplice, municipalties of Turček, Horná Štubňa, Čremošné, Háj, Rakša, Mošovce,

— in the district of Martin, municipalties of Blatnica, Folkušová, Necpaly,

— in the district of Dolný Kubín, the municipalities of Kraľovany, Žaškov, Jasenová, Vyšný Kubín, Oravská Poruba, Leštiny, Osádka, Malatiná, Chlebnice, Krivá,

— in the district of Tvrdošín, the municipalities of Oravský Biely Potok, Habovka, Zuberec,

— in the district of Žarnovica, the municipalities of Rudno nad Hronom, Voznica, Hodruša-Hámre,

— the whole district of Žiar nad Hronom, except municipalities included in zone II.

9. **Italy**

The following restricted zones I in Italy:

Piedmont Region:

— in the province of Alessandria, the municipalities of Casalnoceto, Oviglio, Tortona, Viguzzolo, Frugarolo, Bergamasco, Castellar Guidobono, Berzano Di Tortona, Cerreto Grue, Carbonara Scrivia, Casasco, Carentino, Frascaro, Paderna, Montegioco, Spineto Scrivia, Villaromagnano, Pozzolo Formigaro, Momperone, Merana, Monleale, Terzo, Borgoratto Alessandrino, Casal Cermelli, Montemarzino, Bistagno, Castellazzo Bormida, Bosco Marengo, Castelspina, Volpeglino, Alice Bel Colle, Gamalero, Volpedo, Pozzol Groppo, Sarezzano,

— in the province of Asti, the municipalities of Olmo Gentile, Nizza Monferrato, Incisa Scapaccino, Roccaverano, Castel Boglione, Mombaruzzo, Maranzana, Castel Rocchero, Rocchetta Palafea, Castelletto Molina, Castelnuovo Belbo, Montabone, Quaranti, Fontanile, Calamandrana, Bruno, Sessame, Monastero Bormida, Bubbio, Cassinasco, Serole, Loazzolo, Cessole, Vesime, San Giorgio Scarampi,

— in the province of Cuneo, the municipalities of Bergolo, Pezzolo Valle Uzzone, Cortemilia, Levice, Castelletto Uzzone, Perletto,

Liguria Region:

— in the province of Genova, the Municipalities of Rovegno, Rapallo, Portofino, Cicagna, Avegno, Montebruno, Santa Margherita Ligure, Favale Di Malvaro, Recco, Camogli, Moconesi, Tribogna, Fascia, Uscio, Gorreto, Fontanigorda, Neirone, Rondanina, Lorsica, Propata;

— in the province of Savona, the municipalities of Cairo Montenotte, Quiliano, Dego, Altare, Piana Crixia, Giusvalla, Albissola Marina, Savona,

Emilia-Romagna Region:

— in the province of Piacenza, the municipalities of Ottone, Zerba,

Lombardia Region:

— in the province of Pavia, the municipalities of Rocca Susella, Montesegale, Menconico, Val Di Nizza, Bagnaria, Santa Margherita Di Staffora, Ponte Nizza, Brallo Di Pregola, Varzi, Godiasco, Cecima,

Lazio Region:

— in the province of Rome,

North: the municipalities of Riano, Castelnuovo di Porto, Capena, Fiano Romano, Morlupo, Sacrofano, Magliano Romano, Formello, Campagnano di Roma, Anguillara;

West: the municipality of Fiumicino;

South: the municipality of Rome between the boundaries of the municipality of Fiumicino (West), the limits of Zone 3 (North), the Tiber river up to the intersection with the Grande Raccordo Anulare GRA Highway, the Grande Raccordo Anulare GRA Highway up to the intersection with A24 Highway, A24 Highway up to the intersection with Viale del Tecnopolo, viale del Tecnopolo up to the intersection with the boundaries of the municipality of Guidonia Montecelio;

East: the municipalities of Guidonia Montecelio, Montelibretti, Palombara Sabina, Monterotondo, Mentana, Sant'Angelo Romano, Fonte Nuova.

PART II

1. **Bulgaria**

The following restricted zones II in Bulgaria:

— the whole region of Haskovo,

— the whole region of Yambol,

— the whole region of Stara Zagora,

— the whole region of Pernik,

— the whole region of Kyustendil,

— the whole region of Plovdiv, excluding the areas in Part III,

— the whole region of Pazardzhik, excluding the areas in Part III,

— the whole region of Smolyan,

— the whole region of Dobrich,

— the whole region of Sofia city,

— the whole region of Sofia Province,

— the whole region of Blagoevgrad excluding the areas in Part III,

— the whole region of Razgrad,

— the whole region of Kardzhali,

— the whole region of Burgas,

— the whole region of Varna excluding the areas in Part III,

— the whole region of Silistra,

— the whole region of Ruse,

— the whole region of Veliko Tarnovo,

— the whole region of Pleven,

— the whole region of Targovishte,

— the whole region of Shumen,

— the whole region of Sliven,

— the whole region of Vidin,

— the whole region of Gabrovo,

— the whole region of Lovech,

— the whole region of Montana,

— the whole region of Vratza.

2. **Germany**

The following restricted zones II in Germany:

Bundesland Brandenburg:

— Landkreis Oder-Spree:

  — Gemeinde Grunow-Dammendorf,

  — Gemeinde Mixdorf

  — Gemeinde Schlaubetal,

  — Gemeinde Neuzelle,

  — Gemeinde Neißemünde,

  — Gemeinde Lawitz,

- Gemeinde Eisenhüttenstadt,
- Gemeinde Vogelsang,
- Gemeinde Ziltendorf,
- Gemeinde Wiesenau,
- Gemeinde Friedland,
- Gemeinde Siehdichum,
- Gemeinde Müllrose,
- Gemeinde Briesen,
- Gemeinde Jacobsdorf
- Gemeinde Groß Lindow,
- Gemeinde Brieskow-Finkenheerd,
- Gemeinde Ragow-Merz,
- Gemeinde Beeskow,
- Gemeinde Rietz-Neuendorf,
- Gemeinde Tauche mit den Gemarkungen Stremmen, Ranzig, Trebatsch, Sabrodt, Sawall, Mitweide, Lindenberg, Falkenberg (T), Görsdorf (B), Wulfersdorf, Giesensdorf, Briescht, Kossenblatt und Tauche,
- Gemeinde Langewahl,
- Gemeinde Berkenbrück,
- Gemeinde Steinhöfel mit den Gemarkungen Arensdorf und Demitz und den Gemarkungen Steinhöfel, Hasenfelde und Heinersdorf östlich der L 36 und der Gemarkung Neuendorf im Sande südlich der L36,
- Gemeinde Fürstenwalde östlich der B 168 und südlich der L36,
- Gemeinde Diensdorf-Radlow,
- Gemeinde Wendisch Rietz östlich des Scharmützelsees und nördlich der B 246,
- Gemeinde Bad Saarow mit der Gemarkung Neu Golm und der Gemarkung Bad Saarow-Pieskow östlich des Scharmützelsees und ab nördlicher Spitze östlich der L35,

— Landkreis Dahme-Spreewald:

- Gemeinde Jamlitz,
- Gemeinde Lieberose,
- Gemeinde Schwielochsee mit den Gemarkungen Goyatz, Jessern, Lamsfeld, Ressen, Speichrow und Zaue,

— Landkreis Spree-Neiße:

- Gemeinde Schenkendöbern,
- Gemeinde Guben,
- Gemeinde Jänschwalde,
- Gemeinde Tauer,
- Gemeinde Peitz,
- Gemeinde Kolkwitz mit den Gemarkungen Klein Gaglow, Hähnchen, Kolkwitz, Glinzig und Krieschow südlich der BAB 15,
- Gemeinde Turnow-Preilack mit der Gemarkung Preilack,
- Gemeinde Teichland mit der Gemarkung Bärenbrück,
- Gemeinde Heinersbrück,

- Gemeinde Forst,
- Gemeinde Groß Schacksdorf-Simmersdorf,
- Gemeinde Neiße-Malxetal,
- Gemeinde Jämlitz-Klein Düben,
- Gemeinde Tschernitz,
- Gemeinde Döbern,
- Gemeinde Felixsee,
- Gemeinde Wiesengrund,
- Gemeinde Spremberg,
- Gemeinde Welzow,
- Gemeinde Neuhausen/Spree,
- Gemeinde Drebkau,
- Kreisfreie Stadt Cottbus mit den Gemarkungen Kahren, Gallinchen, Groß Gaglow und der Gemarkung Kiekebusch südlich der BAB 15,

— Landkreis Märkisch-Oderland:

- Gemeinde Bleyen-Genschmar,
- Gemeinde Neuhardenberg
- Gemeinde Golzow,
- Gemeinde Küstriner Vorland,
- Gemeinde Alt Tucheband,
- Gemeinde Reitwein,
- Gemeinde Podelzig,
- Gemeinde Gusow-Platkow,
- Gemeinde Seelow,
- Gemeinde Vierlinden,
- Gemeinde Lindendorf,
- Gemeinde Fichtenhöhe,
- Gemeinde Lietzen,
- Gemeinde Falkenhagen (Mark),
- Gemeinde Zeschdorf,
- Gemeinde Treplin,
- Gemeinde Lebus,
- Gemeinde Müncheberg mit den Gemarkungen Jahnsfelde, Trebnitz, Obersdorf, Münchehofe und Hermersdorf,
- Gemeinde Märkische Höhe mit der Gemarkung Ringenwalde,
- Gemeinde Bliesdorf mit der Gemarkung Metzdorf und Gemeinde Bliesdorf – östlich der B167 bis östlicher Teil, begrenzt aus Richtung Gemarkungsgrenze Neutrebbin südlich der Bahnlinie bis Straße „Sophienhof“ dieser westlich folgend bis „Ruesterchegraben“ weiter entlang Feldweg an den Windrädern Richtung „Herrnhof“, weiter entlang „Letschiner Hauptgraben“ nord-östlich bis Gemarkungsgrenze Alttrebbin und Kunersdorf – östlich der B167,
- Gemeinde Bad Freienwalde mit den Gemarkungen Altglietzen, Altranft, Bad Freienwalde, Bralitz, Hohenwutzen, Schiffmühle, Hohensaaten und Neuenhagen,
- Gemeinde Falkenberg mit der Gemarkung Falkenberg östlich der L35,

— Gemeinde Oderaue,

— Gemeinde Wriezen mit den Gemarkungen Altwriezen, Jäckelsbruch, Neugaul, Beauregard, Eichwerder, Rathsdorf – östlich der B167 und Wriezen – östlich der B167,

— Gemeinde Neulewin,

— Gemeinde Neutrebbin,

— Gemeinde Letschin,

— Gemeinde Zechin,

— Landkreis Barnim:

— Gemeinde Lunow-Stolzenhagen,

— Gemeinde Parsteinsee,

— Gemeinde Oderberg,

— Gemeinde Liepe,

— Gemeinde Hohenfinow (nördlich der B167),

— Gemeinde Niederfinow,

— Gemeinde (Stadt) Eberswalde mit den Gemarkungen Eberswalde nördlich der B167 und östlich der L200, Sommerfelde und Tornow nördlich der B167,

— Gemeinde Chorin mit den Gemarkungen Brodowin, Chorin östlich der L200, Serwest, Neuehütte, Sandkrug östlich der L200,

— Gemeinde Ziethen mit der Gemarkung Klein Ziethen östlich der Serwester Dorfstraße und östlich der B198,

— Landkreis Uckermark:

— Gemeinde Angermünde mit den Gemarkungen Crussow, Stolpe, Gellmersdorf, Neukünkendorf, Bölkendorf, Herzsprung, Schmargendorf und den Gemarkungen Angermünde südlich und südöstlich der B2 und Dobberzin südlich der B2,

— Gemeinde Schwedt mit den Gemarkungen Criewen, Zützen, Schwedt, Stendell, Kummerow, Kunow, Vierraden, Blumenhagen, Oderbruchwiesen, Enkelsee, Gatow, Hohenfelde, Schöneberg, Flemsdorf und der Gemarkung Felchow östlich der B2,

— Gemeinde Pinnow südlich und östlich der B2,

— Gemeinde Berkholz-Meyenburg,

— Gemeinde Mark Landin mit der Gemarkung Landin südlich der B2,

— Gemeinde Casekow mit der Gemarkung Woltersdorf und den Gemarkungen Biesendahlshof und Casekow östlich der L272 und südlich der L27,

— Gemeinde Hohenselchow-Groß Pinnow mit der Gemarkung Groß Pinnow und der Gemarkung Hohenselchow südlich der L27,

— Gemeinde Gartz (Oder) mit der Gemarkung Friedrichsthal und den Gemarkungen Gartz und Hohenreinkendorf südlich der L27 und der B2 bis Kastanienallee, dort links abbiegend dem Schülerweg folgend bis Höhe Bahnhof, von hier in östlicher Richtung den Salveybach kreuzend bis zum Tantower Weg, diesen in nördlicher Richtung bis zu Stettiner Straße, diese weiter folgend bis zur B2, dieser in nördlicher Richtung folgend,

— Gemeinde Mescherin mit der Gemarkung Mescherin, der Gemarkung Neurochlitz östlich der B2 und der Gemarkung Rosow nördlich der K 7311,

— Gemeinde Passow mit der Gemarkung Jamikow,

— Kreisfreie Stadt Frankfurt (Oder),

— Landkreis Prignitz:

— Gemeinde Karstädt mit den Gemarkungen Neuhof und Kribbe und den Gemarkungen Groß Warnow, Klein Warnow, Reckenzin, Streesow und Dallmin östlich der Bahnstrecke Berlin/Spandau-Hamburg/Altona,

— Gemeinde Berge,

— Gemeinde Pirow mit den Gemarkungen Hülsebeck, Pirow, Bresch und Burow,

— Gemeinde Putlitz mit den Gemarkungen Sagast, Nettelbeck, Porep, Lütkendorf, Putlitz, Weitgendorf und Telschow,

— Gemeinde Marienfließ mit den Gemarkungen Jännersdorf, Stepenitz und Krempendorf,

— Landkreis Oberspreewald-Lausitz:

— Gemeinde Vetschau mit den Gemarkungen Wüstenhain und Laasow,

— Gemeinde Altdöbern mit den Gemarkungen Reddern, Ranzow, Pritzen, Altdöbern östlich der Bahnstrecke Altdöbern –Großräschen,

— Gemeinde Großräschen mit den Gemarkungen Woschkow, Dörrwalde, Allmosen,

— Gemeinde Neu-Seeland,

— Gemeinde Neupetershain,

— Gemeinde Senftenberg mit der Gemarkungen Peickwitz, Sedlitz, Kleinkoschen, Großkoschen und Hosena,

— Gemeinde Hohenbocka,

— Gemeinde Grünewald,

— Gemeinde Hermsdorf,

— Gemeinde Kroppen,

— Gemeinde Ortrand,

— Gemeinde Großkmehlen,

— Gemeinde Lindenau,

— Gemeinde Frauendorf,

— Gemeinde Ruhland,

— Gemeinde Guteborn

— Gemeinde Schwarzbach mit der Gemarkung Schwarzbach,

Bundesland Sachsen:

— Landkreis Bautzen,

— Stadt Dresden:

— Stadtgebiet nördlich der BAB4 bis zum Verlauf westlich der Elbe, dann nördlich der B6,

— Landkreis Görlitz,

— Landkreis Meißen:

— Gemeinde Diera-Zehren östlich der Elbe,

— Gemeinde Ebersbach,

— Gemeinde Glaubitz östlich des Grödel-Elsterwerdaer-Floßkanals,

— Gemeinde Klipphausen östlich der S177,

— Gemeinde Lampertswalde,

— Gemeinde Moritzburg,

— Gemeinde Niederau östlich der B101,

— Gemeinde Nünchritz östlich der Elbe und südlich des Grödel-Elsterwerdaer-Floßkanals,

— Gemeinde Priestewitz,

— Gemeinde Röderaue östlich des Grödel-Elsterwerdaer-Floßkanals,

— Gemeinde Schönfeld,

— Gemeinde Stadt Coswig,

— Gemeinde Stadt Gröditz östlich des Grödel-Elsterwerdaer-Floßkanals,

— Gemeinde Stadt Großenhain,

— Gemeinde Stadt Meißen östlich des Straßenverlaufs der S177 bis zur B6, dann B6 bis zur B101, ab der B101 Elbtalbrücke Richtung Norden östlich der Elbe,

— Gemeinde Stadt Radebeul,

— Gemeinde Stadt Radeburg,

— Gemeinde Thiendorf,

— Gemeinde Weinböhla,

— Gemeinde Wülknitz östlich des Grödel-Elsterwerdaer-Floßkanals,

— Landkreis Sächsische Schweiz-Osterzgebirge:

— Gemeinde Stadt Wilsdruff nördlich der BAB4 zwischen den Abfahren Wilsdruff und Dreieck Dresden-West,

Bundesland Mecklenburg-Vorpommern:

— Landkreis Ludwigslust-Parchim:

— Gemeinde Balow mit dem Ortsteil: Balow,

— Gemeinde Brunow mit den Ortsteilen und Ortslagen: Bauerkuhl, Brunow (bei Ludwigslust), Klüß, Löcknitz (bei Parchim),

— Gemeinde Dambeck mit dem Ortsteil und der Ortslage: Dambeck (bei Ludwigslust),

— Gemeinde Ganzlin mit den Ortsteilen und Ortslagen: Barackendorf, Hof Retzow, Klein Damerow, Retzow, Wangelin,

— Gemeinde Gehlsbach mit den Ortsteilen und Ortslagen: Ausbau Darß, Darß, Hof Karbow, Karbow, Karbow-Ausbau, Quaßlin, Quaßlin Hof, Quaßliner Mühle, Vietlübbe, Wahlstorf

— Gemeinde Groß Godems mit den Ortsteilen und Ortslagen: Groß Godems, Klein Godems,

— Gemeinde Karrenzin mit den Ortsteilen und Ortslagen: Herzfeld, Karrenzin, Karrenzin-Ausbau, Neu Herzfeld, Repzin, Wulfsahl,

— Gemeinde Kreien mit den Ortsteilen und Ortslagen: Ausbau Kreien, Hof Kreien, Kolonie Kreien, Kreien, Wilsen,

— Gemeinde Kritzow mit dem Ortsteil und der Ortslage: Benzin,

— Gemeinde Lübz mit den Ortsteilen und Ortslagen: Burow, Gischow, Meyerberg,

— Gemeinde Möllenbeck mit den Ortsteilen und Ortslagen: Carlshof, Horst, Menzendorf, Möllenbeck,

— Gemeinde Muchow mit dem Ortsteil und Ortslage: Muchow,

— Gemeinde Parchim mit dem Ortsteil und Ortslage: Slate,

— Gemeinde Prislich mit den Ortsteilen und Ortslagen: Marienhof, Neese, Prislich, Werle,

— Gemeinde Rom mit dem Ortsteil und Ortslage: Klein Niendorf,

— Gemeinde Ruhner Berge mit den Ortsteilen und Ortslagen: Dorf Poltnitz, Drenkow, Griebow, Jarchow, Leppin, Malow, Malower Mühle, Marnitz, Mentin, Mooster, Poitendorf, Poltnitz, Suckow, Tessenow, Zachow,

— Gemeinde Siggelkow mit den Ortsteilen und Ortslagen: Groß Pankow, Klein Pankow, Neuburg, Redlin, Siggelkow,

— Gemeinde Stolpe mit den Ortsteilen und Ortslagen: Barkow, Granzin, Stolpe Ausbau, Stolpe,

— Gemeinde Ziegendorf mit den Ortsteilen und Ortslagen: Drefahl, Meierstorf, Neu Drefahl, Pampin, Platschow, Stresendorf, Ziegendorf,

— Gemeinde Zierzow mit den Ortsteilen und Ortslagen: Kolbow, Zierzow.

3. **Estonia**

The following restricted zones II in Estonia:

— Eesti Vabariik (välja arvatud Hiiu maakond).

4. **Latvia**

The following restricted zones II in Latvia:

— Aizkraukles novads,

— Alūksnes novads,

— Augšdaugavas novads,

— Ādažu novads,

— Balvu novads,

— Bauskas novads,

— Cēsu novads,

— Dienvidkurzemes novada Aizputes, Cīravas, Lažas, Durbes, Dunalkas, Tadaiķu, Vecpils, Bārtas, Sakas, Bunkas, Priekules, Gramzdas, Kalētu, Virgas, Dunikas, Vaiņodes, Gaviezes, Rucavas, Vērgales, Medzes pagasts, Nīcas pagasta daļa uz dienvidiem no apdzīvotas vietas Bernāti, autoceļa V1232, A11, V1222, Bārtas upes, Embūtes pagasta daļa uz dienvidiem no autoceļa P116, P106, autoceļa no apdzīvotas vietas Dinsdurbe, Kalvenes pagasta daļa uz rietumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz dienvidiem no autoceļa A9, uz rietumiem no autoceļa V1200, Kazdangas pagasta daļa uz rietumiem no ceļa V1200, P115, P117, V1296, Aizputes, Durbes, Pāvilostas, Priekules pilsēta,

— Dobeles novads,

— Gulbenes novads,

— Jelgavas novads,

— Jēkabpils novads,

— Krāslavas novads,

— Kuldīgas novada Alsungas, Gudenieku, Kurmāles, Rendas, Kabiles, Vārmes, Pelču, Snēpeles, Turlavas, Ēdoles, Īvandes, Rumbas, Padures pagasts, Laidu pagasta daļa uz ziemeļiem no autoceļa V1296, Kuldīgas pilsēta,

— Ķekavas novads,

— Limbažu novads,

— Līvānu novads,

— Ludzas novads,

— Madonas novads,

— Mārupes novads,

— Ogres novads,

— Olaines novads,

— Preiļu novads,

— Rēzeknes novads,

— Ropažu novada Garkalnes, Ropažu pagasts, Stopiņu pagasta daļa, kas atrodas uz austrumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes, Vangažu pilsēta,

— Salaspils novads,

— Saldus novads,

— Saulkrastu novads,

— Siguldas novads,

— Smiltenes novads,

— Talsu novads,

— Tukuma novads,

— Valkas novads,

— Valmieras novads,

— Varakļānu novads,

— Ventspils novads,

— Daugavpils valstspilsētas pašvaldība,

— Jelgavas valstspilsētas pašvaldība,

— Jūrmalas valstspilsētas pašvaldība,

— Rēzeknes valstspilsētas pašvaldība.

5. **Lithuania**

The following restricted zones II in Lithuania:

— Alytaus miesto savivaldybė,

— Alytaus rajono savivaldybė,

— Anykščių rajono savivaldybė,

— Akmenės rajono savivaldybė,

— Birštono savivaldybė,

— Biržų miesto savivaldybė,

— Biržų rajono savivaldybė,

— Druskininkų savivaldybė,

— Elektrėnų savivaldybė,

— Ignalinos rajono savivaldybė,

— Jonavos rajono savivaldybė,

— Joniškio rajono savivaldybė,

— Jurbarko rajono savivaldybė: Eržvilko, Juodaičių, Seredžiaus, Smalininkų ir Viešvilės seniūnijos,

— Kaišiadorių rajono savivaldybė,

— Kauno miesto savivaldybė,

— Kauno rajono savivaldybė,

— Kazlų rūdos savivaldybė: Kazlų Rūdos seniūnija, išskyrus vakarinė dalis iki kelio 2602 ir 183, Plutiškių seniūnija,

— Kelmės rajono savivaldybė: Kelmės, Kražių, Liolių, Tytuvėnų, Tytuvėnų apylinkių, Pakražančio ir Vaiguvos seniūnijos,

— Kėdainių rajono savivaldybė,

— Klaipėdos rajono savivaldybė: Judrėnų, Endriejavo ir Veiviržėnų seniūnijos,

— Kupiškio rajono savivaldybė,

— Kretingos rajono savivaldybė,

— Lazdijų rajono savivaldybė,

— Mažeikių rajono savivaldybė,

— Molėtų rajono savivaldybė: Alantos, Balninkų, Čiulėnų, Inturkės, Joniškio, Luokesos, Mindūnų, Suginčių ir Videniškių seniūnijos,

— Pagėgių savivaldybė,

— Pakruojo rajono savivaldybė,

— Panevėžio rajono savivaldybė,

— Panevėžio miesto savivaldybė,

— Pasvalio rajono savivaldybė,

— Radviliškio rajono savivaldybė,

— Rietavo savivaldybė,

— Prienų rajono savivaldybė,

— Plungės rajono savivaldybė,

— Raseinių rajono savivaldybė,

— Rokiškio rajono savivaldybė,

— Skuodo rajono savivaldybė,

— Šakių rajono savivaldybė: Kriūkų, Lekėčių ir Lukšių seniūnijos,

— Šalčininkų rajono savivaldybė,

— Šiaulių miesto savivaldybė,

— Šiaulių rajono savivaldybė: Ginkūnų, Gruzdžių, Kairių, Kužių, Meškuičių, Raudėnų, Šakynos ir Šiaulių kaimiškosios seniūnijos,

— Šilutės rajono savivaldybė,

— Širvintų rajono savivaldybė: Čiobiškio, Gelvonų, Jauniūnų, Kernavės, Musninkų ir Širvintų seniūnijos,

— Šilalės rajono savivaldybė,

— Švenčionių rajono savivaldybė,

— Tauragės rajono savivaldybė,

— Telšių rajono savivaldybė,

— Trakų rajono savivaldybė,

— Ukmergės rajono savivaldybė: Deltuvos, Lyduokių, Pabaisko, Pivonijos, Siesikų, Šešuolių, Taujėnų, Ukmergės miesto, Veprių, Vidiškių ir Žemaitkiemo seniūnijos,

— Utenos rajono savivaldybė,

— Varėnos rajono savivaldybė,

— Vilniaus miesto savivaldybė,

— Vilniaus rajono savivaldybė: Avižienių, Bezdonių, Buivydžių, Dūkštų, Juodšilių, Kalvelių, Lavoriškių, Maišiagalos, Marijampolio, Medininkų, Mickūnų, Nemenčinės, Nemenčinės miesto, Nemėžio, Pagirių, Riešės, Rudaminos, Rukainių, Sudervės, Sužionių, Šatrininkų ir Zujūnų seniūnijos,

— Visagino savivaldybė,

— Zarasų rajono savivaldybė.

6. **Hungary**

The following restricted zones II in Hungary:

— Békés megye 950150, 950250, 950350, 950450, 950550, 950650, 950660, 950750, 950850, 950860, 951050, 951150, 951250, 951260, 951350, 951450, 951460, 951550, 951650, 951750, 952150, 952250, 952350, 952450, 952550, 952650, 953250, 953260, 953270, 953350, 953450, 953550, 953560, 953950, 954050, 954060, 954150, 956250, 956350, 956450, 956550, 956650 és 956750 kódszámú vadgazdálkodási egységeinek teljes területe,

— Borsod-Abaúj-Zemplén megye valamennyi vadgazdálkodási egységének teljes területe,

— Fejér megye 403150, 403160, 403250, 403260, 403350, 404250, 404550, 404560, 404570, 405450, 405550, 405650, 406450 és 407050 kódszámú vadgazdálkodási egységeinek teljes területe,

— Hajdú-Bihar megye valamennyi vadgazdálkodási egységének teljes területe,

— Heves megye valamennyi vadgazdálkodási egységének teljes területe,

— Jász-Nagykun-Szolnok megye 750250, 750550, 750650, 750750, 750850, 750970, 750980, 751050, 751150, 751160, 751250, 751260, 751350, 751360, 751450, 751460, 751470, 751550, 751650, 751750, 751850, 751950, 752150, 752250, 752350, 752450, 752460, 752550, 752560, 752650, 752750, 752850, 752950, 753060, 753070, 753150, 753250, 753310, 753450, 753550, 753650, 753660, 753750, 753850, 753950, 753960, 754050, 754150, 754250, 754360, 754370, 754850, 755550, 755650 és 755750 kódszámú vadgazdálkodási egységeinek teljes területe,

— Komárom-Esztergom megye: 250350, 250850, 250950, 251450, 251550, 251950, 252050, 252150, 252350, 252450, 252460, 252550, 252650, 252750, 252850, 252860, 252950, 252960, 253050, 253150, 253250, 253350, 253450 és 253550 kódszámú vadgazdálkodási egységeinek teljes területe,

— Nógrád megye valamennyi vadgazdálkodási egységeinek teljes területe,

— Pest megye 570150, 570250, 570350, 570450, 570550, 570650, 570750, 570850, 570950, 571050, 571150, 571250, 571350, 571650, 571750, 571760, 571850, 571950, 572050, 573550, 573650, 574250, 577250, 580050 és 580150 kódszámú vadgazdálkodási egységeinek teljes területe,

— Szabolcs-Szatmár-Bereg megye valamennyi vadgazdálkodási egységének teljes területe.

7. **Poland**

The following restricted zones II in Poland:

w województwie warmińsko-mazurskim:

— gminy Kalinowo, Stare Juchy, Prostki oraz gmina wiejska Ełk w powiecie ełckim,

— powiat elbląski,

— powiat miejski Elbląg,

— część powiatu gołdapskiego niewymieniona w części III załącznika I,

— powiat piski,

— powiat bartoszycki,

— część powiatu oleckiego niewymieniona w części III załącznika I,

— część powiatu giżyckiego niewymieniona w części III załącznika I,

— powiat braniewski,

— powiat kętrzyński,

— powiat lidzbarski,

— gminy Dźwierzuty Jedwabno, Pasym, Świętajno, Szczytno i miasto Szczytno w powiecie szczycieńskim,

— powiat mrągowski,

— część powiatu węgorzewskiego niewymieniona w części III załącznika I,

— powiat olsztyński,

— powiat miejski Olsztyn,

— powiat nidzicki,

— gminy Kisielice, Susz, Zalewo w powiecie iławskim,

— część powiatu ostródzkiego niewymieniona w części III załącznika I,

— gmina Iłowo – Osada, część gminy wiejskiej Działdowo położona na południe od linii wyznaczonej przez linię kolejową biegnącą od wchodniej do zachodniej granicy gminy, część gminy Płośnica położona na południe od linii wyznaczonej przez linię kolejową biegnącą od wchodniej do zachodniej granicy gminy, część gminy Lidzbark położona na południe od linii wyznaczonej przez drogę nr 544 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 541 oraz na zachód od linii wyznaczonej przez drogę nr 541 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 544 w powiecie działdowskim,

w województwie podlaskim:

— powiat bielski,

— powiat grajewski,

— powiat moniecki,

— powiat sejneński,

— gminy Łomża, Piątnica, Jedwabne, Przytuły i Wizna w powiecie łomżyńskim,

— powiat miejski Łomża,

— powiat siemiatycki,

— powiat hajnowski,

— gminy Ciechanowiec, Klukowo, Szepietowo, Kobylin-Borzymy, Nowe Piekuty, Sokoły i część gminy Kulesze Kościelne położona na północ od linii wyznaczonej przez linię kolejową w powiecie wysokomazowieckim,

— gmina Rutki i część gminy Kołaki Kościelne położona na północ od linii wyznaczonej przez linię kolejową w powiecie zambrowskim,

— gminy Mały Płock i Stawiski w powiecie kolneńskim,

— powiat białostocki,

— powiat suwalski,

— powiat miejski Suwałki,

— powiat augustowski,

— powiat sokólski,

— powiat miejski Białystok,

w województwie mazowieckim:

— gminy Domanice, Korczew, Kotuń, Mordy, Paprotnia, Przesmyki, Siedlce, Skórzec, Wiśniew, Wodynie, Zbuczyn w powiecie siedleckim,

— powiat miejski Siedlce,

— gminy Ceranów, Jabłonna Lacka, Kosów Lacki, Repki, Sabnie, Sterdyń w powiecie sokołowskim,

— powiat łosicki,

— powiat sochaczewski,

— powiat zwoleński,

— powiat kozienicki,

— powiat lipski,

— powiat radomski

— powiat miejski Radom,

— powiat szydłowiecki,

— gminy Lubowidz i Kuczbork Osada w powiecie żuromińskim,

— gmina Wieczfnia Kościelna w powicie mławskim,

— gminy Bodzanów, Słubice, Wyszogród i Mała Wieś w powiecie płockim,

— powiat nowodworski,

— gminy Czerwińsk nad Wisłą, Naruszewo, Załuski w powiecie płońskim,

— gminy: miasto Kobyłka, miasto Marki, miasto Ząbki, miasto Zielonka, część gminy Tłuszcz ograniczona liniami kolejowymi: na północ od linii kolejowej biegnącej od wschodniej granicy gminy do miasta Tłuszcz oraz na wschód od linii kolejowej biegnącej od północnej granicy gminy do miasta Tłuszcz, część gminy Jadów położona na północ od linii kolejowej biegnącej od wschodniej do zachodniej granicy gminy w powiecie wołomińskim,

— powiat garwoliński,

— gminy Boguty – Pianki, Brok, Zaręby Kościelne, Nur, Małkinia Górna, część gminy Wąsewo położona na południe od linii wyznaczonej przez drogę nr 60, część gminy wiejskiej Ostrów Mazowiecka położona na południe od miasta Ostrów Mazowiecka i na południe od linii wyznaczonej przez drogę 60 biegnącą od zachodniej granicy miasta Ostrów Mazowiecka do zachodniej granicy gminy w powiecie ostrowskim,

— część gminy Sadowne położona na północny- zachód od linii wyznaczonej przez linię kolejową, część gminy Łochów położona na północny – zachód od linii wyznaczonej przez linię kolejową w powiecie węgrowskim,

— gminy Brańszczyk, Długosiodło, Rząśnik, Wyszków, część gminy Zabrodzie położona na wschód od linii wyznaczonej przez drogę nr S8 w powiecie wyszkowskim,

— gminy Cegłów, Dębe Wielkie, Halinów, Latowicz, Mińsk Mazowiecki i miasto Mińsk Mazowiecki, Mrozy, Siennica, miasto Sulejówek w powiecie mińskim,

— powiat otwocki,

— powiat warszawski zachodni,

— powiat legionowski,

— powiat piaseczyński,

— powiat pruszkowski,

— powiat grójecki,

— powiat grodziski,

— powiat żyrardowski,

— powiat białobrzeski,

— powiat przysuski,

— powiat miejski Warszawa,

w województwie lubelskim:

— powiat bialski,

— powiat miejski Biała Podlaska,

— powiat janowski,

— powiat puławski,

— powiat rycki,

— powiat łukowski,

— powiat lubelski,

— powiat miejski Lublin,

— powiat lubartowski,

— powiat łęczyński,

— powiat świdnicki,

— powiat biłgorajski,

— powiat hrubieszowski,

— powiat krasnostawski,

— powiat chełmski,

— powiat miejski Chełm,

— powiat tomaszowski,

— powiat kraśnicki,

— powiat opolski,

— powiat parczewski,

— powiat włodawski,

— powiat radzyński,

— powiat miejski Zamość,

— powiat zamojski,

w województwie podkarpackim:

— powiat stalowowolski,

— powiat lubaczowski,

— gminy Medyka, Stubno, część gminy Orły położona na wschód od linii wyznaczonej przez drogę nr 77, część gminy Żurawica na wschód od linii wyznaczonej przez drogę nr 77 w powiecie przemyskim,

— powiat jarosławski,

— gmina Kamień w powiecie rzeszowskim,

— gminy Cmolas, Dzikowiec, Kolbuszowa, Majdan Królewski i Niwiska powiecie kolbuszowskim,

— powiat leżajski,

— powiat niżański,

— powiat tarnobrzeski,

— gminy Adamówka, Sieniawa, Tryńcza, Przeworsk z miastem Przeworsk, Zarzecze w powiecie przeworskim,

— gmina Ostrów, część gminy Sędziszów Małopolski położona na północ od linii wyznaczonej przez drogę nr A4,

— część gminy Czarna położona na północ od linii wyznaczonej przez drogę nr A4, część gminy Żyraków położona na północ od linii wyznaczonej przez drogę nr A4, część gminy wiejskiej Dębica położona na północ od linii wyznaczonej przez drogę nr A4 w powiecie dębickim,

— część powiatu mieleckiego niewymieniona w części III załącznika I,

w województwie małopolskim:

— gminy Nawojowa, Piwniczna Zdrój, Rytro, Stary Sącz, część gminy Łącko położona na południe od linii wyznaczonej przez rzekę Dunajec w powiecie nowosądeckim,

— gmina Szczawnica w powiecie nowotarskim,

w województwie pomorskim:

— gminy Dzierzgoń i Stary Dzierzgoń w powiecie sztumskim,

— gmina Stare Pole, część gminy Nowy Staw położna na wschód od linii wyznaczonej przez drogę nr 55 w powiecie malborskim,

— gminy Stegny, Sztutowo i część gminy Nowy Dwór Gdański położona na północny - wschód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,

w województwie świętokrzyskim:

— gmina Tarłów i część gminy Ożarów położona na północ od linii wyznaczonej przez drogę nr 74 biegnącą od miejscowości Honorów do zachodniej granicy gminy w powiecie opatowskim,

— część gminy Brody położona wschód od linii wyznaczonej przez drogę nr 9 i na północny - wschód od linii wyznaczonej przez drogę nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie oraz przez drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy i część gminy Mirzec położona na wschód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno – wschodnim do granicy gminy w powiecie starachowickim,

— gmina Gowarczów, część gminy Końskie położona na wschód od linii kolejowej, część gminy Stąporków położona na północ od linii kolejowej w powiecie koneckim,

— gminy Dwikozy i Zawichost w powiecie sandomierskim,

w województwie lubuskim:

— gminy Bogdaniec, Deszczno, Kłodawa, Kostrzyn nad Odrą, Santok, Witnica w powiecie gorzowskim,

— powiat miejski Gorzów Wielkopolski,

— gminy Drezdenko, Strzelce Krajeńskie, Stare Kurowo, Zwierzyn w powiecie strzelecko – drezdeneckim,

— powiat żarski,

— powiat słubicki,

— gminy Brzeźnica, Iłowa, Gozdnica, Małomice Wymiarki, Żagań i miasto Żagań w powiecie żagańskim,

— powiat krośnieński,

— powiat zielonogórski

— powiat miejski Zielona Góra,

— powiat nowosolski,

— powiat sulęciński,

— powiat międzyrzecki,

— powiat świebodziński,

— powiat wschowski,

w województwie dolnośląskim:

— powiat zgorzelecki,

— gminy Gaworzyce, Grębocice, Polkowice i Radwanice w powiecie polkowickim,

— część powiatu wołowskiego niewymieniona w części III załącznika I,

— gmina Jeżów Sudecki w powiecie karkonoskim,

— gminy Rudna, Ścinawa, miasto Lubin i część gminy Lubin niewymieniona w części III załącznika I w powiecie lubińskim,

— gmina Malczyce, Miękinia, Środa Śląska, część gminy Kostomłoty położona na północ od linii wyznaczonej przez drogę nr A4, część gminy Udanin położona na północ od linii wyznaczonej przez drogę nr A4 w powiecie średzkim,

— gmina Wądroże Wielkie w powiecie jaworskim,

— gminy Kunice, Legnickie Pole, Prochowice, Ruja w powiecie legnickim,

— gminy Wisznia Mała, Trzebnica, Zawonia, część gminy Oborniki Śląskie położona na południe od linii wyznaczonej przez drogę nr 340 w powiecie trzebnickim,

— gminy Leśna, Lubań i miasto Lubań, Olszyna, Platerówka, Siekierczyn w powiecie lubańskim,

— powiat miejski Wrocław,

— gminy Czernica, Długołęka, Siechnice, część gminy Żórawina położona na wschód od linii wyznaczonej przez autostradę A4, część gminy Kąty Wrocławskie położona na północ od linii wyznaczonej przez autostradę A4 w powiecie wrocławskim,

— gminy Jelcz - Laskowice, Oława z miastem Oława i część gminy Domaniów położona na północny wschód od linii wyznaczonej przez autostradę A4 w powiecie oławskim,

— gmina Bierutów, miasto Oleśnica, część gminy wiejskiej Oleśnica położona na południe od linii wyznaczonej przez drogę nr S8, część gminy Dobroszyce położona na zachód od linii wyznaczonej przez linię kolejową biegnącą od północnej do południowej granicy gminy w powiecie oleśnickim,

— gmina Cieszków, Krośnice, część gminy Milicz położona na wschód od linii łączącej miejscowości Poradów – Piotrkosice – Sulimierz – Sułów - Gruszeczka w powiecie milickim,

— część powiatu bolesławieckiego niewymieniona w części III załącznika I,

— powiat głogowski,

— gmina Niechlów w powiecie górowskim,

— gmina Świerzawa, Wojcieszów, część gminy Zagrodno położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Jadwisin – Modlikowice Zagrodno oraz na zachód od linii wyznaczonej przez drogę nr 382 biegnącą od miejscowości Zagrodno do południowej granicy gminy w powiecie złotoryjskim,

— gmina Gryfów Śląski, Lubomierz, Lwówek Śląski, Wleń w powiecie lwóweckim,

— gminy Czarny Bór, Stare Bogaczowice, Walim, miasto Boguszów - Gorce, miasto Jedlina – Zdrój, miasto Szczawno – Zdrój w powiecie wałbrzyskim,

— powiat miejski Wałbrzych,

— gmina Świdnica, miasto Świdnica, miasto Świebodzice w powiecie świdnickim,

w województwie wielkopolskim:

— gminy Siedlec, Wolsztyn, część gminy Przemęt położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Borek – Kluczewo – Sączkowo – Przemęt – Błotnica – Starkowo – Boszkowo – Letnisko w powiecie wolsztyńskim,

— gmina Wielichowo, Rakoniewice, Granowo, część gminy Kamieniec położona na zachód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,

— powiat międzychodzki,

— powiat nowotomyski,

— powiat obornicki,

— część gminy Połajewo na położona na południe od drogi łączącej miejscowości Chraplewo, Tarnówko-Boruszyn, Krosin, Jakubowo, Połajewo - ul. Ryczywolska do północno-wschodniej granicy gminy w powiecie czarnkowsko-trzcianeckim,

— powiat miejski Poznań,

— gminy Buk, Czerwonak, Dopiewo, Komorniki, Rokietnica, Stęszew, Swarzędz, Suchy Las, Tarnowo Podgórne, część gminy wiejskiej Murowana Goślina położona na północ od linii kolejowej biegnącej od północnej granicy miasta Murowana Goślina do północno-wschodniej granicy gminy w powiecie poznańskim,

— gminy

— część powiatu szamotulskiego niewymieniona w części I i III załącznika I,

— gmina Pępowo w powiecie gostyńskim,

— gminy Kobylin, Zduny, część gminy Krotoszyn położona na zachód od linii wyznaczonej przez drogi: nr 15 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 36, nr 36 biegnącą od skrzyżowania z drogą nr 15 do skrzyżowana z drogą nr 444, nr 444 biegnącą od skrzyżowania z drogą nr 36 do południowej granicy gminy w powiecie krotoszyńskim,

— gmina Wijewo w powiecie leszczyńskim,

w województwie łódzkim:

— gminy Białaczów, Drzewica, Opoczno i Poświętne w powiecie opoczyńskim,

— gminy Biała Rawska, Regnów i Sadkowice w powiecie rawskim,

— gmina Kowiesy w powiecie skierniewickim,

w województwie zachodniopomorskim:

— gmina Boleszkowice i część gminy Dębno położona na zachód od linii wyznaczonej przez drogę nr 126 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 23 w miejscowości Dębno, następnie na zachód od linii wyznaczonej przez drogę nr 23 do skrzyżowania z ul. Jana Pawła II w miejscowości Cychry, następnie na południe od ul. Jana Pawła II do skrzyżowania z ul. Ogrodową i dalej na południe od linii wyznaczonej przez ul. Ogrodową, której przedłużenie biegnie do wschodniej granicy gminy w powiecie myśliborskim,

— gminy Cedynia, Gryfino, Mieszkowice, Moryń, część gminy Chojna położona na zachód od linii wyznaczonej przez drogi nr 31 biegnącą od północnej granicy gminy i 124 biegnącą od południowej granicy gminy w powiecie gryfińskim,

— gmina Kołbaskowo w powiecie policki,

w województwie opolskim:

— gminy Brzeg, Lubsza, Lewin Brzeski, Olszanka, Skarbimierz w powiecie brzeskim,

— gminy Dąbrowa, Dobrzeń Wielki, Popielów w powiecie opolskim,

— gminy Świerczów, Wilków, część gminy Namysłów położona na południe od linii wyznaczonej przez linię kolejową biegnącą od wschodniej do zachodniej granicy gminy w powiecie namysłowskim.

8. **Slovakia**

The following restricted zones II in Slovakia:

— the whole district of Gelnica except municipalities included in zone III,

— the whole district of Poprad

— the whole district of Spišská Nová Ves,

— the whole district of Levoča,

— the whole district of Kežmarok

— in the whole district of Michalovce except municipalities included in zone III,

— the whole district of Košice-okolie,

— the whole district of Rožnava,

— the whole city of Košice,

— in the district of Sobrance: Remetské Hámre, Vyšná Rybnica, Hlivištia, Ruská Bystrá, Podhoroď, Choňkovce, Ruský Hrabovec, Inovce, Beňatina, Koňuš,

— the whole district of Vranov nad Topľou,

— the whole district of Humenné except municipalities included in zone III,

— the whole district of Snina,

— the whole district of Prešov except municipalities included in zone III,

— the whole district of Sabinov except municipalities included in zone III,

— the whole district of Svidník, except municipalities included in zone III,

— the whole district of Stropkov, except municipalities included in zone III,

— the whole district of Bardejov,

— the whole district of Stará Ľubovňa,

— the whole district of Revúca,

— the whole district of Rimavská Sobota,

— in the district of Veľký Krtíš, the whole municipalities not included in part I,

— the whole district of Lučenec,

— the whole district of Poltár,

— the whole district of Zvolen, except municipalities included in zone III,

— the whole district of Detva,

— the whole district of Krupina, except municipalities included in zone I,

— the whole district of Banska Stiavnica,

— in the district of Žiar nad Hronom the municipalities of Hronská Dúbrava, Trnavá Hora,

— the whole district of Banska Bystica, except municipalities included in zone III,

— the whole district of Brezno,

— the whole district of Liptovsky Mikuláš,

— the whole district of Trebišov'.

9. **Italy**

The following restricted zones II in Italy:

Piedmont Region:

— in the Province of Alessandria, the municipalities of Cavatore, Castelnuovo Bormida, Cabella Ligure, Carrega Ligure, Francavilla Bisio, Carpeneto, Costa Vescovato, Grognardo, Orsara Bormida, Pasturana, Melazzo, Mornese, Ovada, Predosa, Lerma, Fraconalto, Rivalta Bormida, Fresonara, Malvicino, Ponzone, San Cristoforo, Sezzadio, Rocca Grimalda, Garbagna, Tassarolo, Mongiardino Ligure, Morsasco, Montaldo Bormida, Prasco, Montaldeo, Belforte Monferrato, Albera Ligure, Bosio, Cantalupo Ligure, Castelletto D'orba, Cartosio, Acqui Terme, Arquata Scrivia, Parodi Ligure, Ricaldone, Gavi, Cremolino, Brignano-Frascata, Novi Ligure, Molare, Cassinelle, Morbello, Avolasca, Carezzano, Basaluzzo, Dernice, Trisobbio, Strevi, Sant'Agata Fossili, Pareto, Visone, Voltaggio, Tagliolo Monferrato, Casaleggio Boiro, Capriata D'orba, Castellania, Carrosio, Cassine, Vignole Borbera, Serravalle Scrivia, Silvano D'orba, Villalvernia, Roccaforte Ligure, Rocchetta Ligure, Sardigliano, Stazzano, Borghetto Di Borbera, Grondona, Cassano Spinola, Montacuto, Gremiasco, San Sebastiano Curone, Fabbrica Curone, Spigno Monferrato, Montechiaro d'Acqui, Castelletto d'Erro, Ponti, Denice,

— in the province of Asti, the municipality of Mombaldone,

Liguria Region:

— in the province of Genova, the municipalities of Bogliasco, Arenzano, Ceranesi, Ronco Scrivia, Mele, Isola Del Cantone, Lumarzo, Genova, Masone, Serra Riccò, Campo Ligure, Mignanego, Busalla, Bargagli, Savignone, Torriglia, Rossiglione, Sant'Olcese, Valbrevenna, Sori, Tiglieto, Campomorone, Cogoleto, Pieve Ligure, Davagna, Casella, Montoggio, Crocefieschi, Vobbia;

in the province of Savona, the municipalities of Albisola Superiore, Celle Ligure, Stella, Pontinvrea, Varazze, Urbe, Sassello, Mioglia,

Lazio Region:

— the Area of the Municipality of Rome within the administrative boundaries of the Local Heatlh Unit "ASL RM1".

PART III

1. **Bulgaria**

The following restricted zones III in Bulgaria:

— in Blagoevgrad region:
  — the whole municipality of Sandanski
  — the whole municipality of Strumyani
  — the whole municipality of Petrich,
— the Pazardzhik region:
  — the whole municipality of Pazardzhik,
  — the whole municipality of Panagyurishte,
  — the whole municipality of Lesichevo,
  — the whole municipality of Septemvri,
  — the whole municipality of Strelcha,
— in Plovdiv region
  — the whole municipality of Hisar,
  — the whole municipality of Suedinenie,
  — the whole municipality of Maritsa
  — the whole municipality of Rodopi,
  — the whole municipality of Plovdiv,
— in Varna region:
  — the whole municipality of Byala,
  — the whole municipality of Dolni Chiflik.

2. **Italy**

The following restricted zones III in Italy:

— Sardinia Region: the whole territory.

3. **Latvia**

The following restricted zones III in Latvia:

— Dienvidkurzemes novada Embūtes pagasta daļa uz ziemeļiem autoceļa P116, P106, autoceļa no apdzīvotas vietas Dinsdurbe, Kalvenes pagasta daļa uz austrumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz ziemeļiem no autoceļa A9, uz austrumiem no autoceļa V1200, Kazdangas pagasta daļa uz austrumiem no ceļa V1200, P115, P117, V1296,

— Kuldīgas novada Rudbāržu, Nīkrāces, Raņķu, Skrundas pagasts, Laidu pagasta daļa uz dienvidiem no autoceļa V1296, Skrundas pilsēta.

4. **Lithuania**

The following restricted zones III in Lithuania:

— Jurbarko rajono savivaldybė: Jurbarko miesto seniūnija, Girdžių, Jurbarkų Raudonės, Skirsnemunės, Veliuonos ir Šimkaičių seniūnijos,

— Molėtų rajono savivaldybė: Dubingių ir Giedraičių seniūnijos,

— Marijampolės savivaldybė: Sasnavos ir Šunskų seniūnijos,

— Šakių rajono savivaldybė: Barzdų, Gelgaudiškio, Griškabūdžio, Kidulių, Kudirkos Naumiesčio, Sintautų, Slavikų, Sudargo, Šakių, Plokščių ir Žvirgždaičių seniūnijos.

— Kazlų rūdos savivaldybė: Antanavos, Jankų ir Kazlų Rūdos seniūnijos: vakarinė dalis iki kelio 2602 ir 183,

— Kelmės rajono savivaldybė: Kelmės apylinkių, Kukečių, Šaukėnų ir Užvenčio seniūnijos,

— Vilkaviškio rajono savivaldybė: Gižų, Kybartų, Klausučių, Pilviškių, Šeimenos ir Vilkaviškio miesto seniūnijos.

— Širvintų rajono savivaldybė: Alionių ir Zibalų seniūnijos,

— Šiaulių rajono savivaldybė: Bubių, Kuršėnų kaimiškoji ir Kuršėnų miesto seniūnijos,

— Ukmergės rajono savivaldybė: Želvos seniūnija,

— Vilniaus rajono savivaldybė: Paberžės seniūnija.

5. **Poland**

The following restricted zones III in Poland:

w województwie zachodniopomorskim:

— gminy Banie, Trzcińsko – Zdrój, Widuchowa, część gminy Chojna położona na wschód linii wyznaczonej przez drogi nr 31 biegnącą od północnej granicy gminy i 124 biegnącą od południowej granicy gminy w powiecie gryfińskim,

w województwie warmińsko-mazurskim:

— część powiatu działdowskiego niewymieniona w części II załącznika I,

— część powiatu iławskiego niewymieniona w części II załącznika I,

— powiat nowomiejski,

— gminy Dąbrówno, Grunwald i Ostróda z miastem Ostróda w powiecie ostródzkim,

— gmina Banie Mazurskie, część gminy Gołdap położona na południe od linii wyznaczonej przez drogę bignącą od zachodniej granicy gminy i łączącą miejscowości Pietraszki – Grygieliszki – Łobody - Bałupiany - Piękne Łąki do skrzyżowania z drogą nr 65, następnie od tego skrzyżowania na zachód od linii wyznaczonej przez drogę nr 65 biegnącą do skrzyżowania z drogą nr 650 i dalej na zachód od linii wyznaczonej przez drogę nr 650 biegnącą od skrzyżowania z drogą nr 65 do miejscowości Wronki Wielkie i dalej na zachód od linii wyznaczonej przez drogę łączącą miejscowości Wronki Wielkie – Suczki – Pietrasze – Kamionki – Wilkasy biegnącą do południowej granicy gminy w powiecie gołdapskim,

— część gminy Pozdezdrze położona na wschód od linii wyznaczonej przez drogę biegnącą od zachodniej do południowej granicy gminy i łączącą miejscowości Stręgiel – Gębałka – Kuty – Jakunówko – Jasieniec, część gminy Budry położona na wschód od linii wyznaczonej przez drogę biegnącą od wschodniej do południowej granicy gminy i łączącą miejscowości Skalisze – Budzewo – Budry – Brzozówko w powiecie węgorzewskim,

— część gminy Kruklanki położona na północ od linii wyznaczonej przez drogę biegnącą od północnej do wschodniej granicy gminy i łączącą miejscowości Jasieniec – Jeziorowskie – Podleśne w powiecie giżyckim,

— część gminy Kowale Oleckie położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej do południowej granicy gminy i łączącą miejscowości Wierzbiadnki – Czerwony Dwór – Mazury w powiecie oleckim,

w województwie podkarpackim:

— gminy Borowa, Czermin, Radomyśl Wielki, Wadowice Górne w powiecie mieleckim,

w województwie lubuskim:

— gminy Niegosławice, Szprotawa w powiecie żagańskim,

w województwie wielkopolskim:

— gminy Krzemieniewo, Lipno, Osieczna, Rydzyna, Święciechowa, Włoszakowice w powiecie leszczyńskim,

— powiat miejski Leszno,

— gminy Kościan i miasto Kościan, Krzywiń, Śmigiel w powiecie kościańskim,

— część gminy Dolsk położona na zachód od linii wyznaczonej przez drogę nr 434 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 437, a następnie na zachód od drogi nr 437 biegnącej od skrzyżowania z drogą nr 434 do południowej granicy gminy, część gminy Śrem położona na zachód od linii wyznaczonej przez drogę nr 310 biegnącą od zachodniej granicy gminy do miejscowości Śrem, następnie na zachód od drogi nr 432 w miejscowości Śrem oraz na zachód od drogi nr 434 biegnącej od skrzyżowania z drogą nr 432 do południowej granicy gminy w powiecie śremskim,

— gminy Gostyń, Krobia i Poniec w powiecie gostyńskim,

— część gminy Przemęt położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Borek – Kluczewo – Sączkowo – Przemęt – Błotnica – Starkowo – Boszkowo – Letnisko w powiecie wolsztyńskim,

— powiat rawicki,

— gmina Pniewy, część gminy Duszniki położona na północ od linii wyznaczonej przez autostradę A2 oraz na zachód od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy, łączącą miejscowości Ceradz Kościelny – Grzebienisko – Wierzeja – Wilkowo, biegnącą do skrzyżowania z autostradą A2, część gminy Kaźmierz położona zachód od linii wyznaczonej przez rzekę Sarna, część gminy Ostroróg położona na południe od linii wyznaczonej przez drogę nr 184 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 116 oraz na południe od linii wyznaczonej przez drogę nr 116 biegnącą od skrzyżowania z drogą nr 184 do zachodniej granicy gminy, część gminy Szamotuły położona na zachód od linii wyznaczonej przez rzekę Sarna biegnącą od południowej granicy gminy do przecięcia z drogą nr 184 oraz na zachód od linii wyznaczonej przez drogęn r 184 biegnącą od przecięcia z rzeką Sarna do północnej granicy gminy w powiecie szamotulskim,

w województwie dolnośląskim:

— część powiatu górowskiego niewymieniona w części II załącznika I,

— część gminy Lubin położona na południe od linii wyznaczonej przez drogę nr 335 biegnącą od zachodniej granicy gminy do granicy miasta Lubin oraz na zachód od linii wyznaczonej przez drogę nr 333 biegnącą od granicy miasta Lubin do południowej granicy gminy w powiecie lubińskim

— gminy Prusice, Żmigród, część gminy Oborniki Śląskie położona na północ od linii wyznaczonej przez drogę nr 340 w powiecie trzebnickim,

— część gminy Zagrodno położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Jadwisin – Modlikowice - Zagrodno oraz na wschód od linii wyznaczonej przez drogę nr 382 biegnącą od miejscowości Zagrodno do południowej granicy gminy, część gminy wiejskiej Złotoryja położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w miejscowości Nowa Wieś Złotoryjska do granicy miasta Złotoryja oraz na północ od linii wyznaczonej przez drogę nr 382 biegnącą od granicy miasta Złotoryja do wschodniej granicy gminy w powiecie złotoryjskim

— gmina Gromadka w powiecie bolesławieckim,

— gminy Chocianów i Przemków w powiecie polkowickim,

— gminy Chojnów i miasto Chojnów, Krotoszyce, Miłkowice w powiecie legnickim,

— powiat miejski Legnica,

— część gminy Wołów położona na wschód od linii wyznaczonej przez lnię kolejową biegnącą od północnej do południowej granicy gminy, część gminy Wińsko położona na południe od linii wyznaczonej przez drogę nr 36 biegnącą od północnej do zachodniej granicy gminy, część gminy Brzeg Dolny położona na wschód od linii wyznaczonej przez linię kolejową od północnej do południowej granicy gminy w powiecie wołowskim,

— część gminy Milicz położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Poradów – Piotrkosice - Sulimierz-Sułów - Gruszeczka w powiecie milickim,

w województwie świętokrzyskim:

— gminy Gnojno, Pacanów w powiecie buskim,

— gminy Łubnice, Oleśnica, Połaniec, część gminy Rytwiany położona na zachód od linii wyznaczonej przez drogę nr 764, część gminy Szydłów położona na zachód od linii wyznaczonej przez drogę nr 756 w powiecie staszowskim,

— gminy Chmielnik, Masłów, Miedziana Góra, Mniów, Łopuszno, Piekoszów, Pierzchnica, Sitkówka-Nowiny, Strawczyn, Zagnańsk, część gminy Raków położona na zachód od linii wyznaczonej przez drogi nr 756 i 764, część gminy Chęciny położona na północ od linii wyznaczonej przez drogę nr 762, część gminy Górno położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy łączącą miejscowości Leszczyna – Cedzyna oraz na północ od linii wyznczonej przez ul. Kielecką w miejscowości Cedzyna biegnącą do wschodniej granicy gminy, część gminy Daleszyce położona na południe od linii wyznaczonej przez drogę nr 764 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą łączącą miejscowości Daleszyce – Słopiec – Borków, dalej na południe od linii wyznaczonej przez tę drogę biegnącą od skrzyżowania z drogą nr 764 do przecięcia z linią rzeki Belnianka, następnie na południe od linii wyznaczonej przez rzeki Belnianka i Czarna Nida biegnącej do zachodniej granicy gminy w powiecie kieleckim,

— powiat miejski Kielce,

— gminy Krasocin, część gminy Włoszczowa położona na wschód od linii wyznaczonej przez drogę nr 742 biegnącą od północnej granicy gminy do miejscowości Konieczno i dalej na wschód od linii wyznaczonej przez drogę łączącą miejscowości Konieczno – Rogienice – Dąbie – Podłazie, część gminy Kluczewsko położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy i łączącą miejscowości Krogulec – Nowiny - Komorniki do przecięcia z linią rzeki Czarna, następnie na południe od linii wyznaczonej przez rzekę Czarna biegnącą do przecięcia z linią wyznaczoną przez drogę nr 742 i dalej na wschód od linii wyznaczonej przez drogę nr 742 biegnącą od przecięcia z linią rzeki Czarna do południowej granicy gminyw powiecie włoszczowskim,

— gmina Kije w powiecie pińczowskim,

— gminy Małogoszcz, Oksa w powiecie jędrzejowskim,

w województwie małopolskim:

— gminy Dąbrowa Tarnowska, Radgoszcz, Szczucin w powiecie dąbrowskim.

6. **Romania**

The following restricted zones III in Romania:

— Zona orașului București,

— Județul Constanța,

— Județul Satu Mare,

— Județul Tulcea,

— Județul Bacău,

— Județul Bihor,

— Județul Bistrița Năsăud,

— Județul Brăila,

— Județul Buzău,

— Județul Călărași,

— Județul Dâmbovița,

— Județul Galați,

— Județul Giurgiu,

— Județul Ialomița,

— Județul Ilfov,

— Județul Prahova,

— Județul Sălaj,

— Județul Suceava

— Județul Vaslui,

— Județul Vrancea,

— Județul Teleorman,

— Județul Mehedinți,

— Județul Gorj,

— Județul Argeș,

— Județul Olt,

— Județul Dolj,

— Județul Arad,

— Județul Timiș,

— Județul Covasna,

— Județul Brașov,

— Județul Botoșani,

— Județul Vâlcea,

— Județul Iași,

— Județul Hunedoara,

— Județul Alba,

— Județul Sibiu,

— Județul Caraș-Severin,

— Județul Neamț,

— Județul Harghita,

— Județul Mureș,

— Județul Cluj,

— Județul Maramureş.

7. **Slovakia**

The following restricted zones III in Slovakia:

— The whole district of Vranov and Topľou,

— In the district of Humenné: Lieskovec, Myslina, Humenné, Jasenov, Brekov, Závadka, Topoľovka, Hudcovce, Ptičie, Chlmec, Porúbka, Brestov, Gruzovce, Ohradzany, Slovenská Volová, Karná, Lackovce, Kochanovce, Hažín nad Cirochou, Závada, Nižná Sitnica, Vyšná Sitnica, Rohožník, Prituľany, Ruská Poruba, Ruská Kajňa,

— In the district of Michalovce: Strážske, Staré, Oreské, Zbudza, Voľa, Nacina Ves, Pusté Čemerné, Lesné, Rakovec nad Ondavou, Petrovce nad Laborcom, Trnava pri Laborci, Vinné, Kaluža, Klokočov, Kusín, Jovsa, Poruba pod Vihorlatom, Hojné, Lúčky,Závadka, Hažín, Zalužice, Michalovce, Krásnovce, Šamudovce, Vŕbnica, Žbince, Lastomír, Zemplínska Široká, Čečehov, Jastrabie pri Michalovciach, Iňačovce, Senné, Palín, Sliepkovce, Hatalov, Budkovce, Stretava, Stretávka, Pavlovce nad Uhom, Vysoká nad Uhom, Bajany,

— In the district of Gelnica: Hrišovce, Jaklovce, Kluknava, Margecany, Richnava,

— In the district Of Sabinov: Daletice,

— In the district of Prešov: Hrabkov, Krížovany, Žipov, Kvačany, Ondrašovce, Chminianske Jakubovany, Klenov, Bajerov, Bertotovce, Brežany, Bzenov, Fričovce, Hendrichovce, Hermanovce, Chmiňany, Chminianska Nová Ves, Janov, Jarovnice, Kojatice, Lažany, Mikušovce, Ovčie, Rokycany, Sedlice, Suchá Dolina, Svinia, Šindliar, Široké, Štefanovce, Víťaz, Župčany,

— the whole district of Medzilaborce,

— In the district of Stropkov: Havaj, Malá Poľana, Bystrá, Mikové, Varechovce, Vladiča, Staškovce, Makovce, Veľkrop, Solník, Korunková, Bukovce, Krišľovce, Jakušovce, Kolbovce,

— In the district of Svidník: Pstruša,

— In the district of Zvolen: Očová, Zvolen, Sliač, Veľká Lúka, Lukavica, Sielnica, Železná Breznica, Tŕnie, Turová, Kováčová, Budča, Hronská Breznica, Ostrá Lúka, Bacúrov, Breziny, Podzámčok, Michalková, Zvolenská Slatina, Lieskovec,

— In the district of Banská Bystrica: Sebedín-Bečov, Čerín, Dúbravica, Oravce, Môlča, Horná Mičiná, Dolná Mičiná, Vlkanová, Hronsek, Badín, Horné Pršany, Malachov, Banská Bystrica,

— The whole district of Sobrance except municipalities included in zone II.’

DECISIONS

COUNCIL DECISION (EU) 2022/2349

of 21 November 2022

authorising the opening of negotiations on behalf of the European Union for a Council of Europe convention on artificial intelligence, human rights, democracy and the rule of law

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

(1) In 2021, the Council of Europe Committee of Ministers established a Committee on Artificial Intelligence (CAI) for the period 2022-2024, with the task of establishing an international negotiation process to develop a legal framework on the development, design and application of artificial intelligence (AI), based on the Council of Europe's standards on human rights, democracy and the rule of law, and conducive to innovation.

(2) On 30 June 2022, the Council of Europe Committee of Ministers instructed the CAI to speedily proceed with the elaboration of a legally binding instrument of a transversal nature, either a convention or a framework convention, on AI, based on the Council of Europe's standards on human rights, democracy and the rule of law, in line with its terms of reference, focused on general common principles, conducive to innovation, and open to participation by non-member States, while taking into account other relevant existing international legal frameworks or those under development.

(3) Subsequently, the Chair of the CAI proposed a zero draft of a Council of Europe convention or framework convention on artificial intelligence, human rights, democracy and the rule of law (the 'convention'). That zero draft includes provisions on purpose and object, scope, definitions, fundamental principles, including procedural safeguards and rights applicable to all AI systems irrespective of their level of risk, additional measures for AI systems in the public sector and for AI systems posing 'unacceptable' and 'significant' levels of risk, a follow-up and cooperation mechanism, final provisions, including a possibility for the Union to accede to such a convention, and an appendix, under development, on a methodology for risk and impact assessment of AI systems.

(4) The Union has adopted common rules that will be affected by the elements considered with regard to the convention. Those elements include in particular a comprehensive set of rules in the area of the single market for products ([1]) and services ([2])for which AI systems can be used, as well as secondary Union legislation ([3]) implementing the EU Charter of Fundamental Rights ([4]), considering that those rights are likely to be adversely affected in certain circumstances by the development and use of certain AI systems.

(5) Moreover, on 21 April 2021 the Commission submitted a legislative proposal for a regulation laying down harmonised rules for AI, which is currently being negotiated by the European Parliament and the Council. The convention overlaps to a large extent with that legislative proposal in its scope, since both instruments aim to lay down rules applicable to the design, development and application of AI systems, provided and used by either public or private entities.

(6) Therefore, the conclusion of the convention may affect existing and foreseeable future common Union rules or alter their scope within the meaning of Article 3(2) of the Treaty on the Functioning of the European Union (TFEU).

(7) Negotiations should be opened with a view to concluding the convention as regards matters falling within the exclusive competence of the Union, in order to protect the integrity of Union law and to ensure that the rules of international law and Union law remain consistent.

(8) It is possible that the convention will set high international standards concerning the regulation of AI impacting human rights, the functioning of democracy and the observance of the rule of law, in particular in light of the work already carried out by the Council of Europe in that field.

([1]) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29); Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4); Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24); Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1); Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62); 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 (OJ L 117, 5.5.2017, p. 1); Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1).

([2]) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1); Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market on services in the internal market (OJ L 376, 27.12.2006, p. 36); Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on credit agreements for consumers and repealing Council Directive 87/102/EEC (OJ L 133, 22.5.2008, p. 66).

([3]) Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin (OJ L 180, 19.7.2000, p. 22); Council Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation (OJ L 303, 2.12.2000, p. 16); Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37); 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); Directive (EU) 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89).

([4]) Charter of Fundamental Rights of the European Union (OJ C 326, 26.10.2012, p. 391).

(9) This Decision should be without prejudice to the participation of Member States in negotiations for the convention and to any subsequent Member State decision to conclude, sign or ratify the convention, or to the participation of Member States in negotiations for the Union to accede to the convention.

(10) National security remains the sole responsibility of each Member State in accordance with Article 4(2) of the Treaty on European Union (TEU). In the implementation of the convention, it is for the Member States to define, in accordance with Article 216(2) TFEU, their essential security interests and to adopt appropriate measures to ensure their internal and external security while not rendering Union law inapplicable or exempting them from their obligation to comply with Union law.

(11) All Member States are also Members of the Council of Europe. In view of that special situation, Member States present at the negotiations for the convention should, in accordance with the principle of sincere cooperation referred to in Article 4(3) TEU, in full mutual respect, support the Union negotiator in carrying out tasks which flow from the Treaties.

(12) 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 ([5]) and delivered an opinion on 13 October 2022 ([6]),

HAS ADOPTED THIS DECISION:

Article 1

1. The Commission is hereby authorised to open negotiations, on behalf of the Union, as regards matters falling within the exclusive competence of the Union, for a Council of Europe convention on artificial intelligence, human rights, democracy and the rule of law.

2. The negotiations shall be conducted on the basis of the negotiating directives of the Council set out in the addendum to this Decision, which may be revised and further developed as appropriate depending on the evolution of the negotiations.

Article 2

The negotiations referred to in Article 1 shall be conducted in consultation with the Working Party on Telecommunications and Information Society, which is hereby designated as the special committee within the meaning of Article 218(4) TFEU.

The Commission shall regularly report to the special committee referred to in the first subparagraph on the steps undertaken pursuant to this Decision and consult it on a regular basis.

Whenever so requested by the Council, the Commission shall report to it on the conduct and the outcome of the negotiations, including in writing.

To the extent that the subject matter of the negotiations falls partially within the competence of the Union and partially within the competence of its Member States, the Commission and the Member States shall cooperate closely during the negotiating process, with a view to ensuring unity in the external representation of the Union.

([5]) 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).

([6]) Opinion 20/2022 of the European Data Protection Supervisor on the Recommendation for a Council Decision authorising the opening of negotiations on behalf of the European Union for a Council of Europe convention on artificial intelligence, human rights, democracy and the rule of law (not yet published in the Official Journal).

Article 3

This Decision is addressed to the Commission.

Done at Brussels, 21 November 2022.

For the Council
The President
Z. NEKULA

COUNCIL DECISION (EU) 2022/2350

of 21 November 2022

appointing a member, proposed by the Italian Republic, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ([1]),

Having regard to the proposal of the Italian Government,

Whereas:

(1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.

(2) On 20 January 2020 the Council adopted Decision (EU) 2020/102 ([2]), appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.

(3) A member's seat on the Committee of the Regions has become vacant following the resignation of Mr Sebastiano MUSUMECI.

(4) The Italian Government has proposed Mr Christian SOLINAS, representative of a regional body who holds a regional authority electoral mandate, *Presidente della Regione Sardegna* (President of the Autonomous Region of Sardinia), as a member of the Committee of the Regions until 23 February 2024,

HAS ADOPTED THIS DECISION:

Article 1

Mr Christian SOLINAS, representative of a regional body who holds an electoral mandate, *Presidente della Regione Sardegna* (President of the Autonomous Region of Sardinia), is hereby appointed as a member of the Committee of the Regions until 23 February 2024.

Article 2

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

Done at Brussels, 21 November 2022.

For the Council
The President
Z. NEKULA

([1]) OJ L 139, 27.5.2019, p. 13.
([2]) Council Decision (EU) 2020/102 of 20 January 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 20, 24.1.2020, p. 2).

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2022/2351

of 29 November 2022

on the appointment of the EU Mission Force Commander of the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali), and repealing Decision (CFSP) 2022/657 (EUTM Mali/2/2022)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular Article 38 thereof,

Having regard to Council Decision 2013/34/CFSP of 17 January 2013 on a European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali) ([1]), and in particular Article 5 thereof,

Whereas:

(1) Pursuant to Article 5(1) of Decision 2013/34/CFSP, the Council authorised the Political and Security Committee (PSC) to take decisions concerning the political control and strategic direction of EUTM Mali, including decisions on the appointment of subsequent EU Mission Force Commanders for EUTM Mali.

(2) On 12 April 2022, the PSC adopted Decision (CFSP) 2022/657 ([2]), appointing Brigadier General Radek HASALA as the EU Mission Force Commander of EUTM Mali.

(3) On 17 October 2022, the EU Mission Commander recommended the appointment of Colonel Santiago FERNÁNDEZ ORTIZ-REPISO to succeed Brigadier General Radek HASALA as the EU Mission Force Commander of EUTM Mali. The Spanish authorities indicated that Colonel Santiago FERNÁNDEZ ORTIZ-REPISO would be promoted to Brigadier General before his appointment as the EU Mission Force Commander of EUTM Mali.

(4) On 25 October 2022, the EU Military Committee agreed to recommend that Colonel Santiago FERNÁNDEZ ORTIZ-REPISO be appointed to succeed Brigadier General Radek HASALA from mid-December 2022.

(5) A decision on the appointment of Brigadier General Santiago FERNÁNDEZ ORTIZ-REPISO as the EU Mission Force Commander of EUTM Mali from 15 December 2022 should therefore be taken.

(6) Decision (CFSP) 2022/657 should be repealed,

HAS ADOPTED THIS DECISION:

Article 1

Brigadier General Santiago FERNÁNDEZ ORTIZ-REPISO is hereby appointed as the EU Mission Force Commander of the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali) from 15 December 2022.

Article 2

Decision (CFSP) 2022/657 is hereby repealed.

([1]) OJ L 14, 18.1.2013, p. 19.

([2]) Political and Security Committee Decision (CFSP) 2022/657 of 12 April 2022 on the appointment of the EU Mission Force Commander of the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali), and repealing Decision (CFSP) 2021/2209 (EUTM Mali/1/2022) (OJ L 119, 21.4.2022, p. 108).

Article 3

This Decision shall enter into force on 15 December 2022.

Done at Brussels, 29 November 2022.

For the Political and Security Committee
The Chairperson
D. PRONK

COUNCIL DECISION (CFSP) 2022/2352

of 1 December 2022

on an assistance measure under the European Peace Facility to support the Georgian Defence Forces

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 41(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) Council Decision (CFSP) 2021/509 ([1]) establishes the European Peace Facility (EPF) for the financing by Member States of Union actions under the common foreign and security policy to preserve peace, prevent conflicts and strengthen international security pursuant to Article 21(2), point (c), of the Treaty. In particular, pursuant to Article 1(2) of Decision (CFSP) 2021/509, the EPF is to be used for the financing of assistance measures such as actions to strengthen the capacities of third States and regional and international organisations relating to military and defence matters.

(2) The 2016 Global Strategy for the European Union's Foreign and Security Policy sets the objectives of strengthening security and defence, investing in the resilience of States and societies to the east of the Union, developing an integrated approach to conflict and crises, promoting and supporting cooperative regional orders, and reinforcing global governance on the basis of international law, including compliance with international human rights law and international humanitarian law.

(3) On 21 March 2022, the Union approved the Strategic Compass, with the objective of becoming a stronger and more capable security provider, including through the increased use of the EPF in support of partners' defence capabilities.

(4) The Union is committed to a close relationship in support of a strong, independent and prosperous Georgia, based on the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part ([2]) (the 'Association Agreement'), including the Deep and Comprehensive Free Trade Area, and to promoting political association and economic integration while firmly supporting Georgia's territorial integrity within its internationally recognised borders. Pursuant to Article 5 of the Association Agreement, the Union and Georgia are to intensify their dialogue and cooperation and promote gradual convergence in the area of foreign and security policy, including the common security and defence policy (CSDP), and are to address in particular issues of conflict prevention, peaceful conflict resolution and crisis management, regional stability, disarmament, non-proliferation, arms control and export control.

(5) The Union recognises Georgia's important contribution to the Union's CSDP, including Georgia's continued contribution to CSDP crisis-management missions in the Central African Republic and in the Republic of Mali.

(6) This Decision builds upon Council Decision (CFSP) 2021/2134 ([3]) with regard to the Union's continued commitment to support the strengthening of capacities of the Georgian Defence Forces in priority-need areas.

(7) On 13 May 2022, the High Representative of the Union for Foreign Affairs and Security Policy (the 'High Representative') received a request from Georgia for the Union to support the Georgian Defence Forces by strengthening the capacities of the military medical, engineering, mobility and cyber-defence services.

([1]) Council Decision (CFSP) 2021/509 of 22 March 2021 establishing a European Peace Facility, and repealing Decision (CFSP) 2015/528 (OJ L 102, 24.3.2021, p. 14).

([2]) OJ L 261, 30.8.2014, p. 4.

([3]) Council Decision (CFSP) 2021/2134 of 2 December 2021 on an assistance measure under the European Peace Facility to support the Georgian Defence Forces (OJ L 432, 3.12.2021, p. 55).

(8) Assistance measures are to be implemented taking into account the principles and requirements set out in Decision (CFSP) 2021/509, in particular compliance with Council Common Position 2008/944/CFSP ([4]), and in accordance with the rules for the implementation of revenue and expenditure financed under the EPF.

(9) The Council reaffirms its determination to protect, promote and fulfil human rights, fundamental freedoms and democratic principles and to strengthen the rule of law and good governance, in compliance with the United Nations Charter, with the Universal Declaration of Human Rights and with international law, in particular international human rights law and international humanitarian law,

HAS ADOPTED THIS DECISION:

Article 1

Establishment, objectives, scope and duration

1. An assistance measure benefitting Georgia (the 'beneficiary') to be financed under the European Peace Facility (EPF) (the 'assistance measure') is hereby established.

2. The overall objective of the assistance measure is to contribute to strengthening the Georgian Defence Forces' capacities to enhance national security, stability and resilience in the defence sector, in line with Union policy on Georgia. Building on previous support provided by the EPF, the assistance measure will allow the Georgian Defence Forces to enhance operational effectiveness, accelerate compliance with Union standards and interoperability, and thereby better protect civilians in crises and emergencies. It will also strengthen the beneficiary's capacities with regard to its participation in EU military CSDP missions and operations as well as in other multinational operations. The specific objective of the assistance measure is to strengthen the capacities of the Georgian Defence Forces' military medical, engineering, mobility and cyber-defence units.

3. To achieve the objectives set out in paragraph 2, the assistance measure shall finance the provision of the following equipment not designed to deliver lethal force, supplies and services, including equipment-related training to the units of the Land Forces component of the Georgian Defence Forces supported under the assistance measure:

(a) military medical equipment;

(b) engineering equipment;

(c) mobility equipment;

(d) cyber-defence equipment.

4. The duration of the assistance measure shall be 36 months from the date of conclusion of the first contract between the administrator for assistance measures, acting as authorising officer, and the entities referred to in Article 4(2) of this Decision in accordance with Article 32(2), point (a), of Decision (CFSP) 2021/509.

5. The contract for the implementation of the assistance measure shall be concluded no earlier than after the adoption of an amendment of the EPF Implementing Rules by the Facility Committee.

Article 2

Financial arrangements

1. The financial reference amount intended to cover the expenditure related to the assistance measure shall be EUR 20 000 000.

2. All expenditure shall be managed in accordance with Decision (CFSP) 2021/509 and the rules for the implementation of revenue and expenditure financed under the EPF.

([4]) Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment (OJ L 335, 13.12.2008, p. 99).

Article 3

Arrangements with the beneficiary

1. The High Representative shall make the necessary arrangements with the beneficiary to ensure its compliance with the requirements and conditions established by this Decision as a condition for the provision of support under the assistance measure.

2. The arrangements referred to in paragraph 1 shall include provisions obliging the beneficiary to ensure:

(a) the compliance of the units of the Georgian Defence Forces supported under the assistance measure with relevant international law, in particular international human rights law and international humanitarian law;

(b) the proper and efficient use of any assets provided under the assistance measure for the purposes for which they were provided;

(c) the sufficient maintenance of any assets provided under the assistance measure to ensure their usability and their operational availability over their life cycle;

(d) that any assets provided under the assistance measure will not be lost, or that they will not be transferred without the consent of the Facility Committee established under Decision (CFSP) 2021/509 to persons or entities other than those identified in those arrangements, at the end of their life cycle.

3. The arrangements referred to in paragraph 1 shall include provisions on the suspension and termination of support under the assistance measure in the event of the beneficiary being found in breach of the obligations set out in paragraph 2.

Article 4

Implementation

1. The High Representative shall be responsible for ensuring the implementation of this Decision in accordance with Decision (CFSP) 2021/509 and with the rules for the implementation of revenue and expenditure financed under the EPF, in line with the Integrated Methodological Framework for assessing and identifying the required measures and controls for assistance measures under the EPF.

2. The implementation of the activities referred to in Article 1(3) shall be carried out by:

(a) the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) as regards Article 1(3), points (a), (b) and (c); and

(b) the e-Governance Academy as regards Article 1(3), point (d).

Article 5

Monitoring, control and evaluation

1. The High Representative shall monitor the compliance of the beneficiary with the obligations set out in Article 3. That monitoring shall be used to provide awareness of the context and the risks of breaches of the obligations set out in Article 3, and to contribute to the prevention of such breaches, including violations of international human rights law and international humanitarian law by the units of the Georgian Defence Forces supported under the assistance measure.

2. The post-shipment control of equipment and supplies shall be organised as follows:

(a) delivery verification, whereby delivery certificates are to be signed by the end-user forces upon transfer of ownership;

(b) reporting on the inventory, whereby the beneficiary is to report annually on the inventory of designated items until such reporting is no longer deemed necessary by the Political and Security Committee (PSC);

(c) on-site control, whereby the beneficiary is to grant the High Representative access to conduct on-site control upon request.

3. The High Representative shall conduct an evaluation, in the form of a structured first assessment of the assistance measure, six months after the first delivery of equipment. This may entail on-site visits to check the equipment, supplies and services delivered under the assistance measure, or any other forms of independently provided information. A final evaluation shall be conducted upon completion of the delivery of equipment, supplies and services under the assistance measure to assess whether the assistance measure has contributed to reaching the stated objectives.

Article 6

Reporting

During the period of implementation, the High Representative shall provide the PSC with six-monthly reports on the implementation of the assistance measure, in accordance with Article 63 of Decision (CFSP) 2021/509. The administrator for assistance measures shall regularly inform the Facility Committee established by Decision (CFSP) 2021/509 of the implementation of revenue and expenditure, in accordance with Article 38 of that Decision, including by providing information on the suppliers and subcontractors involved.

Article 7

Suspension and termination

1. The PSC may decide to suspend wholly or partially the implementation of the assistance measure in accordance with Article 64 of Decision (CFSP) 2021/509.

2. The PSC may recommend that the Council terminate the assistance measure.

Article 8

Entry into force

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

Done at Brussels, 1 December 2022.

For the Council
The President
J. SÍKELA

COUNCIL DECISION (EU) 2022/2353

of 1 December 2022

on an assistance measure under the European Peace Facility to strengthen the capacities of the Armed Forces of Bosnia and Herzegovina

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 41(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) In accordance with Council Decision (CFSP) 2021/509 ([1]), the European Peace Facility (EPF) was established for the financing by Member States of Union actions under the common foreign and security policy to preserve peace, prevent conflicts and strengthen international security pursuant to Article 21(2), point (c), of the Treaty. In particular, pursuant to Article 1(2) of Decision (CFSP) 2021/509, the EPF can finance actions to strengthen the capacities of third States and regional and international organisations relating to military and defence matters.

(2) In the Brdo Declaration of 6 October 2021, the leaders of the Union and its Member States, in consultation with Western Balkans leaders, called for the further development of Western Balkans partners' capabilities through the EPF.

(3) The conclusions of the Political and Security Committee of 17 March 2022 on the strategic orientations of the EPF for 2022 retained as a key priority for this period an assistance measure for bilateral support to a Western Balkans country.

(4) On 21 March 2022, the Council approved the Strategic Compass with the objective of the Union becoming a stronger and more capable security provider, including through the increased use of the EPF in support of partners' defence capabilities, among others in Bosnia and Herzegovina.

(5) The Union repeatedly reiterated its commitment to the European perspective of Bosnia and Herzegovina, including in the European Council conclusions in March and June 2022, underlining the need for stability and the full functioning of the country to allow it to implement all key reforms, including constitutional and electoral reforms, and to advance decisively on its European path.

(6) Since their creation in 2005, the Armed Forces of Bosnia and Herzegovina ('AFBiH') have played an essential stabilising role as one of the most successful State institutions in maintaining a safe and secure environment in the country. The High Representative for Bosnia and Herzegovina reiterated, in his 61st report to the Secretary-General of the United Nations, the need to maintain the focus of defence reforms enabling the country to take the lead in preserving peace and security. This entails strengthening the AFBiH in particular at the current juncture, which is marked by political tensions and divisive rhetoric.

(7) The purpose of this measure is to improve the capacities of the AFBiH, contribute in a balanced way to strengthening Bosnia and Herzegovina's ownership of its processes and increase military interoperability with Union capabilities with a view to increasing the AFBiH's participation in future missions and operations under the common security and defence policy (CSDP), without prejudice to any other possible support funded by the North Atlantic Treaty Organization (NATO) or other international partners.

([1]) Council Decision (CFSP) 2021/509 of 22 March 2021 establishing a European Peace Facility, and repealing Decision (CFSP) 2015/528 (OJ L 102, 24.3.2021, p. 14).

(8) The equipment provided will improve the security and deployment conditions of the AFBiH and upgrade a limited number of operational capabilities, specifically chemical, biological, radiological and nuclear (CBRN) capabilities and defensive and early-warning capabilities. By increasing the capacity of the tactical support brigade, the assistance measure will also allow for better protection of the civilian population and a swift and sustainable deployment of the NATO designated battalion, whether as part of a Union CSDP mission or operation, or as part of another format under the auspices of, inter alia, the United Nations (UN), NATO or the Organization for Security and Cooperation in Europe (OSCE), or as part of military field-training exercises

(9) On 29 June 2022, the High Representative of the Union for Foreign Affairs and Security Policy ('the High Representative') received a request from Bosnia and Herzegovina for the Union to assist the AFBiH further with the procurement of key equipment to strengthen their capacity.

(10) Upon completion of the assistance measure, the High Representative will conduct an evaluation of its impact, as well as on the management and use of the equipment provided. This exercise will inform a lessons-learned process which will be aimed at assessing the effectiveness of the assistance measure and its consistency with the overall Union strategy and policies in Bosnia and Herzegovina.

(11) Assistance measures are to be implemented taking into account the principles and requirements set out in Decision (CFSP) 2021/509, and in particular compliance with Council Common Position 2008/944/CFSP ([2]), and in accordance with the rules for the implementation of revenue and expenditure financed under the EPF.

(12) The Council reaffirms its determination to protect, promote and fulfil human rights, fundamental freedoms and democratic principles and to strengthen the rule of law and good governance, in compliance with the United Nations Charter, with the Universal Declaration of Human Rights and with international law, in particular international human rights law and international humanitarian law,

HAS ADOPTED THIS DECISION:

Article 1

Establishment, objectives, scope and duration

1. An assistance measure benefitting Bosnia and Herzegovina ('the beneficiary'), to be financed under the European Peace Facility (EPF) ('the assistance measure'), is hereby established.

2. The objective of the assistance measure is to strengthen the capacities of the AFBiH by enhancing and upgrading the equipment of its tactical support brigade. Through the provision of adequate equipment, the assistance measure will contribute to increasing the AFBiH's contribution to military CSDP missions and operations, as well as UN peace-keeping operations, while strengthening Euro-Atlantic cooperation, and better protecting civilians.

3. To achieve the objective stated in paragraph 2, the assistance measure shall finance the following types of equipment not designed to deliver lethal force:

(a) field equipment;

(b) key tools for military engineering;

(c) CBRN materiel.

4. The duration of the assistance measure shall be 36 months from the date of conclusion of the contract between the administrator for assistance measures, acting as authorising officer, and the entity referred to in Article 4(2) of this Decision in accordance with Article 32(2), point (a), of Decision (CFSP) 2021/509.

([2]) Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment (OJ L 335, 13.12.2008, p. 99).

5. The contract for the implementation of the Assistance Measure shall be concluded no earlier than after the adoption of an amendment of the EPF Implementing Rules by the Facility Committee.

Article 2

Financial arrangements

1. The financial reference amount intended to cover the expenditure related to the assistance measure shall be EUR 10 000 000.

2. All expenditure shall be managed in accordance with Decision (CFSP) 2021/509 and the rules for the implementation of revenue and expenditure financed under the EPF.

Article 3

Arrangements with the beneficiary

1. The High Representative shall make the necessary arrangements with the beneficiary to ensure its compliance with the requirements and conditions established by this Decision as a condition for the provision of support under the assistance measure.

2. The arrangements referred to in paragraph 1 shall include provisions obliging the beneficiary to ensure:

(a) the compliance of the units of the AFBiH supported under the assistance measure with relevant international law, in particular international human rights law and international humanitarian law;

(b) the proper and efficient use of any assets provided under the assistance measure for the purposes for which they were provided;

(c) the sufficient maintenance of any assets provided under the assistance measure to ensure their usability and their operational availability over their life cycle;

(d) that any assets provided under the assistance measure will not be lost, or that they will not be transferred without the consent of the Facility Committee established under Decision (CFSP) 2021/509 to persons or entities other than those identified in those arrangements, at the end of their life cycle.

3. The arrangements referred to in paragraph 1 shall include provisions on the suspension and termination of support under the assistance measure in the event of the beneficiary being found in breach of the obligations set out in paragraph 2.

Article 4

Implementation

1. The High Representative shall be responsible for ensuring the implementation of this Decision in accordance with Decision (CFSP) 2021/509 and with the rules for the implementation of revenue and expenditure financed under the EPF, consistently with the Integrated Methodological Framework for assessing and identifying the required measures and controls for assistance measures under the EPF.

2. The implementation of the activities referred to in Article 1(3) shall be carried out by the Central Project Management Agency (CPMA).

Article 5

Monitoring, control and evaluation

1. The High Representative shall monitor the compliance of the beneficiary with the obligations established in accordance with Article 3. That monitoring shall be used to provide awareness of the context and the risks of breaches of the obligations established in accordance with Article 3, and to contribute to the prevention of such breaches, including violations of international human rights law and international humanitarian law by units of the AFBiH supported under the assistance measure.

2. The post-shipment control of equipment and supplies shall be organised as follows:

(a) delivery verification, whereby delivery certificates are to be signed by the end-user forces upon transfer of ownership;

(b) reporting on the activities, whereby the beneficiary is to report annually on activities conducted with the equipment, supplies and services provided under the assistance measure until such reporting is no longer deemed necessary by the Political and Security Committee (PSC);

(c) on-site control, whereby the beneficiary is to grant the High Representative access to conduct on-site control upon request.

3. The High Representative shall conduct an evaluation, in the form of a structured first assessment of the assistance measure, 12 months after the delivery of the equipment. This may entail on-site visits to check the equipment, supplies and services delivered under the assistance measure, or any other forms of independently provided information. A final evaluation shall be conducted upon completion of the assistance measure to assess whether the assistance measure has contributed to reaching the stated objectives.

Article 6

Reporting

During the period of implementation, the High Representative shall provide the PSC with six-monthly reports on the implementation of the assistance measure, in accordance with Article 63 of Decision (CFSP) 2021/509. The administrator for assistance measures shall regularly inform the Facility Committee established by Decision (CFSP) 2021/509 of the implementation of revenue and expenditure, in accordance with Article 38 of that Decision, including by providing information on the suppliers and subcontractors involved.

Article 7

Suspension and termination

1. The PSC may decide to suspend wholly or partially the implementation of the assistance measure in accordance with Article 64 of Decision (CFSP) 2021/509.

2. The PSC may recommend that the Council terminate the assistance measure.

Article 8

Entry into force

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

Done at Brussels, 1 December 2022.

For the Council
The President
J. SÍKELA

COUNCIL DECISION (CFSP) 2022/2354

of 1 December 2022

on an assistance measure under the European Peace Facility to support the deployment of the Rwanda Defence Force in Mozambique

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 41(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) Council Decision (CFSP) 2021/509 ([1]) establishes the European Peace Facility (EPF) for the financing by Member States of Union actions under the Common Foreign and Security Policy to preserve peace, prevent conflicts and strengthen international security in accordance with Article 21(2), point (c), of the Treaty. In particular, pursuant to Article 1(2), point (b)(i), of Decision (CFSP) 2021/509, the EPF is to be used for the financing of assistance measures such as actions to strengthen the capacities of third States and regional and international organisations relating to military and defence matters.

(2) The current crisis in Mozambique's northern Cabo Delgado province is multidimensional, with a severe risk of spillover to other provinces of the country and to neighbouring countries. The Mozambican government and the African Union Peace and Security Council have welcomed the deployment of the Rwanda Defence Force as it contributes to the return to peace, security and stability in Cabo Delgado.

(3) On 6 December 2021, the High Representative of the Union for Foreign Affairs and Security Policy (the 'High Representative') received a request for the Union to support the deployment of the Rwanda Defence Force in the Cabo Delgado province of Mozambique.

(4) On 27 June 2022, the Council approved a Concept note for an assistance measure under the EPF to support the deployment of the Rwanda Defence Force in Mozambique.

(5) Assistance measures are to be implemented taking into account the principles and requirements set out in Decision (CFSP) 2021/509, in particular compliance with Council Common Position 2008/944/CFSP ([2]), and in accordance with the rules for the implementation of revenue and expenditure financed under the EPF.

(6) The Council reaffirms its determination to protect, promote and fulfil human rights, fundamental freedoms and democratic principles and to strengthen the rule of law and good governance, in compliance with the United Nations Charter, with the Universal Declaration of Human Rights and with international law, in particular international human rights and international humanitarian law,

HAS ADOPTED THIS DECISION:

Article 1

Establishment, objectives, scope and duration

1. An assistance measure benefiting the Republic of Rwanda (the 'beneficiary') to be financed under the European Peace Facility (EPF) (the 'assistance measure') is hereby established.

([1]) Council Decision (CFSP) 2021/509 of 22 March 2021 establishing a European Peace Facility, and repealing Decision (CFSP) 2015/528 (OJ L 102, 24.3.2021, p. 14).

([2]) Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment (OJ L 335, 13.12.2008, p. 99).

2. The objective of the assistance measure is to support the continued deployment of units of the Rwanda Defence Force in Mozambique's northern province of Cabo Delgado in order to extend, protect and sustain the territorial and tactical gains they have made so far. This should ensure the security and the protection of the civilian population in Mozambique's northern provinces and facilitate the return of law enforcement agencies and of other accountable state structures that deliver services for the benefit of the population.

3. To achieve the objective set out in paragraph 2, the assistance measure shall contribute to supporting the deployment of the Rwanda Defence Force units referred to in that paragraph. The assistance measure shall not be used for the supply of military equipment, or platforms, designed to deliver lethal force.

4. The duration of the assistance measure shall be 20 months from the date of conclusion of the contract between the Administrator for assistance measures acting as authorising officer and the entity referred to in Article 4(2) of this Decision, in accordance with Article 32(2), point (a), of Decision (CFSP) 2021/509.

5. The contract for the implementation of the assistance measure shall be concluded no earlier than after the adoption of an amendment of the EPF Implementing Rules by the Facility Committee.

Article 2

Financial arrangements

1. The financial reference amount intended to cover the expenditure related to the assistance measure shall be EUR 20 000 000.

2. All expenditure shall be managed in accordance with Decision (CFSP) 2021/509 and the rules for the implementation of revenue and expenditure financed under the EPF.

Article 3

Arrangements with the beneficiary

1. The High Representative shall make the necessary arrangements with the beneficiary to ensure its compliance with the requirements and conditions established by this Decision as a condition for the provision of support under the assistance measure.

2. The arrangements referred to in paragraph 1 shall include provisions obliging the beneficiary to ensure that:

(a) financing provided under the assistance measure shall be used exclusively in support of the deployment of the Rwanda Defence Force in Mozambique;

(b) financing provided under the assistance measure shall not be used to acquire military equipment or platforms designed to deliver lethal force, or to pay salaries or allowances of the Rwanda Defence Force troops;

(c) the Rwanda Defence Force troops supported under the assistance measure shall respect and fully comply with relevant international law, in particular international human rights law and international humanitarian law;

(d) the beneficiary shall actively monitor, follow up on and prosecute any violations of relevant international law, in particular international human rights law and international humanitarian law, by the Rwanda Defence Force troops supported under the assistance measure;

(e) the beneficiary shall regularly provide reports on the Rwanda Defence Force deployment in Cabo Delgado during the period of support;

(f) the beneficiary shall agree to bilateral strategic dialogues with the European External Action Service (EEAS) on the basis of this regular reporting;

(g) at least three months prior to the completion of the Rwanda Defence Force deployment in Mozambique, the beneficiary will submit for approval by the High Representative arrangements regarding the handover to the Mozambican Armed Forces of collective equipment.

3. The arrangements referred to in paragraph 1 shall include provisions on the suspension and termination of support under the assistance measure in the event of the beneficiary being found in breach of the obligations set out in paragraph 2.

4. The High Representative shall only grant the approval mentioned in paragraph 2, point (g), after verifying that the collective equipment to be handed over corresponds, taking into account its initial value, to the amount spent under this assistance measure on collective equipment.

Article 4

Implementation

1. The High Representative shall be responsible for ensuring the implementation of this Decision in accordance with Decision (CFSP) 2021/509 and with the rules for the implementation of revenue and expenditure financed under the EPF, in line with the Integrated Methodological Framework for assessing and identifying the required measures and controls for assistance measures under the EPF.

2. The implementation of the activities referred to in Article 1(3) shall be carried out by the Ministry of Finance and Economic Planning of the Republic of Rwanda.

Article 5

Monitoring, control and evaluation

1. The High Representative shall monitor the respect by the beneficiary of the obligations set out in Article 3. This monitoring shall be used to provide awareness of the context and the risks of breaches of the obligations established in accordance with Article 3, and to contribute to the prevention of such breaches, including violations of international human rights law and international humanitarian law by the units of the Rwanda Defence Force supported under the assistance measure.

2. The High Representative shall conduct a final evaluation at the end of the implementation period to assess whether the assistance measure has contributed to achieving the stated objectives. This may entail on-site visits or any other effective forms of independently provided information.

Article 6

Reporting

During the period of implementation, the High Representative shall provide the Political and Security Committee (PSC) with six-monthly reports on the implementation of the assistance measure, in accordance with Article 63 of Decision (CFSP) 2021/509. At the relevant time, the High Representative shall inform the PSC on the arrangements made in accordance with Article 3 (2), point (g). The administrator for assistance measures shall regularly inform the Facility Committee established by Decision (CFSP) 2021/509 on the implementation of revenue and expenditure in accordance with Article 38 of that Decision, including by providing information on the suppliers and subcontractors involved.

Article 7

Suspension and termination

1. The PSC may decide to suspend wholly or partially the implementation of the assistance measure in accordance with Article 64 of Decision (CFSP) 2021/509.

2. The PSC may also recommend that the Council terminate the assistance measure.

Article 8

Entry into force

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

Done at Brussels, 1 December 2022.

For the Council
The President
J. SÍKELA

COUNCIL DECISION (CFSP) 2022/2355

of 1 December 2022

on an assistance measure under the European Peace Facility to strengthen the capacities of the armed forces of the Islamic Republic of Mauritania

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 41(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) Council Decision (CFSP) 2021/509 ([1]) establishes the European Peace Facility (EPF) for the financing by Member States of Union actions under the common foreign and security policy to preserve peace, prevent conflicts and strengthen international security pursuant to Article 21(2), point (c), of the Treaty. In particular, pursuant to Article 1(2) of Decision (CFSP) 2021/509, the EPF is to be used for the financing of assistance measures such as actions to strengthen the capacities of third States and regional and international organisations relating to military and defence matters.

(2) Mauritania plays a major role in key regional, European and international initiatives aimed at strengthening peace and development in the Sahel including the 'European Union's Integrated Strategy in the Sahel', the 'Sahel Coalition' and the 'Partnership for Security and Stability in the Sahel', as well as the 'Sahel Alliance'. Mauritania is one of the largest African overall contributors to the United Nations Multidimensional Integrated Stabilization Mission in the Central African Republic. The international community, including the Union, has made considerable efforts to support Mauritania in its fight against terrorism over the recent period. The Union is committed to a close relationship with Mauritania in support of its fight against terrorism.

(3) In the Sahel region, Mauritania is a key country for the Union in the fight against terrorism. The Union has a strong partnership with the government of Mauritania, with the aim of achieving long-term development through a comprehensive and integrated approach.

(4) On 4 October 2022, the High Representative of the Union for Foreign Affairs and Security Policy (the 'High Representative') received a request for the Union to assist the Armed Forces of Mauritania with the procurement of key equipment to the *Bataillon des fusiliers marins* of Rosso, the *Bataillon des fusiliers de l'air* and military medical centres in the Military Regions 2 and 3.

(5) Assistance measures are to be implemented taking into account the principles and requirements set out in Decision (CFSP) 2021/509, in particular compliance with Council Common Position 2008/944/CFSP ([2]), and in accordance with the rules for the implementation of revenue and expenditure financed under the EPF.

(6) The Council reaffirms its determination to protect, promote and fulfil human rights, fundamental freedoms and democratic principles and to strengthen the rule of law and good governance, in compliance with the United Nations Charter, with the Universal Declaration of Human Rights and with international law, in particular international human rights law and international humanitarian law,

([1]) Council Decision (CFSP) 2021/509 of 22 March 2021 establishing a European Peace Facility, and repealing Decision (CFSP) 2015/528 (OJ L 102, 24.3.2021, p. 14).

([2]) Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment (OJ L 335, 13.12.2008, p. 99).

HAS ADOPTED THIS DECISION:

Article 1

Establishment, objectives, scope and duration

1. An assistance measure benefiting the Islamic Republic of Mauritania (the 'beneficiary') to be financed under the EPF (the 'assistance measure') is hereby established.

2. The objective of the assistance measure is to enhance the capacities of the *Bataillon des fusiliers marins* of Rosso, the *Bataillon des fusiliers de l'air* and military medical centres in the Military Regions 2 and 3. By enhancing the capacities of these units, this assistance measure will also contribute to better protecting the civilian population.

3. To achieve the objective set out in paragraph 2, the assistance measure shall finance the following types of equipment not designed to deliver lethal force: riverine and technical equipment for the *Bataillon des fusiliers marins*; protective equipment kits including military uniforms for the *Bataillon des fusiliers de l'air*; intensive care equipment and surgical equipment for the medical centres in the Military Regions 2 and 3.

4. The duration of the assistance measure shall be 36 months from the date of conclusion of the first contract signed by the administrator for assistance measures, acting as authorising officer, in accordance with Article 32(2), point (a), including in the context of administrative arrangements in accordance with Article 37, of Decision (CFSP) 2021/509.

5. The contract for the implementation of the assistance measure shall be concluded no earlier than after the adoption of an amendment of the EPF Implementing Rules by the Facility Committee.

Article 2

Financial arrangements

1. The financial reference amount intended to cover the expenditure related to the assistance measure shall be EUR 12 000 000.

2. All expenditure shall be managed in accordance with Decision (CFSP) 2021/509 and the rules for the implementation of revenue and expenditure financed under the EPF.

Article 3

Arrangements with the beneficiary

1. The High Representative shall make the necessary arrangements with the beneficiary to ensure its compliance with the requirements and conditions established by this Decision as a condition for the provision of support under the assistance measure.

2. The arrangements referred to in paragraph 1 of this Article shall include provisions obliging the beneficiary to ensure:

(a) compliance of the units of the Armed Forces of Mauritania supported under the assistance measure with relevant international law, in particular international human rights law and international humanitarian law;

(b) proper and efficient use of any assets provided under the assistance measure for the purposes for which they were provided;

(c) sufficient maintenance of any assets provided under the assistance measure to ensure their usability and their operational availability over their life-cycle;

(d) that any assets provided under the assistance measure will not be lost, or transferred without the consent of the Facility Committee established under Decision (CFSP) 2021/509 to persons or entities other than those identified in those arrangements, at the end of their life-cycle.

3. The arrangements referred to in paragraph 1 shall include provisions on the suspension and termination of support under the assistance measure in the event of the beneficiary being found in breach of the obligations set out in paragraph 2.

Article 4

Implementation

1. The High Representative shall be responsible for ensuring the implementation of this Decision in accordance with Decision (CFSP) 2021/509 and with the rules for the implementation of revenue and expenditure financed under the EPF, in line with the Integrated Methodological Framework for assessing and identifying the required measures and controls for assistance measures under the EPF.

2. The implementation of the activities referred to in Article 1(3) of this Decision shall be carried out by the administrator for assistances measures, including through administrative arrangements in accordance with Article 37 of Decision (CFSP) 2021/509.

Article 5

Monitoring, control and evaluation

1. The High Representative shall monitor the respect by the beneficiary of the obligations set out in Article 3. This monitoring shall be used to provide awareness of the context and the risks of breaches of the obligations set out in Article 3, and to contribute to the prevention of such breaches, including violations of international human rights law and international humanitarian law by the units supported under the assistance measure.

2. The post-shipment control of equipment and supplies shall be organised as follows:

(a) delivery verification, whereby EPF delivery certificates are to be signed by the end-user forces upon transfer of ownership;

(b) reporting on the inventory, whereby the beneficiary is to report annually on the inventory of designated items until such reporting is no longer deemed to be necessary by the Political and Security Committee (PSC);

(c) on-site inspection, whereby the beneficiary is to grant the High Representative access to conduct on-site control upon request.

3. The High Representative shall conduct an evaluation, in the form of a structured first assessment of the assistance measure, six months after the first delivery of equipment. This may entail on-site visits to inspect the equipment, supplies and services delivered under the assistance measure, or any other effective forms of independently provided information. A final evaluation shall be conducted upon completion of the delivery of equipment, supplies and services under the assistance measure to assess whether the assistance measure has contributed to reaching the objectives referred to in Article 1(2).

Article 6

Reporting

During the period of implementation, the High Representative shall provide the PSC with six-monthly reports on the implementation of the assistance measure, in accordance with Article 63 of Decision (CFSP) 2021/509. The administrator for assistance measures shall regularly inform the Facility Committee established by Decision (CFSP) 2021/509 on the implementation of revenue and expenditure in accordance with Article 38 of that Decision, including by providing information on the suppliers and subcontractors involved.

Article 7

Suspension and termination

1. The PSC may decide to suspend wholly or partially the implementation of the assistance measure in accordance with Article 64 of Decision (CFSP) 2021/509.

2. The PSC may also recommend that the Council terminate the assistance measure.

Article 8

Entry into force

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

Done at Brussels, 1 December 2022.

For the Council
The President
J. SÍKELA

COUNCIL DECISION (CFSP) 2022/2356

of 1 December 2022

on an assistance measure under the European Peace Facility to support the Lebanese Armed Forces

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 28(1) and Article 41(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) Council Decision (CFSP) 2021/509 ([1]) establishes the European Peace Facility (EPF) for the financing by Member States of Union actions under the common foreign and security policy to preserve peace, prevent conflicts and strengthen international security pursuant to Article 21(2), point (c), of the Treaty. In particular, pursuant to Article 1(2) of Decision (CFSP) 2021/509, the EPF is to be used for the financing of assistance measures such as actions to strengthen the capacities of third States and regional and international organisations relating to military and defence matters.

(2) The national security and stability of Lebanon is key for the Union and for the international community. Considerable efforts have been invested in supporting Lebanon, and in particular the Lebanese Armed Forces (LAF), to contribute to this matter.

(3) Resolution 1701 of the United Nations Security Council (UNSC) has established the UN Interim Force in Lebanon (UNIFIL) mission to support the LAF to maintain peace and stability in South Lebanon. The Union reaffirms its support to UNIFIL, to which several Union Member States make significant contributions. The UNSC also called upon the international community to support the LAF to ensure the national security and stability of Lebanon.

(4) On 25 October 2022, the High Representative of the Union for Foreign Affairs and Security Policy (the 'High Representative') received a request for the Union to support the LAF.

(5) Assistance measures are to be implemented taking into account the principles and requirements set out in Decision (CFSP) 2021/509, in particular compliance with Council Common Position 2008/944/CFSP ([2]), and in accordance with the rules for the implementation of revenue and expenditure financed under the EPF.

(6) The Council reaffirms its determination to protect, promote and fulfil human rights, fundamental freedoms and democratic principles and to strengthen the rule of law and good governance, in compliance with the United Nations Charter, with the Universal Declaration of Human Rights and with international law, in particular international human rights law and international humanitarian law,

HAS ADOPTED THIS DECISION:

Article 1

Establishment, objectives, scope and duration

1. An assistance measure benefitting Lebanon (the 'beneficiary') to be financed under the European Peace Facility (EPF) (the 'assistance measure') is hereby established.

([1]) Council Decision (CFSP) 2021/509 of 22 March 2021 establishing a European Peace Facility, and repealing Decision (CFSP) 2015/528 (OJ L 102, 24.3.2021, p. 14).

([2]) Council Common Position 2008/944/CFSP of 8 December 2008 defining common rules governing control of exports of military technology and equipment (OJ L 335, 13.12.2008, p. 99).

2. The objective of the assistance measure is to enhance the capabilities and the resilience of the Lebanese Armed Forces (LAF) to ensure the national security and stability of Lebanon, through the enhancement of their military medical capacities, and the provision of equipment for the LAF's operational personnel.

3. To achieve the objective set out in paragraph 2, the assistance measure shall finance the following types of equipment not designed to deliver lethal force:

(a) healthcare equipment to support the military medical services (central and regional centres);

(b) individual equipment for the logistic brigade.

4. The duration of the assistance measure shall be 36 months from the date of conclusion of the first contract by the administrator for assistance measures, acting as authorising officer, in accordance with Article 32(2), point (a), of Decision (CFSP) 2021/509, including in the context of administrative arrangements in accordance with Article 37 of the same Decision.

5. The contract for the implementation of the assistance measure shall be concluded no earlier than after the adoption of an amendment of the EPF Implementing Rules by the Facility Committee.

Article 2

Financial arrangements

1. The financial reference amount intended to cover the expenditure related to the assistance measure shall be EUR 6 000 000.

2. All expenditure shall be managed in accordance with Decision (CFSP) 2021/509 and the rules for the implementation of revenue and expenditure financed under the EPF.

Article 3

Arrangements with the beneficiary

1. The High Representative shall make the necessary arrangements with the beneficiary to ensure its compliance with the requirements and conditions established by this Decision as a condition for the provision of support under the assistance measure.

2. The arrangements referred to in paragraph 1 shall include provisions obliging the beneficiary to ensure:

(a) the compliance of the units of the LAF supported under the assistance measure with relevant international law, in particular international human rights law and international humanitarian law;

(b) the proper and efficient use of any assets provided under the assistance measure for the purposes for which they were provided;

(c) the sufficient maintenance of any assets provided under the assistance measure to ensure their usability and their operational availability over their life cycle;

(d) that any assets provided under the assistance measure will not be lost, or be transferred without the consent of the Facility Committee established under Decision (CFSP) 2021/509 to persons or entities other than those identified in those arrangements, at the end of their life cycle.

3. The arrangements referred to in paragraph 1 shall include provisions on the suspension and termination of support under the assistance measure in the event of the beneficiary being found in breach of the obligations set out in paragraph 2.

Article 4

Implementation

1. The High Representative shall be responsible for ensuring the implementation of this Decision in accordance with Decision (CFSP) 2021/509 and with the rules for the implementation of revenue and expenditure financed under the EPF, in line with the Integrated Methodological Framework for assessing and identifying the required measures and controls for assistance measures under the EPF.

2. The implementation of the activities referred to in Article 1(3) shall be carried out by the administrator for assistance measures, including through administrative arrangements in accordance with Article 37 of Decision (CFSP) 2021/509.

Article 5

Monitoring, control and evaluation

1. The High Representative shall monitor the respect by the beneficiary of the obligations set out in Article 3. This monitoring shall provide awareness of the context and the risks of breaches of the obligations set out in Article 3, and shall contribute to the prevention of such breaches, including violations of international human rights and international humanitarian law by the units of the LAF supported under the assistance measure.

2. The post-shipment control of equipment and supplies shall be organised as follows:

(a) delivery verification, whereby delivery certificates are to be signed by the end-user forces upon transfer of ownership;

(b) reporting on the inventory, whereby the beneficiary is to report annually on the inventory of designated items until such reporting is no longer deemed necessary by the Political and Security Committee (PSC);

(c) on-site control, whereby the beneficiary is to grant the High Representative access to conduct on-site control upon request.

3. The High Representative shall conduct a final evaluation upon completion of the assistance measure to assess whether the assistance measure has contributed to reaching the objectives stated in Article 1(2).

Article 6

Reporting

During the period of implementation, the High Representative shall provide the PSC with six-monthly reports on the implementation of the assistance measure, in accordance with Article 63 of Decision (CFSP) 2021/509. The Administrator for assistance measures shall regularly inform the Facility Committee established by Decision (CFSP) 2021/509 on the implementation of revenue and expenditure in accordance with Article 38 of that Decision, including by providing information on the suppliers and subcontractors involved.

Article 7

Suspension and termination

1. The PSC may decide to suspend wholly or partially the implementation of the assistance measure in accordance with Article 64 of Decision (CFSP) 2021/509.

2. The PSC may also recommend that the Council terminate the assistance measure.

Article 8

Entry into force

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

Done at Brussels, 1 December 2022.

For the Council
The President
J. SÍKELA

COMMISSION IMPLEMENTING DECISION (EU) 2022/2357

of 1 December 2022

amending Implementing Decision (EU) 2019/451 as regards the harmonised standard for retroreflecting road studs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC ([1]), and in particular Article 17(5) thereof,

Whereas:

(1) In accordance with Regulation (EU) No 305/2011 manufacturers are to use the methods and the criteria provided in harmonised standards, the references of which have been published in the *Official Journal of the European Union*, for assessing the performance of construction products covered by those standards in relation to their essential characteristics.

(2) By letter M/111 of 29 August 1996, the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) for the drafting of harmonised standards in support of Council Directive 89/106/EEC ([2]) ('the mandate'). The mandate allows for a revision of the harmonised standards drafted on its basis.

(3) In order to take account of the technical developments as well as the requirements of Regulation (EU) No 305/2011, CEN revised the existing harmonised standard EN 1463-1:2009 on retroreflecting road studs, the reference of which has been published by Commission communication (2018/C 092/06) ([3]). This resulted in the adoption of the revised harmonised standard EN 1463-1:2021 on retroreflecting road studs.

(4) The revised harmonised standard EN 1463-1:2021 contains improved methods for assessing the performance of the construction products concerned. Further, the wording of certain provisions needed to be improved in order to ensure their correct and uniform interpretation in all Member States. It was also necessary to remove from the scope of standard products installed only temporary since such products are not construction products for the purposes of Regulation (EU) No 305/2011. The revised standard thus importantly contributes to the road safety and the removal of technical barriers to trade.

(5) The Commission has assessed whether the harmonised standard revised by CEN is in conformity with the relevant mandate and Regulation (EU) No 305/2011.

(6) The harmonised standard revised by CEN is in conformity with the relevant mandate and Regulation (EU) No 305/2011. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

([1]) OJ L 88, 4.4.2011, p. 5.

([2]) Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (OJ L 40, 11.2.1989, p. 12).

([3]) Commission communication in the framework of the implementation of Regulation (EU) No 305/ 2011 of the European Parliament and of the Council laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (Publication of titles and references of harmonised standards under Union harmonisation legislation) (OJ C 92, 9.3.2018, p. 139).

(7) Annex I to Commission Implementing Decision (EU) 2019/451 ([4]) lists the references of harmonised standards drafted in support of Regulation (EU) No 305/2011. The reference of the harmonised standard EN 1463-1:2021 should therefore be included in that Annex.

(8) In accordance with Article 17(5) of Regulation (EU) No 305/2011, a coexistence period is to be indicated for each harmonised standard that supersedes another harmonised standard.

(9) Implementing Decision (EU) 2019/451 should therefore be amended accordingly.

(10) In order to allow the manufacturers to use the revised harmonised standard as soon as possible, this Decision should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Implementing Decision (EU) 2019/451 is amended in accordance with the Annex to this Decision.

Article 2

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

Done at Brussels, 1 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

([4]) Commission Implementing Decision (EU) 2019/451 of 19 March 2019 on the harmonised standards for construction products drafted in support of Regulation (EU) No 305/2011 of the European Parliament and of the Council (OJ L 77, 20.3.2019, p. 80).

ANNEX

In Annex I to Implementing Decision (EU) 2019/451, the following entry is added:

No	Reference to the standard	Reference to the superseded standard	Beginning of the coexistence period (dd.mm. yyyy.)	End of the coexistence period (dd.mm.yyyy.)
'7.	EN 1463-1:2021 Road marking materials - Retroreflecting road studs - Part 1: Initial performance requirements	EN 1463-1:2009 Road marking materials - Retroreflecting road studs - Part 1: Initial performance requirements	2.12.2022	2.12.2023'.

COMMISSION IMPLEMENTING DECISION (EU) 2022/2358

of 1 December 2022

on the French measure establishing a limitation on the exercise of traffic rights due to serious environmental problems, pursuant to Article 20 of Regulation (EC) No 1008/2008 of the European Parliament and of the Council

(notified under document C(2022) 8694)

(Only the French text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1008/2008 of the European Parliament and of the Council of 24 September 2008 on common rules for the operation of air services in the Community ([1]), and in particular Article 20 thereof,

After consulting the Committee referred to in Article 25(1) of Regulation (EC) No 1008/2008,

Whereas:

I. PROCEDURE

(1) By letter of 17 November 2021 ([2]), France informed, pursuant to Article 20(2) of Regulation (EC) No 1008/2008 (the 'Regulation'), the Commission of its intention to introduce a temporary limitation subject to conditions on the exercise of traffic rights due to serious environmental problems (the 'Initial Measure').

(2) The information initially submitted by France included: (1) Article 145 of Law No 2021-1104 of 22 August 2021 on combating climate change and strengthening resilience to its effects ('Loi Climat et Résilience' or the 'Law') ([3]); (2) the consolidated version of Article L. 6412-3 of the Transport Code following Law No 2021-1104; (3) a draft decree setting out the conditions for the application of the prohibition (the 'Draft Decree') as well as (4) additional elements outlining the context, content and justification for the Initial Measure under Article 20(2) of the Regulation.

(3) The Commission received two complaints (one from airports and one from airlines) ([4]) alleging that Article 145 of the Law does not meet the conditions of Article 20(1) of the Regulation and hence is incompatible with EU law.

(4) The complainants allege, in particular, that Article 145 of the Law would be ineffective and disproportionate to the intended objective, that it would discriminate between air carriers and that its duration would not be limited in time. The complainants also argue that the impact assessment carried out by the French authorities would not be sufficiently detailed and referred in this context to the Opinion of the French Council of State ([5]) and, moreover, that the air transport sector is already subject to other measures pursuing the same objective, such as the EU Emissions Trading System (ETS), and will soon be subject to other new legislative measures such as those proposed in the Fit for 55 package ([6]). The Initial Measure would also come in addition to the obligation, pursuant to Article 147 of the same Law, on all airlines operating in France to offset their emissions on domestic routes.

([1]) OJ L 293, 31.10.2008, p. 3.
([2]) Registered under ARES (2021) 7093428.
([3]) Authenticated Electronic Official Journal of the French Republic No 0196 of 24 August 2021 https://www.legifrance.gouv.fr/download/pdf?id=x7Gc7Ys-Z3hzgxO5KgI0zSu1fmt64dDetDQxhvJZNMc=
([4]) CHAP(2021)03705 on 6 October 2021 and CHAP(2021)03855 on 20 October 2021.
([5]) https://www.conseil-etat.fr/avis-consultatifs/derniers-avis-rendus/au-gouvernement/avis-sur-un-projet-de-loi-portant-lutte-contre-le-dereglement-climatique-et-ses-effets
([6]) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: 'Fit for 55': delivering the EU's 2030 Climate Target on the way to climate neutrality, COM/2021/550 final

(5) In view of its preliminary assessment, the Commission decided on 15 December 2021 to take up the Initial Measure for further examination pursuant to Article 20(2) of the Regulation (the 'Commission Decision of 15 December 2021'). It also decided that the Initial Measure could not be implemented until the Commission had completed its examination ([7]).

(6) By letter dated 7 January 2022, the Commission services requested additional information from the French authorities to allow them to assess the compatibility of the Initial Measure with the conditions laid down in Article 20(1) of the Regulation.

(7) By letter of 9 May 2022, France provided additional elements on the content and justification for the Initial Measure under Article 20 of the Regulation. By letter of 21 June 2022, France submitted updated information regarding its notification containing an amended Draft Decree without derogations (the 'Final Draft Decree') as well as additional elements intended to take account of the concerns raised by the Commission and its services as to its compatibility with the conditions laid down in Article 20(1) of the Regulation (jointly the 'Measure').

II. **THE FACTS**

II.1. **Description of the Measure**

(8) France adopted Law No 2021-1104 on combating climate change and strengthening resilience to its effects on 22 August 2021.

(9) Article 145.I of the Law prohibits, on the basis of Article 20 of the Regulation, scheduled public passenger air transport services on all air routes within French territory for which there are several direct rail connections per day of less than two and a half hours.

(10) Pursuant to Article 145.II and IV of the Law, the application of the prohibition will be evaluated after three years from the date of its entry into force.

(11) Article 145.I, second paragraph, of the Law requires a subsequent decree to be adopted having regard to the opinion of the French Council of State (Conseil d'Etat) to specify the conditions for the application of the first paragraph, 'in particular the characteristics of the rail connections concerned, which must ensure sufficient service, and the modalities under which this prohibition may be derogated from when the air services mainly provide the transport of connecting passengers or can be regarded as providing carbon-free air transport. It also sets the level of CO_2 emissions per passenger that services regarded as carbon free need to comply with'.

(12) The Final Draft Decree sets out the conditions for the application of the prohibition.

(13) According to Article 1 of the Final Draft Decree, the prohibition applies to those scheduled public passenger air transport services for which a rail connection provides, in each direction, a journey of less than two and a half hours:

'1° between train stations serving the same cities as the airports concerned; where the most important in terms of traffic at the two airports concerned is directly served by a high-speed rail service, the train station used shall be the one serving this airport;

2° without change of train between these two train stations;

3° several times a day with sufficient frequencies and satisfactory timetables;

4° and allowing more than eight hours of presence on the spot during the day.'

(14) The Final Draft Decree does not include the derogations on connections and for services that can be considered decarbonised referred to in Recital (11) of the Commission Decision of 15 December 2021.

([7]) Commission Implementing Decision of 15 December 2021, C(2021)9550

(15) Pursuant to Article 2 of the Final Draft Decree, the Decree will enter into force the day after its publication for a duration of three years.

(16) The French authorities have indicated the following ([8]) about the Measure:

'1. A differentiation has been introduced into the calculation of alternative rail journey times, taking full account of the potential of certain airports for intermodality:

— where the most important airport in terms of traffic is served directly by a high-speed rail service, the train station used to calculate the alternative rail service shall be the one serving this airport;

— in all other cases, the station used to calculate the alternative rail service shall be the one serving the same city as the airport concerned.

In practice, of the eight routes identified, only two airports are directly served by a high-speed rail service: Paris-Charles de Gaulle and Lyon-Saint Exupéry.

Paris-Charles de Gaulle airport has the fifth highest transfer rate in Europe (30 %, source IATA 2019) and its current infrastructure includes a high-speed train link. The French authorities therefore consider that – unlike Paris-Orly, which is a point-to-point airport (7 % connections, same source) – the intermodal potential of Paris-Charles de Gaulle, reinforced by the location of a station linked to the high-speed rail network at this hub, must be taken into consideration, and it should be understood as a destination in its own right when analysing alternative rail journeys from Bordeaux, Lyon, Nantes or Rennes.

In the same vein, Lyon-Saint Exupéry airport is equipped with a high-speed train station which must be regarded as a destination in its own right when analysing various relevant routes, in particular the Marseille-Lyon link.

2. The French authorities have also decided to further specify the conditions for a rail service to be considered as acceptable ([9]): it must provide sufficient frequencies and suitable timings in accordance with the wording of Article 16 of Regulation (EC) No 1008/2008 on public service obligations. This definition must make it possible to ensure compliance with Article 20 of this Regulation, by framing the Measure with a precise definition of the concept of 'appropriate levels of service'.

(17) The French authorities further specify ([10]) that 'In practice, (…), the situation regarding the eight routes referred to in the original notification would be as follows:

'— the three routes between Paris-Orly and Bordeaux, Nantes and Lyon will be prohibited for any carrier;

— the routes between Paris-Charles de Gaulle, on the one hand, and Bordeaux and Nantes on the other, are excluded from the scope of the Measure owing to the rail journey time of more than 2 hours 30 minutes to the Paris-Charles de Gaulle airport station (with the best travel times of around 3 hours 30 minutes and 3 hours respectively);

— the routes between Paris-Charles de Gaulle, on the one hand, and Rennes and Lyon on the other, as well as the Lyon-Marseille route, are excluded from the Measure given the rail services available at present. This is because, even if the journey times by rail can be less than 2 hours 30 minutes, they do not make it possible to get to Paris-Charles de Gaulle airport (or Lyon-Saint Exupéry airport in the case of the Lyon-Marseille route) early enough in the morning or to depart from there late enough in the evening.

— future improvements in the rail services, with services operating at sufficient frequencies and suitable timings, in particular for the purposes of connecting flights, will enable these air routes to be banned.'

The French authorities moreover included in their reply an annex which provides details on how the criteria of the Final Draft Decree are applied to the eight air routes mentioned above.

([8]) In the additional information provided on 9 May 2022.

([9]) In the additional information provided on 9 May 2022, the French authorities had erroneously stated 'The French authorities have also decided to further specify the conditions for a rail service to be considered as substitutable'. The text was corrected after verifying it with the French authorities.

([10]) In the additional information provided on 21 June 2022.

(18) The French authorities also specify that 'The situation regarding banned routes and routes potentially affected by the ban (mainly domestic routes connecting Paris-Charles de Gaulle, Paris-Orly, and Lyon Saint Exupéry airports to destinations served by high-speed rail routes) will be examined ahead of each scheduling season' (i.e. each time a programme is submitted). 'In addition, during the period of application of the Measure, the French Civil Aviation Authority (DGAC) will keep the list of routes that are effectively banned updated for the public, clarifying the link between these bans and the criteria of the Decree'.

(19) Furthermore, the French authorities reiterate and further specify their commitment made at the request of the Commission, to 'produce and transmit to the services of the European Commission an assessment of the Measure 24 months after its entry into force. This review will take particular account of the effects of the Measure on the environment, including climate change, and on the internal market for air services'.

II.2. **Commission Decision of 15 December 2021**

(20) In its Decision of 15 December 2021, the Commission considered, based on its preliminary assessment, that the Initial Measure as notified by France on 17 November 2021 raised concerns as to its compatibility with the conditions laid down in Article 20(1) of the Regulation in terms of non-discrimination, distortion of competition, justification and proportionality.

(21) The Commission considered that the first two initial derogations benefitting air services carrying a majority of connecting passengers bore a risk of possible discrimination and distortion of competition between air carriers and that the third derogation benefiting air services that would meet a maximum emission threshold required further analysis as to its potential effects on competition and possible discrimination between air carriers.

(22) The scope of the derogations also raised questions as to the effectiveness of the Initial Measure vis-à-vis the objective pursued, as the pursuance of the environmental objective would be limited by the application of the first two derogations.

III. **ASSESSMENT OF THE MEASURE**

(23) As a preliminary observation, the Commission notes that as a derogation from Article 15 of the Regulation and the right of EU air carriers to freely operate intra-EU air services, Article 20 of the Regulation must be interpreted in a manner which limits its scope to what is strictly necessary in order to safeguard the interests which it allows the Member States to protect.

Whether serious environmental problems exist

(24) The Commission supports measures to promote increased use of low-carbon modes of transport, while ensuring the proper functioning of the internal market. One of the objectives of the Commission's Sustainable and Smart Mobility Strategy (the 'Mobility Strategy') is to create the conditions for transport operators to offer carbon neutral options by 2030 to their customers on scheduled collective journeys of less than 500 km in the EU.

(25) In its Decision of 15 December 2021, the Commission already acknowledged that the intended objective of the Measure as notified by France is to contribute to address climate change by using less CO_2-intensive transport modes where suitable alternatives exist.

(26) In their reply of 9 May 2022, the French authorities indicate that 'the Measure notified by the French authorities is the result of the work of the Citizens Convention for Climate which led to the drafting of 149 measures aimed at speeding up the fight against climate change'. They further specify that 'the prime focus of reducing flights, in coordination with a number of other measures, is to tackle climate change' while stressing that 'the positive secondary impact on noise and local pollution will stem naturally from the Measure thanks to the resulting reduction in air traffic'.

(27) In its proposal for a Regulation establishing the framework for achieving climate neutrality and amending Regulation (EU) 2018/1999 (the 'European Climate Law') ([11]), the Commission acknowledges that 'tackling climate change is an urgent challenge' and refers to the Intergovernmental Panel on Climate Change's (IPCC) Special Report on the impacts of global warming of 1,5 °C above pre-industrial levels and related global greenhouse gas emission pathways, which notably confirms that greenhouse gas emissions need to be urgently reduced ([12]).

(28) The European Green Deal calls for a 90 % reduction in greenhouse gas (GHG) emissions from transport by 2050 and making the transport system as a whole sustainable. As stressed in the Mobility Strategy, 'to achieve this systemic change, we need to (1) make all transport modes more sustainable, (2) make sustainable alternatives widely available in a multimodal transport system, and (3) put into place the right incentives to drive the transition. (…) This implies that all policy levers must be pulled'.

(29) Promoting sustainable transport choices, such as high-speed rail, is necessary in order to achieve that goal. As highlighted in the Mobility Strategy, this requires that suitable (rail) services are in place at competitive prices, frequencies and comfort levels.

(30) In this context, the Commission believes that France is entitled to consider that a serious environmental problem exists in the situation at issue, which includes the urgent need to reduce GHG emissions, and that a measure, such as the one envisaged by the French authorities, could be justified under Article 20(1) of the Regulation provided it is non-discriminatory, does not distort competition between air carriers, is not more restrictive than necessary to relieve the problem, and has a limited period of validity not exceeding three years, after which it should be reviewed, as provided for in Article 20(1) of the Regulation.

Non-discrimination and distortion of competition

(31) As regards non-discrimination and impact on competition, the Initial Measure contained two derogations benefitting air services carrying a majority of connecting passengers, which would have, in the Commission's initial assessment ([13]) borne a risk of possible discrimination and distortion of competition between air carriers.

(32) Based on the additional information provided by the French authorities, the Commission considers that such derogations would, regardless of the proportion of connecting passengers being considered, have constituted *de facto* discrimination and would have led to a distortion of competition to the detriment of existing or potential point-to-point air carriers whose business model is not focused on connecting passengers.

(33) By France's withdrawal of the two derogations, the concerns in relation to these two derogations regarding the risk of possible discrimination and distortion of competition between air carriers were resolved.

(34) The criteria used for the ban in the Final Draft Decree are based on the length of the train connections and frequency and suitability of timings, and, hence, are objective in nature. The prohibition applies to all scheduled public passenger air transport services for which a rail connection provides, in each direction, a journey of less than two and a half hours and fulfils the conditions of Article 1 of the Final Draft Decree as referred to in Recital 13. As no air services will be exempted from the prohibition, the Measure does not lead to discrimination on grounds of nationality, identity or business model of an air carrier, nor does it give rise to distortion of competition between air carriers.

The measure should not be more restrictive than necessary to relieve the problems

(35) Article 20(1) of the Regulation requires such measure not to be more restrictive than necessary to relieve the problems.

([11]) Proposal for a Regulation of the European Parliament and of the Council establishing the framework for achieving climate neutrality and amending Regulation (EU) 2018/1999 (European Climate Law), COM(2020) 80 final, 2020/0036 (COD).

([12]) See Recital 2. Also included in Recital 3 of the European Climate Law (OJ L 243, 9.7.2021, p. 1).

([13]) See Recital 21 above.

(36) As stated in Recital 30, the problem identified by the French authorities in this case includes the urgent need to reduce GHG emissions. In its assessment of whether the Measure is not more restrictive than necessary to relieve the problem at issue, the Commission will look at whether the Measure is capable of attaining the objective- which is to contribute to the reduction of GHG emissions, and does not go beyond what is necessary in order to attain it, taking into account whether other modes of transport provide appropriate levels of service to ensure the necessary connectivity.

(37) In this context, the negative impacts on European citizens and connectivity of any restriction of traffic rights must be offset by the availability of affordable, convenient and more sustainable alternative transport modes.

(38) As a preliminary remark, the Commission notes that a variety of legislative and non-legislative tools are being developed to help and further encourage the air transport sector to significantly reduce its CO_2 emissions and become more sustainable. As part of its 'Fit for 55 package', the Commission presented a proposal to revise the EU Emissions Trading System (ETS) ([14]) to strengthen the carbon price signal, a proposal to revise the Energy Taxation Directive ([15]) that removes the mandatory exemption on jet fuels, as well as a new legislative proposal, the 'ReFuelEU Aviation' ([16]). That initiative aims to decarbonise the aviation sector by mandating the uptake of sustainable aviation fuels (SAF) while ensuring a well-functioning aviation market. The Commission proposals to update the legislation on the Single European Sky and the rules on air traffic management ([17]) also hold great potential for modernisation and sustainability, helping to cut excess fuel burn and CO_2 emissions caused by flight inefficiencies and airspace fragmentation. These legislative proposals are currently being discussed by the co-legislators and are not yet applicable. Once in place, they should effectively contribute to the decarbonisation of the air transport sector to such extent that the Measure at hand should no longer be needed.

(39) Notwithstanding this, in order to contribute to the reduction of greenhouse gas emissions in the air transport sector in the meantime, the Commission notes that France has chosen to temporarily limit the exercise of traffic rights for domestic scheduled public passenger air transport services for which there are several direct daily rail connections of less than two and a half hours with sufficient frequencies and suitable timings.

(40) As regards whether other modes of transport provide appropriate levels of service, the Commission notes that Article 1 of the Final Draft Decree provides for a more detailed set of relevant and objective requirements that take into account the quality of the connection both for point to point and connecting passengers. Moreover, the French competent authorities have committed to assess *ex ante*, before each scheduling season, whether or not the rail connection offers an appropriate level of service on a given route (as defined in Article 1 of the Final Draft Decree), and thereafter to properly inform potentially interested carriers of which routes can continue to be served. It also means that a route that was banned could potentially be served again if the quality of the rail service changes and no longer fulfils the conditions of appropriate levels of service, thereby incentivising the provision of quality rail services offering appropriate levels of service. The Commission considers that such a dynamic approach which takes into account the future development of rail services would promote multimodality in line with the objectives of the Mobility Strategy and benefit connectivity.

(41) As regards the environmental benefit of the Measure, the French authorities state that 'the already effective closure of the three routes of Orly-Bordeaux, Orly-Lyon and Orly-Nantes ([18])leads to an overall reduction of 55 000 tonnes of CO_2 emissions from air transport' ([19]).

([14]) COM(2021)552 final of 14.7.2021.
([15]) COM(2021) 563 final of 14.7.2021.
([16]) COM(2021)561 final of 14.7.2021.
([17]) COM(2020) 577 final and COM(2020) 579 final of 22.9.2020.
([18]) The Commission notes that Air France had already decided to stop its operations on these three routes in 2020, notably in the context of the loan and State guarantee on loans granted by France. Banning those routes will therefore not lead to an actual reduction in emissions. However, unquantifiable environmental benefits may nonetheless be generated since air carriers potentially interested in operating these routes will be prevented from doing so.
([19]) DGAC estimates based on 2019 traffic.

(42) They also explain that the global offer of seats by Air France on the routes Paris Charles de Gaulle (CDG)-Bordeaux, CDG-Lyon and CDG-Nantes has remained stable since 2019 (between -1 % and +3 % depending on the route concerned) and has not led to a transfer of capacity from Orly.

(43) The French authorities anticipate that people will primarily switch to high speed train rather than to coaches or cars. Available data referred to ([20]) seem to point to a historical preference for rail connections amongst the people who use air connections. To obtain estimates on the potential impact of the modal shift on emission reductions, the French authorities calculated two extreme scenarios for the Orly-Bordeaux route: according to the French authorities, the Measure would result in the worst-case scenario ([21]) to a reduction of CO_2 emissions by almost 50 % (-48,2 %) and in the best-case scenario (full modal shift to rail) to 98,3 % less emissions.

(44) The air routes CDG-Lyon, CDG-Rennes and Lyon-Marseille are currently not in the scope of the Measure because one or several of the conditions set out in Article 1 of the Final Draft Decree are not (yet) fulfilled. However, the French authorities indicate these three air routes may fall within the scope of the prohibition as soon as a rail operator improves the conditions of its services (mainly in terms of proposed schedules). The French authorities estimate that the prohibition of these three additional routes could lead to potential emission reductions of 54 900 tonnes of CO_2. By contrast the routes CDG-Bordeaux and CDG-Nantes do not, and will not, according to the explanations provided by the French authorities (see Recital 17), fall within the scope of the Measure without structural improvements in the rail services.

(45) The French authorities also point to a potential positive impact of the Measure as it 'will prevent the creation of air services for point-to-point traffic from the Paris region to 60 % of the 40 most populous cities in metropolitan France' to the extent that '24 of these cities are accessible by train from Paris in under 2 hours 30 minutes'. To support this, they refer to the freedom of air carriers to operate within the internal market and to the growth dynamics in point to point traffic in pre-pandemic times.

(46) While awaiting the adoption and implementation of those more effective measures to lower CO_2 emissions in air transport mentioned in Recital 38, the Commission considers that the Measure, although it is in itself unable to eliminate the serious problems at issue, nevertheless is capable of making a short-term contribution towards the reduction of emissions in the air transport sector and the fight against climate change.

(47) Moreover, the Commission notes that the Measure provides for a limited restriction to the freedom to provide air services. It targets only those routes where a more sustainable transport mode is available and offers an appropriate level of service as defined in Article 1 of the Final Draft Decree.

(48) Furthermore, the Commission takes note of the French commitments, referred to in Recital 18, to review 'The situation in respect of banned routes and routes potentially affected by the ban […] ahead of each scheduling season' and, in Recital 19, to 'produce and transmit to the European Commission an assessment of the Measure 24 months after its entry into force. This review will take particular account of the effects of the Measure on the environment, including climate change, and on the internal market for air services'. This should enable the French authorities to properly enforce the Measure so that it does not go beyond what is necessary to relieve the serious problems at issue or, as the case may be, to lift the Measure if it is no longer considered necessary and proportionate to the aim pursued.

([20]) See 'High-speed rail: lessons for policy makers from experiences abroad', D Albalate, G Bel – Public Administration Review (2012) (referred to in the French letter of 17 November 2021).

([21]) The assumption is that 'air passengers would switch to road and rail in the same proportions as passengers already travelling on these alternative modes of transport at times when there was a flight available (overlooking the 'other' reason). The proportions applied are taken from the 2019 People's Mobility Survey'. They however add that 'a worst-case scenario must be assumed for the switch to road transport to halve the gains from the closure of the air route'.

(49) The Commission also notes that 'during the period of application of the Measure, the French Civil Aviation Authority will keep the list of routes that are effectively banned updated for the public, clarifying the link between these bans and the criteria of the Decree'. This will ensure the transparency necessary towards European citizens and relevant stakeholders and allow them, as the case may be, to challenge the Measure at national level.

(50) In view of the above considerations, the Commission considers that the Measure is, pending the adoption and implementation of those more effective measures to lower CO_2 emissions in air transport mentioned in Recital 38, not more restrictive than necessary to relieve the problems.

Limited period of validity

(51) Article 20(1) of the Regulation requires the Measure to have a limited period of validity, not exceeding three years, after which it shall be reviewed.

(52) As recalled in Recital 10 the application of the prohibition will be evaluated after three years from the date of its entry into force, which is the maximum allowed under Article 20(1) of the Regulation.

(53) Following concerns expressed by the Commission, and in line with Article 20(1) of the Regulation, the period of validity of the Final Draft Decree has been limited to three years (Recital 15). In addition, France has committed to 'produce and transmit to the services of the European Commission an assessment of the Measure 24 months after its entry into force. This review will take particular account of the effects of the Measure on the environment, including climate change, and on the internal market for air services'. If, as a result of that analysis, a new measure is envisaged, pursuant to Article 20(2) of the Regulation France is to notify it to the Commission.

(54) The Commission therefore considers that the Measure has a limited period of validity of three years.

IV. **CONCLUSION**

(55) Based on the examination of the notification, and in view of the above, the Commission considers that the Measure envisaged complies with the conditions laid down in Article 20(1) of the Regulation.

HAS ADOPTED THIS DECISION:

Article 1

The Measure as notified by France on 17 November 2021 and amended by letter of 21 June 2022 complies with Article 20(1) of the Regulation.

France shall review the Measure after 24 months from its entry into force and pursuant to Article 20(2) of the Regulation it shall notify to the Commission any new measure envisaged as a result of such review.

Article 2

This Decision is addressed to the French Republic.

Done at Brussels, 1 December 2022.

For the Commission
Adina-Ioana VĂLEAN
Member of the Commission

DECISION (EU) 2022/2359 OF THE EUROPEAN CENTRAL BANK

of 22 November 2022

adopting internal rules concerning restrictions of rights of data subjects in connection with the European Central Bank's internal functioning (*ECB/2022/42*)

THE EXECUTIVE BOARD OF THE EUROPEAN CENTRAL BANK,

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

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Article 11.6 thereof,

Having regard to 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 ([1]), and in particular Article 25 thereof,

Whereas:

(1) The European Central Bank (ECB) carries out its tasks in accordance with the Treaties.

(2) In accordance with Article 45(3) of Regulation (EU) 2018/1725, Decision (EU) 2020/655 of the European Central Bank (ECB/2020/28) ([2]) sets out the general rules implementing Regulation (EU) 2018/1725 as regards the ECB. In particular, it specifies the rules relating to the appointment and role of the data protection officer of the ECB (DPO), including the DPO's tasks, duties and powers.

(3) In exercising the tasks conferred on the ECB, the ECB and in particular the organisational unit concerned acts as data controller in so far as it determines, alone or jointly with others, the purposes and means of the processing of personal data.

(4) In connection with the internal functioning of the ECB, various business areas of the ECB (including Directorate General Human Resources (DG/HR), the Compliance and Governance Office (CGO), the Directorate Internal Audit (D/IA) and the Directorate General Legal Services (DG/L)) are entrusted with tasks within the legal framework governing employment at the ECB which involve the processing of personal data. Such tasks could include, for example, actions taken in relation to potential breaches of professional duties (including investigations of inappropriate behaviour pursuant to the ECB's dignity at work framework and the follow-up of the reporting of any illegal activity or any breach of professional duties submitted via any channel, including inter alia, via the ECB's whistleblowing tool); tasks relating to selection procedures; tasks undertaken by DG/HR in the performance of its functions relating to performance management, promotion, the direct appointment of ECB personnel, professional development including calibrations of talent within and across business areas, salary increases and bonuses and decisions on mobility and leave; the examination of internal appeals brought by ECB personnel (including through administrative review, grievance procedures, special appeal procedures or medical committees) and their follow-up; the CGO's advisory tasks under the Ethics Framework of the ECB (set out in Part 0 of the ECB Staff Rules) and the CGO's tasks relating to the monitoring for compliance purposes of private financial activities (including cooperation with any external service provider appointed pursuant to Article 0.4.3.3 of the ECB Staff Rules); and audits performed by the D/IA and the tasks performed in the context of Administrative Circular 01/2006 on internal administrative inquiries ([3]) when conducting investigative activities and administrative inquiries in situations which may have a possible disciplinary dimension involving ECB personnel (including the tasks of the persons conducting the inquiry or the members of the inquiry panel where they are required to gather evidence and establish the relevant facts).

([1]) OJ L 295, 21.11.2018, p. 39.

([2]) Decision (EU) 2020/655 of the European Central Bank of 5 May 2020 adopting implementing rules concerning data protection at the European Central Bank and repealing Decision ECB/2007/1 (ECB/2020/28) (OJ L 152, 15.5.2020, p. 13).

([3]) Administrative Circular 01/2006 was adopted on 21 March 2006 and is available on the ECB's website.

(5) Pursuant to Decision (EU) 2016/456 of the European Central Bank (ECB/2016/3) ([4]) the ECB must transmit to the European Anti-Fraud Office, at its request or on the ECB's own initiative, information in the ECB's possession which gives rise to a suspicion of the existence of possible cases of fraud, corruption or any other illegal activity affecting the Union's financial interest. Decision (EU) 2016/456 (ECB/2016/3) provides that in such a case interested parties are informed rapidly, if this will not be harmful to the investigation, and that, in any event, no conclusions referring by name to interested parties may be drawn without giving interested parties the opportunity to express their views on all the facts relating to them, including any evidence existing against them.

(6) Pursuant to point (b) of Article 4 of Decision (EU) 2020/655 (ECB/2020/28) the DPO must investigate matters and incidents relating to data protection either on its own initiative or at the request of the ECB.

(7) The Security and Safety Division within Directorate Administration is responsible for conducting investigations for the purposes of ensuring the protection of physical security at the ECB of person, premises and property, for gathering threat intelligence and for security incidents analysis.

(8) The ECB has a duty of loyal cooperation with national authorities, including national criminal prosecution authorities. In particular, pursuant to Decision (EU) 2016/1162 of the European Central Bank (ECB/2016/19) ([5]), the ECB may, at the request of a national criminal investigation authority, provide confidential information held by it and related to the tasks conferred on the ECB by Council Regulation (EU) No 1024/2013 ([6]) or other ESCB/Eurosystem-related tasks to an NCA or NCB respectively for disclosure to the national criminal investigation authority in question under certain conditions.

(9) Pursuant to Council Regulation (EU) 2017/1939 ([7]), the ECB must provide without delay any information to the European Public Prosecutor's Office (EPPO) where a suspicion of an offence within its competence is identified.

(10) The ECB must cooperate with the EU bodies exercising a supervisory, oversight or auditing function to which the ECB is subject, such as the European Data Protection Supervisor, the European Court of Auditors and the European Ombudsman, in the performance of their respective tasks. In this context, the ECB may process personal data to be able to respond to requests, consult with and provide information to such bodies.

(11) Pursuant to the internal dispute resolution framework at the ECB, ECB personnel may contact a mediator at any time and by any means to request the mediator's support in resolving or preventing a work-related dispute. That framework provides that all communication with the mediator is protected by confidentiality. Anything mentioned during the mediation process is regarded as privileged and each party involved in mediation must use such information solely for the purpose of the mediation process, without prejudice to any legal proceedings. Exceptionally, the mediator may disclose information when disclosure appears necessary to prevent an imminent risk of serious harm to the physical or mental integrity of a person.

(12) The ECB strives to ensure working conditions which protect the health and safety of its personnel and respect their dignity at work by providing counselling services to support them. ECB personnel may solicit the services of a social counsellor with respect to any issues including emotional, personal and work-related issues. The social counsellor may not have access to the personal file of ECB personnel, unless explicitly authorised by them. No information received or statements made by an individual to the social counsellor may be disclosed, unless explicitly authorised by such individual or so required by the law.

([4]) Decision (EU) 2016/456 of the European Central Bank of 4 March 2016 concerning the terms and conditions for European Anti-Fraud Office investigations of the European Central Bank, in relation to the prevention of fraud, corruption and any other illegal activities affecting the financial interests of the Union (ECB/2016/3) (OJ L 79, 30.3.2016, p. 34).

([5]) Decision (EU) 2016/1162 of the European Central Bank of 30 June 2016 on disclosure of confidential information in the context of criminal investigations (ECB/2016/19) (OJ L 192, 16.7.2016, p.73).

([6]) Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions (OJ L 287, 29.10.2013, p.63).

([7]) Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p.1).

(13) In connection with its internal functioning, the ECB processes several categories of data that may be related to an identified or identifiable natural person. Non-exhaustive lists of those categories of personal data which are processed by the ECB in connection with its internal functioning are contained in the Annexes to this Decision. Personal data could also form part of an assessment including an assessment conducted by the responsible business area relating to the matter being examined, including, for instance, an assessment by DG/HR, DG/L, D/IA or by a disciplinary committee or an inquiry panel on a breach of professional duties.

(14) In the context of recitals 4 to 13, it is appropriate to specify the grounds on which the ECB may restrict the rights of data subjects.

(15) The aim of the ECB in performing its tasks is to pursue important objectives of general public interest of the Union. Therefore, the performance of such tasks should be safeguarded as contemplated by Regulation (EU) 2018/1725, in particular points (b), (c), (d), (f), (g) and (h) of Article 25(1).

(16) In accordance with Article 25(1) of Regulation (EU) 2018/1725, restrictions of the application of Articles 14 to 22, 35 and 36 and, in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 22, Article 4 of that Regulation should be set out in internal rules or legal acts adopted on the basis of the Treaties. Accordingly, the ECB should set out the rules under which it may restrict the rights of data subjects in the performance of its tasks.

(17) The ECB should justify why such restrictions of data subjects' rights are strictly necessary and proportionate in a democratic society to safeguard the objectives pursued in the exercise of its official authority and the functions connected to it, and how the ECB respects the essence of fundamental rights and freedoms whilst imposing any such restriction.

(18) Within this framework the ECB is bound to respect, to the maximum extent possible, the fundamental rights of data subjects, in particular those relating to the right of provision of information, access and rectification, right to erasure, restriction of processing, right of communication of a personal data breach to the data subject or confidentiality of communication as provided for in Regulation (EU) 2018/1725.

(19) However, the ECB may be obliged to restrict the information provided to data subjects and the rights of other data subjects to protect the performance of its tasks, in particular its own investigations and procedures, the investigations and procedures of other public authorities and the fundamental rights and freedoms of other persons related to its investigations or other procedures.

(20) The ECB should lift a restriction which has already been applied to the extent it is no longer needed.

(21) The DPO should review the application of restrictions with a view to ensuring compliance with this Decision and with Regulation (EU) 2018/1725.

(22) Whilst this Decision sets out the rules under which the ECB may restrict the rights of data subjects when the ECB processes personal data in connection with its internal functioning, the Executive Board has adopted a separate decision adopting internal rules concerning the restriction of rights in the performance of its supervisory tasks.

(23) The ECB may be able to apply an exception in accordance with Regulation (EU) 2018/1725 which makes the need to consider a restriction unnecessary including in particular those set out in Articles 15(4), 16(5), 19(3) and 35(3) of that Regulation.

(24) Derogations from the rights of data subjects referred to in Articles 17, 18, 20, 21, 22 and 23 of Regulation (EU) 2018/1725 for archiving purposes in the public interest may be provided for in internal rules or legal acts adopted on the basis of the Treaties by the ECB in relation to its archiving subject to the conditions and safeguards required in accordance with Article 25(4) of Regulation (EU) 2018/1725.

(25) The European Data Protection Supervisor was consulted in accordance with Article 41(2) of Regulation (EU) 2018/1725 and delivered an opinion on 12 March 2021.

(26) The Staff Committee has been consulted,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1. This Decision sets out rules relating to the restriction of the rights of data subjects by the ECB when conducting personal data processing activities, as recorded in the central register, in connection with its internal functioning.

2. The rights of data subjects which may be restricted are specified in the following Articles of Regulation (EU) 2018/1725:

(a) Article 14 (transparent information, communication and modalities for the exercise of the rights of the data subject);

(b) Article 15 (information to be provided where personal data are collected from the data subject);

(c) Article 16 (information to be provided where personal data have not been obtained from the data subject);

(d) Article 17 (right of access by the data subject);

(e) Article 18 (right to rectification);

(f) Article 19 (right to erasure ('right to be forgotten'));

(g) Article 20 (right to restriction of processing);

(h) Article 21 (notification obligation regarding rectification or erasure of personal data or restriction of processing);

(i) Article 22 (right to data portability);

(j) Article 35 (communication of a personal data breach to the data subject);

(k) Article 36 (confidentiality of electronic communications);

(l) Article 4 in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 22 of Regulation (EU) 2018/1725.

Article 2

Definitions

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

(1) 'processing' means processing as defined in point (3) of Article 3 of Regulation (EU) 2018/1725;

(2) 'personal data' means personal data as defined in point (1) of Article 3 of Regulation (EU) 2018/1725;

(3) 'data subject' means an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;

(4) 'central register' means the publicly available repository of all personal data processing activities conducted at the ECB which is kept by the DPO and referred to in Article 9 of Decision (EU) 2020/655 (ECB/2020/28);

(5) 'controller' means the ECB, and in particular the competent organisational unit within the ECB which, alone or jointly with others, determines the purposes and means of the processing of personal data and which is responsible for the processing operation;

(6) 'Union institutions and bodies' means Union institutions and bodies as defined in point (10) of Article 3 of Regulation (EU) 2018/1725.

Article 3

Application of restrictions

1. For personal data processing activities set out in Article 1(1) the controller may restrict the rights referred to in Article 1(2) to safeguard the interests and objectives referred to in Article 25(1) of Regulation (EU) 2018/1725, where the exercise of those rights would endanger any of the following:

(a) the assessment and reporting of potential breaches of professional duties and, where necessary, their subsequent investigation and follow-up, including suspension from duties, the safeguarding of which is in accordance with points (b), (c), (f) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(b) the informal and/or formal dignity at work procedures, including the consideration of cases that may result in such a procedure as set out in Part 0.5 of the ECB Staff Rules, the safeguarding of which is in accordance with points (b), (c), (f) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(c) the proper performance of DG/HR's functions under the employment law framework at the ECB relating to performance management, promotion procedures or the direct appointment of ECB personnel, selection procedures and professional development, the safeguarding of which is in accordance with points (c) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(d) the examination of internal appeals brought by ECB personnel (including through administrative review or grievance procedures, special appeal procedures or medical committees) and their follow up, the safeguarding of which is in accordance with points (b), (c) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(e) the reporting of any illegal activity or breach of professional duties via the ECB's whistleblowing tool or the assessment of requests by the Compliance and Governance Office (CGO) for protection of whistle-blowers or witnesses from retaliation, the safeguarding of which is in accordance with points (b), (c), (f) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(f) the activities of the CGO under the Ethics Framework of the ECB set out in Part 0 of the ECB Staff Rules and the rules on selection and appointment set out in Part 1A of the ECB Staff Rules, and the monitoring for compliance purposes of private financial activities including both the functions exercised by the external service provider appointed pursuant to Article 0.4.3.3 of the ECB Staff Rules and the assessment and follow-up of potential breaches resulting from such monitoring by the CGO, the safeguarding of which is in accordance with points (b), (c), (f) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(g) audits undertaken by the Directorate Internal Audit, investigative activities and internal administrative inquiries, the safeguarding of which is in accordance with points (b), (c) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(h) the performance of the ECB's functions pursuant to Decision (EU) 2016/456 (ECB/2016/3), in particular the duty of the ECB to report any information about illegal activity, the safeguarding of which is in accordance with points (b), (c), (g) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(i) investigations conducted by the DPO on processing activities carried out at the ECB pursuant to point (b) of Article 4 of Decision (EU) 2020/655 (ECB/2020/28), the safeguarding of which is in accordance with points (b) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(j) investigations for the purposes of ensuring physical security at the ECB of persons, premises and property, whether handled internally or with external support, the gathering of threat intelligence and security incidents analysis, the safeguarding of which is in accordance with points (b), (c), (d) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(k) judicial proceedings, the safeguarding of which is in accordance with points (b), (c) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(l) the cooperation between the ECB and national criminal investigation authorities, in particular the provision of confidential information held by the ECB for disclosure to a national criminal investigation authority at the request of the latter, the safeguarding of which is in accordance with points (b), (c), (d) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(m) the cooperation between the ECB and the EPPO pursuant to Regulation (EU) 2017/1939, in particular the duty of the ECB to provide information about offences, the safeguarding of which is in accordance with points (b), (c), (d) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(n) the cooperation with EU bodies exercising a supervisory, oversight or auditing function to which the ECB is subject, the safeguarding of which is in accordance with points (c), (d), (g) and/or (h) of Article 25(1) of Regulation (EU) 2018/1725;

(o) the performance of a mediator's tasks pursuant to the internal dispute resolution framework at the ECB, in particular giving support to help resolve or prevent a work-related dispute, the safeguarding of which is in accordance with point (h) of Article 25(1) of Regulation (EU) 2018/1725;

(p) the provision of the counselling services by the social counsellor to support ECB personnel, the safeguarding of which is in accordance with point (h) of Article 25(1) of Regulation (EU) 2018/1725.

The categories of personal data in relation to which restrictions referred to in paragraph 1 may be applied are specified in Annexes I to XIV to this Decision.

2. The controller may only apply a restriction where on a case-by-case assessment it concludes that the restriction:

(a) is necessary and proportionate taking into account the risks to the rights and freedoms of the data subject; and

(b) respects the essence of the fundamental rights and freedoms in a democratic society.

3. The controller shall document its assessment in an internal assessment note which shall include the legal basis, the reasons for the restriction, the rights of the data subjects that are restricted, the data subjects affected, the necessity and proportionality of the restriction and the likely duration of the restriction.

4. A decision to restrict the rights of a data subject pursuant to paragraph 1 to be taken by the controller shall be made at the level of the relevant business area head or deputy head in whose business area the main processing operation involving the personal data is carried out.

Article 4

Provision of general information on restrictions

The controller shall provide general information on the potential restriction of data subject rights as follows:

(a) the controller shall specify the rights which may be restricted, the reasons for restriction and the potential duration;

(b) the controller shall include the information referred to in point (a) in its data protection notices, privacy statements and records of processing activities as referred to in Article 31 of Regulation (EU) 2018/1725.

Article 5

Restriction of right of access by data subjects, right to rectification, right of erasure or restriction of processing

1. Where the controller restricts, wholly or partially, the right of access, the right to rectification, the right of erasure or the right to restriction of processing, respectively referred to in Articles 17, 18, 19(1) and 20(1) of Regulation (EU) 2018/1725, it shall, within the period referred to in Article 11(5) of Decision (EU) 2020/655 (ECB/2020/28), inform the data subject concerned, in its written reply to the request, of the restriction applied, the principal reasons for the restriction, the possibility of lodging a complaint with the European Data Protection Supervisor and of seeking a judicial remedy in the Court of Justice of the European Union.

2. The controller shall keep the internal assessment note referred to in Article 3(3) and, where applicable, the documents containing underlying factual and legal elements and make these available to the DPO and European Data Protection Supervisor on request.

3. The controller may defer, omit or deny the provision of information concerning the reasons for the restriction referred to in paragraph 1 for as long as that provision of information would undermine the purpose of the restriction. As soon as the controller determines that providing the information no longer undermines the purpose of the restriction, the controller shall provide that information to the data subject.

Article 6

Duration of restrictions

1. The controller shall lift a restriction as soon as the circumstances that justified that restriction no longer apply.

2. Where the controller lifts a restriction pursuant to paragraph 1, the controller shall promptly:

(a) to the extent it has not already done so, inform the data subject of the principal reasons on which the application of a restriction was based;

(b) inform the data subject of his or her right to lodge a complaint with the European Data Protection Supervisor or to seek a judicial remedy before the Court of Justice of the European Union;

(c) grant the data subject the right that was subject to the restriction that has been lifted.

3. The controller shall reassess every six months the need to maintain a restriction applied pursuant to this Decision and shall document its reassessment in an internal assessment note.

Article 7

Safeguards

The ECB shall apply organisational and technical safeguards as set out in Annex XV to prevent abuse or unlawful access or transfer.

Article 8

Review by the DPO

1. Where the controller restricts the application of a data subject's rights, it shall continuously involve the DPO. In particular, the following shall apply:

(a) the controller shall, without undue delay, consult the DPO;

(b) on the DPO's request, the controller shall provide the DPO with access to any documents containing underlying factual and legal elements, including the internal assessment note referred to in Article 3(3);

(c) the controller shall document how the DPO was involved including relevant information that was shared, in particular the date of its first consultation as referred to in point (a);

(d) the DPO may request the controller to review the restriction;

(e) the controller shall inform the DPO in writing of the outcome of the review requested without undue delay and in any case before any restriction is applied.

2. The controller shall inform the DPO when the restriction has been reassessed in accordance with Article 6(3) or when it has been lifted.

Article 9

Entry into force

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

Done at Frankfurt am Main, 22 November 2022.

The President of the ECB
Christine LAGARDE

ANNEX I

Assessment and reporting of potential breaches of professional duties and, where necessary, their subsequent investigation and follow-up

The restriction referred to in point (a) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) location data;

g) data concerning goods or services provided;

h) data on external activities;

i) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

j) any other data relating to the assessment and reporting of potential breaches of professional duties and, where necessary, subsequent investigation and follow-up.

ANNEX II

Informal and/or formal dignity at work procedures, including the consideration of cases that may result in such a procedure as set out in Part 0.5 of the ECB Staff Rules

The restriction referred to in point (b) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) location data;

g) data concerning goods or services provided;

h) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

i) any other data relating to informal and/or formal dignity at work procedures, including the consideration of cases that may result in such a procedure as set out in Part 0.5 of the ECB Staff Rules.

ANNEX III

The performance of DG/HR's functions under the employment law framework at the ECB

The restriction referred to in point (c) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) location data;

g) data concerning goods or services provided;

h) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

i) any other data included in, or relating to, considerations of individual cases, in particular those that may result in a decision adversely affecting ECB personnel and the examination of internal appeals brought by ECB personnel and their follow-up;

j) any other data relating to selection procedures.

ANNEX IV

The examination of internal appeals and their follow-up

The restriction referred to in point (d) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) location data;

g) data concerning goods or services provided;

h) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

i) any other data included in, or relating to, considerations of individual cases, in particular those that may result in a decision adversely affecting ECB personnel and the examination of internal appeals brought by ECB personnel and their follow-up.

ANNEX V

The reporting of any illegal activity or any breach of professional duties submitted via any channel, including via the ECB's whistleblowing tool, or the Compliance and Governance Office's assessment of requests for protection of whistle-blowers or witnesses

The restriction referred to in point (e) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) location data;

g) data concerning goods or services provided;

h) data on external activities;

i) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

j) any other data relating to any alleged illegal activity or alleged breach of professional duties or to any request for the protection of whistle-blowers or witnesses.

ANNEX VI

Activities of the CGO under the ECB Staff Rules

The restriction referred to in point (f) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about private transactions);

e) data concerning family, lifestyle and social circumstances;

f) data on external activities;

g) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership, genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

h) any other data relating to any activities reported to, or investigated by, the CGO.

ANNEX VII

Audits undertaken by the Directorate Internal Audit and investigative activities or internal administrative inquiries

The restriction referred to in point (g) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) data on external activities;

g) location data;

h) data concerning goods or services provided;

i) social and behavioural data and other types of data specific to the processing operation;

j) information regarding administrative proceedings or any other investigations;

k) electronic traffic data;

l) video surveillance data;

m) audio recordings;

n) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

o) data relating to criminal proceedings, any sanction or other administrative penalty;

p) any other data relating to audits undertaken by the Directorate Internal Audit and any investigative activity or internal administrative inquiry.

ANNEX VIII

The performance of the ECB's functions pursuant to Decision (EU) 2016/456 (ECB/2016/3)

The restriction referred to in point (h) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay or allowances, or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) data on external activities;

g) location data;

h) data on goods or services provided;

i) electronic traffic data;

j) video surveillance data;

k) audio recordings;

l) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

m) any other data relating to the performance of the ECB's functions pursuant to Decision (EU) 2016/456 (ECB/2016/3).

ANNEX IX

Investigations conducted by the DPO pursuant to point (b) of Article 4 of Decision (EU) 2020/655 (ECB/2020/28)

The restriction referred to in point (i) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay or allowances, or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) data on external activities;

g) location of data;

h) data concerning goods or services provided;

i) electronic traffic data;

j) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

k) any other data relating to any investigation conducted by the DPO pursuant to point (b) of Article 4 of Decision (EU) 2020/655 (ECB/2020/28).

ANNEX X

Investigations for the purpose of ensuring physical security at the ECB of persons, premises and property, the gathering of threat intelligence and security incidents analysis

The restriction referred to in point (j) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) location data;

e) data concerning family, lifestyle and social circumstances;

f) electronic traffic data;

g) video surveillance data;

h) audio recordings;

i) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

j) data concerning pending criminal cases or criminal records;

k) any other data relating to investigations for the purpose of ensuring physical security at the ECB of persons, premises and property, to threat intelligence or to security incidents analysis.

ANNEX XI

Judicial Proceedings

The restriction referred to in point (k) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) data on external activities;

g) location of data;

h) electronic traffic data;

i) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

j) any other data relating to judicial proceedings.

ANNEX XII

The cooperation between the ECB and national criminal investigation authorities, the EPPO and EU bodies exercising a supervisory, oversight or auditing function to which the ECB is subject

The restriction referred to in points (l) to (n) of Article 3(1) of this Decision may be applied in relation to all the categories of personal data mentioned in Annex I to XI, as well as the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) identification data;

b) contact data;

c) professional data, including data concerning education, training and employment details;

d) financial details (e.g. information about pay, allowances or private transactions);

e) data concerning family, lifestyle and social circumstances;

f) data on external activities;

g) location data;

h) data concerning goods or services provided;

i) video surveillance data;

j) electronic traffic data;

k) audio recordings;

l) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

m) information regarding administrative proceedings or any other investigations;

n) data relating to criminal proceedings, any sanction or other administrative penalty;

o) any other data relating to the cooperation between the ECB and national criminal investigation authorities, the EPPO and EU bodies exercising a supervisory, oversight or auditing function to which the ECB is subject.

ANNEX XIII

The performance of the mediator's tasks

The restriction referred to in point (o) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) contact data;

b) professional data, including data concerning education, training and employment details;

c) financial details (e.g. information about pay, allowances or private transactions);

d) data concerning family, lifestyle and social circumstances;

e) social and behavioural data and other types of data specific to the processing operation;

f) information regarding administrative proceedings or any other regulatory investigations;

g) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

h) any other data relating to the performance of the mediator's tasks.

ANNEX XIV

The provision of the counselling services by the social counsellor

The restriction referred to in point (p) of Article 3(1) of this Decision may be applied in relation to the categories of data mentioned in the relevant records of processing, in particular, the following categories of personal data:

a) contact data;

b) professional data, including data concerning education, training and employment details;

c) financial details (e.g. information about pay, allowances or private transactions);

d) data concerning family, lifestyle and social circumstances;

e) social and behavioural data and other types of data specific to the processing operation;

f) information regarding administrative proceedings or any other regulatory investigations;

g) data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or trade union membership; genetic data or biometric data; data concerning health; or data regarding a natural person's sex life or sexual orientation;

h) any other data relating to the provision of the counselling services by the social counsellor.

ANNEX XV

Organisational and technical safeguards at the ECB to prevent abuse or unlawful processing of personal data include:

(a) as regard persons:

(i) all persons who have access to non-public ECB information being responsible for knowing and applying the ECB's policy and rules on the management and confidentiality of information;

(ii) a security clearance process which ensures that only vetted and authorised persons have access to the ECB premises and its non-public information;

(iii) IT, information and physical security awareness measures and trainings which are regularly held for ECB personnel and external service providers;

(iv) ECB personnel being subject to strict rules of professional secrecy set out in the ECB Conditions of Employment and Staff Rules, the breach of which gives rise to disciplinary sanctions;

(v) rules and obligations governing external service providers' or contractors' access to non-public ECB information which are set out in contractual arrangements;

(vi) access controls including security zoning which are enforced ensuring that access of persons to ECB non-public information is authorised and restricted based on business needs and security requirements;

(b) as regard processes:

(i) processes being in place to ensure the controlled implementation, operation and maintenance of IT applications supporting the ECB's business;

(ii) using IT applications for the ECB's business which comply with the ECB's security standards;

(iii) having a comprehensive physical security programme in operation which continuously assesses security threats and encompasses physical security measures to ensure an adequate level of protection;

(c) as regard technology:

(i) all electronic data being stored in IT applications complying with the ECB's security standards and thus being protected against unauthorised access or alteration;

(ii) IT applications being implemented, operated and maintained at a level of security commensurate to the IT applications' confidentiality, integrity and availability needs, which are based on business impact analyses;

(iii) the level of security of IT applications being regularly validated through technical and non-technical security assessments;

(iv) access to ECB non-public information being granted in accordance with the need-to-know principle, and privileged access being strictly limited and tightly controlled;

(v) controls being implemented to detect and follow up on actual and potential security breaches.

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2022/2105 of 29 July 2022 laying down rules on conformity checks of marketing standards for olive oil and methods of analysis of the characteristics of olive oil

(Official Journal of the European Union L 284 of 4 November 2022)

On page 36, Annex III, Table 3, rows 3, 5 and 8.

On page 37, Annex III, Table 4, rows 3, 5 and 9.

On page 40, Annex III, Table 7, rows 2 and 4.

On page 41, Annex III, Table 8, rows 2 and 4.

On page 44, Annex III, Table 11, rows 3 and 5.

for: 'Commission Delegated Regulation (EU) …/… [20220707-034]',

read: 'Commission Delegated Regulation (EU) 2022/2104'.

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