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I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2022/858 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 30 May 2022****on a pilot regime for market infrastructures based on distributed ledger technology, and amending Regulations (EU) No 600/2014 and (EU) No 909/2014 and Directive 2014/65/EU****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Central Bank ⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) It is important to ensure that Union financial services legislation is fit for the digital age and contributes to a future-proof economy that works for citizens, including by enabling the use of innovative technologies. The Union has a policy interest in exploring, developing and promoting the uptake of transformative technologies in the financial sector, including the uptake of distributed ledger technology (DLT). Crypto-assets are one of the main applications of distributed ledger technology in the financial sector.
- (2) Most crypto-assets fall outside the scope of Union financial services legislation and create challenges in terms of, among other things, investor protection, market integrity, energy consumption and financial stability. Such crypto-assets therefore require a dedicated regulatory framework at Union level. By contrast, other crypto-assets qualify as financial instruments within the meaning of Directive 2014/65/EU of the European Parliament and of the Council ⁽⁴⁾. Insofar as crypto-assets qualify as financial instruments under that Directive, a full set of Union financial

⁽¹⁾ OJ C 244, 22.6.2021, p. 4.

⁽²⁾ OJ C 155, 30.4.2021, p. 31.

⁽³⁾ Position of the European Parliament of 24 March 2022 (not yet published in the Official Journal) and decision of the Council of 12 April 2022.

⁽⁴⁾ Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (OJ L 173, 12.6.2014, p. 349).

services legislation, including Regulations (EU) No 236/2012 ⁽⁵⁾, (EU) No 596/2014 ⁽⁶⁾, (EU) No 909/2014 ⁽⁷⁾ and (EU) 2017/1129 ⁽⁸⁾ and Directives 98/26/EC ⁽⁹⁾ and 2013/50/EU ⁽¹⁰⁾ of the European Parliament and of the Council potentially apply to issuers of such crypto-assets and to firms conducting activities related to such crypto-assets.

- (3) The so-called 'tokenisation' of financial instruments, that is to say, the digital representation of financial instruments on distributed ledgers or the issuance of traditional asset classes in tokenised form to enable them to be issued, stored and transferred on a distributed ledger, is expected to open up opportunities for efficiency improvements in the trading and post-trading process. However, as fundamental trade-offs involving credit risk and liquidity remain in a tokenised world, the success of token-based systems will depend on how well they interact with traditional account-based systems, at least in the interim.
- (4) Union financial services legislation was not designed with distributed ledger technology and crypto-assets in mind, and contains provisions that potentially preclude or limit the use of distributed ledger technology in the issuance, trading and settlement of crypto-assets that qualify as financial instruments. Currently, there is also a lack of authorised financial market infrastructures which use distributed ledger technology to provide trading or settlement services, or a combination of such services, for crypto-assets that qualify as financial instruments. The development of a secondary market for such crypto-assets could bring multiple benefits, such as enhanced efficiency, transparency and competition in relation to trading and settlement activities.
- (5) At the same time, regulatory gaps exist due to legal, technological and operational specificities related to the use of distributed ledger technology and to crypto-assets that qualify as financial instruments. For instance, there are no transparency, reliability or safety requirements imposed on the protocols and 'smart contracts' that underpin crypto-assets that qualify as financial instruments. The underlying technology could also raise some novel forms of risk that are not adequately addressed by the existing rules. Several projects for the trading of crypto-assets that qualify as financial instruments and related post-trading services and activities have been developed in the Union, but few are already in operation, and those that are in operation are of limited scale. Furthermore, as highlighted by the European Central Bank's (ECB) Advisory Group on Market Infrastructures for Securities and Collateral and its Advisory Group on Market Infrastructures for Payments, the use of distributed ledger technology would entail similar challenges to those faced by conventional technology, such as fragmentation and interoperability issues, and would potentially also create new issues, for instance in relation to the legal validity of tokens. Given the limited experience as regards the trading of crypto-assets that qualify as financial instruments and related post-trading services and activities, it is currently premature to significantly modify Union financial services legislation to enable the full deployment of such crypto-assets and their underlying technology. At the same time, the creation of financial market infrastructure for crypto-assets that qualify as financial instruments is currently constrained by requirements embedded in Union financial services legislation that are not well suited to crypto-assets that qualify as financial instruments or the use of distributed ledger technology. For instance, platforms for trading crypto-assets usually give direct access to retail investors, whereas traditional trading venues usually give access to retail investors only through financial intermediaries.

⁽⁵⁾ Regulation (EU) No 236/2012 of the European Parliament and of the Council of 14 March 2012 on short selling and certain aspects of credit default swaps (OJ L 86, 24.3.2012, p. 1).

⁽⁶⁾ Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC (OJ L 173, 12.6.2014, p. 1).

⁽⁷⁾ Regulation (EU) No 909/2014 of the European Parliament and of the Council of 23 July 2014 on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012 (OJ L 257, 28.8.2014, p. 1).

⁽⁸⁾ Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC (OJ L 168, 30.6.2017, p. 12).

⁽⁹⁾ Directive 98/26/EC of the European Parliament and of the Council of 19 May 1998 on settlement finality in payment and securities settlement systems (OJ L 166, 11.6.1998, p. 45).

⁽¹⁰⁾ Directive 2013/50/EU of the European Parliament and of the Council of 22 October 2013 amending Directive 2004/109/EC of the European Parliament and of the Council on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market, Directive 2003/71/EC of the European Parliament and of the Council on the prospectus to be published when securities are offered to the public or admitted to trading and Commission Directive 2007/14/EC laying down detailed rules for the implementation of certain provisions of Directive 2004/109/EC (OJ L 294, 6.11.2013, p. 13).

- (6) In order to allow for the development of crypto-assets that qualify as financial instruments and for the development of distributed ledger technology, while preserving a high level of investor protection, market integrity, financial stability and transparency, and avoiding regulatory arbitrage and loopholes, it would be useful to create a pilot regime for market infrastructures based on distributed ledger technology to test such DLT market infrastructures (the 'pilot regime'). The pilot regime should allow for certain DLT market infrastructures to be temporarily exempted from some of the specific requirements of Union financial services legislation that could otherwise prevent operators from developing solutions for the trading and settlement of transactions in crypto-assets that qualify as financial instruments, without weakening any existing requirements or safeguards applied to traditional market infrastructures. DLT market infrastructures and their operators should have in place adequate safeguards related to the use of distributed ledger technology to ensure the effective protection of investors, including clearly defined chains of liability to clients for any losses due to operational failures. The pilot regime should also enable the European Supervisory Authority (European Securities and Markets Authority) established by Regulation (EU) No 1095/2010 of the European Parliament and of the Council⁽¹⁾ (ESMA) and competent authorities to draw lessons from the pilot regime and to gain experience of the opportunities and specific risks relating to crypto-assets that qualify as financial instruments and to their underlying technologies. The experience gained with the pilot regime should help identify possible practical proposals for a suitable regulatory framework in order to make targeted adjustments to Union law as regards the issuance, safekeeping and asset servicing, trading and settlement of DLT financial instruments.
- (7) To meet the objectives of the pilot regime, a new Union status as DLT market infrastructure should be created in order to ensure that the Union is able to play a leading role regarding financial instruments in tokenised form and to contribute to the development of a secondary market for such assets. The status as DLT market infrastructure should be optional and should not prevent financial market infrastructures, such as trading venues, central securities depositories (CSDs) and central counterparties (CCPs), from developing trading and post-trading services and activities for crypto-assets that qualify as financial instruments, or are based on distributed ledger technology, under existing Union financial services legislation.
- (8) DLT market infrastructures should only admit to trading or record DLT financial instruments on a distributed ledger. DLT financial instruments should be crypto-assets that qualify as financial instruments and which are issued, transferred and stored on a distributed ledger.
- (9) Union legislation on financial services is intended to be neutral as regards the use of any particular technology over another. Therefore, references to a specific type of distributed ledger technology are to be avoided. Operators of DLT market infrastructures should ensure that they are able to comply with all applicable requirements, irrespective of the technology used.
- (10) When applying this Regulation, the principles of technology neutrality, proportionality, the level playing field, and 'same activity, same risks, same rules' should be taken into account in order to ensure that market participants have the regulatory space to innovate, in order to uphold the values of transparency, fairness, stability, investor protection, accountability and market integrity, and in order to ensure the protection of privacy and personal data as guaranteed by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union.
- (11) Access to the pilot regime should not be limited to incumbents but should also be open to new entrants. An entity that is not authorised under Regulation (EU) No 909/2014 or Directive 2014/65/EU could apply for authorisation under that Regulation or under that Directive, respectively, and, simultaneously, for a specific permission under this Regulation. In such cases, the competent authority should not assess whether such an entity fulfils the requirements of Regulation (EU) No 909/2014 or Directive 2014/65/EU in respect of which an exemption has been requested under this Regulation. Such entities should only be able to operate DLT market infrastructures in accordance with this Regulation, and their authorisation should be revoked once their specific permission has expired, unless the entities submit a complete request for authorisation under Regulation (EU) No 909/2014 or under Directive 2014/65/EU.

⁽¹⁾ Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

- (12) The concept of DLT market infrastructure comprises DLT multilateral trading facilities (DLT MTF), DLT settlement systems (DLT SS) and DLT trading and settlement systems (DLT TSS). DLT market infrastructures should be able to cooperate with other market participants in order to test innovative solutions based on distributed ledger technology in different segments of the value chain for financial services.
- (13) A DLT MTF should be a multilateral trading facility that is operated by an investment firm or a market operator authorised under Directive 2014/65/EU and that has received a specific permission under this Regulation. A credit institution authorised under Directive 2013/36/EU that provides investment services or performs investment activities should only be allowed to operate a DLT MTF when authorised as an investment firm or market operator under Directive 2014/65/EU. DLT MTFs and their operators should be subject to all requirements that apply to multilateral trading facilities and their operators under Regulation (EU) No 600/2014 of the European Parliament and of the Council ⁽¹²⁾, under Directive 2014/65/EU or under any other applicable Union financial services legislation, except for requirements in respect of which an exemption has been granted by the competent authority in accordance with this Regulation.
- (14) The use of distributed ledger technology, by which all transactions are recorded on a distributed ledger, can expedite and combine trading and settlement in near real-time and could enable the combination of trading and post-trading services and activities. However, the combination of trading and post-trading activities within a single entity is not envisaged by the existing rules, irrespective of the technology used, due to policy choices related to risk specialisation and unbundling for the purposes of encouraging competition. The pilot regime should not be a precedent to justify a fundamental overhaul of the separation of trading and post-trading activities or of the landscape of financial market infrastructures. However, in view of the potential benefits of distributed ledger technology in terms of combining trading and settlement, it is justified to provide for a dedicated DLT market infrastructure in the pilot regime, namely, the DLT TSS, which combines the activities normally performed by multilateral trading facilities and securities settlement systems.
- (15) A DLT TSS should be either a DLT MTF that combines the services performed by a DLT MTF and by a DLT SS, and should be operated by an investment firm or market operator that has received a specific permission to operate a DLT TSS under this Regulation, or should be a DLT SS that combines the services performed by a DLT MTF and by a DLT SS, and should be operated by a CSD that has received a specific permission to operate a DLT TSS under this Regulation. A credit institution authorised under Directive 2013/36/EU that provides investment services or performs investment activities should only be allowed to operate a DLT TSS when authorised as an investment firm or market operator under Directive 2014/65/EU. An investment firm or market operator operating a DLT TSS should be subject to the requirements that apply to a DLT MTF, and a CSD operating a DLT TSS should be subject to the requirements that apply to a DLT SS. Since a DLT TSS would enable an investment firm or market operator also to provide settlement services, and would enable a CSD also to provide trading services, it is necessary that investment firms or market operators also comply with the requirements that apply to a DLT SS, and that CSDs comply with the requirements that apply to a DLT MTF. Since CSDs are not subject to certain authorisation and organisational requirements under Directive 2014/65/EU when providing investment services or activities in accordance with Regulation (EU) No 909/2014, it is appropriate to take a similar approach in the pilot regime both for investment firms and market operators and for CSDs operating a DLT TSS. Therefore, an investment firm or market operator operating a DLT TSS should be exempted from a limited set of authorisation and organisational requirements under Regulation (EU) No 909/2014, since the investment firm or market operator will be required to comply with the authorisation and organisational requirements under Directive 2014/65/EU. Conversely, a CSD operating a DLT TSS should be exempted from a limited set of authorisation and organisational requirements under Directive 2014/65/EU, since the CSD will be required to comply with the authorisation and organisational requirements under Regulation (EU) No 909/2014. Such exemptions should be temporary and should not apply to a DLT market infrastructure operating outside the pilot regime. ESMA should be able to assess technical standards on record-keeping and operational risks adopted pursuant to Regulation (EU) No 909/2014 with a view to ensuring that they are applied proportionately to investment firms or market operators operating a DLT TSS.
- (16) Operators of DLT TSSs should be able to request the same exemptions as those available to operators of DLT MTFs and of DLT SSs, provided that they comply with the conditions attached to the exemptions and with any compensatory measures required by the competent authorities. Considerations similar to those that apply to DLT MTFs and DLT SSs should apply to the exemptions that are available to DLT TSSs, to any conditions attached to those exemptions, and to compensatory measures.

⁽¹²⁾ Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 (OJ L 173, 12.6.2014, p. 84).

- (17) In order to provide for additional flexibility in the application of certain requirements of Regulation (EU) No 909/2014 to investment firms or market operators operating a DLT TSS while ensuring a level playing field with CSDs providing settlement services under the pilot regime, certain exemptions from the requirements of that Regulation concerning measures to prevent and address settlement fails, from requirements for participation and transparency, and from requirements to use certain communication procedures with participants and other market infrastructures, should be available to CSDs operating a DLT SS or a DLT TSS, and to investment firms or market operators operating a DLT TSS. Those exemptions should be subject to conditions attached to them, including certain minimum requirements, and any compensatory measures required by the competent authority, in order to meet the objectives of the provisions of Regulation (EU) No 909/2014 in respect of which an exemption is requested or in order to safeguard investor protection, market integrity or financial stability. The operator of a DLT TSS should demonstrate that the exemption requested is proportionate and justified by the use of distributed ledger technology.
- (18) A DLT SS should be a settlement system operated by a CSD authorised under Regulation (EU) No 909/2014 that has received a specific permission to operate a DLT SS under this Regulation. A DLT SS, and the CSD which operates it, should be subject to all relevant requirements under Regulation (EU) No 909/2014, and any other applicable Union financial services legislation, except for requirements in respect of which an exemption has been granted in accordance with this Regulation.
- (19) Where the ECB and national central banks, or other institutions run by Member States that perform similar functions, or other public bodies charged with or intervening in the management of public debt in the Union, operate a DLT SS, they should not be required to seek a specific permission from a competent authority in order to benefit from an exemption under this Regulation, since such entities are not required to report to competent authorities or to comply with their instructions and are subject to a limited set of requirements under Regulation (EU) No 909/2014.
- (20) The creation of the pilot regime should be without prejudice to the tasks and responsibilities of the ECB and the national central banks in the European System of Central Banks, set out in the Treaty on the Functioning of the European Union and in Protocol No 4 on the Statute of the European System of Central Banks and of the European Central Bank, to promote the smooth operation of payment systems and to ensure efficient and sound clearing and payment systems within the Union and with third countries.
- (21) The assignment of supervisory responsibilities provided for in this Regulation is justified by the specific characteristics and risks of the pilot regime. Therefore, the supervisory architecture of the pilot regime should not be understood as setting a precedent for any future act of Union financial services legislation.
- (22) Operators of DLT market infrastructures should be liable in the case of a loss of funds, of collateral or of a DLT financial instrument. The liability of the operator of a DLT market infrastructure should be limited to the market value of the asset lost as of the time when the loss was incurred. The operator of a DLT market infrastructure should not be liable for events that are not attributable to the operator, in particular any event that the operator demonstrates occurred independently of its operations, including problems arising as a result of an external event beyond its reasonable control.
- (23) In order to allow for innovation and experimentation in a sound regulatory environment while preserving investor protection, market integrity and financial stability, the types of financial instrument admitted to trading or recorded on a DLT market infrastructure should be limited to shares, bonds, and units in collective investment undertakings that benefit from the execution-only exemption under Directive 2014/65/EU. This Regulation should set value thresholds that could be lowered in certain situations. In particular, to avoid any risk to financial stability, the aggregate market value of DLT financial instruments admitted to trading or recorded on a DLT market infrastructure should be limited.

- (24) In order to move closer to a level playing field for financial instruments admitted to trading on traditional trading venues within the meaning of Directive 2014/65/EU and in order to ensure high levels of investor protection, market integrity and financial stability, DLT financial instruments admitted to trading on a DLT MTF or on a DLT TSS should be subject to the provisions prohibiting market abuse under Regulation (EU) No 596/2014.
- (25) At the request of an operator of a DLT MTF, the competent authorities should be allowed to grant one or several exemptions on a temporary basis, if the operator complies with the conditions attached to such exemptions and with any additional requirements set by this Regulation to address novel forms of risks raised by the use of distributed ledger technology. An operator of a DLT MTF should also comply with any compensatory measure required by the competent authority in order to meet the objectives of the provision in respect of which an exemption has been requested, or in order to safeguard investor protection, market integrity or financial stability.
- (26) At the request of an operator of a DLT MTF, the competent authorities should be allowed to grant an exemption from the obligation of intermediation under Directive 2014/65/EU. At present, traditional multilateral trading facilities are allowed to admit as members or participants only investment firms, credit institutions and other persons who have a sufficient level of trading ability and competence and who maintain adequate organisational arrangements and resources. By contrast, many platforms for trading crypto-assets offer disintermediated access and provide direct access for retail investors. Accordingly, one potential regulatory obstacle to the development of multilateral trading facilities for DLT financial instruments could be the obligation of intermediation under Directive 2014/65/EU. At the request of an operator of a DLT MTF, the competent authority should therefore be allowed to grant a temporary exemption from that obligation of intermediation in order to provide direct access for retail investors and to enable them to deal on their own account, provided that adequate safeguards regarding investor protection are in place, that such retail investors fulfil certain conditions and that the operator complies with any possible additional investor protection measures that the competent authority requires. Retail investors that have direct access to a DLT MTF as members or participants under an exemption from the obligation of intermediation should not be considered to be investment firms within the meaning of Directive 2014/65/EU solely by virtue of being members of, or participants in, a DLT MTF.
- (27) At the request of an operator of a DLT MTF, the competent authorities should also be allowed to grant an exemption from the transaction reporting requirements under Regulation (EU) No 600/2014, provided that the DLT MTF fulfils certain conditions.
- (28) In order to be eligible for an exemption under this Regulation, an operator of a DLT MTF should demonstrate that the requested exemption is proportionate and limited to the use of distributed ledger technology as described in its business plan, and that the requested exemption is limited to the DLT MTF and does not extend to any other multilateral trading facility operated by the same investment firm or market operator.
- (29) At the request of a CSD operating a DLT SS, competent authorities should be allowed to grant one or more exemptions on a temporary basis if it complies with the conditions attached to such exemptions and with any additional requirements set by this Regulation to address novel forms of risks raised by the use of distributed ledger technology. The CSD operating the DLT SS should also comply with any compensatory measure required by the competent authority in order to meet the objectives of the provision in respect of which the exemption was requested or in order to safeguard investor protection, market integrity or financial stability.
- (30) It should be allowed to exempt CSDs operating a DLT SS from certain provisions of Regulation (EU) No 909/2014 that are likely to create regulatory obstacles for the development of DLT SSs. For instance, exemptions should be possible to the extent that the rules of that Regulation applicable to CSDs and which refer to the terms 'dematerialised form', 'securities account' or 'transfer orders' do not apply to CSDs operating a DLT SS, with the exception of the requirements for CSD links which should apply *mutatis mutandis*. With respect to the term 'securities account', the exemption would cover the rules on the recording of securities, integrity of issue and segregation of accounts. Whereas CSDs operate securities settlement systems by crediting and debiting the securities accounts of their participants, double-entry or multiple-entry book keeping securities accounts might not always be feasible in a DLT SS. Therefore, an exemption should also be possible for a CSD operating a DLT SS from the rules in Regulation (EU) No 909/2014 that refer to the term 'book-entry form' where such an exemption is necessary to allow for the recording of DLT financial instruments on a distributed ledger. However, a CSD operating a DLT SS should still ensure the integrity of the DLT financial instruments issue on the distributed ledger and the segregation of the DLT financial instruments belonging to the various participants.

- (31) A CSD operating a DLT SS should always remain subject to the provisions of Regulation (EU) No 909/2014, pursuant to which a CSD that outsources services or activities to a third party remains fully responsible for discharging all of its obligations under that Regulation and is required to ensure that any outsourcing does not result in the delegation of its responsibility. Regulation (EU) No 909/2014 only permits CSDs operating a DLT SS to outsource a core service or activity after receiving authorisation from the competent authority. A CSD operating a DLT SS should therefore be able to request an exemption from that authorisation requirement where the CSD demonstrates that the requirement is incompatible with the use of distributed ledger technology as envisaged in its business plan. The delegation of tasks pertaining to the functioning of a DLT SS, or to the use of distributed ledger technology, to perform settlement, should not be considered to be outsourcing within the meaning of Regulation (EU) No 909/2014.
- (32) The obligation of intermediation through a credit institution or an investment firm in order to prevent retail investors from obtaining direct access to the settlement and delivery systems operated by a CSD could create a regulatory obstacle to the development of alternative models of settlement based on distributed ledger technology that allows direct access by retail investors. Therefore, an exemption should be allowed for CSDs operating a DLT SS in the sense that the term 'participant' in Directive 98/26/EC is deemed to include, under certain conditions, persons other than those referred to in that Directive. When seeking an exemption from the obligation of intermediation of Regulation (EU) No 909/2014, the CSD operating a DLT SS should ensure that the persons to be admitted as participants fulfil certain conditions. A CSD operating a DLT SS should ensure that its participants have a sufficient level of ability, competence, experience and knowledge of post-trading activities and the functioning of distributed ledger technology.
- (33) Entities that are eligible to participate in a CSD under Regulation (EU) No 909/2014 correspond to the entities that are eligible to participate in a securities settlement system that is designated and notified in accordance with Directive 98/26/EC, because Regulation (EU) No 909/2014 requires securities settlement systems operated by CSDs to be designated and notified under Directive 98/26/EC. Accordingly, an operator of a securities settlement system based on distributed ledger technology that requests to be exempted from the participation requirements of Regulation (EU) No 909/2014 would as a result not comply with the participation requirements of Directive 98/26/EC. Consequently, that securities settlement system cannot be designated and notified under that Directive and for that reason is not referred to as a 'DLT securities settlement system' in this Regulation but rather as a DLT SS. This Regulation should allow a CSD to operate a DLT SS that does not qualify as a securities settlement system designated under Directive 98/26/EC, and an exemption from the rules on settlement finality in Regulation (EU) No 909/2014 should be available, subject to certain compensatory measures, including specific compensatory measures to mitigate risks arising from insolvency, as insolvency protection measures under Directive 98/26/EC do not apply. However, such an exemption would not preclude a DLT SS that complies with all the requirements of Directive 98/26/EC from being designated and notified as a securities settlement system in accordance with that Directive.
- (34) Regulation (EU) No 909/2014 encourages the settlement of transactions in central bank money. Where the settlement of cash payments in central bank money is not practical and available, it should be possible for settlement to take place through the CSD's own accounts in accordance with that Regulation or through accounts opened with a credit institution ('commercial bank money'). That rule can be difficult to apply for a CSD operating a DLT SS, however, because the CSD would have to effect movements in cash accounts at the same time as the delivery of securities recorded on the distributed ledger. A temporary exemption should therefore be allowed for CSDs operating a DLT SS from the provision of that Regulation on cash settlement in order to develop innovative solutions under the pilot regime by facilitating access to commercial bank money, or the use of 'e-money tokens'. Settlement in central bank money could be considered as not practical and available if settlement in central bank money on a distributed ledger is not available.
- (35) Other than the requirements that have proven to be impractical in a distributed ledger technology environment, the requirements linked to cash settlement under Regulation (EU) No 909/2014 continue to apply outside the pilot regime. Operators of DLT market infrastructures should therefore describe in their business plans how they intend to comply with Title IV of Regulation (EU) No 909/2014 in the event that they eventually exit the pilot regime.

- (36) Regulation (EU) No 909/2014 requires that a CSD give access to another CSD, or to other market infrastructures, on a non-discriminatory and transparent basis. Giving access to a CSD operating a DLT SS can be technically more challenging, burdensome or difficult to achieve, as the interoperability of legacy systems with distributed ledger technology has not yet been tested. It should therefore also be possible to grant a DLT SS an exemption from that requirement if it demonstrates that the application of the requirement is disproportionate to the scale of the activities of the DLT SS.
- (37) Irrespective of the requirement in respect of which an exemption has been requested, a CSD operating a DLT SS should demonstrate that the exemption requested is proportionate and justified by the use of distributed ledger technology. The exemption should be limited to the DLT SS and should not cover other settlement systems operated by the same CSD.
- (38) DLT market infrastructures and their operators should be subject to additional requirements compared to traditional market infrastructures. The additional requirements are necessary to avoid risks related to the use of distributed ledger technology or the way in which the DLT market infrastructure would operate. Therefore, an operator of DLT market infrastructure should establish a clear business plan that details how the distributed ledger technology would be used and the applicable legal terms.
- (39) Operators of DLT market infrastructures should establish or document, as appropriate, rules on the functioning of the distributed ledger technology they use, including rules on access to, and admission to trading on, the distributed ledger, rules on the participation of the validating nodes and rules to address potential conflicts of interests, as well as risk management measures.
- (40) An operator of a DLT market infrastructure should be required to provide information to members, participants, issuers and clients on how it intends to perform its activities and how the use of distributed ledger technology deviates from the way services are normally provided by a traditional multilateral trading facility or by a CSD operating a securities settlement system.
- (41) DLT market infrastructures should have specific and robust IT and cyber arrangements related to the use of distributed ledger technology. Such arrangements should be proportionate to the nature, scale and complexity of the business plan of the operator of the DLT market infrastructure. Those arrangements should also ensure the continuity and continued transparency, availability, reliability and security of the services provided, including the reliability of any smart contracts that are used, irrespective of whether those smart contracts are created by the DLT market infrastructure itself or by a third party following outsourcing procedures. DLT market infrastructures should also ensure the integrity, security, confidentiality, availability and accessibility of data stored on the distributed ledger. The competent authority for a DLT market infrastructure should be allowed to require an audit to ensure that the overall IT and cyber arrangements of the DLT market infrastructure are fit for purpose. The costs of the audit should be borne by the operator of the DLT market infrastructure.
- (42) Where the business plan of an operator of a DLT market infrastructure involves the safekeeping of clients' funds, such as cash or cash equivalents, or of DLT financial instruments, or of the means of access to such DLT financial instruments, including in the form of cryptographic keys, the DLT market infrastructure should have adequate arrangements in place to safeguard those assets. Operators of DLT market infrastructures should not use clients' assets on those operators' own account, other than with the prior express written consent of their clients. DLT market infrastructures should segregate clients' funds and DLT financial instruments, and the means of access to such assets, from their own assets or from other clients' assets. The overall IT and cyber arrangements of DLT market infrastructures should ensure that clients' assets are protected against fraud, cyber-attacks and other serious operational malfunctions.
- (43) At the time when a specific permission is granted, operators of DLT market infrastructures should also have in place a credible exit strategy in case the pilot regime is discontinued, the specific permission or some of the exemptions granted are withdrawn, or the thresholds set out in this Regulation are exceeded. That strategy should include the transition or reversion of their distributed ledger technology operations to traditional market infrastructures. For that purpose, new entrants or operators of DLT TSS that do not operate a traditional market infrastructure to which they could transfer DLT financial instruments should seek to conclude arrangements with operators of traditional

market infrastructures. That is of particular importance for the recording of DLT financial instruments. Therefore, CSDs should be subject to certain requirements to put in place such arrangements. In addition, CSDs should conclude such arrangements in a non-discriminatory manner and should be able to charge a reasonable commercial fee based on actual costs.

- (44) A specific permission granted to an operator of DLT market infrastructure should broadly follow the same procedures as those for authorisation under Regulation (EU) No 909/2014 or Directive 2014/65/EU. However, when applying for a specific permission under this Regulation, the applicant should indicate the exemptions it is requesting. Before granting a specific permission to a DLT market infrastructure, the competent authority should provide ESMA with all relevant information. Where necessary, ESMA should issue a non-binding opinion on the exemptions requested or on the adequacy of the distributed ledger technology for the purposes of this Regulation. Such a non-binding opinion should not be deemed to be an opinion within the meaning of Regulation (EU) No 1095/2010. ESMA should consult the competent authorities of other Member States when preparing its opinion. With its non-binding opinion, ESMA should aim to ensure investor protection, market integrity and financial stability. In order to ensure a level-playing field and fair competition throughout the internal market, ESMA's non-binding opinion and guidelines should aim to ensure the consistency and proportionality of the exemptions granted by different competent authorities in the Union, including when evaluating the adequacy of different types of distributed ledger technology used by operators for the purposes of this Regulation.
- (45) The recording of securities, the maintenance of securities accounts and the management of settlement systems are activities that are also covered by non-harmonised provisions of national law, such as corporate and securities law. It is therefore important that operators of DLT market infrastructures comply with all applicable rules and enable their users to do so.
- (46) The competent authority that examines an application submitted by an operator of a DLT market infrastructure should have the possibility of refusing to grant a specific permission if there are reasons to believe that the DLT market infrastructure would not be able to comply with applicable provisions laid down by Union law or with provisions of national law falling outside the scope of Union law, if there are reasons to believe that the DLT market infrastructure would pose a risk to investor protection, market integrity or financial stability, or if the application is an attempt to circumvent existing requirements.
- (47) A specific permission granted by a competent authority to an operator of DLT market infrastructure should indicate the exemptions granted to that DLT market infrastructure. It should be valid throughout the Union, but only for the duration of the pilot regime. ESMA should publish on its website a list of DLT market infrastructures and a list of the exemptions granted to each of them.
- (48) Specific permissions and exemptions should be granted on a temporary basis, for a period of up to six years from the date on which the specific permission was granted, and should be valid only for the duration of the pilot regime. That six-year period should give operators of DLT market infrastructures sufficient time to adapt their business models to any modifications of the pilot regime and operate under the pilot regime in a commercially viable manner. It would also allow ESMA and the Commission to gather a useful data set on the operation of the pilot regime following the granting of a critical mass of specific permissions and related exemptions and to report thereon. And finally, it would also give time for the operators of DLT market infrastructures to take the necessary steps either to cease their operations or to transition to a new regulatory framework following the reports to be issued by ESMA and the Commission.
- (49) Without prejudice to Regulation (EU) No 909/2014 and Directive 2014/65/EU, competent authorities should have the power to withdraw a specific permission or any exemptions granted to a DLT market infrastructure where a flaw has been discovered in the underlying technology or in the services and activities provided by the operator of the DLT market infrastructure, if that flaw outweighs the benefits of the service and activities at stake, or where the operator of the DLT market infrastructure has breached any obligations attached to the permissions or exemptions granted by the competent authority, or where the operator of the DLT market infrastructure has recorded financial instruments that exceed the thresholds set out in this Regulation or that do not fulfil other conditions that apply to DLT financial instruments under this Regulation. In the course of its activity, the operator of a DLT market

infrastructure should have the possibility of requesting additional exemptions in addition to those requested at the time of the initial application. In such a case, the additional exemptions should be requested from the competent authority in the same way as those requested at the time of the initial request for permission for the DLT market infrastructure.

- (50) Since, under the pilot regime, operators of DLT market infrastructures would be able to receive temporary exemptions from certain provisions of existing Union legislation, they should cooperate closely with the competent authorities and with ESMA during the period in which their specific permission is valid. Operators of DLT market infrastructures should inform competent authorities of any material changes to their business plans or to their critical staff, of any evidence of cyber-attacks or other cyber-threats, fraud or serious malpractice, of any change in the information provided at the time of the initial application for specific permission, of any technical or operational difficulties, in particular those linked to the use of distributed ledger technology, and of any risks to investor protection, market integrity or financial stability that were not envisaged at the time when the specific permission was granted. To ensure investor protection, market integrity and financial stability, when notified of such a material change, the competent authority should be able to require the DLT market infrastructure to apply for a new specific permission or exemption, or to take any corrective measures that the competent authority deems appropriate. The operators of DLT market infrastructures should also provide any relevant information to the competent authority when requested. Competent authorities should forward the information received from operators of DLT market infrastructures and the information on corrective measures to ESMA.
- (51) Operators of DLT market infrastructures should submit regular reports to their competent authorities. ESMA should organise discussions on those reports to enable all competent authorities across the Union to gain experience from the impact of distributed ledger technology and to understand whether there are any amendments to Union financial services legislation that could be necessary to allow for the use of distributed ledger technology on a greater scale.
- (52) During the course of the pilot regime, it is important that the framework and its functioning be subject to frequent monitoring and evaluation in order to maximise information for operators of DLT market infrastructures. ESMA should publish annual reports in order to provide market participants with a better understanding of the functioning and development of the markets and to provide clarification on the application of the pilot regime. Those annual reports should include updates on the most important trends and risks. Those annual reports should be submitted to the European Parliament, to the Council and to the Commission.
- (53) Three years from the date of application of this Regulation, ESMA should present a report to the Commission containing its assessment of the pilot regime. On the basis of ESMA's report, the Commission should report to the European Parliament and to the Council. That report should assess the costs and benefits of extending the pilot regime for a further period, extending the pilot regime to other types of financial instruments, otherwise amending the pilot regime, making the pilot regime permanent by proposing appropriate amendments of Union financial services legislation, or terminating the pilot regime. It would not be desirable to have two parallel regimes for DLT-based and non-DLT-based market infrastructures. If the pilot regime is successful, it could be made permanent by amending relevant Union financial services legislation to establish a single coherent framework.
- (54) Some potential gaps have been identified in existing Union financial services legislation as regards its application to crypto-assets that qualify as financial instruments. In particular, the regulatory technical standards under Regulation (EU) No 600/2014 relating to certain data reporting requirements and pre- and post-trade transparency requirements are not well adapted to financial instruments issued by means of distributed ledger technology. Secondary markets in financial instruments issued by means of distributed ledger technology or similar technology are still nascent and therefore their features potentially differ from markets in financial instruments using traditional technology. The rules set out in those regulatory technical standards should apply to all financial instruments, regardless of the technology used. Therefore, in line with existing mandates in Regulation (EU) No 600/2014 to develop draft regulatory technical standards, ESMA should carry out a comprehensive assessment of those regulatory technical standards and propose any necessary amendment to ensure that the rules set out therein could be effectively applied to DLT financial instruments. In carrying out that assessment, ESMA should take into account the specificities of DLT financial instruments and whether they require standards to be adapted to allow for the development of those financial instruments without undermining the objectives of the rules laid down in the regulatory technical standards adopted pursuant to Regulation (EU) No 600/2014.

- (55) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, but can rather, by reason of the regulatory obstacles to the development of DLT market infrastructures for crypto-assets that qualify as financial instruments being embedded in Union financial services legislation, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (56) This Regulation is without prejudice to Directive (EU) 2019/1937 of the European Parliament and of the Council ⁽¹³⁾. At the same time, in respect of entities authorised under Directive 2014/65/EU, the mechanisms for the reporting of infringements of Regulation (EU) No 600/2014 or Directive 2014/65/EU as established under that Directive should be used. In respect of entities authorised under Regulation (EU) No 909/2014, the mechanisms for the reporting of infringements of that Regulation as established under that Regulation should be used.
- (57) The operation of DLT market infrastructures could involve the processing of personal data. Where it is necessary for the purposes of this Regulation to process personal data, that processing should be carried out in accordance with applicable Union law on the protection of personal data. This Regulation is without prejudice to Regulations (EU) 2016/679 ⁽¹⁴⁾ and (EU) 2018/1725 ⁽¹⁵⁾ of the European Parliament and of the Council. The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725, and delivered its opinion on 23 April 2021.
- (58) Regulation (EU) No 600/2014 provides for a transitional period during which non-discriminatory access to a CCP or trading venue under that Regulation does not apply to CCPs or trading venues that applied to their competent authorities to benefit from transitional arrangements in respect of exchange-traded derivatives. The period during which a CCP or a trading venue could be exempted by its competent authority in respect of exchange-traded derivatives from the rules on non-discriminatory access expired on 3 July 2020. The increased uncertainty and volatility of the markets negatively impacted the operational risks of CCPs and trading venues and, therefore, the date of application of the new open-access regime for CCPs and trading venues offering trading and clearing services in respect of exchange-traded derivatives was postponed by Article 95 of Regulation (EU) 2021/23 of the European Parliament and of the Council ⁽¹⁶⁾ by one year, until 3 July 2021. The reasons for postponing the date of application of the new open-access regime persist. Furthermore, the open-access regime could run counter to parallel policy objectives to foster trading and innovation within the Union, since it could disincentivise innovation in exchange-traded derivatives by allowing competitors, who are beneficiaries of open access, to rely on incumbents' infrastructure and investments in order to offer competing products with low upfront costs. Maintaining a system whereby derivatives are cleared and traded in a vertically integrated entity is also consistent with long-standing international trends. The date of application of the new open-access regime should therefore be postponed by two more years, until 3 July 2023.
- (59) At present, the definition of financial instrument in Directive 2014/65/EU does not explicitly include financial instruments issued by means of a class of technologies that supports the distributed recording of encrypted data, namely, distributed ledger technology. In order to ensure that such financial instruments can be traded on the market under the existing legal framework, the definition of financial instruments in Directive 2014/65/EU should be amended to include them.

⁽¹³⁾ Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).

⁽¹⁴⁾ 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).

⁽¹⁵⁾ 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).

⁽¹⁶⁾ Regulation (EU) 2021/23 of the European Parliament and of the Council of 16 December 2020 on a framework for the recovery and resolution of central counterparties and amending Regulations (EU) No 1095/2010, (EU) No 648/2012, (EU) No 600/2014, (EU) No 806/2014 and (EU) 2015/2365 and Directives 2002/47/EC, 2004/25/EC, 2007/36/EC, 2014/59/EU and (EU) 2017/1132 (OJ L 22, 22.1.2021, p. 1).

- (60) While this Regulation sets out the regulatory framework for DLT market infrastructures, including those providing settlement services, the general regulatory framework for securities settlement systems operated by CSDs is laid down in Regulation (EU) No 909/2014, which includes provisions on settlement discipline. The settlement discipline regime comprises rules for the reporting of settlement fails, the collection and distribution of cash penalties and mandatory buy-ins. Pursuant to regulatory technical standards adopted under Regulation (EU) No 909/2014, the provisions on settlement discipline apply from 1 February 2022. However, stakeholders have provided evidence that mandatory buy-ins could increase liquidity pressure and the costs of securities at risk of being bought in. Such impact could be further exacerbated in cases of market volatility. Against that background, applying the rules on mandatory buy-ins as laid down in Regulation (EU) No 909/2014 could have a negative impact on the efficiency and competitiveness of capital markets in the Union. That impact could in turn lead to wider bid-offer spreads, reduced market efficiency and reduced incentives to lend securities in the securities lending and repo markets and to settle transactions with CSDs established in the Union. The costs of applying the rules on mandatory buy-ins are, therefore, expected to outweigh the potential benefits. Taking into account that potential negative impact, Regulation (EU) No 909/2014 should be amended to allow for a different date of application for each settlement discipline measure, so that the date of application of the rules on mandatory buy-ins can be further postponed. That postponement would allow the Commission to assess, within the context of the forthcoming legislative proposal reviewing Regulation (EU) No 909/2014, how the settlement discipline framework, and in particular the rules on mandatory buy-ins, should be amended to take into account and address the aforementioned issues. Furthermore, such postponement would ensure that market participants, including those DLT market infrastructures that would be subject to the settlement discipline regime, do not incur implementation costs twice in the event that those rules are amended as a result of the review of Regulation (EU) No 909/2014.
- (61) The operation of a DLT market infrastructure should not undermine climate policies of Member States. Thus, it is important to encourage further the development of, and investment in, low-emission or zero-emission distributed ledger technologies,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down requirements in relation to DLT market infrastructures and their operators in respect of:

- (a) granting and withdrawing specific permissions to operate DLT market infrastructures in accordance with this Regulation;
- (b) granting, modifying and withdrawing exemptions related to specific permissions;
- (c) mandating, modifying and withdrawing the conditions attached to exemptions and in respect of mandating, modifying and withdrawing compensatory or corrective measures;
- (d) operating DLT market infrastructures;
- (e) supervising DLT market infrastructures; and
- (f) cooperation between operators of DLT market infrastructures, competent authorities and the European Supervisory Authority (European Securities and Markets Authority) established by Regulation (EU) No 1095/2010 (ESMA).

Article 2

Definitions

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

- (1) 'distributed ledger technology' or 'DLT' means a technology that enables the operation and use of distributed ledgers;
- (2) 'distributed ledger' means an information repository that keeps records of transactions and that is shared across, and synchronised between, a set of DLT network nodes using a consensus mechanism;

- (3) 'consensus mechanism' means the rules and procedures by which an agreement is reached, among DLT network nodes, that a transaction is validated;
- (4) 'DLT network node' means a device or process that is part of a network and that holds a complete or partial replica of records of all transactions on a distributed ledger;
- (5) 'DLT market infrastructure' means a DLT multilateral trading facility, a DLT settlement system or a DLT trading and settlement system;
- (6) 'DLT multilateral trading facility' or 'DLT MTF' means a multilateral trading facility that only admits to trading DLT financial instruments;
- (7) 'DLT settlement system' or 'DLT SS' means a settlement system that settles transactions in DLT financial instruments against payment or against delivery, irrespective of whether that settlement system has been designated and notified in accordance with Directive 98/26/EC, and that allows the initial recording of DLT financial instruments or allows the provision of safekeeping services in relation to DLT financial instruments;
- (8) 'settlement' means settlement as defined in Article 2(1), point (7), of Regulation (EU) No 909/2014;
- (9) 'settlement fail' means settlement fail as defined in Article 2(1), point (15), of Regulation (EU) No 909/2014;
- (10) 'DLT trading and settlement system' or 'DLT TSS' means a DLT MTF or DLT SS that combines services performed by a DLT MTF and a DLT SS;
- (11) 'DLT financial instrument' means a financial instrument that is issued, recorded, transferred and stored using distributed ledger technology;
- (12) 'financial instrument' means a financial instrument as defined in Article 4(1), point (15), of Directive 2014/65/EU;
- (13) 'multilateral trading facility' means a multilateral trading facility as defined in Article 4(1), point (22), of Directive 2014/65/EU;
- (14) 'central securities depository' or 'CSD' means a central securities depository as defined in Article 2(1), point (1), of Regulation (EU) No 909/2014;
- (15) 'securities settlement system' means a securities settlement system as defined in Article 2(1), point (10), of Regulation (EU) No 909/2014;
- (16) 'business day' means business day as defined in Article 2(1), point (14), of Regulation (EU) No 909/2014;
- (17) 'delivery versus payment' means delivery versus payment as defined in Article 2(1), point (27), of Regulation (EU) No 909/2014;
- (18) 'credit institution' means a credit institution as defined in Article 4(1), point (1), of Regulation (EU) No 575/2013 of the European Parliament and of the Council ⁽¹⁷⁾;
- (19) 'investment firm' means an investment firm as defined in Article 4(1), point (1), of Directive 2014/65/EU;
- (20) 'market operator' means a market operator as defined in Article 4(1), point (18), of Directive 2014/65/EU;
- (21) 'competent authority' means one or more competent authorities:
 - (a) designated in accordance with Article 67 of Directive 2014/65/EU;
 - (b) designated in accordance with Article 11 of Regulation (EU) No 909/2014; or
 - (c) otherwise designated by a Member State to oversee the application of this Regulation.

⁽¹⁷⁾ Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

*Article 3***Limitations on the financial instruments admitted to trading or recorded on DLT market infrastructure**

1. DLT financial instruments shall only be admitted to trading on a DLT market infrastructure, or be recorded on a DLT market infrastructure, if, at the moment of admission to trading or the moment of recording on a distributed ledger, the DLT financial instruments are:

- (a) shares, the issuer of which has a market capitalisation, or a tentative market capitalisation, of less than EUR 500 million;
- (b) bonds, other forms of securitised debt, including depositary receipts in respect of such securities, or money market instruments, with an issue size of less than EUR 1 billion, excluding those that embed a derivative or incorporate a structure which makes it difficult for the client to understand the risk involved; or
- (c) units in collective investment undertakings covered by Article 25(4), point (a)(iv), of Directive 2014/65/EU, the market value of the assets under management of which is less than EUR 500 million.

Corporate bonds issued by issuers whose market capitalisation did not exceed EUR 200 million at the time of their issuance shall be excluded from the calculation of the threshold referred to in the first subparagraph, point (b).

2. The aggregate market value of all the DLT financial instruments that are admitted to trading on a DLT market infrastructure or that are recorded on a DLT market infrastructure shall not exceed EUR 6 billion at the moment of admission to trading, or initial recording, of a new DLT financial instrument.

Where the admission to trading or initial recording of a new DLT financial instrument would result in the aggregate market value referred to in the first subparagraph reaching EUR 6 billion, the DLT market infrastructure shall not admit that DLT financial instrument to trading or record it.

3. Where the aggregate market value of all the DLT financial instruments that are admitted to trading on a DLT market infrastructure or that are recorded on a DLT market infrastructure has reached EUR 9 billion, the operator of the DLT market infrastructure shall activate the transition strategy referred to in Article 7(7). The operator of the DLT market infrastructure shall notify the competent authority of the activation of its transition strategy and of the timescale for the transition in the monthly report provided for in paragraph 5.

4. The operator of a DLT market infrastructure shall calculate the monthly average aggregate market value of DLT financial instruments traded or recorded on that DLT market infrastructure. That monthly average shall be calculated as the average of the daily closing prices of each DLT financial instrument, multiplied by the number of DLT financial instruments that are traded or recorded on that DLT market infrastructure with the same International Securities Identification Number (ISIN).

The operator of the DLT market infrastructure shall use that monthly average:

- (a) when assessing whether the admission to trading or recording of a new DLT financial instrument in the following month would result in the aggregate market value of DLT financial instruments reaching the threshold referred to in paragraph 2 of this Article; and
- (b) when deciding whether to activate the transition strategy referred to in Article 7(7).

5. The operator of a DLT market infrastructure shall submit monthly reports to its competent authority demonstrating that all DLT financial instruments that are admitted to trading or recorded on the DLT market infrastructure do not exceed the thresholds set out in paragraphs 2 and 3.

6. A competent authority may set lower thresholds than the values set out in paragraphs 1 and 2. If a competent authority lowers the threshold referred to in paragraph 2, the value set out in paragraph 3 shall be deemed to be commensurately lowered.

For the purposes of the first subparagraph of this paragraph, the competent authority shall consider the market size and the average capitalisation of DLT financial instruments of a given type that have been admitted to trading platforms in the Member States where the services and activities will be carried out and shall consider the risks that relate to the issuers, to the type of distributed ledger technology used and to the services and activities of the DLT market infrastructure.

7. Regulation (EU) No 596/2014 applies to DLT financial instruments admitted to trading on a DLT MTF or on a DLT TSS.

Article 4

Requirements and exemptions regarding DLT MTFs

1. A DLT MTF shall be subject to the requirements that apply to a multilateral trading facility under Regulation (EU) No 600/2014 and Directive 2014/65/EU.

The first subparagraph does not apply in respect of those requirements from which the investment firm or market operator operating the DLT MTF has been exempted under paragraphs 2 and 3 of this Article, provided that that investment firm or market operator complies with:

- (a) Article 7;
 - (b) paragraphs 2, 3 and 4 of this Article; and
 - (c) any compensatory measures that the competent authority deems appropriate in order to meet the objectives of the provisions in respect of which an exemption has been requested or in order to ensure investor protection, market integrity or financial stability.
2. In addition to the persons specified in Article 53(3) of Directive 2014/65/EU, if requested by an operator of a DLT MTF, the competent authority may permit that operator to admit natural and legal persons to deal on own account as members or participants, provided that such persons fulfil the following requirements:
- (a) they are of sufficient good repute;
 - (b) they have a sufficient level of trading ability, competence and experience, including knowledge of the functioning of distributed ledger technology;
 - (c) they are not market makers on the DLT MTF;
 - (d) they do not use a high-frequency algorithmic trading technique on the DLT MTF;
 - (e) they do not provide other persons with direct electronic access to the DLT MTF;
 - (f) they do not deal on their own account when executing client orders on the DLT market infrastructure; and
 - (g) they have given informed consent to trading on the DLT MTF as members or participants and have been informed by the DLT MTF of the potential risks of using its systems to trade DLT financial instruments.

Where the competent authority grants the exemption referred to in the first subparagraph of this paragraph, it may require additional measures for the protection of natural persons admitted to the DLT MTF as members or participants. Such measures shall be proportionate to the risk profile of those members or participants.

3. At the request of an operator of a DLT MTF, the competent authority may exempt that operator or its members or participants from Article 26 of Regulation (EU) No 600/2014.

Where the competent authority grants an exemption as referred to in the first subparagraph of this paragraph, the DLT MTF shall keep records of all transactions executed through its systems. Those records shall contain all the details specified in Article 26(3) of Regulation (EU) No 600/2014 that are relevant, having regard to the system used by the DLT MTF and the member or participant executing the transaction. The DLT MTF shall also ensure that the competent authorities entitled to receive the data directly from the multilateral trading facility in accordance with Article 26 of that Regulation have direct and immediate access to those details. In order to access those records, such competent authority shall be admitted to the DLT MTF as a regulatory observer participant.

The competent authority shall make available any information it has accessed in accordance with this Article to ESMA without undue delay.

4. Where an operator of a DLT MTF requests an exemption under paragraph 2 or 3, it shall demonstrate that the exemption requested is:

- (a) proportionate to, and justified by, the use of distributed ledger technology; and
- (b) limited to the DLT MTF and does not extend to any other multilateral trading facility operated by that operator.

5. Paragraphs 2, 3 and 4 of this Article apply, *mutatis mutandis*, to a CSD operating a DLT TSS in accordance with Article 6(2).

6. ESMA shall prepare guidelines on the compensatory measures referred to in paragraph 1, second subparagraph, point (c).

Article 5

Requirements and exemptions regarding DLT SSs

1. A CSD operating a DLT SS shall be subject to the requirements that apply to a CSD operating a securities settlement system under Regulation (EU) No 909/2014.

The first subparagraph does not apply in respect of those requirements from which the CSD operating the DLT SS has been exempted under paragraphs 2 to 9 of this Article, provided that that CSD complies with:

- (a) Article 7;
- (b) paragraphs 2 to 10 of this Article; and
- (c) any compensatory measures that the competent authority deems appropriate in order to meet the objectives of the provisions in respect of which an exemption has been requested or in order to ensure investor protection, market integrity or financial stability.

2. At the request of a CSD operating a DLT SS, the competent authority may exempt that CSD from Article 2(1), points (4), (9) or (28), or Article 3, 37 or 38 of Regulation (EU) No 909/2014, provided that that CSD:

- (a) demonstrates that the use of a 'securities account' as defined in Article 2(1), point (28), of that Regulation or the use of the book-entry form as provided for in Article 3 of that Regulation is incompatible with the use of the particular distributed ledger technology;
- (b) proposes compensatory measures to meet the objectives of the provisions in respect of which an exemption has been requested, and ensures at a minimum that:
 - (i) the DLT financial instruments are recorded on the distributed ledger;
 - (ii) the number of DLT financial instruments in an issue or in part of an issue recorded by the CSD operating the DLT SS is equal to the total number of DLT financial instruments making up such issue or part of an issue that are recorded on the distributed ledger at any given time;
 - (iii) it keeps records that enable the CSD operating the DLT SS at any given time to segregate the DLT financial instruments of a member, participant, issuer or client from those of any other member, participant, issuer or client without delay; and
 - (iv) it does not allow securities overdrafts, debit balances or the improper creation or deletion of securities.

3. At the request of a CSD operating DLT SS, the competent authority may exempt that CSD from Article 6 or 7 of Regulation (EU) No 909/2014 provided that that CSD ensures, at a minimum, by means of robust procedures and arrangements, that the DLT SS:

- (a) enables clear, accurate and timely confirmation of the details of transactions in DLT financial instruments, including any payments made in respect of DLT financial instruments, as well as the discharge of any collateral in respect of those instruments or calls for collateral in respect of DLT financial instruments; and

(b) either prevents settlement fails or addresses settlement fails if it is not possible to prevent them.

4. At the request of a CSD operating a DLT SS, the competent authority may exempt that CSD from Article 19 of Regulation (EU) No 909/2014 in relation only to the outsourcing of a core service to a third party, provided that the application of that Article is incompatible with the use of distributed ledger technology as envisaged by the DLT SS operated by that CSD.

5. At the request of a CSD operating a DLT SS, the competent authority may permit that CSD to admit natural and legal persons in addition to those listed in Article 2, point (f), of Directive 98/26/EC as participants in the DLT SS, provided that such persons:

- (a) are of sufficient good repute;
- (b) have a sufficient level of ability, competence, experience and knowledge in relation to settlement, the functioning of distributed ledger technology, and risk assessment; and
- (c) have given informed consent to be included in the pilot regime provided for in this Regulation and are adequately informed of its experimental nature and the potential risks associated with it.

6. At the request of a CSD operating a DLT SS, the competent authority may exempt that CSD from Article 33, 34 or 35 of Regulation (EU) No 909/2014, provided that that CSD proposes compensatory measures to meet the objectives of those Articles and, at a minimum, ensures that:

- (a) the DLT SS publicly discloses criteria for participation that allow fair and open access for all persons that intend to become participants, and that those criteria are transparent, objective, and non-discriminatory; and
- (b) the DLT SS publicly discloses prices and fees associated with the settlement services that it provides.

7. At the request of a CSD operating a DLT SS, the competent authority may exempt that CSD from Article 39 of Regulation (EU) No 909/2014, provided that that CSD proposes compensatory measures to meet the objectives of that Article, and ensures at a minimum, by means of robust procedures and arrangements, that:

- (a) the DLT SS settles transactions in DLT financial instruments at close to real time or intraday and in any case no later than on the second business day after the conclusion of the trade;
- (b) the DLT SS publicly discloses the rules governing the settlement system; and
- (c) the DLT SS mitigates any risk arising from the non-designation of the DLT SS as a system for the purposes of Directive 98/26/EC, in particular with regard to insolvency proceedings.

For the purposes of operating a DLT SS, the definition of a CSD in Regulation (EU) No 909/2014 as a legal person who operates a securities settlement system shall not result in Member States being required to designate and notify a DLT SS as a securities settlement system under Directive 98/26/EC. However, Member States shall not be precluded from designating and notifying a DLT SS as a securities settlement system under Directive 98/26/EC where the DLT SS fulfils the requirements of that Directive.

Where a DLT SS is not designated and notified as a securities settlement system under Directive 98/26/EC, the CSD operating that DLT SS shall propose compensatory measures to mitigate risks arising from insolvency.

8. At the request of a CSD operating a DLT SS, the competent authority may exempt that CSD from Article 40 of Regulation (EU) No 909/2014, provided that that CSD settles on the basis of delivery versus payment.

The settlement of payments shall be carried out through central bank money, including in tokenised form, where practical and available or, where not practical and available, through the account of the CSD in accordance with Title IV of Regulation (EU) No 909/2014 or through commercial bank money, including in tokenised form, in accordance with that Title, or using 'e-money tokens'.

By way of derogation from the second subparagraph of this paragraph, Title IV of Regulation (EU) No 909/2014 does not apply to a credit institution when it provides the settlement of payments using commercial bank money to a DLT market infrastructure that records DLT financial instruments whose aggregate market value, at the time of the initial recording of a new DLT financial instrument, does not exceed EUR 6 billion, as calculated in accordance with Article 3(4) of this Regulation.

Where the settlement occurs using commercial bank money provided by a credit institution to which Title IV of Regulation (EU) No 909/2014 does not apply by virtue of the third subparagraph of this paragraph, or where the settlement of payments occurs using 'e-money tokens', the CSD operating the DLT SS shall identify, measure, monitor, manage, and minimise any risks arising from the use of such means.

Services related to 'e-money tokens' that are equivalent to the services listed in Section C, points (b) and (c), of the Annex to Regulation (EU) No 909/2014 shall be provided by the CSD operating the DLT SS in accordance with Title IV of Regulation (EU) No 909/2014 or by a credit institution.

9. At the request of a CSD operating a DLT SS, the competent authority may exempt that CSD from Article 50, 51 or 53 of Regulation (EU) No 909/2014, provided that that CSD demonstrates that the use of distributed ledger technology is incompatible with legacy systems of other CSDs or other market infrastructures or that granting access to another CSD or access to another market infrastructure using legacy systems would trigger disproportionate costs, given the scale of the activities of the DLT SS.

Where a CSD operating a DLT SS has been exempted in accordance with the first subparagraph of this paragraph, it shall give other operators of DLT SSs or other operators of DLT TSSs access to its DLT SS. The CSD operating the DLT SS shall inform the competent authority of its intention to give such access. The competent authority may prohibit such access to the extent that such access would be detrimental to the stability of the Union financial system, or the financial system of the Member State concerned.

10. Where a CSD operating a DLT SS requests an exemption under paragraphs 2 to 9, it shall demonstrate that the exemption requested is:

- (a) proportionate to, and justified by, the use of distributed ledger technology; and
- (b) limited to the DLT SS and does not extend to a securities settlement system that is operated by the same CSD.

11. Paragraphs 2 to 10 of this Article apply, *mutatis mutandis*, to an investment firm or market operator operating a DLT TSS in accordance with Article 6(1).

12. ESMA shall prepare guidelines on the compensatory measures referred to in paragraph 1, second subparagraph, point (c), of this Article.

Article 6

Requirements and exemptions regarding DLT TSSs

1. An investment firm or market operator operating a DLT TSS shall be subject to:

- (a) the requirements that apply to a multilateral trading facility under Regulation (EU) No 600/2014 and Directive 2014/65/EU; and
- (b) *mutatis mutandis*, the requirements that apply to a CSD under Regulation (EU) No 909/2014, with the exception of Articles 9, 16, 17, 18, 20, 26, 27, 28, 31, 42, 43, 44, 46 and 47 of that Regulation.

The first subparagraph does not apply in respect of those requirements from which the investment firm or market operator operating the DLT TSS has been exempted under Article 4(2) and (3) and Article 5(2) to (9), provided that that investment firm or market operator complies with:

- (a) Article 7;
- (b) Article 4(2), (3) and (4) and Article 5(2) to (10); and

- (c) any compensatory measures that the competent authority deems appropriate in order to meet the objectives of the provisions in respect of which an exemption has been requested, or in order to ensure investor protection, market integrity or financial stability.

2. A CSD operating a DLT TSS shall be subject to:

- (a) the requirements that apply to a CSD under Regulation (EU) No 909/2014; and
- (b) *mutatis mutandis*, the requirements that apply to a multilateral trading facility under Regulation (EU) No 600/2014 and Directive 2014/65/EU, with the exception of Articles 5 to 13 of that Directive.

The first subparagraph does not apply in respect of those requirements from which the CSD operating the DLT TSS has been exempted under Article 4(2) and (3) and Article 5(2) to (9), provided that that CSD complies with:

- (a) Article 7;
- (b) Article 4(2), (3) and (4) and Article 5(2) to (10); and
- (c) any compensatory measures that the competent authority deems appropriate in order to meet the objectives of the provisions in respect of which an exemption has been requested or in order to ensure investor protection, market integrity or financial stability.

Article 7

Additional requirements for DLT market infrastructures

1. Operators of DLT market infrastructures shall establish clear and detailed business plans describing how they intend to carry out their services and activities, which shall include a description of their critical staff, the technical aspects and use of the distributed ledger technology, and the information required under paragraph 3.

Operators of DLT market infrastructures shall also make publicly available up-to-date, clear and detailed written documentation that defines the rules under which the DLT market infrastructures and their operators are to operate, including the legal terms defining the rights, obligations, responsibilities and liabilities of operators of DLT market infrastructures, as well as those of the members, participants, issuers and clients using their DLT market infrastructure. Such legal terms shall specify the governing law, any pre-litigation dispute settlement mechanisms, any insolvency protection measures under Directive 98/26/EC and the jurisdictions in which legal action may be brought. Operators of DLT market infrastructures may make their written documentation available by electronic means.

2. Operators of DLT market infrastructures shall establish or document, as appropriate, rules on the functioning of the distributed ledger technology they use, including rules on accessing the distributed ledger, on the participation of the validating nodes, on addressing potential conflicts of interests, and on risk management including any mitigation measures to ensure investor protection, market integrity and financial stability.

3. Operators of DLT market infrastructures shall provide their members, participants, issuers and clients with clear and unambiguous information on their website regarding how the operators carry out their functions, services and activities and how their performance of those functions, services and activities deviates from those performed by a multilateral trading facility or securities settlement system that is not based on distributed ledger technology. That information shall include the type of distributed ledger technology used.

4. Operators of DLT market infrastructures shall ensure that the overall IT and cyber arrangements related to the use of their distributed ledger technology are proportionate to the nature, scale and complexity of their businesses. Those arrangements shall ensure the continuity and continued transparency, availability, reliability and security of their services and activities, including the reliability of smart contracts used on the DLT market infrastructure. Those arrangements shall also ensure the integrity, security and confidentiality of any data stored by those operators, and shall ensure that those data are available and accessible.

Operators of DLT market infrastructures shall have in place specific operational risk management procedures for the risks posed by the use of distributed ledger technology and crypto-assets and for how to address those risks if they materialise.

To assess the reliability of the overall IT and cyber arrangements of a DLT market infrastructure, the competent authority may require an audit of those arrangements. If the competent authority requires an audit, it shall appoint an independent auditor to carry it out. The DLT market infrastructure shall bear the costs of the audit.

5. Where an operator of a DLT market infrastructure ensures the safekeeping of members', participants', issuers' or clients' funds, collateral or DLT financial instruments and ensures the means of access to such assets, including in the form of cryptographic keys, that operator shall have adequate arrangements in place to prevent the use of those assets on the operator's own account without the prior express written consent of the member, participant, issuer, or client concerned, which may be made through electronic means.

Operators of DLT market infrastructure shall maintain safe, accurate, reliable and retrievable records of the funds, collateral and DLT financial instruments held by their DLT market infrastructure for their members, participants, issuers or clients, as well as of the means of access to those funds, collateral and DLT financial instruments.

Operators of DLT market infrastructure shall segregate the funds, collateral and DLT financial instruments of the members, participants, issuers or clients using the DLT market infrastructure, and the means of access to such assets, from those of the operator as well as from those of other members, participants, issuers and clients.

The overall IT and cyber arrangements referred to in paragraph 4 shall ensure that those funds, collateral and DLT financial instruments held by a DLT market infrastructure for its members, participants, issuers or clients, as well as the means of access to them, are protected from the risks of unauthorised access, hacking, degradation, loss, cyber-attack, theft, fraud, negligence and other serious operational malfunctions.

6. In the event of a loss of funds, a loss of collateral or a loss of a DLT financial instrument, the operator of a DLT market infrastructure that lost the funds, collateral or DLT financial instrument shall be liable for the loss, up to the market value of the asset lost. The operator of the DLT market infrastructure shall not be liable for the loss where it proves that the loss arose as a result of an external event beyond its reasonable control, the consequences of which were unavoidable despite all reasonable efforts to the contrary.

Operators of DLT market infrastructure shall establish transparent and adequate arrangements to ensure investor protection, and shall establish mechanisms for handling client complaints and procedures for compensation or redress in cases of investor loss as a result of any of the circumstances referred to in the first subparagraph of this paragraph or as a result of the cessation of the business due to any of the circumstances referred to in Articles 8(13), 9(11) and 10(10).

A competent authority may decide, on a case-by-case basis, to require additional prudential safeguards from the operator of a DLT market infrastructure in the form of own funds or an insurance policy if the competent authority determines that potential liabilities for damages to clients of the operator of the DLT market infrastructure as a result of any of the circumstances referred to in the first subparagraph of this paragraph are not adequately covered by the prudential requirements provided for in Regulation (EU) No 909/2014, Regulation (EU) 2019/2033 of the European Parliament and of the Council ⁽¹⁸⁾, Directive 2014/65/EU or Directive (EU) 2019/2034 of the European Parliament and of the Council ⁽¹⁹⁾, in order to ensure investor protection.

7. An operator of a DLT market infrastructure shall establish and make publicly available a clear and detailed strategy for reducing the activity of a particular DLT market infrastructure or for transitioning out of, or ceasing to operate, a particular DLT market infrastructure ('transition strategy'), including the transition or reversion of its distributed ledger technology operations to traditional market infrastructures, in the event:

(a) that the threshold referred to in Article 3(3) has been exceeded;

⁽¹⁸⁾ Regulation (EU) 2019/2033 of the European Parliament and of the Council of 27 November 2019 on the prudential requirements of investment firms and amending Regulations (EU) No 1093/2010, (EU) No 575/2013, (EU) No 600/2014 and (EU) No 806/2014 (OJ L 314, 5.12.2019, p. 1).

⁽¹⁹⁾ Directive (EU) 2019/2034 of the European Parliament and of the Council of 27 November 2019 on the prudential supervision of investment firms and amending Directives 2002/87/EC, 2009/65/EC, 2011/61/EU, 2013/36/EU, 2014/59/EU and 2014/65/EU (OJ L 314, 5.12.2019, p. 64).

- (b) that a specific permission or exemption granted under this Regulation is to be withdrawn or otherwise discontinued, including where the specific permission or exemption is discontinued as a consequence of the events envisaged under Article 14(2); or
- (c) of any voluntary or involuntary cessation of the business of the DLT market infrastructure.

The transition strategy shall be ready to be deployed in a timely manner.

The transition strategy shall set out how members, participants, issuers and clients are to be treated in the event of a withdrawal or discontinuation of a specific permission or the cessation of the business as referred to in the first subparagraph of this paragraph. The transition strategy shall set out how clients, in particular retail investors, are to be protected from any disproportionate impact from the withdrawal or discontinuation of a specific permission or the cessation of the business. The transition strategy shall be updated on an ongoing basis subject to the prior approval of the competent authority.

The transition strategy shall specify what is to be done in the event that the threshold referred to in Article 3(3) is exceeded.

8. Investment firms or market operators that are only permitted to operate a DLT MTF under Article 8(2) of this Regulation and that do not indicate in their transition strategies that they intend to obtain an authorisation to operate a multilateral trading facility under Directive 2014/65/EU, as well as CSDs operating a DLT TSS, shall use best efforts to conclude arrangements with investment firms or market operators operating a multilateral trading facility under Directive 2014/65/EU to take over their operations, and shall specify those arrangements in their transition strategies.

9. CSDs operating a DLT SS that are only permitted to operate a DLT SS under Article 9(2) of this Regulation and that do not indicate in their transition strategies that they intend to obtain an authorisation to operate a securities settlement system under Regulation (EU) No 909/2014, and investment firms or market operators operating a DLT TSS, shall use best efforts to conclude arrangements with CSDs operating a securities settlement system to take over their operations, and shall specify those arrangements in their transition strategies.

CSDs operating a securities settlement system that receive a request to conclude the arrangements referred to in the first subparagraph of this paragraph shall respond within three months of the date of receipt of the request. The CSD operating the securities settlement system shall conclude the arrangements in a non-discriminatory manner and may charge a reasonable commercial fee based on actual costs. It shall deny such a request only where it considers that the arrangements would affect the smooth and orderly functioning of the financial markets or would pose a systemic risk. It shall not deny a request on the grounds of loss of market share. If it denies a request, it shall inform the operator of the DLT market infrastructure that made the request of its reasons in writing.

10. The arrangements referred to in paragraphs 8 and 9 shall be in place no later than five years from the date of granting of the specific permission, or shall be in place at an earlier date if required by the competent authority in order to address any risk of early termination of the specific permission.

Article 8

Specific permission to operate DLT MTF

1. A legal person who is authorised as an investment firm, or authorised to operate a regulated market, under Directive 2014/65/EU may apply for a specific permission to operate a DLT MTF under this Regulation.

2. Where a legal person applies for authorisation as an investment firm or for authorisation to operate a regulated market under Directive 2014/65/EU and, simultaneously, applies for a specific permission under this Article, for the sole purpose of operating a DLT MTF, the competent authority shall not assess whether the applicant fulfils the requirements of Directive 2014/65/EU in respect of which the applicant has requested an exemption in accordance with Article 4 of this Regulation.

3. Where, as referred to in paragraph 2 of this Article, a legal person simultaneously applies for authorisation as an investment firm, or for authorisation to operate a regulated market, and for a specific permission, it shall submit in its application the information required under Article 7 of Directive 2014/65/EU, except for information that would be necessary to demonstrate compliance with the requirements in respect of which the applicant has requested an exemption in accordance with Article 4 of this Regulation.

4. An application for a specific permission to operate a DLT MTF under this Regulation shall contain the following information:

- (a) the applicant's business plan, the rules of the DLT MTF and any legal terms as referred to in Article 7(1), as well as information regarding the functioning, services and activities of the DLT MTF as referred to in Article 7(3);
- (b) a description of the functioning of the distributed ledger technology used, as referred to in Article 7(2);
- (c) a description of the applicant's overall IT and cyber arrangements as referred to in Article 7(4);
- (d) evidence that the applicant has in place sufficient prudential safeguards to meet its liabilities and to compensate its clients, as referred to in Article 7(6), third subparagraph;
- (e) where applicable, a description of the safekeeping arrangements for clients' DLT financial instruments as referred to in Article 7(5);
- (f) a description of the arrangements for ensuring investor protection and a description of the mechanisms for handling client complaints and redress, as referred to in Article 7(6), second subparagraph;
- (g) the applicant's transition strategy; and
- (h) the exemptions that the applicant is requesting under Article 4, the justification for each exemption requested and any compensatory measures proposed and the means by which it intends to comply with the conditions attached to those exemptions.

5. By 23 March 2023, ESMA shall develop guidelines to establish standard forms, formats and templates for the purposes of paragraph 4.

6. Within 30 working days of the date of receipt of an application for a specific permission to operate a DLT MTF, the competent authority shall assess whether the application is complete. If the application is not complete, the competent authority shall set a time limit by which the applicant is to provide the missing or any additional information. The competent authority shall inform the applicant when the competent authority considers the application to be complete.

As soon as the competent authority considers the application to be complete, it shall send a copy of that application to ESMA.

7. Where necessary to promote the consistency and proportionality of exemptions, or where necessary to ensure investor protection, market integrity and financial stability, ESMA shall provide the competent authority with a non-binding opinion on the exemptions requested or on the adequacy of the type of distributed ledger technology used for the purposes of this Regulation, within 30 calendar days of receiving the copy of that application.

Before issuing a non-binding opinion, ESMA shall consult the competent authorities of the other Member States and shall take the utmost account of their views when issuing its opinion.

Where ESMA issues a non-binding opinion, the competent authority shall give that opinion due consideration and shall provide ESMA with a statement regarding any significant deviations from that opinion if ESMA so requests. ESMA's opinion and the competent authority's statement shall not be made public.

8. By 24 March 2025, ESMA shall develop guidelines to promote the consistency and proportionality of:

- (a) exemptions granted to operators of DLT MTFs throughout the Union, including in the context of evaluating the adequacy of different types of distributed ledger technology used by operators of DLT MTFs for the purposes of this Regulation; and
- (b) the exercise of the option provided for in Article 3(6).

Those guidelines shall ensure investor protection, market integrity and financial stability.

ESMA shall periodically update those guidelines.

9. Within 90 working days of the date of receipt of a complete application for a specific permission to operate a DLT MTF, the competent authority shall carry out an assessment of the application and decide whether to grant the specific permission. Where an applicant applies simultaneously for authorisation under Directive 2014/65/EU and for a specific permission under this Regulation, the assessment period may be extended for a further period up to that specified in Article 7(3) of Directive 2014/65/EU.

10. Without prejudice to Articles 7 and 44 of Directive 2014/65/EU, the competent authority shall refuse to grant a specific permission to operate a DLT MTF if there are grounds for believing that:

- (a) there are significant risks to investor protection, market integrity or financial stability that are not properly addressed and mitigated by the applicant;
- (b) the specific permission to operate a DLT MTF and the exemptions requested are being sought for the purpose of circumventing legal or regulatory requirements; or
- (c) the operator of the DLT MTF will not be able to comply, or will not allow its users to comply, with applicable provisions of Union law or provisions of national law falling outside the scope of Union law.

11. A specific permission shall be valid throughout the Union for a period of up to six years from the date of issuance. The specific permission shall specify the exemptions that are granted in accordance with Article 4, any compensatory measures and any lower thresholds set by the competent authority in accordance with Article 3(6).

The competent authority shall inform ESMA of the grant, refusal or withdrawal of a specific permission under this Article without delay, including any information specified under the first subparagraph of this paragraph.

ESMA shall publish on its website:

- (a) the list of DLT MTFs, the start and end dates of their specific permissions, the list of exemptions granted to each of them, and any lower thresholds set by competent authorities for each of them; and
- (b) the total number of requests for exemptions that have been made under Article 4, indicating the number and types of exemptions granted or refused, together with the justifications for any refusals.

The information referred to in the third subparagraph, point (b), shall be published on an anonymous basis.

12. Without prejudice to Articles 8 and 44 of Directive 2014/65/EU, the competent authority shall withdraw a specific permission or any related exemptions where:

- (a) a flaw has been discovered in the functioning of the distributed ledger technology used, or in the services and activities provided by the operator of the DLT MTF, that poses a risk to investor protection, market integrity or financial stability, and the risk outweighs the benefits of the services and activities under experimentation;
- (b) the operator of the DLT MTF has breached the conditions attached to the exemptions;
- (c) the operator of the DLT MTF has admitted to trading financial instruments that do not fulfil the conditions set out in Article 3(1);
- (d) the operator of the DLT MTF has exceeded the threshold referred to in Article 3(2);
- (e) the operator of the DLT MTF has exceeded the threshold referred to in Article 3(3) and has not activated the transition strategy; or
- (f) the operator of the DLT MTF obtained the specific permission or related exemptions on the basis of misleading information or a material omission.

13. Where an operator of a DLT MTF intends to introduce a material change to the functioning of the distributed ledger technology used, or to the services or activities of that operator, and that material change requires a new specific permission, a new exemption, or the modification of one or more of the operator's existing exemptions or of any conditions attached to an exemption, the operator of the DLT MTF shall request a new specific permission, exemption or modification.

Where an operator of a DLT MTF requests a new specific permission, exemption or modification, the procedure set out in Article 4 shall apply. That request shall be processed by the competent authority in accordance with this Article.

Article 9

Specific permission to operate a DLT SS

1. A legal person who is authorised as a CSD under Regulation (EU) No 909/2014 may apply for a specific permission to operate a DLT SS under this Regulation.

2. Where a legal person applies for authorisation as a CSD under Regulation (EU) No 909/2014 and simultaneously applies for a specific permission under this Article, for the sole purpose of operating a DLT SS, the competent authority shall not assess whether the applicant fulfils those requirements of Regulation (EU) No 909/2014 in respect of which the applicant has requested an exemption in accordance with Article 5 of this Regulation.

3. Where, as referred to in paragraph 2 of this Article, a legal person simultaneously applies for authorisation as a CSD and for a specific permission, it shall submit in its application the information referred to in Article 17(2) of Regulation (EU) No 909/2014, except for information that would be necessary to demonstrate compliance with the requirements in respect of which the applicant has requested an exemption in accordance with Article 5 of this Regulation.

4. An application for a specific permission to operate a DLT SS under this Regulation shall contain the following information:

- (a) the applicant's business plan, the rules of the DLT SS and any legal terms as referred to in Article 7(1), as well as information regarding the functioning, services and activities of the DLT SS as referred to in Article 7(3);
- (b) a description of the functioning of the distributed ledger technology used, as referred to in Article 7(2);
- (c) a description of the applicant's overall IT and cyber arrangements as referred to in Article 7(4);
- (d) evidence that the applicant has in place sufficient prudential safeguards to meet its liabilities and to compensate its clients, as referred to in Article 7(6), third subparagraph;
- (e) where applicable, a description of the safekeeping arrangements for clients' DLT financial instruments as referred to in Article 7(5);
- (f) a description of the arrangements for ensuring investor protection and a description of the mechanisms for handling client complaints and redress, as referred to in Article 7(6), second subparagraph;
- (g) the applicant's transition strategy; and
- (h) the exemptions that the applicant is requesting under Article 5, the justification for each exemption requested and any compensatory measures proposed and the means by which it intends to comply with the conditions attached to those exemptions.

5. By 23 March 2023, ESMA shall develop guidelines to establish standard forms, formats and templates for the purposes of paragraph 4.

6. Within 30 working days of the date of receipt of an application for a specific permission to operate a DLT SS, the competent authority shall assess whether the application is complete. If the application is not complete, the competent authority shall set a time limit by which the applicant is to provide the missing or any additional information. The competent authority shall inform the applicant when the competent authority considers the application to be complete.

As soon as the competent authority considers the application to be complete, it shall send a copy of that application to:

- (a) ESMA; and
- (b) the relevant authorities specified in Article 12 of Regulation (EU) No 909/2014.

7. Where necessary to promote the consistency and proportionality of exemptions, or where necessary to ensure investor protection, market integrity and financial stability, ESMA shall provide the competent authority with a non-binding opinion on the exemptions requested or on the adequacy of the type of distributed ledger technology used for the purposes of this Regulation, within 30 calendar days of receiving a copy of that application.

Before issuing a non-binding opinion, ESMA shall consult the competent authorities of the other Member States and shall take the utmost account of their views when issuing its opinion.

Where ESMA issues a non-binding opinion, the competent authority shall give that opinion due consideration and shall provide ESMA with a statement regarding any significant deviations from that opinion if ESMA so requests. ESMA's opinion and the competent authority's statement shall not be made public.

The relevant authorities specified in Article 12 of Regulation (EU) No 909/2014 shall provide the competent authority with a non-binding opinion on the features of the DLT SS operated by the applicant within 30 calendar days of receiving a copy of that application.

8. By 24 March 2025, ESMA shall develop guidelines to promote the consistency and proportionality of:

- (a) exemptions granted to CSDs operating DLT SSs throughout the Union, including in the context of evaluating the adequacy of different types of distributed ledger technology used by market operators for the purposes of this Regulation; and
- (b) the exercise of the option provided for in Article 3(6).

Those guidelines shall ensure investor protection, market integrity and financial stability.

ESMA shall periodically update those guidelines.

9. Within 90 working days of the date of receipt of a complete application for a specific permission to operate a DLT SS, the competent authority shall carry out an assessment of the application and decide whether to grant the specific permission. Where the applicant applies simultaneously for authorisation as a CSD under Regulation (EU) No 909/2014 and for a specific permission under this Regulation, the assessment period may be extended for a further period up to that specified in Article 17(8) of Regulation (EU) No 909/2014.

10. Without prejudice to Article 17 of Regulation (EU) No 909/2014, the competent authority shall refuse to grant a specific permission to operate a DLT SS if there are grounds for believing that:

- (a) there are significant risks to investor protection, market integrity or financial stability that are not properly addressed and mitigated by the applicant;
- (b) the specific permission to operate a DLT SS and the exemptions requested are being sought for the purpose of circumventing legal or regulatory requirements; or
- (c) the CSD will not be able to comply, or will not allow its users to comply, with applicable provisions of Union law or provisions of national law falling outside the scope of Union law.

11. A specific permission shall be valid throughout the Union for a period of up to six years from the date of issuance. The specific permission shall specify the exemptions that are granted in accordance with Article 5, any compensatory measures and any lower thresholds set by the competent authority in accordance with Article 3(6).

The competent authority shall inform ESMA and the relevant authorities specified in paragraph 7 of this Article of the grant, refusal or withdrawal of a specific permission under this Article without delay, including any information specified under the first subparagraph of this paragraph.

ESMA shall publish on its website:

- (a) the list of DLT SSs, the start and end dates of their specific permissions, the list of exemptions granted to each of them, and any lower thresholds set by the competent authorities for each of them; and
- (b) the total number of requests for exemptions that have been made under Article 5, indicating the number and types of exemptions granted or refused, together with the justifications for any refusals.

The information referred to in the third subparagraph, point (b), shall be published on an anonymous basis.

12. Without prejudice to Article 20 of Regulation (EU) No 909/2014, the competent authority shall withdraw a specific permission or any related exemptions where:

- (a) a flaw has been discovered in the functioning of the distributed ledger technology used, or in the services and activities provided by the CSD operating the DLT SS, that poses a risk to investor protection, market integrity or financial stability, and the risk outweighs the benefits of the services and activities under experimentation;
- (b) the CSD operating the DLT SS has breached the conditions attached to the exemptions;
- (c) the CSD operating the DLT SS has recorded financial instruments that do not fulfil the conditions set out in Article 3(1);
- (d) the CSD operating the DLT SS has exceeded the threshold referred to in Article 3(2);
- (e) the CSD operating the DLT SS has exceeded the threshold referred to in Article 3(3) and has not activated the transition strategy; or
- (f) the CSD operating the DLT SS obtained the specific permission or related exemptions on the basis of misleading information or a material omission.

13. Where a CSD operating a DLT SS intends to introduce a material change to the functioning of the distributed ledger technology used, or to the services or activities of that CSD, and that material change requires a new specific permission, a new exemption, or the modification of one or more of that CSD's existing exemptions or of any conditions attached to an exemption, the CSD operating the DLT SS shall request a new specific permission, exemption or modification.

Where a CSD operating a DLT SS requests a new specific permission, exemption or modification, the procedure set out in Article 5 shall apply. That request shall be processed by the competent authority in accordance with this Article.

Article 10

Specific permission to operate DLT TSS

1. A legal person who is authorised as an investment firm, or authorised to operate a regulated market, under Directive 2014/65/EU, or authorised as a CSD under Regulation (EU) No 909/2014, may apply for a specific permission to operate a DLT TSS under this Regulation.

2. Where a legal person applies for authorisation as an investment firm or for authorisation to operate a regulated market under Directive 2014/65/EU, or as a CSD under Regulation (EU) No 909/2014, and, simultaneously, applies for a specific permission under this Article, for the sole purpose of operating a DLT TSS, the competent authority shall not assess whether the applicant fulfils those requirements of Directive 2014/65/EU or those of Regulation (EU) No 909/2014 in respect of which the applicant has requested an exemption in accordance with Article 6 of this Regulation.

3. Where, as referred to in paragraph 2 of this Article, a legal person simultaneously applies for authorisation as an investment firm or for authorisation to operate a regulated market, or for authorisation as a CSD, and for a specific permission, it shall submit in its application the information required under Article 7 of Directive 2014/65/EU or Article 17 of Regulation (EU) No 909/2014 respectively, except for information that would be necessary to demonstrate compliance with the requirements in respect of which the applicant has requested an exemption in accordance with Article 6 of this Regulation.

4. An application for a specific permission to operate a DLT TSS under this Regulation shall contain the following information:

- (a) the applicant's business plan, the rules of the DLT TSS and any legal terms as referred to in Article 7(1), as well as information regarding the functioning, services and activities of the DLT TSS as referred to in Article 7(3);
- (b) a description of the functioning of the distributed ledger technology used, as referred to in Article 7(2);
- (c) a description of the applicant's overall IT and cyber arrangements as referred to in Article 7(4);
- (d) evidence that the applicant has in place sufficient prudential safeguards to meet its liabilities and to compensate its clients, as referred to in Article 7(6), third subparagraph;
- (e) where applicable, a description of the safekeeping arrangements for clients' DLT financial instruments as referred to in Article 7(5);
- (f) a description of the arrangements for ensuring investor protection and a description of the mechanisms for handling client complaints and redress, as referred to in Article 7(6), second subparagraph;
- (g) the applicant's transition strategy; and
- (h) the exemptions that the applicant is requesting under Article 6, the justification for each exemption requested and any compensatory measures proposed and the means by which it intends to comply with the conditions attached to those exemptions.

5. In addition to the information referred to in paragraph 4 of this Article, an applicant that intends to operate a DLT TSS as an investment firm or market operator shall submit the information on how it intends to comply with the applicable requirements of Regulation (EU) No 909/2014 as referred to in Article 6(1) of this Regulation, except for information that would be necessary to demonstrate compliance with requirements in respect of which the applicant has requested an exemption in accordance with that Article.

In addition to the information referred to in paragraph 4 of this Article, an applicant that intends to operate a DLT TSS as a CSD shall submit the information on how it intends to comply with the applicable requirements of Directive 2014/65/EU as referred to in Article 6(2) of this Regulation, except for information that would be necessary to demonstrate compliance with requirements in respect of which the applicant has requested an exemption in accordance with that Article.

6. By 23 March 2023, ESMA shall develop guidelines to establish standard forms, formats and templates for the purposes of paragraph 4.

7. Within 30 working days of the date of receipt of an application for a specific permission to operate a DLT TSS, the competent authority shall assess whether the application is complete. If the application is not complete, the competent authority shall set a time limit by which the applicant is to provide the missing or any additional information. The competent authority shall inform the applicant when the competent authority considers the application to be complete.

As soon as the competent authority considers the application to be complete, it shall send a copy of that application to:

- (a) ESMA; and
- (b) the relevant authorities specified in Article 12 of Regulation (EU) No 909/2014.

8. Where necessary to promote the consistency and proportionality of exemptions, or where necessary to ensure investor protection, market integrity and financial stability, ESMA shall provide the competent authority with a non-binding opinion on the exemptions requested or on the adequacy of the type of distributed ledger technology used for the purposes of this Regulation, within 30 calendar days of receiving a copy of that application.

Before issuing a non-binding opinion, ESMA shall consult the competent authorities of the other Member States and shall take the utmost account of their views when issuing its opinion.

Where ESMA issues a non-binding opinion, the competent authority shall give that opinion due consideration and shall provide ESMA with a statement regarding any significant deviations from that opinion if ESMA so requests. ESMA's opinion and the competent authority's statement shall not be made public.

The relevant authorities specified in Articles 12 of Regulation (EU) No 909/2014 shall provide the competent authority with a non-binding opinion on the features of the DLT TSS operated by the applicant within 30 calendar days of receiving a copy of that application.

9. Within 90 working days of the date of receipt of a complete application for a specific permission to operate a DLT TSS, the competent authority shall carry out an assessment of the application and decide whether to grant the specific permission. Where the applicant applies simultaneously for authorisation under Directive 2014/65/EU or under Regulation (EU) No 909/2014 and for a specific permission under this Article, the assessment period may be extended for a further period up to that specified in Article 7(3) of Directive 2014/65/EU or Article 17(8) of Regulation (EU) No 909/2014 respectively.

10. Without prejudice to Articles 7 and 44 of Directive 2014/65/EU and Article 17 of Regulation (EU) No 909/2014, the competent authority shall refuse to grant a specific permission to operate a DLT TSS if there are grounds for believing that:

- (a) there are significant risks to investor protection, market integrity or financial stability that are not properly addressed and mitigated by the applicant;
- (b) the specific permission to operate a DLT TSS and the exemptions requested are being sought for the purpose of circumventing legal or regulatory requirements; or
- (c) the operator of DLT TSS will not be able to comply, or will not allow its users to comply, with applicable provisions of Union law or provisions of national law falling outside the scope of Union Law.

11. A specific permission shall be valid throughout the Union for a period of up to six years from the date of issuance. The specific permission shall specify the exemptions that are granted in accordance with Article 6, any compensatory measures and any lower thresholds set by the competent authority in accordance with Article 3(6).

The competent authority shall inform ESMA and the relevant authorities specified in Article 12 of Regulation (EU) No 909/2014 of the grant, refusal, or withdrawal of a specific permission under this Article without delay, including any information specified under the first subparagraph of this paragraph.

ESMA shall publish on its website:

- (a) the list of DLT TSSs, the start and end dates of their specific permissions, the list of exemptions granted to each of them, and any lower thresholds set by competent authorities for each of them; and
- (b) the total number of requests for exemptions that have been made under Article 6, indicating the number and types of exemptions granted or refused, together with the justifications for any refusals.

The information referred to in the third subparagraph, point (b), shall be published on an anonymous basis.

12. Without prejudice to Articles 8 and 44 of Directive 2014/65/EU and Article 20 of Regulation (EU) No 909/2014, the competent authority shall withdraw a specific permission or any related exemptions where:

- (a) a flaw has been discovered in the functioning of the distributed ledger technology used, or in the services and activities provided by the operator of a DLT TSS that poses a risk to investor protection, market integrity or financial stability, and the risk outweighs the benefits of the services and activities under experimentation;
- (b) the operator of the DLT TSS has breached the conditions attached to the exemptions;
- (c) the operator of the DLT TSS has admitted to trading or recorded financial instruments that do not fulfil the conditions set out in Article 3(1);
- (d) the operator of the DLT TSS has exceeded the threshold referred to in Article 3(2);
- (e) the operator of the DLT TSS has exceeded the threshold referred to in Article 3(3) and has not activated the transition strategy; or
- (f) the operator of the DLT TSS obtained the specific permission or related exemptions on the basis of misleading information or a material omission.

13. Where an operator of a DLT TSS intends to introduce a material change to the functioning of the distributed ledger technology used, or to the services or activities of that operator, and that material change requires a new specific permission, a new exemption, or the modification of one or more of the operator's existing exemptions or of any conditions attached to an exemption, the operator of the DLT TSS shall request a new specific permission, exemption or modification.

Where an operator of a DLT TSS requests a new specific permission, exemption or modification, the procedure set out in Article 6 shall apply. That request shall be processed by the competent authority in accordance with this Article.

Article 11

Cooperation between operators of DLT market infrastructures, competent authorities and ESMA

1. Without prejudice to Regulation (EU) No 909/2014 and Directive 2014/65/EU, operators of DLT market infrastructures shall cooperate with the competent authorities.

In particular, operators of DLT market infrastructures shall notify their competent authorities upon becoming aware of any of the following matters, without delay:

- (a) any proposed material change to their business plan, including changes in relation to critical staff, the rules of the DLT market infrastructure and the legal terms;
- (b) any evidence of unauthorised access, material malfunctioning, loss, cyber-attacks or other cyber-threats, fraud, theft or other serious malpractice suffered by the operator of the DLT market infrastructure;
- (c) any material change to the information provided to the competent authority;
- (d) any technical or operational difficulties in performing the activities or providing the services that are subject to the specific permission, including difficulties related to the development or use of the distributed ledger technology and DLT financial instruments; or
- (e) any risks affecting investor protection, market integrity or financial stability that have arisen and that were not anticipated in the application requesting the specific permission or that were not anticipated at the time when the specific permission was granted.

Changes referred to in the second subparagraph, point (a) shall be notified at least four months before the change is planned, regardless of whether the proposed material change requires a change to the specific permission or related exemptions or conditions attached to those exemptions in accordance with Article 8, 9 or 10.

Where notified of the matters listed in the second subparagraph, points (a) to (e), the competent authority may require the operator of the DLT market infrastructure to make an application in accordance with Article 8(13), Article 9(13) or Article 10(13), or may require the operator of the DLT market infrastructure to take corrective measures as referred to in paragraph 3 of this Article.

2. The operator of the DLT market infrastructure shall provide the competent authority with any relevant information it requires.

3. The competent authority may require any corrective measures with respect to the business plan of the operator of the DLT market infrastructure, the rules of the DLT market infrastructure and the legal terms in order to ensure investor protection, market integrity or financial stability. The operator of the DLT market infrastructure shall report on the implementation of any corrective measures required by the competent authority in its reports as referred to in paragraph 4.

4. Every six months from the date of the specific permission, the operator of a DLT market infrastructure shall submit a report to the competent authority. That report shall include:

- (a) a summary of the information listed in paragraph 1, second subparagraph;
- (b) the number and value of DLT financial instruments admitted to trading on the DLT MTF or DLT TSS and the number and value of DLT financial instruments recorded by the operator of the DLT SS or DLT TSS;
- (c) the number and value of transactions traded on the DLT MTF or DLT TSS and settled by the operator of the DLT SS or DLT TSS;
- (d) a reasoned assessment of any difficulties in applying Union financial services legislation or national law; and
- (e) any actions taken to implement the conditions attached to the exemptions or to implement any compensatory or corrective measures required by the competent authority.

5. ESMA shall fulfil a coordination role with respect to competent authorities with a view to building a common understanding of distributed ledger technology and DLT market infrastructure, to establishing a common supervisory culture and the convergence of supervisory practices, and to ensuring consistent approaches and convergence in supervisory outcomes.

Competent authorities shall forward to ESMA the information and reports received from operators of DLT market infrastructures pursuant to paragraphs 1, 2 and 4 of this Article in a timely manner, and shall inform ESMA of any measures taken pursuant to paragraph 3 of this Article.

ESMA shall inform competent authorities on a regular basis of:

- (a) any reports submitted pursuant to paragraph 4 of this Article;
- (b) any specific permissions and exemptions granted under this Regulation as well as the conditions attached to those exemptions;
- (c) any refusal by a competent authority to grant a specific permission or exemption, any withdrawal of a specific permission or exemption and any cessations of business of a DLT market infrastructure.

6. ESMA shall monitor the application of specific permissions, and any related exemptions and conditions attached to those exemptions, as well as any compensatory or corrective measures required by competent authorities. ESMA shall submit an annual report to the Commission on how such specific permissions, exemptions, conditions and compensatory or corrective measures are applied in practice.

Article 12

Designation of competent authorities

1. The competent authority for an investment firm operating a DLT MTF or DLT TSS shall be the competent authority designated by the Member State determined in accordance with Article 4(1), points (55)(a)(ii) and (iii), of Directive 2014/65/EU.

2. The competent authority for a market operator operating a DLT MTF or DLT TSS shall be the competent authority designated by the Member State in which the registered office of the market operator operating the DLT MTF or DLT TSS is situated or, if in accordance with the law of that Member State the market operator has no registered office, the Member State in which the head office of the market operator operating the DLT MTF or DLT TSS is situated.

3. The competent authority for a CSD operating a DLT SS or DLT TSS shall be the competent authority designated by the Member State determined in accordance with Article 2(1), point (23), of Regulation (EU) No 909/2014.

Article 13

Notification of competent authorities

The Member States shall notify any competent authorities within the meaning of Article 2, point (21)(c), to ESMA and the Commission. ESMA shall publish a list of those competent authorities on its website.

Article 14

Report and review

1. By 24 March 2026, ESMA shall present a report to the Commission on:
 - (a) the functioning of DLT market infrastructures throughout the Union;
 - (b) the number of DLT market infrastructures;
 - (c) the types of exemption requested by DLT market infrastructures and the types of exemption granted;
 - (d) the number and value of DLT financial instruments that are admitted to trading and that are recorded on DLT market infrastructures;
 - (e) the number and value of transactions traded or settled on DLT market infrastructures;
 - (f) the types of distributed ledger technology used and technical issues related to the use of distributed ledger technology, including the matters listed in Article 11(1), second subparagraph, point (b), and on the impact of the use of distributed ledger technology on the climate policy objectives of the Union;
 - (g) the procedures put in place by operators of DLT SSs or DLT TSSs in accordance with Article 5(3), point (b);
 - (h) any risks, vulnerabilities or inefficiencies posed by the use of distributed ledger technology to investor protection, market integrity or financial stability, including any novel types of legal, systemic and operational risks, which are not sufficiently addressed by Union financial services legislation, and any other unintended effects on liquidity, volatility, investor protection, market integrity or financial stability;
 - (i) any risks of regulatory arbitrage or issues affecting the level playing field between DLT market infrastructures under the pilot regime provided for in this Regulation and between DLT market infrastructures and other market infrastructures using legacy systems;
 - (j) any issues relating to interoperability between DLT market infrastructures and other infrastructures using legacy systems;
 - (k) any benefits and costs resulting from the use of a distributed ledger technology in terms of additional liquidity and financing for start-ups and small- and medium-sized enterprises, safety and efficiency improvements, energy consumption and risk mitigation throughout the entire trading and post-trading chain, including with regard to the recording and safekeeping of DLT financial instruments, the traceability of transactions and enhanced compliance with know-your-customer and anti-money laundering processes, corporate actions and direct exercise of investor rights by means of smart contracts, and reporting and supervisory functions at the level of the DLT market infrastructure;
 - (l) any refusals to grant specific permissions or exemptions, any modifications or withdrawals of such specific permissions or exemptions as well as any compensatory or corrective measures;

- (m) any cessation of business by a DLT market infrastructure and the reasons for that cessation of business;
- (n) the appropriateness of the thresholds referred to in Article 3 and Article 5(8), including the potential implications resulting from an increase of those thresholds, taking into account, in particular, systemic considerations and different types of distributed ledger technology; and
- (o) an overall assessment of the costs and benefits of the pilot regime provided for in this Regulation and a recommendation whether, and under which conditions, to continue this pilot regime.

2. On the basis of the report referred to in paragraph 1, within three months of receipt of that report, the Commission shall present a report to the European Parliament and to the Council. That report shall include a cost-benefit analysis on whether the pilot regime provided for in this Regulation should be:

- (a) extended for a further period of up to three years;
- (b) extended to other types of financial instrument that can be issued, recorded, transferred or stored using a distributed ledger technology;
- (c) amended;
- (d) made permanent through appropriate amendments of the relevant Union financial services legislation; or
- (e) terminated, including all specific permissions granted under this Regulation.

In its report, the Commission may propose any appropriate amendment to Union financial services legislation or any harmonisation of national laws that would facilitate the use of distributed ledger technology in the financial sector, as well as any measures needed for the transition of DLT market infrastructures away from the pilot regime provided for in this Regulation.

In the event that this pilot regime is extended for a further period as provided for in the first subparagraph, point (a), of this paragraph, the Commission shall ask ESMA to submit an additional report in accordance with paragraph 1 no later than three months before the end of the extension period. Upon receipt of that report, the Commission shall submit to the European Parliament and the Council an additional report in accordance with this paragraph.

Article 15

Interim reports

ESMA shall publish annual interim reports in order to provide market participants with information on the functioning of the markets, to address incorrect behaviour of operators of DLT market infrastructures, to provide clarifications on the application of this Regulation and to update previous indications based on the evolution of distributed ledger technology. Those reports shall also provide an overall description of the application of the pilot regime provided for in this Regulation, focusing on trends and emerging risks, and shall be submitted to the European Parliament, the Council and the Commission. The first such report shall be published by 24 March 2024.

Article 16

Amendment to Regulation (EU) No 600/2014

In Article 54(2) of Regulation (EU) No 600/2014, the first subparagraph is replaced by the following:

'If the Commission concludes that there is no need to exclude exchange-traded derivatives from the scope of Articles 35 and 36 in accordance with Article 52(12), a CCP or a trading venue may, before 22 June 2022, apply to its competent authority for permission to avail itself of transitional arrangements. The competent authority, taking into account the risks to the orderly functioning of the relevant CCP or trading venue resulting from the application of the access rights under Article 35 or 36 as regards exchange-traded derivatives, may decide that Article 35 or 36 does not apply to the relevant CCP or trading venue, respectively, in respect of exchange-traded derivatives, for a transitional period until 3 July 2023. Where the competent authority decides to approve such a transitional period, the CCP or trading venue shall not benefit

from the access rights under Article 35 or 36 as regards exchange-traded derivatives for the duration of the transitional period. The competent authority shall notify ESMA and, in the case of a CCP, the college of competent authorities for that CCP, whenever it approves a transitional period.’.

Article 17

Amendment to Regulation (EU) No 909/2014

In Article 76(5) of Regulation (EU) No 909/2014, the first subparagraph is replaced by the following:

‘Each of the settlement discipline measures referred to in Article 7(1) to (13) shall apply from the date of application specified for each settlement discipline measure in the delegated act adopted by the Commission pursuant to Article 7(15).’.

Article 18

Amendments to Directive 2014/65/EU

Directive 2014/65/EU is amended as follows:

(1) in Article 4(1), point (15) is replaced by the following:

‘(15) ‘financial instrument’ means those instruments specified in Section C of Annex I, including such instruments issued by means of distributed ledger technology;’;

(2) in Article 93, the following paragraph is inserted:

‘3a. By 23 March 2023, Member States shall adopt and publish the provisions necessary to comply with point (15) of Article 4(1) and shall communicate them to the Commission. They shall apply those provisions from 23 March 2023.

By way of derogation from the first subparagraph, Member States that cannot adopt provisions necessary to comply with point (15) of Article 4(1) by 23 March 2023, because their legislative procedures take more than nine months, shall benefit from an extension of a maximum of six months from 23 March 2023, provided that they notify the Commission of their need to make use of that extension by 23 March 2023.’.

Article 19

Entry into force and 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 23 March 2023, except for:

(a) Articles 8(5), 9(5), 10(6) and 17, which shall apply from 22 June 2022; and

(b) Article 16, which shall apply from 4 July 2021.

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

Done at Brussels, 30 May 2022.

For the European Parliament
The President
R. METSOLA

For the Council
The President
B. LE MAIRE

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/859**of 24 May 2022****amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature
and on the Common Customs Tariff**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽¹⁾, and in particular Article 9(1) and Article 12 thereof,

Whereas:

- (1) Regulation (EEC) No 2658/87 established a combined goods nomenclature (the 'CN') to meet, at one and the same time, the requirements of the Common Customs Tariff, the external trade statistics of the Union, and other Union policies concerning the importation or exportation of goods.
- (2) The CN is based on the World Customs Organization's Harmonized System ('HS') nomenclature, which was amended pursuant to the Recommendation of 28 June 2019 of the Customs Cooperation Council ('the 2022 HS'). Commission Implementing Regulation (EU) 2021/1832 ⁽²⁾, which replaced Annex I to Regulation (EEC) No 2658/87 from 1 January 2022, implemented those amendments in the 2022 version of the CN ('the 2022 CN').
- (3) In the 2022 HS, a separate subheading 4421 20 00 for 'coffins' was created. In the 2021 CN, 'coffins of fibreboard' were classified under CN code 4421 99 10 with a customs duty rate of 4 %, whilst 'coffins of other materials' were classified under CN code 4421 99 91 with a customs duty rate of 'Free'. With the amendments to the 2022 HS, in the 2022 CN, 'coffins of fibreboard' were transferred to the new CN code 4421 20 00 with a custom duty rate of 'Free'.
- (4) In order to impose, in 2022, the same tariff treatment as in the 2021 CN, it is necessary to amend the 2022 CN in order to take into account the amendments to the 2022 HS and to provide for a separate subdivision for 'coffins of fibreboard'.

⁽¹⁾ OJ L 256, 7.9.1987, p. 1.⁽²⁾ Commission Implementing Regulation (EU) 2021/1832 of 12 October 2021 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 385, 29.10.2021, p. 1).

- (5) In the 2022 HS, a separate heading 8485 was created for 'Machines for additive manufacturing', also known as '3D printers', which was further subdivided into different categories according to the various material deposit (for example 'by metal deposit', 'by plaster, cement, ceramics or glass deposit', etc.). The creation of heading 8485 entailed the transfer of those machines from different subheadings of the 2021 CN ⁽³⁾ and the creation of specific CN codes in order to grant the same tariff treatment as in the 2021 CN.
- (6) In the 2021 CN, 'machines for additive manufacturing by sand, concrete or other mineral deposit' were classified under subheading 8474 80 90 'Other', with a customs duty rate of 'Free'. After amendments to the 2022 HS, those products are classified, in the 2022 CN, under the new subheading 8485 80 00, with a customs duty rate of 1,7 %.
- (7) In order to continue to grant the same tariff treatment as in 2021 for those 'machines for additive manufacturing with additive of sand, concrete or other mineral products', it is necessary to amend the 2022 CN by providing for a separate duty free subdivision.
- (8) In addition, in the 2022 CN, parts of those machines should also get the same tariff treatment as in 2021 CN. It is, therefore, appropriate to amend the description of CN code 8485 90 10 in order to include therein parts of the 'machines for additive manufacturing by sand, concrete or other mineral products deposit'.
- (9) Regulation (EEC) No 2658/87 should therefore be amended accordingly.
- (10) In order to ensure that the tariff treatment in 2022 for 3D printers and their parts is the same as it was in 2021 the corresponding amendments should apply from 1 January 2022.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EEC) No 2658/87 is amended as set out in the Annex to this Regulation.

Article 2

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

Point 2 of the Annex shall apply from 1 January 2022.

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

Done at Brussels, 24 May 2022.

*For the Commission,
On behalf of the President,
Gerassimos THOMAS
Director-General
Directorate-General for Taxation and Customs Union*

⁽³⁾ Commission Implementing Regulation (EU) 2020/1577 of 21 September 2020 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 361, 30.10.2020, p. 1).

ANNEX

1) In Annex I, Part Two, of Regulation (EEC) No 2658/87, the entry for code **4421 20 00** is replaced by the following:

CN code	Description	Conventional rate of duty (%)	Supplementary unit
4421 20 00	– Coffins	Free ⁽¹⁾	p/st

⁽¹⁾ Of fibreboard: **4**.

2) In Annex I, Part Two, of Regulation (EEC) No 2658/87, the entries for codes **8485 80 00** to **8485 90 90** are replaced by the following:

CN code	Description	Conventional rate of duty (%)	Supplementary unit
1	2	3	4
8485 80 00	– Other	1,7 ⁽¹⁾	p/st
8485 90	– Parts:		
8485 90 10	– – Parts of machines of subheading 8485 30 10; Parts of machines for additive manufacturing by sand, concrete or other mineral products deposit	Free	p/st
8485 90 90	– – Other	1,7	p/st

⁽¹⁾ Machines for additive manufacturing by sand, concrete or other mineral products deposit: **Free**.

COMMISSION REGULATION (EU) 2022/860**of 1 June 2022****amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council
as regards monacolins from red yeast rice****(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 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ⁽¹⁾, and in particular Article 8(2)(a)(ii) and (b) thereof,

Whereas:

- (1) Pursuant to Article 8(2) of Regulation (EC) No 1925/2006, on its own initiative or on the basis of information provided by Member States, the Commission may initiate a procedure to include a substance or an ingredient containing a substance other than a vitamin or a mineral in Annex III to that Regulation listing the substances whose use in foods is prohibited, restricted or under Union scrutiny, if that substance is associated with a potential risk to consumers as provided for in Article 8(1) of Regulation (EC) No 1925/2006.
- (2) In 2010, the European Food Safety Authority ('the Authority') was asked to provide an opinion on scientific substantiation of a health claim related to monacolin K submitted pursuant to Article 13 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council ⁽²⁾. On 30 June 2011 ⁽³⁾, the Authority issued a scientific opinion on the substantiation of a health claim related to monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations. The Authority concluded that a cause and effect relationship has been established between the consumption of monacolin K from red yeast rice and maintenance of normal blood LDL-cholesterol concentrations at the level of 10 mg daily dose.
- (3) In 2012, the Authority was asked to provide an opinion on the scientific substantiation of a health claim submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 related to the combination of ingredients, among which monacolin K from red yeast rice. On 12 July 2013 ⁽⁴⁾, the Authority issued a scientific opinion establishing a cause and effect relationship between the consumption of a product containing 2 mg of monacolin K from red yeast rice in combination with other ingredients, and the reduction of blood LDL-cholesterol concentrations.
- (4) In the abovementioned scientific opinions, in relation to restrictions of use, the Authority referred to the Summary of Product Characteristics (SmPC) for lovastatin-containing medicinal products available on the Union market, as the Authority considered that monacolin K in lactone form is identical to lovastatin. The SmPC provides information to healthcare professionals on the safe and effective use of these medicinal products. The SmPC for lovastatin-containing medicinal products describes the properties and officially approved conditions for their use and includes special warnings and precautions for use that refer to the risk of myopathy/rhabdomyolysis, which is increased by concomitant use of lovastatin with certain other medicinal products, and discourages use of lovastatin by pregnant and lactating women.
- (5) During discussions of the working group on nutrition and health claims on the abovementioned scientific opinions, the Member States raised potential safety concerns associated with the consumption of foods containing monacolins from red yeast rice.

⁽¹⁾ OJ L 404, 30.12.2006, p. 26.

⁽²⁾ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

⁽³⁾ EFSA Journal 2011;9(7):2304.

⁽⁴⁾ EFSA Journal 2013;11(7):3327.

- (6) Red yeast rice is made by fermentation of rice with yeasts, mainly *Monascus purpureus*, resulting in the production of monacolins, the most abundant of which is monacolin K. It is traditionally used in China as a food colouring and as a traditional remedy to promote digestion and blood circulation. In the EU, it is not authorised for use as a food colour as it is not included in the Union list of Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽⁵⁾ on food additives. Food supplements containing red yeast rice preparations have been marketed and consumed to a significant degree before 15 May 1997 and therefore, are not subject to Regulation (EU) 2015/2283 of the European Parliament and of the Council ⁽⁶⁾ on novel foods. The use of red yeast rice preparations in other food categories is subject to an authorisation under Regulation (EU) 2015/2283 on novel foods. The application of the provisions of this Regulation is without prejudice to Regulations (EU) 2015/2283 and (EC) No 1333/2008.
- (7) The Commission, on its own initiative, started the procedure under Article 8 of Regulation (EC) No 1925/2006 for monacolins in red yeast rice as it considered that on the basis of the available information that was provided by the Member States during a consultation on the safety of monacolins from red yeast rice, the necessary conditions and requirements laid down in Article 8 of that Regulation and Articles 3 and 4 of Commission Implementing Regulation (EU) No 307/2012 ⁽⁷⁾ were fulfilled. This available information included an opinion from the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) on the risk associated with the presence of 'red yeast rice' in food supplements ⁽⁸⁾. That opinion concluded that 'due to the composition of red yeast rice and in particular: the presence of monacolin K (also called lovastatin when marketed as a drug) that shares the adverse effects of statins; the presence at varying levels of the other monacolins, compounds whose safety has not been established, consumption of "red yeast rice" exposes some consumers to a health risk'. The available information also included a scientific advisory report adopted by the Belgian Superior Health Council on 13 February 2016 ⁽⁹⁾ that provided an evaluation of the supposed beneficial effects and possible toxicity of dietary supplements based on red yeast rice for the Belgian population. That report referred to the risk associated with the presence of monacolins, in particular monacolin K, in red yeast rice that includes adverse effects identical to those observed in patients taking statin drugs and referred to a higher risk of developing toxic effects for certain vulnerable groups such as pregnant women, people suffering from liver, kidney and muscle disorders, persons aged over 70 years and children and adolescents. Another relevant scientific assessment was carried out by the German research funding organisation DFG in 2013 ⁽¹⁰⁾ that concluded that 'red mould rice is not a safe food/food supplement'.
- (8) Therefore, the Commission in 2017, in accordance with Article 8 of Regulation (EC) No 1925/2006, requested the Authority to deliver a scientific opinion on the evaluation of the safety of monacolins in red yeast rice.
- (9) On 25 June 2018 ⁽¹¹⁾, the Authority adopted a scientific opinion on the safety of monacolins in red yeast rice. The Authority considered that monacolin K in lactone form was identical to lovastatin, the active ingredient of several medicinal products authorised for the treatment of hypercholesterolemia in the EU. Monacolin K from red yeast rice is available in food supplements at varying recommended daily intakes for its effect on the maintenance of normal blood LDL-cholesterol levels. On the basis of the information available, the Authority concluded that intake of monacolins from red yeast rice via food supplements could lead to estimated exposure to monacolin K within the range of the therapeutic doses of lovastatin. The Authority noted that the profile of adverse effects to red yeast rice

⁽⁵⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

⁽⁶⁾ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

⁽⁷⁾ Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).

⁽⁸⁾ ANSES Opinion Request No 2012-SA-0228: Opinion of the French Agency for Food, Environmental and Occupational Health & Safety on the risks associated with the presence of 'red yeast rice' in food supplements, 14 February 2014.

⁽⁹⁾ Avis du Conseil Supérieur de la Santé N° 9312 : Compléments alimentaires à base de «levure de riz rouge », 3.2.2016.

⁽¹⁰⁾ Stellungnahme der Gemeinsamen Expertenkommission BfL/BfArM: Einstufung von Rotschimmelreisprodukten, 8.2.2016.

⁽¹¹⁾ EFSA Journal 2019;16(8):5368.

was similar to that of lovastatin. It reported, through consultation of four sources ⁽¹²⁾ of case reports, that the most important targets for adverse events were musculoskeletal and connective tissue (including rhabdomyolysis), liver, nervous system, gastro-intestinal tract, skin and subcutaneous tissue, in descending order of occurrence. The Authority considered that the available information on the adverse effects reported in humans were judged to be sufficient to conclude that monacolins from red yeast rice when used as food supplements were of significant safety concern at the use level of 10 mg/day. The Authority further considered that individual cases of severe adverse reactions had been reported for monacolins from red yeast rice at intake levels as low as 3 mg/day taken for a period of between 2 weeks and 1 year, and that cases of rhabdomyolysis, hepatitis and skin disorders occurred and required hospitalisation.

- (10) On the basis of the information available and several uncertainties highlighted in its opinion, the Authority was unable to provide advice on a daily intake of monacolins from red yeast rice that does not give rise to concerns about harmful effects to health, for the general population, and as appropriate, for vulnerable subgroups of the population as requested by the Commission. The Authority explained that there are uncertainties as to the composition and content of monacolins in food supplements containing red yeast rice and that monacolins in red yeast rice are used in multi-ingredient products, the components of which have not been fully evaluated individually or in combination. Furthermore, due to the lack of data, the safe use of monacolins in certain vulnerable groups of consumers cannot be evaluated and there is uncertainty as to the effects of concomitant consumption of red yeast rice-based food supplements with foods or drugs that inhibit the enzyme (CYP3A4) that is involved in the metabolism of monacolins.
- (11) In accordance with Article 4(5) of Implementing Regulation (EU) No 307/2012 and following publication by the Authority of its opinion on monacolins from red yeast rice, the Commission received comments from interested parties on the scientific risk assessment carried out by the Authority. Interested parties also provided statements to support the safe use of monacolins from red yeast rice in combination with adequate consumer information on the safe use of the substance.
- (12) Those comments that were of a scientific nature were clarified by the Authority during post-adoption teleconferences held with the interested parties. The Authority provided clarifications on the sources of evidence for its scientific opinion and explained why certain studies submitted by interested parties during a public call for data were not considered to be sufficiently reliable and scientifically robust to be included in its safety assessment. The Authority explained the scientific rationale for considering safety data for lovastatin as relevant for the safety assessment of monacolins and clarified how post-marketing data on adverse events provided by interested parties was used as supporting evidence in its assessment.
- (13) The Commission asked the Authority for technical assistance on two scientific studies, a systematic review and meta-analysis of the safety of red yeast rice supplementation ⁽¹³⁾, and a review and expert opinion on the role of red yeast rice supplementation in plasma cholesterol control ⁽¹⁴⁾, that were submitted to the Commission by an interested party following adoption of the scientific opinion by the Authority. The Authority noted that irrespective of the results of any intervention study or meta-analysis on the safety of red yeast rice supplementation, reports of side effects associated with the consumption of red yeast rice in humans exist and monacolin K in lactone form is identical to lovastatin for which adverse effects are well documented, and therefore those submitted studies would have to be considered together with the whole body of evidence to draw an overall conclusion. The Authority explained that the existence of reports of adverse effects cannot be neglected or invalidated by results of trials that were relatively small in size and not designed to detect these effects, and that studies, such as the review and expert opinion study submitted, providing comparative risk-benefit ratio of products containing red yeast rice were not relevant to the evaluation of the safety of substances intentionally added to food.

⁽¹²⁾ World Health Organisation; French Agency for Food, Environmental and Occupational Health and Safety; Italian Surveillance System of Natural Health Products; Food and Drug Administration.

⁽¹³⁾ Fogacci F, Banach M, Mikhailidis DP et al. Safety of red yeast rice supplementation: A systematic review and meta-analysis of randomised controlled trials. *Pharmacological Research* 143 (2019) 1–16.

⁽¹⁴⁾ Banach M, Bruckert E, Descamps OS et al. The role of red yeast rice (RYR) supplementation in plasma cholesterol control: A review and expert opinion. *Atheroscler Suppl.* 2019 Aug 17.

- (14) Considering that no daily intake of monacolins from red yeast rice that does not give rise to concerns for human health could be set, and considering the significant harmful effect on health associated with the use of monacolins from red yeast rice at levels of 10 mg/day, and individual cases of severe adverse health reactions at levels as low as 3 mg/day, the use of monacolins from red yeast rice at levels of 3 mg and more per portion of the product recommended for daily consumption should be prohibited. That substance should therefore be placed in Part B of Annex III to Regulation (EC) No 1925/2006 and its addition to foods or its use in the manufacture of foods should only be allowed under the conditions specified in that Annex.
- (15) Food supplements are required by Article 6 of Directive 2002/46/EC of the European Parliament and of the Council ⁽¹⁵⁾ to be labelled with the portion of the product that is recommended for daily consumption together with a warning not to exceed the stated recommended daily dose. As different foods or food supplements containing monacolins from red yeast rice may be consumed simultaneously, there is the possibility of exceeding the limit laid down in Annex III to Regulation (EC) No 1925/2006, therefore, it is necessary to provide for appropriate labelling requirements for all foods containing monacolins from red yeast rice.
- (16) In order to provide complete information about the content of monacolins on the labels of foods containing monacolins from red yeast rice, it is necessary to provide for appropriate labelling requirements for all foods containing monacolins from red yeast rice.
- (17) As the Authority identified a risk of adverse effects due to interactions with medicinal products, it is necessary to warn persons using cholesterol-lowering medicines, to avoid concomitant use of foods containing monacolins from red yeast rice. The Authority noted that the profile of adverse effects to red yeast rice was similar to that of lovastatin, therefore, it is appropriate to warn persons to seek medical advice if they experience any health problems. Furthermore, as the Authority could not evaluate the safe use of monacolins in certain vulnerable groups of consumers because of the lack of data, and as therefore, there is still the possibility of harmful effects on health associated with the use of monacolins from red yeast rice, it is appropriate to advise against the use of foods containing monacolins from red yeast rice for pregnant or lactating women, persons aged over 70 years, children and adolescents. Considering the above, it is necessary to provide for appropriate labelling requirements for all foods containing monacolins from red yeast rice.
- (18) The Authority could not identify a dietary intake of monacolins from red yeast rice that does not give rise to concerns about harmful effects to health, for the general population, and as appropriate, for vulnerable subgroups of the population. As there is still a possibility of harmful effects on health associated with the use of monacolins from red yeast rice, but scientific uncertainty in this regard persists, and considering that monacolins from red yeast rice may only be used in food supplements and that the extent of use of those food supplements could not be determined by the Authority, the use of monacolins from red yeast rice in food supplements should be placed under Union scrutiny and therefore, should be included in Part C of Annex III to Regulation (EC) No 1925/2006. Considering the uncertainties outlined by the Authority in its scientific opinion and considering the statements given by interested parties on the safety profile of monacolins from red yeast rice, those interested parties have under Article 8(4) of Regulation (EC) No 1925/2006 the possibility to submit data demonstrating the safety of monacolins from red yeast rice to the Authority in accordance with Article 5 of Implementing Regulation (EU) No 307/2012. In accordance with Article 8(5) of Regulation (EC) No 1925/2006 the Commission should take a decision within four years from the entry into force of this Regulation, whether to list monacolins from red yeast rice in Annex III, Part A or Part B, as appropriate, taking into account the opinion of the Authority on any submitted data.
- (19) Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁵⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1925/2006 is amended as follows:

1. The following entry is added in the table in Part B 'Restricted substances' in alphabetical order:

Restricted substance	Conditions of use	Additional requirements
'Monacolins from red yeast rice'	Individual portion of the product for daily consumption shall provide less than 3 mg of monacolins from red yeast rice.	The label shall provide the number of individual portions of the product for maximum daily consumption and a warning not to consume a daily amount of 3 mg of monacolins from red yeast rice or more. The label shall indicate the content of monacolins per portion of the product. The label shall include the following warnings: "Should not be consumed by pregnant or lactating women, children below 18 years old and adults above 70 years old". "Seek advice from a doctor on consumption of this product if you experience any health problems"; "Should not be consumed if you are taking cholesterol-lowering medication"; "Should not be consumed if you are already consuming other products containing red yeast rice".

2. The following entry is added in the table in Part C 'Substances under Community scrutiny' in alphabetical order:

'Monacolins from red yeast rice'

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 June 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/861**of 1 June 2022****laying down exceptional rules for the Member States' second requests for Union aid for school fruit and vegetables and for school milk and derogating from Implementing Regulation (EU) 2017/39 as regards the reallocation of Union aid, for the period from 1 August 2022 to 31 July 2023**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 25, first paragraph, point (d), thereof,

Having regard to Council Regulation (EU) No 1370/2013 of 16 December 2013 determining measures on fixing certain aids and refunds related to the common organisation of the markets in agricultural products ⁽²⁾, and in particular Article 5(5) thereof,

Whereas:

- (1) The military aggression by Russia against Ukraine on 24 February 2022 has led to a mass inflow of displaced persons from Ukraine to the Union, most of whom are women and children. Several Member States are meeting unprecedented challenges in order to integrate quickly displaced children from Ukraine into their education system.
- (2) The aid scheme for the supply of fruit and vegetables and of milk and milk products in educational establishments ('the school scheme'), set out by Regulation (EU) No 1308/2013 is aimed at children who regularly attend nurseries, pre-schools or primary or secondary-level educational establishments in the Member States. Displaced children from Ukraine integrated in the Member States' education systems are therefore eligible for participation in the school scheme. Due to the increase in number of eligible children, in absolute terms or in percentage of the population, several Member States in the frontline for action in response to the Russia's invasion of Ukraine may encounter difficulties in implementing the school scheme as planned if their allocation of Union aid is not increased.
- (3) In accordance with Article 3, first paragraph, point (a), of Commission Implementing Regulation (EU) 2017/39 ⁽³⁾, Member States submitted their requests for Union aid for school fruit and vegetables and for school milk relating to the school year 2022/2023, which runs from 1 August 2022 to 31 July 2023, to the Commission by 31 January 2022. Based on those requests, submitted before Russia's invasion of Ukraine, the Commission fixed the definitive allocations of Union aid by Member State in Commission Implementing Decision (EU) 2022/493 ⁽⁴⁾. Available information on the level of use of the definitive allocations of Union aid in past school years by some Member States indicates the risk that some Member States may not be able to use their definitive allocation in full.
- (4) In the light of the newly arisen needs and as a token of solidarity by the Union and the Member States with Ukraine, it is appropriate to set out exceptional rules allowing Member States to submit a second request for Union aid for school fruit and vegetables and for school milk regarding the period from 1 August 2022 to 31 July 2023 by 15 June 2022. This possibility should be linked to the need to cater for the displaced children from Ukraine enrolled in the Member States' educational establishments in that period. Member States should be able to indicate either their

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 346, 20.12.2013, p. 12.

⁽³⁾ Commission Implementing Regulation (EU) 2017/39 of 3 November 2016 on rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to Union aid for the supply of fruit and vegetables, bananas and milk in educational establishments (OJ L 5, 10.1.2017, p. 1).

⁽⁴⁾ Commission Implementing Decision (EU) 2022/493 of 21 March 2022 fixing the definitive allocation of Union aid to Member States for school fruit and vegetables and for school milk for the period from 1 August 2022 to 31 July 2023 and amending Implementing Decision (EU) 2021/462 (OJ L 100, 28.3.2022, p. 55).

willingness to use more than their definitive allocation of Union aid set out in Annex I to Implementing Decision (EU) 2022/493 or the amount of the definitive allocation that is not requested, in case there is no willingness to use the entire amount of that allocation. The former possibility should be limited to the Member States having demonstrated a suitable absorption of their definitive allocation of Union aid, based on the financial execution in school year 2018/2019, which was the last school year before the COVID-19 pandemic. Their requests should be based solely on the number of displaced children from Ukraine falling within the target group defined in the Member States' strategy according to Article 2(1), point (f), of Implementing Regulation (EU) 2017/39, duly justified on the grounds of available data. Member States not submitting a second request should be regarded as having confirmed the definitive allocations set out in Annex I to Implementing Decision (EU) 2022/493.

- (5) Article 7(1) of Implementing Regulation (EU) 2017/39 lays down the rules for the reallocation of Union aid. The Commission is to fix the definitive amount of aid by reallocating unrequested indicative allocations or unrequested parts thereof. It is appropriate to derogate from those rules to allow the Commission to also take into account new requests linked to Russia's invasion of Ukraine in order to fix a revised definitive allocation of Union aid for the period from 1 August 2022 to 31 July 2023. The reallocation of any unrequested amount of definitive allocations of Union aid is to be based on the number of six- to ten-year old children in the Member States, in accordance with Article 5(5), second subparagraph, of Regulation (EU) No 1370/2013.
- (6) As the fixing of the definitive allocations of Union aid for school fruit and vegetables and for school milk for the period from 1 August 2022 to 31 July 2023 taking into account the second request for Union aid would need to take place as soon as possible to allow Member States to plan and carry out the necessary preparatory activities in due time for the implementation of the school scheme, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

For the period from 1 August 2022 to 31 July 2023, Member States may submit by 15 June 2022 a second request for Union aid, indicating:

- (a) the willingness to use more than the definitive allocation of Union aid for school fruit and vegetables and/or for school milk set out in Annex I to Implementing Decision (EU) 2022/493 and the additional amount requested, in the case an additional allocation be available; or
- (b) the amount of the definitive allocation of Union aid for school fruit and vegetables and/or for school milk set out in Annex I to Implementing Decision (EU) 2022/493 that is not requested, in the case there is no willingness to use the entire amount of that allocation.

Member States may only request an additional amount of Union aid pursuant to first paragraph, point (a), where the use of the definitive allocation of Union aid for school year 2018/2019 running during the period from 1 August 2018 to 31 July 2019 is equal or above 75 %, taking into account the declarations of expenditure sent to the Commission concerning expenditure effected up to 31 December 2021 in accordance with Article 10 of Commission Implementing Regulation (EU) No 908/2014 ⁽³⁾. Their request shall be linked to the number of displaced children from Ukraine falling within the target group defined in the Member States' strategy in accordance with Article 2(1), point (f), of Implementing Regulation (EU) 2017/39, at the time of the submission of that request and shall be duly justified on the grounds of available data.

⁽³⁾ Commission Implementing Regulation (EU) No 908/2014 of 6 August 2014 laying down rules for the application of Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to paying agencies and other bodies, financial management, clearance of accounts, rules on checks, securities and transparency (OJ L 255, 28.8.2014, p. 59).

Where a Member State does not submit a request for Union aid pursuant to the first paragraph, it shall be regarded as having confirmed the definitive allocations set out in Annex I to Implementing Decision (EU) 2022/493.

Article 2

By way of derogation from Article 7(1) of Implementing Regulation (EU) 2017/39, the Commission may decide, by 15 July 2022, to also take into account the second requests for Union aid submitted pursuant to Article 1 of this Regulation to fix the definitive allocations of Union aid for the period from 1 August 2022 to 31 July 2023.

Article 3

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

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

Done at Brussels, 1 June 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/862**of 1 June 2022****amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union****(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 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating carrier, and repealing Article 9 of Directive 2004/36/EC ⁽¹⁾, and in particular Article 4(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 474/2006 ⁽²⁾ establishes the list of air carriers, which are subject to an operating ban within the Union.
- (2) Certain Member States and the European Union Aviation Safety Agency ('the Agency') communicated to the Commission, pursuant to Article 4(3) of Regulation (EC) No 2111/2005, information that is relevant for updating that list. Third countries and international organisations also provided relevant information. On the basis of the information provided, the list should be updated.
- (3) The Commission informed all air carriers concerned, either directly or through the authorities responsible for their regulatory oversight, about the essential facts and considerations, which would form the basis of a decision to impose an operating ban on them within the Union or to modify the conditions of an operating ban imposed on an air carrier, which is included in the list set out in Annex A or B to Regulation (EC) No 474/2006.
- (4) The Commission gave the air carriers concerned the opportunity to consult all relevant documentation, to submit written comments and to make an oral presentation to the Commission and to the Committee established by Article 15 of Regulation (EC) No 2111/2005 (the 'EU Air Safety Committee').
- (5) The Commission has informed the EU Air Safety Committee about the ongoing joint consultations, within the framework of Regulation (EC) No 2111/2005 and Commission Regulation (EC) No 473/2006 ⁽³⁾, with the competent authorities and air carriers of Armenia, Iraq, Kazakhstan, Moldova, Pakistan, Russia, and South Sudan. The Commission also informed the EU Air Safety Committee about the aviation safety situation in Congo Brazzaville, Equatorial Guinea, Madagascar, and Suriname.
- (6) The Agency informed the Commission and the EU Air Safety Committee about the technical assessments conducted for the initial evaluation and the continuous monitoring of third country operator ('TCO') authorisations, issued pursuant to Commission Regulation (EU) No 452/2014 ⁽⁴⁾.

⁽¹⁾ OJ L 344, 27.12.2005, p. 15.

⁽²⁾ Commission Regulation (EC) No 474/2006 of 22 March 2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 14).

⁽³⁾ Commission Regulation (EC) No 473/2006 of 22 March 2006 laying down implementing rules for the Community list of air carriers, which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 8).

⁽⁴⁾ Commission Regulation (EU) No 452/2014 of 29 April 2014 laying down technical requirements and administrative procedures related to air operations of third country operators pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 133, 6.5.2014, p. 12).

- (7) The Agency also informed the Commission and the EU Air Safety Committee about the results of the analysis of ramp inspections carried out under the Safety Assessment of Foreign Aircraft programme ('SAFA'), in accordance with Commission Regulation (EU) No 965/2012 ⁽⁵⁾.
- (8) In addition, the Agency informed the Commission and the EU Air Safety Committee about the technical assistance projects carried out in third countries affected by an operating ban under Regulation (EC) No 474/2006. Furthermore, the Agency provided information on the plans and requests for further technical assistance and cooperation to improve the administrative and technical capability of civil aviation authorities in third countries with a view to helping them resolve non-compliance with applicable international civil aviation safety standards. Member States were invited to respond to such requests on a bilateral basis in coordination with the Commission and the Agency. In that regard, the Commission reiterated the usefulness of providing information to the international aviation community, particularly through the International Civil Aviation Organisation's ('ICAO') Aviation Safety Implementation Assistance Partnership tool, on technical assistance to third countries provided by the Union and Member States to improve aviation safety around the world.
- (9) Eurocontrol provided the Commission and the EU Air Safety Committee with an update on the status of the SAFA and TCO alarming functions, including statistics about alert messages for banned air carriers.

Union air carriers

- (10) Following the Agency's analysis of information resulting from ramp inspections carried out on the aircraft of Union air carriers, as well as standardisation inspections carried out by the Agency, complemented also with information stemming from specific inspections and audits carried out by national aviation authorities, several Member States and the Agency, acting as competent authorities, have taken certain corrective and enforcement measures, and informed the Commission and the EU Air Safety Committee about those measures.
- (11) Member States and the Agency, acting as competent authorities, reiterated their readiness to act, as necessary, in the event that pertinent safety information indicates imminent safety risks resulting from non-compliance by Union air carriers with relevant safety standards.

Air carriers from Armenia

- (12) In June 2020, air carriers certified in Armenia were included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2020/736 ⁽⁶⁾.
- (13) On 29 April 2022, the Commission, the Agency, Member States, and the Civil Aviation Committee of Armenia ('CAC') held a technical meeting, during which CAC provided an update regarding the measures taken since the technical meeting held on 3 November 2021 to address the identified safety deficiencies. The main measures are the amendment of its civil aviation legislation and supporting regulations, improvements relating to the structure and staff of the CAC, and the update of the CAC system for managing the qualification and training of its inspectors, including additional initial, recurrent and on-the-job training. Furthermore, the CAC explained that it developed additional oversight procedures and checklists in various domains, and drafted the national aviation safety plan and the safety occurrence reporting regulation, both of which are to be adopted in 2022. All of this material will be carefully scrutinised by the Commission and the Agency.

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

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/736 of 2 June 2020 amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union (OJ L 172, 3.6.2020, p. 7).

- (14) The CAC provided an update of measures taken in connection with its corrective action plan ('CAP') with regard to the observations raised during the 2020 Union on-site assessment visit. These measures included the update of human resources planning and training processes, of several procedures and checklists to improve its safety oversight activities, the implementation of an electronic database to support its oversight activities, and the development of its safety occurrence reporting system.
- (15) Furthermore, as part of the Union's efforts to assist CAC in addressing its aviation safety improvement needs, the Agency launched, in March 2022, a dedicated technical project aimed at strengthening the CAC safety oversight in the Air Operations and Airworthiness domains.
- (16) On the basis of all available information, it is considered that the CAC has made some noteworthy improvements to its safety oversight capacity. It is also recognised that the CAC appears committed to continuing its efforts to further develop its oversight capabilities and the resolution of identified safety concerns. Notwithstanding these positive developments, there is currently not enough substantiated evidence given that CAC has effectively addressed all the deficiencies that were identified during the on-site assessment visit in February 2020 that led to the decision to impose an operating ban pursuant to Implementing Regulation (EU) 2020/736. Information provided about the potential improvements requires further verification through additional technical meetings, and possibly through confirmation on-site.
- (17) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers from Armenia.
- (18) Member States should continue verifying the effective compliance of air carriers certified in Armenia with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.

Air carriers from Iraq

- (19) In December 2015, the air carrier *Iraqi Airways* was included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2015/2322 ⁽⁷⁾.
- (20) In February 2022 the Iraqi Civil Aviation Authority ('ICAA') and *Iraqi Airways* submitted to the Commission information on the actions and measures taken to improve their safety oversight and management systems and capacities. Based on information received, the Commission notes that some progress has been made to address identified safety concerns. However certain deficiencies were identified, including the quality of the check-lists used by ICAA inspectors for both certification and oversight processes, as well as the ICAA training plan and its implementation. Assessment of the ICAA oversight results showed several shortcomings, notably in the way oversight findings are drafted, and their follow up assured. In this regard, it was also noted that appropriate enforcement measures were not taken by ICAA inspectors when needed.
- (21) The assessment of the information provided by *Iraqi Airways* demonstrated that the air carrier has made significant progress in different domains. It was noted that the air carrier had hired the services of an external consultant for the purpose of auditing the air carrier and developing a CAP, which is currently being implemented.
- (22) A Flight Data Monitoring Programme was initiated to further improve the amount of data to be analysed and used for developing safety improvement measures. Moreover, an internal reporting system was established, safety meetings on different strategic levels were launched, and some of the organisation's manuals were reviewed.
- (23) Notwithstanding the aforementioned progress, a number of challenges remain, including that several software applications in maintenance, flight operations and document management still need to be installed. The air carrier also needs to improve its functions and procedures related to addressing oversight findings raised by ICAA. Moreover, whereas *Iraqi Airways* has developed a Quality Management System ('QMS'), it seems that it is not capable to perform an appropriate follow-up of all findings raised under this system.

⁽⁷⁾ Commission Implementing Regulation (EU) 2015/2322 of 10 December 2015 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers, which are subject to an operating ban within the Community (OJ L 328, 12.12.2015, p. 67).

- (24) On 14 December 2021 and on 4 May 2022, at Iraq's request and as part of the Commission's continuous monitoring activities, the Commission, the Agency, Member States, ICAA, and *Iraqi Airways* held two technical meetings. At both occasions, ICAA presented the progress it made in addressing the safety concerns regarding its capacity to ensure effective safety oversight in the country, and notably as regards oversight of *Iraqi Airways*. *Iraqi Airways* presented the progress made in order to address previously identified safety deficiencies that ultimately led to a negative TCO decision adopted by the Agency, as well as other associated safety improvements.
- (25) ICAA and *Iraqi Airways* have shown a clear vision and ambition to improve their regulatory compliance and safety performance. However, additional improvements are still needed. The Commission will continue to engage with ICAA and *Iraqi Airways* to monitor and contribute to their efforts to enhance their safety oversight and management capabilities. In this context, it was noted that the Agency will launch a technical assistance project in the course of 2022 to support ICAA in its efforts to improve aviation safety oversight in Iraq.
- (26) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers from Iraq.
- (27) Member States should continue verifying the effective compliance of air carriers certified in Iraq with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.
- (28) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Kazakhstan

- (29) In December 2016, air carriers certified in Kazakhstan were removed from Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2016/2214 ⁽⁸⁾, with the exception of *Air Astana*, which had been removed from Annex B in 2015 by Implementing Regulation (EU) 2015/2322.
- (30) In October 2021, as part of the Commission's continuous monitoring of the safety oversight system in Kazakhstan, experts from the Commission, the Agency, and Member States (the 'assessment team') conducted a Union on-site assessment visit in Kazakhstan at the offices of the Civil Aviation Committee of Kazakhstan ('CAC KZ'), and the Aviation Administration of Kazakhstan Joint Stock Company ('AAK'), as well as at the offices of three air carriers certified in Kazakhstan, namely *Air Astana*, *Jupiter Jet*, and *Qazaq Air*.
- (31) On 2 February 2022, AAK submitted to the Commission a CAP to address the shortcomings observed and reported by the assessment team. The Commission, together with the Agency, assessed the CAP, and provided CAC KZ and AAK with comments and adjustment suggestions.
- (32) On 27 and 28 April 2022, the Commission, the Agency, Member States and representatives of the CAC KZ and AAK held a technical meeting. The purpose of that meeting was to review the CAP development and implementation by CAC KZ and AAK, as well as the associated actions undertaken by them to ensure effective compliance of their safety oversight system with the relevant international safety standards.
- (33) Based on the submitted CAP and on the discussions and evidence provided during the technical meeting, it was noted that progress has been made in terms of addressing the observations made during the on-site assessment visit. It is apparent that all of the observations have been addressed to some degree, and that some can be considered closed.

⁽⁸⁾ Commission Implementing Regulation (EU) 2016/2214 of 8 December 2016 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are subject to an operating ban within the Union (OJ L 334, 9.12.2016, p. 6).

- (34) The meeting showed that the CAC KZ and AAK still need to provide the Commission with further clarifications and evidence regarding certain actions and measures taken. The Commission also asked CAC KZ and AAK to review the CAP by further developing the root cause analysis of the safety deficiencies identified during the Union on-site assessment visit, with the aim to discuss it at the next technical meeting.
- (35) As a follow up to the EU Air Safety Committee's deliberations of November 2021, and confirmed during the April 2022 technical meeting, the Commission invited CAC KZ, AAK, and the air carrier *Air Astana* to a hearing before the EU Air Safety Committee on 17 May 2022.
- (36) At the hearing, CAC KZ and AAK provided the Commission and the EU Air Safety Committee with an overview of the system put in place to ensure safety oversight of the air carriers certified in Kazakhstan. They explained the Kazakh national safety development plan, which includes measures to improve the effectiveness of Kazakh air transport, including the effective implementation of the relevant international safety standards. Furthermore, AAK reported on the latest developments regarding its organisational structure, the size of the aviation industry in Kazakhstan, as well as the results of the ICAO Coordinated Validation Mission carried out in August 2021.
- (37) Underlining their commitment for continued improvement, CAC KZ and AAK provided the Commission and the EU Air Safety Committee with a comprehensive and detailed overview of the implementation of the CAP developed on the basis of the results of the Union on-site assessment visit of October 2021. This included the strategic objectives defined for the future, such as amendments to the Kazakh legal framework, AAK's manuals and procedures, the continuation of the improvements of its QMS, and the further effective implementation of the relevant international safety standards.
- (38) During the hearing, CAC KZ and AAK committed to keeping the Commission informed about the future actions to be taken with respect to the remaining observations made during the 2021 Union on-site assessment visit. Furthermore, they committed to a continued safety dialogue, including through the provision of relevant safety information and through additional meetings, at least twice a year, or when deemed necessary by the Commission.
- (39) Evidence indicates that the measures undertaken by CAC KZ and AAK already contribute to strengthening their capabilities to oversee the aviation activities in Kazakhstan. However, further improvements are needed as regards their ability to oversee that operations by air carriers certified in Kazakhstan are conducted in accordance with the relevant international safety standards, including by ensuring that appropriate resources for such safety oversight activities are assured.
- (40) On the basis of the information presented, it appears that since October 2021 CAC KZ and AAK have made noteworthy progress in the implementation of the relevant international safety standards. The Commission and the Agency noted their intent to further support CAC KZ and AAK with their efforts to further strengthen the aviation safety system in Kazakhstan.
- (41) During the hearing, the air carrier *Air Astana* gave an overview of its current fleet, and of the available resources and facilities. It described its robust and well-developed Safety Management System ('SMS') and QMS. The air carrier noted that it uses a set of software tools in order to integrate the safety, quality, and risk management data, including the fatigue risk management system.
- (42) When queried by the EU Air Safety Committee, the air carrier also debriefed on the oversight activities that AAK has performed on *Air Astana* in 2021-2022, and confirmed improvements in its interaction with the CAC KZ and AAK.
- (43) Based on its deliberations, the EU Air Safety Committee came to the conclusion that particular attention should be given to the continuous monitoring of the safety situation and developments in Kazakhstan, including through regular progress reporting from CAC KZ and AAK, and the possibility of inviting them for another hearing at a future meeting of the EU Air Safety Committee.

- (44) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers from Kazakhstan.
- (45) Member States should continue verifying the effective compliance of air carriers certified in Kazakhstan with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (46) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Moldova

- (47) In November 2021, air carriers from Moldova, were removed from Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2021/2070 ⁽⁹⁾, with the exception of *Air Moldova*, *Aerotranscargo*, and *Fly One*, which have never been included in either Annex A or B.
- (48) By letter of 31 March 2022, the Civil Aviation Authority of Moldova ('CAAM') provided information and an update on the safety oversight activities for the period from November 2021 to March 2022. In addition to the update on the CAP developed on the basis of the Union on-site assessment visit in September 2021, the information provided by CAAM also included updates with respect to the latest amendments to the Moldovan national aviation legislative framework.
- (49) The Commission, having examined the information and documentation received, considers that the remaining open observations, stemming from the September 2021 on-site assessment visit, have been successfully addressed and can be closed. In view of the progress made, the Commission considers it sufficient that CAAM sends an annual update until such that it may be decided otherwise.
- (50) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers from Moldova.
- (51) Member States should continue verifying the effective compliance of air carriers certified in Moldova with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.
- (52) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Pakistan

- (53) In March 2007, *Pakistan International Airlines* was included in Annex B to Regulation (EC) No 474/2006 by Commission Regulation (EC) No 235/2007 ⁽¹⁰⁾, and subsequently removed in November 2007 by Commission Regulation (EC) No 1400/2007 ⁽¹¹⁾.
- (54) On 24 June 2020, a statement from the Pakistan Federal Minister for Aviation revealed that a high number of pilot licenses, issued by the Pakistan Civil Aviation Authority ('PCAA'), were obtained by fraudulent means.

⁽⁹⁾ Commission Implementing Regulation (EU) 2021/2070 of 25 November 2021 amending Regulation (EC) No 474/2006 as regards the list of air carriers, which are banned from operating or are subject to operational restrictions within the Union (OJ L 421, 26.11.2021, p. 31).

⁽¹⁰⁾ Commission Regulation (EC) No 235/2007 of 5 March 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 66, 6.3.2007, p. 3).

⁽¹¹⁾ Commission Regulation (EC) No 1400/2007 of 28 November 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 311, 29.11.2007, p. 12)

- (55) That event, and the apparent lack of effective safety oversight by the PCAA, led the Agency to suspend the TCO authorisations of *Pakistan International Airlines* and *Vision Air* with effect from 1 July 2020.
- (56) On 1 July 2020, the Commission opened consultations with PCAA pursuant to Article 3(2) of Regulation (EC) No 473/2006. In that context, the Commission, in cooperation with the Agency and Member States, has organised a number of technical meetings with PCAA on respectively 9 July and 25 September 2020, 15 and 16 March 2021, 15 October 2021, and on 16 March 2022.
- (57) During those meetings, various issues were discussed, in particular the oversight of Pakistan-certified air carriers, including their SMS. The Commission requested information and evidence to verify whether a similar situation is not prevalent in other domains, such as cabin crew licensing, the licensing of maintenance engineers, or the certification of air carriers.
- (58) The information exchanged with PCAA on 16 March 2022 focussed on the outcome of the recent ICAO Universal Safety Oversight Audit Programme ('USOAP') visit. The Commission highlighted that due consideration will be given to the content of the audit report in order to determine the next steps of its own Air Safety List consultation process. During the meeting PCAA provided an overview of key aspects of the report, and committed to sharing the report with the Commission when finalised.
- (59) Upon receipt of the report, the Commission has been able to note that it does not contain any indication of areas requiring immediate remedial action. Nevertheless, whereas the report does indicate that most of the elements to discharge PCAA's responsibilities are there, it notes the need for PCAA to amend, supplement, or improve guidance and procedures, notably in the areas of pilot licensing. Furthermore, it notes the need for Pakistan's national legislation to be improved by incorporating provisions on enforcement policy and unrestricted access of inspection personnel to ensure an effective oversight.
- (60) On the basis of available information and exchanges with PCAA, the Commission acknowledges PCAA's efforts in adopting a CAP to address the identified safety deficiencies. The Commission, with the assistance of the Agency and Member States, notes that, after the ICAO USOAP visit, Pakistan is undergoing a major development process, including changes to its primary aviation legislation.
- (61) On this basis, the Commission, for the purpose of determining whether further action is required pursuant to Regulation (EC) No 2111/2005, will continue to engage with PCAA, and monitor the progress made to address the safety oversight situation in Pakistan. Through these continuous monitoring activities a determination will be made as to when to carry out a Union on-site assessment visit.
- (62) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers from Pakistan.
- (63) Member States should continue verifying the effective compliance of air carriers certified in Pakistan with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.
- (64) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Russia

- (65) On 8 April 2022, air carriers from Russia, which had operated one or more of the aircraft mentioned in recital 4 or 5 of Commission Implementing Regulation (EU) 2022/594 ⁽¹²⁾, were included in Annex A to Regulation (EC) No 474/2006, by Implementing Regulation (EU) 2022/594.
- (66) On 28 April 2022, the Russian Federal Air Transport Agency ('FATA') informed the Commission that it considers any allegations of violations of the international civil aviation standards, as well as any safety concerns referred to in Implementing Regulation (EU) 2022/594, unfounded. FATA did not, however, provide any information to support its statement.
- (67) As part of its continuous monitoring activities, the Commission has determined that there is evidence that the air carrier *I Fly* has entered aircraft mentioned in recital 5 of Implementing Regulation (EU) 2022/594 in the aircraft registry of Russia, and that they have knowingly operated these aircraft in breach of the relevant international safety standards. The entry of the aircraft on the registry of Russia has been done without the consent of the owners, and without subsequent safety related collaboration of the Irish Aviation Authority, as the recognised State of Registry for these aircraft.
- (68) In accordance with Implementing Regulation (EU) 2022/594 and the common criteria in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Russia, the list of air carriers, which are subject to an operating ban within the Union should be amended to include *I Fly* in Annex A to Regulation (EC) No 474/2006.
- (69) Member States should continue verifying the effective compliance of air carriers certified by FATA with the relevant international safety standards, through prioritisation of ramp inspections of those air carriers pursuant to Regulation (EU) No 965/2012.

Air carriers from South Sudan

- (70) Air carriers certified in South Sudan have never been included in Annex A or B to Regulation (EC) No 474/2006.
- (71) Four fatal accidents, and several other accidents and serious incidents, have occurred in South Sudan in the last four years, often involving aircraft with suspicious registration marks.
- (72) On 26 March 2021, the Commission opened formal consultations with the South Sudan Civil Aviation Authority ('SSCAA') pursuant to Article 3(2) of Regulation (EC) No 473/2006.
- (73) In the ensuing exchange of correspondence, SSCAA communicated that the Air Operator Certificate ('AOC') of *South Sudan Supreme Airlines*, whose aircraft was involved in a fatal accident, was suspended, and that due to suspicions related to the registration of the aircraft involved in that accident, SSCAA was reviewing all aircraft operators and AOCs in the country. Also, SSCAA communicated that improvement actions were ongoing in the development and review of Regulations, Manuals and Training. Documents that include information regarding SSCAA's Inspection, Surveillance and Audit Programme, as well as reports on reviews of certain air carriers and on foreign registered aircraft operating in South Sudan, were provided on 5 November 2021.
- (74) On 28 March 2022, SSCAA communicated its answers to the questionnaire sent by the Commission on 26 March 2021. According to this, the SSCAA has yet to develop and rollout an effective oversight system. Also, SSCAA notes that, whereas it has not issued any licence or AOC, and that there are no aircraft registered in the country, SSCAA has issued air-operating permits to foreign registered aircraft to operate in South Sudan. There is no evidence of any oversight activity leading to the issuance of such permits or of the relevant continuous monitoring.

⁽¹²⁾ Commission Implementing Regulation (EU) 2022/594 of 8 April 2022 amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union (OJ L 114, 12.4.2022, p. 49).

- (75) On 22 February 2022, the Commission informed SSCAA of its intention to put the review of the oversight situation of civil aviation in South Sudan on the agenda of the next meeting of the EU Air Safety Committee, and invited SSCAA to a hearing before the EU Air Safety Committee on 18 May 2022.
- (76) At the hearing, SSCAA provided the Commission and the EU Air Safety Committee with an overview of its organisational structure, and information regarding the size of the aviation industry in South Sudan. It described the functions of the different SSCAA Directorates and their responsibilities, and provided general information on the staffing of the authority. It explained that SSCAA is still heavily dependent on the support of the East African Community Civil Aviation Safety and Security Oversight Agency (EAC-CASSOA) for the establishment of civil aviation regulations, and for the development of an effective oversight process. In this regard, SSCAA noted that any assistance and support to its efforts would be welcome.
- (77) SSCAA confirmed that it has not issued any AOC, and it has not yet established an aircraft registry. However, SSCAA informed that, following a training that EAC-CASSOA will provide from 23 May 2022, it expects to reach the objective of establishing an aircraft registry, and of achieving a capability of certifying air carriers by means of the 5-phase certification process as per ICAO guidance.
- (78) SSCAA informed the Commission and the EU Air Safety Committee that it has issued 24 air operating permits to foreign air carriers, and that some of these authorised air carriers conduct domestic flights in the country. It would appear that this is the only certification activity conducted by SSCAA. SSCAA described the process for the issuance of such permits, by means of a validation of the AOCs, which comprises the inspection of documentation and the physical check of aircraft. However, this information was provided during the hearing only, and it was not possible to verify how the validation process is conducted.
- (79) During the hearing, SSCAA also provided an example of enforcement action taken against a foreign air carrier by revoking the operating permit when it found out that the air carrier's AOC had been revoked by its competent authority.
- (80) The Commission and the EU Air Safety Committee took note that there is no air carrier for which SSCAA has regulatory oversight responsibilities, since it has not issued any AOC, and that all air operations in the country are conducted by air carriers whose AOC have been issued by foreign authorities. As a consequence, taking into account the common criteria set out in the Annex to Regulation (EC) No 2111/2005, there is no air carrier certified by SSCAA that might qualify for action at Union level.
- (81) Furthermore, the Commission and the EU Air Safety Committee took note of SSCAA indications that it does not intend to issue any AOC until it has reached certification and oversight capabilities, which would make it able to implement and enforce the relevant international safety standard.
- (82) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from South Sudan, there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union.
- (83) As part of its continuous monitoring activities, the Commission will continue to closely follow the safety situation in South Sudan. The EU Air Safety Committee came to the conclusion that particular attention should be given to the safety situation and developments in South Sudan, and SSCAA should be requested to provide regular reports regarding the progress made with respect to the establishment of civil aviation regulations, the development of an effective safety oversight process, and the capacity to issue AOCs. Should the Commission become aware of an imminent safety risk resulting from a non-compliance with the relevant international safety standards, such as the issuance of an AOC in the absence of an adequate certification and oversight capability of the SSCAA, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005, such as the imposition of an operating ban on the air carriers concerned and their inclusion in Annex A to Regulation (EC) No 474/2006.
- (84) Regulation (EC) No 474/2006 should therefore be amended accordingly.

- (85) Articles 5 and 6 of Regulation (EC) No 2111/2005 recognise the need for decisions to be taken swiftly and, where appropriate, urgently, given the safety implications. It is therefore essential, for the protection of sensitive information and the traveling public, that any decisions in the context of updating the list of air carriers which are subject to an operating ban or restriction within the Union, are published and enter into force immediately after their adoption.
- (86) The measures provided for in this Regulation are in accordance with the opinion of the EU Air Safety Committee established by Article 15 of Regulation (EC) No 2111/2005,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 474/2006 is amended as follows:

- (1) Annex A is replaced by the text in Annex I to this Regulation;
- (2) Annex B is replaced by the text in Annex II 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*.

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

Done at Brussels, 1 June 2022.

*For the Commission,
On behalf of the President,
Adina VĂLEAN
Member of the Commission*

ANNEX I

‘ANNEX A

LIST OF AIR CARRIERS WHICH ARE BANNED FROM OPERATING WITHIN THE UNION, WITH
EXCEPTIONS ⁽¹⁾

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate (“AOC”) Number or Operating Licence Number	ICAO three letter designator	State of the Operator
AVIOR AIRLINES	ROI-RNR-011	ROI	Venezuela
BLUE WING AIRLINES	SRBWA-01/2002	BWI	Suriname
IRAN ASEMAN AIRLINES	FS-102	IRC	Iran
IRAQI AIRWAYS	001	IAW	Iraq
MED-VIEW AIRLINE	MVA/AOC/10-12/05	MEV	Nigeria
AIR ZIMBABWE (PVT)	177/04	AZW	Zimbabwe
All air carriers certified by the authorities with responsibility for regulatory oversight of Afghanistan, including			Afghanistan
ARIANA AFGHAN AIRLINES	AOC 009	AFG	Afghanistan
KAM AIR	AOC 001	KMF	Afghanistan
All air carriers certified by the authorities with responsibility for regulatory oversight of Angola, with the exception of TAAG Angola Airlines and Heli Malongo, including			Angola
AEROJET	AO-008/11-07/17 TEJ	TEJ	Angola
GUICANGO	AO-009/11-06/17 YYY	Unknown	Angola
AIR JET	AO-006/11-08/18 MBC	MBC	Angola
BESTFLYA AIRCRAFT MANAGEMENT	AO-015/15-06/17YYY	Unknown	Angola
HELIANG	AO 007/11-08/18 YYY	Unknown	Angola
SJL	AO-014/13-08/18YYY	Unknown	Angola
SONAIR	AO-002/11-08/17 SOR	SOR	Angola
All air carriers certified by the authorities with responsibility for regulatory oversight of Armenia, including			Armenia
AIRCOMPANY ARMENIA	AM AOC 065	NGT	Armenia
ARMENIA AIRWAYS	AM AOC 063	AMW	Armenia
ARMENIAN HELICOPTERS	AM AOC 067	KAV	Armenia

⁽¹⁾ Air carriers listed in Annex A could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

FLYONE ARMENIA	AM AOC 074		Armenia
NOVAIR	AM AOC 071	NAI	Armenia
SHIRAK AVIA	AM AOC 072	SHS	Armenia
SKYBALL	AM AOC 073	N/A	Armenia
All air carriers certified by the authorities with responsibility for regulatory oversight of Congo (Brazzaville), including			Congo (Brazzaville)
CANADIAN AIRWAYS CONGO	CG-CTA 006	TWC	Congo (Brazzaville)
EQUAFLIGHT SERVICES	CG-CTA 002	EKA	Congo (Brazzaville)
EQUAJET	RAC06-007	EKJ	Congo (Brazzaville)
TRANS AIR CONGO	CG-CTA 001	TSG	Congo (Brazzaville)
SOCIETE NOUVELLE AIR CONGO	CG-CTA 004	Unknown	Congo (Brazzaville)
All air carriers certified by the authorities with responsibility for regulatory oversight of Democratic Republic of Congo (DRC), including			Democratic Republic of Congo (DRC)
AIR FAST CONGO	AAC/DG/OPS-09/03	Unknown	Democratic Republic of Congo (DRC)
AIR KATANGA	AAC/DG/OPS-09/08	Unknown	Democratic Republic of Congo (DRC)
BUSY BEE CONGO	AAC/DG/OPS-09/04	Unknown	Democratic Republic of Congo (DRC)
COMPAGNIE AFRICAINE D'AVIATION (CAA)	AAC/DG/OPS-09/02	Unknown	Democratic Republic of Congo (DRC)
CONGO AIRWAYS	AAC/DG/OPS-09/01	Unknown	Democratic Republic of Congo (DRC)
KIN AVIA	AAC/DG/OPS-09/10	Unknown	Democratic Republic of Congo (DRC)
MALU AVIATION	AAC/DG/OPS-09/05	Unknown	Democratic Republic of Congo (DRC)
SERVE AIR CARGO	AAC/DG/OPS-09/07	Unknown	Democratic Republic of Congo (DRC)

SWALA AVIATION	AAC/DG/OPS-09/06	Unknown	Democratic Republic of Congo (DRC)
MWANT JET	AAC/DG/OPS-09/09	Unknown	Democratic Republic of Congo (RDC)
All air carriers certified by the authorities with responsibility for regulatory oversight of Djibouti, including			Djibouti
DAALLO AIRLINES	Unknown	DAO	Djibouti
All air carriers certified by the authorities with responsibility for regulatory oversight of Equatorial Guinea, including			Equatorial Guinea
CEIBA INTERCONTINENTAL	2011/0001/MTTCT/DGAC/SOPS	CEL	Equatorial Guinea
CRONOS AIRLINES	2011/0004/MTTCT/DGAC/SOPS	Unknown	Equatorial Guinea
All air carriers certified by the authorities with responsibility for regulatory oversight of Eritrea, including			Eritrea
ERITREAN AIRLINES	AOC No 004	ERT	Eritrea
NASAIR ERITREA	AOC No 005	NAS	Eritrea
All air carriers certified by the authorities with responsibility for regulatory oversight of Kyrgyzstan, including			Kyrgyzstan
AEROSTAN	08	BSC	Kyrgyzstan
AIR COMPANY AIR KG	50	Unknown	Kyrgyzstan
AIR MANAS	17	MBB	Kyrgyzstan
AVIA TRAFFIC COMPANY	23	AVJ	Kyrgyzstan
FLYSKY AIRLINES	53	FSQ	Kyrgyzstan
HELI SKY	47	HAC	Kyrgyzstan
KAP.KG AIRCOMPANY	52	KGS	Kyrgyzstan
SKY KG AIRLINES	41	KGK	Kyrgyzstan
TEZ JET	46	TEZ	Kyrgyzstan
VALOR AIR	07	VAC	Kyrgyzstan
All air carriers certified by the authorities with responsibility for regulatory oversight of Liberia.			Liberia

All air carriers certified by the authorities with responsibility for regulatory oversight of Libya, including			Libya
AFRIQYAH AIRWAYS	007/01	AAW	Libya
AIR LIBYA	004/01	TLR	Libya
AL MAHA AVIATION	030/18	Unknown	Libya
BERNIQ AIRWAYS	032/21	BNL	Libya
BURAQ AIR	002/01	BRQ	Libya
GLOBAL AIR TRANSPORT	008/05	GAK	Libya
HALA AIRLINES	033/21	HTP	Libya
LIBYAN AIRLINES	001/01	LAA	Libya
LIBYAN WINGS AIRLINES	029/15	LWA	Libya
PETRO AIR	025/08	PEO	Libya
All air carriers certified by the authorities with responsibility for regulatory oversight of Nepal, including			Nepal
AIR DYNASTY HELI. S.	035/2001	Unknown	Nepal
ALTITUDE AIR	085/2016	Unknown	Nepal
BUDDHA AIR	014/1996	BHA	Nepal
FISHTAIL AIR	017/2001	Unknown	Nepal
SUMMIT AIR	064/2010	Unknown	Nepal
HELI EVEREST	086/2016	Unknown	Nepal
HIMALAYA AIRLINES	084/2015	HIM	Nepal
KAILASH HELICOPTER SERVICES	087/2018	Unknown	Nepal
MAKALU AIR	057A/2009	Unknown	Nepal
MANANG AIR PVT	082/2014	Unknown	Nepal
MOUNTAIN HELICOPTERS	055/2009	Unknown	Nepal
PRABHU HELICOPTERS	081/2013	Unknown	Nepal
NEPAL AIRLINES CORPORATION	003/2000	RNA	Nepal
SAURYA AIRLINES	083/2014	Unknown	Nepal
SHREE AIRLINES	030/2002	SHA	Nepal
SIMRIK AIR	034/2000	Unknown	Nepal
SIMRIK AIRLINES	052/2009	RMK	Nepal
SITA AIR	033/2000	Unknown	Nepal
TARA AIR	053/2009	Unknown	Nepal
YETI AIRLINES	037/2004	NYT	Nepal

The following air carriers certified by the authorities with responsibility for regulatory oversight of Russia			Russia
AURORA AIRLINES	486	SHU	Russia
AVIACOMPANY "AVIASTAR-TU" CO. LTD	458	TUP	Russia
IZHAVIA	479	IZA	Russia
JOINT STOCK COMPANY "AIR COMPANY 'YAKUTIA'"	464	SYL	Russia
JOINT STOCK COMPANY "RUSJET"	498	RSJ	Russia
JOINT STOCK COMPANY "UVT AERO"	567	UVT	Russia
JOINT STOCK COMPANY SIBERIA AIRLINES	31	SBI	Russia
JOINT STOCK COMPANY SMARTAVIA AIRLINES	466	AUL	Russia
JOINT-STOCK COMPANY "IRAERO" AIRLINES	480	IAE	Russia
JOINT-STOCK COMPANY "URAL AIRLINES"	18	SVR	Russia
JOINT-STOCK COMPANY ALROSA AIR COMPANY	230	DRU	Russia
JOINT-STOCK COMPANY NORDSTAR AIRLINES	452	TYA	Russia
JS AVIATION COMPANY "RUSLINE"	225	RLU	Russia
JSC YAMAL AIRLINES	142	LLM	Russia
LLC "NORD WIND"	516	NWS	Russia
LLC "AIRCOMPANY IKAR"	36	KAR	Russia
LTD I FLY	533	RSY	Russia
POBEDA AIRLINES LIMITED LIABILITY COMPANY	562	PBD	Russia
PUBLIC JOINT STOCK COMPANY "AEROFLOT - RUSSIAN AIRLINES"	1	AFL	Russia
ROSSIYA AIRLINES, JOINT STOCK COMPANY	2	SDM	Russia
SKOL AIRLINE LLC	228	CDV	Russia
UTAIR AVIATION, JOINT-STOCK COMPANY	6	UTA	Russia
All air carriers certified by the authorities with responsibility for regulatory oversight of Sao Tome and Principe, including			Sao Tome and Principe

AFRICA'S CONNECTION	10/AOC/2008	ACH	Sao Tome and Principe
STP AIRWAYS	03/AOC/2006	STP	Sao Tome and Principe
All air carriers certified by the authorities with responsibility for regulatory oversight of Sierra Leone			Sierra Leone
All air carriers certified by the authorities with responsibility for regulatory oversight of Sudan, including			Sudan
ALFA AIRLINES SD	54	AAJ	Sudan
BADR AIRLINES	35	BDR	Sudan
BLUE BIRD AVIATION	11	BLB	Sudan
ELDINDER AVIATION	8	DND	Sudan
GREEN FLAG AVIATION	17	GNF	Sudan
HELEJETIC AIR	57	HJT	Sudan
KATA AIR TRANSPORT	9	KTV	Sudan
KUSH AVIATION CO.	60	KUH	Sudan
NOVA AIRWAYS	46	NOV	Sudan
SUDAN AIRWAYS CO.	1	SUD	Sudan
SUN AIR	51	SNR	Sudan
TARCO AIR	56	TRQ	Sudan'

ANNEX II

ANNEX B

LIST OF AIR CARRIERS WHICH ARE SUBJECT TO OPERATIONAL RESTRICTIONS WITHIN THE UNION ⁽¹⁾

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ("AOC") Number	ICAO three letter designator	State of the Operator	Aircraft type restricted	Registration mark(s) and, when available, construction serial number(s) of restricted aircraft	State of registry
IRAN AIR	FS100	IRA	Iran	All aircraft of type Fokker F100 and of type Boeing B747	Aircraft of type Fokker F100 as mentioned on the AOC; aircraft of type Boeing B747 as mentioned on the AOC	Iran
AIR KORYO	GAC-AOC/ KOR-01	KOR	North Korea	All fleet with the exception of: 2 aircraft of type TU- 204.	All fleet with the exception of: P-632, P-633.	North Korea'

⁽¹⁾ Air carriers listed in Annex B could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

DECISIONS

COUNCIL DECISION (EU) 2022/863

of 24 May 2022

on the position to be taken on behalf of the European Union within the EU-CTC Joint Committee established by the Convention of 20 May 1987 on a common transit procedure as regards amendments to that Convention

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), first subparagraph, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Convention on a common transit procedure ('the Convention') ⁽¹⁾ was concluded by the Union by means of Council Decision 87/415/EEC ⁽²⁾ and entered into force on 1 January 1988.
- (2) Pursuant to Article 15(3), point (a), of the Convention, the Joint Committee established pursuant to Article 14(1) of the Convention (the 'EU-CTC Joint Committee') may adopt, by means of decisions, amendments to the Appendices to the Convention.
- (3) The EU-CTC Joint Committee is to adopt a Decision on the amendment of Appendices I, IIIa and IV to the Convention in early 2022.
- (4) It is appropriate to establish the position to be taken on the Union's behalf in the EU-CTC Joint Committee, as the Decision will have legal effects in the Union. As the EU-CTC Joint Committee usually meets only once a year, it is appropriate to allow the Union's position to be expressed either at an upcoming meeting or by means of a written procedure.
- (5) Annex B to Commission Delegated Regulation (EU) 2015/2446 ⁽³⁾ and Annex B to Commission Implementing Regulation (EU) 2015/2447 ⁽⁴⁾ have been amended by Commission Delegated Regulation (EU) 2021/234 ⁽⁵⁾ and Commission Implementing Regulation (EU) 2021/235 ⁽⁶⁾, respectively. Those Annexes lay down the common data requirements, formats and codes for the transit declaration, in order to better harmonise the common data elements for the storage of information and for its exchange between customs authorities, as well as between customs authorities and economic operators. Those amendments were necessary to ensure inter-operability between the customs electronic systems used for the different types of declarations and notifications. Therefore, Appendix IIIa to the Convention, which mirrors Annex B to Delegated Regulation (EU) 2015/2446 and Annex B to Implementing Regulation (EU) 2015/2447, should be amended accordingly.

⁽¹⁾ OJ L 226, 13.8.1987, p. 2.

⁽²⁾ Council Decision 87/415/EEC of 15 June 1987 concerning the conclusion of a Convention between the European Community, the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Kingdom of Norway, the Kingdom of Sweden and the Swiss Confederation on a common transit procedure (OJ L 226, 13.8.1987, p. 1).

⁽³⁾ Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code (OJ L 343, 29.12.2015, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

⁽⁵⁾ Commission Delegated Regulation (EU) 2021/234 of 7 December 2020 amending Delegated Regulation (EU) 2015/2446 as regards common data requirements, and Delegated Regulation (EU) 2016/341 as regards the codes to be used in certain forms (OJ L 63, 23.2.2021, p. 1).

⁽⁶⁾ Commission Implementing Regulation (EU) 2021/235 of 8 February 2021 amending Implementing Regulation (EU) 2015/2447 as regards formats and codes of common data requirements, certain rules on surveillance and the competent customs office for placing goods under a customs procedure (OJ L 63, 23.2.2021, p. 386).

- (6) The amendments to Appendix IIIa to the Convention require the renumbering of paragraphs and sections. Therefore, references to Appendix IIIa in Appendix I to the Convention should be aligned with the new numbering.
- (7) Appendix IV to the Convention sets out the rules on mutual assistance for the recovery of claims. Those rules are important as they safeguard the financial interests of the common transit countries, of the Union and of the Member States. Those rules should be revised in order to align them with the respective Union rules,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in an upcoming meeting of the EU-CTC Joint Committee or by means of a written procedure in the EU-CTC Joint Committee shall be based on the draft Decision of the EU-CTC Joint Committee attached to this Decision ⁽⁷⁾.

Article 2

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

Done at Brussels, 24 May 2022.

For the Council
The President
B. LE MAIRE

⁽⁷⁾ See document ST 7680/22 ADD 1 at <http://register.consilium.europa.eu>

COUNCIL DECISION (EU) 2022/864**of 24 May 2022****amending Decision 1999/70/EC concerning the external auditors of the national central banks, as regards the external auditors of Lietuvos bankas**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Protocol No 4 on the Statute of the European System of Central Banks and of the European Central Bank, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, and in particular Article 27.1 thereof,

Having regard to the Recommendation of the European Central Bank of 29 March 2022 to the Council of the European Union on the external auditors of Lietuvos bankas (ECB/2022/15) ⁽¹⁾,

Whereas:

- (1) The accounts of the European Central Bank (ECB) and of the national central banks of the Member States whose currency is the euro are to be audited by independent external auditors recommended by the Governing Council of the ECB and approved by the Council of the European Union.
- (2) The mandate of the current external auditors of Lietuvos bankas, Ernst & Young Baltic UAB, ended following the audit for the financial year 2021. It is therefore necessary to appoint external auditors from the financial year 2022.
- (3) Lietuvos bankas has selected UAB ROSK Consulting as its external auditors for the financial years 2022 to 2024.
- (4) The Governing Council of the ECB recommended that UAB ROSK Consulting be appointed as the external auditors of Lietuvos bankas for the financial years 2022 to 2024.
- (5) Following the recommendation of the Governing Council of the ECB, Council Decision 1999/70/EC ⁽²⁾ should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 1 of Decision 1999/70/EC, paragraph 19 is replaced by the following:

‘19. UAB ROSK Consulting are hereby approved as the external auditors of Lietuvos bankas for the financial years 2022 to 2024.’.

Article 2

This Decision shall take effect on the date of its notification.

⁽¹⁾ OJ C 153, 7.4.2022, p. 7.

⁽²⁾ Council Decision 1999/70/EC of 25 January 1999 concerning the external auditors of the national central banks (OJ L 22, 29.1.1999, p. 69).

Article 3

This Decision is addressed to the European Central Bank.

Done at Brussels, 24 May 2022.

For the Council

The President

B. LE MAIRE

COUNCIL IMPLEMENTING DECISION (EU) 2022/865**of 24 May 2022****authorising the Czech Republic to introduce a special measure derogating from Article 287 of Directive 2006/112/EC on the common system of value added tax**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax ⁽¹⁾, and in particular Article 395(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Article 287, point (7), of Directive 2006/112/EC allows the Czech Republic (Czechia) to exempt from value added tax (VAT) taxable persons whose annual turnover is no higher than the equivalent in national currency of EUR 35 000 at the conversion rate on the day of its accession.
- (2) By letter registered with the Commission on 23 November 2021, Czechia requested an authorisation to introduce a special measure derogating from Article 287, point (7), of Directive 2006/112/EC and thus to exempt from VAT taxable persons whose annual turnover is no higher than the equivalent in national currency of EUR 85 000 at the conversion rate on the day of its accession ('the special measure'). The special measure would be applicable until 31 December 2024, the date by which Member States are to transpose Council Directive (EU) 2020/285 ⁽²⁾. It follows from that Directive that, from 1 January 2025, Member States will be allowed to exempt from VAT the supply of goods and services made by taxable persons whose annual turnover in a given Member State does not exceed a threshold of EUR 85 000 or the equivalent in national currency.
- (3) Pursuant to Article 395(2), second subparagraph, of Directive 2006/112/EC, the Commission transmitted the request made by Czechia to the other Member States by letter dated 16 December 2021. By letter dated 20 December 2021, the Commission notified Czechia that it had all the information necessary for the appraisal of the request.
- (4) The special measure is in line with Directive (EU) 2020/285, which seeks to reduce the compliance burden of small enterprises and avoid distortions of competition in the internal market.
- (5) The special measure will remain optional for taxable persons as they may still opt for the normal VAT arrangements pursuant to Article 290 of Directive 2006/112/EC.
- (6) According to the information provided by Czechia, the special measure will only have a negligible effect on the overall amount of tax revenue Czechia collects at the stage of final consumption.
- (7) Following the entry into force of Council Regulation (EU, Euratom) 2021/769 ⁽³⁾, there is to be no compensation calculation carried out by Czechia with regard to the VAT own resource statement for the financial year 2022 onwards.

⁽¹⁾ OJ L 347, 11.12.2006, p. 1.

⁽²⁾ Council Directive (EU) 2020/285 of 18 February 2020 amending Directive 2006/112/EC on the common system of value added tax as regards the special scheme for small enterprises and Regulation (EU) No 904/2010 as regards the administrative cooperation and exchange of information for the purpose of monitoring the correct application of the special scheme for small enterprises (OJ L 62, 2.3.2020, p. 13).

⁽³⁾ Council Regulation (EU, Euratom) 2021/769 of 30 April 2021 amending Regulation (EEC, Euratom) No 1553/89 on the definitive uniform arrangements for the collection of own resources accruing from value added tax (OJ L 165, 11.5.2021, p. 9).

- (8) Given that Czechia expects that the special measure will result in reduced VAT obligations and thus a reduction in the administrative burden and compliance costs for both small enterprises and the tax authorities, and given the lack of any major impact on the total VAT revenue generated, Czechia should be authorised to introduce the special measure.
- (9) The application of the special measure should be limited in time. The time limit should be sufficient to allow the Commission to evaluate the effectiveness and appropriateness of the threshold. Moreover, pursuant to Article 3(1) of Directive (EU) 2020/285, Member States are to adopt and publish, by 31 December 2024, the laws, regulations and administrative provisions necessary to comply with Article 1 of that Directive, which amends Directive 2006/112/EC and lays down simpler VAT rules for small enterprises, and apply those provisions from 1 January 2025. It is therefore appropriate to authorise Czechia to apply the special measure until 31 December 2024,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from Article 287, point (7), of Directive 2006/112/EC, Czechia is authorised to exempt from VAT taxable persons whose annual turnover is no higher than the equivalent in national currency of EUR 85 000 at the conversion rate on the day of its accession.

Article 2

This Decision shall take effect on the date of its notification.

It shall apply until 31 December 2024.

Article 3

This Decision is addressed to the Czech Republic.

Done at Brussels, 24 May 2022.

For the Council
The President
B. LE MAIRE

COMMISSION IMPLEMENTING DECISION (EU) 2022/866**of 25 May 2022****on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Primer PIP in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2022) 3318)***(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 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 36(3) thereof,

Whereas:

- (1) On 11 March 2016, the company Lanxess Deutschland GmbH ('the applicant') submitted an application to France for the mutual recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Primer PIP ('the biocidal product'). The biocidal product is a wood preservative of product-type 8 to be used for the preventive treatment against wood discolouring fungi, wood destroying basidiomycetes and wood boring beetles (larvae). The biocidal product is applied by manual dipping, automated dipping or automated spraying and contains as active substances propiconazole, IPBC and permethrin. Germany is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.
- (2) On 9 March 2020, pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group, indicating that the conditions of the authorisation set by Germany do not ensure that the biocidal product meets the requirement laid down in Article 19(1), point (b)(iii), of that Regulation. France considers that in order to ensure the safe handling of the biocidal product, wearing of personal protective equipment, consisting of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type-6 as specified in European Standard EN 13034, is required for application by manual dipping and automated spraying, wearing of personal protective equipment consisting of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by automated dipping, and wearing of chemical resistant gloves meeting the requirements of the European Standard EN 374 is required for subsequent manual processing of the freshly treated timber. According to France, the application of technical and organisational measures in accordance with Council Directive 98/24/EC ⁽²⁾ as a possible replacement for wearing personal protective equipment does not ensure an adequate protection if those measures are not specified and evaluated in the assessment of the biocidal product.
- (3) Germany considers that Directive 98/24/EC establishes the order of preference of different risk mitigation measures for protection of workers and prioritises the application of technical and organisational measures over wearing personal protection equipment for the use of the biocidal product. According to Germany, pursuant to that Directive the employer is to decide which technical and organisational measures are to be applied, and as there is a broad range of such measures, it is not feasible to describe and evaluate the measures in the authorisation of the biocidal product.
- (4) As no agreement was reached by the coordination group, on 28 October 2020 Germany referred the unresolved objection to the Commission pursuant to Article 36(1) of Regulation (EU) No 528/2012. It thereby provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. That statement was forwarded to the Member States concerned and the applicant.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

- (5) Article 2(3), points (b) and (c), of Regulation (EU) No 528/2012 provides that that Regulation is to be without prejudice to Council Directive 89/391/EEC ⁽⁷⁾ and Directive 98/24/EC.
- (6) Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 indicates as one of the criteria for granting an authorisation that the biocidal product has no unacceptable effects itself, or as a result of its residues, on the health of humans.
- (7) Point 9 of Annex VI to Regulation (EU) No 528/2012 states that the application of the common principles laid down in that Annex for the evaluation of dossiers for biocidal products referred to in Article 19(1), point (b), of that Regulation, when taken together with the other conditions set out in its Article 19, is to lead to the competent authorities or the Commission deciding whether or not a biocidal product is to be authorised. Such authorisation may include restrictions on the use of the biocidal product or other conditions.
- (8) Point 18(d) of Annex VI to Regulation (EU) No 528/2012 states that the risk assessment conducted for the product is to determine the measures necessary to protect humans, animals and the environment, both during the proposed normal use of the biocidal product and in a realistic worst-case situation.
- (9) Point 56(2) of Annex VI to Regulation (EU) No 528/2012 indicates that in establishing compliance with the criteria set out in Article 19(1), point (b), of that Regulation, one of the conclusions to which the evaluating body is to make, is that subject to specific conditions/restrictions the biocidal product can comply with the criteria.
- (10) Point 62 of Annex VI to Regulation (EU) No 528/2012 states that the evaluating body is, where appropriate, to conclude that the criterion under Article 19(1), point (b)(iii), of that Regulation can only be complied with by application of prevention and protection measures including the design of work processes, engineering controls, use of adequate equipment and materials, application of collective protection measures and, where exposure cannot be prevented by other means, application of individual protection measures including the wearing of personal protective equipment such as respirators, breathing-masks, overalls, gloves and goggles, in order to reduce exposure for professional operators.
- (11) However, point 62 of Annex VI to Regulation (EU) No 528/2012 does not provide that the assessment leading to the conclusion that the criterion under Article 19(1), point (b)(iii), of that Regulation can only be complied with by application of prevention and protection measures is to be done in accordance with Directive 98/24/EC. It also does not explicitly provide that that Directive would not apply. Therefore, it should not be inferred from those provisions that Directive 98/24/EC does not apply. In addition, the relevant obligations under Directive 98/24/EC are imposed on employers, not on the authorities of Member States.
- (12) Article 4 of Directive 98/24/EC provides that for the assessment of any risk to the safety and health of workers arising from the presence of chemical agents, employers are to obtain additional information needed from the supplier or from other readily available sources and that where appropriate, that information is to comprise the specific assessment concerning the risk to users established on the basis of Union legislation on chemical agents.
- (13) Article 6 of Directive 98/24/EC lays down prioritisation of the measures to be taken by the employer for the protection of workers from the risks related to chemical agents at work. Priority is to be given to replacement of the hazardous substance and when this is not possible, the risk from a hazardous chemical agent to the safety and health of workers at work needs to be reduced to a minimum by application of protection and prevention measures. If it is not possible to prevent exposure to the hazardous substance by other means, protection of the workers is to be ensured by applying individual protection measures including personal protective equipment.

⁽⁷⁾ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

- (14) Taking into account the methods of application of the biocidal product and the available information from the evaluating body, no such technical or organisational measures have been identified in the application for authorisation of the biocidal product, nor during the evaluation of that application.
- (15) The Commission therefore considers that the biocidal product meets the criterion laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012, provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: 'The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in the European Standard EN 13034 is required for application by manual dipping and automated spraying, wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by automated dipping, and wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work'.
- (16) However, if the applicant for authorisation identifies effective technical or organisational measures and the authorising authority agrees that such measures lead to an equivalent or higher level of exposure reduction, or the authorising authority itself identifies measures leading to an equivalent or higher level of exposure reduction, those measures should replace the wearing of personal protective equipment and should be specified in the authorisation and on the label of the biocidal product.
- (17) On 15 February 2021, the Commission provided the applicant with the opportunity to provide written comments in accordance with Article 36(2) of Regulation (EU) No 528/2012. The applicant did not provide comments.
- (18) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the case number BC-XP022475-16 in the Register for Biocidal Products meets the condition laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 provided that the following condition regarding its use is included in the authorisation and on the label of the biocidal product: 'The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and coverall of at least type 6 as specified in European Standard EN 13034 is required for application by manual dipping and automated spraying, wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for application by automated dipping, and wearing of chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) meeting the requirements of European Standard EN 374 is required for subsequent manual processing of the freshly treated timber. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.'

However, where the applicant for authorisation identifies technical or organisational measures and the authorising authority agrees that such measures achieve a level of exposure reduction equivalent to or higher than the reduction achieved by wearing the protective equipment referred to in the first paragraph, or the authorising authority itself identifies such measures leading to an equivalent or higher level of exposure reduction than the reduction achieved by wearing the protective equipment referred to in the first paragraph, those measures shall be used instead of that personal protective equipment and shall be specified in the authorisation and on the label of the biocidal product. In that case the obligation to include the condition regarding the use of the biocidal product laid down in the first paragraph shall not apply.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 25 May 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2022/867

of 1 June 2022

on the release of emergency oil stocks by Member States following the invasion of Ukraine

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Council Directive 2009/119/EC ⁽¹⁾ aims at ensuring a high level of security of oil supply in the Union through reliable and transparent mechanisms based on solidarity among Member States. In particular, it lays down rules and procedures to be applied in case of emergency. On 1st March and 1 April 2022, the IEA Governing Board decided coordinated oil emergency stockdraw plans to release 60 and 120 million barrels of oil, respectively ⁽²⁾.
- (2) The Commission and Member States discussed the opportunity, expected benefits and impact of IEA collective action at four meetings of the Oil Coordination Group (on 22 and 25 February and on 2 and 31st March). By letters of 4 March and 5 April 2022 addressed to the Oil Coordination Group, the Commission's services reminded Member States of the relevant provisions and obligations applicable under Union law.
- (3) Eighteen Member States (including two Member States not members of IEA) participated in IEA collective action and pledged voluntary contributions for approximately 40 million barrels of crude oil equivalent.
- (4) Emergency oil stocks held currently in the Union are at the lowest volume since 2013. Pursuant to Article 3 of Directive 2009/119/EC, they reflect the net imports of crude oil and petroleum products during 2020, which were unusually low, due to reduced consumption resulting from sanitary measures to fight the COVID-19 pandemic (confinement and reduced mobility). The volumes of crude oil and petroleum products needed to meet the new yearly stockholding obligation applicable as from 1 July 2022 for a 12-month-period, are expected to increase for some Member States by up to 30 %.
- (5) In the current situation of uncertainty concerning the evolution of the war in Ukraine, it is of utmost importance to restrain the demand for crude oil and petroleum products as much as possible and to avoid putting additional stress on the oil market. It is therefore not desirable for Member States to replenish in the short term those emergency oil stocks that are being released or will be released pursuant to Article 20 of Directive 2009/119/EC, unless there is a risk for their security of supply preparedness. It is however premature to set a definite time frame for the replenishment of the stocks released.
- (6) Member States should avoid purchasing additional crude oil and petroleum products in preparation for the upcoming new yearly stockholding obligation as from July 2022, which would necessarily increase the current demand for these commodities. With reference to Article 20(6) of Directive 2009/119/EC, the Commission will review the time frame within which Member States must bring their stocks back up to the minimum required levels, in light of the evolution of the current crisis.
- (7) The Commission consulted the Oil Coordination group on this Recommendation at the meeting held on 14 March 2021, where representatives of IEA's Secretariat participated,

⁽¹⁾ Council Directive 2009/119/EC of 14 September 2009 imposing an obligation on Member States to maintain minimum stocks of crude oil and/or petroleum products (OJ L 265, 9.10.2009, p. 9).

⁽²⁾ 277th and 279th extraordinary Governing Board meetings.

RECOMMENDS:

1. Member States should not bring their emergency oil stocks back up to the minimum levels required by Directive 2009/119/EC before 1 November 2022, insofar as this would not jeopardize their security of supply preparedness.
2. In consultation with the Oil Coordination Group and in coordination with the International Energy Agency, the Commission will review this Recommendation in order to set a date to apply the stockholding obligation, taking into account the evolution of the current crisis.

Done at Brussels, 1 June 2022.

For the Commission
Kadri SIMSON
Member of the Commission

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