

Official Journal of the European Union

L 185



English edition

Legislation

Volume 66

24 July 2023

Contents

I *Legislative acts*

REGULATIONS

- ★ **Regulation (EU) 2023/1524 of the European Parliament and of the Council of 20 July 2023 on temporary trade-liberalisation measures supplementing trade concessions applicable to products from the Republic of Moldova under the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part** 1
- ★ **Regulation (EU) 2023/1525 of the European Parliament and of the Council of 20 July 2023 on supporting ammunition production (ASAP)** 7

II *Non-legislative acts*

DIRECTIVES

- ★ **Commission Delegated Directive (EU) 2023/1526 of 16 May 2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in *in vitro* diagnostic medical devices ⁽¹⁾** 26

DECISIONS

- ★ **Council Decision (CFSP) 2023/1527 of 20 July 2023 extending the mandate of the European Union Special Representative in Kosovo and amending Decision (CFSP) 2020/1135** 30
- ★ **Council Decision (CFSP) 2023/1528 of 20 July 2023 amending Decision (CFSP) 2018/907 extending the mandate of the European Union Special Representative for the South Caucasus and the crisis in Georgia** 32

⁽¹⁾ Text with EEA relevance.

EN

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

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

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2023/1524 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 July 2023

on temporary trade-liberalisation measures supplementing trade concessions applicable to products from the Republic of Moldova under the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part

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 207(2) thereof,

Having regard to the proposal from the European Commission,

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

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part ⁽²⁾ (the 'Association Agreement'), constitutes the basis of the relationship between the Union and the Republic of Moldova. In accordance with Council Decision 2014/492/EU ⁽³⁾, Title V of the Association Agreement, which relates to trade and trade-related matters, has been applied provisionally since 1 September 2014, and entered into force on 1 July 2016 following ratification by all Member States.
- (2) The Association Agreement expresses the desire of the Parties to the Association Agreement (the 'Parties') to strengthen and widen relations in an ambitious and innovative way, to facilitate and achieve gradual economic integration, and to do so in compliance with the rights and obligations arising out of the World Trade Organization membership of the Parties.
- (3) Article 143 of the Association Agreement provides for the progressive establishment of a free trade area between the Parties in accordance with Article XXIV of the General Agreement on Tariffs and Trade 1994 (GATT 1994). To that end, Article 147 of the Association Agreement provides for the progressive elimination of customs duties in accordance with the Schedules included in Annex XV to the Association Agreement and for the possibility of accelerating and broadening the scope of such elimination.

⁽¹⁾ Position of the European Parliament of 11 July 2023 (not yet published in the Official Journal) and decision of the Council of 20 July 2023.

⁽²⁾ OJ L 260, 30.8.2014, p. 4.

⁽³⁾ Council Decision 2014/492/EU of 16 June 2014 on the signing, on behalf of the European Union, and provisional application of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part (OJ L 260, 30.8.2014, p. 1).

- (4) Russia's war of aggression against Ukraine, which has been ongoing since 24 February 2022, has a profoundly negative impact on the ability of the Republic of Moldova to trade with the rest of the world, in particular because exports from the Republic of Moldova rely on transit via Ukrainian territory and using Ukrainian infrastructure, which are currently largely unavailable. Under such critical circumstances and to mitigate the negative effects on the Republic of Moldova's economy of Russia's war of aggression against Ukraine, it is necessary to accelerate the development of closer economic relations between the Union and the Republic of Moldova and to provide quick support to the Republic of Moldova's economy. It is therefore necessary and appropriate to continue to stimulate trade flows and grant concessions in the form of trade-liberalisation measures for all products, in line with the acceleration of the elimination of customs duties on trade between the Union and the Republic of Moldova.
- (5) In accordance with Article 21(3) of the Treaty on European Union, the Union is to ensure consistency between the different areas of its external action. Pursuant to Article 207(1) of the Treaty on the Functioning of the European Union, the common commercial policy is to be conducted in the context of the principles and objectives of the Union's external action.
- (6) Regulation (EU) 2022/1279 of the European Parliament and of the Council ⁽⁴⁾ expires on 24 July 2023.
- (7) The trade-liberalisation measures established by this Regulation should take the following form: (i) the suspension of the application of the entry price system to fruit and vegetables; and (ii) the suspension of all tariff-rate quotas and import duties. Through those measures, the Union will deepen economic integration between the Republic of Moldova and the Union and temporarily provide appropriate economic support to the benefit of the Republic of Moldova and the economic operators that are affected by Russia's war of aggression against Ukraine.
- (8) In order to prevent fraud, the entitlement to the trade-liberalisation measures established by this Regulation should be conditional upon the Republic of Moldova having complied with all the relevant conditions for obtaining benefits under the Association Agreement, including the rules of origin of the products concerned and the procedures related thereto, as well as the Republic of Moldova's involvement in close administrative cooperation with the Union, as provided for by the Association Agreement.
- (9) The Republic of Moldova should abstain from introducing new duties or charges having equivalent effect and new quantitative restrictions or measures having equivalent effect for imports originating in the Union, from increasing existing levels of duties or charges or from introducing any other restrictions, unless clearly justified in the context of Russia's war of aggression against Ukraine. In the event that the Republic of Moldova fails to comply with any of those conditions, the Commission should be empowered to suspend temporarily all or part of the trade-liberalisation measures established by this Regulation.
- (10) Article 2 of the Association Agreement provides that, among other things, respect for democratic principles, human rights and fundamental freedoms as well as the countering of the proliferation of weapons of mass destruction, related materials and their means of delivery constitute essential elements of the Association Agreement. Under the same Article, the Parties commit in particular to the following general principles: respect for the principles of the rule of law and good governance, the fight against corruption, criminal activities, organised or otherwise, including those of transnational character, and terrorism, and respect for the principles of sustainable development and effective multilateralism. It is appropriate to introduce the possibility of temporarily suspending the trade-liberalisation measures provided for in this Regulation if the Republic of Moldova fails to respect either those essential elements or those general principles.

⁽⁴⁾ Regulation (EU) 2022/1279 of the European Parliament and of the Council of 18 July 2022 on temporary trade liberalisation measures supplementing trade concessions applicable to products from the Republic of Moldova under the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part (OJ L 195, 22.7.2022, p. 6).

- (11) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to temporarily suspend the trade-liberalisation measures provided for in this Regulation in cases where Union producers of like or directly competing products are adversely affected by imports under this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽⁹⁾.
- (12) Subject to an assessment of three months by the Commission based on the regular monitoring of the impact of this Regulation and launched either following a duly substantiated request from a Member State or at the Commission's own initiative, it is necessary to provide for the possibility to reintroduce the customs duties otherwise applicable under the Association Agreement for imports of any products falling under the scope of this Regulation which are adversely affecting the Union market for like or directly competing products.
- (13) The Commission's annual report on the implementation of the Deep and Comprehensive Free Trade Area, which is an integral part of the Association Agreement, should include a detailed assessment of the implementation of the trade-liberalisation measures established by this Regulation.
- (14) In light of the economic situation in the Republic of Moldova and of the expiry of Regulation (EU) 2022/1279 on 24 July 2023, this Regulation should, as a matter of urgency, enter into force on 25 July 2023,

HAVE ADOPTED THIS REGULATION:

Article 1

Trade-liberalisation measures

The following trade-liberalisation measures are introduced:

- (a) all tariff-rate quotas established under Annex XV-A to the Association Agreement shall be suspended and the products covered by those quotas shall be admitted for importation into the Union from the Republic of Moldova without any customs duties;
- (b) the application of the entry price system shall be suspended for those products to which it applies as specified in Annex XV-B to the Association Agreement; no customs duties shall apply to imports of those products.

Article 2

Conditions for entitlement to the trade-liberalisation measures

The trade-liberalisation measures provided for in Article 1 shall be subject to the following conditions:

- (a) compliance by the Republic of Moldova with the rules of origin of products and the procedures related thereto, as provided for in the Association Agreement;
- (b) the Republic of Moldova abstaining from introducing new duties or charges having equivalent effect and new quantitative restrictions or measures having equivalent effect for imports originating in the Union, from increasing existing levels of duties or charges or from introducing any other restrictions, including discriminatory internal administrative measures, unless clearly justified in the context of Russia's war of aggression against Ukraine; and

⁽⁹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (c) the Republic of Moldova respecting democratic principles, human rights and fundamental freedoms as well as the countering of the proliferation of weapons of mass destruction, related materials and their means of delivery, respect for the principles of the rule of law and good governance, the fight against corruption, criminal activities, organised or otherwise, including those of transnational character, and terrorism, and respecting the principles of sustainable development and effective multilateralism provided for in Articles 2, 9 and 16 of the Association Agreement.

Article 3

Temporary suspension of measures

1. Where the Commission finds that there is sufficient evidence of a failure by the Republic of Moldova to comply with the conditions set out in Article 2, it may, by means of an implementing act, suspend in whole or in part the trade-liberalisation measures provided for in this Regulation. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 5(3).
2. Where a Member State requests that the Commission suspend any of the trade-liberalisation measures provided for in this Regulation on the basis of a failure by the Republic of Moldova to comply with the conditions set out in Article 2, point (b), the Commission shall provide a reasoned opinion within four months of that request on whether the Member State's claim of a failure to comply is substantiated. If the Commission concludes that the claim is substantiated, it shall initiate the procedure referred to in paragraph 1 of this Article.

Article 4

Expedited safeguard

1. Where a product originating in the Republic of Moldova is imported under conditions which adversely affect the Union market for like or directly competing products, the Commission may reintroduce the customs duties otherwise applicable under the Association Agreement on imports of that product at any time by means of an implementing act. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 5(3).

The customs duties otherwise applicable under the Association Agreement may be reintroduced for as long as necessary to counteract the adverse effects on the Union market for like or directly competing products.

2. The Commission shall regularly monitor the impact of this Regulation, taking into account the information on exports, imports, prices on the Union market and Union production of the products subject to the trade-liberalisation measures under Article 1, point (a).

The Commission shall inform the Member States every two months of the results of the regular monitoring, starting from the date of entry into force of this Regulation.

3. The Commission shall carry out an assessment of the situation of the Union market for like or directly competing products with a view to reintroducing customs duties. That assessment shall be launched:
 - (a) following a duly substantiated request from a Member State including sufficient *prima facie* evidence reasonably available to that Member State pursuant to paragraph 4 of imports adversely affecting the Union market as referred to in paragraph 1; or
 - (b) on its own initiative, after it has become apparent to the Commission that there is sufficient *prima facie* evidence of imports adversely affecting the Union market as referred to in paragraph 1.

The assessment referred to in the first subparagraph shall be concluded within three months of its launch.

4. In carrying out the assessment pursuant to paragraph 3, the Commission shall take into consideration all relevant market developments, including the impact of the imports concerned on the situation of the Union market for like or directly competing products. That assessment shall include factors such as:

- (a) the rate and amount of the increase in imports from the Republic of Moldova of the product concerned in absolute and relative terms; and
- (b) the effect of the imports concerned on Union production and prices, while taking into consideration the development of imports from other sources.

This list is not exhaustive and other relevant factors may also be taken into consideration.

5. Where, as a result of the assessment referred to in paragraph 3, the Commission considers that the Union market for like or directly competing products has been adversely affected and intends to reintroduce customs duties, it shall publish a notice in the *Official Journal of the European Union* announcing the reintroduction of the customs duties otherwise applicable under the Association Agreement on imports of that product. The notice shall provide a summary of the main results of the assessment and specify the period within which interested parties may submit their views in writing. That period shall not exceed 10 days from the date of publication of the notice.

6. Where exceptional circumstances require immediate action, the Commission may, without following the procedure set out in paragraph 5 and after informing the Committee on Safeguards established by Article 3(1) of Regulation (EU) 2015/478 of the European Parliament and of the Council ⁽⁶⁾, take any preventive measure which it considers necessary.

Article 5

Committee procedure

1. The Commission shall be assisted by the Customs Code Committee established by Article 285(1) of Regulation (EU) No 952/2013 of the European Parliament and of the Council ⁽⁷⁾ with regard to Article 3(1) of this Regulation. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. The Commission shall be assisted by the Committee on Safeguards established by Article 3(1) of Regulation (EU) 2015/478 with regard to Article 4(1) of this Regulation. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 6

Assessment of the implementation of the trade-liberalisation measures

The Commission's annual report on the implementation of the Deep and Comprehensive Free Trade Area shall include a detailed assessment of the implementation of the trade-liberalisation measures provided for in this Regulation and shall include, insofar as appropriate, an assessment of the social impact of those measures in the Republic of Moldova and in the Union. Information on imports of products under Article 1, point (a), shall be made available via the website of the Commission and shall be updated on a monthly basis.

Article 7

Entry into force and application

This Regulation shall enter into force on 25 July 2023.

⁽⁶⁾ Regulation (EU) 2015/478 of the European Parliament and of the Council of 11 March 2015 on common rules for imports (OJ L 83, 27.3.2015, p. 16).

⁽⁷⁾ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

It shall apply until 24 July 2024.

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

Done at Brussels, 20 July 2023.

For the European Parliament

The President

R. METSOLA

For the Council

The President

P. NAVARRO RÍOS

REGULATION (EU) 2023/1525 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 July 2023
on supporting ammunition production (ASAP)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 173(3) thereof,

Having regard to the proposal from the European Commission,

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

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

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

Whereas:

- (1) Russia's war of aggression against Ukraine has put the European defence industry and defence equipment market to the test and exposed a number of flaws which undermine their ability to satisfy in the requisite, secure and timely manner the Member States' urgent needs for defence products and systems, such as ammunition and missiles, considering the high consumption rate of those products and systems during a high-intensity conflict.
- (2) Since 24 February 2022 the Union and its Member States have been steadily stepping up their efforts to help meet Ukraine's pressing defence needs. Furthermore, in that context, confronted with growing instability, strategic competition and security threats, the Union Heads of State or Government, meeting in Versailles on 11 March 2022, decided to take more responsibility for the Union's own security and take further decisive steps towards building European sovereignty. They committed to 'bolster European defence capabilities' and agreed to increase defence expenditure, to step up cooperation through joint projects and common procurement of defence capabilities, to close shortfalls, to boost innovation and to strengthen and develop the Union defence industry. On 21 March 2022, the 'Strategic Compass for a stronger Union security and defence in the next decade' (the 'Strategic Compass') was approved by the Council, and subsequently endorsed by the European Council on 24 March 2022. The Strategic Compass stresses the need to increase defence spending and invest more in capabilities, both at Union and national levels.
- (3) The Commission and the High Representative of the Union for Foreign Affairs and Security Policy presented a Joint Communication on the Defence Investment Gaps Analysis and Way Forward on 18 May 2022 highlighting the existence, within the Union, of defence financial, industrial and capability gaps. On 19 July 2022 the Commission presented a proposal for a Regulation of the European Parliament and of the Council on establishing the European defence industry Reinforcement through common Procurement Act (EDIRPA), aimed at supporting collaboration between Member States in the procurement phase to fill the most urgent and critical gaps, especially those created by the response to Russia's war of aggression against Ukraine, in a collaborative way. EDIRPA will contribute to the reinforcement of the common defence procurement and, through the associated Union financing, to the strengthening of Union defence industrial capacities and to the adaptation of the Union defence industry to structural market changes resulting from increased demand due to new challenges, such as the return of high-intensity conflict.
- (4) In light of the situation in Ukraine and of its pressing defence needs, in particular for ammunition, on 20 March 2023 the Council agreed on a three-track approach, aimed at providing one million rounds of artillery ammunition for Ukraine in a joint effort within the next 12 months. It agreed to urgently deliver ground-to-ground and artillery ammunition to Ukraine and, if requested, missiles, from existing stocks or by means of reprioritisation of existing orders. It further called on Member States to jointly procure ammunition and, if requested, missiles from the European defence industry (and Norway) in the context of an existing European Defence Agency (EDA) project or through complementary Member States-led acquisition projects, in order to refill their stocks while enabling the

⁽¹⁾ Opinion of 14 June 2023 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 13 July 2023 (not yet published in the Official Journal) and decision of the Council of 20 July 2023.

continuation of support to Ukraine. To support those efforts, the Council agreed to mobilise appropriate funding including through the European Peace Facility (EPF). The Council also tasked the Commission with presenting concrete proposals to urgently support the ramp-up of manufacturing capacities of the European defence industry, secure supply chains, facilitate efficient procurement procedures, address shortfalls in production capacities and promote investments, including, where appropriate, by mobilising the Union budget. Such promotion of investments is essential in order to ensure that the Union's own security needs are adequately met at all times and that the Union defence industry and internal market are up to the current challenges. The three interlinked tracks need to be pursued in parallel and in a coordinated way. In order to ensure an adequate implementation of the three tracks, regular meetings at the level of National Armament Directors with the Defence Joint Procurement Task Force (consisting of the representatives of the Commission, the European External Action Service (EEAS) and the EDA) will also be organised to assess the needs and industrial capabilities as well as to ensure the necessary close coordination.

- (5) On 13 April 2023, the Council adopted an assistance measure under the EPF worth EUR 1 billion to support the Ukrainian Armed Forces, allowing for the reimbursement to Member States of the costs of ground-to-ground and artillery ammunition, and possibly missiles, donated to Ukraine from existing stocks or by reprioritisation of existing orders during the period from 9 February to 31 May 2023. Regarding joint procurement, thus far 24 Member States together with Norway have signed the EDA's Project Arrangement for the collaborative procurement of ammunition.
- (6) Joint efforts to enable Member States to replenish their depleted stocks and to support Ukraine can only be effective if the Union's supply side can deliver the required defence products on time. But, with stocks rapidly dwindling, with production in the Union almost at maximum capacity from Member States' or third countries' orders, and with prices already spiralling, additional Union industrial policy measures are necessary to ensure a rapid ramp-up of manufacturing capacities.
- (7) As highlighted by the work of the Defence Joint Procurement Task Force on coordinating very short-term defence procurement needs and engaging with Member States and with Union defence manufacturers to support common procurement to replenish stocks, particularly in light of the support provided to Ukraine, the Union industry has manufacturing capacities in the area of ground-to-ground and artillery ammunition as well as missiles ('relevant defence products'). However, production capacities within the Union defence industry sector have been tailored for times when the challenges were different from those currently posed to the Union. Supply flows have been adapted on the basis of a more modest demand, with a minimal level of stocks and globally diversified suppliers to reduce costs, exposing the Union defence industry sector to dependencies. As a consequence, in this context, the current manufacturing capacity and the existing supply and value chains do not allow for a secure and timely delivery of defence products necessary to meet the Member States' security needs and for the continued support of Ukrainian needs, creating tensions on the market for the relevant defence products, and a risk of a crowding-out effect. Additional intervention at Union level is therefore necessary.
- (8) In accordance with Article 173(3) of the Treaty on the Functioning of the European Union (TFEU), the Union is to contribute to the achievement of the objective of speeding up the adjustment of the industry to structural changes. Therefore, it appears appropriate to support Union industry to increase its volume of production, reduce its lead production time and address potential bottlenecks or factors that could delay or impede timely availability and supply of relevant defence products.
- (9) The measures taken at Union level should aim at reinforcing the competitiveness and resilience of the European Defence Technological and Industrial Base (EDTIB) in the field of ammunition and missiles, to allow its urgent adaptation to structural change.
- (10) To that end, an instrument for the financial support of the industry's reinforcement throughout the supply and value chains related to the production of relevant defence products in the Union (the 'Instrument') should be established.
- (11) The specific structure, eligibility conditions and criteria laid down in this Regulation are particular to this short-term Instrument and are determined by specific circumstances and the current emergency situation.

- (12) The Instrument will be coherent with existing collaborative Union defence-related initiatives such as in the European Defence Fund, the proposed EDIRPA, as well as the EPF, and will generate synergies with other Union programmes. The Instrument is fully coherent with the ambition of the Strategic Compass.
- (13) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽¹⁾ (the 'Financial Regulation') should apply to the Instrument, unless otherwise specified.
- (14) In accordance with Article 193(2) of the Financial Regulation, a grant may be awarded for an action which has already begun, provided that the applicant can demonstrate the need for starting the action prior to signature of the grant agreement. However, costs incurred prior to the date of submission of the grant application are not eligible, except in duly justified exceptional cases. In order to address the call by the Council of 20 March 2023 to speed up the delivery of relevant defence products, in the financing decision it should be possible to provide for financial contributions in relation to actions that cover a period starting from that date.
- (15) This Regulation lays down a financial envelope for the entire duration of the Instrument which is to constitute the prime reference amount, within the meaning of point 18 of the Interinstitutional Agreement of 16 December 2020 between the European Parliament, the Council of the European Union and the European Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management, as well as on new own resources, including a roadmap towards the introduction of new own resources ⁽²⁾, for the European Parliament and for the Council during the annual budgetary procedure.
- (16) The possibilities provided for in Article 73(4) of Regulation (EU) 2021/1060 of the European Parliament and of the Council ⁽³⁾ could be applied provided that the project complies with the rules set out in that Regulation and the scope of the European Regional Development Fund and the European Social Fund Plus as set out in Regulations (EU) 2021/1058 ⁽⁴⁾ and (EU) 2021/1057 ⁽⁵⁾ of the European Parliament and of the Council, respectively. In line with Article 24 of Regulation (EU) 2021/1060, the Commission is to assess the amended programmes submitted by the Member State and make observations within two months of the submission of the amended programme. Given the urgency of the situation, the Commission should strive to conclude the assessment of the amended national programmes without undue delay.
- (17) When proposing amended or new recovery and resilience plans, in accordance with Article 21 of Regulation (EU) 2021/241 of the European Parliament and of the Council ⁽⁶⁾, Member States should be able to propose measures which also contribute to the objectives of the Instrument, in line with the purposes and requirements laid down by Council Decision (EU, Euratom) 2020/2053 ⁽⁷⁾, Council Regulation (EU) 2020/2094 ⁽⁸⁾ and Regulation

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

⁽²⁾ OJ L 433 I, 22.12.2020, p. 28.

⁽³⁾ Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy (OJ L 231, 30.6.2021, p. 159).

⁽⁴⁾ Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60).

⁽⁵⁾ Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21).

⁽⁶⁾ Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).

⁽⁷⁾ Council Decision (EU, Euratom) 2020/2053 of 14 December 2020 on the system of own resources of the European Union and repealing Decision 2014/335/EU, Euratom (OJ L 424, 15.12.2020, p. 1).

⁽⁸⁾ Council Regulation (EU) 2020/2094 of 14 December 2020 establishing a European Union Recovery Instrument to support the recovery in the aftermath of the COVID-19 crisis (OJ L 433 I, 22.12.2020, p. 23).

(EU) 2021/241. To that end, Member States should consider in particular measures linked to proposals submitted to a call for proposals under the Instrument, which were awarded a Seal of Excellence in accordance with the Instrument.

- (18) In accordance with the Financial Regulation, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council ⁽¹¹⁾ and Council Regulations (EC, Euratom) No 2988/95 ⁽¹²⁾, (Euratom, EC) No 2185/96 ⁽¹³⁾ and (EU) 2017/1939 ⁽¹⁴⁾, the financial interests of the Union are to be protected by means of proportionate measures, including measures relating to the prevention, detection, correction and investigation of irregularities, including fraud, to the recovery of funds lost, wrongly paid or incorrectly used, and, where appropriate, to the imposition of administrative penalties. In particular, in accordance with Regulations (Euratom, EC) No 2185/96 and (EU, Euratom) No 883/2013, the European Anti-Fraud Office (OLAF) has the power to carry out administrative investigations, including on-the-spot checks and inspections, with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union. The European Public Prosecutor's Office (EPPO) is empowered, in accordance with Regulation (EU) 2017/1939, to investigate and prosecute criminal offences affecting the financial interests of the Union as provided for in Directive (EU) 2017/1371 of the European Parliament and of the Council ⁽¹⁵⁾. In accordance with the Financial Regulation, any person or entity receiving Union funds is to cooperate fully in the protection of the financial interests of the Union, to grant the necessary rights and access to the Commission, OLAF, the Court of Auditors and, in respect of those Member States participating in enhanced cooperation pursuant to Regulation (EU) 2017/1939, the EPPO, and to ensure that any third parties involved in the implementation of Union funds grant equivalent rights.
- (19) Members of the European Free Trade Association which are members of the European Economic Area (EEA) should be able to participate in the Instrument as associated countries in the framework of the cooperation established under the Agreement on the European Economic Area ⁽¹⁶⁾, which provides for the implementation of their participation in Union programmes on the basis of a decision adopted under that Agreement. This Regulation should require those third countries to grant the necessary rights and access required for the authorising officer responsible, OLAF and the Court of Auditors to comprehensively exercise their respective competences.
- (20) Given the specificities of the defence industry, where demand comes almost exclusively from Member States and associated countries, which also control all acquisition of defence-related products and technologies, including exports, the functioning of the defence industry sector does not follow the conventional rules and business models that govern more traditional markets. The industry does not therefore engage in substantial self-funded industrial investments but only does so as a consequence of firm orders. While firm orders from Member States are a precondition for any investment, the Commission can intervene by de-risking industrial investments via grants and loans allowing a faster adaptation to ongoing structural market change. In the current emergency context, Union support should cover up to 50 % of direct eligible costs in order to enable beneficiaries to implement actions as soon as possible, to de-risk their investment and therefore to speed up the availability of relevant defence products.
- (21) The Instrument should provide financial support, via means provided for in the Financial Regulation, to actions contributing to the timely availability and supply of relevant defence products such as industrial coordination and networking activities, access to finance for undertakings involved in the manufacturing of relevant defence

⁽¹¹⁾ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

⁽¹²⁾ Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

⁽¹³⁾ Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

⁽¹⁴⁾ Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p. 1).

⁽¹⁵⁾ Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

⁽¹⁶⁾ OJ L 1, 3.1.1994, p. 3.

products, reservation of capacities, industrial processes of reconditioning of expired products, expansion, optimisation, modernisation, upgrading or repurposing of existing, or the establishment of new, production capacities in that field as well as the training of personnel.

- (22) As the Instrument aims to enhance the competitiveness and efficiency of the Union defence industry, only entities, whether public or privately owned, which are established and have their executive management structures in the Union or in associated countries should be eligible for support. Those entities should either not be subject to control by a non-associated third country or by a non-associated third country entity or, alternatively, they should have been subject to screening within the meaning of Regulation (EU) 2019/452 of the European Parliament and of the Council ⁽¹⁷⁾ and, where necessary, to mitigation measures, taking into account the objectives referred to in Article 4 of this Regulation. An entity which is established in a non-associated third country or an entity which is established in the Union or in an associated country, but which has its executive management structures in a non-associated third country should not be eligible to be a recipient involved in an action.
- (23) Entities established in the Union or in an associated country that are controlled by a non-associated third country or a non-associated third-country entity and that have not been subject to screening within the meaning of Regulation (EU) 2019/452 and, where necessary, to mitigation measures, should only be eligible to be recipients provided that strict conditions relating to the security and defence interests of the Union and its Member States, as established in the framework of the Common Foreign and Security Policy pursuant to Title V of the Treaty on European Union (TEU), including in terms of strengthening the EDTIB, are fulfilled. The participation of such entities should not contravene the objectives of the Instrument. In that context, control should be understood to be the ability to exercise a decisive influence on an entity directly, or indirectly through one or more intermediate entities. Applicants should provide all relevant information about the infrastructure, facilities, assets and resources to be used in the action. Member States' concerns regarding security of supply should also be taken into account in that respect. In view of the urgency of the situation stemming from the existing ammunition supply crisis, the Instrument should take into account existing supply chains.
- (24) Infrastructure, facilities, assets and resources of the recipients involved in an action supported under the Instrument should be located on the territory of a Member State or of an associated country for the entire duration of the action.
- (25) The Instrument should not financially support the ramp-up of production capacities for relevant defence products that are subject to a restriction by a non-associated third country or a non-associated third country entity that limits the Member States' ability to use those relevant defence products. The recipient should aim to ensure that the action funded by the Instrument will allow for the delivery of outputs to Ukraine.
- (26) Pursuant to Article 85 of Council Decision (EU) 2021/1764 ⁽¹⁸⁾, natural persons and bodies and institutions established in overseas countries and territories (OCTs) are eligible for funding subject to the rules and objectives of the Instrument and possible arrangements applicable to the Member State to which the relevant OCT is linked.
- (27) When assessing proposals submitted by applicants, the Commission should pay particular attention to their contribution to the objectives of the Instrument. The proposals should be assessed, in particular, against their contribution to the increase, ramp-up, reservation or modernisation of manufacturing capacities, as well as the reskilling and upskilling of the related workforce. They should also be assessed against their contribution to the reduction of the lead production time of relevant defence products, including through order reprioritisation mechanisms, to the identification and elimination of bottlenecks along their supply chains as well as to the

⁽¹⁷⁾ Regulation (EU) 2019/452 of the European Parliament and of the Council of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union (OJ L 79 I, 21.3.2019, p. 1).

⁽¹⁸⁾ Council Decision (EU) 2021/1764 of 5 October 2021 on the association of the Overseas Countries and Territories with the European Union including relations between the European Union on the one hand, and Greenland and the Kingdom of Denmark on the other (Decision on the Overseas Association, including Greenland) (OJ L 355, 7.10.2021, p. 6).

development of the resilience of those supply chains through the development and the operationalisation of cross-border cooperation of undertakings, in particular, to a significant extent, small and medium-sized enterprises (SMEs) and mid-cap companies (mid-caps) operating in the supply chains concerned.

- (28) When designing, awarding and implementing Union financial support, the Commission should pay particular attention to ensuring that such support does not adversely affect the conditions of competition in the internal market.
- (29) Furthermore, the crisis resulting from Russia's war of aggression against Ukraine has not only demonstrated deficiencies in the Union's defence industrial sector, but has also posed challenges to the functioning of the internal market for defence products. Indeed, the current geopolitical context entails a significant increase in the demand that affects the functioning of the internal market for the production and sale of relevant defence products and of their components in the Union. While certain Member States have taken or are likely to take measures to preserve their own stocks as a matter of national security, others are faced with difficulties of access to the goods needed to manufacture or acquire the relevant defence products. Sometimes, difficulties in accessing one raw material or a specific component hamper entire production chains. To ensure the functioning of the internal market, it is necessary to establish, in a coordinated way, harmonised rules for increasing the security of supply of relevant defence products. Those measures should include an acceleration of the permit-granting process and facilitation of procurement procedures. Those measures should be based on Article 114 TFEU.
- (30) In light of the importance of ensuring the security of supply of relevant defence products, Member States should ensure that administrative applications related to the planning, construction and operation of production facilities, transfer of inputs within the Union, as well as the qualification and certification of relevant end products are processed in an efficient and timely manner.
- (31) To pursue the general public policy objective of security, it is necessary that production facilities related to the production of relevant defence products are set up as quickly as possible, while keeping the administrative burden to a minimum. For that reason, Member States should treat applications related to the planning, construction and operation of plants and installations for the production of relevant defence products in the most rapid manner possible. Such applications should be given priority when balancing legal interests in the individual case.
- (32) In view of the objective of this Regulation, and of the emergency situation and the exceptional context of its adoption, Member States should consider using defence-related exemptions under national and applicable Union law, on a case-by-case basis, if they deem that the use of such exemptions would facilitate the achievement of that objective. That could in particular apply to Union law concerning environmental, health and safety issues, which is indispensable to improving the protection of human health and the environment, as well as to achieving a sustainable and safe development. However, the implementation of that law could also produce regulatory barriers hampering the Union defence industry's potential to ramp up the production and deliveries of relevant defence products. It is a collective responsibility for the Union and its Member States to urgently look into any action they could take to mitigate possible obstacles. Any such action, whether at Union, regional, or national level, should not compromise the environment, health and safety.
- (33) Directive 2009/81/EC of the European Parliament and of the Council ⁽¹⁹⁾ aims at harmonising procurement procedures for the award of public contracts in the field of defence and security thus enabling the security requirements of Member States and the obligations arising from the TFEU to be met. That Directive contains, in particular, specific provisions governing situations of urgency resulting from a crisis, in particular shortened periods for the receipt of tenders and the possibility to use the negotiated procedure without prior publication of a contract notice. However, the extreme urgency caused by the current ammunition supply crisis could be

⁽¹⁹⁾ Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC (OJ L 216, 20.8.2009, p. 76).

incompatible even with those provisions in cases where two or more Member States intend to engage in a common procurement. In some cases, the only solution that ensures the security interests of those Member States is to open an existing framework agreement to contracting authorities/entities of Member States that were not originally party to it, even though that possibility had not been provided for in the original framework agreement.

- (34) In accordance with the case law of the Court of Justice of the European Union, modifications to a public contract are to be strictly limited to what is absolutely necessary in the circumstances, while complying to the maximum extent possible with the principles of non-discrimination, transparency and proportionality. In that regard, it should be possible to derogate from Directive 2009/81/EC by increasing the quantities provided for in a framework agreement while opening it to contracting authorities/entities of other Member States. With respect to those additional quantities, those contracting authorities/entities should enjoy the same conditions as the original contracting authority/entity that concluded the original framework agreement. In such cases, the original contracting authority/entity should also allow any economic operator who fulfils the contracting authority's/entity's conditions initially laid down in the procurement procedure for the framework agreement, including requirements for qualitative selections as referred to in Articles 39 to 46 of Directive 2009/81/EC, to join that framework agreement. In addition, appropriate transparency measures should be taken to ensure that all potentially interested parties are informed. In order to limit the effects of those modifications on the smooth functioning of the internal market and to prevent disproportionate distortions of competition, it should only be possible to conclude such modifications of framework agreements until 30 June 2025.
- (35) In order to be competitive, innovative and resilient, as well as to be able to ramp up its production capacities, the EDTIB needs to access both public and private financing. As provided in the communication of the Commission of 15 February 2022 entitled 'Commission contribution to European defence', Union initiatives on sustainable finance remain consistent with the Union's efforts to facilitate the European defence industry's sufficient access to finance and investment. In that context, the Union's sustainable finance framework does not prevent investment in defence-related activities. The Union defence industry is a crucial contributor to the resilience and the security of the Union, and therefore to peace and social sustainability. Within Union initiatives on sustainable finance policies, controversial weapons subject to international conventions prohibiting their development, production, stockpiling, use, transfer and delivery, and signed by Member States, are deemed incompatible with the requirements of social sustainability. The Union defence industry sector is subject to close regulatory scrutiny implemented by Member States for the transfer and export of military and dual-use items. In that perspective, a commitment of national and European financial actors - such as national promotional banks and institutions - to support the European defence industry, would send a strong signal to the private sector. While pursuing in full its other economic development and public policy financing missions, including the twin green and digital transitions and in line with Article 309 TFEU as well as its statute, the European Investment Bank should enhance its support to the European defence industry and joint procurement beyond its ongoing support for dual use, where such investments would clearly serve to implement the Strategic Compass priorities.
- (36) Undertakings in the value chains of relevant defence products should have access to debt financing in order to speed up investments needed to increase manufacturing capacities. The Instrument should facilitate access to finance for Union undertakings in the ammunition and missile sector. This Regulation should in particular ensure that those undertakings are granted the same conditions offered to other undertakings, taking charge of any additional cost arising specifically for the defence sector.
- (37) The Commission should be able to set up a dedicated facility as part of the investment facilitation activities to be referred to as the 'Ramp-up Fund'. The Ramp-up Fund should be implemented under indirect management. The Commission should explore in that regard the most appropriate way to leverage the Union budget to unlock public and private investment in support of the rapid ramp-up sought, for instance through a blending facility, including under the InvestEU Fund established by Regulation (EU) 2021/523 of the European Parliament and Council ⁽²⁰⁾, in close cooperation with its implementing partners. The Ramp-up Fund activities should support the increase of manufacturing capacities in the ammunition and missiles sector by providing opportunities for increased availability of funds to companies across the value chains.

⁽²⁰⁾ Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017 (OJ L 107, 26.3.2021, p. 30).

- (38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the adoption of the work programme and the award of funding to selected actions. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽²¹⁾.
- (39) Since the objective of this Regulation, namely to respond to the impact of the security crisis, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the proposed action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary to achieve that objective.
- (40) This Regulation should apply without prejudice to Union competition rules, in particular Articles 101 to 109 TFEU and the legal acts that give effect to those Articles.
- (41) In accordance with Article 41(2) TEU, operating expenditure arising from Chapter 2 of Title V TEU is to be charged to the Union budget, except for such expenditure arising from operations having military or defence implications.
- (42) Pursuant to paragraphs 22 and 23 of the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ⁽²²⁾, this Regulation should be evaluated on the basis of information collected in accordance with specific monitoring requirements, while avoiding overregulation and administrative burdens, in particular on Member States. Where appropriate, such requirements should include measurable indicators as a basis for evaluating the effects of this Regulation on the ground. The Commission should carry out an evaluation of this Regulation no later than 30 June 2024, including with a view to submitting proposals for amendments to this Regulation, where appropriate.
- (43) In light of the imminent danger to the security of supply brought about by Russia's war of aggression against Ukraine, this Regulation should enter into force the on the day following that of its publication in the *Official Journal of the European Union*.
- (44) This Regulation should apply without prejudice to the specific character of the security and defence policy of certain Member States,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes a set of measures and lays down a budget aimed at urgently strengthening the responsiveness and ability of the European Defence Technological and Industrial Base (EDTIB) to ensure the timely availability and supply of ground-to-ground and artillery ammunition as well as missiles ('relevant defence products'), in particular by means of the following:

- (a) an instrument financially supporting industrial reinforcement for the production of relevant defence products in the Union, including through the supply of their components (the 'Instrument');
- (b) the establishment of mechanisms, principles and temporary rules to secure the timely and lasting availability of relevant defence products to their acquirers in the Union.

⁽²¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽²²⁾ OJ L 123, 12.5.2016, p. 1.

Based on an evaluation, pursuant to Article 23, of the results achieved by the implementation of this Regulation by 30 June 2024, particularly with regard to the evolution of the security context, the Commission may consider the opportunity to extend the applicability of the set of measures provided for in this Regulation and the allocation of the corresponding additional budget.

Article 2

Definitions

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

- (1) 'raw materials' means the materials required to produce relevant defence products;
- (2) 'bottleneck' means a point of congestion in a production system that stops or severely slows down the production;
- (3) 'recipient' means an entity with which a funding or financing agreement has been signed, or to which a funding or financing decision has been notified;
- (4) 'applicant' means a natural person or an entity that has submitted an application in a grant award procedure;
- (5) 'control' means the ability to exercise a decisive influence over an entity directly or indirectly through one or more intermediate entities;
- (6) 'executive management structure' means a body of an entity, appointed in accordance with national law, and, where applicable, reporting to the chief executive officer, which is empowered to establish that entity's strategy, objectives and overall direction, and which oversees and monitors the entity's management decision-making;
- (7) 'entity' means a legal person created and recognised as such under Union, national or international law, which has legal personality and the capacity to act in its own name, exercise rights and be subject to obligations, or an entity which does not have legal personality as referred to in Article 197(2), point (c), of the Financial Regulation;
- (8) 'classified information' means information or material, in any form, the unauthorised disclosure of which could cause varying degrees of prejudice to the interests of the Union, or of one or more of the Member States, and which bears an EU classification marking or a corresponding classification marking, as established in the Agreement between the Member States of the European Union, meeting within the Council, regarding the protection of classified information exchanged in the interests of the European Union ⁽²³⁾;
- (9) 'sensitive information' means information and data that are to be protected from unauthorised access or disclosure because of obligations laid down in Union or national law or in order to safeguard the privacy or security of a natural or legal person;
- (10) 'non-associated third-country entity' means an entity that is established in a non-associated third country or, where it is established in the Union or in an associated country, that has its executive management structures in a non-associated third country;
- (11) 'lead production time' means the period of time between a purchase order being placed and the manufacturer completing the order;
- (12) 'relevant defence products' means ground-to-ground and artillery ammunition as well as missiles;
- (13) 'blending operation' means an action supported by the Union budget, including within a blending facility or platform as defined in Article 2, point (6), of the Financial Regulation, that combines non-repayable forms of support or financial instruments from the Union budget with repayable forms of support from development or other public finance institutions as well as from commercial finance institutions and investors;

⁽²³⁾ OJ C 202, 8.7.2011, p. 13.

- (14) 'Seal of Excellence' means a quality label which shows that a proposal submitted to a call for proposals under the Instrument has passed all of the evaluation thresholds set out in the work programme, but could not be funded due to a lack of budget available for that call for proposals in the work programme, and might receive support from other Union or national sources of funding.

Article 3

Third countries associated to the Instrument

The Instrument shall be open to the participation of members of the European Free Trade Association which are members of the European Economic Area ('associated countries'), in accordance with the conditions laid down in the Agreement on the European Economic Area.

CHAPTER II

THE INSTRUMENT

Article 4

Objectives of the Instrument

1. The objective of the Instrument is to foster the efficiency and competitiveness of the European Defence Technological and Industrial Base (EDTIB) to support the ramp-up of the production capacity and timely delivery of relevant defence products through industrial reinforcement.
2. The industrial reinforcement shall in particular consist of initiating and speeding up the adjustment of industry to the rapid structural changes imposed by the supply crisis affecting the relevant defence products which are necessary for the swift replenishment of the ammunition and missile stocks of the Member States and of Ukraine. That shall include the improvement of the capacity of adaptation of supply chains for relevant defence products and the acceleration of such adaptation, the creation of manufacturing capacities or their ramp-up, and a reduction of the lead production time for relevant defence products throughout the Union, in particular through the intensification and widening of cross-border cooperation between the relevant entities.

Article 5

Budget

1. The financial envelope for the implementation of the Instrument for the period 25 July 2023 to 30 June 2025 shall be EUR 500 million in current prices.
2. Within the financial envelope referred to in paragraph 1 of this Article, up to EUR 50 million may be used as a blending operation in the framework of the Ramp-up Fund provided for in Article 15.
3. The financial envelope referred to in paragraph 1 may also be used for technical and administrative assistance for the implementation of the Instrument, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems.
4. Budgetary commitments for activities extending over more than one financial year may be broken down over several years into annual instalments.
5. The budget of the Instrument may be reinforced, where necessary or where the applicability of this Regulation is extended in accordance with Article 1, second paragraph.

*Article 6***Cumulative and alternative funding**

1. The Instrument shall be implemented in synergy with other Union programmes. An action that has received a contribution under the Instrument may also receive a contribution from another Union programme, provided that the contributions do not cover the same costs. The rules of the relevant Union programme shall apply to the corresponding contribution to the action. The cumulative financing shall not exceed the total eligible costs of the action. The support from the different Union programmes may be calculated on a pro rata basis in accordance with the documents setting out the conditions for support.
2. In order to be attributed a Seal of Excellence label, the actions shall comply with the following cumulative conditions:
 - (a) they have been assessed in a call for proposals under the Instrument;
 - (b) they comply with the minimum quality requirements of that call for proposals; and
 - (c) they are not financed under that call for proposals due to budgetary constraints.
3. When proposing amended or new recovery and resilience plans in accordance with Regulation (EU) 2021/241, Member States may include measures which also contribute to the objectives of the Instrument, particularly measures linked to proposals submitted to a call for proposals under the Instrument which were awarded a Seal of Excellence.
4. Article 8(5) shall apply by analogy to actions funded in accordance with this Article.

*Article 7***Forms of Union funding**

1. The Instrument shall be implemented under direct management and, with regard to the Ramp-up Fund provided for in Article 15 of this Regulation, under indirect management with bodies referred to in Article 62(1), point (c), of the Financial Regulation. The Instrument may provide funding in any of the forms laid down in the Financial Regulation, including financing in the form of financial instruments within blending operations. Blending operations shall be carried out in accordance with Title X of the Financial Regulation, Regulation (EU) 2021/523 and Article 15 of this Regulation.
2. By way of derogation from Article 193(2) of the Financial Regulation, financial contributions may, where relevant and necessary for the implementation of an action, cover actions started prior to the date of the submission of the proposal for those actions, provided that those actions did not start before 20 March 2023 and have not been completed before the signature of the grant agreement.

*Article 8***Eligible actions**

1. Only actions implementing the objectives set out in Article 4 shall be eligible for funding.
2. The Instrument shall provide financial support for actions addressing identified bottlenecks in production capacities and supply chains with a view to securing and accelerating the production of relevant defence products in order to ensure their effective supply and timely availability.
3. Eligible actions shall relate to one or more of the following activities and shall be exclusively related to the production capacities of relevant defence products, including their components and corresponding raw materials insofar as they are intended or used wholly for the production of relevant defence products:

- (a) the optimisation, expansion, modernisation, upgrading or repurposing of existing, or the establishment of new, production capacities, in relation to relevant defence products or their components and corresponding raw materials, insofar as those components and raw materials are used as direct input for the production of relevant defence products, in particular with a view to increasing production capacity or reducing lead production times, including on the basis of the procurement or acquisition of the requisite machine tools and any other necessary input;
- (b) the establishment of cross-border industrial partnerships, including through public private partnerships or other forms of industrial cooperation, in a joint industrial effort, including activities that aim to coordinate the sourcing or reservation of components and the corresponding raw materials insofar as those components and raw materials are used as direct input for the production of relevant defence products, as well as to coordinate production capacities and production plans;
- (c) the building-up and making available of reserved surge manufacturing capacities of relevant defence products, their components and corresponding raw materials, insofar as those components and raw materials are used as direct input for the production of relevant defence products, in accordance with ordered or planned production volumes;
- (d) the testing, including the necessary infrastructure, and, as appropriate, reconditioning certification of relevant defence products with a view to addressing their obsolescence and making them useable by end users;
- (e) the training, reskilling or upskilling of personnel in relation to the activities referred to in points (a) to (d);
- (f) the improvement of the access to finance for the relevant economic operators active in the production of or making available of relevant defence products, by means of the offset of any additional cost arising specifically from the defence industry sector, for investments related to activities referred to in points (a) to (e).

4. The following actions shall not be eligible for funding under the Instrument:

- (a) actions related to the production of goods or delivery of services which are prohibited by applicable international law;
- (b) actions related to the production of lethal autonomous weapons without the possibility of meaningful human control over selection and engagement decisions when carrying out strikes against humans;
- (c) actions or parts thereof, that are already fully financed from other public or private sources.

5. When concluding agreements with individual recipients the Commission shall ensure that the Instrument only finances activities which exclusively benefit production capacities of relevant defence products, or of their components and corresponding raw materials insofar as they are intended or used wholly for the production of relevant defence products.

Article 9

Financing rate

1. The Instrument shall finance up to 35 % of the eligible costs of an eligible action related to the production capacities of relevant defence products, and up to 40 % of the eligible costs of an eligible action related to the production capacities of components and raw materials insofar as they are intended or used wholly for the production of relevant defence products.

2. By way of derogation from paragraph 1, an action shall be eligible for an increased funding rate of 10 additional percentage points where it fulfils one of the following criteria:

- (a) where applicants demonstrate a contribution to the creation of new cross-border cooperation between entities established in Member States or associated countries, as described in Article 8(3), point (b);

- (b) where applicants commit to prioritising, for the duration of the action, orders stemming from:
 - (i) the common procurement of relevant defence products by at least three Member States or associated countries; or
 - (ii) the procurement of relevant defence products by at least one Member State for the purpose of transferring those relevant defence products to Ukraine; or
- (c) where the beneficiary is an SME or mid-cap established in a Member State or in an associated country or where the majority of beneficiaries participating in a consortium are SMEs or mid-caps established in Member States or in associated countries.

The commitment referred to in the first subparagraph, point (b), shall apply to the procurement of any product directly or indirectly benefitting from support under the Instrument.

The increased funding rate referred to in the first subparagraph shall be fixed at 10 additional percentage points even in the event that more than one of the criteria set out in points (a), (b) and (c) of that subparagraph are met.

By way of derogation from paragraph 1 of this Article, support from the Instrument may cover up to 100 % of the eligible costs of an activity referred to in Article 8(3), point (f).

3. The recipients shall demonstrate that the costs of an action that are not covered by Union support are to be covered by other means of financing.

Article 10

Eligible entities

1. Recipients involved in an action supported under the Instrument shall be entities, whether public or privately owned, which are established and have their executive management structures in the Union or in an associated country. Those recipients shall either not be subject to control by a non-associated third country or by a non-associated third country entity or, alternatively, they shall have been subject to screening within the meaning of Regulation (EU) 2019/452 and, where necessary, to mitigation measures, taking into account the objectives referred to in Article 4 of this Regulation.

2. An undertaking established in the Union or in an associated country that is controlled by a non-associated third country or a non-associated third-country entity and that has not been subject to screening within the meaning of Regulation (EU) 2019/452 and, where necessary, to mitigation measures, shall only be eligible to be a recipient involved in an action supported under the Instrument if guarantees approved by the Member State or the associated country in which the undertaking is established are made available to the Commission in accordance with its national procedures.

The guarantees shall ensure that the involvement of such an undertaking in an action would not contravene the security and defence interests of the Union and its Member States as established in the framework of the common foreign and security policy pursuant to Title V TEU, or the objectives set out in Article 4 of this Regulation.

The guarantees shall in particular substantiate that, for the purposes of an action, measures are in place to ensure that:

- (a) the recipient is able to carry out the action and to deliver results without any restrictions concerning its infrastructure, facilities, assets, resources, intellectual property or knowhow needed for the purposes of the action, or restrictions that undermine its capabilities and standards necessary to carry out the action; and
- (b) access by a non-associated third country or by a non-associated third-country entity to sensitive or classified information relating to the action is prevented and the employees or other persons involved in the action have national security clearance issued by a Member State or an associated country, where appropriate.

3. If considered to be appropriate by the Member State or the associated country in which the undertaking is established, additional guarantees may be provided.
4. Member States shall provide the Commission with a notification on the mitigation measures applied within the meaning of Regulation (EU) 2019/452 referred to in paragraph 1 of this Article or the guarantees referred to in paragraph 2 of this Article. Further information on the mitigation measures applied or the guarantees shall be made available to the Commission upon request. The Commission shall inform the committee referred to in Article 16 of any notification provided in accordance with this paragraph.
5. The infrastructure, facilities, assets and resources of the recipients involved in an action which are used for the purposes of an action supported by the Instrument shall be located on the territory of a Member State or of an associated country for the entire duration of an action.
6. The Instrument shall not financially support the ramp-up of production capacities for relevant defence products that are subject to a restriction by a non-associated third country or a non-associated third country entity that limits Member States' ability to use them. The recipient shall make every effort to ensure that the action funded by the Instrument will allow for the delivery of outputs to Ukraine.

Article 11

Award criteria

Each proposal submitted by an applicant shall be assessed on the basis of one or more of the following criteria measuring the contribution of the action concerned to the industrial reinforcement sought to foster the efficiency and overall competitiveness of the EDTIB with respect to the relevant defence products:

- (a) increase in production capacity in the Union: the contribution of the action to the increase, ramp-up or reservation of manufacturing capacities, their modernisation or the reskilling and upskilling of the related workforce;
- (b) reduction of lead production time: the contribution of the action to the timely satisfaction of the demand expressed through procurement in terms of reduced lead production times, including via order reprioritisation mechanisms;
- (c) elimination of sourcing and production bottlenecks: the contribution of the action to the swift identification and rapid and lasting elimination of any sourcing (raw material and any other input) or production (manufacturing capability) bottlenecks;
- (d) resilience through cross-border cooperation: the contribution of the action to the development and operationalisation of cross-border cooperation between undertakings established in different Member States or associated countries, involving in particular, to a significant extent, SMEs or mid-caps as recipients, as subcontractors or as other undertakings in the supply chain;
- (e) support to procurement: the demonstration by the applicants of the link between the action and newly placed orders stemming from the joint procurement of relevant defence products by at least three Member States or associated countries especially if done in a Union framework;
- (f) the quality of the implementation plan of the action, including in terms of its processes and monitoring.

The Commission shall, by means of implementing acts, award the funding under this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 16(3).

*Article 12***Work programme**

1. The Instrument shall be implemented through a work programme as referred to in Article 110 of the Financial Regulation. The work programme shall set out, where applicable, the overall amount reserved for blending operations.
2. The work programme shall set out the funding priorities taking into account the work of the Defence Joint Procurement Task Force.
3. The Commission shall, by means of an implementing act, adopt the work programme referred to in paragraph 1 of this Article. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 16(3).

CHAPTER III

SECURITY OF SUPPLY*Article 13***Acceleration of the permit-granting process for the timely availability and supply of relevant defence products**

1. Member States shall ensure that administrative applications related to the planning, construction and operation of production facilities, transfer of inputs within the Union as well as qualification and certification of end products are processed in an efficient and timely manner. To that end, all national authorities concerned shall ensure that the most rapid treatment legally possible is given to such applications.
2. Member States shall ensure that in the planning and permit-granting process, the construction and operation of plants and installations for the production of relevant defence products are given priority when balancing legal interests in the individual case concerned.

*Article 14***Facilitation of common procurement during the ammunition supply crisis**

1. Where at least two Member States enter into an agreement to commonly procure relevant defence products and where the extreme urgency deriving from the crisis resulting from Russia's war of aggression against Ukraine prevents the use of any of the procedures provided for by Directive 2009/81/EC for the conclusion of a framework agreement, the rules provided for in this Article may be applied.
2. By way of derogation from Article 29(2), second subparagraph, of Directive 2009/81/EC, a contracting authority/entity may modify an existing framework agreement which has been concluded following one of the procedures provided for by Article 25 of that Directive so that its provisions may apply to contracting authorities/entities which are not originally party to the framework agreement.
3. By way of derogation from Article 29(2), third subparagraph, of Directive 2009/81/EC, a contracting authority/entity may make substantial amendments to the quantities laid down in an existing framework agreement insofar as that is strictly necessary for the application of paragraph 2 of this Article. Where quantities laid down in an existing framework agreement are substantially modified pursuant to this paragraph, any economic operator that meets the contracting authority's/entity's conditions initially laid down in the public procurement procedure for the framework agreement, including requirements for qualitative selection as referred to in Articles 39 to 46 of Directive 2009/81/EC, shall be given the opportunity to join that framework agreement. The contracting authority/entity shall open that possibility by means of an ad hoc notice published in the *Official Journal of the European Union*.

4. The principle of non-discrimination shall apply to framework agreements referred to in paragraphs 2 and 3 with regard to the additional quantities, and particularly to the relationships between contracting authorities/entities of Member States referred to in paragraph 1.
5. Contracting authorities/entities which modified a contract in the cases referred to in paragraphs 2 and 3 of this Article shall publish a notice to that effect in the *Official Journal of the European Union*. Such notice shall be published in accordance with Article 32 of Directive 2009/81/EC.
6. Contracting authorities/entities may not use this Article improperly or in such a way as to prevent, restrict or distort competition.
7. Modifications introduced in the framework agreements pursuant to this Article shall be concluded by 30 June 2025.

CHAPTER IV

SPECIFIC PROVISIONS APPLICABLE TO ACCESS TO FINANCE

Article 15

Ramp-up Fund

1. In order to leverage, de-risk and speed-up investments needed to increase manufacturing capacities, a blending facility offering debt solutions may be established (the 'Ramp-up Fund').
2. The specific objectives pursued by the Ramp-up Fund shall be the following:
 - (a) improving the leverage effect of the Union budget spending and achieving a higher multiplier effect in terms of attracting private-sector financing;
 - (b) providing support to companies facing difficulties in accessing finance, and addressing the need to underpin the resilience of the Union defence industry;
 - (c) accelerating investment in the field of manufacturing relevant defence products and leveraging funding from both the public and the private sectors, while increasing the security of supply for the whole Union defence industry value chain;
 - (d) enhancing access to finance for investments related to activities referred to in Article 8(3), points (a) to (e).

CHAPTER V

FINAL PROVISIONS

Article 16

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. The EDA shall be invited to provide its views and expertise to the committee as an observer. The EEAS shall also be invited to assist in the work of the committee.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

*Article 17***Security of information**

1. The Commission shall protect classified information received in relation to the implementation of this Regulation in accordance with the security rules set out in Commission Decision (EU, Euratom) 2015/444 ⁽²⁴⁾.
2. The Commission shall make use of existing or set up secured exchange systems in order to facilitate the exchange of sensitive and classified information between the Commission, the High Representative of the Union for Foreign Affairs and Security Policy, the EDA and the Member States and, where appropriate, with the entities subject to measures set out in this Regulation. That system shall take into account the Member States' national security regulations.

*Article 18***Confidentiality and processing of information**

1. Information received as a result of the application of this Regulation shall be used only for the purpose for which it was requested.
2. Member States and the Commission shall ensure the protection of trade and business secrets and other sensitive and classified information acquired and generated in application of this Regulation in accordance with Union law and the respective national law.
3. Member States and the Commission shall ensure that classified information provided or exchanged under this Regulation is not downgraded or declassified without the prior written consent of the originator.
4. The Commission shall not share any information in a way that can lead to the identification of an entity when the sharing of the information results in potential commercial or reputational damage to that entity or in divulging any trade secrets.

*Article 19***Personal data protection**

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽²⁵⁾ and Directive 2002/58/EC of the European Parliament and of the Council ⁽²⁶⁾, or the obligations of the Commission and, where appropriate, other Union institutions, bodies, offices and agencies, relating to their processing of personal data under Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽²⁷⁾, when fulfilling their responsibilities.
2. Personal data shall not be processed or communicated except in cases where this is strictly necessary for the purposes of this Regulation. In such cases Regulations (EU) 2016/679 and (EU) 2018/1725 shall apply as appropriate.
3. Where the processing of personal data is not strictly necessary to the fulfilment of the mechanisms established in this Regulation, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

⁽²⁴⁾ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

⁽²⁵⁾ 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).

⁽²⁶⁾ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

⁽²⁷⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

*Article 20***Audits**

Audits on the use of the Union contribution carried out by persons or entities, including by persons or entities other than those mandated by the Union institutions, bodies, offices or agencies, shall form the basis of the overall assurance pursuant to Article 127 of the Financial Regulation. The Court of Auditors shall examine the accounts of all revenue and expenditure of the Union in accordance with Article 287 TFEU.

*Article 21***Protection of the financial interests of the Union**

Where an associated country participates in the Instrument by means of a decision adopted pursuant to the Agreement on the European Economic Area, the associated country shall grant the necessary rights and access required for the authorising officer responsible, OLAF and the Court of Auditors to comprehensively exercise their respective competences. In the case of OLAF, such rights shall include the right to carry out investigations, including on-the-spot checks and inspections, as provided for in Regulation (EU, Euratom) No 883/2013.

*Article 22***Information, communication and publicity**

1. The recipients of Union funding shall acknowledge the origin of the funds and ensure the visibility of the Union funding, in particular when promoting the actions and their results, by providing coherent, effective and proportionate targeted information to multiple audiences, including the media and the public.
2. The Commission shall implement information and communication actions relating to the Instrument, to actions taken pursuant to the Instrument and to the results obtained.
3. Financial resources allocated to the Instrument shall contribute to the corporate communication of the political priorities of the Union, insofar as those priorities are related to the objectives referred to in Article 4.
4. Financial resources allocated to the Instrument may contribute to the organisation of dissemination activities, match-making events and awareness-raising activities, in particular aiming at opening up supply chains to foster the cross-border participation of SMEs.

*Article 23***Evaluation**

1. By 30 June 2024, the Commission shall draw up a report evaluating the implementation of the measures set out in this Regulation and their results, as well as the opportunity to extend their applicability and provide for their funding, particularly with regard to the evolution of the security context. The evaluation report shall build on consultations of the Member States and key stakeholders and be communicated to the European Parliament and to the Council.
2. Taking into account the evaluation report, the Commission may submit proposals for any appropriate amendments to this Regulation, particularly with a view to continuing to address any persistent risks in relation to the supply of relevant defence products.

*Article 24***Entry into force and application**

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 apply until 30 June 2025. That shall not affect the continuation or modification of actions initiated pursuant to this Regulation or any actions necessary to protect the financial interests of the Union.

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

Done at Brussels, 20 July 2023.

For the European Parliament

The President

R. METSOLA

For the Council

The President

P. NAVARRO RÍOS

II

(Non-legislative acts)

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2023/1526

of 16 May 2023

amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in *in vitro* diagnostic medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁽¹⁾, and in particular Article 5(1), point (a), thereof,

Whereas:

- (1) Article 4(1) of Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications listed in Annex IV to that Directive.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.
- (3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) On 1 December 2021, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption to be listed in Annex IV to that Directive, for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in *in vitro* diagnostic medical devices ('the requested exemption').
- (5) The *in vitro* diagnostic medical devices described in the requested exemption fall under category 8 'medical devices' of Annex I to Directive 2011/65/EU.
- (6) A technical and scientific assessment study ⁽²⁾ was carried out to evaluate the requested exemption. The evaluation included stakeholder consultations as required by Article 5(7) of Directive 2011/65/EU. The comments received during those consultations were made publicly available on a dedicated website.

⁽¹⁾ OJ L 174, 1.7.2011, p. 88.

⁽²⁾ Study to assess request for one (-1-) exemption, for lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in *in-vitro* diagnostic medical devices for the analysis of creatinine and blood urea nitrogen (BUN) in whole blood, in Annex IV of Directive 2011/65/EU (Pack 26).

- (7) The evaluation of the requested exemption concluded that the substitution of lead in specific sensors is not completed yet. The availability of substitutes for such specific devices is not ensured as current lead substitutions are not reliable for all parameters (for example, creatinine and blood urea nitrogen) or have a low accuracy for such parameters. In addition, the evaluation concluded that rejecting the requested exemption would negatively affect the health service.
- (8) The requested exemption thus meets at least one of the relevant conditions specified in Article 5(1), point (a), of Directive 2011/65/EU as the reliability of substitutes for the specific application subject to the exemption request is not ensured. Also, the overall negative environmental, health and consumer safety impacts and the socioeconomic impacts of not granting an exemption are being taken into account.
- (9) The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾ and thus does not weaken the environmental and health protection afforded by that Regulation.
- (10) It is, therefore, appropriate to grant the requested exemption by including the relevant application in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 8.
- (11) In light of the expected availability of substitution of lead in the application subject to the exemption and of possible future restrictions on lead in polyvinyl chloride in Regulation (EC) No 1907/2006, it is necessary to grant the exemption for a limited validity period until 31 December 2023. That validity period is set in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU.
- (12) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by XX.XX.XXXX at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate the text of those provisions to the Commission.

They shall apply those provisions from YY.XX.XXXX.

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

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

Article 3

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

⁽³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 16 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex IV to Directive 2011/65/EU, the following entry 41a is added:

- ‘41a. Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in *in vitro* diagnostic medical devices for the analysis of creatinine and blood urea nitrogen in whole blood.

Applies to category 8 and expires on 31 December 2023.’

DECISIONS

COUNCIL DECISION (CFSP) 2023/1527

of 20 July 2023

extending the mandate of the European Union Special Representative in Kosovo * and amending Decision (CFSP) 2020/1135

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 33 and Article 31(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 4 February 2008, the Council agreed to appoint a European Union Special Representative (EUSR) in Kosovo.
- (2) On 30 July 2020, the Council adopted Decision (CFSP) 2020/1135 ⁽¹⁾ appointing Mr Tomáš SZUNYOG as the EUSR in Kosovo. The EUSR's mandate has been extended by Council Decision (CFSP) 2021/1194 ⁽²⁾, and is to expire on 31 August 2023.
- (3) The EUSR's mandate should be extended for a further period of 12 months and a new financial reference amount for the period from 1 September 2023 to 31 August 2024 should be established.
- (4) The EUSR will implement the mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2020/1135 is amended as follows:

- (1) Article 1 is replaced by the following:

'Article 1

European Union Special Representative

The mandate of Mr Tomáš SZUNYOG as the European Union Special Representative (EUSR) in Kosovo is extended until 31 August 2024. The Council may decide that the mandate of the EUSR be terminated earlier, based on an assessment by the Political and Security Committee (PSC) and a proposal from the High Representative of the Union for Foreign Affairs and Security Policy (HR).';

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

⁽¹⁾ Council Decision (CFSP) 2020/1135 of 30 July 2020 appointing the European Union Special Representative in Kosovo (OJ L 247, 31.7.2020, p. 25).

⁽²⁾ Council Decision (CFSP) 2021/1194 of 19 July 2021 extending the mandate of the European Union Special Representative in Kosovo and amending Decision (CFSP) 2020/1135 (OJ L 258, 20.7.2021, p. 48).

(2) in Article 5(1), the following subparagraph is added:

‘The financial reference amount intended to cover the expenditure related to the EUSR’s mandate for the period from 1 September 2023 to 31 August 2024 shall be EUR 2 850 000’;

(3) in Article 14, the second sentence is replaced by the following:

‘The EUSR shall present the Council, the HR and the Commission with regular progress reports and a final comprehensive mandate implementation report by 31 May 2024.’.

Article 2

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

Done at Brussels, 20 July 2023.

For the Council

The President

J. BORRELL FONTELLES

COUNCIL DECISION (CFSP) 2023/1528**of 20 July 2023****amending Decision (CFSP) 2018/907 extending the mandate of the European Union Special Representative for the South Caucasus and the crisis in Georgia**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 33 and Article 31(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 7 July 2003, the Council agreed to appoint a European Union Special Representative (EUSR) for the South Caucasus.
- (2) On 13 November 2017, the Council adopted Decision (CFSP) 2017/2071 ⁽¹⁾ appointing Mr Toivo KLAAR as the EUSR for the South Caucasus and the crisis in Georgia. The EUSR's mandate has been successively extended, most recently by Council Decision (CFSP) 2022/1237 ⁽²⁾, and is to expire on 31 August 2023.
- (3) The EUSR's mandate should be extended for a further period of 12 months and a new financial reference amount for the period from 1 September 2023 to 31 August 2024 should be established.
- (4) The EUSR will implement the mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2018/907 is amended as follows:

- (1) Article 1 is replaced by the following:

'Article 1

European Union Special Representative

The mandate of Toivo KLAAR as the European Union Special Representative (EUSR) for the South Caucasus and the crisis in Georgia (South Caucasus) is extended until 31 August 2024. The Council may decide that the mandate of the EUSR be terminated earlier, based on an assessment by the Political and Security Committee (PSC) and a proposal from the High Representative of the Union for Foreign Affairs and Security Policy (HR).;

- (2) in Article 5(1), the following sub-paragraph is added:

'The financial reference amount intended to cover the expenditure related to the EUSR's mandate for the period from 1 September 2023 to 31 August 2024 shall be EUR 2 763 000.'

⁽¹⁾ Council Decision (CFSP) 2017/2071 of 13 November 2017 appointing the European Union Special Representative for the South Caucasus and the crisis in Georgia (OJ L 295, 14.11.2017, p. 55).

⁽²⁾ Council Decision (CFSP) 2022/1237 of 18 July 2022 amending Decision (CFSP) 2018/907 extending the mandate of the European Union Special Representative for the South Caucasus and the crisis in Georgia (OJ L 190, 19.7.2022, p. 125).

(3) in Article 14, first paragraph, the second sentence is replaced by the following:

‘The EUSR shall present the Council, the HR and the Commission with regular progress reports and a final comprehensive mandate implementation report by 31 May 2024.’.

Article 2

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

Done at Brussels, 20 July 2023.

For the Council

The President

J. BORRELL FONTELLES

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN