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<sup>(1)</sup> Text with EEA relevance.

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## I

(Legislative acts)

## REGULATIONS

## REGULATION (EU) 2021/522 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 24 March 2021

establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) 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 <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) According to Article 3(1) of the Treaty on European Union (TEU), among the aims of the Union is the promotion of the well-being of its peoples.
- (2) According to Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.
- (3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of Member States for the definition of their health policies and for the organisation, management and delivery of health services and medical care.

<sup>(1)</sup> OJ C 429, 11.12.2020, p. 251.

<sup>(2)</sup> OJ C 440, 18.12.2020, p. 131.

<sup>(3)</sup> Position of the European Parliament of 9 March 2021 (not yet published in the Official Journal) and decision of the Council of 17 March 2021.

- (4) Actions have been taken in particular under the previous programmes of Union action in the field of public health, namely those provided for by Decisions No 1786/2002/EC <sup>(4)</sup> and No 1350/2007/EC <sup>(5)</sup> of the European Parliament and of the Council and by Regulation (EU) No 282/2014 of the European Parliament and of the Council <sup>(6)</sup>, to meet the requirements set out in Article 168 TFEU.
- (5) On 11 March 2020, the World Health Organization (WHO) declared the novel coronavirus (COVID-19) outbreak a global pandemic. That pandemic has caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, which particularly affect people with chronic conditions. In addition, staff in health care settings, who have been essential during the COVID-19 crisis, have been exposed to great health risks.
- (6) While Member States are responsible for their health policies, they should protect public health in a spirit of European solidarity, as called for in the communication of the Commission of 13 March 2020 on coordinated economic response to the COVID-19 outbreak. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for further action at Union level to support cooperation and coordination among the Member States. That cooperation should improve preparedness for, and the prevention and control of, the spread of severe human infections and diseases across borders in order to combat other serious cross-border threats to health and to safeguard and improve the health and well-being of all people in the Union. Preparedness is the key to improving resilience to future threats. In that regard, Member States should be given the possibility of carrying out stress tests on a voluntary basis to improve preparedness and increase resilience.
- (7) It is therefore appropriate to establish a new and reinforced programme for Union action in the field of health, called the 'EU4Health Programme' (the 'Programme'), for the period 2021-2027. In line with the goals of the Union's action and the Union's competences in the area of public health, the Programme should emphasise actions in relation to which there are advantages and efficiency gains from collaboration and cooperation at Union level, and actions that have an impact on the internal market.
- (8) The Programme should be a means of promoting actions in areas where there is a Union added value that can be demonstrated. Such actions should include, inter alia, strengthening the exchange of best practices between Member States, supporting networks for the sharing of knowledge or for mutual learning, addressing cross-border threats to health so as to reduce the risks of such threats and to mitigate their consequences, addressing certain issues relating to the internal market in relation to which the Union can achieve Union-wide high-quality solutions, thereby unlocking the potential of innovation in health, and improving efficiency by avoiding the duplication of activities and optimising the use of financial resources. The Programme should also support capacity-building actions to strengthen strategic planning, access to multisource financing and the capacity to invest in and implement actions of the Programme. In that respect, the Programme should provide country-specific tailor-made assistance to the Member States, or groups of Member States, with the greatest needs.
- (9) This Regulation lays down a financial envelope for the Programme 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 <sup>(7)</sup>, for the European Parliament and the Council during the annual budgetary procedure. This financial envelope comprises an amount of EUR 500 000 000 in 2018 prices in line with the joint declaration by the European Parliament, Council and Commission on the reinforcement of specific programmes and adaptation of basic acts of 22 December 2020 <sup>(8)</sup>.

<sup>(4)</sup> Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008) (OJ L 271, 9.10.2002, p. 1).

<sup>(5)</sup> Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (OJ L 301, 20.11.2007, p. 3).

<sup>(6)</sup> Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1).

<sup>(7)</sup> OJ L 433L, 22.12.2020, p. 28.

<sup>(8)</sup> OJ C 444I, 22.12.2020, p. 1.

- (10) In order for the Programme to be balanced and focused, minimum and maximum shares of the overall budget should be laid down in this Regulation, for certain areas of action, with a view to providing guidance for the allocation of resources in relation to the implementation of the Programme.
- (11) Due to the serious nature of cross-border threats to health, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthening the capability in the Union to prepare for, respond to and manage any future health crises, the Programme should provide support to actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council <sup>(9)</sup> and other relevant mechanisms and structures referred to in the communication of the Commission of 11 November 2020 entitled 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats', including actions directed at strengthening preparedness planning and response capacity at national and Union level, at reinforcing the role of the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and at establishing a health emergency preparedness and response authority. Such actions could include building capacity for responding to health crises, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, provision of health information, and platforms to share best practices. In this context, the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness and surveillance, and the management capacity and response capacity of actors at Union and Member State levels, including contingency planning and preparedness exercises, in keeping with the 'One Health' and 'Health in All Policies' approaches. The Programme should facilitate the setting up of an integrated cross-cutting risk communication framework for all phases of a health crisis, namely prevention, preparedness and response.
- (12) With a view to strengthening capabilities in the Union to prevent, prepare for, respond to and manage health crises, the Programme should provide support to actions taken in the framework of the mechanisms and structures established under relevant Union legislation. That support could include capacity building in health crisis response, including contingency planning and preparedness, preventive measures such as those related to vaccination and immunisation, strengthened surveillance programmes and improved coordination and cooperation.
- (13) In the context of public health crises, clinical trials and health technology assessment (HTA) can contribute to speeding up the development and identification of effective medical countermeasures. It should therefore be possible for the Programme to provide support to facilitate actions in those fields.
- (14) With a view to protecting people in vulnerable situations, including those suffering from mental illness and those living with or most affected by communicable or non-communicable diseases and chronic diseases, the Programme should also promote actions which address and prevent the collateral impact of health crises on people belonging to such vulnerable groups and actions which improve mental health.
- (15) The COVID-19 crisis has highlighted many challenges, including the dependence of the Union on third countries in ensuring the supply of raw materials, active pharmaceutical ingredients, medicinal products, medical devices and personal protective equipment needed in the Union during health crises, in particular pandemics. The Programme should therefore provide support to actions that foster the production, procurement and management of crisis-relevant products within the Union to mitigate the risk of shortages, while ensuring complementarity with other Union instruments.
- (16) In order to minimise the public health consequences of serious cross-border threats to health, it should be possible for actions supported under the Programme to improve the interoperability of Member States' health systems through cooperation and the exchange of best practices and also by increasing the number of joint actions. Those actions should ensure that Member States are able to respond to health emergencies, including by undertaking contingency planning, preparedness exercises and the upskilling of the healthcare and public health workforce as well as the establishment, in accordance with national strategies, of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in times of crisis.

<sup>(9)</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

- (17) The provision of information to individuals plays an important role in preventing and responding to diseases. The Programme should therefore support communication activities addressed to the general public or to specific groups of people or professionals, in order to promote disease prevention and healthy lifestyles, to counter misinformation and disinformation as regards the prevention, cause and treatment of diseases, to address vaccine hesitancy and to support efforts to strengthen altruistic behaviour, such as organ and blood donations, in a manner that complements national campaigns on those matters.
- (18) In synergy with other Union programmes, such as the Digital Europe programme established by a Regulation of the European Parliament and of the Council establishing the Digital Europe programme and repealing Decision (EU) 2015/2240, Horizon Europe - the Framework Programme for Research and Innovation established by a Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 ('Horizon Europe'), the European Regional Development Fund ('ERDF') established by a Regulation of the European Parliament and of the Council on the European Regional Development Fund and on the Cohesion Fund, the European Social Fund Plus (ESF+) established by a Regulation of the European Parliament and of the Council on the European Social Fund Plus (ESF+), the InvestEU Programme established by Regulation (EU) 2021/523 of the European Parliament and of the Council <sup>(10)</sup>, and the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council <sup>(11)</sup>, actions that advance the digital transformation of health services and increase the interoperability of such services, including the development of a European health data space, could be supported under the Programme.
- (19) Health is an investment, and the Programme should have this concept at its core. Keeping people healthy and active longer and empowering them to take an active role in managing their health by improving their health literacy will have positive effects on health, health inequalities and inequities, access to sexual and reproductive healthcare, quality of life, workers' health, productivity, competitiveness and inclusiveness, while reducing pressures on national healthcare systems and national budgets. The Programme should also support actions to reduce inequalities in the provision of healthcare, in particular in rural and remote areas, including in the outermost regions, for the purposes of achieving inclusive growth. The Commission has committed to helping Member States to reach the sustainable development targets set in the UN resolution of 25 September 2015 entitled 'Transforming our world: the 2030 Agenda for Sustainable Development'(the 'UN 2030 Agenda'), in particular Sustainable Development Goal 3 'Ensure healthy lives and promote well-being for all at all ages'. The Programme should therefore contribute to the actions towards reaching those targets.
- (20) Non-communicable diseases are often the result of a combination of genetic, physiological, environmental and behavioural factors. Non-communicable diseases such as cardiovascular disease, cancer, mental illness, neurological disorders, chronic respiratory disease and diabetes represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, and cause a considerable social and economic impact. To decrease the impact of non-communicable diseases on individuals and society in the Union and to reach Goal 3 of the UN 2030 Agenda Sustainable Development Goals, in particular but not exclusively Target 3.4 of that Goal, namely to reduce premature mortality from non-communicable diseases by one third by 2030, it is essential to provide an integrated response that focuses on health promotion and disease prevention across relevant sectors.
- (21) The Programme therefore should support health promotion and disease prevention and improve mental health throughout the lifetime of an individual by addressing health risk factors, and health determinants, which would also contribute to the attainment of Goal 3 of the UN 2030 Agenda Sustainable Development Goals. The Programme should also therefore contribute to the objectives set out in the Commission communication of 11 December 2019 entitled 'The European Green Deal' (the 'European Green Deal').

<sup>(10)</sup> 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 (see page 30 of this Official Journal).

<sup>(11)</sup> 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).

- (22) The Programme should continue to support actions in the area of reducing and preventing alcohol-related harm, with particular emphasis on protecting the young.
- (23) The burden of chronic diseases is significant in the Union. It is well acknowledged that prevention and early detection are important in that regard. The Programme should support actions in those areas and should support the development of specific Union preventive and disease management guidelines and therefore aim to reduce the burden of Member States by working together to achieve better and more effective management of chronic diseases. Demographic changes, in particular the ageing of society, challenge the sustainability of health systems. Age-related diseases and disorders, such as dementia, and age-related disabilities, necessitate specific attention.
- (24) Cancer is the second leading cause of mortality in the Member States after cardiovascular disease. It is also one of the non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. Poor nutrition, physical inactivity, obesity, tobacco use and harmful use of alcohol are risk factors common to other chronic diseases, such as cardiovascular disease, and therefore cancer prevention programmes should be implemented within the context of an integrated approach to preventing chronic diseases. Relevant measures in the 'Europe's Beating Cancer Plan' set out in the communication of the Commission of 3 February 2021 should benefit from the Programme and from Horizon Europe's mission on cancer, and should contribute to fostering an integrated approach that covers prevention, screening, early diagnosis, monitoring, treatment and care, as well as improving the quality of life of patients and survivors.
- (25) It should be possible to support studies on the influence of gender on the characteristics of diseases in order to contribute to improving knowledge and education in that area, thereby improving prevention, diagnosis, monitoring and treatment.
- (26) The Programme should work in synergy with and in a manner that complements other Union policies, programmes and funds, such as the Digital Europe Programme, Horizon Europe, the rescEU reserve under the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council<sup>(12)</sup> (the 'rescEU reserve'), the Emergency Support Instrument established by Council Regulation (EU) 2016/369<sup>(13)</sup>, the ESF+, of which the Employment and Social Innovation strand forms part, including as regards synergies in relation to better protecting the health and safety of millions of workers in the Union, the InvestEU Programme, the Single Market Programme established by a Regulation of the European Parliament and of the Council establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014 and (EU) No 652/2014, the ERDF, the Recovery and Resilience Facility, Erasmus+ established by a Regulation of the European Parliament and of the Council establishing Erasmus+: the Union Programme for education and training, youth and sport and repealing Regulation (EU) No 1288/2013, the European Solidarity Corps Programme established by a Regulation of the European Parliament and of the Council establishing the European Solidarity Corps Programme and repealing Regulations (EU) 2018/1475 and (EU) No 375/2014,

and external action instruments of the Union, such as the Neighbourhood, Development and International Cooperation Instrument established by a Regulation of the European Parliament and of the Council establishing the Neighbourhood, Development and International Cooperation Instrument – Global Europe, amending and repealing Decision No 466/2014/EU of the European Parliament and of the Council and repealing Regulation (EU) 2017/1601 of the European Parliament and of the Council and Council Regulation (EC, Euratom) No 480/2009, and the Instrument for Pre-accession Assistance III established by a Regulation of the European Parliament and of the Council establishing the Instrument for Pre-accession Assistance (IPA III). Where appropriate, common rules should be established with a view to ensuring that there is consistency and complementarity between Union policies, programmes and funds, while ensuring that the specificities of those policies are respected, and with a view to aligning with the strategic requirements of those policies, programmes and funds, such as the

<sup>(12)</sup> Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77I, 20.3.2019, p. 1).

<sup>(13)</sup> Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union (OJ L 70, 16.3.2016, p. 1).

enabling conditions under the ERDF and ESF+. The Commission and the Member States should ensure that such synergies and complementarities are duly taken into consideration when drafting the annual work programmes as provided for in this Regulation.

- (27) The Commission should consult the Member States through a 'EU4Health Steering Group' to be established by this Regulation on the priorities and strategic orientations of the Programme, in order to ensure that there is consistency and complementarity between the Programme and other policies, instruments and actions of the Union, as well as on the implementation of the Programme.
- (28) The Programme should contribute to the establishment of a reserve of essential crisis-relevant products, in synergy and complementarity with the rescEU reserve, with the emergency support established under Regulation (EU) 2016/369, with the Recovery and Resilience Facility and with other Union policies, programmes and funds, complementing national stockpiles at Union level where needed.
- (29) Given rising healthcare demand, Member States' healthcare systems face challenges regarding the availability and affordability of medicinal products. To ensure that there is better public health protection, as well as that patients in the Union are safe and empowered, it is essential that patients and health systems have access to sustainable, efficient, equitable, affordable and high-quality medicinal products, including in the cross-border context, and that they can fully benefit from those medicinal products on the basis of transparent, consistent, and patient-oriented medical information.
- (30) Given rising healthcare demand, inter alia, the Programme should support the development of a Union system for the monitoring, reporting and notification of shortages of medicinal products and medical devices in order to avoid fragmentation of the internal market and to ensure greater availability and affordability of those medicinal products and medical devices while limiting the extent to which their supply chains depend on third countries. The Programme should therefore encourage the production of medicinal products and medical devices within the Union. In particular, in order to address unmet medical needs, the Programme should provide support to the generation of clinical and real-world evidence to enable the development of, authorisation of, evaluation of and access to effective medicinal products, including generics and biosimilars, to medical devices and to treatment, should promote research and development with respect to new medicinal products, with particular attention to be given to antimicrobials and vaccines to tackle antimicrobial resistance and vaccine-preventable diseases, respectively, should promote incentives to boost the production capacity for antimicrobials, personalised treatment and vaccination, and should foster the digital transformation of healthcare products and platforms for monitoring and collecting information on medicinal products. The Programme should also strengthen decision-making regarding medicinal products by enabling access to and the analysis of real-world healthcare data. The Programme should also help to ensure that the best use is made of research results and facilitate the uptake, scaling-up and deployment of health innovations in healthcare systems and clinical practice.
- (31) As the optimal delivery and use of medicinal products, and of antimicrobials in particular, yield benefits for individuals and health systems, the Programme should promote their prudent and efficient use in accordance with the One Health approach, with the 'European One Health Action Plan against Antimicrobial Resistance (AMR)' set out in the communication of the Commission of 29 June 2017, and with the 'European Union Strategic Approach to Pharmaceuticals in the Environment' set out in the communication of the Commission of 11 March 2019. The Programme should also foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products.
- (32) Union health legislation has an immediate impact on public health, on the lives of people, on the efficiency and resilience of health systems and on the proper functioning of the internal market. The regulatory framework for medical products and technologies, including medicinal products, medical devices and substances of human origin, and the regulatory frameworks for tobacco, patients' rights in cross-border healthcare and serious cross-border threats to health, are essential to the protection of health in the Union. The Programme therefore should support

the development, implementation and enforcement of Union health legislation and, in conjunction with relevant bodies such as EMA and ECDC, should provide high-quality, comparable and reliable data, including real-world healthcare data, to support policymaking and monitoring, set targets and develop tools to measure progress.

- (33) European Reference Networks (ERNs), which were established pursuant to Directive 2011/24/EU of the European Parliament and of the Council <sup>(14)</sup>, are virtual networks of healthcare providers across Europe. They aim to facilitate discussion regarding complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As ERNs can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through ERNs and other transnational networks.
- (34) ERNs and cross-border cooperation in the provision of healthcare to patients moving between Member States are examples of areas where integrated work between Member States has been shown to have strong added value and great potential to increase the efficiency of health systems and thus to improve public health in general. Collaboration as regards HTA is another area that is bringing added value to Member States. The Programme should therefore support activities that enable integrated and sustained coordinated work, thereby also serving to foster the implementation of best practices that are aimed at distributing the available resources to the population and areas concerned in the most effective way so as to maximise their impact.
- (35) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council <sup>(15)</sup> (the 'Financial Regulation') applies to this Programme. The Financial Regulation lays down rules on the implementation of the Union budget, including the rules on grants, prizes, procurement, indirect management, financial instruments, budgetary guarantees, financial assistance and the reimbursement of external experts.
- (36) The types of financing and the methods of implementation under this Regulation should be chosen on the basis of their ability to achieve the specific objectives of the actions concerned and to deliver results, taking into account, in particular, the costs of controls, the administrative burden, and the expected risk of non-compliance. That choice should include consideration of the use of lump sums, flat-rate financing and unit costs, as well as the use of financing that is not linked to costs as envisaged in Article 125(1) of the Financial Regulation. Technical and financial reporting requirements for the beneficiaries should be such as to ensure that there is compliance with applicable financial provisions while minimising the administrative burden.
- (37) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme and other Union programmes, including those under shared-management. To maximise those synergies, and avoid duplications, appropriate mechanisms should be provided for, including cumulative funding in an action from the Programme and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility of declaring the same cost or expenditure on a pro-rata basis under the Programme and another Union programme, in order to ensure that there is detailed and transparent reporting.
- (38) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States will be best placed, in some cases, to implement actions related to the Programme. Those authorities, designated by the Member States, should therefore be considered to be identified beneficiaries for

<sup>(14)</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

<sup>(15)</sup> 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).

the purpose of Article 195 of the Financial Regulation and grants should therefore be awarded to those authorities without the prior publication of calls for proposals. Investments under the Programme should be implemented in close cooperation with Member States.

- (39) Under 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 to start the action prior to the signature of the grant agreement. However, costs incurred prior to the date of submission of the grant application are not eligible costs, except in duly justified exceptional cases. In order to avoid any disruption to Union support which could be prejudicial to the Union's interests, it should be possible to provide for the eligibility of activities and costs from the beginning of the 2021 financial year in the financing decision, for a limited period at the beginning of the multiannual financial framework 2021-2027, and only in duly justified cases, even if those activities were implemented and those costs were incurred before the grant application was submitted.
- (40) ERNs are approved by the Board of Member States of the ERNs, following the approval procedure set out in Commission Implementing Decision 2014/287/EU<sup>(16)</sup>. ERNs should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation, and the grants to ERNs should therefore be awarded without prior publication of calls for proposals. Direct grants should also be awarded to other entities that have been designated in accordance with Union rules, for example reference laboratories and centres, centres of excellence and transnational networks.
- (41) Given the commonly agreed values of solidarity in relation to equitable and universal coverage of quality health services as a basis for the Union's policies in this area and the fact that the Union has a central role to play in accelerating progress, coordination and cooperation in tackling global health challenges as set out in the Council conclusions of 10 May 2010 on the EU role in Global Health, and as expressed in the UN 2030 Agenda Sustainable Development Goals, the Programme should reinforce the Union's support for international and global health initiatives, in particular for initiatives by the WHO, with a view to improving health, addressing health inequalities and strengthening protection against global health threats.
- (42) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD), when implementing the Programme. In order to increase impact, synergies should also be sought with the national organisations of Member States that are active in global health. In accordance with Council Decision 2013/755/EU<sup>(17)</sup>, persons and entities established in Overseas Countries and Territories (OCTs) should be eligible for funding under the Programme, subject to the rules and objectives of the Programme and to possible arrangements applicable to the Member State to which the relevant OCTs are linked.
- (43) The implementation of the Programme should be supported by extensive outreach activities to ensure that the views and needs of civil society are duly represented and taken into account. To this end, the Commission should seek feedback on the Programme's priorities and strategic orientations and on the needs to be addressed through its actions from relevant stakeholders once a year, including from representatives of civil society and patients' associations, academics and organisations of healthcare professionals. Each year, before the end of the preparatory work for the work programmes, the Commission should also inform the European Parliament about the progress regarding such preparatory work and on the outcome of its outreach activities towards stakeholders.

<sup>(16)</sup> Commission Implementing Decision 2014/287/EU of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 147, 17.5.2014, p. 79).

<sup>(17)</sup> Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ('Overseas Association Decision') (OJ L 344, 19.12.2013, p. 1).

- (44) Third countries which are members of the European Economic Area (EEA) are able to participate in Union programmes in the framework of the cooperation established under the Agreement on the European Economic Area <sup>(18)</sup>, which provides for the implementation of such programmes on the basis of a decision adopted under that agreement. A specific provision should be introduced in this Regulation requiring third countries that participate in the Programme to grant the necessary rights and access required for the authorising officer responsible, the European Anti-Fraud Office (OLAF) and the Court of Auditors to comprehensively exercise their respective competences.
- (45) Cooperation with third countries should be strengthened as regards the exchange of knowledge and best practices in order to improve health systems' preparedness and response capacity.
- (46) In accordance with the Financial Regulation, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council <sup>(19)</sup> and Council Regulations (EC, Euratom) No 2988/95 <sup>(20)</sup>, (Euratom, EC) No 2185/96 <sup>(21)</sup> and (EU) 2017/1939 <sup>(22)</sup>, 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, 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 <sup>(23)</sup>.
- (47) In accordance with the Financial Regulation, any person or entity receiving Union funds is to fully cooperate in the protection of the financial interests of the Union, 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 ensure that any third parties involved in the implementation of Union funds grant equivalent rights.
- (48) Horizontal financial rules adopted by the European Parliament and the Council on the basis of Article 322 TFEU apply to this Regulation. Those rules are laid down in the Financial Regulation and determine in particular the procedure for establishing and implementing the budget through grants, procurement, prizes, indirect implementation, financial instruments, budgetary guarantees, financial assistance and the reimbursement of external experts and provide for checks on the responsibility of financial actors. Rules adopted on the basis of Article 322 TFEU also include a general regime of conditionality for the protection of the Union budget.
- (49) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement adopted under the United Nations Framework Convention on Climate Change and the UN Agenda 2030 Sustainable Development Goals, the Programme should contribute to mainstreaming climate action in the Union's policies and to the achievement of an overall target of at least 30 % of the total amount of the Union budget and the European Union Recovery Instrument, established by Council Regulation (EU) 2020/2094 <sup>(24)</sup>, expenditures, supporting climate objectives. The Programme should support activities that would respect the climate and

<sup>(18)</sup> OJ L 1, 3.1.1994, p. 3.

<sup>(19)</sup> 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).

<sup>(20)</sup> 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).

<sup>(21)</sup> 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).

<sup>(22)</sup> 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).

<sup>(23)</sup> 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).

<sup>(24)</sup> 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 433I, 22.12.2020, p. 23).

environmental standards and priorities of the Union and the 'do no harm' principle of the European Green Deal. Relevant actions should be identified during the Programme's preparation and implementation, and reassessed in the context of its interim evaluation.

- (50) According to Article 8 TFEU, in all its activities, the Union shall aim to eliminate inequalities and to promote equality between men and women. Gender equality, as well as rights and equal opportunities for all, and the mainstreaming of those objectives should be taken into account and promoted throughout the assessment, preparation, implementation and monitoring of the Programme.
- (51) It should be possible for the policy objectives of the Programme to also be addressed through financial instruments and budgetary guarantees under the InvestEU Fund provided for by the InvestEU Programme. Financial support should be used to address market failures and sub-optimal investment situations, in a proportionate manner. Actions funded by the Programme should not duplicate or crowd out private financing or distort competition in the internal market. In general, actions should have Union added value.
- (52) The implementation of the Programme should be such that the responsibilities of the Member States for the definition of their health policies and for the organisation and delivery of health services and medical care are respected. Strong involvement of Member States in the governance and implementation of the Programme should be ensured.
- (53) Given the nature and potential scale of cross-border threats to health, the objectives of protecting people in the Union from such threats and increasing health crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 TEU, action at Union level can also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability, sustainability, acceptability, accessibility, safety and affordability in the Union of medicinal products, medical devices and crisis-relevant products and services, to support innovation, to support integrated and coordinated work and the implementation of best practices among Member States, and to address inequalities and inequities in access to healthcare throughout the Union in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level, while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (54) In order to allow possible adjustments necessary to achieve the Programme's objectives to be made, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the review, amendment and addition of the indicators set out in Annex II to this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making <sup>(25)</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (55) Member States and participating countries have designated National Focal Points to assist the Commission in the promotion of the third Programme for the Union's action in the field of health (2014-2020) established by Regulation (EU) No 282/2014, and, where relevant, in the dissemination of its results and the information available on its impact in the Member States and participating countries. Given the importance of such activities, it is appropriate to support such activities under the Programme in order to continue them.

<sup>(25)</sup> OJ L 123, 12.5.2016, p. 1.

- (56) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts establishing annual work programmes in accordance with the criteria set out in this Regulation, approving certain eligible actions and establishing rules on technical and administrative arrangements necessary for the implementation of the actions of the Programme and on uniform templates for the collection of data necessary to monitor the implementation of the Programme. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of European Parliament and of the Council <sup>(26)</sup>. The examination procedure should be used for the adoption of those implementing acts given that they relate to a programme with substantial implications.
- (57) The value and impact of the Programme should be regularly and closely monitored and evaluated. The evaluation should focus on the goals of the Programme and take into account the fact that the achievement of the Programme's objectives could require a period that is longer than the length of the Programme. To that end, an interim evaluation report should be drawn up, as well as an evaluation report at the end of the Programme, in order to assess the implementation of the priorities of the Programme.
- (58) As the third Programme for the Union's action in the field of health (2014-2020) has come to an end, Regulation (EU) No 282/2014 has become obsolete and should be repealed.
- (59) In order to ensure continuity in providing support in the field of health and to allow implementation to start from the beginning of the multiannual financial framework 2021-2027, this Regulation should enter into force as a matter of urgency and should apply, with retroactive effect, from 1 January 2021,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### *Article 1*

#### **Subject matter**

This Regulation establishes the EU4Health Programme (the 'Programme') for the period of the multiannual financial framework 2021 to 2027. The duration of the Programme is aligned with the duration of the multiannual financial framework.

This Regulation also lays down the objectives of the Programme, the budget for the period from 2021 to 2027, the forms of Union funding and the rules for providing such funding.

#### *Article 2*

#### **Definitions**

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

- (1) 'associated country' means a third country which is party to an agreement with the Union that allows for its participation in the Programme, in accordance with Article 6;
- (2) 'blending operations' means actions supported by the Union budget, including within blending facilities pursuant to point (6) of Article 2 of the Financial Regulation, combining non-repayable forms of support, and/or financial instruments from the Union budget with repayable forms of support from development institutions or other public finance institutions, as well as from commercial finance institutions and commercial investors;

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<sup>(26)</sup> 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).

- (3) 'health crisis' means a crisis or serious incident arising from a threat of human, animal, plant, food, biological, chemical, environmental or unknown origin, which has a public health dimension and which requires urgent action by authorities;
- (4) 'crisis-relevant products' means products, tools and substances that are necessary, in the context of a health crisis, for the prevention, diagnosis or treatment of a disease and its consequences, or for the monitoring and the epidemiological surveillance of diseases and infections, including, but not limited to, medicinal products, such as vaccines and their intermediates, active pharmaceutical ingredients and raw materials, as well as medical devices and hospital and medical equipment, such as ventilators, protective clothing and equipment, diagnostic materials and tools, personal protective equipment, disinfectants and their intermediary products, and the raw materials necessary for their production;
- (5) 'One Health approach' means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;
- (6) 'European Reference Networks (ERNs)' means the networks referred to in Article 12 of Directive 2011/24/EU;
- (7) 'legal entity' means a natural person, or a legal person created and recognised as such under national, Union or international law which has legal personality and which can, acting in its own name, exercise rights and be subject to obligations, or an entity without legal personality as referred to in point (c) of Article 197(2) of the Financial Regulation;
- (8) 'third country' means a country that is not a Member State of the European Union;
- (9) 'serious cross-border threat to health' means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;
- (10) 'Health in All Policies' means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;
- (11) 'health determinants' means a range of factors that influence the health status of a person, such as behaviour-related, biological, socio-economic and environmental factors;
- (12) 'emergency support' means a needs-based emergency response that complements the response of the affected Member States and is aimed at preserving life, preventing and alleviating human suffering, and maintaining human dignity, wherever the need arises as a result of serious cross-border threats to health.

### Article 3

#### General objectives

The Programme shall have a Union added value and complement the policies of the Member States, in order to improve human health throughout the Union and to ensure a high level of protection of human health in all Union policies and activities. It shall pursue the following general objectives in keeping with the One Health approach, where applicable:

- (a) improving and fostering health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare;
- (b) protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health;
- (c) improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products;

- (d) strengthening health systems by improving their resilience and resource efficiency, in particular through:
  - (i) supporting integrated and coordinated work between Member States;
  - (ii) promoting the implementation of best practices and promoting data sharing;
  - (iii) reinforcing the healthcare workforce;
  - (iv) tackling the implications of demographic challenges; and
  - (v) advancing digital transformation.

#### Article 4

### Specific objectives

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, ensuring a high level of human health protection in all Union policies and activities in keeping with the One Health approach, where applicable:

- (a) in synergy with other relevant Union actions, supporting actions for disease prevention, for health promotion and for addressing health determinants, including through the reduction of damage to health resulting from illicit drug use and addiction, supporting actions to address inequalities in health, to improve health literacy, to improve patient rights, patient safety, quality of care and cross-border healthcare, and supporting actions for the improvement of the surveillance, diagnosis and treatment of communicable and non-communicable diseases, in particular cancer and paediatric cancer, as well as supporting actions to improve mental health, with special attention given to new care models and the challenges of long term care, in order to strengthen the resilience of the health systems in the Union;
- (b) strengthening the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross-border threats to health in accordance with relevant Union legislation, and improving the management of health crises, particularly through the coordination, provision and deployment of emergency healthcare capacity, supporting data gathering, information exchange, surveillance, the coordination of voluntary stress testing of national healthcare systems, and the development of quality healthcare standards at national level;
- (c) supporting actions to enhance the availability, accessibility and affordability of medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union, while supporting the prudent and efficient use of medicinal products, in particular antimicrobials, and actions to support the development of medicinal products that are less harmful for the environment, as well as the environmentally friendly production and disposal of medicinal products and medical devices;
- (d) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences, and in close cooperation with relevant Union bodies, supporting actions complementing national stockpiling of essential crisis-relevant products, at Union level, where needed;
- (e) in synergy with other Union instruments, programmes and funds, without prejudice to Member State competences and in close cooperation with the ECDC, establishing a structure and training resources for a reserve of medical, healthcare and support staff allocated voluntarily by Member States for its mobilisation in the event of a health crisis;
- (f) strengthening the use and re-use of health data for the provision of healthcare and for research and innovation, promoting the uptake of digital tools and services, as well as the digital transformation of healthcare systems, including by supporting the creation of a European health data space;
- (g) enhancing access to quality, patient-centred, outcome-based healthcare and related care services, with the aim of achieving universal health coverage;
- (h) supporting the development, implementation and enforcement and, where necessary, the revision of Union health legislation and supporting the provision of valid, reliable and comparable high-quality data for evidence-based decision-making and monitoring, and promoting the use of health impact assessments of other relevant Union policies;

- (i) supporting integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, supporting work on HTA, and strengthening and scaling up networking through ERNs and other transnational networks, including in relation to diseases other than rare diseases, to increase the coverage of patients and improve the response to low prevalence and complex communicable and non-communicable diseases;
- (j) supporting global commitments and health initiatives by reinforcing the Union's support for actions by international organisations, in particular actions by the WHO, and fostering cooperation with third countries.

#### Article 5

#### Budget

1. The financial envelope for the implementation of the Programme for the period 2021 - 2027 shall be EUR 2 446 000 000 in current prices.
2. As a result of the Programme-specific adjustment provided for in Article 5 of Council Regulation (EU, Euratom) 2020/2093 <sup>(27)</sup>, the amount referred to in paragraph 1 of this Article shall be increased by an additional allocation of EUR 2 900 000 000 in 2018 prices as specified in Annex II to that Regulation.
3. The amounts referred to in paragraphs 1 and 2 may also be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems.
4. The distribution of the amounts referred to in paragraphs 1 and 2 shall comply with the following:
  - (a) a minimum of 20 % of the amounts shall be reserved for health promotion and disease prevention actions as referred to in point (a) of Article 4;
  - (b) a maximum of 12,5 % of the amounts shall be reserved for procurement complementing national stockpiling of essential crisis-relevant products at Union level as referred to in point (d) of Article 4;
  - (c) a maximum of 12,5 % of the amounts shall be reserved for supporting global commitments and health initiatives as referred to in point (j) of Article 4;
  - (d) a maximum of 8 % of the amounts shall be reserved for covering administrative expenses as referred to in paragraph 3.
5. Appropriations related to activities under point (c) of Article 9(1) of this Regulation, shall constitute assigned revenue within the meaning of point (a) of paragraph 3, and paragraph 5, of Article 21 of the Financial Regulation.
6. Budgetary commitments extending over more than one financial year may be broken down over several years into annual instalments.
7. In accordance with point (a) of the second subparagraph of Article 193(2) of the Financial Regulation, for a limited period in duly justified cases specified in the financing decision, activities supported under this Regulation and their underlying costs may be considered eligible as of 1 January 2021, even if those activities were implemented and those costs were incurred before the grant application was submitted.
8. If necessary, appropriations may be entered in the budget beyond 31 December 2027 to cover the expenses referred to in paragraph 3 to enable the management of actions not completed by 31 December 2027.

<sup>(27)</sup> Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L 433I, 22.12.2020, p. 11).

*Article 6***Third countries associated to the Programme**

1. The Programme shall be open to the participation of the following third countries:
  - (a) members of the European Free Trade Association which are members of the European Economic Area, in accordance with the conditions laid down in the Agreement on the European Economic Area;
  - (b) acceding countries, candidate countries and potential candidates, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions, or similar agreements and in accordance with the specific conditions laid down in agreements between the Union and those countries;
  - (c) European Neighbourhood Policy countries, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions, or in similar agreements and in accordance with the specific conditions laid down in agreements between the Union and those countries;
  - (d) other third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country in any Union programme, provided that the agreement:
    - (i) ensures a fair balance as regards the contributions and benefits of the third country participating in the Union programme;
    - (ii) lays down the conditions of participation in the Union programme, including the calculation of financial contributions to individual programmes, and their administrative costs;
    - (iii) does not confer on the third country a decision-making power in respect of the Union programme;
    - (iv) guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.
2. The contributions referred to in point (d)(ii) of paragraph 1 shall constitute assigned revenue in accordance with Article 21(5) of the Financial Regulation.

## CHAPTER II

**FUNDING***Article 7***Implementation and forms of Union funding**

1. The Programme shall be implemented in direct management in accordance with the Financial Regulation or in indirect management with the bodies referred to in point (c) of Article 62(1) of that Regulation.
2. The Programme may provide funding in any of the forms laid down in the Financial Regulation, in particular in the form of grants, prizes and procurement.
3. Contributions to a mutual insurance mechanism may cover the risk associated with the recovery of funds due by recipients and may be considered as a sufficient guarantee under the Financial Regulation. The Commission shall lay down specific rules for the operation of the mechanism.

4. Where the Commission implements emergency support operations through a non-governmental organisation, the criteria concerning financial and operational capacity shall be deemed to be satisfied if there is a framework partnership agreement in force between that organisation and the Commission pursuant to Council Regulation (EC) No 1257/96 <sup>(28)</sup>.

#### Article 8

##### Grants

1. Grants under the Programme shall be awarded and managed in accordance with Title VIII of the Financial Regulation.
2. Grants may be used in combination with financing from the European Investment Bank, from national promotional banks or from other development or public financial institutions, as well as in combination with financing from private-sector finance institutions and from public-sector or private-sector investors, including through public-public or public-private partnerships.
3. Grants paid by the Union shall not exceed 60 % of eligible costs for an action relating to an objective of the Programme or for the functioning of a non-governmental body. In cases of exceptional utility, the contribution by the Union may be up to 80 % of eligible costs. Actions with a clear Union added value shall be considered to have exceptional utility, inter alia, where:
  - (a) at least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average; or
  - (b) bodies from at least 14 participating Member States participate in the action, of which at least four are Member States whose GNI per inhabitant is less than 90 % of the Union average.
4. In the case of the direct grants referred to in Article 13(6) and (7), such grants may be up to 100 % of eligible costs.

#### Article 9

##### Procurement in health emergency situations

1. In cases where the emergence or development of a serious cross-border threat to health has been notified under Article 9 of Decision No 1082/2013/EU, or where a situation of public health emergency has been recognised under Article 12 of that Decision, procurement under this Regulation may take any of the following forms:
  - (a) joint procurement with the Member States as referred to in Article 165(2) of the Financial Regulation whereby Member States may acquire, rent or lease fully the jointly procured capacities;
  - (b) procurement by the Commission on behalf of the Member States on the basis of an agreement between the Commission and the Member States;
  - (c) procurement by the Commission acting as wholesaler by buying, stocking and reselling or donating supplies and services, including rentals, for the benefit of Member States or partner organisations selected by the Commission.
2. In the event of the procurement procedure referred to in point (b) of paragraph 1 being used, the ensuing contracts shall be concluded by either of the following:
  - (a) by the Commission, where the services or goods are to be provided or delivered to Member States or to partner organisations selected by the Commission;
  - (b) by the participant Member States, where they are to directly acquire, rent or lease the capacities procured for them by the Commission.

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<sup>(28)</sup> Council Regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid (OJ L 163, 2.7.1996, p. 1).

3. In the event of the procurement procedures referred to in points (b) and (c) of paragraph 1 being used, the Commission shall comply with the Financial Regulation for its own procurement.

#### *Article 10*

### **Blending operations**

Blending operations under the Programme shall be implemented in accordance with Regulation (EU) 2021/523 and Title X of the Financial Regulation.

#### *Article 11*

### **Cumulative funding**

1. An action that has received a contribution under the Programme may also receive a contribution from any other Union programme, including Funds under shared management, provided that the contributions do not cover the same costs.
2. The rules of the relevant Union programme shall apply to the corresponding contribution to the action.
3. The cumulative funding 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.

## CHAPTER III

### **ACTIONS**

#### *Article 12*

### **Eligible actions**

Only actions that implement the objectives listed in Articles 3 and 4, in particular the actions set out in Annex I, shall be eligible for funding.

#### *Article 13*

### **Eligible legal entities**

1. In order to be eligible for funding, legal entities shall, in addition to the criteria set out in Article 197 of the Financial Regulation:
  - (a) be established in any of the following:
    - (i) a Member State or an overseas country or territory linked to it;
    - (ii) a third country associated to the Programme; or
    - (iii) a third country listed in the annual work programme established in accordance with Article 17 ('annual work programme') under the conditions specified in paragraphs 2 and 3; or
  - (b) be a legal entity created under Union law or an international organisation.
2. Legal entities that are established in a third country which is not associated to the Programme may in exceptional cases be eligible to participate in the Programme where such participation is necessary for the achievement of the objectives of a given action. The assessment of that necessity shall be duly reflected in the funding decision.
3. Legal entities that are established in a third country which is not associated to the Programme shall bear the cost of their participation.

4. Natural persons shall not be eligible for grants under the Programme.
5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions, if such grants are duly justified, and if those actions have a Union added value that is explicitly provided for in the annual work programmes and are co-financed by the competent authorities that are responsible for health in the Member States or in third countries associated to the Programme, by relevant international health organisations, or by public sector bodies or non-governmental bodies that are mandated by those competent authorities, regardless of whether those bodies act individually or as a network.
6. Under the Programme, direct grants shall be awarded without a call for proposals to ERNs. Direct grants may also be awarded to other transnational networks set out in accordance with Union law.
7. Under the Programme, direct grants may be awarded without a call for proposals to fund actions of the WHO where financial support is necessary for the implementation of one or more of the specific objectives of the Programme that have a Union added value that is explicitly provided for in the annual work programmes.
8. Under the Programme, grants may be awarded without a call for proposals to fund the functioning of non-governmental bodies where financial support is necessary for the implementation of one or more of the specific objectives of the Programme that have a Union added value that is explicitly provided for in the annual work programmes, as long as those bodies fulfil all of the following criteria:
  - (a) they are non-profit-making and independent of industry, commercial and business or other conflicting interests;
  - (b) they work in the public health area, pursue at least one of the specific objectives of the Programme and play an effective role at Union level;
  - (c) they are active at Union level and in at least half of the Member States, with a balanced geographical coverage of the Union.

The Commission shall duly reflect the analysis of the fulfilment of those criteria in the funding decision.

#### Article 14

#### Eligible costs

1. Subject to Article 186 of the Financial Regulation, and point (a) of the second subparagraph of Article 193(2) of that Regulation, costs incurred prior to the date of submission of the grant application shall be eligible for funding with respect to actions:
  - (a) implementing the objective referred to in point (b) of Article 3 of this Regulation; or
  - (b) implementing objectives other than those referred to in point (a) of this paragraph, in duly justified exceptional cases, provided that those costs are directly linked to the implementation of the supported actions and activities.
2. Costs eligible under point (a) of paragraph 1 that relate to measures aiming to address suspected occurrences of a disease that could trigger a cross-border threat to health shall be eligible from the date of notification of the suspected occurrence of that disease to the Commission, provided that the occurrence or presence of that disease is subsequently confirmed.
3. In exceptional cases, during a health crisis caused by a serious cross-border threat to health as defined in point (g) of Article 3 of Decision No 1082/2013/EU, costs incurred by entities established in non-associated countries may be considered eligible if those costs are duly justified for reasons concerning countering the spread of the risk for the protection of the health of people in the Union.

## CHAPTER IV

## GOVERNANCE

*Article 15***Joint policy implementation**

1. A EU4Health Steering Group shall be established.
2. The Members of the EU4Health Steering Group shall be the Commission and the Member States. Each Member State shall appoint one member and one alternate member to the EU4Health Steering Group. The Commission shall provide the secretariat of the EU4Health Steering Group.
3. The Commission shall consult the EU4Health Steering Group:
  - (a) on the Commission's preparatory work for the annual work programmes;
  - (b) each year, at least 6 months in advance of the presentation of the draft of the annual work programme to the committee referred to in Article 23(1), on the priorities and strategic orientations of the annual work programme.
4. The EU4Health Steering Group shall:
  - (a) work towards ensuring that there is consistency and complementarity between the Member States' health policies as well as between the Programme and other policies, instruments and actions of the Union, including those relevant to the Union agencies;
  - (b) follow up the implementation of the Programme and propose any necessary adjustments based on evaluations;
  - (c) adopt its rules of procedure, which shall contain provisions to ensure that the group will meet at least three times a year, in person where appropriate, thus allowing for a regular and transparent exchange of views among Member States.

*Article 16***Stakeholder consultation and information of the European Parliament**

1. The Commission shall consult with relevant stakeholders, including representatives of civil society and patient organisations, to seek their views on:
  - (a) the priorities and strategic orientation of the annual work programme;
  - (b) the needs to be addressed through the annual work programme and the results achieved through it.
2. For the purposes of paragraph 1, the Commission shall organise the consultation and information of stakeholders at least once a year, in the six months preceding the presentation of the draft work programme to the committee referred to in Article 23(1).
3. The Commission may at any time seek the views of relevant decentralised agencies and of independent experts in the field of health on technical or scientific matters of relevance for the implementation of the Programme.
4. Each year, prior to the last meeting of the EU4Health Steering Group, the Commission shall present to the European Parliament the outcomes of the proceedings of the EU4Health Steering Group and the consultation of stakeholders referred to in paragraphs 1 and 2.

*Article 17***Implementation of the Programme**

1. The Commission shall implement the Programme by establishing annual work programmes in accordance with the Financial Regulation.

2. The Commission shall adopt, by means of implementing acts:
  - (a) the annual work programmes, which shall set out, in particular:
    - (i) the actions to be undertaken, including the indicative allocation of financial resources;
    - (ii) the overall amount reserved for blending operations;
    - (iii) eligible actions falling under Article 7(3) and (4);
    - (iv) eligible actions by legal entities referred to in point (b) of Article 13(1);
    - (v) eligible actions by legal entities from a third country not associated to the Programme but listed in the annual work programme under the conditions laid down in Article 13(2) and (3);
  - (b) decisions approving actions with a cost of EUR 20 000 000 or more;
  - (c) rules establishing:
    - (i) the technical and administrative arrangements necessary for the implementation of the actions of the Programme;
    - (ii) uniform templates for the collection of data necessary to monitor the implementation of the Programme.
3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

#### *Article 18*

### **Data protection**

In managing and implementing the Programme, the Commission and the Member States shall ensure that there is compliance with all relevant legal provisions regarding personal data protection and, where appropriate, that mechanisms are introduced to ensure that such data remain confidential and safe.

#### CHAPTER V

### **MONITORING, EVALUATION AND CONTROL**

#### *Article 19*

### **Monitoring and reporting**

1. Indicators to report on progress of the Programme towards the achievement of the general and specific objectives listed in Articles 3 and 4 are set out in Annex II.
2. The Commission is empowered to adopt delegated acts in accordance with Article 25 to amend Annex II with regard to the indicators where considered necessary.
3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner. To that end, the Commission shall adopt implementing acts establishing proportionate reporting requirements for recipients of Union funds and, where appropriate, for Member States.

#### *Article 20*

### **Evaluation**

1. Evaluations provided for in Article 34(3) of the Financial Regulation shall be carried out by the Commission in a sufficiently timely manner to feed into the decision-making process.

2. The Commission shall present an interim evaluation of the Programme no later than 31 December 2024. The interim evaluation shall be the basis for adjusting the implementation of the Programme as appropriate.
3. The Commission shall present a final evaluation at the end of the Programme and no later than four years after the end of the period referred to in Article 1.
4. The Commission shall publish and communicate the conclusions of both the interim and final evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

#### Article 21

##### **Audits**

Audits of the use of Union contributions, including audits carried out by persons or entities other than those mandated by the Union institutions or bodies, shall form the basis of the overall assurance referred to in Article 127 of the Financial Regulation.

#### Article 22

##### **Protection of the financial interests of the Union**

Where a third country participates in the Programme by means of a decision adopted pursuant to an international agreement or on the basis of any other legal instrument, the third 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 23

##### **Committee procedure**

1. The Commission shall be assisted by a EU4Health Programme Committee. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. 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 the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

#### Article 24

##### **Consistency and complementarity with other Union policies, instruments and actions**

The Commission and the Member States shall ensure that there is overall consistency, synergy and complementarity between the Programme and other Union policies, instruments and actions, including those relevant to the Union agencies, including through their common work in the EU4Health Steering Group.

#### Article 25

##### **Exercise of the delegation**

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

2. The power to adopt delegated acts referred to in Article 19(2) shall be conferred on the Commission for a period of seven years from 26 March 2021.
3. The delegation of power referred to in Article 19(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 19(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

## CHAPTER VI

### TRANSITIONAL AND FINAL PROVISIONS

#### *Article 26*

#### **Information, communication and publicity**

1. The recipients of Union funding shall acknowledge the origin of those 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 related to the Programme, to actions taken pursuant to the Programme and to the results obtained.
3. Financial resources allocated to the Programme shall also contribute to the corporate communication of the political priorities of the Union, insofar as those priorities are related to the objectives referred to in Articles 3 and 4.

#### *Article 27*

#### **Repeal**

Regulation (EU) No 282/2014 is repealed with effect from 1 January 2021, without prejudice to Article 28 of this Regulation.

#### *Article 28*

#### **Transitional provisions**

1. This Regulation shall not affect the continuation of or modification of actions initiated pursuant to Regulation (EU) No 282/2014 which shall continue to apply to those actions until their closure.
2. The financial envelope for the Programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the measures adopted under Regulation (EU) No 282/2014 and the Programme.

*Article 29***Entry into force and application**

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

It shall apply from 1 January 2021.

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

Done at Brussels, 24 March 2021.

*For the European Parliament*  
*The President*  
D. M. SASSOLI

*For the Council*  
*The President*  
A.P. ZACARIAS

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## ANNEX I

## LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 12

## 1. Actions meeting the objective laid down in point (a) of Article 4

- (a) Supporting the establishment and implementation of programmes assisting Member States and supporting the actions of Member States to improve health promotion and disease prevention;
- (b) Supporting the implementation and further development of surveys, studies, collection of comparable data and statistics, where relevant including disaggregated data by gender and age, methodologies, classifications, microsimulations, pilot studies, indicators, knowledge brokering and benchmark exercises;
- (c) Supporting Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices, to promote healthy diets and regular physical activity, taking into account the needs of vulnerable groups at every stage of their life, with the aim of promoting life-long health;
- (d) Supporting Member States in delivering effective responses to communicable diseases, and in the prevention, surveillance, diagnosis and treatment of such diseases;
- (e) Supporting Member States' actions in health promotion and disease prevention throughout the lifetime of an individual and by addressing health risk factors, such as obesity, unhealthy diets and physical inactivity;
- (f) Supporting actions to improve mental health;
- (g) Supporting actions to complement measures of Member States in reducing damage to health due to illicit drug use and addiction, including information and prevention;
- (h) Supporting implementing policies and actions to reduce health inequalities and inequities in relation to healthcare;
- (i) Supporting actions to enhance health literacy;
- (j) Supporting the promotion and implementation of the recommendations of the European Code against Cancer and supporting the revision of the current edition of that Code;
- (k) Actions to support the implementation of cancer registries in all Member States;
- (l) Furthering the cooperation among relevant national bodies of participating Member States with a view to supporting the creation of a virtual European network of excellence in order to strengthen research on all types of cancer, including paediatric cancer, and further the collection and exchange of clinical data and the translation of research findings into everyday care and treatment of cancer patients;
- (m) Supporting actions to improve the quality of cancer care, including as regards prevention, screening, early diagnosis, monitoring and treatment, supportive and palliative care, in an integrative and patient-centred approach and supporting the establishment of quality assurance schemes for cancer centres or other centres treating cancer patients, including those treating paediatric cancer;
- (n) Supporting the establishment of quality assurance schemes for cancer centres and centres treating cancer patients;
- (o) Supporting mechanisms for cross-specialty capacity building and continuous education, in particular in the area of cancer care;
- (p) Actions supporting the quality of life of cancer survivors and caregivers, including provision of psychological support, pain management and health-related aspects of professional reintegration;
- (q) Strengthening collaboration on patient rights, patient safety and quality of care;
- (r) Supporting actions regarding epidemiological surveillance, thus contributing to assessment of factors that affect or determine the health of people;

- (s) Supporting, in synergy with other programmes, actions to improve the geographical distribution of the healthcare workforce and actions for the avoidance of ‘medical deserts’, without prejudice to Member State competences;
- (t) Supporting the development of guidelines for preventing and managing communicable and non-communicable diseases, and of tools and networks for the exchange of best practices in that area;
- (u) Supporting Member States’ actions to address health determinants, including reducing alcohol-related harm and tobacco use;
- (v) Supporting tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use;
- (w) Supporting initiatives to improve vaccination coverage rates in the Member States;
- (x) Communication activities addressed to the public and stakeholders to promote Union action in the areas mentioned in this Annex;
- (y) Awareness-raising campaigns and communications activities for the general public as well as for targeted groups, aimed at preventing and addressing vaccine hesitancy, misinformation and disinformation as regards prevention, causes and treatment of diseases, in a manner that complements national campaigns and communications activities on those matters;
- (z) Communication activities addressed to the public on health risks and health determinants;
- (za) Supporting actions to reduce the risk of healthcare-acquired infections.

2. Actions meeting the objective laid down in point (b) of Article 4

- (a) Strengthening the critical health infrastructure to cope with health crises, by supporting the setup of tools for surveillance, forecast, prevention and management of outbreaks;
- (b) Supporting actions to foster Union-wide health crisis prevention and preparedness, and the management capacity and response capacity of actors at Union and national level, including voluntary stress tests, contingency planning and preparedness exercises; supporting the development of quality health standards at national level, mechanisms for the efficient coordination of preparedness and response, and the coordination of those actions at Union level;
- (c) Supporting actions for setting up an integrated cross-cutting risk communication framework covering all phases of a health crisis, namely prevention, preparedness, response and recovery;
- (d) Supporting preventive actions to protect vulnerable groups from health threats and actions to adapt the response to and the management of health crises to the needs of those vulnerable groups such as actions to secure basic care for patients with chronic or rare diseases;
- (e) Supporting actions to address the collateral health consequences of a health crisis, in particular the consequences for mental health, on patients suffering from cancer, from chronic diseases and other vulnerable situations, including people living with addiction, with HIV/AIDS, or suffering from hepatitis and tuberculosis;
- (f) Supporting, in synergy with other programmes, training and educational programmes for the upskilling of healthcare and public health workforces, and programmes for temporary exchanges of staff, in particular with the aim of improving their digital skills;
- (g) Supporting the establishment and coordination of Union Reference Laboratories, Union Reference Centres, and Centres of Excellence;
- (h) Auditing Member States’ preparedness and response arrangements, for example regarding health crisis management, antimicrobial resistance and vaccination;
- (i) Communicating to the public in the context of risk management and health crisis preparedness;

- (j) Supporting upwards convergence of national systems' performance through health indicator development, analysis and knowledge brokering and the organisation of voluntary stress tests of national healthcare systems;
  - (k) Supporting investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.
3. Actions meeting the objective laid down in point (c) of Article 4
- (a) Supporting actions to strengthen laboratory capacity and the production, research, development, and deployment of health products and crisis-relevant niche products within the Union;
  - (b) Supporting actions and interoperable IT tools to monitor, prevent, manage, report and notify shortages of medicinal products and medical devices, while contributing to their affordability;
  - (c) Supporting, in synergy with other programmes, clinical trials to speed up the development, market authorisation and access to innovative, safe and effective medicinal products and vaccines;
  - (d) Supporting actions to encourage the development of innovative medicinal products and vaccines to meet rising healthcare challenges and patients' needs, and of less commercially profitable products such as antimicrobials;
  - (e) Supporting actions to improve the environmentally friendly production and disposal of medicinal products and medical devices and actions to support the development of medicinal products that are less harmful for the environment;
  - (f) Supporting actions to promote the prudent and efficient use of medicinal products, in particular of antimicrobials;
  - (g) Supporting actions aimed at stimulating the increase in the production of essential active pharmaceutical ingredients and medicinal products in the Union, including by diversifying supply chain production of active pharmaceutical ingredients and generics within the Union, to reduce Member States' dependence on certain third countries;
  - (h) Supporting actions to enhance the availability, accessibility and affordability of medicinal products and medical devices;
  - (i) Supporting actions to foster innovation in repurposing, reformulation and combining of off-patent medicinal products, in synergy with other programmes;
  - (j) Actions to strengthen the environmental risk assessment of medicinal products;
  - (k) Supporting the establishment and operation of a mechanism for cross-sectorial coordination following the One-Health approach.
4. Actions meeting the objective laid down in point (d) of Article 4
- (a) Monitoring of information on national stockpiling activities regarding essential crisis-relevant products to identify potential needs for additional stockpiling at Union level;
  - (b) Ensuring consistent management of stockpiling of essential crisis-relevant products at Union level, in a manner that complements other Union instruments, programmes and funds and in close coordination with relevant Union bodies;
  - (c) Supporting actions for the procurement and supply of essential crisis-relevant products, which contribute to their affordability, in a manner that complements Member States' stockpiling actions.
5. Actions meeting the objective laid down in point (e) of Article 4

Supporting actions for the preparatory work for mobilising and training at Union level a reserve of medical, healthcare and support staff to be mobilised in the event of a health crisis, in close collaboration with the ECDC, in synergy with other Union instruments, and in full respect of Member State competences; facilitating the exchange of best practices between existing national reserves of medical, healthcare and support staff.

6. Actions meeting the objective laid down in point (f) of Article 4
  - (a) Supporting a Union framework and the respective interoperable digital tools for cooperation among Member States and cooperation in networks, including those needed for HTA cooperation;
  - (b) Supporting the deployment, operation and maintenance of mature, secure and interoperable digital service infrastructure and data quality assurance processes for the exchange of, access to, and use and reuse of, data; supporting cross-border networking, including through the use and interoperability of electronic health records, registries and other databases; developing appropriate governance structures and interoperable health information systems;
  - (c) Supporting the digital transformation of healthcare and health systems, including through benchmarking and capacity building, for the uptake of innovative tools and technologies such as artificial intelligence, and supporting the digital upskilling of healthcare professionals;
  - (d) Supporting the optimal use of telemedicine and telehealth, including through satellite communication for remote areas, fostering digitally-driven organisational innovation in healthcare facilities and promoting digital tools to support citizen empowerment and patient-centred care;
  - (e) Supporting the development, operation and maintenance of databases and digital tools and their interoperability, including already established projects, where appropriate, with other sensing technologies, such as space-based technologies and artificial intelligence;
  - (f) Supporting actions to strengthen citizens' access to and control over their health data;
  - (g) Supporting the deployment and interoperability of digital tools and infrastructure within and between Member States and with Union institutions, agencies and bodies;
  - (h) Supporting preparatory activities and projects for the European health data space;
  - (i) Actions to support e-health, such as the transition to telemedicine and at-home administration of medication;
  - (j) Supporting the establishment of interoperable electronic health records, in line with the European Electronic Health Record Exchange format in order to increase the use of e-health and improve the sustainability and resilience of healthcare systems.
7. Actions meeting the objective laid down in point (g) of Article 4
  - (a) Actions promoting access to health services and related facilities and care for people with disabilities;
  - (b) Supporting the strengthening of primary care and reinforcing the integration of care, with a view to providing universal health coverage and equal access to good quality healthcare;
  - (c) Supporting Member States' actions to promote access to sexual and reproductive healthcare and supporting integrated and intersectional approaches to prevention, diagnosis, treatment and care.
8. Actions meeting the objective laid down in point (h) of Article 4
  - (a) Supporting the establishment and operation of a health intelligence and knowledge infrastructure;
  - (b) Supporting the implementation, enforcement, monitoring of Union health legislation and action; and providing technical support for the implementation of legal requirements;
  - (c) Supporting studies and analysis, health impact assessment of other Union policy actions and the provision of scientific advice to support evidence-based policymaking;
  - (d) Supporting expert groups and panels providing advice, data and information to support health policy development and implementation, including follow-up evaluations of the implementation of health policies;

- (e) Supporting national contact and focal points in providing guidance, information and assistance related to the promotion and implementation of Union health legislation and of the Programme;
  - (f) Auditing and assessment work in accordance with Union legislation, where appropriate;
  - (g) Supporting the implementation and further development of the Union's tobacco control policy and legislation;
  - (h) Supporting national systems as regards the implementation of legislation on substances of human origin, and as regards the promotion of the sustainable and safe supply of such substances through networking activities;
  - (i) Supporting Member States to strengthen the administrative capacity of their healthcare systems through cooperation and exchange of best practices;
  - (j) Supporting knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience of health systems, while linking available Union funding;
  - (k) Supporting capacity building for investing in and implementing health system reforms, including strategic planning and access to multi-source financing.
9. Actions meeting the objective laid down in point (i) of Article 4
- (a) Supporting the transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value between Member States, and in particular providing country-specific tailor-made assistance to the Member States, or groups of Member States, with the greatest needs, through the funding of specific projects including twinning, expert advice and peer support;
  - (b) Supporting cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;
  - (c) Strengthening cross-sectoral collaboration and coordination;
  - (d) Supporting the functioning of ERNs and the establishment and operation of new transnational networks as provided for in Union health legislation, and supporting Member States' actions to coordinate the activities of such networks with the operation of national health systems;
  - (e) Supporting further the implementation of ERNs in Member States and fostering their strengthening, inter alia, by continuous assessment, monitoring, evaluation and improvement;
  - (f) Supporting the creation of new ERNs, to cover rare, complex and low prevalence diseases, where appropriate, and supporting collaboration among ERNs to address the multi-systemic needs arising from low prevalence diseases and rare diseases and to facilitate diagonal networking between different specialities and disciplines;
  - (g) Support Member States to improve and further develop and implement ERN registries;
  - (h) Stakeholder consultation activities.
10. Actions meeting the objective laid down in point (j) of Article 4
- (a) Supporting actions contributing to the objectives of the programme presented by the WHO, as the directing and coordinating authority for health within the United Nations;
  - (b) Supporting collaboration among Union institutions, Union agencies, and international organisations and networks, and supporting the Union's contribution to global initiatives;
  - (c) Supporting collaboration with third countries as regards the areas covered by the Programme;
  - (d) Supporting actions to foster international regulatory convergence on medicinal products and medical devices.
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## ANNEX II

## INDICATORS FOR THE EVALUATION OF THE PROGRAMME

## Programme indicators:

1. Preparedness and response planning of the Union and of Member States for serious cross-border threats to health
  2. Access to centrally authorised medicinal products, for example the number of existing and new orphan authorisations, advanced therapy medicinal products (ATMPs), medicinal products for paediatric use or vaccines, for unmet needs
  3. Number of actions contributing to the reduction of avoidable mortality in the area of non-communicable diseases and risk factors
  4. Number of Member States implementing best practices regarding health promotion, disease prevention and addressing health inequalities
  5. Number of Member States participating in the European health data space
  6. Number of Member States with improved preparedness and response planning
  7. Vaccination coverage by age for vaccine-preventable-diseases such as measles, flu, HPV and COVID-19
  8. EU Laboratory capacity index (EULabCap)
  9. Age-standardised five-year net survival rate for paediatric cancer by type, age, gender and Member State (to the extent available)
  10. Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, target population, and Member State
  11. Percentage of population covered by Cancer Registries and number of Member States reporting information on cervical, breast, colorectal and paediatric cancer stage at diagnosis
  12. Number of actions addressing the prevalence of major chronic diseases per Member State, by disease, gender and age
  13. Number of actions addressing the age prevalence of tobacco use, if possible differentiated by gender
  14. Number of actions addressing the prevalence of harmful use of alcohol, if possible differentiated by gender and age
  15. Number of shortages of medicinal products in the Member States as reported through the single point of contact network
  16. Number of actions aimed at increasing the security and continuity of the global supply chains and addressing dependence on imports from third countries for the production of essential active pharmaceutical ingredients and medicinal products in the Union
  17. Number of audits conducted in the Union and in third countries to ensure good manufacturing practices and good clinical practices (Union control)
  18. Antimicrobial consumption for systemic use ATC (group J01) per Member State
  19. Number of healthcare units involved in ERNs and of patients diagnosed and treated by the members of ERNs
  20. Number of HTA reports jointly carried out
  21. Number of health impact assessments of Union policies
  22. Number of actions addressing the fight against communicable diseases
  23. Number of actions addressing environmental risk factors for health
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**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**

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 173 and the third paragraph of Article 175 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 <sup>(1)</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

- (1) The COVID-19 pandemic is a major shock to the global and Union economy and is having a major social and economic impact across Member States and regions. Due to the necessary containment measures, economic activity in the Union dropped significantly. The contraction in Union GDP in 2020 is expected to be around 7,4 %, far deeper than during the financial crisis in 2009. Investment activity has dropped significantly. Vulnerabilities such as the over-reliance on non-diversified external supply sources and a lack of critical infrastructure need to be addressed, in particular for small and medium-sized enterprises (SMEs), including micro-enterprises, for instance by diversifying and strengthening strategic value chains, to improve the Union's emergency response as well as the resilience of the entire economy, while maintaining its openness to competition and trade in line with its rules. Even before the pandemic, while a recovery in investment-to-GDP ratios in the Union could be observed, it remained below what might be expected in a strong recovery and was insufficient to compensate for years of underinvestment following the 2009 crisis. More importantly, the current investment levels and forecasts do not cover the Union's needs for structural investment to restart and sustain long-term growth in the face of technological change and global competitiveness, including for innovation, skills, infrastructure, SMEs and the need to address key societal challenges such as sustainability and population ageing. Consequently, in order to achieve the Union's policy objectives and to support a swift, sustainable, inclusive, lasting and healthy economic recovery, support is necessary to address market failures and suboptimal investment situations and to reduce the investment gap in targeted sectors.
- (2) Evaluations have underlined that the variety of financial instruments delivered under the 2014-2020 Multiannual Financial Framework period has led to some overlaps in their scope. That variety has also produced complexity for intermediaries and final recipients who were confronted with different eligibility and reporting rules. The absence of compatible rules also hampered the combination of several Union funds, although such combinations would have been beneficial in order to support projects in need of different types of funding. Therefore, a single fund, the InvestEU Fund, which builds on the experience of the European Fund for Strategic Investments (EFSI) set up under the Investment Plan for Europe, should be set up in order to provide more efficiently functioning support to final recipients by integrating and simplifying the financing offered under a single budgetary guarantee scheme, thereby improving the impact of Union support while reducing the cost to the Union payable from the budget.

<sup>(1)</sup> OJ C 364, 28.10.2020, p. 139.

<sup>(2)</sup> Position of the European Parliament of 9 March 2021 (not yet published in the Official Journal) and decision of the Council of 17 March 2021.

- (3) In recent years, the Union has adopted ambitious strategies to complete the internal market and to stimulate sustainable and inclusive growth and jobs. Such strategies include 'Europe 2020 – A strategy for smart, sustainable and inclusive growth' of 3 March 2010, 'Action Plan on Building a Capital Markets Union' of 30 September 2015, 'Closing the loop – An EU action plan for the Circular Economy' of 2 December 2015, 'A European Strategy for Low-Emission Mobility' of 20 July 2016, 'Space Strategy for Europe' of 26 October 2016, 'Clean Energy for all Europeans' of 30 November 2016, 'European Defence Action Plan' of 30 November 2016, 'Launching the European Defence Fund' of 7 June 2017, the Interinstitutional Proclamation on the European Pillar of Social Rights of 13 December 2017, 'A new European Agenda for Culture' of 22 May 2018, the 'European Green Deal' of 11 December 2019, the 'European Green Deal Investment Plan' of 14 January 2020, the 'Strong Social Europe for Just Transitions' of 14 January 2020, the strategy for 'Shaping Europe's digital future', 'A European Strategy for Data' and the White Paper 'On Artificial Intelligence - A European approach to excellence and trust' of 19 February 2020, 'A New Industrial Strategy for Europe' of 10 March 2020 and 'SME Strategy for a sustainable and digital Europe' of 10 March 2020. The InvestEU Fund should exploit and reinforce synergies between those mutually reinforcing strategies by providing support for investment and access to financing. In addition, the Union has adopted Regulation (EU) 2020/852 of the European Parliament and of the Council <sup>(3)</sup>.
- (4) At Union level, the European Semester of economic policy coordination is the framework for identifying national reform priorities and monitoring their implementation. Member States, where appropriate in cooperation with local and regional authorities, develop their own national multiannual investment strategies in support of those reform priorities. Those strategies should be presented alongside the yearly national reform programmes as a way of outlining and coordinating priority investment projects that are to be supported by national funding, Union funding, or both. Those strategies should also use Union funding in a coherent manner and maximise the added value of the financial support to be received in particular from the European structural and investment funds, the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council <sup>(4)</sup> and the InvestEU Programme.
- (5) The InvestEU Fund should contribute to improving the competitiveness and socio-economic convergence and cohesion of the Union, including in the fields of innovation and digitisation, to the efficient use of resources in accordance with the circular economy, to the sustainability and inclusiveness of the Union's economic growth and to the social resilience and integration of Union capital markets, including through solutions that address the fragmentation of Union capital markets and that diversify sources of financing for Union enterprises. To that end, the InvestEU Fund should support projects that are technically and economically viable by providing a framework for the use of debt, risk sharing and equity and quasi-equity instruments backed up by a guarantee from the Union budget and by financial contributions from implementing partners as relevant. The InvestEU Fund should be demand-driven, while at the same time focused on providing strategic, long-term benefits in relation to key areas of Union policy which would otherwise not be funded or would be insufficiently funded, thereby contributing to meeting the Union's policy objectives. Support from the InvestEU Fund should cover a wide range of sectors and regions, but should avoid excessive sectoral or geographical concentration and should facilitate access to financing of projects composed of partner entities in multiple regions across the Union, including projects that foster the development of networks, clusters and digital innovation hubs.
- (6) The cultural and creative sectors are key as well as fast growing sectors in the Union that can play an important part in ensuring a sustainable recovery, generating both economic and cultural value from intellectual property and individual creativity. However, restrictions on social contacts put in place during the COVID-19 crisis have had a significant negative economic impact on those sectors. Moreover, the intangible nature of assets in those sectors limits the access of SMEs and organisations from those sectors to private financing which is essential to be able to invest, scale up and compete at an international level. The InvestEU Programme should continue to facilitate access to finance for SMEs and organisations from those sectors. The cultural and creative, audiovisual and media sectors

<sup>(3)</sup> Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (OJ L 198, 22.6.2020, p. 13).

<sup>(4)</sup> 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).

are essential for freedom of speech and cultural diversity and for building democratic and cohesive societies in the digital age, and are an intrinsic part of our sovereignty and autonomy. Investment in those sectors would determine their competitiveness and their long-term capacity to produce and distribute high-quality content to wide audiences across national borders.

- (7) With a view to fostering sustainable and inclusive growth, investment and employment, and thereby contributing to improved well-being, to fairer income distribution and to greater economic, social and territorial cohesion in the Union, the InvestEU Fund should support investments in tangible and intangible assets, including in cultural heritage. Projects funded by the InvestEU Fund should meet Union environmental and social standards, including standards on labour rights. Interventions through the InvestEU Fund should complement Union support delivered through grants.
- (8) The Union endorsed the objectives set out in the United Nations 2030 Agenda for Sustainable Development (the '2030 Agenda'), its Sustainable Development Goals (SDGs) and the Paris Agreement adopted under the United Nations Framework Convention on Climate Change <sup>(<sup>7</sup>)</sup> (Paris Agreement) as well as the Sendai Framework for Disaster Risk Reduction 2015-2030. To achieve those objectives, as well as the objectives set out in the environmental policies of the Union, action pursuing sustainable development needs to be significantly stepped up. Therefore, the principles of sustainable development should feature prominently in the design of the InvestEU Fund.
- (9) The InvestEU Programme should contribute to building a sustainable finance system in the Union which supports the reorientation of private capital towards sustainable investments in accordance with the objectives set out in the communication of the Commission of 8 March 2018 entitled 'Action Plan: Financing Sustainable Growth' and the communication of the Commission of 14 January 2020 on the European Green Deal Investment Plan.
- (10) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement, and the commitment to the United Nations Sustainable Development Goals, as well as the objective of EU climate neutrality by 2050 and the Union's new 2030 climate targets, actions under this Regulation should contribute to the achievement of a target of 30 % of all MFF expenditure being spent on mainstreaming climate objectives and the ambition of 7,5 % of the budget reflecting biodiversity expenditures in 2024 and 10 % in 2026 and 2027, while considering the existing overlaps between climate and biodiversity goals. Actions under the InvestEU Programme are expected to contribute at least 30 % of the overall financial envelope of the InvestEU Programme to climate objectives.
- (11) The contribution of the InvestEU Fund to the achievement of the climate target will be tracked through a Union climate tracking system to be developed by the Commission in cooperation with potential implementing partners, appropriately using the criteria established by Regulation (EU) 2020/852 for determining whether an economic activity is environmentally sustainable. The InvestEU Programme should also contribute to the implementation of other dimensions of the SDGs.
- (12) According to the 2018 Global Risks Report issued by the World Economic Forum, five of the ten most critical risks threatening the global economy relate to the environment. Such risks include the pollution of air, soil, inland waters and oceans, extreme weather events, biodiversity losses and failures of climate-change mitigation and adaptation. Environmental principles are strongly embedded in the Treaties and many of the Union's policies. Therefore, the mainstreaming of environmental objectives should be promoted in operations related to the InvestEU Fund. Environmental protection and the prevention and management of related risks should be integrated in the preparation and implementation of investments. The Union should also track its biodiversity-related and air pollution control-related expenditures in order to fulfil the reporting obligations under the Convention on

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<sup>(7)</sup> OJ L 282, 19.10.2016, p. 4.

Biological Diversity<sup>(6)</sup> and under Directive (EU) 2016/2284 of the European Parliament and of the Council<sup>(7)</sup>. Investment allocated to environmental sustainability objectives should therefore be tracked using common methodologies that are consistent with methodologies developed under other Union programmes that apply to climate, biodiversity and air pollution management in order to allow the assessment of the individual and combined impact of investments on the principal components of natural capital, namely air, water, land and biodiversity.

- (13) Investment projects that receive substantial Union support, in particular in the area of infrastructure, should be screened by the implementing partner to determine whether they have an environmental, climate or social impact. Investment projects that have such an impact should be subject to sustainability proofing in accordance with guidance that should be developed by the Commission in close cooperation with potential implementing partners under the InvestEU Programme. This guidance should appropriately use the criteria established by Regulation (EU) 2020/852 for determining whether an economic activity is environmentally sustainable, including the principle of 'do no significant harm', and consistent with the guidance developed for other programmes of the Union. Consistent with the principle of proportionality, such guidance should include adequate provisions for avoiding undue administrative burdens, and projects below a certain size as to be defined in the guidance should be excluded from the sustainability proofing. Where an implementing partner concludes that no sustainability proofing is to be carried out, it should provide a justification to the investment committee established for the InvestEU Fund (the 'Investment Committee'). Operations that are inconsistent with the achievement of the climate objectives should not be eligible for support under this Regulation.
- (14) Low infrastructure investment rates in the Union during the financial crisis and again during the COVID-19 crisis have undermined the Union's ability to boost sustainable growth, its efforts towards climate neutrality, its competitiveness and convergence and the creation of jobs. This also creates the risk of consolidating imbalances and divergences and inequalities within and between Member States, impacting on long-term development at Union, national or regional level. Sizeable investments in Union infrastructure, in particular with regard to interconnection and energy efficiency and to creating a Single European Transport Area, are essential to meeting the Union's sustainability targets, including the Union's commitments towards the SDGs, and the 2030 energy and climate targets. Accordingly, support from the InvestEU Fund should target investments in transport, energy, including energy efficiency and renewable energy sources and other safe and sustainable low-emission energy sources, environmental infrastructure, infrastructure related to climate action, maritime infrastructure and digital infrastructure, including fast and ultra-fast broadband connectivity throughout the Union, to accelerate the digital transformation of the Union economy. The InvestEU Programme should prioritise areas that are under-invested, and in which additional investment is required. To maximise the impact and added value of Union financing support, it is appropriate to promote a streamlined investment process that enables visibility of the project pipeline and maximises synergies across relevant Union programmes in areas such as transport, energy and digitisation.

Bearing in mind threats to safety and security, investment projects receiving Union support should include measures for infrastructure resilience, including infrastructure maintenance and safety, and should take into account principles for the protection of citizens in public spaces. This should be complementary to the efforts made by other Union funds that provide support for security components of investments in public spaces, transport, energy and other critical infrastructure, such as the European Regional Development Fund.

<sup>(6)</sup> OJ L 309, 13.12.1993, p. 3.

<sup>(7)</sup> Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1).

- (15) Where appropriate, the InvestEU Programme should contribute to the objectives of Directive (EU) 2018/2001 of the European Parliament and of the Council <sup>(8)</sup> and Regulation (EU) 2018/1999 of the European Parliament and of the Council <sup>(9)</sup>, as well as promote energy efficiency in investment decisions.
- (16) Genuine multimodality is an opportunity to create an efficient and environmentally friendly transport network that uses the maximum potential of all means of transport and generates synergy between them. The InvestEU Programme should support investments in multimodal transport hubs, which – in spite of their significant economic potential and business cases – carry a significant risk for private investors. The InvestEU Programme should also contribute to the development and deployment of Intelligent Transport Systems (ITS). The InvestEU Programme should help to boost efforts to design and apply technologies that help to improve the safety of vehicles and road infrastructure.
- (17) The InvestEU Programme should contribute to Union policies concerning seas and oceans through the development of projects and enterprises in the area of the blue economy, and the Sustainable Blue Economy Finance Principles. This may include interventions in the area of maritime entrepreneurship and industry, an innovative and competitive maritime industry, as well as renewable marine energy and circular economy.
- (18) Although the level of overall investment in the Union was increasing before the COVID-19 crisis, investment in higher-risk activities such as research and innovation was still inadequate and is now expected to have suffered a significant hit as a result of the crisis. Research and innovation have a crucial role to play in overcoming the crisis, consolidating the resilience of the Union to tackle future challenges and creating the necessary technologies to achieve Union policies and goals. The InvestEU Fund should contribute to reaching the overall target of investing at least 3 % of Union GDP in research and innovation. The achievement of that target would require Member States and the private sector to proceed with their own reinforced investment actions in research, development and innovation, to avoid underinvestment in research and innovation, which is damaging to the industrial and economic competitiveness of the Union and the quality of life of its citizens. The InvestEU Fund should provide appropriate financial products to cover different stages of the innovation cycle and a wide range of stakeholders, in particular to allow the upscaling of and deployment of solutions at a commercial scale in the Union in order to make such solutions competitive on world markets and to promote Union excellence in sustainable technologies at a global level, in synergy with Horizon Europe to be established by a Regulation of the European Parliament and of the Council establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (the ‘Horizon Europe Regulation’), including the European Innovation Council. In that regard, the experience gained from the financial instruments, such as InnovFin – EU Finance for Innovators, deployed under Horizon 2020 to facilitate and accelerate access to finance for innovative businesses should serve as a strong basis to deliver this targeted support.
- (19) Tourism, including the hospitality industry, is an area of great importance for the Union economy and is currently experiencing a particularly severe contraction as a result of the COVID-19 pandemic. That contraction is particularly damaging for SMEs and family businesses and has caused large-scale unemployment. The InvestEU Programme should contribute to strengthening the recovery, long-term competitiveness and sustainability of the sector, and its value chains, by supporting operations promoting sustainable, innovative and digital tourism including innovative measures to reduce the climate and environmental footprint of the sector.

<sup>(8)</sup> Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82).

<sup>(9)</sup> Regulation (EU) 2018/1999 of the European Parliament and of the Council of 11 December 2018 on the Governance of the Energy Union and Climate Action, amending Regulations (EC) No 663/2009 and (EC) No 715/2009 of the European Parliament and of the Council, Directives 94/22/EC, 98/70/EC, 2009/31/EC, 2009/73/EC, 2010/31/EU, 2012/27/EU and 2013/30/EU of the European Parliament and of the Council, Council Directives 2009/119/EC and (EU) 2015/652 and repealing Regulation (EU) No 525/2013 of the European Parliament and of the Council (OJ L 328, 21.12.2018, p. 1).

- (20) A significant effort is urgently needed to invest in and boost the digital transformation and to distribute the benefits of it to all Union citizens and businesses. The strong policy framework of the Digital Single Market Strategy should now be matched by investment of a similar ambition, including in artificial intelligence in line with the Digital Europe Programme to be established by a Regulation of the European Parliament and of the Council establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240.
- (21) SMEs represent over 99 % of businesses in the Union and their economic value is significant and crucial. However, they face difficulties when accessing finance because of their perceived high risk and lack of sufficient collateral. Additional challenges arise from the need for SMEs and social economy enterprises to stay competitive by engaging in digitisation, internationalisation, transformation in a logic of circular economy, innovation activities and skilling up their workforce. SMEs have been particularly badly hit by the COVID-19 crisis. Moreover, SMEs and social economy enterprises have access to a more limited set of financing sources than larger enterprises, because they typically do not issue bonds, and have only limited access to stock exchanges and large institutional investors. Innovative solutions such as the acquisition of a business or ownership stake in a business by employees are also increasingly common for SMEs and social economy enterprises. The difficulty in accessing finance is even greater for those SMEs whose activities focus on intangible assets. SMEs in the Union rely heavily on banks and on debt financing in the form of bank overdrafts, bank loans or leasing. Supporting SMEs that face the above challenges by making it easier for them to gain access to finance and by providing more diversified sources of funding is necessary to increase the ability of SMEs to finance their creation, growth, innovation and sustainable development, ensure their competitiveness and withstand economic shocks to make the economy and the financial system more resilient during economic downturns and to maintain SMEs' ability to create jobs and social well-being. This Regulation is also complementary to the initiatives already undertaken in the context of the Capital Markets Union.

The InvestEU Fund should therefore build on successful Union programmes, such as the Programme for the Competitiveness of Enterprises and SMEs (COSME); provide support to digital start-ups and innovative SMEs to enable them to better compete and scale up; provide working capital and investment throughout the life cycle of a company; provide financing for leasing transactions; and provide an opportunity to focus on specific, more targeted financial products. It should also maximise the firepower of public/private fund vehicles, such as the SME IPO (Initial Public Offering) Fund, seeking to support SMEs through channelling more private and public equity.

- (22) As set out in the Commission's Reflection paper on the social dimension of Europe of 26 April 2017, the Communication on European Pillar of Social Rights, the Union framework for the UN Convention on the Rights of Persons with Disabilities and the Communication on 'Strong Social Europe for Just Transitions' of 14 January 2020, building a more inclusive and fair Union is a key priority for the Union to tackle inequality and foster social inclusion policies in Europe. Inequality of opportunities affects in particular access to education, training, culture, employment, health and social services. Investment in the social, skills and human capital-related economy, as well as in the integration of vulnerable populations in the society, can enhance economic opportunities, especially if coordinated at Union level. The COVID-19 crisis has revealed a significant need for investment in social infrastructure. The InvestEU Fund should be used to support investment in education and training, including the re-skilling and upskilling of workers, inter alia in regions depending on a carbon intensive economy and affected by the structural transition to a low-carbon economy. It should be used to support projects that generate positive social impacts and enhance social inclusion by helping to increase employment across all regions, in particular among the unskilled and long-term unemployed, and to improve the situation with regard to gender equality, equal opportunities, non-discrimination, accessibility, intergenerational solidarity, the health and social services sector, social housing, homelessness, digital inclusiveness, community development, the role and place of young people in society as well as vulnerable people, including third country nationals. The InvestEU Programme should also support European culture and creativity that has a social goal.

- (23) The COVID-19 crisis has had a particularly serious impact on women, from both a social and an economic perspective. Bearing that in mind, the InvestEU Programme should contribute to the achievement of the Union's policies on equality between women and men, inter alia, by addressing the digital gap between them and by helping to encourage female creativity and entrepreneurial potential.
- (24) To counter the negative effects of profound transformations of societies in the Union and of the labour market in the coming decade, it is necessary to invest in human capital, social infrastructure, microfinance, ethical and social enterprise finance and new social economy business models, including social impact investment and social outcomes contracting. The InvestEU Programme should strengthen nascent social market ecosystem to increase the supply of and access to finance to micro- and social enterprises and social solidarity institutions, in order to meet the demand of those who need it the most. The report of the High-Level Task Force on Investing in Social Infrastructure in Europe of January 2018 entitled 'Boosting Investment in Social Infrastructure in Europe' has identified a total investment gap of at least EUR 1,5 trillion in social infrastructure and services for the period between 2018 and 2030, including education, training, health and housing. This calls for support, including at the Union level. Therefore, the collective power of public, commercial and philanthropic capital, as well as support from foundations and from alternative types of finance providers such as ethical, social and sustainable actors, should be harnessed to support the development of the social market value chain and a more resilient Union.
- (25) In the economic crisis caused by the COVID-19 pandemic, market allocation of resources is not fully efficient and perceived risk impairs private investment flow significantly. Under such circumstances, the key feature of the InvestEU Fund of de-risking economically viable projects to crowd in private finance is particularly valuable, inter alia in order to counteract the risk of an asymmetric recovery. The InvestEU Programme should be able to provide crucial support to companies in the recovery phase, including capital support for SMEs that were negatively affected by the COVID-19 crisis and were not already in difficulty in State aid terms at the end of 2019, and at the same time ensure a strong focus of investors on the Union's medium- and long-term policy priorities such as the European Green Deal, the European Green Deal Investment Plan, the Strategy on shaping Europe's digital future, the New Industrial Strategy for Europe, and the Strong Social Europe for Just Transitions, taking account of the principle of 'do no significant harm'. It should significantly increase the risk-taking capacity of the European Investment Bank (EIB) Group and national promotional banks and institutions and other implementing partners in support of economic recovery.
- (26) The deep contraction in Union GDP resulting from the COVID-19 crisis renders adverse social effects inevitable. The COVID-19 pandemic has shown the need for strategic vulnerabilities to be urgently and efficiently addressed in order to improve the Union's emergency response as well as the resilience and sustainability of the entire economy. Only a resilient, sustainable, inclusive and integrated Union economy can preserve the integrity of the internal market and the level playing field also to the benefit of the hardest-hit Member States and regions.
- (27) The InvestEU Fund should operate through four policy windows that mirror the key Union policy priorities, namely, sustainable infrastructure; research, innovation and digitisation; SMEs; and social investment and skills.
- (28) Although the SME policy window should primarily focus on benefitting SMEs, small mid-cap companies should also be eligible under it. Mid-cap companies should be eligible for support under the other three policy windows.
- (29) As set out in the European Green Deal and the European Green Deal Investment Plan, a Just Transition Mechanism is to be established in order to address the social, economic and environmental consequences of reaching the Union's 2030 climate target and its target of achieving climate neutrality by 2050. That mechanism would be composed of three pillars, namely a Just Transition Fund to be established by a Regulation of the European Parliament and of the Council establishing the Just Transition Fund (the 'Just Transition Fund Regulation') (pillar 1), a dedicated just transition scheme under the InvestEU Programme (pillar 2) and a public sector loan facility to be established by a Regulation of the European Parliament and of the Council on the public sector loan facility under the Just Transition Mechanism (the 'Public Sector Loan Facility Regulation for 2021-2027') (pillar 3). That mechanism should focus on the regions that are most affected by the transition given their dependence on fossil fuels, including

coal, peat and oil shale or greenhouse gas-intensive industrial processes, and that have less capacity to finance the necessary investments. The just transition scheme should also provide support for financing to generate investment to the benefit of just transition territories. The InvestEU Advisory Hub should provide for the possibility for the respective territories to benefit from technical assistance.

- (30) To implement pillar 2 under the Just Transition Mechanism, a dedicated just transition scheme under the InvestEU Programme should be established horizontally across all policy windows, supporting additional investment to benefit the territories identified in territorial just transition plans, established in accordance with the Just Transition Fund Regulation. That scheme should enable investments in a wide range of projects, in line with the eligibility criteria of the InvestEU Programme. Projects in territories identified in territorial just transition plans, or projects that benefit the transition of those territories, even if they are not located in the territories themselves, may benefit from the Scheme, but only when funding outside the just transition territories is key to the transition in those territories.
- (31) It should be possible to support strategic investments, including important projects of common European interest, under any policy window, particularly in view of the green and digital transitions and the need to enhance competitiveness and resilience, promote entrepreneurship and job creation and strengthen strategic value chains.
- (32) Each policy window should be composed of two compartments, that is to say an EU compartment and a Member State compartment. The EU compartment should address Union-wide or Member State specific market failures or suboptimal investment situations in a proportionate manner. Operations supported should have a clear Union added value. The Member State compartment should give Member States as well as regional authorities via their Member State the possibility of contributing a share of their resources from the funds under shared management to the provisioning for the EU guarantee and of using the EU guarantee for financing or investment operations in order to address specific market failures or suboptimal investment situations in their own territories, including in vulnerable and remote areas such as the outermost regions of the Union, as to be set out in the contribution agreement, in order to achieve objectives of the funds under shared management. The Member State compartment should also give Member States the possibility of contributing other additional amounts, including those made available pursuant to Regulation (EU) 2021/241, to the provisioning for the EU guarantee and of using the EU guarantee for financing or investment operations for the purposes laid down in the contribution agreement, which should include, where relevant, the purposes of measures under a recovery and resilience plan. This could, inter alia, allow for capital support for SMEs that were negatively affected by the COVID-19 crisis and were not already in difficulty in State aid terms at the end of 2019. Operations supported by the InvestEU Fund through either EU or Member State compartments should not duplicate or crowd out private financing or distort competition in the internal market.
- (33) The Member State compartment should be specifically designed to allow the use of funds under shared management or other additional amounts contributed by Member States, including those made available pursuant to Regulation (EU) 2021/241 to provision a guarantee issued by the Union. That possibility would increase the added value of the EU guarantee by providing support under it to a wider range of final recipients and projects and diversifying the means of achieving the objectives of the funds under shared management or recovery and resilience plans, while ensuring a consistent risk management of the contingent liabilities by implementing the EU guarantee under indirect management. The Union should guarantee the financing and investment operations provided for in the guarantee agreements concluded between the Commission and implementing partners under the Member State compartment. The funds under shared management or other additional amounts contributed by Member States, including those made available pursuant to Regulation (EU) 2021/241, should provide the provisioning for the guarantee, following a provisioning rate determined by the Commission and set out in the contribution agreement concluded with the Member State, based on the nature of the operations and the resulting expected losses. The

Member State would assume losses above the expected losses by issuing a back-to-back guarantee in favour of the Union that should remain in place as long as any financing and investment operations under that Member State compartment are outstanding. Such arrangements should be concluded in a single contribution agreement with each Member State that voluntarily chooses such option.

The contribution agreement should encompass the one or more specific guarantee agreements to be implemented within the Member State concerned on the basis of the rules of the InvestEU Fund, and any regional ring-fencing. The setting out of the provisioning rate on a case-by-case basis requires a derogation from Article 211(1) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council<sup>(10)</sup> (the 'Financial Regulation'). This set-up provides also a single set of rules for budgetary guarantees supported by funds that are managed centrally or by funds under shared management, which would facilitate their combination. The provisioning for an EU guarantee relating to a Member State compartment underpinned by other additional amounts contributed by Member States, including those made available pursuant to Regulation (EU) 2021/241, should constitute external assigned revenue.

- (34) A partnership between the Commission and the EIB Group should be established, drawing on the relative strengths of each partner to ensure maximum policy impact, deployment efficiency, and appropriate budgetary and risk management oversight, which should support effective and inclusive direct access to the EU guarantee.
- (35) The Union represented by the Commission should be in a position to participate in a capital increase of the European Investment Fund (EIF) in order to allow the EIF to continue supporting the European economy and its recovery. The main aim of the increase would be to allow the EIF to contribute to the implementation of the InvestEU Programme. The Union should be able to maintain its overall share in the EIF capital. A sufficient financial envelope to this effect should be foreseen in the Multiannual Financial Framework for 2021-2027. On 3 December 2020, the Board of Directors of the EIF decided to propose to the shareholders an increase in the authorised capital of the EIF that would result in a cash injection of EUR 1 250 000 000. The price of the new shares is based on the net asset value formula agreed among the shareholders of the EIF and consists of the paid-in part and the share premium. In accordance with Article 7 of the EIF Statutes, for each subscribed share, 20 % of the nominal value must be paid in.
- (36) The Commission should seek the views of other potential implementing partners along with the EIB Group on investment guidelines, the climate tracking system, the sustainability proofing guidance documents and common methodologies, as appropriate, with a view to ensuring inclusiveness and operationality until the governance bodies have been set up, after which the involvement of implementing partners should take place within the framework of the Advisory Board and the Steering Board of the InvestEU Programme.
- (37) The InvestEU Fund should be open to contributions from third countries that are members of the European Free Trade Association, acceding countries, candidates and potential candidates, countries covered by the European Neighbourhood Policy and other countries, in accordance with the conditions agreed between the Union and those countries, in particular in view of the positive impact of such opening on the Member States' economies. This should allow continuing cooperation with the relevant countries, where appropriate, in particular in the fields of research and innovation as well as SMEs.
- (38) This Regulation lays down a financial envelope for other measures of the InvestEU Programme than the provisioning of the EU guarantee, 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

<sup>(10)</sup> 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).

on sound financial management, as well as on new own resources, including a roadmap towards the introduction of new own resources <sup>(11)</sup>, for the European Parliament and the Council during the annual budgetary procedure.

- (39) EUR 2 672 292 573 in current prices of the EU guarantee should be provisioned by resources from the additional allocation provided in accordance with Article 5 of and Annex II to Council Regulation (EU, Euratom) 2020/2093 <sup>(12)</sup> corresponding to an amount of EUR 1 000 000 000 in 2018 prices. An amount of EUR 63 800 000 in current prices of the total allocation to the InvestEU Advisory Hub of EUR 430 000 000 in current prices should be provided from that amount.
- (40) The EU guarantee of EUR 26 152 310 073 in current prices for the EU compartment is expected to mobilise more than EUR 372 000 000 000 of additional investment across the Union and should be indicatively allocated between the policy windows.
- (41) On 18 April 2019, the Commission declared that ‘without prejudice to the prerogatives of the Council in the implementation of the Stability and Growth Pact (SGP), one-off contributions by Member States, either by a Member State or by national promotional banks classified in the general government sector or acting on behalf of a Member State, into thematic or multi-country investment platforms should in principle qualify as one-off measures within the meaning of Articles 5(1) and 9(1) of Council Regulation (EC) No 1466/97 <sup>(13)</sup> and Article 3(4) of Council Regulation (EC) No 1467/97 <sup>(14)</sup>. In addition, without prejudice to the prerogatives of the Council in the implementation of the SGP, the Commission will consider to what extent the same treatment as for the EFSI in the context of the Commission communication on flexibility can be applied to the InvestEU Programme as the successor instrument to the EFSI with regard to one-off contributions provided by Member States in cash to finance an additional amount of the EU guarantee for the purposes of the Member State compartment.’
- (42) The EU guarantee underpinning the InvestEU Fund should be implemented indirectly by the Commission relying on implementing partners with outreach to financial intermediaries, where applicable, and final recipients. The selection of the implementing partners should be transparent and free from any conflict of interest. The Commission should conclude a guarantee agreement allocating guarantee capacity from the InvestEU Fund with each implementing partner to support its financing and investment operations that meet the InvestEU Fund eligibility criteria and contribute to meeting its objectives. The management of the risk related to the EU guarantee should not hamper direct access to the EU guarantee by the implementing partners. Once the EU guarantee is granted under the EU compartment to implementing partners, they should be fully responsible for the whole investment process and the due diligence related to the financing and investment operations. The InvestEU Fund should support projects that typically have a higher risk profile than the projects supported by the normal operations of the implementing partners and that could not have been carried out during the period in which the EU guarantee could be used, or could not have been carried out to the same extent, by other public or private sources without support from the InvestEU Fund.
- (43) The InvestEU Fund should be provided with a governance structure, the function of which should be commensurate with its sole purpose of ensuring the appropriate use of the EU guarantee, in line with ensuring the political independence of investment decisions. That governance structure should be composed of an Advisory Board, a Steering Board and a fully independent Investment Committee. The overall composition of the governance structure should strive to achieve gender balance. The governance structure should not encroach upon or interfere with the decision-making of the EIB Group or other implementing partners, and should not be a substitute for their respective governing bodies.

<sup>(11)</sup> OJ L 433I, 22.12.2020, p. 28.

<sup>(12)</sup> Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L 433I, 22.12.2020, p. 11).

<sup>(13)</sup> Council Regulation (EC) No 1466/97 of 7 July 1997 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies (OJ L 209, 2.8.1997, p. 1).

<sup>(14)</sup> Council Regulation (EC) No 1467/97 of 7 July 1997 on speeding up and clarifying the implementation of the excessive deficit procedure (OJ L 209, 2.8.1997, p. 6).

- (44) An Advisory Board consisting of representatives of the implementing partners, representatives of Member States, one expert appointed by the European Economic and Social Committee and one expert appointed by the Committee of the Regions should be established in order to exchange information and exchange views on the take-up of the financial products deployed under the InvestEU Fund and to discuss evolving needs and new products, including specific territorial market gaps.
- (45) In order to be able to constitute the Advisory Board from the start, the Commission should appoint the representatives of the potential implementing partners for a temporary period of one year. Thereafter, the implementing partners having signed guarantee agreements would take over that responsibility.
- (46) A Steering Board composed of representatives of the Commission, representatives of implementing partners and one non-voting expert appointed by the European Parliament should determine the strategic and operational guidance for the InvestEU Fund.
- (47) The Commission should assess the compatibility of financing and investment operations submitted by the implementing partners with all Union law and policies. The decisions on financing and investment operations should ultimately be taken by an implementing partner.
- (48) The Investment Committee composed of independent experts should reach a conclusion on the granting of support from the EU guarantee to financing and investment operations fulfilling the eligibility criteria of the InvestEU Fund, thereby providing external expertise in investment assessments in relation to projects. The Investment Committee should have different configurations to cover different policy areas and sectors in the best way possible.
- (49) An independent secretariat hosted by the Commission and answerable to the chairperson of the Investment Committee should assist the Investment Committee.
- (50) In selecting implementing partners for the deployment of the InvestEU Fund, the Commission should consider their ability to fulfil the objectives of the InvestEU Fund and to contribute their own resources, in order to ensure adequate geographical coverage and diversification, to crowd in private investors and to provide sufficient risk diversification and solutions to address market failures and suboptimal investment situations. Given its role under the Treaties, its capacity to operate in all Member States and the existing experience under the current financial instruments and the EFSI, the EIB Group should remain a privileged implementing partner under the InvestEU Fund's EU compartment. In addition to the EIB Group, national promotional banks and institutions should be able to offer a complementary financial product range, given that their experience and capabilities at national and regional level could be beneficial for the maximisation of the impact of public funds on the whole territory of the Union, and for ensuring a fair geographical balance of projects. The InvestEU Programme should be implemented in such a way as to promote a level playing field for smaller and younger promotional banks and institutions. Moreover, it should be possible for other international financial institutions to become implementing partners, in particular when they present a comparative advantage in terms of specific expertise and experience in certain Member States and when they present a Union majority of shareholding. It should also be possible for other entities fulfilling the criteria laid down in the Financial Regulation to become implementing partners.
- (51) With a view to promoting improved geographic diversification, investment platforms may be established to combine the efforts and expertise of implementing partners with other national promotional banks and institutions that have limited experience in the use of financial instruments. Such structures should be encouraged, including with available support from the InvestEU Advisory Hub. It is appropriate to bring together co-investors, public authorities, experts, education, training and research institutions, relevant social partners and representatives of the civil society and other relevant actors at Union, at national and regional levels to promote the use of investment platforms in relevant sectors.

- (52) The EU guarantee under the Member State compartment should be allocated to any implementing partner eligible in accordance with point (c) of Article 62(1) of the Financial Regulation, including national or regional promotional banks or institutions, the EIB, the EIF and other international financial institutions. When selecting implementing partners under the Member State compartment, the Commission should take into account the proposals made by each Member State, as reflected in the contribution agreement. In accordance with Article 154 of the Financial Regulation, the Commission is to carry out an assessment of the rules and procedures of the implementing partner to ascertain that they provide a level of protection of the financial interest of the Union equivalent to the one provided by the Commission.
- (53) Financing and investment operations should ultimately be decided by the implementing partner in its own name, implemented in accordance with its internal rules, policies and procedures, and accounted for in its own financial statements or, where applicable, disclosed in the notes to the financial statements. Therefore, the Commission should exclusively account for any financial liability arising from the EU guarantee and should disclose the maximum guarantee amount, including all relevant information concerning the guarantee provided.
- (54) Where appropriate, the InvestEU Fund should allow for the smooth, seamless and efficient blending of grants, financial instruments or both, funded by the Union budget or by other funds, such as the EU Emissions Trading System (ETS) Innovation Fund with the EU guarantee in situations where this is necessary to best underpin investments to address particular market failures or suboptimal investment situations.
- (55) Projects submitted by implementing partners for support under the InvestEU Programme, which include blending support from the InvestEU Fund with support from other Union programmes, should as a whole be consistent with the objectives and eligibility criteria of the relevant other Union programmes. The use of the EU guarantee should be decided under the InvestEU Programme.
- (56) The InvestEU Advisory Hub should support the development of a robust pipeline of investment projects in each policy window through advisory initiatives that are implemented by the EIB Group or other advisory partners, or are implemented directly by the Commission. The InvestEU Advisory Hub should promote geographic diversification with a view to contributing to the Union objectives of economic, social, and territorial cohesion and reducing regional disparities. The InvestEU Advisory Hub should pay particular attention to the aggregation of small-sized projects into larger portfolios. The Commission, the EIB Group and the other advisory partners should cooperate closely with a view to ensuring efficiency, synergies and effective geographic coverage of support across the Union, taking into account the expertise and local capacity of local implementing partners, as well as the European Investment Advisory Hub established under Regulation (EU) 2015/1017 of the European Parliament and of the Council<sup>(15)</sup>. The findings of the European Court of Auditors' Special Report No 12/2020 'The European Investment Advisory Hub: Launched to boost investment in the EU, the Hub's impact remains limited'<sup>(16)</sup> should be carefully considered in order to maximise the InvestEU Advisory Hub's effectiveness and impact. The InvestEU Advisory Hub should provide a central entry point for project development assistance delivered under the InvestEU Advisory Hub to public authorities and for project promoters.
- (57) The InvestEU Advisory Hub should be established by the Commission with the EIB Group as the main partner, building on the experience acquired through the European Investment Advisory Hub. The Commission should be responsible for the policy steer of the InvestEU Advisory Hub and for the management of the central entry point. The EIB Group should deliver advisory initiatives under the policy windows. In addition, the EIB Group should provide operational services to the Commission, including by providing input to the strategic and policy guidelines regarding advisory initiatives, mapping existing and emerging advisory initiatives, assessing advisory needs and advising the Commission on optimal ways to address these needs through existing or new advisory initiatives.

<sup>(15)</sup> Regulation (EU) 2015/1017 of the European Parliament and of the Council of 25 June 2015 on the European Fund for Strategic Investments, the European Investment Advisory Hub and the European Investment Project Portal and amending Regulations (EU) No 1291/2013 and (EU) No 1316/2013 — the European Fund for Strategic Investments (OJ L 169, 1.7.2015, p. 1).

<sup>(16)</sup> OJ C 170, 18.5.2020, p. 22.

- (58) In order to ensure a wide geographic outreach of the advisory services across the Union and to successfully leverage local knowledge about the InvestEU Fund, a local presence of the InvestEU Advisory Hub should be ensured, where needed, taking into account existing support schemes and the presence of local partners, with a view to providing tangible, proactive, tailor-made assistance on the ground. In order to facilitate the provision of advisory support at local level and to ensure efficiency, synergies and effective geographic coverage of support across the Union, the InvestEU Advisory Hub should cooperate with national promotional banks and institutions, and should benefit from and make use of their expertise.
- (59) The InvestEU Advisory Hub should provide advisory support to small-sized projects and projects for start-ups, especially when start-ups seek to protect their research and innovation investments by obtaining intellectual property titles, such as patents, taking into account the existence of other services able to cover such actions and seeking synergies with those services.
- (60) In the context of the InvestEU Fund, there is a need to provide support for project development and capacity building to develop the organisational capacities and market development activities needed to originate quality projects. Such support should also target financial intermediaries that are key to help SMEs access financing and realise their full potential. Moreover, the aim of the advisory support is to create the conditions for the expansion of the potential number of eligible recipients in nascent market segments, in particular where the small size of individual projects considerably raises the transaction cost at the project level, such as for the social finance ecosystem, including philanthropic organisations, or for the cultural and creative sectors. The capacity-building support should be complementary and in addition to actions taken under other Union programmes that cover specific policy areas. An effort should also be made to support the capacity building of potential project promoters, in particular local organisations and authorities.
- (61) The InvestEU Portal should be established to provide for an easily accessible and user-friendly project database to promote visibility of investment projects searching for financing with enhanced focus on the provision of a possible pipeline of investment projects, compatible with Union law and policies, to the implementing partners.
- (62) In accordance with Council Regulation (EU) 2020/2094 <sup>(17)</sup> and within the limits of resources allocated therein, recovery and resilience measures under the InvestEU Programme should be carried out to address the unprecedented impact of the COVID-19 crisis. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation (EU) 2020/2094.
- (63) Pursuant to paragraphs 22 and 23 of the Interinstitutional Agreement of 13 April 2016 on Better Law-Making <sup>(18)</sup>, the InvestEU Programme should be evaluated on the basis of information collected in accordance with specific monitoring requirements, while avoiding an administrative burden, in particular on Member States, and overregulation. Those requirements, where appropriate, should include measurable indicators, as a basis for evaluating the effects of the InvestEU Programme on the ground.
- (64) A solid monitoring framework that is based on output, outcome and impact indicators should be implemented to track progress towards the Union's objectives. In order to ensure accountability to the Union's citizens, the Commission should report annually to the European Parliament and the Council on the progress, impact and operations of the InvestEU Programme.
- (65) Horizontal financial rules adopted by the European Parliament and the Council on the basis of Article 322 of the Treaty on the Functioning of the European Union (TFEU) apply to this Regulation. Those rules are laid down in the Financial Regulation and determine in particular the procedure for establishing and implementing the budget through grants, procurement, prizes, indirect implementation, and provide for checks on the responsibility of financial actors. Rules adopted on the basis of Article 322 TFEU also include a general regime of conditionality for the protection of the Union budget.

<sup>(17)</sup> 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 433I, 22.12.2020, p. 23).

<sup>(18)</sup> OJ L 123, 12.5.2016, p. 1.

- (66) The Financial Regulation applies to the InvestEU Programme. It lays down rules on the implementation of the Union budget, including the rules on budgetary guarantees.
- (67) In accordance with the Financial Regulation, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council <sup>(19)</sup> and Council Regulations (EC, Euratom) No 2988/95 <sup>(20)</sup>, (Euratom, EC) No 2185/96 <sup>(21)</sup> and (EU) 2017/1939 <sup>(22)</sup>, 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 <sup>(23)</sup>.

In accordance with the Financial Regulation, any person or entity receiving Union funds is to fully cooperate in the protection of the financial interests of the Union, 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 ensure that any third parties involved in the implementation of Union funds grant equivalent rights.

- (68) Third countries which are members of the European Economic Area (EEA) may participate in Union programmes in the framework of the cooperation established under the Agreement on the European Economic Area <sup>(24)</sup>, which provides for the implementation of the programmes on the basis of a decision adopted under that Agreement. Third countries may also participate on the basis of other legal instruments. A specific provision should be introduced in this Regulation requiring 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.
- (69) Pursuant to Council Decision 2013/755/EU <sup>(25)</sup>, individuals and entities established in overseas countries or territories are eligible for funding subject to the rules and objectives of the InvestEU Programme and possible arrangements applicable to the Member State to which the relevant overseas country or territory is linked.
- (70) In order to supplement the non-essential elements of this Regulation with investment guidelines and with a scoreboard of indicators, to facilitate the prompt and flexible adaptation of the performance indicators and to adjust the provisioning rate, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of drawing-up investment guidelines for the financing and investment operations under different policy windows, of the scoreboard, of the amendment of Annex III to this Regulation to review or complement the indicators and of the adjustment of the provisioning rate. In line with the principle of

<sup>(19)</sup> 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).

<sup>(20)</sup> 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).

<sup>(21)</sup> 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).

<sup>(22)</sup> 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).

<sup>(23)</sup> 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).

<sup>(24)</sup> OJ L 1, 3.1.1994, p. 3.

<sup>(25)</sup> Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ('Overseas Association Decision') (OJ L 344, 19.12.2013, p. 1).

proportionality, such investment guidelines should include adequate provisions to avoid undue administrative burden. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

- (71) Financing and investment operations signed or entered into by an implementing partner during the period from 1 January 2021 until the signature of their respective guarantee agreements should be eligible for the EU guarantee provided that such operations are indicated in the guarantee agreement, pass the policy check or receive a favourable opinion within the framework of the procedure provided for in Article 19 of Protocol No 5 on the Statute of the European Investment Bank annexed to the Treaty on European Union (TEU) and the TFEU (the EIB Statute), and are in both cases approved by the Investment Committee.
- (72) In order to optimise the use of budgetary resources, a combination of relevant portfolios of financial instruments established under the 2014-2020 Multiannual Financial Framework and the EU guarantee under Regulation (EU) 2015/1017 with the EU guarantee under this Regulation should be possible. The increased risk bearing capacity established by such combination should enhance the efficiency of the EU guarantee under this Regulation and allow for more support to final recipients. The modalities of the combination should be defined in the guarantee agreement between the Commission and the EIB or the EIF. The conditions of the combination should be consistent with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community <sup>(26)</sup>.
- (73) Since the objectives of this Regulation, namely to address Union-wide and Member State specific market failures and suboptimal investment situations and provide for Union-wide market testing of innovative financial products designed to address new or complex market failures or suboptimal investment situations and of systems to spread such products, cannot be sufficiently achieved by the Member States, but can rather 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 in order to achieve those objectives.
- (74) In order to ensure continuity in providing support in the relevant policy area and to allow implementation to start from the beginning of the multi-annual financial framework 2021-2027, this Regulation should enter into force as a matter of urgency and should apply, with retroactive effect, from 1 January 2021,

HAVE ADOPTED THIS REGULATION:

#### CHAPTER I

### **General provisions**

#### *Article 1*

### **Subject matter**

This Regulation establishes the InvestEU Fund, which shall provide for an EU guarantee to support financing and investment operations carried out by the implementing partners that contribute to objectives of the Union's internal policies.

<sup>(26)</sup> OJ L 29, 31.1.2020, p. 7.

This Regulation also establishes an advisory support mechanism to provide support for the development of investable projects and access to financing and to provide related capacity building assistance (the 'InvestEU Advisory Hub'). It further establishes a database granting visibility to projects for which project promoters seek financing and which provides investors with information about investment opportunities (the 'InvestEU Portal').

This Regulation establishes the objectives of the InvestEU Programme, its budget and the amount of the EU guarantee for the period 2021 to 2027, the forms of Union funding and the rules for providing such funding.

## Article 2

### Definitions

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

- (1) 'InvestEU Programme' means the InvestEU Fund, the InvestEU Advisory Hub, the InvestEU Portal and blending operations, collectively;
- (2) 'EU guarantee' means an overall irrevocable, unconditional and on demand budgetary guarantee provided by the Union budget under which the budgetary guarantees in accordance with Article 219(1) of the Financial Regulation take effect through the entry into force of individual guarantee agreements with implementing partners;
- (3) 'policy window' means a targeted area for support by the EU guarantee as laid down in Article 8(1);
- (4) 'compartment' means a part of the EU guarantee defined in terms of the origin of the resources backing it;
- (5) 'blending operation' means an operation supported by the Union budget that combines non-repayable forms of support, repayable forms of support, or both, from the Union budget with repayable forms of support from development or other public finance institutions, or from commercial finance institutions and investors; for the purposes of this definition, Union programmes financed from sources other than the Union budget, such as the EU ETS Innovation Fund, may be assimilated to Union programmes financed by the Union budget;
- (6) 'EIB Group' means the EIB, its subsidiaries and other entities established in accordance with Article 28(1) of Protocol No 5 on the Statute of the European Investment Bank annexed to the TEU and the TFEU (the EIB Statute);
- (7) 'financial contribution' means a contribution from an implementing partner in the form of own risk-taking capacity that is provided on a *pari passu* basis with the EU guarantee or in another form that allows an efficient implementation of the InvestEU Programme while ensuring appropriate alignment of interest;
- (8) 'contribution agreement' means a legal instrument whereby the Commission and one or more Member States specify the conditions of the EU guarantee under the Member State compartment, as laid down in Article 10;
- (9) 'financial product' means a financial mechanism or arrangement under the terms of which the implementing partner provides direct or intermediated financing to final recipients using any of the types of financing referred to in Article 16;
- (10) 'financing and investment operations' or 'financing or investment operations' means operations to provide finance directly or indirectly to final recipients through financial products, carried out by an implementing partner in its own name, provided by the implementing partner in accordance with its internal rules, policies and procedures and accounted for in the implementing partner's financial statements or, where applicable, disclosed in the notes to those financial statements;
- (11) 'funds under shared management' means funds that provide for the possibility of allocating a portion of those funds to the provisioning for a budgetary guarantee under the Member State compartment of the InvestEU Fund, namely the European Regional Development Fund (ERDF) and the Cohesion Fund to be established by a Regulation of the European Parliament and of the Council on the European Regional Development Fund and on the Cohesion Fund for the years 2021-2027, the European Social Fund Plus (ESF+) to be established by a Regulation of the European Parliament and of the Council on the European Social Fund Plus (ESF+) (the 'ESF+ Regulation for 2021-2027'), the

European Maritime, Fisheries and Aquaculture Fund (EMFAF) to be established by a Regulation of the European Parliament and of the Council on the European Maritime, Fisheries and Aquaculture Fund and repealing Regulation (EU) No 508/2014 and the European Agriculture Fund for Rural Development (EAFRD) to be established by a Regulation of the European Parliament and of the Council establishing rules on support for strategic plans to be drawn up by Member States under the Common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulation (EU) No 1305/2013 of the European Parliament and of the Council and Regulation (EU) No 1307/2013 of the European Parliament and of the Council (the 'CAP Strategic Plans Regulation');

- (12) 'guarantee agreement' means a legal instrument whereby the Commission and an implementing partner specify the conditions for proposing financing and investment operations in order for them to be granted the benefit of the EU guarantee, for providing the EU guarantee for those operations and for implementing them in accordance with this Regulation;
- (13) 'implementing partner' means an eligible counterpart such as a financial institution or other financial intermediary with whom the Commission has concluded a guarantee agreement;
- (14) 'important project of common European interest' means a project that fulfils all the criteria laid down in the Commission Communication on Criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest or any subsequent revision of that Communication;
- (15) 'advisory agreement' means a legal instrument whereby the Commission and the advisory partner specify the conditions for the implementation of the InvestEU Advisory Hub;
- (16) 'advisory initiative' means technical assistance and advisory services that support investment, including capacity building activities, provided by advisory partners, by external service providers contracted by the Commission, or by executive agencies;
- (17) 'advisory partner' means an eligible counterpart such as a financial institution or other entity with whom the Commission has concluded an advisory agreement for the purpose of implementing one or more advisory initiatives, other than advisory initiatives implemented through external service providers contracted by the Commission or through executive agencies;
- (18) 'investment platform' means a special purpose vehicle, managed account, contract-based co-financing or risk-sharing arrangement or an arrangement established by any other means by which entities channel a financial contribution in order to finance a number of investment projects, and which may include:
- (a) a national or sub-national platform that groups together several investment projects on the territory of a given Member State;
  - (b) a cross-border, multi-country, regional or macro-regional platform that groups together partners from several Member States, regions or third countries interested in investment projects in a given geographic area;
  - (c) a thematic platform that groups together investment projects in a given sector;
- (19) 'microfinance' means microfinance as defined in the relevant provisions of the ESF+ Regulation for 2021-2027;
- (20) 'national promotional bank or institution' means a legal entity that carries out financial activities on a professional basis which has been given mandate by a Member State or a Member State's entity at central, regional or local level to carry out development or promotional activities;
- (21) 'small and medium-sized enterprise' or 'SME' means a micro, small or medium-sized enterprise within the meaning of the Annex to Commission Recommendation 2003/361/EC <sup>(27)</sup>;

<sup>(27)</sup> Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

- (22) 'small mid-cap company' means an entity that is not an SME and that employs up to 499 employees;
- (23) 'social enterprise' means a social enterprise as defined in the relevant provisions of the ESF+ Regulation for 2021-2027.

### Article 3

#### **Objectives of the InvestEU Programme**

1. The general objective of the InvestEU Programme is to support the policy objectives of the Union by means of financing and investment operations that contribute to:
  - (a) the competitiveness of the Union, including research, innovation and digitisation;
  - (b) growth and employment in the Union economy, the sustainability of the Union economy and its environmental and climate dimension contributing to the achievement of the SDGs and the objectives of the Paris Agreement and to the creation of high-quality jobs;
  - (c) the social resilience, inclusiveness and innovativeness of the Union;
  - (d) the promotion of scientific and technological advances, of culture, education and training;
  - (e) the integration of Union capital markets and the strengthening of the internal market, including solutions to address the fragmentation of Union capital markets, diversify sources of financing for Union enterprises and promote sustainable finance;
  - (f) the promotion of economic, social and territorial cohesion; or
  - (g) the sustainable and inclusive recovery of the Union economy after the COVID-19 crisis, including by providing capital support for SMEs that were negatively affected by the COVID-19 crisis and were not already in difficulty in State aid terms at the end of 2019, upholding and strengthening existing strategic value chains of tangible or intangible assets, developing new ones, and maintaining and reinforcing activities of strategic importance to the Union, including important projects of common European interest, in relation to critical infrastructure, whether physical or virtual, transformative technologies, game-changing innovations and inputs to businesses and consumers and supporting a sustainable transition.
2. The InvestEU Programme has the following specific objectives:
  - (a) supporting financing and investment operations related to sustainable infrastructure in the areas referred to in point (a) of Article 8(1);
  - (b) supporting financing and investment operations related to research, innovation and digitisation, including support for the scaling up of innovative companies and the rolling out of technologies to market, in the areas referred to in point (b) of Article 8(1);
  - (c) increasing the access to and the availability of finance for SMEs and for small mid-cap companies and to enhance the global competitiveness of such SMEs;
  - (d) increasing access to and the availability of microfinance and finance for social enterprises, to support financing and investment operations related to social investment, competences and skills, and to develop and consolidate social investment markets, in the areas referred to in point (d) of Article 8(1).

### Article 4

#### **Budget and amount of the EU guarantee**

1. The EU guarantee for the purposes of the EU compartment referred to in point (a) of Article 9(1) shall be EUR 26 152 310 073 in current prices. It shall be provisioned at the rate of 40 %. The amount referred to in point (a) of the first subparagraph of Article 35(3) shall be also taken into account for contributing to the provisioning resulting from that provisioning rate.

An additional amount of the EU guarantee may be provided for the purposes of the Member State compartment referred to in point (b) of Article 9(1) of this Regulation, subject to the allocation by Member States, pursuant to the provisions on the use of the ERDF, the ESF+, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in a Regulation of the European Parliament and of the Council 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 (the 'Common Provisions Regulation for 2021-2027') and the provisions on the use of the EAFRD delivered through the InvestEU Programme laid down in the CAP Strategic Plans Regulation, of the corresponding amounts.

An additional amount of the EU guarantee may also be provided in the form of cash or guarantee by Member States for the purposes of the Member State compartment. The amount provided in cash shall constitute an external assigned revenue in accordance with the second sentence of Article 21(5) of the Financial Regulation.

The contributions from third countries referred to in Article 5 of this Regulation shall also increase the EU guarantee referred to in the first subparagraph, providing a provisioning in cash in full in accordance with Article 218(2) of the Financial Regulation.

2. An amount of EUR 14 825 000 000 in current prices of the amount referred to in the first subparagraph of paragraph 1 of this Article shall be allocated for operations implementing measures referred to in Article 1 of Regulation (EU) 2020/2094 for the objectives referred to in Article 3(2) of this Regulation.

An amount of EUR 11 327 310 073 in current prices of the amount referred to in the first subparagraph of paragraph 1 of this Article shall be allocated for the objectives referred to in Article 3(2).

The amounts referred to in the first subparagraph of this paragraph shall only be available as of the date referred to in Article 3(3) of Regulation (EU) 2020/2094.

The indicative distribution of the EU guarantee for the purposes of the EU compartment is set out in Annex I to this Regulation. Where appropriate, the Commission may depart from the amounts referred to in Annex I by up to 15 % for each objective referred to in points (a) to (d) of Article 3(2). The Commission shall inform the European Parliament and the Council of any such departure.

3. The financial envelope for the implementation of the measures provided in Chapters VI and VII shall be EUR 430 000 000 in current prices.

4. The amount referred to in paragraph 3 may also be used for technical and administrative assistance for the implementation of the InvestEU Programme, such as preparatory, monitoring, control, audit and evaluation activities, including for corporate information technology systems.

#### *Article 5*

### **Third countries associated to the InvestEU Fund**

The EU compartment of the InvestEU Fund referred to in point (a) of Article 9(1) of this Regulation and each of the policy windows referred to in Article 8(1) of this Regulation may receive contributions from the following third countries for the purpose of participation in certain financial products pursuant to Article 218(2) of the Financial Regulation:

- (a) members of the European Free Trade Association (EFTA) which are members of the EEA, in accordance with the conditions laid down in the Agreement on the European Economic Area;
- (b) acceding countries, candidate countries and potential candidates, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions or in similar agreements and in accordance with the specific conditions laid down in agreements between the Union and those countries;

- (c) European Neighbourhood Policy countries, in accordance with the general principles and general terms and conditions for the participation of those countries in Union programmes established in the respective framework agreements and Association Council decisions or in similar agreements and in accordance with the specific conditions laid down in agreements between the Union and those countries;
- (d) other third countries, in accordance with the conditions laid down in a specific agreement covering the participation of the third country to any Union programme, provided that the agreement:
  - (i) ensures a fair balance as regards the contributions and benefits of the third country participating in the Union programmes;
  - (ii) lays down the conditions of participation in the programmes, including the calculation of financial contributions to individual programmes, and their administrative costs;
  - (iii) does not confer on the third country any decision-making power in respect of the Union programme;
  - (iv) guarantees the rights of the Union to ensure sound financial management and to protect its financial interests.

The contributions referred to in point (d)(ii) of the first paragraph of this Article shall constitute assigned revenues in accordance with Article 21(5) of the Financial Regulation.

#### Article 6

### Implementation and forms of Union funding

1. The EU guarantee shall be implemented in indirect management with bodies referred to in points (c)(ii), (c)(iii), (c)(v) and (c)(vi) of Article 62(1) of the Financial Regulation. Other forms of Union funding under this Regulation shall be implemented in direct or indirect management in accordance with the Financial Regulation, including grants implemented in accordance with Title VIII of the Financial Regulation and blending operations implemented in accordance with this Article as smoothly as possible, in a manner that ensures efficient and coherent support for Union policies.
2. Financing and investment operations covered by the EU guarantee which form part of the blending operation combining support under this Regulation with support provided under one or more other Union programmes or covered by the EU ETS Innovation Fund shall:
  - (a) be consistent with the policy objectives and comply with the eligibility criteria set out in the rules of the Union programme under which the support is decided;
  - (b) comply with this Regulation.
3. Blending operations that include a financial instrument that is fully financed by other Union programmes or by the EU ETS Innovation Fund without the use of the EU guarantee under this Regulation shall be consistent with the policy objectives and comply with the eligibility criteria set out in the rules of the Union programme under which the support is provided.
4. In accordance with paragraph 2 of this Article, the non-repayable forms of support and financial instruments from the Union budget forming part of the blending operation referred to in paragraphs 2 and 3 of this Article shall be decided under the rules of the relevant Union programme and shall be implemented within the blending operation in accordance with this Regulation and with Title X of the Financial Regulation.

The reporting relating to such blending operations shall also cover their consistency with the policy objectives and eligibility criteria set out in the rules of the Union programme under which the support is decided as well as their compliance with this Regulation.

*Article 7***Combination of portfolios**

1. Support from the EU guarantee under this Regulation, Union support provided through the financial instruments established by the programmes in the programming period 2014-2020 and Union support from the EU guarantee established by Regulation (EU) 2015/1017 may be combined in financial products to be implemented by the EIB or the EIF under this Regulation.
2. By way of derogation from Article 19(2) and the second subparagraph of Article 16(1), the EU guarantee under this Regulation may also cover losses referred to in Article 19(2) in relation to the entire portfolio of financing and investment operations supported by the financial products referred to in paragraph 1 of this Article.

Notwithstanding the objectives of the financial instruments referred to in paragraph 1, the provisions made to cover the financial liabilities arising from financial instruments referred to in paragraph 1 may be used to cover losses in relation to the entire portfolio of financing and investment operations supported by the financial products referred to in paragraph 1.

3. Losses, revenues and repayments from financial products as referred to in paragraph 1, as well as potential recoveries, shall be attributed pro rata between the financial instruments and EU guarantees referred to in that paragraph providing the combined Union support to that financial product.
4. The terms and conditions of the financial products referred to in paragraph 1 of this Article, including the respective pro rata shares of losses, revenues, repayments and recoveries, shall be set out in the guarantee agreement referred to in Article 17.

*CHAPTER II***InvestEU Fund***Article 8***Policy windows**

1. The InvestEU Fund shall operate through the following four policy windows that shall address market failures or suboptimal investment situations within their specific scope:
  - (a) a sustainable infrastructure policy window which comprises sustainable investment in the areas of transport, including multimodal transport, road safety, including in accordance with the Union objective of eliminating fatal road accidents and serious injuries by 2050, the renewal and maintenance of rail and road infrastructure, energy, in particular renewable energy, energy efficiency in accordance with the 2030 energy framework, buildings renovation projects focused on energy savings and the integration of buildings into a connected energy, storage, digital and transport systems, improving interconnection levels, digital connectivity and access, including in rural areas, supply and processing of raw materials, space, oceans, water, including inland waterways, waste management in accordance with the waste hierarchy and the circular economy, nature and other environment infrastructure, cultural heritage, tourism, equipment, mobile assets and the deployment of innovative technologies that contribute to the environmental or climate resilience or social sustainability objectives of the Union and that meet the environmental or social sustainability standards of the Union;
  - (b) a research, innovation and digitisation policy window which comprises research, product development and innovation activities, the transfer of technologies and research results to the market to support market enablers and cooperation between enterprises, the demonstration and deployment of innovative solutions and support for the scaling up of innovative companies, as well as digitisation of Union industry;
  - (c) an SME policy window which comprises access to and the availability of finance primarily for SMEs, including for innovative SMEs and SMEs operating in the cultural and creative sectors, as well as for small mid-cap companies;

(d) a social investment and skills policy window, which comprises microfinance, social enterprise finance, social economy and measures to promote gender equality, skills, education, training and related services, social infrastructure, including health and educational infrastructure and social and student housing, social innovation, health and long-term care, inclusion and accessibility, cultural and creative activities with a social goal, and the integration of vulnerable people, including third country nationals.

2. A just transition scheme shall be established horizontally across all policy windows. That scheme shall comprise investments that address social, economic and environmental challenges deriving from the transition process towards the achievement of the Union's 2030 climate target and its target of achieving climate neutrality by 2050, as well as benefit territories identified in a just transition plan prepared by a Member State in accordance with the relevant provisions of the Just Transition Fund Regulation.

3. All policy windows may include strategic investments including important projects of common European interest to support final recipients whose activities are of strategic importance to the Union, in particular in view of the green and digital transitions, of enhanced resilience and of strengthening strategic value chains.

In the case of strategic investments in defence and space sectors and in cybersecurity, as well as in specific types of projects with actual and direct security implications in critical sectors, the investment guidelines adopted in accordance with paragraph 9 of this Article (the 'investment guidelines') shall set out limitations with respect to final recipients controlled by a third country or third country entities and final recipients having their executive management outside the Union with a view to protecting the security of the Union and its Member States. Those limitations shall be set out in line with the principles concerning eligible entities set out in the relevant provisions of a Regulation of the European Parliament and of the Council establishing the European Defence Fund and repealing Regulation (EU) 2018/1092 and in the relevant provisions of a Regulation of the European Parliament and of the Council establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013, (EU) No 377/2014 and Decision No 541/2014/EU.

The investment guidelines shall set out any necessary requirements relating to the control and executive management of final recipients for other areas, and to the control of intermediaries, in the light of any applicable public order or security considerations. Taking account of those requirements, the Steering Board shall set out any necessary additional requirements.

4. Where a financing or investment operation proposed to the Investment Committee falls under more than one policy window, it shall be attributed to the policy window under which its main objective or the main objective of most of its sub-projects falls, unless the investment guidelines provide otherwise.

5. Financing and investment operations shall be screened to determine whether they have an environmental, climate or social impact. If those operations have such an impact they shall be subject to climate, environmental and social sustainability proofing with a view to minimising detrimental impacts and to maximising benefits to the climate, environment and social dimensions. For that purpose, project promoters that request financing shall provide adequate information based on the guidance referred to in paragraph 6. Projects below a certain size specified in the guidance shall be excluded from the proofing. Projects that are inconsistent with the climate objectives shall not be eligible for support under this Regulation. In the event that the implementing partner concludes that no sustainability proofing is to be carried out, it shall provide a justification to the Investment Committee.

6. The Commission shall develop sustainability guidance that, in accordance with Union environmental and social objectives and standards and, taking appropriate account of the principle of 'do no significant harm' allows for:

- (a) as regards adaptation, ensuring resilience to the potential adverse impacts of climate change through a climate vulnerability and risk assessment, including through relevant adaptation measures, and, as regards mitigation, integrating the cost of greenhouse gas emissions and the positive effects of climate mitigation measures in the cost-benefit analysis;
- (b) accounting for the consolidated impact of projects in terms of the principal components of natural capital, namely air, water, land and biodiversity;

- (c) estimating the social impact of projects, including on gender equality, on the social inclusion of certain areas or populations and on the economic development of areas and sectors affected by structural challenges such as the need to decarbonise the economy;
- (d) identifying projects that are inconsistent with the achievement of climate objectives;
- (e) providing implementing partners with guidance for the purpose of the screening provided for under paragraph 5.

7. Implementing partners shall provide the information necessary to allow the tracking of investment that contributes to meeting the Union objectives on climate and environment, on the basis of guidance to be provided by the Commission.

8. Implementing partners shall apply a target of at least 60 % of the investment under the sustainable infrastructure policy window contributing to meeting the Union objectives on climate and environment.

The Commission, together with implementing partners, shall seek to ensure that the part of the EU guarantee used for the sustainable infrastructure policy window is distributed with the aim of achieving a balance between the different areas referred to in point (a) of paragraph 1.

9. The Commission is empowered to adopt delegated acts in accordance with Article 34 in order to supplement this Regulation by defining the investment guidelines for each of the policy windows. The investment guidelines shall also set out the arrangements for the implementation of the just transition scheme, as referred to in paragraph 2 of this Article. The investment guidelines shall be prepared in close dialogue with the EIB Group and other potential implementing partners.

10. For strategic financing and investment operations in defence and space sectors and in cybersecurity, the investment guidelines may set out limitations with respect to transfer and licensing of intellectual property rights to critical technologies and technologies instrumental to safeguarding the security of the Union and its Member States while respecting Member State competence within export control.

11. The Commission shall make the information on the application and interpretation of the investment guidelines available to the implementing partners, the Investment Committee and the advisory partners.

#### *Article 9*

### **Compartments**

1. The policy windows referred to in Article 8(1) shall consist of an EU compartment and a Member State compartment. Those compartments shall address market failures or suboptimal investment situations as follows:

- (a) the EU compartment shall address any of the following situations:
  - (i) market failures or suboptimal investment situations related to Union policy priorities;
  - (ii) Union-wide or Member State specific market failures or suboptimal investment situations; or
  - (iii) market failures or suboptimal investment situations, which require the development of innovative financial solutions and market structures, in particular new or complex market failures or suboptimal investment situations;
- (b) the Member State compartment shall address specific market failures or suboptimal investment situations in one or several regions or Member States to deliver the policy objectives of the contributing funds under shared management or of the additional amount provided by a Member State under the third subparagraph of Article 4(1), in particular to strengthen economic, social and territorial cohesion in the Union by addressing imbalances between its regions.

2. Where appropriate, the compartments referred to in paragraph 1 shall be used in a complementary manner to support a given financing or investment operation, including by combining support from both compartments.

*Article 10***Specific provisions applicable to the Member State compartment**

1. Amounts allocated by a Member State on a voluntary basis pursuant to the provisions on the use of the ERDF, the ESF +, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in the Common Provisions Regulation for 2021-2027 or to the provisions on the use of the EAFRD delivered through the InvestEU Programme laid down in the CAP Strategic Plans Regulation or amounts provided in cash in accordance with the third subparagraph of Article 4(1) of this Regulation shall be used for the provisioning for the part of the EU guarantee under the Member State compartment covering financing and investment operations in the Member State concerned or for the possible contribution to the InvestEU Advisory Hub. Those amounts shall be used to contribute to the achievement of the policy objectives specified in the Partnership Agreement referred to in the provisions on the preparation and submission of the Partnership Agreement laid down in the Common Provisions Regulation for 2021-2027, in the programmes or in the CAP Strategic Plan which contribute to the InvestEU Programme, in order to implement relevant measures set out in the recovery and resilience plan established under Regulation (EU) 2021/241 or, in other cases, for the purposes laid down in the contribution agreement, depending on the origin of the amount contributed.
2. The establishment of the part of the EU guarantee under the Member State compartment shall be subject to the conclusion of a contribution agreement between a Member State and the Commission.

The fourth subparagraph of this paragraph and paragraph 5 of this Article shall not apply to the additional amount provided by a Member State under the third subparagraph of Article 4(1).

The provisions in this Article relating to amounts allocated pursuant to the provisions on the use of the ERDF, the ESF+, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in the Common Provisions Regulation for 2021-2027 or to the provisions on the use of the EAFRD delivered through the InvestEU Programme laid down in the CAP Strategic Plans Regulation are not applicable to a contribution agreement concerning an additional amount by a Member State, referred to in the third subparagraph of Article 4(1) of this Regulation.

The Member State and the Commission shall conclude a contribution agreement or an amendment to it within four months following the Commission Decision approving the Partnership Agreement pursuant to the provisions on the approval of the Partnership Agreement laid down in the Common Provisions Regulation for 2021-2027 or the CAP Strategic Plan under the CAP Strategic Plans Regulation or simultaneously to the Commission Decision amending a programme in accordance with the provisions on the use of the ERDF, the ESF+, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in the Common Provisions Regulation for 2021-2027 or a CAP Strategic Plan in accordance with the provisions on the amendment to the CAP Strategic Plan laid down in the CAP Strategic Plans Regulation.

Two or more Member States may conclude a joint contribution agreement with the Commission.

By way of derogation from Article 211(1) of the Financial Regulation, the provisioning rate of the EU guarantee under the Member State compartment shall be set at 40 % and may be adjusted downwards or upwards in each contribution agreement to take account of the risks attached to the financial products intended to be used.

3. The contribution agreement shall at least contain the following elements:
  - (a) the overall amount of the part of the EU guarantee under the Member State compartment pertaining to the Member State concerned, its provisioning rate, the amount of the contribution from funds under shared management or provided in accordance with the third subparagraph of Article 4(1), the constitution phase of the provisioning and the amount of the resulting contingent liability to be covered by a back-to-back guarantee provided by the Member State concerned;

- (b) the Member State strategy, consisting of the financial products and their minimum leverage, the geographical coverage, including regional coverage if necessary, types of projects, the investment period and, where applicable, the categories of final recipients and of eligible intermediaries;
- (c) the potential implementing partner or partners proposed in accordance with fourth subparagraph of Article 15(1) and the obligation of the Commission to inform the Member State concerned of the implementing partner or partners selected;
- (d) any contribution from funds under shared management or from amounts provided in accordance with the third subparagraph of Article 4(1) to the InvestEU Advisory Hub;
- (e) the obligations to provide annual reports to the Member State, including reporting on the relevant indicators related to the policy objectives covered in the Partnership Agreement, programme, CAP Strategic Plan or in the recovery and resilience plans and referred to in the contribution agreement;
- (f) provisions on the remuneration for the part of the EU guarantee under the Member State compartment;
- (g) any combination with resources under the EU compartment in accordance with Article 9(2), including in a layered structure to achieve better risk coverage.

4. The contribution agreements shall be implemented by the Commission through guarantee agreements concluded with implementing partners in accordance with Article 17 and advisory agreements concluded with advisory partners in accordance with the second subparagraph of Article 25(1).

Where no guarantee agreement has been concluded within nine months from the conclusion of the contribution agreement, the contribution agreement shall be terminated or prolonged by mutual agreement. Where the amount of a contribution agreement has not been fully committed under one or more guarantee agreements within nine months from the conclusion of the contribution agreement, that amount shall be amended accordingly. The unused amount of provisioning attributable to amounts allocated by Member States pursuant to the provisions on the use of the ERDF, the ESF+, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in the Common Provisions Regulation for 2021-2027 or to the provisions on the use of the EAFRD delivered through the InvestEU Programme laid down in the CAP Strategic Plans Regulation shall be re-used in accordance with those Regulations. The unused amount of provisioning attributable to amounts allocated by a Member State under the third subparagraph of Article 4(1) of this Regulation shall be paid back to the Member State.

Where a guarantee agreement has not been duly implemented within the period specified in the provisions on the use of the ERDF, the ESF+, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in the Common Provisions Regulation for 2021-2027 or in the provisions on the use of the EAFRD delivered through the InvestEU Programme laid down in the CAP Strategic Plans Regulation, or, in the case of a guarantee agreement related to amounts provided in accordance with the third subparagraph of Article 4(1) of this Regulation, in the relevant contribution agreement, the contribution agreement shall be amended. The unused amount of provisioning attributable to amounts allocated by Member States pursuant to the provisions on the use of the ERDF, the ESF+, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in the Common Provisions Regulation for 2021-2027 or to the provisions on the use of the EAFRD delivered through the InvestEU Programme laid down in the CAP Strategic Plans Regulation shall be re-used in accordance with those Regulations. The unused amount of provisioning attributable to amounts allocated by a Member State under the third subparagraph of Article 4(1) of this Regulation shall be paid back to the Member State.

5. The following rules shall apply to the provisioning for the part of the EU guarantee under the Member State compartment established by a contribution agreement:

- (a) after the constitution phase referred to in point (a) of paragraph 3 of this Article, any annual surplus of provisions, calculated by comparing the amount of provisions required by the provisioning rate set in the contribution agreement and the actual amount of provisions, shall be re-used pursuant to the provisions on the use of the ERDF, the ESF+, the Cohesion Fund and the EMFAF delivered through the InvestEU Programme laid down in the Common Provisions Regulation for 2021-2027 and to the provisions on the use of the EAFRD delivered through the InvestEU Programme laid down in the CAP Strategic Plans Regulation;

- (b) by way of derogation from Article 213(4) of the Financial Regulation, after the constitution phase referred to in point (a) of paragraph 3 of this Article, the provisioning shall not give rise to annual replenishments during the availability of that part of the EU guarantee under the Member State compartment;
  - (c) the Commission shall immediately inform the Member State where the level of provisions for that part of the EU guarantee falls below 20 % of the initial provisioning as a result of calls on that part of the EU guarantee under the Member State compartment;
  - (d) if the level of provisions for that part of the EU guarantee under the Member State compartment reaches 10 % of the initial provisioning, the Member State concerned shall provide up to 5 % of the initial provisioning to the common provisioning fund referred to in Article 212 of the Financial Regulation upon request by the Commission.
6. In relation to amounts referred to in the third subparagraph of Article 4(1), the management of the annual surpluses and replenishments after the constitution phase shall be defined in the contribution agreement.

### CHAPTER III

#### ***Partnership between the Commission and the EIB Group***

#### *Article 11*

#### **Scope of the partnership**

1. The Commission and the EIB Group shall form a partnership under this Regulation with the objective of supporting the implementation of the InvestEU Programme and fostering consistency, inclusivity, additionality, and efficient deployment. In accordance with this Regulation and as further specified in the agreements referred to in paragraph 3, the EIB Group:
- (a) shall implement the portion of the EU guarantee specified in Article 13(4);
  - (b) shall support the implementation of the EU compartment of the InvestEU Fund, and, where applicable, the Member State compartment, in particular by:
    - (i) contributing, together with potential implementing partners, to the investment guidelines in accordance with Article 8(9), contributing to the design of the Scoreboard in accordance with Article 22 and contributing to other documents that set out the operational guidance of the InvestEU Fund;
    - (ii) defining, together with the Commission and potential implementing partners, the risk methodology and risk mapping system that relate to the financing and investment operations of the implementing partners in order to allow such operations to be assessed on a common rating scale;
    - (iii) at the request of the Commission and in agreement with the potential implementing partner concerned, carrying out an assessment of the systems of that potential implementing partner and providing targeted technical advice on those systems, where and to the extent required by the conclusions of the audit of the pillar assessment in view of the implementation of the financial products envisaged by that potential implementing partner;
    - (iv) providing a non-binding opinion on the banking-related aspects, in particular on the financial risk and financial terms related to the portion of the EU guarantee to be allocated to the implementing partner, other than to the EIB Group, as defined in the guarantee agreement to be concluded with that implementing partner;
    - (v) carrying out simulations and projections of the financial risk and remuneration of the aggregate portfolio on the basis of assumptions agreed with the Commission;
    - (vi) measuring the financial risk of the aggregate portfolio and providing financial reports on the aggregate portfolio; and

- (vii) providing restructuring and recovery services as set out in the agreement referred to in point (b) of paragraph 3 of this Article to the Commission at the request of the Commission and in agreement with the implementing partner in accordance with point (g) of Article 17(2) where that implementing partner is no longer responsible for pursuing restructuring and recovery activities under the relevant guarantee agreement;
- (c) may provide capacity building as referred to in point (h) of Article 25(2) to a national promotional bank or institution and other services, in relation to the implementation of financial products supported by the EU guarantee if requested by that national promotional bank or institution;
- (d) shall, in relation to the InvestEU Advisory Hub:
  - (i) be allocated an amount of up to EUR 300 000 000 for the advisory initiatives referred to in Article 25 and operational tasks referred to in point (ii) of this point out of the financial envelope referred to in Article 4(3);
  - (ii) advise the Commission and perform operational tasks set out in the agreement referred to in point (c) of paragraph 3, by:
    - providing support to the Commission in the design, the establishment and operation of the InvestEU Advisory Hub;
    - providing an assessment of requests for advisory support that the Commission does not consider to fall under existing advisory initiatives, with a view to supporting the allocation decision of the Commission in relation to advisory requests received under the central point of entry defined in point (a) of Article 25(2);
    - providing support to national promotional banks and institutions by providing capacity building referred to in point (h) of Article 25(2) in relation to the development of their advisory capabilities to enable them to participate in advisory initiatives, at the request of such banks or institutions;
    - at the request of the Commission and of a potential advisory partner, and subject to the agreement of the EIB Group, concluding on behalf of the Commission an agreement with the advisory partner for the delivery of advisory initiatives.

The EIB Group shall ensure that its tasks as referred to in point (d)(ii) of the first subparagraph are conducted entirely independently from its role as an advisory partner.

As appropriate, the Commission shall engage with the implementing partner on the basis of the findings of the opinion of the EIB Group referred to in point (b)(iv) of the first subparagraph. The Commission shall inform the EIB Group of the outcome of its decision-making.

2. The banking-related information transmitted to the EIB Group by the Commission in accordance with points (b)(ii), (b)(iv), (b)(v) and (b)(vi) of the first subparagraph of paragraph 1 shall be limited to information strictly necessary for the EIB Group to fulfil its obligations under those points. The Commission, in close dialogue with the EIB Group and potential implementing partners, shall define the nature and scope of that banking-related information, taking into account the requirements for the sound financial management of the EU guarantee, the legitimate interests of the implementing partner regarding commercially sensitive information and the needs of the EIB Group in meeting its obligations under those points.

3. The terms of the partnership shall be laid down in agreements, including:

- (a) on the granting and implementation of the portion of the EU guarantee specified in Article 13(4):
  - (i) a guarantee agreement between the Commission and the EIB Group; or
  - (ii) separate guarantee agreements between the Commission and the EIB and its subsidiaries or other entities established in accordance with Article 28(1) of the EIB Statute, as applicable;
- (b) an agreement between the Commission and the EIB Group in relation to points (b) and (c) of the first subparagraph of paragraph 1;
- (c) an agreement between the Commission and the EIB Group in relation to the InvestEU Advisory Hub;

(d) service agreements between the EIB Group and national promotional banks and institutions concerning capacity building and other services provided under point (c) of the first subparagraph of paragraph 1.

4. Without prejudice to Articles 18(3) and 25(4) of this Regulation, the costs incurred by the EIB Group in the performance of tasks referred to in points (b) and (c) of the first subparagraph of paragraph 1 of this Article shall be in accordance with the terms of the agreement referred to in point (b) of paragraph 3 of this Article and may be covered from the repayments or revenues attributable to the EU guarantee, or from the provisioning, in accordance with Article 211(4) and (5) of the Financial Regulation, or may be charged to the financial envelope referred to in Article 4(3) of this Regulation, upon justification of those costs by the EIB Group, subject to an overall cap of EUR 7 000 000.

5. The costs incurred by the EIB Group for the performance of the operational tasks referred to in point (d)(ii) of the first subparagraph of paragraph 1 shall be fully covered by and paid from the amount referred to in point (d)(i) of the first subparagraph of paragraph 1, upon justification of those costs by the EIB Group, subject to an overall cap of EUR 10 000 000.

#### Article 12

##### **Conflicts of interest**

1. Within the framework of the partnership as referred to in Article 11, the EIB Group shall take all necessary measures and precautions to avoid conflicts of interest with other implementing partners, including by putting in place a dedicated and independent team for the tasks referred to in points (b)(iii) to (vi) of the first subparagraph of Article 11(1). That team shall be subject to strict confidentiality rules, which shall continue to apply to members of the team after they have left the team.

2. The EIB Group and other implementing partners shall inform the Commission without delay of any situation that constitutes a conflict of interest or is likely to lead to a conflict of interest. In the event of doubt, the Commission shall determine whether a conflict of interest exists and shall inform the EIB Group of its conclusion. In the event of a conflict of interest, the EIB Group shall take appropriate measures. The EIB Group shall inform the Steering Board of those measures and their results.

3. The EIB Group shall take the necessary precautions to avoid situations in which a conflict of interest could arise in the implementation of the InvestEU Advisory Hub, in particular in relation to its operational tasks in its role of supporting the Commission as referred to in point (d)(ii) of the first subparagraph of Article 11(1). In the event of a conflict of interest, the EIB Group shall take appropriate measures.

#### CHAPTER IV

##### **EU guarantee**

#### Article 13

##### **EU guarantee**

1. The EU guarantee shall be granted as an irrevocable, unconditional and on demand guarantee to the implementing partners in accordance with Article 219(1) of the Financial Regulation and implemented in indirect management in accordance with Title X of that Regulation.

2. The remuneration for the EU guarantee shall be linked to the characteristics and risk profile of the financial products, taking into account the nature of the underlying financing and investment operations and the fulfilment of the policy objectives targeted by the financial products.

Where duly justified by the nature of the policy objectives targeted by the financial product and the need for the financial products to be affordable to the targeted final recipients, the cost of the financing provided to the final recipient may be reduced or the terms of that financing may be improved, by reducing the remuneration for the EU guarantee, or, where necessary, by covering the outstanding administrative costs borne by the implementing partner through the Union budget, in particular:

- (a) where stressed financial market conditions would prevent the realisation of a financing or investment operation under market-based pricing; or
- (b) where necessary to catalyse financing and investment operations in sectors or areas experiencing a significant market failure or suboptimal investment situation or to facilitate the establishment of investment platforms.

The reduction of the remuneration for the EU guarantee or the coverage of the outstanding administrative costs borne by the implementing partner, referred to in the second subparagraph, may only be done to the extent that it does not significantly impact the provisioning for the EU guarantee.

The reduction of the remuneration for the EU guarantee shall fully benefit final recipients.

3. The condition set out in Article 219(4) of the Financial Regulation shall apply to each implementing partner on a portfolio basis.

4. 75 % of the EU guarantee under the EU compartment as referred to in the first subparagraph of Article 4(1), amounting to EUR 19 614 232 554, shall be granted to the EIB Group. The EIB Group shall provide an aggregate financial contribution amounting to EUR 4 903 558 139. That contribution shall be provided in a manner and form that facilitates the implementation of the InvestEU Fund and the achievement of the objectives set out in Article 15(2).

5. The remaining 25 % of the EU guarantee under the EU compartment shall be granted to other implementing partners, which shall also provide a financial contribution to be determined in the guarantee agreements.

6. Best efforts shall be made to ensure that, at the end of the investment period, a wide range of sectors and regions are covered and excessive sectoral or geographical concentration is avoided. Those efforts shall include incentives for smaller or less sophisticated national promotional banks and institutions that have a comparative advantage due to their local presence, knowledge and investment competencies. The Commission shall develop a coherent approach to support those efforts.

7. Support under the EU guarantee referred to in the first subparagraph of Article 4(2) of this Regulation shall be granted under the conditions set out in Article 3(6) of Regulation (EU) 2020/2094. In other cases, support under the EU guarantee may be granted for financing and investment operations covered by this Regulation for an investment period ending on 31 December 2027.

Contracts between the implementing partner and the final recipient or the financial intermediary or other entity referred to in point (a) of Article 16(1) under the EU guarantee referred to in the first subparagraph of Article 4(2) shall be signed at the latest one year after the approval of the relevant financing or investment operation by the implementing partner. In other cases, contracts between the implementing partner and the final recipient or the financial intermediary or other entity referred to in point (a) of Article 16(1) shall be signed by 31 December 2028.

#### Article 14

#### **Eligible financing and investment operations**

1. The InvestEU Fund shall only support financing and investment operations that:

- (a) comply with the conditions set out in points (a) to (e) of Article 209(2) of the Financial Regulation, in particular regarding market failures, suboptimal investment situations and additionality as set out in points (a) and (b) of Article 209(2) of the Financial Regulation and in Annex V to this Regulation and, where appropriate, maximising private investment in accordance with point (d) of Article 209(2) of the Financial Regulation;

- (b) contribute to the Union policy objectives and fall within the scope of the areas eligible for financing and investment operations under the appropriate policy window in accordance with Annex II to this Regulation;
- (c) do not provide financial support to the excluded activities set out in Section B of Annex V to this Regulation; and
- (d) are consistent with the investment guidelines.

2. In addition to projects situated in the Union, or in an overseas country or territory linked to a Member State as set out in Annex II to the TFEU, the InvestEU Fund may support the following projects and operations through financing and investment operations:

- (a) projects involving entities located or established in one or more Member States that extend to one or more third countries, including acceding countries, candidate countries and potential candidates, countries falling within the scope of the European Neighbourhood Policy, the EEA or the EFTA, to an overseas country or territory as set out in Annex II to the TFEU, or to an associated third country, regardless of whether there is a partner in those third countries or overseas countries or territories;
- (b) financing and investment operations in third countries as referred to in Article 5 which have contributed to a specific financial product.

3. The InvestEU Fund may support financing and investment operations that provide finance to final recipients which are legal entities established in any of the following countries or territories:

- (a) a Member State or an overseas country or territory linked to a Member State as set out in Annex II to the TFEU;
- (b) a third country associated to the InvestEU Programme in accordance with Article 5;
- (c) a third country referred to in point (a) of paragraph 2, where applicable;
- (d) other third countries, where necessary for the financing of a project in a country or territory referred to in points (a), (b) or (c).

#### Article 15

### **Selection of implementing partners other than the EIB Group**

1. The Commission shall select implementing partners other than the EIB Group in accordance with Article 154 of the Financial Regulation.

Implementing partners may form a group. An implementing partner may be a member of one or more groups.

For the EU compartment, the eligible counterparties shall have expressed their interest in relation to the portion of the EU guarantee referred to in Article 13(5).

For the Member State compartment, the Member State concerned may propose one or more counterparties as implementing partners from among those counterparties that have expressed their interest. The Member State concerned may also propose the EIB Group as an implementing partner and, at its own expense, may contract the EIB Group to provide the services listed in Article 11.

Where the Member State concerned does not propose an implementing partner, the Commission shall proceed in accordance with the third subparagraph of this paragraph and shall select as implementing partners eligible counterparties that are able to cover the financing and investment operations in the geographical areas concerned.

2. When selecting implementing partners, the Commission shall ensure that the portfolio of financial products under the InvestEU Fund meets the following objectives:

- (a) maximising the coverage of the objectives laid down in Article 3;
- (b) maximising the impact of the EU guarantee through the own resources committed by the implementing partner;
- (c) maximising, where appropriate, private investment;

- (d) promoting innovative financial and risk solutions to address market failures and suboptimal investment situations;
  - (e) achieving geographical diversification via gradual allocation of the EU guarantee, and to allow for the financing of smaller projects;
  - (f) providing sufficient risk diversification.
3. When selecting the implementing partners, the Commission shall also take into account:
- (a) the possible cost and remuneration to the Union budget;
  - (b) the capacity of the implementing partner to implement thoroughly the requirements of Article 155(2) and (3) of the Financial Regulation related to tax avoidance, tax fraud, tax evasion, money laundering, terrorism financing and non-cooperative jurisdictions.
4. National promotional banks and institutions may be selected as implementing partners, provided that they fulfil the requirements laid down in this Article.

#### Article 16

##### **Eligible types of financing**

1. The EU guarantee may be used towards risk coverage for the following types of financing provided by the implementing partners:
- (a) loans, guarantees, counter-guarantees, capital market instruments, any other form of funding or credit enhancement, including subordinated debt, or equity or quasi-equity investments, provided directly or indirectly through financial intermediaries, funds, investment platforms or other vehicles to be channelled to final recipients;
  - (b) funding or guarantees by an implementing partner to another financial institution enabling the latter to undertake financing referred to in point (a).

In order to be covered by the EU guarantee, the financing referred to in points (a) and (b) of the first subparagraph of this paragraph shall be granted, acquired or issued for the benefit of financing and investment operations referred to in Article 14(1), where the financing by the implementing partner was granted in accordance with a financing agreement or transaction signed or entered into by the implementing partner after the signature of the guarantee agreement and that has not expired or been cancelled.

2. Financing and investment operations through funds or other intermediate structures shall be supported by the EU guarantee in accordance with provisions to be laid down in the investment guidelines, even if such structures invest a minority of their invested amounts outside the Union and in third countries referred to Article 14(2) or invest a minority of their invested amounts into assets other than those eligible under this Regulation.

#### Article 17

##### **Guarantee agreements**

1. The Commission shall conclude a guarantee agreement with each implementing partner on the granting of the EU guarantee up to an amount to be determined by the Commission.

In the event that implementing partners form a group, a single guarantee agreement shall be concluded between the Commission and each implementing partner within the group or with one implementing partner on behalf of the group.

2. The guarantee agreement shall contain:
- (a) the amount and the terms of the financial contribution which is to be provided by the implementing partner;
  - (b) the terms of the funding or the guarantees which are to be provided by the implementing partner to another legal entity participating in the implementation, whenever that is the case;

- (c) detailed rules on the provision of the EU guarantee in accordance with Article 19, including on the coverage of portfolios of specific types of instruments and the respective events that trigger possible calls on the EU guarantee;
- (d) the remuneration for risk-taking that is to be allocated in proportion to the respective share of the risk-taking of the Union and of the implementing partner or as reduced in duly justified cases pursuant to Article 13(2);
- (e) the payment conditions;
- (f) the commitment of the implementing partner to accept the decisions by the Commission and the Investment Committee as regards the use of the EU guarantee for the benefit of a proposed financing or investment operation, without prejudice to the decision-making of the implementing partner in respect of the proposed financing or investment operation without the EU guarantee;
- (g) provisions and procedures relating to the recovery of claims that is to be entrusted to the implementing partner;
- (h) financial and operational reporting and monitoring of the financing and investment operations under the EU guarantee;
- (i) key performance indicators, in particular as regards the use of the EU guarantee, the fulfilment of the objectives and criteria laid down in Articles 3, 8 and 14, and the mobilisation of private capital;
- (j) where applicable, provisions and procedures relating to blending operations;
- (k) other relevant provisions in compliance with the requirements of Article 155(2) and Title X of the Financial Regulation;
- (l) the existence of adequate mechanisms for addressing the potential concerns of private investors.

3. A guarantee agreement shall also provide that remuneration attributable to the Union from financing and investment operations covered by this Regulation is to be provided after the deduction of payments due upon calls on the EU guarantee.

4. In addition, a guarantee agreement shall provide that any amount due to the implementing partner that relates to the EU guarantee shall be deducted from the overall amount of remuneration, revenues and repayments due by the implementing partner to the Union from financing and investment operations covered by this Regulation. Where that amount is not sufficient to cover the amount due to the implementing partner in accordance with Article 18(3), the outstanding amount shall be drawn from the provisioning for the EU guarantee.

5. Where the guarantee agreement is concluded under the Member State compartment, it may provide for the participation of representatives from the Member State or the regions concerned in the monitoring of the implementation of that guarantee agreement.

#### *Article 18*

#### **Requirements for the use of the EU guarantee**

1. The granting of the EU guarantee shall be subject to the entry into force of the guarantee agreement with the relevant implementing partner.
2. Financing and investment operations shall be covered by the EU guarantee only where they fulfil the criteria laid down in this Regulation and in the relevant investment guidelines, and where the Investment Committee has concluded that those operations fulfil the requirements for benefiting from the EU guarantee. The implementing partners shall remain responsible for ensuring that the financing and investment operations comply with this Regulation and the relevant investment guidelines.

3. No administrative costs or fees related to the implementation of financing and investment operations under the EU guarantee shall be due to the implementing partner by the Commission unless the nature of the policy objectives targeted by the financial product to be implemented and the affordability for the targeted final recipients or the type of financing provided allow the implementing partner to duly justify to the Commission the need for an exception. The coverage of such costs by the Union budget shall be limited to the amount strictly required to implement the relevant financing and investment operations, and shall be provided only to the extent to which the costs are not covered by revenues received by the implementing partners from the financing and investment operations concerned. The fee arrangements shall be laid down in the guarantee agreement and shall comply with Article 17(4) of this Regulation and with point (g) of Article 209(2) of the Financial Regulation.

4. In addition, the implementing partner may use the EU guarantee to meet the relevant share of any recovery costs in accordance with Article 17(4), unless those costs have been deducted from recovery proceeds.

#### Article 19

### Coverage and terms of the EU guarantee

1. Remuneration for risk-taking shall be allocated between the Union and an implementing partner in proportion to their respective share of the risk-taking with respect to a portfolio of financing and investment operations or, where relevant, with respect to individual financing and investment operations. The remuneration for the EU guarantee may be reduced in duly justified cases referred to in Article 13(2).

The implementing partner shall have appropriate exposure at its own risk to financing and investment operations supported by the EU guarantee, unless exceptionally the policy objectives targeted by the financial product to be implemented are of such nature that the implementing partner could not reasonably contribute its own risk-bearing capacity to it.

2. The EU guarantee shall cover:

(a) for debt products referred to in point (a) of Article 16(1):

(i) the principal and all interest and amounts due to the implementing partner but not received by it in accordance with the terms of the financing operations prior to the event of default;

(ii) restructuring losses;

(iii) losses arising from fluctuations of currencies other than the euro in markets where possibilities for long-term hedging are limited;

(b) for equity or quasi-equity investments referred to in point (a) of Article 16(1): the amounts invested and the associated funding costs and losses arising from fluctuations of currencies other than the euro;

(c) for funding or guarantees by an implementing partner to another financial institution in accordance with point (b) of Article 16(1): the amounts used and their associated funding costs.

For the purposes of point (a)(i) of the first subparagraph, for subordinated debt a deferral, reduction or required exit shall be considered to be an event of default.

3. Where the Union makes a payment to the implementing partner as the result of a call on the EU guarantee, the Union shall be subrogated into the relevant rights of the implementing partner relating to any of its financing or investment operations covered by the EU guarantee, to the extent that those rights continue to exist.

The implementing partner shall pursue the recovery of claims for the subrogated amounts on behalf of the Union and shall reimburse the Union from the amounts recovered.

## CHAPTER V

**Governance**

## Article 20

**Advisory Board**

1. The Commission and the Steering Board established pursuant to Article 21 shall be advised by an advisory board (the 'Advisory Board').
2. The Advisory Board shall strive to ensure gender balance and shall comprise:
  - (a) one representative of each implementing partner;
  - (b) one representative of each Member State;
  - (c) one expert appointed by the European Economic and Social Committee;
  - (d) one expert appointed by the Committee of the Regions.
3. The Advisory Board shall be chaired by a representative of the Commission. The representative of the EIB Group shall be the vice-chair.

The Advisory Board shall meet regularly, at least twice a year, at the request of the Chairperson.

4. The Advisory Board shall:
  - (a) provide advice to the Commission and the Steering Board on the design of financial products to be deployed under this Regulation;
  - (b) provide advice to the Commission and the Steering Board about market developments, market conditions, market failures and suboptimal investment situations;
  - (c) exchange views on market developments and share best practices.
5. The Commission shall nominate the first Advisory Board members representing the implementing partners other than the EIB Group after consultation of potential implementing partners. Their term is limited to one year.
6. Meetings of representatives of the Member States in a separate format shall also be organised at least twice a year and chaired by the Commission.
7. The Advisory Board and the meetings of the representatives of the Member States referred to in paragraph 6 may issue recommendations to the Steering Board for its consideration regarding the implementation and operation of the InvestEU Programme.
8. Detailed minutes of the meetings of the Advisory Board shall be made public as soon as possible after they have been approved by the Advisory Board.

The Commission shall establish the operating rules and procedures for the Advisory Board and shall manage the secretariat of the Advisory Board. All relevant documentation and information shall be made available to the Advisory Board to enable it to exercise its tasks.

9. The national promotional banks and institutions represented on the Advisory Board shall select from among themselves the representatives of the implementing partners other than the EIB Group in the Steering Board established pursuant to Article 21. The national promotional banks and institutions shall aim to achieve a balanced representation in the Steering Board in terms of size and geographical location. The representatives selected shall represent the agreed common position of all implementing partners other than the EIB Group.

*Article 21***Steering Board**

1. A steering board for the InvestEU Programme (the 'Steering Board') shall be established. It shall be composed of four representatives of the Commission, three representatives of the EIB Group and two representatives of the implementing partners other than the EIB Group and one expert appointed as a non-voting member by the European Parliament. The expert appointed as a non-voting member by the European Parliament shall not seek or take instructions from Union institutions, bodies, offices or agencies, from any Member State government or from any other public or private body and shall act with full independence. That expert shall perform his or her duties impartially and in the interest of the InvestEU Programme.

Members of the Steering Board shall be appointed for a term of four years, renewable once, with the exception of the representatives of the implementing partners other than the EIB Group, who shall be appointed for a term of two years.

2. The Steering Board shall select a Chairperson from among the Commission representatives for a term of four years, renewable once. The Chairperson shall report biannually to the representatives of the Member States on the Advisory Board on the implementation and operation of the InvestEU Programme.

Detailed minutes of Steering Board meetings shall be published as soon as they have been approved by the Steering Board.

3. The Steering Board shall:

- (a) provide strategic and operational guidance for the implementing partners, including guidance on the design of financial products and on other operating policies and procedures necessary for the operation of the InvestEU Fund;
- (b) adopt the risk methodological framework developed by the Commission in cooperation with the EIB Group and the other implementing partners;
- (c) oversee the implementation of the InvestEU Programme;
- (d) be consulted, reflecting the views of all its member, on the shortlist of candidates for the Investment Committee before their selection in accordance with Article 24(2);
- (e) adopt the rules of procedure of the secretariat to the Investment Committee referred to in Article 24(4).
- (f) adopt the rules applicable to the operations with investment platforms.

4. The Steering Board shall use a consensual approach in its discussions, therefore taking the utmost possible account of the positions of all members. If the members cannot converge in their positions, decisions of the Steering Board are taken by qualified majority of its voting members, consisting of at least seven votes.

*Article 22***Scoreboard**

1. A scoreboard of indicators (the 'Scoreboard') shall be established to ensure that the Investment Committee is able to carry out an independent, transparent and harmonised assessment of requests for the use of the EU guarantee for financing and investment operations proposed by implementing partners.

2. Implementing partners shall fill out the Scoreboard for their proposals for financing and investment operations.

3. The Scoreboard shall cover the following elements:

- (a) a description of the proposed financing or investment operation;
- (b) how the proposed financing or investment operation contributes to EU policy objectives;
- (c) a description of additionality;
- (d) a description of the market failure or suboptimal investment situation;

- (e) the financial and technical contribution by the implementing partner;
- (f) the impact of the investment;
- (g) the financial profile of the financing or investment operation;
- (h) complementary indicators.

4. The Commission is empowered to adopt delegated acts in accordance with Article 34 in order to supplement this Regulation by establishing additional elements of the Scoreboard, including detailed rules for the Scoreboard to be used by the implementing partners.

#### Article 23

##### **Policy check**

1. The Commission shall conduct a check to confirm that the financing and investment operations proposed by the implementing partners other than the EIB comply with Union law and policies.
2. EIB financing and investment operations that fall within the scope of this Regulation shall not be covered by the EU guarantee where the Commission delivers an unfavourable opinion within the framework of the procedure provided for in Article 19 of the EIB Statute.

#### Article 24

##### **Investment Committee**

1. A fully independent investment committee shall be established for the InvestEU Fund (the 'Investment Committee'). The Investment Committee shall:
  - (a) examine the proposals for financing and investment operations submitted by implementing partners for coverage under the EU guarantee that have passed the policy check referred to in Article 23(1) of this Regulation or that have received a favourable opinion within the framework of the procedure provided for in Article 19 of the EIB Statute;
  - (b) verify the compliance of the proposals referred to in point (a) with this Regulation and the relevant investment guidelines; and
  - (c) check whether the financing and investment operations that would benefit from the support under the EU guarantee comply with all relevant requirements.

When performing the tasks referred to in the first subparagraph of this paragraph, the Investment Committee shall give particular attention to the additionality requirements set out in point (b) of Article 209(2) of the Financial Regulation and in Annex V to this Regulation and to the requirement to crowd in private investment set out in point (d) of Article 209(2) of the Financial Regulation.

2. The Investment Committee shall meet in four different configurations, corresponding to the four policy windows referred to in Article 8(1).

Each configuration of the Investment Committee shall be composed of six remunerated external experts. The experts shall be selected and shall be appointed by the Commission, at the recommendation of the Steering Board. The experts shall be appointed for a term of up to four years, renewable once. They shall be remunerated by the Union. The Commission, at the recommendation of the Steering Board, may decide to renew the term of office of an incumbent member of the Investment Committee without following the procedure laid down in this paragraph.

The experts shall have a high level of relevant market experience in project structuring and financing or financing of SMEs or corporates.

The composition of the Investment Committee shall ensure that it has a wide knowledge of the sectors covered by the policy windows referred to in Article 8(1) and a wide knowledge of the geographic markets in the Union, and shall ensure that the Investment Committee as a whole is gender-balanced.

Four members of the Investment Committee shall be permanent members of each of the four configurations of the Investment Committee. At least one of the permanent members shall have expertise in sustainable investment. In addition, each of the four configurations shall have two experts with experience in investment in sectors covered by the corresponding policy window. The Steering Board shall assign the Investment Committee members to the appropriate configuration or configurations. The Investment Committee shall elect a chairperson from among its permanent members.

3. When participating in the activities of the Investment Committee, its members shall perform their duties impartially and in the sole interest of the InvestEU Fund. They shall not seek or take instructions from the implementing partners, the institutions of the Union, the Member States, or any other public or private body.

The curricula vitae and declarations of interest of each member of the Investment Committee shall be made public and kept up to date. Each member of the Investment Committee shall without delay communicate to the Commission and the Steering Board all information needed to confirm the absence of any conflict of interest on an ongoing basis.

The Steering Board may recommend to the Commission that it remove a member from his or her functions if that member does not comply with the requirements laid down in this paragraph or for other duly justified reasons.

4. When acting in accordance with this Article, the Investment Committee shall be assisted by a secretariat. The secretariat shall be independent and answerable to the chairperson of the Investment Committee. The secretariat shall be administratively located in the Commission. The rules of procedure of the secretariat shall ensure the confidentiality of exchanges of information and documents between implementing partners and the respective governing bodies. The EIB Group may submit its proposals for financing and investment operations directly to the Investment Committee and shall notify them to the secretariat.

The documentation to be provided by the implementing partners shall comprise a standardised request form, the Scoreboard referred to in Article 22 and any other document the Investment Committee considers relevant, in particular a description of the character of the market failure or suboptimal investment situation and how it will be alleviated by the financing or investment operation, as well as a reliable assessment of the operation that demonstrates the additionality of the financing or investment operation. The secretariat shall check the completeness of the documentation provided by implementing partners other than the EIB Group. The Investment Committee may seek clarifications from the implementing partner concerned in relation to a proposal for an investment or financing operation, including by requesting the direct presence of a representative of the implementing partner concerned during the discussion of the aforementioned operation. Any project assessment conducted by an implementing partner shall not be binding on the Investment Committee for the purposes of granting a financing or investment operation coverage by the EU guarantee.

The Investment Committee shall use the Scoreboard referred to in Article 22 in its assessment and verification of the proposed financial and investment operations.

5. Conclusions of the Investment Committee shall be adopted by simple majority of all members, provided that such simple majority includes at least one of the non-permanent members of the configuration relating to the policy window under which the proposal is made. In the event of a draw, the chair of the Investment Committee shall have the casting vote.

Conclusions of the Investment Committee approving the coverage of the EU guarantee for a financing or investment operation shall be publicly accessible and shall include the rationale for the approval and information on the operation, in particular its description, the identity of the promoters or financial intermediaries, and the objectives of the operation. The conclusions shall also refer to the global assessment stemming from the Scoreboard.

The relevant Scoreboard shall be made publicly accessible after the signature of the financing or investment operation or sub-project, if applicable.

Information to be made publicly accessible under the second and third subparagraphs shall not contain commercially sensitive information or personal data that are not to be disclosed under the Union data protection rules. Commercially sensitive parts of the conclusions of the Investment Committee shall be forwarded by the Commission to the European Parliament and to the Council upon request subject to strict confidentiality requirements.

Twice a year, the Investment Committee shall submit to the European Parliament and to the Council a list of all conclusions of the Investment Committee in the preceding six months, as well as the published Scoreboards relating thereto. That submission shall include any decisions rejecting the use of the EU guarantee. Those decisions shall be subject to strict confidentiality requirements.

Conclusions of the Investment Committee shall be made available in a timely manner to the implementing partner concerned by the secretariat of the Investment Committee.

The secretariat of the Investment Committee shall record all information related to proposals for financing and investment operations provided to the Investment Committee and the conclusions of the Investment Committee on those proposals in a central repository.

6. Where the Investment Committee is requested to approve the use of the EU guarantee for a financing or investment operation that is a facility, programme or structure which has underlying sub-projects, that approval shall comprise those underlying sub-projects unless the Investment Committee decides to retain the right to approve them separately. The Investment Committee shall not have the right to separately approve sub-projects of a size below EUR 3 000 000.

7. Where it deems it necessary, the Investment Committee may bring to the Commission any operational issue relating to the application or interpretation of the investment guidelines.

#### CHAPTER VI

### **InvestEU Advisory Hub**

#### Article 25

### **InvestEU Advisory Hub**

1. The Commission shall establish the InvestEU Advisory Hub. The InvestEU Advisory Hub shall provide advisory support for the identification, preparation, development, structuring, procuring and implementation of investment projects, and for enhancing the capacity of project promoters and financial intermediaries to implement financing and investment operations. Such support may cover any stage of the life cycle of a project or financing of a supported entity.

The Commission shall conclude advisory agreements with the EIB Group and other potential advisory partners and task them with the provision of advisory support as referred to in the first subparagraph of this paragraph and of the services referred to in paragraph 2. The Commission may also implement advisory initiatives, including through contracting external service providers. The Commission shall establish a central entry point to the InvestEU Advisory Hub and shall allocate requests for advisory support to be dealt under the appropriate advisory initiative. The Commission, the EIB Group and the other advisory partners shall cooperate closely with a view to ensuring efficiency, synergies and effective geographic coverage of support across the Union, while taking due account of existing structures and work.

Advisory initiatives shall be available as a component under each policy window referred to in Article 8(1), covering sectors under that window. In addition, advisory initiatives shall be available under a cross-sectoral component.

2. The InvestEU Advisory Hub shall in particular:

- (a) provide a central point of entry, managed and hosted by the Commission, for project development assistance under the InvestEU Advisory Hub for public authorities and for project promoters;
- (b) disseminate to public authorities and project promoters all available additional information regarding the investment guidelines, including information on their application or on the interpretation provided by the Commission;

- (c) where appropriate, assist project promoters in developing their projects so that they fulfil the objectives set out in Articles 3 and 8 and the eligibility criteria set out in Article 14, and facilitate the development of among others important projects of common European interest and aggregators for small-sized projects, including through investment platforms as referred to in point (f) of this paragraph, provided that such assistance does not prejudice the conclusions of the Investment Committee with respect to the coverage of the EU guarantee with respect to such projects;
- (d) support actions and leverage local knowledge to facilitate the use of InvestEU Fund support across the Union and contribute actively where possible to the objective of the sectorial and geographical diversification of the InvestEU Fund by supporting implementing partners in originating and developing potential financing and investment operations;
- (e) facilitate the establishment of collaborative platforms for peer-to-peer exchanges and the sharing of data, knowhow and best practices to support project pipeline and sector development;
- (f) provide proactive advisory support with respect to the establishment of investment platforms, including cross-border and macro-regional investment platforms and investment platforms that bundle small and medium-sized projects in one or more Member States by theme or by region;
- (g) support the use of blending with grants or financial instruments funded by the Union budget or by other sources in order to strengthen synergies and complementarities between Union instruments and to maximise the leverage and impact of the InvestEU Programme;
- (h) support capacity building actions to develop organisational capacities, skills and processes and to accelerate the investment readiness of organisations in order for public authorities and project promoters to build investment project pipelines, develop financing mechanisms and investment platforms and to manage projects and for financial intermediaries to implement financing and investment operations for the benefit of entities that face difficulties in obtaining access to finance, including through support for developing risk assessment capacity or sector specific knowledge;
- (i) providing advisory support for start-ups, especially when they seek to protect their research and innovation investments by obtaining intellectual property titles, such as patents.

3. The InvestEU Advisory Hub shall be available to public and private project promoters, including SMEs and start-ups, to public authorities, to national promotional banks and institutions, and to financial and non-financial intermediaries.

4. The Commission shall conclude an advisory agreement with each advisory partner on the implementation of one or more advisory initiatives. The InvestEU Advisory Hub may charge fees for the services referred to in paragraph 2 to cover part of the costs for providing those services, except for services provided to public project promoters or non-profit institutions, which shall be free of charge where justified. Fees charged to SMEs for those services referred to in paragraph 2 shall be capped at one third of the cost of providing those services.

5. In order to carry out the activities referred to in paragraph 1 and to facilitate the provision of advisory support, the InvestEU Advisory Hub shall build upon the expertise of the Commission, the EIB Group and the other advisory partners.

6. Each advisory initiative shall incorporate a cost-sharing mechanism between the Commission and the advisory partner, except where the Commission agrees to cover all costs of the advisory initiative in a duly justified case where the specificities of the advisory initiative so require and the coherent and equitable treatment of advisory partners concerned is ensured.

7. The InvestEU Advisory Hub shall have local presence where necessary. Local presence shall be established in particular in Member States or regions that face difficulties in developing projects under the InvestEU Fund. The InvestEU Advisory Hub shall assist in the transfer of knowledge to the regional and local level with a view to building up regional and local capacity and expertise to be able to provide advisory support referred to in paragraph 1, including support to implement and accommodate small-sized projects.

8. In order to provide the advisory support referred in paragraph 1 and to facilitate the provision of that advisory support at local level, the InvestEU Advisory Hub shall cooperate where possible with and take advantage of the expertise of national promotional banks and institutions. Where appropriate, cooperation agreements with national promotional banks and institutions shall be concluded under the InvestEU Advisory Hub, with at least one national promotional bank or institution per Member State.

9. The implementing partners shall, as appropriate, propose to project promoters applying for financing, including in particular small-sized projects, that they request the InvestEU Advisory Hub support for their projects, where appropriate, in order to enhance the preparation of their projects and to allow for the assessment of the possibility of bundling projects.

Where relevant, the implementing partners and advisory partners shall also inform the project promoters of the possibility of listing their projects on the InvestEU Portal referred to in Article 26.

#### CHAPTER VII

##### **InvestEU Portal**

#### Article 26

##### **InvestEU Portal**

1. The Commission shall establish the InvestEU Portal. The InvestEU Portal shall be an easily accessible and user-friendly project database that provides relevant information for each project.
2. The InvestEU Portal shall provide a channel for project promoters to make projects for which they are seeking finance visible to investors. The inclusion of projects in the InvestEU Portal shall be without prejudice to decisions on the final projects selected for support under this Regulation or under any other Union instrument, or to decisions for public funding. Only projects that are compatible with Union law and policies shall be listed on the InvestEU Portal.
3. The Commission shall transmit projects that are compatible with Union law and policies to the relevant implementing partners. Where appropriate and where an advisory initiative exists, the Commission shall also transmit such projects to the InvestEU Advisory Hub.
4. Implementing partners shall examine projects falling within their geographic and activity scope.

#### CHAPTER VIII

##### **Accountability, monitoring and reporting, evaluation and control**

#### Article 27

##### **Accountability**

1. At the request of the European Parliament or of the Council, the Chairperson of the Steering Board shall report on the performance of the InvestEU Fund to the requesting institution, including by participating in a hearing before the European Parliament.
2. The Chairperson of the Steering Board shall reply orally or in writing to questions addressed to the InvestEU Fund by the European Parliament or by the Council within five weeks of their receipt.

*Article 28***Monitoring and reporting**

1. Indicators to report on the progress of the InvestEU Programme towards the achievement of the general and specific objectives laid down in Article 3 are set out in Annex III.
2. The performance reporting system shall ensure that data for monitoring the implementation and the results of the InvestEU Programme are collected efficiently, effectively and in a timely manner, and that those data allow for adequate risk and guarantee portfolio monitoring. To that end, proportionate reporting requirements shall be imposed on the implementing partners, the advisory partners and other recipients of Union funds, as appropriate.
3. The Commission shall report on the implementation of the InvestEU Programme in accordance with Articles 241 and 250 of the Financial Regulation. In accordance with Article 41(5) of the Financial Regulation, the annual report shall provide information on the level of implementation of the Programme with respect to its objectives and performance indicators. For that purpose, each implementing partner shall provide on an annual basis the information necessary to allow the Commission to comply with its reporting obligations, including information on the operation of the EU guarantee.
4. Every six months, each implementing partner shall submit a report to the Commission on the financing and investment operations covered by this Regulation, broken down by EU compartment and Member State compartment, as appropriate. Each implementing partner shall also submit information on the Member State compartment to the Member State whose compartment it implements. The report shall include an assessment of compliance with the requirements on the use of the EU guarantee and with the key performance indicators laid down in Annex III to this Regulation. The report shall also include operational, statistical, financial and accounting data on each financing or investment operation and an estimation of expected cash flows, at the level of compartment, policy window and the InvestEU Fund. Once a year, the report from the EIB Group and, where appropriate, from other implementing partners, shall also include information on barriers to investment encountered when carrying out financing and investment operations covered by this Regulation. The reports shall contain the information the implementing partners have to provide under point (a) of Article 155(1) of the Financial Regulation.
5. To ensure the effective assessment of the progress of the InvestEU Programme towards the achievement of its objectives, the Commission is empowered to adopt delegated acts, in accordance with Article 34, to amend Annex III with regard to the indicators where considered necessary as well as to supplement this Regulation with provisions on the establishment of a monitoring and evaluation framework.

*Article 29***Evaluation**

1. Evaluations of the InvestEU Programme shall be carried out so that they feed into the decision-making process in a timely manner.
2. By 30 September 2024, the Commission shall submit to the European Parliament and to the Council an independent interim evaluation report on the InvestEU Programme, in particular on the use of the EU guarantee, on the fulfilment of the EIB Group's obligations under points (b) and (c) of the first subparagraph of Article 11(1), on the allocation of the EU guarantee provided for in Article 13(4) and (5), on the implementation of the InvestEU Advisory Hub, on the budgetary allocation provided for in point (d)(i) of the first subparagraph of Article 11(1), and on Article 8(8). The evaluation shall in particular demonstrate how the inclusion of the implementing partners and advisory partners in the implementation of the InvestEU Programme has contributed to the reaching of InvestEU Programme targets as well as EU policy goals, especially with regard to added value and the geographical and sectoral balance of the supported financing and investment operations. The evaluation shall also assess the application of sustainability proofing pursuant to Article 8(5) and the focus on SMEs reached under the SME policy window referred to in point (c) of Article 8(1).

3. At the end of the implementation of the InvestEU Programme, but no later than 31 December 2031, the Commission shall submit to the European Parliament and to the Council an independent final evaluation report on the InvestEU Programme, in particular on the use of the EU guarantee.
4. The Commission shall communicate the conclusions of the evaluations, accompanied by its observations, to the European Parliament, to the Council, to the European Economic and Social Committee and to the Committee of the Regions.
5. The implementing partners and advisory partners shall contribute to and provide the Commission with the information necessary to perform the evaluations referred to in paragraphs 2 and 3.
6. In accordance with Article 211(1) of the Financial Regulation, every three years the Commission shall include in the annual report referred to in Article 250 of the Financial Regulation a review of the adequacy of the provisioning rate laid down in Article 4(1) of this Regulation with respect to the actual risk profile of the financing and investment operations covered by the EU guarantee. The Commission is empowered to adopt delegated acts in accordance with Article 34 of this Regulation in order to amend this Regulation by adjusting the provisioning rate laid down in Article 4(1) of this Regulation by up to 15 % on the basis of that review.

#### *Article 30*

#### **Audits**

Audits of the use of the Union funding carried out by persons or entities, including by persons or entities other than those mandated by Union institutions or bodies, shall form the basis of the overall assurance pursuant to Article 127 of the Financial Regulation.

#### *Article 31*

#### **Protection of the financial interests of the Union**

Where a third country participates in the InvestEU Programme by means of a decision adopted pursuant to an international agreement or on the basis of any other legal instrument, the third 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.

#### *CHAPTER IX*

#### ***Transparency and visibility***

#### *Article 32*

#### **Information, communication and publicity**

1. Implementing partners and advisory partners shall acknowledge the origin 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.

The application of the requirements under the first subparagraph to projects in defence and space sectors and in cybersecurity shall be subject to respect for any confidentiality or secrecy obligations.

2. The implementing partners and advisory partners shall inform the final recipients, including SMEs, of the existence of support under the InvestEU Programme, or oblige other financial intermediaries to inform such final recipients of that support, by making that information clearly visible in the relevant agreement providing support under the InvestEU Programme, particularly in the case of SMEs, in order to increase public awareness and improve visibility.

3. The Commission shall implement information and communication actions relating to the InvestEU Programme, to actions taken pursuant to the InvestEU Programme and to the results obtained. Financial resources allocated to the InvestEU Programme shall also 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 3.

#### CHAPTER X

### ***Participation of the European Union in the capital increase of the European Investment Fund***

#### *Article 33*

#### **Participation in a capital increase of the EIF**

In addition to its shareholding in the EIF at 3 December 2020, the Union shall subscribe for up to 853 shares in the EIF, each of a nominal value of EUR 1 000 000, so that its relative share in the capital remains at a level equivalent to that on 3 December 2020. The subscription of the shares and the payment of up to EUR 375 000 000 for the paid-in part of the shares and for the share premium shall be carried out in accordance with terms and conditions that shall be approved by the General Meeting of the EIF and before 31 December 2021. The resulting subscribed but not paid-in part of the shares acquired under this Article shall not exceed EUR 682 400 000.

#### CHAPTER XI

### ***Transitional and final provisions***

#### *Article 34*

#### **Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. Where delegated acts concern activities to be carried out by or involving the EIB Group and other implementing partners, the Commission shall consult with the EIB Group and other potential implementing partners before preparing those delegated acts.

2. The power to adopt delegated acts referred to in Articles 8(9), 22(4), 28(5) and 29(6) shall be conferred on the Commission until 31 December 2028. The Commission shall draw up a report in respect of the delegation of power not later than nine months before that date. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 8(9), 22(4), 28(5) and 29(6) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles 8(9), 22(4), 28(5) and 29(6) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### Article 35

##### Transitional provisions

1. By way of derogation from the first and fourth subparagraphs of Article 209(3) of the Financial Regulation, any revenues, repayments and recoveries from financial instruments established by programmes referred to in Annex IV to this Regulation may be used for the provisioning of the EU guarantee under this Regulation, taking into account the relevant provisions concerning the budget laid down in the Public Sector Loan Facility Regulation for 2021-2027.
2. By way of derogation from point (a) of Article 213(4) of the Financial Regulation, any surplus of provisions for the EU guarantee established by Regulation (EU) 2015/1017 may be used for the provisioning of the EU guarantee under this Regulation, taking into account the relevant provisions concerning the budget laid down in the Public Sector Loan Facility Regulation for 2021-2027.
3. The amount of EUR 6 074 000 000 in current prices referred to in point (c) of Article 2(2) of Regulation (EU) 2020/2094 shall be used:
  - (a) for the provisioning of the EU guarantee under this Regulation with an amount of EUR 5 930 000 000 in current prices, in addition to the resources mentioned in the first subparagraph of Article 211(4) of the Financial Regulation;
  - (b) for the implementation of the measures provided in Chapters VI and VII of this Regulation and the measures referred to in the second sentence of Article 1(3) of Regulation (EU) 2020/2094, subject to Article 3(4) and (8) of that Regulation, with an amount of EUR 142 500 000 in current prices.

That amount shall constitute an external assigned revenue in accordance with Article 21(5) of the Financial Regulation.

4. By way of derogation from the second subparagraph of Article 16(1) of this Regulation, financing and investment operations signed or entered into by an implementing partner during the period from 1 January 2021 until the signature of their respective guarantee agreements may be covered by the EU guarantee provided that those operations are indicated in the guarantee agreement, pass the policy check referred to in Article 23(1) of this Regulation or receive a favourable opinion within the framework of the procedure provided for in Article 19 of the EIB Statute and are in both cases approved by the Investment Committee in accordance with Article 24 of this Regulation.

#### Article 36

##### Amendment of Regulation (EU) 2015/1017

The following article is inserted in Regulation (EU) 2015/1017:

*Article 11a*

##### Combination of EFSI portfolio with other portfolios

By way of derogation from Article 11(6) of this Regulation and the second subparagraph of Article 10(2) of this Regulation, the EU guarantee may cover losses referred to in Article 11(6) of this Regulation in relation to the entire portfolio of financing and investment operations supported by the financial products referred to in Article 7(1) of Regulation (EU) 2021/523 of the European Parliament and of the Council (\*).

(\*). 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).'

*Article 37***Entry into force**

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

It shall apply from 1 January 2021.

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

Done at Brussels, 24 March 2021.

*For the European Parliament*  
*The President*  
D. M. SASSOLI

*For the Council*  
*The President*  
A. P. ZACARIAS

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## ANNEX I

**AMOUNTS OF EU GUARANTEE PER SPECIFIC OBJECTIVE**

The indicative distribution referred to in the fourth subparagraph of Article 4(2) towards financial and investment operations shall be as follows:

- (a) up to EUR 9 887 682 891 for objectives referred to in point (a) of Article 3(2);
- (b) up to EUR 6 575 653 460 for objectives referred to in point (b) of Article 3(2);
- (c) up to EUR 6 906 732 440 for objectives referred to in point (c) of Article 3(2);
- (d) up to EUR 2 782 241 282 for objectives referred to in point (d) of Article 3(2).

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## ANNEX II

**AREAS ELIGIBLE FOR FINANCING AND INVESTMENT OPERATIONS**

The financing and investment operations may include strategic investment to support final recipients whose activities are of strategic importance to the Union, in particular in view of the green and digital transitions, of enhanced resilience and of strengthening strategic value chains. They may include important projects of common European interest. The financing and investment operations may fall under one or more of the following areas:

- (1) the development of the energy sector in accordance with the Energy Union priorities, including security of energy supply, clean energy transition and the commitments taken under the 2030 Agenda for Sustainable Development and the Paris Agreement, in particular through:
  - (a) the expansion of the generation, supply or use of clean and sustainable renewable and safe and sustainable other zero and low-emission energy sources and solutions;
  - (b) energy efficiency and energy savings (with a focus on reducing demand through demand side management and the refurbishment of buildings);
  - (c) the development, smartening and modernisation of sustainable energy infrastructure, in particular storage technologies, electricity interconnections between Member States and smart grids, both at the transmission and distribution level;
  - (d) the development of innovative zero- and low-emission heat supply systems and the combined production of electricity and heat;
  - (e) the production and supply of sustainable synthetic fuels from renewable/carbon-neutral sources and other safe and sustainable zero- and low-emission sources, biofuels, biomass and alternative fuels, including fuels for all modes of transport, in accordance with the objectives of Directive (EU) 2018/2001;
  - (f) infrastructure for carbon capture, and storage in industrial processes, bioenergy plants and manufacturing facilities towards the energy transition; and
  - (g) critical infrastructure, whether physical or virtual, including infrastructure elements identified as critical as well as land and real estate crucial for the use of such critical infrastructure and the provision of goods and services instrumental to the operation and maintenance of the critical infrastructure.
- (2) the development of sustainable and safe transport infrastructures and mobility solutions, equipment and innovative technologies in accordance with Union transport priorities and the commitments taken under the Paris Agreement, in particular through:
  - (a) projects that support the development of the trans-European transport network (TEN-T) infrastructure, including infrastructure maintenance and safety, the urban nodes of TEN-T, maritime and inland ports, airports, multimodal terminals and the connection of such multimodal terminals to the TEN-T networks, and the telematic applications referred to in Regulation (EU) No 1315/2013 of the European Parliament and of the Council <sup>(1)</sup>;
  - (b) TEN-T infrastructure projects that make provision for the use of at least two different modes of transport, in particular multimodal freight terminals and passenger transport hubs;
  - (c) smart and sustainable urban mobility projects that target low-emission urban transport modes, including inland waterway solutions and innovative mobility solutions, non-discriminatory accessibility, reduced air pollution and noise, energy consumption, networks of smart cities, maintenance, and increasing safety levels and decreasing the frequency of accidents, including for cyclists and pedestrians);
  - (d) supporting the renewal and retrofitting of transport mobile assets with the view of deploying low and zero-emission mobility solutions, including through the use of alternative fuels in vehicles of all transport modes;

<sup>(1)</sup> Regulation (EU) No 1315/2013 of the European Parliament and of the Council of 11 December 2013 on Union guidelines for the development of the trans-European transport network and repealing Decision No 661/2010/EU (OJ L 348, 20.12.2013, p. 1).

- (e) railway infrastructure, other rail projects, inland waterway infrastructure, mass transit projects and maritime ports and motorways of the sea;
  - (f) alternative fuel infrastructure for all modes of transport, including electric charging infrastructure;
  - (g) other smart and sustainable mobility projects that target:
    - (i) road safety;
    - (ii) accessibility;
    - (iii) emission reduction; or
    - (iv) the development and deployment of new transport technologies and services such as services that relate to connected and autonomous modes of transport or integrated ticketing;
  - (h) projects to maintain or upgrade existing transport infrastructure, including motorways on the TEN-T where necessary to upgrade, maintain or improve road safety, to develop Intelligent Transport Systems (ITS) services or to guarantee infrastructure integrity and standards, to develop safe parking areas and facilities, recharging and refuelling stations for alternative fuels; and
  - (i) critical infrastructure including infrastructure elements identified as critical as well as land and real estate crucial for the use of such critical infrastructure and the provision of goods and services instrumental to the operation and maintenance of the critical infrastructure.
- (3) environment and resources, in particular with respect to:
- (a) water, including drinking water supply and sanitation, and network efficiency, leakage reduction, infrastructure for the collection and treatment of waste water, coastal infrastructure and other water-related green infrastructure;
  - (b) waste management infrastructure;
  - (c) projects and enterprises in the fields of environmental resource management and sustainable technologies;
  - (d) the enhancement and restoration of ecosystems and their services including through the enhancement of nature and biodiversity by means of green and blue infrastructure projects;
  - (e) sustainable urban, rural and coastal development;
  - (f) climate change actions, climate adaptation and mitigation, including natural hazard disaster risk reduction;
  - (g) projects and enterprises that implement the circular economy by integrating resource efficiency aspects in the production and product life cycle, including the sustainable supply of primary and secondary raw materials;
  - (h) the decarbonisation of energy-intensive industries and the substantial reduction of emissions in such industries, including the demonstration of innovative low-emission technologies and their deployment;
  - (i) the decarbonisation of the energy production and distribution chain by phasing out the use of coal and oil; and
  - (j) projects that promote sustainable cultural heritage.
- (4) the development of digital connectivity infrastructure, whether physical or virtual, in particular through projects that support the deployment of very high capacity digital networks or 5G connectivity or that improve digital connectivity and access, particularly in rural areas and peripheral regions.

- (5) research, development and innovation, in particular through:
  - (a) research and innovation projects that contribute to the objectives of Horizon Europe, including research infrastructure and support to academia;
  - (b) corporate projects, including training and promoting the creation of clusters and business networks;
  - (c) demonstration projects and programmes, as well as deployment of related infrastructures, technologies and processes;
  - (d) collaborative research and innovation projects involving academia, research and innovation organisations and industry; public-private partnerships and civil society organisations;
  - (e) knowledge and technology transfer;
  - (f) research in the field of key enabling technologies (KETs) and their industrial applications, including new and advanced materials; and
  - (g) new effective and accessible healthcare products, including research, development, innovation and manufacturing of pharmaceuticals, medical devices, diagnostics and advanced therapy medicinal products and new antimicrobials, as well as innovative development processes that avoid using animal testing.
- (6) the development, deployment and scaling-up of digital technologies and services, especially digital technologies and services, including media, online service platforms and secure digital communication, that contribute to the objectives of the Digital Europe Programme, in particular through:
  - (a) artificial intelligence;
  - (b) quantum technology;
  - (c) cybersecurity and network protection infrastructures;
  - (d) the internet of things;
  - (e) blockchain and other distributed ledger technologies;
  - (f) advanced digital skills;
  - (g) robotics and automation;
  - (h) photonics;
  - (i) other advanced digital technologies and services contributing to the digitisation of the Union industry and the integration of digital technologies, services and skills in the transport sector of the Union; and
  - (j) recycling and manufacturing facilities for the production of information and communication technologies components and devices in the Union.
- (7) financial support to entities employing up to 499 employees, with a particular focus on SMEs, and small mid-cap companies, in particular through:
  - (a) the provision of working capital and investment;
  - (b) the provision of risk financing from seed to expansion stages to ensure their technological leadership in innovative and sustainable sectors including by enhancing their digitisation and innovation capacity, and their global competitiveness;
  - (c) the provision of financing for the acquisition of a business by employees or participation in the ownership of a business by employees.
- (8) cultural and creative sectors, cultural heritage, media, the audio-visual sector, journalism and press, in particular through the development of new technologies, the use of digital technologies and technological management of intellectual property rights.

- (9) tourism.
- (10) the rehabilitation of industrial sites (including contaminated sites) and the restoration of such sites for sustainable use.
- (11) sustainable agriculture, forestry, fishery, aquaculture and other elements of the wider sustainable bioeconomy.
- (12) social investments, including those supporting the implementation of the European Pillar of Social Rights, in particular through:
  - (a) microfinance, ethical, social enterprise finance and social economy;
  - (b) demand for and the supply of skills;
  - (c) education, training and related services, including for adults;
  - (d) social infrastructure, in particular:
    - (i) inclusive education and training, including early childhood education and care, and related educational infrastructure and facilities, alternative childcare, student housing and digital equipment, that are accessible for all;
    - (ii) affordable social housing <sup>(?)</sup>;
    - (iii) health and long-term care, including clinics, hospitals, primary care, home services and community-based care;
  - (e) social innovation, including innovative social solutions and schemes aimed at promoting social impacts and outcomes in the areas referred to in points (a) to (d) and (f) to (j);
  - (f) cultural activities with a social objective;
  - (g) measures to promote gender equality;
  - (h) the integration of vulnerable people, including third country nationals;
  - (i) innovative health solutions, including e-health, health services and new care models;
  - (j) the inclusion of and accessibility for persons with disabilities.
- (13) the development of the defence industry in order to contribute to the Union's strategic autonomy, in particular through support for:
  - (a) the Union's defence industry supply chain, in particular through financial support to SMEs and mid-caps;
  - (b) companies participating in disruptive innovation projects in the defence sector and closely related dual-use technologies;
  - (c) the defence sector supply chain when participating in collaborative defence research and development projects, including those supported by the European Defence Fund;
  - (d) infrastructure for defence research and training.
- (14) space, in particular in relation to the development of the space sector in line with the objectives of the Space Strategy for Europe:
  - (a) to maximise the benefits for the Union society and economy;
  - (b) to foster the competitiveness of space systems and technologies, addressing in particular vulnerability of supply chains;
  - (c) to underpin space entrepreneurship, including downstream development;
  - (d) to foster Union's autonomy for safe and secure access to space, including dual use aspects.

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<sup>(?)</sup> Affordable social housing is to be understood as aimed at disadvantaged persons or socially less advantaged groups, who due to solvency constraints live in severe housing deprivation or are unable to obtain housing at market conditions.

- (15) seas and oceans, through the development of projects and enterprises in the area of the blue economy, and the Sustainable Blue Economy Finance Principles, in particular through maritime entrepreneurship and industry, renewable marine energy and circular economy.
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## ANNEX III

## KEY PERFORMANCE AND MONITORING INDICATORS

1. Volume of financing supported by the InvestEU Fund (broken down by policy window)
  - 1.1 Volume of operations signed
  - 1.2 Investment mobilised
  - 1.3 Amount of private finance mobilised
  - 1.4 Leverage and multiplier effect achieved
2. Geographical coverage of financing supported by the InvestEU Fund (broken down by policy window, country and region at the common classification of territorial units for statistics (NUTS) 2 level)
  - 2.1 Number of countries (Member States and third countries) covered by operations
  - 2.2 Number of regions covered by operations
  - 2.3 Volume of operations per country (Member State and third country) and per region
3. Impact of financing supported by the InvestEU Fund
  - 3.1 Number of jobs created or supported
  - 3.2 Investment supporting climate objectives and, where applicable, broken down by policy window
  - 3.3 Investment supporting digitisation
  - 3.4 Investment supporting industrial transition
  - 3.5 Investment supporting just transition
  - 3.6 Strategic investment
    - Number and volume of operations contributing to the provision of critical infrastructure
    - Number and volume of operations contributing to investment in cybersecurity, space and defence
4. Sustainable infrastructure
  - 4.1 Energy: Additional renewable and other safe and sustainable zero and low-emission energy generation capacity installed (in megawatts (MW))
  - 4.2 Energy: Number of households, number of public and commercial premises with improved energy consumption classification
  - 4.3 Energy: Estimated energy savings generated by the projects (in kilowatt-hours (kWh))
  - 4.4 Energy: Annual green-house gas emissions reduced/avoided in tonnes of CO<sub>2</sub> equivalent
  - 4.5 Energy: Volume of investment in the development, smartening and modernisation of sustainable energy infrastructure
  - 4.6 Digital: Additional households, enterprises or public buildings with broadband access of at least 100 Mbps upgradable to gigabit speed, or number of WIFI-hotspots created
  - 4.7 Transport: Investment mobilised, in particular in TEN-T
    - Number of cross-border and missing links projects (including projects relating to urban nodes, regional cross-border rail connections, multimodal platforms, maritime ports, inland ports, connections to airports and rail-road terminals of the TEN-T core and comprehensive network)
    - Number of projects contributing to the digitisation of transport, in particular through the deployment of European Rail Traffic Management System (ERTMS), River Information System (RIS), Intelligent Transportation System (ITS), vessel traffic monitoring and information system (VTMIS)/e-maritime services and Single European Sky ATM Research (SESAR)

- Number of alternative fuel supply points built or upgraded
  - Number of projects contributing to the safety of transport
  - 4.8 Environment: Investment contributing to the implementation of plans and programmes required by the Union environmental acquis relating to air quality, water, waste and nature
  - 5. Research, innovation and digitisation
    - 5.1 Contribution to the objective of 3 % of the Union's gross domestic product (GDP) invested in research, development and innovation
    - 5.2 Number of enterprises supported by size carrying out research and innovation projects
  - 6. SMEs
    - 6.1 Number of enterprises supported by size (micro, small, medium-sized and small mid-cap companies)
    - 6.2 Number of enterprises supported by stage (early, growth/expansion)
    - 6.3 Number of enterprises supported by Member State and region at NUTS 2 level
    - 6.4 Number of enterprises supported by sectors by statistical classification of economic activities in the European Union (NACE) code
    - 6.5 Percentage of investment volume under the SME policy window directed towards SMEs
  - 7. Social investment and skills
    - 7.1 Social infrastructure: Capacity and access to supported social infrastructure by sector: housing, education, health, other
    - 7.2 Microfinance and social enterprise finance: Number of microfinance recipients and social enterprises supported
    - 7.3 Skills: Number of individuals acquiring new skills or having their skills validated and certified: formal, education and training qualification
  - 8. InvestEU Advisory Hub
    - 8.1 Number of engagements of the InvestEU Advisory Hub to provide advisory support, by sector and Member State
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## ANNEX IV

## THE INVESTEU PROGRAMME – PREDECESSOR INSTRUMENTS

## A. Equity instruments:

- European Technology Facility (ETF98): Council Decision 98/347/EC of 19 May 1998 on measures of financial assistance for innovative and job-creating small and medium-sized enterprises (SMEs) - the growth and employment initiative (OJ L 155, 29.5.1998, p. 43)
- Technology Transfer Pilot project (TTP): Commission decision adopting a complementary financing decision concerning the financing of actions of the activity ‘Internal market of goods and sectoral policies’ of the Directorate-General Enterprises & Industry for 2007 and adopting the framework decision concerning the financing of the preparatory action ‘The EU assuming its role in a globalised world’ and of four pilot projects ‘Erasmus young entrepreneurs’, ‘Measures to promote cooperation and partnerships between micro and SMEs’, ‘Technological Transfer’ and ‘European Destinations of excellence’ of the Directorate-General Enterprises & Industry for 2007
- European Technology Facility (ETF01): Council Decision 2000/819/EC of 20 December 2000 on a multiannual programme for enterprise and entrepreneurship, and in particular for small and medium-sized enterprises (SMEs) (2001-2005) (OJ L 333, 29.12.2000, p. 84)
- Competitiveness and Innovation Programme High Growth and Innovative SME Facility (CIP GIF): Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013) (OJ L 310, 9.11.2006, p. 15)
- Connecting Europe Facility (CEF): Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010 (OJ L 348, 20.12.2013, p. 129) as amended by Regulation (EU) 2015/1017 of the European Parliament and of the Council of 25 June 2015 on the European Fund for Strategic Investments, the European Investment Advisory Hub and the European Investment Project Portal and amending Regulations (EU) No 1291/2013 and (EU) No 1316/2013 — the European Fund for Strategic Investments (OJ L 169, 1.7.2015, p. 1)
- COSME Equity Facility for Growth (COSME EFG): Regulation (EU) No 1287/2013 of the European Parliament and of the Council of 11 December 2013 establishing a Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (COSME) (2014 - 2020) and repealing Decision No 1639/2006/EC (OJ L 347, 20.12.2013, p. 33)
- InnovFin Equity:
  - Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104);
  - Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in “Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)” and repealing Regulation (EC) No 1906/2006 (OJ L 347, 20.12.2013, p. 81);
  - Council Decision 2013/743/EU of 3 December 2013 establishing the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC (OJ L 347, 20.12.2013, p. 965)
- EaSI Capacity Building Investments Window: Regulation (EU) No 1296/2013 of the European Parliament and of the Council of 11 December 2013 on a European Union Programme for Employment and Social Innovation (“EaSI”) and amending Decision No 283/2010/EU establishing a European Progress Microfinance Facility for employment and social inclusion (OJ L 347, 20.12.2013, p. 238)

**B. Guarantee instruments:**

- SME Guarantee Facility '98 (SMEG98): Council Decision 98/347/EC of 19 May 1998 on measures of financial assistance for innovative and job-creating small and medium-sized enterprises (SMEs) - the growth and employment initiative (OJ L 155, 29.5.1998, p. 43).
- SME Guarantee Facility '01 (SMEG01): Council Decision 2000/819/EC of 20 December 2000 on a multiannual programme for enterprise and entrepreneurship, and in particular for small and medium-sized enterprises (SMEs) (2001-2005) (OJ L 333, 29.12.2000, p. 84)
- Competitiveness and Innovation Programme SME Guarantee Facility '07 (CIP SMEG07): Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013) (OJ L 310, 9.11.2006, p. 15)
- European Progress Microfinance Facility – Guarantee (EPMF-G): Decision No 283/2010/EU of the European Parliament and of the Council of 25 March 2010 establishing a European Progress Microfinance Facility for employment and social inclusion (OJ L 87, 7.4.2010, p. 1)
- Risk Sharing Finance Facility Risk-Sharing Instrument (RSI):
  - Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) Statements by the Commission (OJ L 412, 30.12.2006, p. 1)
  - Council Decision 2006/971/EC of 19 December 2006 concerning the Specific Programme Cooperation implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 86)
  - Council Decision 2006/974/EC of 19 December 2006 on the Specific Programme: Capacities implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 299)
- EaSI Guarantee Instrument: Regulation (EU) No 1296/2013 of the European Parliament and of the Council of 11 December 2013 on a European Union Programme for Employment and Social Innovation (“EaSI”) and amending Decision No 283/2010/EU establishing a European Progress Microfinance Facility for employment and social inclusion (OJ L 347, 20.12.2013, p. 238)
- COSME Loan Guarantee Facility (COSME LGF): Regulation (EU) No 1287/2013 of the European Parliament and of the Council of 11 December 2013 establishing a Programme for the Competitiveness of Enterprises and small and medium-sized enterprises (COSME) (2014 - 2020) and repealing Decision No 1639/2006/EC (OJ L 347, 20.12.2013, p. 33)
- InnovFin Debt:
  - Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in “Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)” and repealing Regulation (EC) No 1906/2006 (OJ L 347, 20.12.2013, p. 81)
  - Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104)
  - Council Decision 2013/743/EU of 3 December 2013 establishing the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC (OJ L 347, 20.12.2013, p. 965)
- Cultural and Creative Sectors Guarantee Facility (CCS GF): Regulation (EU) No 1295/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Creative Europe Programme (2014 to 2020) and repealing Decisions No 1718/2006/EC, No 1855/2006/EC and No 1041/2009/EC (OJ L 347, 20.12.2013, p. 221)

- Student Loan Guarantee Facility (SLGF): Regulation (EU) No 1288/2013 of the European Parliament and of the Council of 11 December 2013 establishing “Erasmus+”: the Union programme for education, training, youth and sport and repealing Decisions No 1719/2006/EC, No 1720/2006/EC and No 1298/2008/EC (OJ L 347, 20.12.2013, p. 50)
- Private Finance for Energy Efficiency (PF4EE): Regulation (EU) No 1293/2013 of the European Parliament and of the Council of 11 December 2013 on the establishment of a Programme for the Environment and Climate Action (LIFE) and repealing Regulation (EC) No 614/2007 (OJ L 347, 20.12.2013, p. 185)

#### C. Risk-sharing instruments:

- Risk Sharing Finance Facility (RSFF): Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) Statements by the Commission (OJ L 412, 30.12.2006, p. 1)
- InnovFin:
  - Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104)
  - Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in “Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)” and repealing Regulation (EC) No 1906/2006 (OJ L 347, 20.12.2013, p. 81)
- Connecting Europe Facility Debt Instrument (CEF DI): Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010 (OJ L 348, 20.12.2013, p. 129)
- Natural Capital Financing Facility (NCFF): Regulation (EU) No 1293/2013 of the European Parliament and of the Council of 11 December 2013 on the establishment of a Programme for the Environment and Climate Action (LIFE) and repealing Regulation (EC) No 614/2007 (OJ L 347, 20.12.2013, p. 185)

#### D. Dedicated investment vehicles:

- European Progress Microfinance Facility – Fonds commun de placement – fonds d’investissement spécialisé (EPMF FCP-FIS): Decision No 283/2010/EU of the European Parliament and of the Council of 25 March 2010 establishing a European Progress Microfinance Facility for employment and social inclusion (OJ L 87, 7.4.2010, p. 1)
  - Marguerite:
    - Regulation (EC) No 680/2007 of the European Parliament and of the Council of 20 June 2007 laying down general rules for the granting of Community financial aid in the field of the trans-European transport and energy networks (OJ L 162, 22.6.2007, p. 1)
    - Commission Decision C(2010)0941 of 25 February 2010 on European Union participation in the 2020 European Fund for Energy, Climate Change and Infrastructure (the Marguerite Fund)
  - European Energy Efficiency Fund (EEEF): Regulation (EU) No 1233/2010 of the European Parliament and of the Council of 15 December 2010 amending Regulation (EC) No 663/2009 establishing a programme to aid economic recovery by granting Community financial assistance to projects in the field of energy (OJ L 346, 30.12.2010, p. 5)
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## ANNEX V

**MARKET FAILURES, SUBOPTIMAL INVESTMENT SITUATIONS, ADDITIONALITY AND EXCLUDED ACTIVITIES****A. Market failures, suboptimal investment situations and additionality**

In accordance with Article 209 of the Financial Regulation, the EU guarantee shall address market failures or suboptimal investment situations (point (a) of Article 209(2) of the Financial Regulation) and shall achieve additionality by preventing the replacement of potential support and investment from other public or private sources (point (b) of Article 209(2) of the Financial Regulation).

In order to comply with points (a) and (b) of Article 209(2) of the Financial Regulation, the financing and investment operations benefitting from the EU guarantee shall fulfil the following requirements laid down in points 1 and 2:

**1. Market failures and suboptimal investment situations**

To address market failures or suboptimal investment situations as referred to in point (a) of Article 209(2) of the Financial Regulation, the investments targeted by the financing and investment operations shall include one of following features:

- (a) Have the nature of a public good for which the operator or company cannot capture sufficient financial benefits (such as education and skills, healthcare and accessibility, security and defence, and infrastructure available at no or negligible cost).
- (b) Externalities which the operator or company generally fails to internalise, such as R&D investment, energy efficiency, climate or environmental protection.
- (c) Information asymmetries, in particular in the case of SMEs and small mid-cap companies, including higher risk levels related to early stage firms, firms with mainly intangible assets or insufficient collateral, or firms focusing on higher risk activities.
- (d) Cross-border infrastructure projects and related services or funds that invest on a cross-border basis to address the fragmentation of the internal market and to enhance coordination within the internal market.
- (e) Exposure to higher levels of risks in certain sectors, countries or regions beyond levels that private financial actors are able or willing to accept, including where the investment would not have been undertaken or would not have been undertaken to the same extent because of its novelty or because of risks associated with innovation or unproven technology.
- (f) New or complex market failures or suboptimal investment situations in accordance with point (a)(iii) of Article 9(1) of this Regulation.

**2. Additionality**

Financing and investment operations shall fulfil both aspects of additionality as referred to in point (b) of Article 209(2) of the Financial Regulation. That means that the operations would not have been carried out or would not have been carried out to the same extent by other public or private sources without support from the InvestEU Fund. For the purposes of this Regulation, those operations shall be understood as financing and investment operations having to meet the following two criteria:

- (1) to be considered additional to the private sources referred to in point (b) of Article 209(2) of the Financial Regulation, the InvestEU Fund shall support the financing and investment operations of the implementing partners by targeting investments which, due to their characteristics (public good nature, externalities, information asymmetries, socio-economic cohesion considerations or other), are unable to generate sufficient market-level financial returns or are perceived to be too risky (compared to the risk levels that the relevant private entities are willing to accept). Because of those characteristics, such financing and investment operations cannot access market financing at reasonable conditions in terms of pricing, collateral requirements, the type of finance, the tenor of financing provided or other conditions, and would not be undertaken in the Union at all or to the same extent without public support;

- (2) to be considered additional to existing support from other public sources referred to in point (b) of Article 209(2) of the Financial Regulation the InvestEU Fund shall only support financing and investment operations for which the following conditions apply:
- (a) the financing and investment operations would not have been carried out or would not have been carried out to the same extent by the implementing partner without support from the InvestEU Fund; and
  - (b) the financing and investment operations would not have been carried out or would not have been carried out to the same extent in the Union under other existing public instruments, such as shared management financial instruments that operate at regional or national level, although the complementary use of InvestEU Fund and other public sources has to be possible, in particular where Union added value can be achieved and where the use of public sources to achieve policy objectives in an efficient manner can be optimised.

To demonstrate that the financing and investment operations benefitting from the EU guarantee are additional to the existing market and to existing other public support, the implementing partners shall provide information that demonstrates the presence of at least one of the following features:

- (a) support through subordinated positions in relation to other public or private lenders or within the funding structure;
- (b) support through equity and quasi-equity or through debt with long tenors, pricing, collateral requirements or other conditions not sufficiently available on the market or from other public sources;
- (c) support to operations that carry a higher risk profile than the risk generally accepted by the implementing partner's own standard activities or support to implementing partners in exceeding own capacity to support such operations;
- (d) participation in risk-sharing mechanisms targeting policy areas that exposes the implementing partner to higher risk levels compared to the levels generally accepted by the implementing partner or that private financial actors are able or willing to accept;
- (e) support that catalyses or crowds in additional private or public financing and is complementary to other private and commercial sources, in particular from traditionally risk-averse investor classes or institutional investors, as a result of the signalling effect of the support from the InvestEU Fund;
- (f) support through financial products not available or not offered to a sufficient level in the targeted countries or regions due to missing, underdeveloped or incomplete markets.

For intermediated financing and investment operations, in particular for SME support, additionality shall be verified at the level of the intermediary rather than at the level of the final recipient. Additionality shall be deemed to exist when InvestEU Fund supports a financial intermediary in setting up a new portfolio with a higher level of risk or increasing the volume of activities that are already highly risky as compared with the risk levels that private and public financial actors are currently able or willing to accept in the targeted countries or regions.

The EU guarantee shall not be granted for supporting refinancing operations (such as replacing existing loan agreements or other forms of financial support for projects which have already partially or fully materialised), except in specific exceptional and well justified circumstances in which it is demonstrated that the operation under the EU guarantee will enable a new investment in an eligible area for financing and investment operations under Annex II of an amount, additional to customary volume of activity by the implementing partner or financial intermediary, at least equivalent to the amount of the operation that fulfils the eligibility criteria set out in this Regulation. Such refinancing operations shall respect the requirements set out in Section A of this Annex regarding market failure, suboptimal investment situations and additionality.

## B. Excluded activities

The InvestEU Fund shall not support:

- (1) activities which limit individual rights and freedoms or that violate human rights

- (2) in the area of defence activities, the use, development, or production of products and technologies that are prohibited by applicable international law
- (3) tobacco-related products and activities (production, distribution, processing and trade)
- (4) activities excluded from financing pursuant to the relevant provisions of the Horizon Europe Regulation: research on human cloning for reproductive purposes; activities intended to modify the genetic heritage of human beings which could make such changes heritable; and activities to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer
- (5) gambling (production-, construction-, distribution-, processing-, trade- or software-related activities)
- (6) sex trade and related infrastructure, services and media
- (7) activities involving live animals for experimental and scientific purposes insofar as compliance with the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes <sup>(1)</sup> cannot be guaranteed
- (8) real estate development activity, such as an activity with a sole purpose of renovating and re-leasing or re-selling existing buildings as well as building new projects; however, activities in the real estate sector that are related to the specific objectives of the InvestEU Programme as specified in Article 3(2) and to the areas eligible for financing and investment operations under Annex II, such as investments in energy efficiency projects or social housing, shall be eligible
- (9) financial activities such as purchasing or trading in financial instruments. In particular, interventions targeting buy-out intended for asset stripping or replacement capital intended for asset stripping shall be excluded
- (10) activities forbidden by applicable national legislation
- (11) the decommissioning, operation, adaptation or construction of nuclear power stations
- (12) investments related to mining or to the extraction, processing, distribution, storage or combustion of solid fossil fuels and oil, as well as investments related to the extraction of gas. This exclusion does not apply to:
  - (a) projects where there is no viable alternative technology;
  - (b) projects related to pollution prevention and control;
  - (c) projects equipped with carbon capture and storage or carbon capture and utilisation installations; industrial or research projects that lead to substantial reductions of greenhouse gas emissions as compared with the applicable EU Emission Trading System benchmarks
- (13) investments in facilities for the disposal of waste in landfill. This exclusion does not apply to investments in:
  - (a) on-site landfill facilities that are an ancillary element of an industrial or mining investment project and where it has been demonstrated that landfilling is the only viable option to treat the industrial or mining waste produced by the activity concerned itself;
  - (b) existing landfill facilities to ensure the utilisation of landfill gas and to promote landfill mining and the reprocessing of mining waste
- (14) investments in mechanical biological treatment (MBT) plants. This exclusion does not apply to investments to retrofit existing MBT plants for waste-to-energy purposes or recycling operations of separated waste such as composting and anaerobic digestion
- (15) investments in incinerators for the treatment of waste. This exclusion does not apply to investments in:
  - (a) plants exclusively dedicated to treating non-recyclable hazardous waste;

<sup>(1)</sup> OJ L 222, 24.8.1999, p. 31.

- (b) existing plants, where the investment is for the purpose of increasing energy efficiency, capturing exhaust gases for storage or use or recovering materials from incineration ashes, provided such investments do not result in an increase of the plants' waste processing capacity.

The implementing partners shall remain responsible for ensuring compliance of financing and investment operations with the exclusion criteria set out in this Annex at signature of the relevant agreement, for monitoring such compliance during the implementation of the project and for undertaking appropriate remedial actions where relevant.

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