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DECISIONS

| * | Council Implementing Decision 2014/151/CFSP of 21 March 2014 implementing Decision | | | |
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Ι

(Legislative acts)

REGULATIONS

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

(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 (1),

Having regard to the opinion of the Committee of the Regions (2),

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

Whereas:

(1) In accordance with Article 168 of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. 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 the Member States for the definition of their health policies and the organisation and delivery of health services and medical care.

- (2) Continued effort is required in order to meet the requirements set out in Article 168 TFEU. The promotion of good health at Union level is also an integral part of 'Europe 2020: A strategy for smart, sustainable and inclusive growth' ("the Europe 2020 Strategy"). Keeping people healthy and active longer and empowering them to take an active role in managing their health, will have positive overall effects on health, including a reduction of health inequalities, and a positive impact on quality of life, on productivity and competitiveness, while reducing pressures on national budgets. Support for, and recognition of, innovation, which has an impact on health, helps to take up the challenge of sustainability in the health sector in the context of demographic change; and action to reduce inequalities in health is important for the purposes of achieving 'inclusive growth'. It is appropriate in that context to establish the third Programme for the Union's action in the field of health (2014-2020) ('the Programme').
- According to the definition of the World Health Organisation (WHO), "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." In order to improve the health of the population in the Union and reduce health inequalities, it is essential not to focus only on physical health. According to the WHO, mental health problems account for almost 40 % of years lived with disability. Mental health problems are also wide-ranging, long-lasting and a source of discrimination, and contribute significantly to inequality in health. Moreover, the economic crisis affects factors determining mental health, as protective factors are weakened and risk factors increased.
- (4) The previous programmes of Community action in the field of public health (2003-2008) and in the field of health (2008-2013), adopted respectively by Decisions

⁽¹⁾ OJ C 143, 22.5.2012, p. 102.

⁽²⁾ OJ C 225, 27.7.2012, p. 223.

⁽³⁾ Position of the European Parliament of 26 February 2014 (not yet published in the Official Journal) and decision of the Council of 11 March 2014.

No 1786/2002/EC (1) and 1350/2007/EC of the European Parliament and of the Council (2) ("the previous health programmes"), have been positively assessed as resulting in a number of important developments and improvements. The Programme should build on the achievements of the previous health programmes. It should also take into account the recommendations of the external audits and evaluations carried out, in particular recommendations of the Court of Auditors in its Special Report No 2/2009, according to which, for the period after 2013, the European Parliament, the Council and the Commission should reconsider the scope for Union public health activities and the approach of Union funding in that area. This should be done bearing in mind the budgetary means available and the existence of other cooperation mechanisms as a means of facilitating collaboration and the exchange of information among stakeholders throughout Europe.

- (5) In line with the objectives of the Europe 2020 Strategy, the Programme should focus on a set of well-defined objectives and actions with clear, proven Union added value, and concentrate support on a smaller number of activities in priority areas. The emphasis should be placed, in accordance with the principle of subsidiarity, on areas where there are clear cross-border or internal market issues at stake, or where there are significant advantages and efficiency gains from collaboration at Union level.
- (6) The Programme should be a means of promoting actions in areas where there is a Union added value that can be demonstrated on the basis of the following: exchanging good practices between Member States; supporting networks for knowledge sharing or mutual learning; addressing cross-border threats to reduce their risks and mitigate their consequences; addressing certain issues relating to the internal market where the Union has substantial legitimacy to ensure high-quality solutions across Member States; unlocking the potential of innovation in health; actions that could lead to a system for benchmarking to allow informed decision-making at Union level; improving efficiency by avoiding a waste of resources due to duplication and optimising the use of financial resources.
- (7) The implementation of the Programme should be such that the responsibilities of the Member States, for the definition of their health policy and for the organisation and delivery of health services and medical care, are respected.
- (1) 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).

 (2) 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).

- (8) The WHO European Health Report 2009 identifies scope for increasing investment in public health and health systems. In that regard, Member States are encouraged to identify health improvement as a priority in their national programmes and to benefit from better awareness of the possibilities of Union funding for health. Therefore, the Programme should facilitate the uptake of its results into national health policies.
- Innovation in health should be understood as a public health strategy which is not limited to technological advances in terms of products and services. Fostering innovation in the field of public health interventions, prevention strategies, health system management and in the organisation and provision of health services and medical care, including health promotion and disease prevention interventions, has the potential to improve public health outcomes, enhance the quality of care to patients and respond to unmet needs, and also to foster the competitiveness of stakeholders and to improve the cost-efficiency and sustainability of health services and medical care. Therefore, the Programme should facilitate the voluntary uptake of innovation in health, taking into account the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006 (3).
- (10) The Programme should, in particular in the context of the economic crisis, contribute to addressing health inequalities and the promotion of equity and solidarity through actions under the different objectives and by encouraging and facilitating the exchange of good practices.
- (11) Pursuant to Articles 8 and 10 TFEU, the Union is to promote equality between men and women and aim to combat discrimination. Accordingly, the Programme should support the mainstreaming of gender equality and anti-discrimination objectives in all its actions.
- (12) Patients need to be empowered, *inter alia* by enhancing health literacy, to manage their health and their healthcare more pro-actively, to prevent poor health and make informed choices. The transparency of healthcare activities and systems and the availability of reliable, independent and user-friendly information to patients should be optimised. Healthcare practices should be informed by feedback from, and communication with, patients. Support for Member States, patient organisations and stakeholders is essential and should be coordinated at Union level in order to help patients in an effective manner, in particular those affected by rare diseases, to benefit from cross-border healthcare.

⁽³⁾ Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

- (13) Reducing the burden of resistant infections and healthcare associated infections and securing the availability of effective antimicrobials is essential for the efficiency of health systems and for the safety of patients. The Programme should support sustained efforts to improve methods of analysis to detect and prevent antimicrobial resistance and improve networking among all healthcare actors, including the veterinary sector, in relation to dealing with antimicrobial resistance.
- In the context of an ageing society, well-directed investments to promote health and prevent diseases can increase the number of 'healthy life years' and thus enable the elderly to enjoy a healthy and active life as they get older. Chronic diseases are responsible for over 80% of premature mortality in the Union. The Programme should identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective health promotion and disease prevention measures focused in particular on the key risk factors, such as tobacco use, drug use, harmful use of alcohol and unhealthy dietary habits, obesity and physical inactivity, as well as on HIV/AIDS, tuberculosis and hepatitis. Effective prevention would contribute to increasing the financial sustainability of healthcare systems. Operating within a gender sensitive framework, the Programme should contribute to disease prevention in all its aspects (primary, secondary and tertiary prevention) and throughout the lifetime of the Union's citizens, to health promotion and the fostering of supportive environments for healthy lifestyles, taking into account underlying factors of a social and environmental nature as well as the impact on health of certain disabilities.
- In order to minimise the public health consequences of cross-border threats to health as set out in Decision No 1082/2013/EU of the European Parliament and of the Council (1), which could range from mass contamination caused by chemical incidents to pandemics, like those unleashed recently by E. coli, influenza strain H1N1 or SARS (severe acute respiratory syndrome), or health effects resulting from increasing population movements, the Programme should contribute to the creation and maintenance of robust mechanisms and tools to detect, assess and manage major cross-border health threats. Due to the nature of those threats, the Programme should support coordinated public health measures at Union level to address different aspects of cross-border health threats, building on preparedness and response planning, robust and reliable risk assessment and a strong risk and crisis management framework. In that context, it is important that the Programme benefit from complementarity with the work programme of the European

Centre for disease prevention and control, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council (²), in the fight against communicable diseases and the activities supported under the Union programmes for research and innovation. Special efforts should be undertaken to ensure coherence and synergies between the Programme and global health work carried out under other Union programmes and instruments that address, in particular, the areas of influenza, HIV/AIDS, tuberculosis and other cross-border health threats in third countries.

- (16) It should be possible for action under the Programme to also cover cross-border health threats caused by biological and chemical incidents, environment and climate change. As stated in the Commission's Communication "A Budget for Europe 2020", the Commission has committed to mainstreaming climate change into overall Union spending programmes and to direct at least 20 % of the Union budget to climate-related objectives. Spending in the Programme under the specific objective related to serious cross-border health threats should contribute in a general manner to those objectives by addressing health threats associated with climate change. The Commission should provide information on climate change expenditure within the Programme.
- (17) In accordance with Article 114 TFEU, a high level of health protection should be ensured in the legislation adopted by the Union for the establishment and the functioning of the internal market. In line with that objective, the Programme should undertake special efforts to support actions required by, and contributing to, the aims of Union legislation in the fields of communicable diseases and other health threats, human tissues and cells, blood, human organs, medical devices, medicinal products, patients' rights in cross-border healthcare, and tobacco products and tobacco advertising.
- (18) The Programme should contribute to evidence-based decision-making by fostering a health information and knowledge system, taking into account relevant activities carried out by international organisations, such as the WHO and the Organisation for Economic Cooperation and Development (OECD). That system should consist of, *inter alia*, the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, support to the Scientific

⁽¹) 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).

⁽²⁾ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

Committees set up in accordance with Commission Decision $2008/721/EC\ (^1)$ and the wide dissemination of the results of the Programme.

- (19)Union policy in the field of health is aimed at complementing and supporting national health policies, encouraging cooperation between Member States and promoting the coordination between their programmes. The exchange of good practices is a key instrument of that policy. Such exchange should enable national authorities to benefit from efficient solutions developed in other Member States, reduce duplication of efforts and increase value for money by promoting innovative solutions in the field of health. Therefore, the Programme should focus mainly on cooperation with the competent authorities that are responsible for health in the Member States and provide incentives for a wider participation of all Member States as recommended in the evaluations of the previous health programmes. In particular, Members States whose Gross National Income (GNI) per inhabitant is lower than 90 % of the Union average should be actively encouraged to participate in actions co-financed by the competent authorities that are responsible for health in the Member States or by bodies mandated by those competent authorities. Such actions should be considered to be of exceptional utility and, in particular, respond to the objective of facilitating the participation of Member States whose GNI per inhabitant is lower than 90 % of the Union average and making that participation wider. Further and appropriate non-financial support for the participation of those Member States in such actions, for example in terms of the application process, transfer of knowledge and uptake of expertise, should also be considered.
- (20) Non-governmental bodies and health stakeholders, in particular patients' organisations and health professionals' associations, play an important role in providing the Commission with the information and advice necessary to implement the Programme. In doing so, it is possible that they would require contributions from the Programme to enable them to function. That is why the Programme should be accessible to non-governmental bodies and patient organisations working in the public health area, which play an effective role in civil dialogue processes at Union level, such as participation in consultative groups, and in that way contribute to pursuing the specific objectives of the Programme.
- (21) The Programme should promote synergies, while avoiding duplication with related Union programmes and actions, by promoting, where relevant, the uptake of innovative breakthroughs resulting from research in the health sector. Appropriate use should be made of other Union funds and programmes, in particular the Framework Programme for Research and Innovation 2014-2020 (Horizon 2020), established by Regulation (EU) No 1291/2013 of the European Parliament and of

the Council (²), and its outcomes, the Structural Funds, the Programme for Employment and Social Innovation, established by Regulation (EU) No 1296/2013 of the European Parliament and of the Council (³), the European Union Solidarity Fund, established by Council Regulation (EC) No 2012/2002 (⁴),

the Union strategy on health and safety at work (2007-2012), the Programme for the Competitiveness of Enterprises and small and medium sized enterprises (COSME), established by Regulation (EU) No 1287/2013 of the European Parliament and of the Council (5), the Programme for Environment and Climate Action (LIFE), established by Regulation (EU) No 1293/2013 of the European Parliament and of the Council (6), the Consumer Programme, the Justice Programme, established by Regulation (EU) 1382/2013 of the European Parliament and of the Council (7), the Ambient Assisted Living Joint Programme, the programme for education, training, youth and sport (Erasmus+), established by Regulation (EU) No 1288/2013 of the European Parliament and of the Council (8), the European Statistical Programme, established by Regulation (EU) No 99/2013 of the European Parliament and of the Council (9) and the European Innovation Partnership on Active and Healthy Ageing, within their respective activities.

(22) In accordance with Article 168(3) TFEU, the Union and the Member States are to foster cooperation with third countries and the competent international organisations in the sphere of public health. The Programme should therefore be open to the participation of third countries,

⁽¹) Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (OJ L 241, 10.9.2008, p. 21).

⁽²) 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).

⁽³⁾ 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).

⁽⁴⁾ Council Regulation (EC) No 2012/2002 of 11 November 2002 establishing the European Union Solidarity Fund (OJ L 311, 14.11.2002, p. 3).

⁽⁵⁾ 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).

⁽⁶⁾ 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).

⁽⁷⁾ Regulation (EU) No 1382/2013 of the European Parliament and of the Council of 17 December 2013 establishing a Justice Programme for the period 2014 to 2020 (OJ L 354, 28.12.2013, p. 73).

⁽⁸⁾ 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).

⁽⁹⁾ Regulation (EU) No 99/2013 of the European Parliament and of the Council of 15 January 2013 on the European statistical programme 2013-17 (OJ L 39, 9.2.2013, p. 12).

in particular of acceding countries, candidate countries and potential candidates benefiting from a pre-accession strategy, European Free Trade Association (EFTA)/ European Economic Area (EEA) countries, neighbouring countries and the countries to which the European Neighbourhood Policy (ENP) applies, and other countries in accordance with the conditions laid down by any relevant bilateral or multilateral agreement.

- Appropriate relations with third countries not participating in the Programme should be facilitated in order to help achieve the objectives of the Programme, taking into account any relevant agreements between those countries and the Union. This could involve the Union organising health events or third countries undertaking activities, which are complementary to those financed under the Programme, in areas of mutual interest, but should not involve a financial contribution under the Programme.
- In order to maximise the effectiveness and efficiency of actions at Union and international level, and with a view to implementing the Programme, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, as well as with the Council of Europe and the OECD.
- The Programme should run for a period of seven years to align its duration with that of the Multiannual Financial Framework as set out in Council Regulation (EU, Euratom) No 1311/2013 (1). This Regulation lays down a financial envelope for the entire duration of the Programme which is to constitute the prime reference amount, within the meaning of Point 17 of the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management (2), for the European Parliament and the Council during the annual budgetary procedure.
- In accordance with Article 54 of Regulation (EU, (26)Euratom) No 966/2012 of the European Parliament and of the Council (3), this Regulation provides the legal basis for the action and for the implementation of the Programme.
- In order to ensure continuity in the financial support

provided under the Programme to the functioning of bodies, the Commission should be able, in the annual

(1) Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 (OJ L 347, 20.12.2013, p. 884). OJ C 373, 20.12.2013, p. 1.

(3) Régulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298,

26.10.2012, p. 1).

work programme for 2014, to consider the costs directly linked to the implementation of the supported activities to be eligible for financing, even if they were incurred by the beneficiary before the financing application was

- In order to ensure uniform conditions for the implementation of this Regulation by means of annual work programmes, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council (4).
- The Programme should be implemented in full respect of the principle of transparency. Budgetary resources should be shared between the different objectives of the Programme in a balanced way throughout the duration of the Programme, taking into account the probable advantages for promoting health. Appropriate actions covered by the specific objectives of the Programme and with a clear Union added value should be selected and funded by the Programme. The annual work programmes should set out, in particular, the essential selection criteria applicable to the potential beneficiaries, in accordance with Regulation (EU, Euratom) No 966/2012, in order to ensure they have the financial and operational capacity to undertake actions financed under the Programme, and, where appropriate, the evidence required to demonstrate their independence.
- The value and impact of the Programme should be regularly monitored and evaluated. Its evaluation should take into account the fact that the achievement of the Programme's objectives could require a longer time period than its duration. Half way through the duration of the Programme, but not later than 30 June 2017, the mid-term evaluation report should be drawn up in order to assess the state-of-play of the implementation of thematic priorities of the Programme.
- In order for the Programme to benefit fully from the findings of the mid-term evaluation report on its implementation and to allow for possible adjustments necessary for achieving its objectives, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in order to remove any of the thematic priorities set out in this Regulation or to include new thematic priorities in this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

⁽⁴⁾ 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).

- (32) The cooperation of national authorities is essential in sharing information with potential applicants to allow equitable participation in the Programme, and knowledge produced by the Programme with the different national health sector stakeholders. Thus, National Focal Points should be designated by the Member States in order to support those activities.
- (33) In the application of the Regulation, the Commission should consult the relevant experts, including National Focal Points.
- (34) The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, penalties.
- (35) A transition should be ensured between the Programme and the previous programme it replaces, in particular regarding the continuation of multiannual arrangements for its management, such as the financing of technical and administrative assistance. As of 1 January 2021, the technical and administrative assistance appropriations should cover, if necessary, the expenditure related to the management of actions not yet completed by the end of 2020.
- Since the general objectives of this Regulation, namely to (36)complement, support and add value to the policies of the Member States to improve the health of the population in the Union and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems, and protecting Union citizens from serious cross-border health threats, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of this Regulation, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (37) This Regulation replaces Decision No 1350/2007/EC. That Decision should therefore be repealed.
- (38) It is appropriate to ensure a smooth transition without interruption between the previous programme in the field of health (2008-2013) and the Programme, and to align the duration of the Programme with Regulation (EU, Euratom) No 1311/2013. Therefore, the Programme should apply from 1 January 2014,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Establishment of the Programme

This Regulation establishes the third multi-annual programme for Union action in the field of health for the period from 1 January 2014 to 31 December 2020 ("the Programme").

Article 2

General objectives

The general objectives of the Programme shall be to complement, support and add value to the policies of the Member States to improve the health of Union citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

CHAPTER II

OBJECTIVES AND ACTIONS

Article 3

Specific objectives and indicators

The general objectives referred to in Article 2 shall be pursued through the following specific objectives:

(1) In order to promote health, prevent diseases, and foster supportive environments for healthy lifestyles: identify, disseminate and promote the uptake of evidence-based and good practices for cost-effective health promotion and disease prevention measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value.

This objective shall be measured, in particular, through the increase in the number of Member States involved in health promotion and disease prevention, using evidence-based and good practices through measures and actions taken at the appropriate level in Member States.

(2) In order to protect Union citizens from serious cross-border health threats: identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies.

This objective shall be measured, in particular, through the increase in the number of Member States integrating coherent approaches in the design of their preparedness plans.

(3) In order to support public health capacity-building and contribute to innovative, efficient and sustainable health systems: identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and to facilitate the voluntary uptake of innovations in public health intervention and prevention strategies.

This objective shall be measured, in particular, through the increase in the advice produced and the number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems.

(4) In order to facilitate access to better and safer healthcare for Union citizens: increase access to medical expertise and information for specific conditions beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, *inter alia*, actions contributing to the improvement of health literacy.

This objective shall be measured, in particular, through the increase in the number of European reference networks established in accordance with Directive 2011/24/EU of the European Parliament and of the Council (¹) ("European reference networks"), the increase in the number of healthcare providers and centres of expertise joining European reference networks, and the increase in the number of Member States using the tools developed.

Article 4

Eligible actions

The specific objectives of the Programme shall be achieved through actions in line with the thematic priorities listed in Annex I and implemented via the annual work programmes referred to in Article 11.

CHAPTER III

FINANCIAL PROVISIONS

Article 5

Funding

The financial envelope for the implementation of the Programme for the period from 1 January 2014 to 31 December 2020 shall be EUR 449 394 000 in current prices.

The annual appropriations shall be authorised by the European Parliament and the Council within the limits of the multiannual financial framework.

Article 6

Participation of third countries

The Programme shall be open, on a cost basis, to the participation of third countries, in particular:

- (a) acceding countries, candidate countries and potential candidates benefiting from a pre-accession strategy, in accordance with the general principles and general terms and conditions for their participation in Union programmes established in the respective Framework Agreements, Association Council Decisions or similar agreements;
- (b) EFTA/EEA countries in accordance with the conditions established in the EEA Agreement;
- (c) neighbouring countries and the countries to which, in accordance with the conditions laid down by a relevant bilateral or multilateral agreement, the ENP applies;
- (d) other countries in accordance with the conditions laid down by a relevant bilateral or multilateral agreement.

Article 7

Types of intervention

- 1. In accordance with Regulation (EU, Euratom) No 966/2012, financial contributions by the Union shall take the form of grants, public procurement or any other form of intervention necessary for achieving the objectives of the Programme.
- 2. Grants may be awarded to fund:
- (a) actions having a clear Union added value co-financed by the competent authorities that are responsible for health in the Member States or in the third countries participating in the Programme pursuant to Article 6, or by public sector bodies and non-governmental bodies, as referred to in Article 8(1), acting individually or as a network, mandated by those competent authorities;
- (b) actions having a clear Union added value explicitly provided for and duly justified in the annual work programmes cofinanced by other public, non-governmental or private bodies, as referred to in Article 8(1), including international organisations active in the area of health and, in the latter case, where appropriate, without a previous call for proposals;
- (c) the functioning of non-governmental bodies as referred to in Article 8(2), where financial support is necessary for the pursuit of one or more of the specific objectives of the Programme.
- 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.

⁽¹⁾ 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).

For the actions referred to in point (a) of paragraph 2, exceptional utility is achieved, 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; and
- (b) bodies from at least 14 participating countries participate in the action, out of which at least four are countries whose GNI per inhabitant is less than 90 % of the Union average.
- 4. By way of derogation from Article 130(2) of Regulation (EU, Euratom) No 966/2012 and in duly justified cases, the Commission may, in the annual work programme for 2014, consider the costs directly linked to the implementation of supported actions to be eligible for financing from 1 January 2014, even if they were incurred by the beneficiary before the grant application was submitted.

Article 8

Beneficiaries eligible for grants

- 1. The grants for actions referred to under Article 7(2)(a) and (b) may be awarded to legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.
- 2. The grants for the functioning of bodies referred to under Article 7(2)(c) may be awarded to bodies which fulfil all the following criteria:
- (a) they are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;
- (b) they work in the public health area, play an effective role in civil dialogue processes at Union level and pursue at least one of the specific objectives of the Programme;
- (c) they are active at Union level and in at least half of the Member States, and have a balanced geographical coverage of the Union.

Article 9

Administrative and technical assistance

The financial envelope for the Programme may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities required directly for the management of the Programme and the achievement of its objectives, in particular studies, meetings, information and communication actions, including corporate communication of the political priorities of the Union in so far as they are related to the general objectives of the Programme, expenses pertaining to IT networks focusing on information exchange, as well as all other technical and administrative assistance expenses incurred by the Commission for the management of the Programme.

CHAPTER IV

IMPLEMENTATION

Article 10

Methods of implementation

The Commission shall be responsible for the implementation of the Programme in compliance with the management modes set out in Regulation (EU, Euratom) No 966/2012.

Article 11

Annual work programmes

- 1. The Commission shall implement the Programme by establishing annual work programmes in accordance with Regulation (EU, Euratom) No 966/2012 and the criteria set out in Annex II to this Regulation.
- 2. The Commission shall adopt, by means of implementing acts, annual work programmes which shall set out, in particular, actions to be undertaken, including the indicative allocation of financial resources. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 17(2).
- 3. In implementing the Programme, the Commission, together with the Member States, shall ensure compliance with all relevant legal provisions regarding personal data protection and, where appropriate, the introduction of mechanisms to ensure the confidentiality and safety of such data.

Article 12

Consistency and complementarity with other policies

The Commission shall, in cooperation with the Member States, ensure overall consistency and complementarity between the Programme and other policies, instruments and actions of the Union, including those of the relevant Union agencies.

Article 13

Monitoring, evaluation and dissemination of results

- 1. The Commission shall, in close cooperation with the Member States, monitor the implementation of the actions under the Programme in the light of its objectives and indicators, including available information on the amount of climate-related expenditure. It shall report thereon to the committee referred to in Article 17(1), and shall keep the European Parliament and the Council informed.
- 2. At the request of the Commission, Member States shall submit available information on the implementation and impact of the Programme. Such requests for information shall be proportionate and shall avoid imposing any unnecessary increase in the administrative burden on Member States.

3. Half way through the duration of the Programme, but not later than 30 June 2017, the Commission shall draw up and present to the European Parliament and to the Council a midterm evaluation report on the achievement of the objectives of the Programme, the state-of-play regarding the implementation of the thematic priorities set out in Annex I, and the efficiency of the use of resources and the Union added value of the Programme, in view of a decision on the renewal, modification or suspension of its thematic priorities. The mid-term evaluation report shall, additionally, address the scope for simplification, the internal and external coherence of the Programme, the continued relevance of all objectives, as well as the contribution of the actions to the achievement of the objectives set out in Article 168 TFEU. It shall take into account evaluation results on the long-term impact of the previous programme.

In the mid-term evaluation report, the Commission shall, in particular, indicate the following:

- (a) if it is not possible to implement and achieve one or more
 of the thematic priorities listed in Annex I in line with the
 objectives of the Programme and within the remaining
 duration of the Programme;
- (b) whether the evaluation identified one or more specific, significant thematic priorities which are not listed in Annex I, but which have become necessary to achieve the general and specific objectives of the Programme;
- (c) the reasons for the conclusions referred to in points (a) and (b).

The long-term impact and the sustainability of effects of the Programme shall be evaluated with a view to feeding into a decision on the possible renewal, modification or suspension of a subsequent programme.

4. The Commission shall make the results of actions undertaken pursuant to this Regulation publicly available and shall ensure that they are widely disseminated in order to contribute to improving health in the Union.

Article 14

Follow-up to the mid-term evaluation report

1. Where the mid-term evaluation report identifies that one or more thematic priorities cannot be implemented and achieved in line with the objectives of the Programme and within the duration of the Programme, the Commission shall be empowered to adopt, by 31 August 2017, delegated acts in accordance with Article 18 in order to remove the thematic priority or priorities concerned from Annex I. Only one

delegated act removing one or more thematic priorities may enter into force pursuant to Article 18 throughout the duration of the Programme.

- 2. Where the mid-term evaluation report identifies one or more specific, significant thematic priorities which are not listed in Annex I, but which have become necessary to achieve the general and specific objectives of the Programme, the Commission shall be empowered to adopt, by 31 August 2017, delegated acts in accordance with Article 18 in order to add the thematic priority or priorities concerned to Annex I. A thematic priority shall be achievable within the duration of the Programme. Only one delegated act adding one or more thematic priorities may enter into force pursuant to Article 18 throughout the duration of the Programme.
- 3. Any such removal or addition of thematic priorities shall be in line with the general objectives and with the relevant specific objectives of the Programme.

Article 15

National Focal Points

Member States shall designate National Focal Points which shall assist the Commission in the promotion of the Programme and, as appropriate, the dissemination of the results of the Programme and the available information on the impact of the Programme as referred to in Article 13(2).

Article 16

Protection of the financial interests of the Union

- 1. The Commission shall take appropriate measures to ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by dissuasive administrative and financial penalties.
- 2. The Commission, or its representatives, and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds under this Regulation.
- 3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council (¹) and Council Regulation (Euratom, EC) No 2185/96 (²) with a view to establishing whether there has been fraud, corruption or any other illegal

(2) 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).

⁽¹) 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).

activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under this Regulation.

4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

CHAPTER V

PROCEDURAL PROVISIONS

Article 17

Committee procedure

- 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
- 3. 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 18

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 14(1) and (2) shall be conferred on the Commission for the duration of the Programme.
- 3. The delegation of power referred to in Article 14(1) and (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 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 act already in force.

- 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 5. A delegated act adopted pursuant to Article 14(1) and (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 of the Council.

CHAPTER VI

TRANSITIONAL AND FINAL PROVISIONS

Article 19

Transitional provisions

- 1. The financial envelope for the Programme may also cover technical and administrative assistance expenses necessary to ensure the transition between the Programme and the measures adopted under Decision No 1350/2007/EC.
- 2. If necessary, appropriations may be entered in the budget beyond 2020 to cover the expenses provided for in Article 9, to enable the management of actions not completed by 31 December 2020.

Article 20

Repeal

Decision No 1350/2007/EC shall be repealed with effect from 1 January 2014.

Article 21

Entry into force

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

It shall apply from 1 January 2014.

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

Done at Strasbourg, 11 March 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

ANNEX I

THEMATIC PRIORITIES

- Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into
 account the 'health in all policies' principle
- 1.1. Cost-effective promotion and prevention measures in line, in particular, with the Union strategies on alcohol and nutrition, and including actions to support the exchange of evidence-based and good practices for addressing risk factors such as tobacco use and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity, taking into account the public health aspects of underlying factors, such as those of a social and environmental nature, with a focus on Union added value.
- 1.2. Measures to complement the Member States' action in reducing drug-related health damage, including information and prevention.
- 1.3. Support effective responses to communicable diseases such as HIV/AIDS, tuberculosis and hepatitis by identifying, disseminating and promoting the uptake of evidence-based and good practices for cost effective prevention, diagnosis, treatment and care.
- 1.4. Support cooperation and networking in the Union in relation to preventing and improving the response to chronic diseases including cancer, age-related diseases and neurodegenerative diseases, by sharing knowledge, good practices and developing joint activities on prevention, early detection and management (including health literacy and self management). Follow up work on cancer which has already been undertaken, including relevant actions suggested by the European Partnership Action against Cancer.
- 1.5. Actions required by, or contributing to, the implementation of Union legislation in the field of tobacco products, advertising and marketing. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.
- 1.6. Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments and, where appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, and the wide dissemination of the results of the Programme.

2. Protect Union citizens from serious cross-border health threats

- 2.1. Improve risk assessment and close gaps in risk assessment capacities by providing additional capacities for scientific expertise, and map existing assessments.
- 2.2. Support capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries: develop preparedness and response planning taking into account, and coordinating with, global initiatives, components of generic and specific preparedness planning, public health response coordination, non-binding approaches on vaccination; address the increasing health threats resulting from global population movements; develop guidelines on protective measures in an emergency situation, guidelines on information and guides to good practice; contribute to the framework for a voluntary mechanism, including the introduction of optimal vaccination coverage to effectively combat the resurgence in infectious diseases and for joint procurement of medical countermeasures; develop coherent communication strategies.
- 2.3. Actions required by, or contributing to, the implementation of Union legislation in the fields of communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change. Such action may include activities aimed at facilitating the implementation, application, monitoring and review of that legislation.
- 2.4. Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments and, where appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, and the wide dissemination of the results of the Programme.

3. Contribute to innovative, efficient and sustainable health systems

3.1. Support voluntary cooperation between Member States on health technology assessment under the network on health technology assessment set up by Directive 2011/24/EU. Facilitate the uptake of the results streaming from research projects supported under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), adopted by Decision No 1982/2006/EC of the European Parliament and of the Council (¹), and, in the long term, the activities which will be undertaken in the Framework Programme for Research and Innovation (Horizon 2020).

⁽¹⁾ 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) (OJ L 412, 30.12.2006, p. 1).

- 3.2. Promote the voluntary uptake of health innovation and e-Health by increasing the interoperability of patient registries and other e-Health solutions; support cooperation on e-Health in the Union, in particular on registries, and its uptake by health professionals. This will serve the voluntary network on e-Health set up by Directive 2011/24/EU.
- 3.3. Support the sustainability of the health workforce by developing effective health workforce forecasting and planning in terms of numbers, gender equality, scope of practice and the extent to which training matches the requisite skills, including the ability to make use of new information systems and other advanced technologies, monitor mobility (within the Union) and migration of health professionals, foster efficient recruitment and retention strategies and capacity development, taking due account of issues of dependency and population ageing.
- 3.4. Provide expertise and share good practices to assist Member States undertaking health system reforms by setting up a mechanism for pooling expertise at Union level, to provide sound and evidence-based advice on effective and efficient investment and innovation in public health and health systems. Facilitate the uptake of the results streaming from research projects supported under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) and, in the long term, the activities which will be undertaken in the Framework Programme for Research and Innovation (Horizon 2020).
- 3.5. Support actions which address health issues in an ageing society, including relevant actions suggested by the European Innovation Partnership on Active and Healthy Ageing in its three themes; innovation in awareness, prevention and early diagnosis, innovation in cure and care and innovation in active ageing and independent living.
- 3.6. Actions required by or contributing to the implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare. Such action may include activities aimed at facilitating the implementation, application, monitoring and review of that legislation.
- 3.7. Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments, further development, where appropriate, of standardised health information and tools for monitoring health, collection and analysis of health data, the wide dissemination of the results of the Programme, and support to the Scientific Committees set up in accordance with Decision 2008/721/EC.

4. Facilitate access to better and safer healthcare for Union citizens

- 4.1. Support the establishment of a system of European reference networks for patients with conditions requiring highly specialised care and a particular concentration of resources or expertise, as in the case of rare diseases, on the basis of criteria to be established under Directive 2011/24/EU.
- 4.2. Support Member States, patient organisations and stakeholders by coordinated action at Union level in order to effectively help patients affected by rare diseases. This includes the creation of reference networks (in compliance with point 4.1), Union wide information databases and registries for rare diseases based on common criteria.
- 4.3. Strengthen collaboration on patient safety and quality of healthcare, through, *inter alia*, implementing the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections (¹); exchange good practices on quality assurance systems; develop guidelines and tools to promote quality and patient safety; increase the availability of information to patients on safety and quality, improve feedback and interaction between health providers and patients.
- 4.4. In line with the Action Plan against the rising threats from antimicrobial resistance, improve the prudent use of antimicrobial agents and reduce the practices that increase antimicrobial resistance, particularly in hospitals; promote effective prevention and hygiene measures to prevent and control infections; reduce the burden of resistant infections and healthcare-associated infections and secure the availability of effective antimicrobials.
- 4.5. Actions required by, or contributing to, the implementation of Union legislation in the fields of human tissues and cells, blood, human organs, medical devices, medicinal products, and patients' rights in cross-border healthcare, while fully respecting the competences and ethical choices of Member States in those fields. Such action may include activities aimed at facilitating the implementation, application, monitoring and review of that legislation.
- 4.6. Foster a health information and knowledge system to contribute to evidence-based decision-making, including the use of existing instruments and, as appropriate, further development of standardised health information and tools for monitoring health, collection and analysis of health data, and the wide dissemination of the results of the Programme.

ANNEX II

CRITERIA FOR ESTABLISHING ANNUAL WORK PROGRAMMES

The annual work programmes shall be established in accordance with the following criteria for the duration of the Programme:

- the relevance of proposed actions for the objectives set out in Articles 2 and 3 and for the thematic priorities set out in Annex I and for the EU Health Strategy "Together for Health";
- the Union added value of the proposed actions in line with the thematic priorities in Annex I;
- the public health relevance of proposed actions, in terms of promoting health and preventing diseases, protecting Union citizens from health threats and in terms of improving the performance of health systems;
- the relevance of the proposed actions to supporting the implementation of Union health legislation;
- the pertinence of the geographical coverage of the proposed actions;
- the balanced distribution of budgetary resources between the different objectives of the Programme, taking into account the probable advantages for promoting health;
- the adequate coverage of the thematic priorities set out in Annex I.

REGULATION (EU) No 283/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2014

on guidelines for trans-European networks in the area of telecommunications infrastructure and repealing Decision No 1336/97/EC

(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 172 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 opinions of the European Economic and Social Committee (1),

Having regard to the opinions of the Committee of the Regions (2),

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

Whereas:

- (1) Telecommunications networks and services are increasingly becoming internet-based infrastructures, with broadband networks and digital services closely interrelated. The internet is becoming the dominant platform for communication, services, education, participation in social and political life, cultural content, and business. Therefore, the trans-European availability of widespread, high-speed, secure internet access and digital services in the public interest is essential for social and economic growth, competitiveness, social inclusion and the internal market.
- (2) On 17 June 2010, the European Council endorsed the Commission communication of 26 August 2010 on a Digital Agenda for Europe, which aims to chart a course to maximise the social and economic potential of

(1) Opinion of 22 February 2012 (OJ C 143, 22.5.2012, p. 120) and Opinion of 16 October 2013 (not yet published in the Official Journal)

(2) OJ C 225, 27.7.2012, p. 211 and OJ C 356, 5.12.2013, p. 116. (3) Position of the European Parliament of 26 February 2014 (not yet

information and communication technologies. It seeks to stimulate supply and demand of competitive high-speed internet infrastructure and internet-based digital services with a view to advancing towards a true Digital Single Market, which is essential for smart, sustainable and inclusive growth.

- (3) Regulation (EU) No 1316/2013 of the European Parliament and of the Council (4) determines the conditions, methods and procedures for providing Union financial assistance to trans-European networks in the sectors of transport, telecommunications and energy infrastructures. Given that there are similar challenges and opportunities in the sectors covered by the Connecting Europe Facility (CEF), there is significant scope for exploiting synergies, including by combining CEF funding with other sources of funding.
- A large number of cross-border digital services implementing exchanges between European public administrations in support of Union policies are a reality. When providing new solutions, it is important to capitalise on existing solutions implemented in the context of other European initiatives, avoid duplication of work, and ensure coordination and alignment of approaches and solutions across initiatives and policies, such as for instance the ISA programme established by Decision No 922/2009/EC of the European Parliament and of the Council (5), the Fiscalis programme established by Regulation (EU) No 1286/2013 of the European Parliament and of the Council (6), and Horizon 2020 established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council (7). Similarly, it is important that solutions comply with agreed international and/or European standards or with open specifications for interoperability, particularly those identified

(5) Decision No 922/2009/EC of the European Parliament and of the Council of 16 September 2009 on interoperability solutions for European public administrations (ISA) (OJ L 260, 3.10.2009, p. 20),

(7) 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).

³) Position of the European Parliament of 26 February 2014 (not yet published in the Official Journal) and decision of the Council of 11 March 2014.

⁽⁴⁾ 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).
(5) Decision No 922/2009/EC of the European Parliament and of the

⁽⁶⁾ Regulation (EU) No 1286/2013 of the European Parliament and of the Council of 11 December 2013 establishing an action programme to improve the operation of taxation systems in the European Union for the period 2014-2020 (Fiscalis 2020) and repealing Decision No 1482/2007/EC (OJ L 347, 20.12.2013, p. 25).

by the Commission in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council (¹), and other relevant specifications and orientations, such as the European Interoperability Framework for European public services (EIF).

- (5) The development of high-speed broadband networks will benefit from European technical standards. Union research and development programmes and increased monitoring of standardisation procedures are needed if the Union is to play a pivotal role in the telecommunications industry.
- Large scale pilot projects between Member States and co-(6) financed by the Competitiveness and Innovation Programme (2), such as PEPPOL, STORK, epSOS, eCODEX or SPOCS, have validated key cross-border digital services in the internal market, based on common building blocks, which are being consolidated by the project eSENS. Those pilot projects have already reached or will in the near future reach the maturity level required for deployment. Existing projects of common interest have already demonstrated the clear added value of action at European level, such as in the fields of cultural heritage (Europeana), child protection (Safer Internet), social security (EESSI), while others such as in the field of consumer protection (ODR) have been proposed.
- (7) With regard to digital service infrastructures, building blocks should take priority over other digital service infrastructures, since the former are a pre-condition for the latter. Digital service infrastructures should, inter alia, create European added value and meet proven needs. They should be sufficiently mature for deployment, technically as well as operationally, as proven in particular through successful piloting. They should be based on a concrete sustainability plan to ensure the medium to long-term operation of core service platforms beyond the CEF. Financial assistance under this Regulation should therefore, wherever possible, be phased out over time and funding from sources other than the CEF should be mobilised, where appropriate.
- (¹) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (O) L 316, 14.11.2012, p. 12).
- (2) 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).

- (8) It is important that digital service infrastructures that are necessary to meet legal obligations under Union law and/or are developing or providing building blocks, with a potential high impact on the development of pan-European public services, be funded so as to support multiple digital service infrastructures and, over time, gradually build up a European interoperability ecosystem. In this context, legal obligations mean specific provisions requiring either developing or using digital service infrastructures, or requiring results which can only be achieved through European digital service infrastructures.
- (9) As well-established digital service infrastructure, Europeana and Safer Internet for Children should have priority for funding. In particular, the continuity in Union funding from other Union programmes to CEF should be ensured in the first years of the multiannual financial framework for the period 2014-2020 laid down in Council Regulation (EU, Euratom) No 1311/2013 (³) in order to allow for uninterrupted and successful delivery of service at the same level as provided for under the current funding scheme. On 10 May 2012, the Council underlined the vital importance of ensuring the long-term viability of Europeana, including in terms of governance and funding. (4)
- A safe, inclusive and positive online environment for children and young people should be ensured. As a crucial measure to protect and promote children's rights in the online environment, the functioning of the Safer Internet Program should be ensured after 2014. By implementing this Regulation, the implementation of the European Strategy for a Better Internet for Children at Union as well as at Member State level should be financially supported, in particular as regards Safer Internet Centres (SICs) in the Member States. Activities of SICs, including awareness nodes and other awareness-raising activities, helplines for children, parents and carers on the best means for children to use the Internet, as well as hotlines for reporting child sexual abuse content on the Internet, are a key element and prerequisite for the success of that strategy.
- (11) A future legal act of the Union on electronic identification and trust services for electronic transactions in the internal market is to determine the detailed requirements and conditions for the mutual recognition of key enablers, referred to hereinafter as the building blocks of the digital service infrastructures. That act will cover several of the most important building blocks, for example electronic identification and electronic signature as part of the projects of common interest set out in the Annex to this Regulation.

⁽³⁾ Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 (OJ L 347, 20.12.2013, p. 884).

⁽⁴⁾ OJ C 169, 15.6.2012, p. 5.

- Digital service infrastructures implemented in accordance with Decision No 922/2009/EC will facilitate the electronic cross-border and cross-sector interaction between European public administrations. This, in turn, will enable the provision of essential services in, inter alia, areas such as electronic identification and authentication and procurement, cross-border interconnection of business registers, interoperable electronic cross-border health services, as well as cross-border cooperation on cyber security, thereby contributing to the Digital Single Market. Such interaction between administrations will be achieved through the creation and/or enhancement of interoperable core service platforms, built on existing common building blocks and/or providing additional building blocks essential for the development of other core service platforms, and related generic services linking national infrastructures to core service platforms to deliver cross-border digital services.
- (13) Member States should encourage local and regional authorities to be fully and effectively involved in the governance of digital service infrastructures, and ensure that projects of common interest relating to cross-border delivery of eGovernment services take into account the EIF recommendations.
- (14) In its resolution of 6 July 2011 on European Broadband: investing in digitally driven growth (¹), the European Parliament emphasised that broadband services are key to the competitiveness of Union industry and greatly contribute to Union economic growth, social cohesion and the creation of quality employment. Investment in state-of-the-art and future-proof technology is crucial if the Union is to be home to innovation, knowledge and services.
- (15) A European market with nearly 500 million people connected to high-speed broadband would act as a spearhead for the development of the internal market, creating a globally unique critical mass of users exposing all regions to new opportunities and giving each user increased value, as well as giving the Union the capacity to be a world-leading knowledge-based economy. A rapid deployment of high-speed broadband networks is crucial for the development of Union productivity and for the emergence of new and small enterprises that can be leaders in different sectors such as health care, manufacturing and the service industries.
- (16) The combination of new opportunities in infrastructure and new, innovative and interoperable services should set in motion a virtuous circle by stimulating increasing demand for high-speed broadband to which, in commercial terms, it would be advisable to respond.

- (17) The Digital Agenda for Europe stipulates that by 2020 all Europeans should have access to internet speeds of above 30 Mbps and 50 % or more of European households should subscribe to internet connections above 100 Mbps.
- (18) Given the rapid development of digital services and applications demanding ever faster internet connections and the rapid evolution of state-of-the-art technologies allowing it, it is appropriate in the framework of an evaluation of the Digital Agenda for Europe to consider the revision of broadband targets for 2020 so as to ensure that the Union has competitive broadband speeds when compared to other economies in the world.
- (19) Part of the broadband projects should demonstrate higher ambitions, aiming at higher speeds and thus serve as pilot projects for faster connectivity and models with potential for replicability.
- (20) In its resolution of 12 September 2013 on the Digital Agenda for Growth, Mobility and Employment, time to move up a gear, the European Parliament emphasised that a revised forward-looking Digital Agenda for Europe target for 2020 is to connect all Union households with broadband connections delivering 100 Mbps, with 50 % of households subscribing to 1 Gbps or more.
- (21) The private sector should play the leading role in rolling out and modernising broadband networks, supported by a competitive and investment-friendly regulatory framework. Where private investment falls short, Member States should make the necessary efforts to achieve the targets of the Digital Agenda for Europe. Public financial assistance to broadband should be limited to programmes or initiatives targeting projects which cannot be solely financed by the private sector, confirmed by an ex-ante assessment identifying market failures or sub-optimal investment situations, in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (2).

⁽²⁾ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

⁽¹⁾ OJ C 33 E, 5.2.2013, p. 89.

- (22) Financial instruments for broadband networks are not to unduly distort competition, crowd out private investments or create disincentives for private operators to invest. In particular, they are to be in compliance with Articles 101, 102, 106 and 107 of the Treaty on the Functioning of the European Union (TFEU) as well as, if relevant, with the EU Guidelines for the application of State aid rules in relation to the rapid deployment of broadband networks.
- (23) Public funding for broadband networks is to be spent solely on infrastructures which comply with the applicable law, in particular with competition law, and with access obligations in accordance with Directive 2002/19/EC of the European Parliament and of the Council (1).
- (24) Since the financial resources available under CEF are limited, financial assistance should focus on the establishment of financing mechanisms at Union level to attract additional investments, promote a multiplier effect, and so facilitate the efficient use of private and other public funds for investment. This approach allows for contributions from business and institutional players well beyond the funding levels directly eligible through CEF.
- (25) In view of limited financial resources under CEF and in order to ensure appropriate funding for digital service infrastructures, the total budgetary allocation to broadband should not exceed the minimum amount necessary to establish a cost-efficient intervention, which should be determined by an ex-ante assessment taking into account, inter alia, the type of envisaged financial instruments, potential leverage effect for the minimum efficient project portfolio, and market conditions.
- The CEF support to broadband deployment should complement assistance provided under other Union programmes and initiatives, including the European Structural and Investment Funds (ESI Funds), in cases where an ex-ante assessment identifies market failures or sub-optimal investment situations and where so decided by managing authorities. CEF financial assistance to broadband deployment should contribute to Member States' efforts both directly and by providing an investment vehicle for voluntary, ring-fenced contributions from other sources, including ESI Funds, thus allowing Member States to take advantage of the know-how and scale-effects of Union-managed facilities with a view to increasing the efficiency of public spending.
- (27) In order to ensure best value for money and given the limited resources, CEF funding should be available for
- (¹) Directive 2002/19/EC of the European Parliament and of the Council of 7 March 2002 on access to, and interconnection of, electronic communications networks and associated facilities (Access Directive) (OJ L 108, 24.4.2002, p. 7).

projects which rely on the technology best suited for the specific project, can help spur innovative business models and show a high potential for replication. Where projects are funded through voluntary contributions under CEF, such as ESI Funds or through national or regional funding, eligibility criteria should be more flexible and take account of the specific situation and conditions in the areas that such funding is intended to serve.

- (28) The Union may support the deployment of broadband networks contributing to the objectives of the Digital Agenda for Europe in all types of areas. The reduction of the digital divide and the increase in digital inclusion are important objectives of the Digital Agenda for Europe. All the Union's actions in the field of broadband should therefore address the special needs of suburban, rural, and in particular sparsely populated and less developed regions, which need to be served with connections. This includes the deployment of broadband networks to link islands, landlocked, mountainous, remote and peripheral regions, including island Member States, with the central regions of the Union and/or actions to improve the reliability or performance of connections between such regions and central regions of the Union.
- (29) In order to complete the Digital Single Market, compatibility between the CEF and national and regional broadband actions should be encouraged.
- (30) In implementing this Regulation, the forms of financial assistance should be aligned with the characteristics of the actions in question. Thus, in the field of digital service infrastructures, core service platforms which cannot be funded from other sources should be prioritised for funding in the form of procurement or, exceptionally, grants, while generic services should be given only limited financial assistance from the CEF. Furthermore, any financial assistance from the CEF should aim at efficient use of the Union's funds and, therefore, broadband networks should be supported by financial instruments, which ensure a higher leverage effect than grants.
- (31) Intervention under this Regulation should aim at achieving synergies and interoperability between the different projects of common interest described in the Annex, as well as with other infrastructures, including transport and energy infrastructures supported by the CEF, relevant research infrastructures supported, inter alia, by Horizon 2020 and relevant infrastructures supported by ESI Funds, while avoiding duplication and undue administrative burdens.

- (32) Financial assistance to projects of common interest should be complemented by horizontal actions, including technical assistance, demand stimulation measures and coordination, which should aim to maximise the impact of Union intervention.
- (33) When committing funds to intervention in broadband networks, the Commission should take due account of the results of the evaluations of existing Union financial instruments.
- (34) The Commission should be assisted by an Expert Group of representatives of all Member States which should be consulted on and contribute to, inter alia, monitoring of the implementation of this Regulation, planning, evaluation and addressing implementation problems.
- (35) The Expert Group should also cooperate with those entities involved in the implementation of this Regulation, such as local and regional authorities, internet access providers, public network administrators and component manufacturers as well as national regulatory authorities and the Body of European Regulators for Electronic Communications (BEREC), established by Regulation (EC) No 1211/2009 of the European Parliament and of the Council (1).
- (36) Regulation (EU) No 1316/2013 establishes the CEF Coordination Committee, which is also a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (²). Regulation (EU) No 1316/2013 also confers upon the Commission the powers to adopt in accordance with the examination procedure annual and multiannual work programmes, including in the telecommunications sector, the latter being subject to this Regulation. It is important to clarify in this regard that Member States, when discussing issues related to this Regulation, in particular draft annual and multiannual work programmes, should be represented in the CEF Coordination Committee by experts in the telecommunications infrastructure sector.
- (37) Since the objectives of this Regulation, in particular the coordinated development of the trans-European networks in the area of telecommunications infrastructure, cannot be sufficiently achieved by the Member States but can rather, by reason of the cross-border character of the supported infrastructures, and effects on the entire territory of the Union, be better achieved at Union

level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

- (38) In order to support projects of common interest in the sectors of transport, telecommunications and energy infrastructures, Regulation (EU) No 1316/2013 determines the conditions, methods and procedures for providing Union financial assistance to trans-European networks. It also establishes the breakdown of the resources to be available under Regulation (EU, Euratom) No 1311/2013 in all three sectors. Regulation (EU) No 1316/2013 is applicable from 1 January 2014. It is thus appropriate to align the application of this Regulation with the application of Regulation (EU) No 1316/2013 and with Regulation (EU, Euratom) No 1311/2013. Therefore, this Regulation should apply from 1 January 2014.
- (39) Decision No 1336/97/EC of the European Parliament and of the Council (3) should be repealed,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

- 1. This Regulation lays down guidelines for the timely deployment and interoperability of projects of common interest in the field of trans-European networks in the area of telecommunications infrastructure.
- 2. In particular, this Regulation provides for:
- (a) the objectives for and operational priorities of projects of common interest;
- (b) the identification of projects of common interest;
- (c) the criteria according to which actions contributing to projects of common interest shall be eligible for Union financial assistance in accordance with Regulation (EU) No 1316/2013 in their development, implementation, deployment, interconnection, and interoperability;
- (d) priorities for funding projects of common interest.

(¹) Regulation (EC) No 1211/2009 of the European Parliament and of the Council of 25 November 2009 establishing the Body of European Regulators for Electronic Communications (BEREC) and

the Office (OJ L 337, 18.12.2009, p.1).

(2) 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⁾ Decision No 1336/97/EC of the European Parliament and of the Council of 17 June 1997 on a series of guidelines for trans-European telecommunications networks (OJ L 183, 11.7.1997, p. 12).

Article 2

Definitions

- 1. For the purposes of this Regulation, the definitions set out in Article 2 of Regulation (EU) No 1316/2013 shall apply.
- 2. For the purposes of this Regulation and of Regulation (EU) No 1316/2013, the following definitions shall also apply:
- (a) "telecommunications infrastructure" means broadband networks and digital service infrastructures;
- (b) "digital service infrastructures" means infrastructures which enable networked services to be delivered electronically, typically over the internet, providing trans-European interoperable services of common interest for citizens, businesses and/or public authorities, and which are composed of core service platforms and generic services;
- (c) "building blocks" means basic digital service infrastructures, which are key enablers to be reused in more complex digital services infrastructures;
- (d) "core service platforms" means central hubs of digital service infrastructures aiming to ensure trans-European connectivity, access and interoperability, and which are open to Member States and may be open to other entities;
- (e) "generic services" means gateway services linking one or more national infrastructure(s) to core service platform(s);
- (f) "broadband networks" means wired and wireless access networks, ancillary infrastructure and core networks capable of delivering very high speed connectivity;
- (g) "horizontal actions" means studies and programme support actions as defined in points (6) and (7) of Article 2 of Regulation (EU) No 1316/2013, respectively.

Article 3

Objectives

- 1. The projects of common interest shall contribute to achieving the general objectives specified in Article 3 of Regulation (EU) No 1316/2013.
- 2. In addition to the general objectives, the projects of common interest shall pursue one or more of the following specific objectives:
- (a) economic growth and support to the completion and functioning of the internal market in support of the competitiveness of the European economy, including small and medium-sized enterprises (SMEs);
- (b) improvements in daily life for citizens, businesses and public authorities at every level through the promotion of broadband networks, interconnection and interoperability of national, regional and local broadband networks, as well as non-discriminatory access to such networks and digital inclusion.

- 3. The following operational priorities shall contribute to the achievement of the objectives referred to in paragraphs (1) and (2):
- (a) interoperability, connectivity, sustainable deployment, operation and upgrading of trans-European digital service infrastructures, as well as coordination at European level;
- (b) efficient flow of private and public investments to stimulate the deployment and modernisation of broadband networks with a view to contributing to achieving the broadband targets of the Digital Agenda for Europe.

Article 4

Projects of common interest

- 1. Projects of common interest shall, in particular:
- (a) aim at the creation and/or enhancement of interoperable and, whenever possible, internationally compatible core service platforms, accompanied by generic services for digital service infrastructures;
- (b) provide efficient investment vehicles for broadband networks, attract new categories of investors and project promoters, and encourage replicability of innovative projects and business models.
- 2. Projects of common interest may encompass their entire cycle, including feasibility studies, implementation, continuous operation and upgrading, coordination and evaluation.
- 3. Projects of common interest may be supported through horizontal actions.
- 4. Projects of common interest, and actions contributing to them, are further described in the Annex.

Article 5

Methods of intervention

- 1. In the area of digital service infrastructures, core service platforms shall be implemented primarily by the Union while generic services shall be implemented by the parties connecting to the relevant core service platform. Investments in broadband networks shall be undertaken predominantly by the private sector, supported by a competitive and investment-friendly regulatory framework. Public support for broadband networks shall be provided only where there is market failure or a suboptimal investment situation.
- 2. Member States and other entities in charge of or contributing to the implementation of projects of common interest shall be encouraged to take the measures necessary to facilitate the implementation of projects of common interest. The final decision on the implementation of a project of

common interest which relates to the territory of a Member State shall be taken after the approval of that Member State.

- 3. Actions contributing to projects of common interest, which meet the criteria set out in Article 6 of this Regulation, shall be eligible for Union financial assistance under the conditions and instruments available under Regulation (EU) No 1316/2013. Financial assistance shall be provided in accordance with the relevant rules and procedures adopted by the Union, the funding priorities set out in Article 6 of this Regulation, and the availability of resources, taking into account the specific needs of beneficiaries.
- 4. Actions contributing to projects of common interest in the field of digital service infrastructures shall be supported by:
- (a) procurement; and/or
- (b) grants.
- 5. Actions contributing to projects of common interest in the field of broadband networks shall be supported by:
- (a) financial instruments as defined in Regulation (EU) No 1316/2013, which shall be open to additional contributions from other sectors of the CEF, other instruments, programmes and budget lines in the Union budget, Member States, including regional and local authorities and any other investors, including private investors in accordance with Article 15(2) of Regulation (EU) No 1316/2013; and /or
- (b) the combination of financial instruments and grants from public sources other than the CEF, whether they are public sources of the Union or national.
- 6. Horizontal actions shall be supported by:
- (a) procurement; and/or
- (b) grants.
- 7. The total amount of the budget allocated to financial instruments for broadband networks shall not exceed the minimum necessary to establish cost-efficient interventions which shall be determined on the basis of ex-ante assessments as referred to in Article 14(1) of Regulation (EU) No 1316/2013.

That amount shall be $15\,\%$ of the financial envelope for the telecommunications sector referred to in point (b) of Article 5(1) of Regulation (EU) No 1316/2013.

- 8. At least one-third of the broadband projects receiving financial assistance under this Regulation shall aim at broadband speeds above 100 Mbps.
- 9. Following the report referred to in Article 8(6), the European Parliament and the Council may, upon a proposal

- by the Commission, revise the amount determined in accordance with paragraph 7 of this Article and the proportion of projects referred to in paragraph 8 of this Article.
- 10. Where the support from the CEF complements ESI Funds and other direct public support, the achievement of synergies between CEF actions and support from ESI Funds may be reinforced by using an appropriate coordination mechanism.

Article 6

Eligibility criteria and priorities for funding

- 1. Actions contributing to projects of common interest in the field of digital service infrastructures shall meet all the following criteria in order to be eligible for funding:
- (a) have sufficient maturity to be deployed, as proven in particular through successful piloting under programmes such as the Union programmes related to innovation and research;
- (b) contribute to Union policies and activities in support of the internal market:
- (c) create European added value and have a strategy and planning for long-term sustainability, where appropriate through funding sources other than CEF, the quality of which is to be demonstrated by a feasibility and costbenefit assessment. Such strategy shall be updated when appropriate;
- (d) comply with international and/or European standards or open specifications and orientations for interoperability, such as the European Interoperability Framework, and capitalise on existing solutions.
- 2. The selection of actions contributing to projects of common interest in the field of digital service infrastructures to be funded under the CEF, as well as their level of funding, shall be carried out as part of an annual work programme referred to in Article 17(1) of Regulation (EU) No 1316/2013.
- 3. Building blocks essential for, and with demonstrable prospects of being used in, the development, deployment and operation of other digital service infrastructures as listed in Section 1.1 of the Annex, shall be given top priority for funding.
- 4. Second priority shall be given to other digital service infrastructures in support of Union law, policies and programmes, as listed in Sections 1.2 and 1.3 of the Annex and, where possible, be based on existing building blocks.
- 5. Support to core service platforms shall take priority over generic services.

- 6. On the basis of the objectives provided for in Article 3 of this Regulation, the description of projects of common interest in the Annex to this Regulation and, taking into account the available budget, the annual and multiannual work programmes referred to in Article 17 of Regulation (EU) No 1316/2013 may establish further eligibility and priority criteria in the field of digital service infrastructures.
- 7. Actions contributing to projects of common interest in the field of broadband networks shall meet all the following criteria in order to be eligible for funding:
- (a) make a significant contribution to the realisation of the targets of the Digital Agenda for Europe;
- (b) have sufficiently mature project development and preparation stages that are underpinned by effective implementation mechanisms;
- (c) address market failures or sub-optimal investment situations;
- (d) not lead to market distortions or crowding out of private investment;
- (e) use the technology which is deemed most suitable to address the needs of the geographic area in question, taking into account geographic, social and economic factors based on objective criteria and in keeping with technological neutrality;
- (f) deploy the technology best suited for the specific project, while proposing the best balance between state of the art technologies in terms of data flow capacity, transmission security, network resilience, and cost efficiency;
- (g) have a high potential for replicability and/or be based on innovative business models.
- 8. The criteria referred to in point (g) of paragraph 7 of this Article shall not be required for projects funded from additional ring-fenced contributions provided in accordance with Article 15(2) of Regulation (EU) No 1316/2013.
- 9. Horizontal actions shall meet either of the following criteria in order to be eligible for funding:
- (a) prepare or support implementation actions in their deployment, governance and address existing or emerging implementation problems;
- (b) create new demand for digital service infrastructures.

Article 7

Cooperation with third countries and international organisations

1. The Union may establish contacts, discuss and exchange information, and cooperate with public authorities or any other organisations in third countries to achieve any objective pursued

by this Regulation. Among other objectives, this cooperation shall seek to promote interoperability between networks in the area of telecommunications infrastructure in the Union and similar networks in third countries.

- 2. European Free Trade Association (EFTA) countries which are members of the European Economic Area (EEA) may participate in the sector of the CEF covering telecommunications infrastructure in accordance with the conditions laid down in the EEA Agreement.
- 3. By way of derogation from Articles 8(3) and 9(4) of Regulation (EU) No 1316/2013, acceding States and candidate countries benefiting from a pre-accession strategy may participate in the sector of the CEF covering telecommunications infrastructure in accordance with agreements signed with the Union.
- 4. For the purposes of the participation of EFTA countries, the sector of the CEF covering telecommunications infrastructure shall be considered as a separate programme.

Article 8

Exchange of information, monitoring and reporting

- 1. On the basis of information received under the third subparagraph of Article 22 of Regulation (EU) No 1316/2013, Member States and the Commission shall exchange information and best practices about the progress made in the implementation of this Regulation. Where appropriate, Member States shall involve local and regional authorities in the process. The Commission shall publish a yearly overview of that information and submit it to the European Parliament and to the Council.
- 2. The Commission shall consult and be assisted by an Expert Group composed of a representative of each Member State. In particular, the Expert Group shall assist the Commission in:
- (a) monitoring the implementation of this Regulation;
- (b) taking account of national plans or national strategies, where applicable;
- (c) taking measures to evaluate the implementation of the work programmes on a financial and technical level;
- (d) addressing existing or emerging project implementation problems;
- (e) defining strategic orientations prior to the drawing-up of the annual and multiannual work programmes referred to in Article 17 of Regulation (EU) No 1316/2013, with particular regard to the selection and withdrawal of actions contributing to projects of common interest and the determination of the budget breakdown, as well as the revision of those work programmes.

- 3. The Expert Group may also consider any other issue relating to the development of the trans-European networks in the area of telecommunications infrastructure.
- 4. The Commission shall inform the Expert Group on the progress made in implementing the annual and multiannual work programmes referred to in Article 17 of Regulation (EU) No 1316/2013.
- 5. The Expert Group shall cooperate with entities involved in the planning, development and management of digital networks and services as well as with other relevant stakeholders.

The Commission and other entities in charge of the implementation of this Regulation, such as the European Investment Bank, shall pay particular attention to the Expert Group's observations.

- 6. In conjunction with the mid-term evaluation and the expost evaluation of Regulation (EU) No 1316/2013 as referred to in Article 27 of that Regulation, and with the assistance of the Expert Group, the Commission shall publish a report on the progress in the implementation of this Regulation. That report shall be submitted to the European Parliament and to the Council.
- 7. The report shall provide an evaluation of the progress achieved in the development and implementation of projects of common interest, including where relevant delays in implementation and difficulties are encountered, as well as information about commitments and payments.
- 8. In the report, the Commission shall also evaluate whether the scope of the projects of common interest continues to reflect technological developments and innovations, as well as regulatory or market and economic developments and whether, in view of such developments and the need for long-term sustainability, funding for any of the projects of common

interest supported should be phased out or sourced in other ways. For projects which are likely to have significant effects on the environment, those reports shall include an analysis of the environmental impact, taking into account, where appropriate, climate change adaptation and mitigation needs, and disaster resilience. Such an evaluation may also be carried out at any other time when it is deemed appropriate.

- 9. The achievement of the specific objectives set out in Article 3 shall be measured ex post, inter alia, on the basis of:
- (a) the availability of digital service infrastructures, measured by the number of Member States connected to each digital service infrastructure;
- (b) the percentage of citizens and businesses using digital service infrastructures and the availability of such services across borders;
- (c) the volume of investments attracted in the field of broadband, and the leverage effect, for projects funded through contributions from public sources referred to in point (b) of Article 5(5).

Article 9

Repeal

Decision No 1336/97/EC is hereby repealed.

Article 10

Entry into force

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

It shall apply from 1 January 2014.

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

Done at Strasbourg, 11 March 2014.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
D. KOURKOULAS

ANNEX

PROJECTS OF COMMON INTEREST

SECTION 1. DIGITAL SERVICE INFRASTRUCTURES

Interventions in the area of digital service infrastructure generally rely on a two-layer architecture approach: core service platforms and generic services. The core service platform is a pre-condition for establishing a digital service infrastructure.

The core service platforms address the interoperability and security needs of projects of common interest. They are intended to enable digital interactions between public authorities and citizens, between public authorities and businesses and organisations, or between public authorities of different Member States through standardised, cross-border, and user-friendly interaction platforms.

Building block digital service infrastructures take priority over other digital service infrastructures, since the former are a pre-condition for the latter. The generic services provide the connection to the core service platforms and enable the national added value services to use the core service platforms. They provide gateways between national services and core service platforms and allow national public authorities and organisations, businesses and/or citizens to access the core service platform for their cross-border transactions. The quality of the services and the support for stakeholders involved in cross-border transactions must be ensured. They must support and stimulate the take-up of core service platforms.

The focus must not be entirely on the creation of digital service infrastructures and related services but also on the governance relating to the operation of such platforms.

New core service platforms must mainly be based on existing platforms and their building blocks and/or, when possible, must add new building blocks.

- 1. The building blocks identified to be included in the work programmes, subject to Article 6 (1) and (3), are the following:
 - (a) Electronic identification, and authentication: this refers to services to enable cross-border recognition and validation of e-identification and e-signature.
 - (b) Electronic delivery of documents: this refers to services for the secure, traceable cross-border transmission of electronic documents.
 - (c) Automated translation: this refers to machine-translation engines and specialised language resources including the necessary tools and programming interfaces needed to operate pan-European digital services in a multilingual environment.
 - (d) Critical digital infrastructures support: this refers to communication channels and platforms intended to enhance the Union-wide capability for preparedness, information sharing, coordination and response to cyber threats.
 - (e) Electronic invoicing: this refers to services enabling secure electronic exchange of invoices.
- 2. Well-established digital service infrastructures particularly identified to be eligible for funding contributing to uninterrupted service, subject to Article 6(1):
 - (a) Access to digital resources of European heritage. This refers to the core service platform based on the current Europeana portal. The platform provides the access point to Europeana cultural heritage content at item level, a set of interface specifications to interact with the infrastructure (search for data, download data), support for the metadata adaptation and ingestion of new content, as well as information on conditions for reuse of the content accessible through the infrastructure.
 - (b) Safer internet service infrastructure. This refers to the platform for acquiring, operating and maintaining shared computing facilities, databases, software tools and exchange of best practices for the Safer Internet Centres (SICs) in the Member States. Back-office operations to handle reporting of child sexual abuse content on the Internet are also included, as well as the link with police authorities including international organisations such as Interpol, and when appropriate, the handling of the take-down of this content by the relevant web sites. This will be supported by common databases and by common software systems. SICs and their relevant activities such as helplines, hotlines, awareness nodes and other awareness raising activities represent the key element of the Safer Internet infrastructure.

- 3. Other digital service infrastructures identified to be eligible for funding subject to Article 6(1):
 - (a) Interoperable cross-border electronic procurement services. This refers to a set of services which can be used by public and private sector e-procurement services providers to set up cross-border e-procurement platforms. This infrastructure will enable any company in the Union to respond to public procurement procedures from any contracting authority or entity in any Member State covering pre-award and post-award electronic procurement activities, including functionalities such as electronic submission of offers, virtual company dossier, e-catalogues, eorders and e-invoicing.
 - (b) Interoperable cross-border e-health services. This refers to a platform which enables the interaction between citizens/patients and health care providers, institution-to-institution and organisation-to-organisation transmission of data, or peer-to-peer communication between citizens/patients and/or health professionals and institutions. The services shall comprise cross-border access to electronic health records and electronic prescription services as well as remote health/assisted living teleservices, etc.
 - (c) European Platform for the interconnection of European business registers. This refers to a platform which provides a set of central tools and services enabling business registers in all Member States to exchange information on registered businesses, their branches, mergers and windings-up. It shall also provide a multi-country and multi-lingual search service for users using a central access point accessible via the e-Justice portal.
 - (d) Access to re-usable public sector information. This refers to a platform for the single access point to multilingual (official languages of the institutions of the Union) datasets held by public bodies in the Union at European, national, regional and local levels; query and visualisation tools of the data sets; assurance that the available datasets are properly anonymised, licensed and where applicable priced to be published, redistributed and reused, including a data provenance audit trail.

Electronic procedures for setting up and running a business in another European country. This service will allow all necessary administrative procedures to be dealt with electronically across borders through single contact points. This service is a requirement in Directive 2006/123/EC of the European Parliament and of the Council (1).

(e) Interoperable cross-border online services. This refers to platforms which shall facilitate interoperability and cooperation between Member States in areas of common interest, particularly with a view to improving the functioning of the internal market, such as eJustice, which will enable online cross-border access by citizens, businesses, organisations and legal practitioners to legal resources/documents and judicial procedures, Online Dispute Resolution (ODR) which will enable online resolution of cross-border disputes between consumers and merchants and Electronic Exchange of Social Security Information (EESSI), which will help social security bodies across the Union exchange information more rapidly and securely.

SECTION 2. BROADBAND NETWORKS

1. The scope of actions

Actions shall consist in particular of one or more of the following components:

- (a) the deployment of passive physical infrastructure, active physical infrastructure or the combination of the two and ancillary infrastructure elements, complete with services necessary to operate such infrastructure;
- (b) associated facilities and associated services, such as building wiring, antennae, towers and other supporting constructions, ducts, conduits, masts, manholes, and cabinets;
- (c) where possible, potential synergies shall be exploited between the roll-out of broadband networks and other utilities networks (energy, transport, water, sewerage, etc.), in particular those related to smart electricity distribution.

2. Contribution to the achievement of the targets of the Digital Agenda for Europe

All projects receiving financial assistance under this section shall contribute significantly to the achievement of the targets of the Digital Agenda for Europe.

Actions funded directly by the Union shall:

⁽¹⁾ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (OJ L 376, 27.12.2006, p. 36).

- (a) be based on wired or wireless technology capable of delivering very high-speed broadband services, thus meeting demand for applications which require high bandwidth;
- (b) be based on innovative business models and/or attract new categories of project promoters or new categories of investors; or
- (c) have a high potential for replicability, thus allowing them to achieve broader impact on the market due to their demonstration effect:
- (d) assist in narrowing the digital divide, where possible;
- (e) comply with applicable law, in particular with competition law, and with access obligations in accordance with Directive 2002/19/EC.

Actions funded from additional ring-fenced contributions provided in accordance with Article 15(2) of Regulation (EU) No 1316/2013 shall bring significant new capabilities to the market in terms of broadband service availability, speeds and capacity. Projects which provide speeds of data transmission of less than 30 Mbps should ensure the increase of speeds to at least 30 Mbps and where possible to 100 Mbps and above over time.

3. Project assessment to establish optimal funding structures

The implementation of actions shall be based on a comprehensive project assessment. Such a project assessment shall cover, inter alia, market conditions including information on existing and/or planned infrastructure, regulatory obligations on project promoters, as well as commercial and marketing strategies. In particular, the project assessment shall establish whether the programme:

- (a) is necessary to address market failures or sub-optimal investment situations, which cannot be solved by regulatory measures;
- (b) does not lead to market distortions and crowding out of private investment.

These criteria shall be established primarily on the basis of the revenue potential and the level of risk associated with a project and the type of geographical area covered by an action.

4. Sources of funding

- (a) Projects of common interest in the field of broadband shall be funded through financial instruments. The budget allocated to these instruments shall be sufficient, but shall not exceed, the amount which is necessary to establish a fully operational intervention and to achieve a minimum efficient instrument size.
- (b) Subject to the rules of Regulation (EU, Euratom) No 966/2012, Regulation (EU) No 1316/2013 and all relevant regulations concerning ESI Funds, the financial instruments referred to in point (a) may be combined with additional contributions from:
 - (i) other sectors of the CEF;
 - (ii) other instruments, programmes and budget lines in the Union budget;
 - (iii) Member States, including regional and local authorities, that decide to contribute own resources or resources available from ESI Funds. ESI Funds contributions will be geographically ring-fenced to ensure that they are spent within a Member State or a region which provides a contribution;
 - (iv) any other investors, including private investors.
- (c) Financial instruments referred to in points (a) and (b) may also be combined with grants by Member States, including regional and local authorities, that wish to contribute own resources or resources available from ESI Funds, provided that:
 - (i) the action in question meets all criteria for funding under this Regulation; and
 - (ii) relevant State aid clearance has been obtained.

SECTION 3. HORIZONTAL ACTIONS

The deployment of trans-European networks in the area of telecommunications infrastructure that will help to remove the bottlenecks existing in the Digital Single Market shall be accompanied by studies and programme support actions. These actions may consist of either:

- (a) technical assistance to prepare or support implementation actions in their deployment, governance and addressing existing or emerging implementation problems; or
- (b) actions to create new demand for digital service infrastructures.

Union support under this Regulation shall be coordinated with support from all other available sources, while avoiding duplication of infrastructure and preventing the displacement of private investments.

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) No 284/2014

of 21 March 2014

implementing Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) No 269/2014 of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (1), and in particular Article 14(1) thereof,

Whereas:

- On17 March 2014, the Council adopted Regulation (EU) No 269/2014.
- (2) In view of the gravity of the situation, the Council considers that additional persons should be added to

the list of natural and legal persons, entities and bodies subject to restrictive measures as set out in Annex I to Regulation (EU) No 269/2014.

(3) Annex I to Regulation (EU) No 269/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The persons listed in the Annex to this Regulation shall be added to the list set out in Annex I to Regulation (EU) No 269/2014.

Article 2

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

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

Done at Brussels, 21 March 2014.

For the Council
The President
D. KOURKOULAS

 $\label{eq:annex} \textit{ANNEX}$ List of natural and legal persons, entities and bodies referred to in Article 1

| | Name | Identifying information Reasons | | Date of listing |
|-----|---|--|--|-----------------|
| 1. | Rogozin, Dmitry Olegovich | d.o.b. 21.12.1963; in Moscow | Deputy Prime Minister of the Russian Federation. Publicly called for the annexation of Crimea. | 21.3.2014 |
| 2. | Glazyev, Sergey | d.o.b. 1.1.1961, Zaporozhye, (Ukrainian SSR) | Adviser to the President of the Russian Federation. Publicly called for the annexation of Crimea. | 21.3.2014 |
| 3. | Matviyenko, Valentina Ivanova | d.o.b. 7.4.1949, Shepetovka, Khmelnitskyi oblast (Ukrainian SSR) | Speaker of the Federation Council. On 1 March 2014, publicly supported in the Federation Council the deployment of Russian forces in Ukraine. | 21.3.2014 |
| 4. | Naryshkin, Sergei Evgenevich | d.o.b. 27.10.1954, St Petersburg (former Leningrad) | Speaker of the State Duma. Publicly supported the deployment of Russian forces in Ukraine. Publicly supported the Russia-Crimea reunification treaty and the related federal constitutional law. | 21.3.2014 |
| 5. | Kiselyov, Dmitry Konstantinovich | d.o.b. 26.4.1954 | Appointed by Presidential Decree on 9 December 2013 Head of the Russian Federal State news agency "Rossiya Segodnya". Central figure of the government propaganda supporting the deployment of Russian forces in Ukraine. | |
| 6. | Nosatov, Alexander Mihailovich | d.o.b. 27.3.1963 Sevastopol, (Ukrainian SSR) | Deputy-Commander of the Black Sea Fleet, Rear-Admiral Responsible for commanding Russian forces that have occupied Ukrainian sovereign territory. | 21.3.2014 |
| 7. | Kulikov, Valery Vladimirovich | d.o.b. 1.9.1956, Zaporozhye, (Ukrainian SSR) | Deputy-Commander of the Black Sea Fleet, Rear Admiral Responsible for commanding Russian forces that have occupied Ukrainian sovereign territory. | 21.3.2014 |
| 8. | Surkov, Vladislav Yurievich d.o.b. 21.9.1964, Solntsevo, Lipetsk Aide to the President of the Russian Federation. He was an organiser of the process in Crimea by which loca Crimean communities were mobilised to stage actions undermining the Ukrainian authorities in Crimea. | | 21.3.2014 | |
| 9. | Mikhail Malyshev | Chair of the Crimea Electoral Commission | Responsible for administering the Crimean referendum. Responsible under the Russian system for signing referendum results. | 21.3.2014 |
| 10. | Valery Medvedev | Chair of Sevastopol Electoral Commission | Responsible for administering the Crimean referendum. Responsible under the Russian system for signing referendum results. | 21.3.2014 |



| | Name | Identifying information | Reasons | Date of listing |
|---|-----------------------------|---|--|-----------------|
| 11. | Lt. Gen. Igor Turchenyuk | Commander of the Russian forces in Crimea | The de-facto Commander of Russian troops deployed on the ground in Crimea (whom Russia continues to refer to officially as "local self-defence militias"). | 21.3.2014 |
| 12. Elena Borisovna Deputy in the State Duma Mizulina | | Originator and co-sponsor of recent legislative proposals in Russia that would have allowed regions of other countries to join Russia without their central authorities' prior agreement. | 21.3.2014 | |

DECISIONS

COUNCIL IMPLEMENTING DECISION 2014/151/CFSP

of 21 March 2014

implementing Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Decision 2014/145/CFSP of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (¹), and in particular Article 3(1) thereof,

Whereas:

- (1) On 17 March 2014, the Council adopted Decision 2014/145/CFSP.
- (2) In view of the gravity of the situation, the Council considers that additional persons should be added to the list of persons, entities and bodies subject to restrictive measures as set out in the Annex to Decision 2014/145/CFSP.

(3) The Annex to Decision 2014/145/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The persons listed in the Annex to this Decision shall be added to the list set out in the Annex to Decision 2014/145/CFSP.

Article 2

This Decision shall enter into force on the date of its publication in the Official Journal of the European Union.

Done at Brussels, 21 March 2014.

For the Council
The President
D. KOURKOULAS

ANNEX

List of persons, entities and bodies referred to in Article 1

| | Name | Identifying information | Reasons | Date of listing |
|-----|---|--|--|-----------------|
| 1. | Rogozin, Dmitry Olegovich | d.o.b. 21.12.1963; in Moscow | Moscow Deputy Prime Minister of the Russian Federation. Publicly called for the annexation of Crimea. | |
| 2. | Glazyev, Sergey | d.o.b. 1.1.1961, Zaporozhye, (Ukrainian SSR) | Adviser to the President of the Russian Federation. Publicly called for the annexation of Crimea. | 21.3.2014 |
| 3. | Matviyenko, Valentina Ivanova | d.o.b. 7.4.1949, Shepetovka, Khmelnitskyi oblast (Ukrainian SSR) | Speaker of the Federation Council. On 1 March 2014, publicly supported in the Federation Council the deployment of Russian forces in Ukraine. | 21.3.2014 |
| 4. | Naryshkin, Sergei Evgenevich | d.o.b. 27.10.1954, St Petersburg (former Leningrad) | Speaker of the State Duma. Publicly supported the deployment of Russian forces in Ukraine. Publicly supported the Russia-Crimea reunification treaty and the related federal constitutional law. | 21.3.2014 |
| 5. | Kiselyov, Dmitry Konstantinovich | d.o.b. 26.4.1954 | Appointed by Presidential Decree on 9 December 2013 Head of the Russian Federal State news agency "Rossiya Segodnya". Central figure of the government propaganda supporting the deployment of Russian forces in Ukraine. | 21.3.2014 |
| 6. | Nosatov, Alexander Mihailovich | d.o.b. 27.3.1963 Sevastopol, (Ukrainian SSR) | Deputy-Commander of the Black Sea Fleet, Rear-Admiral Responsible for commanding Russian forces that have occupied Ukrainian sovereign territory. | 21.3.2014 |
| 7. | Kulikov, Valery Vladimirovich | d.o.b. 1.9.1956, Zaporozhye, (Ukrainian SSR) | Deputy-Commander of the Black Sea Fleet, Rear Admiral Responsible for commanding Russian forces that have occupied Ukrainian sovereign territory. | 21.3.2014 |
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| 9. | Mikhail Malyshev | Chair of the Crimea Electoral Commission | Responsible for administering the Crimean referendum. Responsible under the Russian system for signing referendum results. | 21.3.2014 |
| 10. | Valery Medvedev | Chair of Sevastopol Electoral Commission | Responsible for administering the Crimean referendum. Responsible under the Russian system for signing referendum results. | 21.3.2014 |



| | Name | Identifying information | Reasons | Date of listing |
|-----|-----------------------------|---|---|-----------------|
| 11. | Lt. Gen. Igor Turchenyuk | Commander of the Russian forces in Crimea | The de-facto Commander of Russian troops deployed on the ground in Crimea (whom Russia continues to refer to officially as "local self-defence militias"). | 21.3.2014 |
| 12. | Elena Borisovna Mizulina | Deputy in the State Duma | Originator and co-sponsor of recent legislative proposals in Russia that would have allowed regions of other countries to join Russia without their central authorities' prior agreement. | 21.3.2014 |

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