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## Information and Notices

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2020-2021 SESSION

Sittings of 11 to 13 November 2020

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*Key to symbols used*

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure: first reading
- \*\*\*II Ordinary legislative procedure: second reading
- \*\*\*III Ordinary legislative procedure: third reading

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments by Parliament:

New text is highlighted in ***bold italics***. Deletions are indicated using either the **■** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.



**EUROPEAN PARLIAMENT**

2020-2021 SESSION

Sittings of 11 to 13 November 2020

TEXTS ADOPTED

Wednesday 11 November 2020

I

(Resolutions, recommendations and opinions)

RESOLUTIONS

EUROPEAN PARLIAMENT

P9\_TA(2020)0291

**Genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603**

European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D068777/01 — 2020/2836(RSP))

(2021/C 415/01)

The European Parliament,

- having regard to the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D068777/01,
- having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>(1)</sup>, and in particular Articles 7(3) and 19(3) thereof,
- having regard to the vote of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, on 15 September 2020, at which no opinion was delivered,
- having regard to Articles 11 and 13 of 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<sup>(2)</sup>,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 22 May 2019, and published on 8 July 2019<sup>(3)</sup>,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> OJ L 55, 28.2.2011, p. 13.

<sup>(3)</sup> Scientific Opinion of the EFSA Panel on Genetically Modified Organisms on the assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-131), *EFSA Journal* 2019;17(7):5734, <https://doi.org/10.2903/j.efsa.2019.5734>



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- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs')<sup>(4)</sup>,
  - having regard to Rule 112(2) and (3) of its Rules of Procedure,
  - having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas, on 15 February 2016, Monsanto Europe S.A/N.V. submitted, on behalf of Monsanto company, United States, an application to the national competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 ('the stacked GM maize') in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003; whereas the application also covered the placing on the market of products containing or consisting of the stacked GM maize for uses other than food and feed, with the exception of cultivation; whereas, in addition, the application covered the placing on the market of products containing, consisting of or produced from 10 sub-combinations of the single transformation events constituting the stacked GM maize;
- B. whereas the stacked GM maize is derived from crossing four genetically modified ('GM') maize events (MON 87427, MON 89034, MIR162 and NK603), confers tolerance to glyphosate-containing herbicides and produces three insecticidal proteins (Cry1A.105, Cry2Ab2 and Vip3Aa20 known as 'Bt' or 'Cry' proteins) which are toxic to certain lepidopteran (butterfly and moth) larvae<sup>(5)</sup>;

<sup>(4)</sup> In its eighth term, Parliament adopted 36 resolutions objecting to the authorisation of GMOs. Furthermore, in its ninth term Parliament has adopted the following resolutions:

- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZHG0JG (SYN-000JG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0028).
- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean A2704-12 (ACS-GM005-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0029).
- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0030).
- European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton LLCotton25 (ACS-GH001-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0054).
- European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0055).
- European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0056).
- European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0057).
- European Parliament resolution of 14 May 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87708 × MON 89788 × A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2020)0069).

<sup>(5)</sup> EFSA opinion, p. 11.

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- C. whereas previous assessments of the four single events and four of the sub-combinations of the stacked GM maize, which have already been authorised, were used as a basis for the assessment of the four-event stacked GM maize and the remaining six sub-combinations <sup>(6)</sup>;
- D. whereas, on 22 May 2019, EFSA adopted a favourable opinion, which was published on 8 July 2019, in relation to that application;
- E. whereas Regulation (EC) No 1829/2003 states that GM food or feed must not have adverse effects on human health, animal health or the environment, and requires the Commission to take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision;

**Member State comments and additional points**

- F. whereas Member States submitted many critical comments to EFSA during the three-month consultation period <sup>(7)</sup>; whereas those critical comments include concerns that no analysis has been done regarding glyphosate residues or glyphosate metabolites on the stacked GM maize, that there has been no testing of the possible synergistic or antagonistic effects of the Cry proteins and the Vip protein and of herbicide residues, that questions on the safety of GM maize and derived food and feed remain unanswered, that the potential long-term reproductive or developmental effects of the food or feed have not been assessed and that, due to missing information, the safety of the stacked GM maize cannot be fully assessed;
- G. whereas an independent scientific analysis has found that, inter alia, no final conclusion can be drawn regarding the safety of the stacked GM maize, that the toxicological assessment and the environmental risk assessment are unacceptable and that the risk assessment does not fulfil requirements for assessing risks to the immune system <sup>(8)</sup>;
- H. whereas no experimental data was provided by the applicant for the currently unauthorised six sub-combinations of the stacked GM maize;

**Lack of assessment of herbicide residues, metabolites and cocktail effects**

- I. whereas a number of studies show that herbicide-tolerant GM crops result in a higher use of 'complementary' herbicides, due in large part to the emergence of herbicide-tolerant weeds <sup>(9)</sup>; whereas, as a consequence, it has to be expected that the stacked GM maize will be exposed to both higher and repeated doses of glyphosate, and that therefore a higher quantity of residues may be present in the harvest; whereas the stacked GM maize expresses three glyphosate-tolerant proteins, making it even more tolerant to higher dosages and repeated spraying;
- J. whereas questions concerning the carcinogenicity of glyphosate remain; whereas EFSA concluded in November 2015 that glyphosate was unlikely to be carcinogenic and the European Chemicals Agency concluded in March 2017 that no classification was warranted; whereas, on the contrary, in 2015, the International Agency for Research on Cancer, the specialised cancer agency of the World Health Organization, classified glyphosate as a probable carcinogen for humans;

<sup>(6)</sup> Idem, p. 3.

<sup>(7)</sup> Member State comments: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00148>

<sup>(8)</sup> Testbiotech comment on EFSA's assessment of genetically engineered maize MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations, August 2019, <https://www.testbiotech.org/en/content/testbiotech-comment-efsa-assessment-genetically-engineered-maize-mon87427xmon89034xMIR162xNK603>

<sup>(9)</sup> See, for example, Bonny, S., 'Genetically Modified Herbicide-Tolerant Crops, Weeds, and Herbicides: Overview and Impact', *Environmental Management*, January 2016, 57(1), pp. 31-48, <https://www.ncbi.nlm.nih.gov/pubmed/26296738> and Benbrook, C.M., 'Impacts of genetically engineered crops on pesticide use in the U.S. — the first sixteen years', *Environmental Sciences Europe* 24, 24 (2012), <https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24>, and Schütte, G., Eckerstorfer, M., Rastelli, V. et al., 'Herbicide resistance and biodiversity: agronomic and environmental aspects of genetically modified herbicide-resistant plants', *Environmental Sciences Europe* 29, 5 (2017), <https://link.springer.com/article/10.1186/s12302-016-0100-y>

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- K. whereas in its scientific opinion of 22 May 2019, the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel) states that ‘the assessment of herbicide residues in maize herbicide-tolerant crops relevant for this application has been investigated by the EFSA Pesticides Unit’<sup>(10)</sup>; whereas, according to an opinion by the EFSA Pesticides Unit however, data on glyphosate residues on GM maize with EPSPS modifications<sup>(11)</sup> are insufficient to derive maximum residue levels and risk assessment values<sup>(12)</sup>;
- L. whereas, again according to the EFSA Pesticides Unit, toxicological data allowing a consumer risk assessment to be performed for several break-down products of glyphosate relevant for GM glyphosate-tolerant crops are missing<sup>(13)</sup>;
- M. whereas assessment of herbicide residues, and herbicide break-down products, found on GM plants, along with their potential interaction with Bt proteins, is considered outside the remit of the EFSA GMO Panel and is therefore not undertaken as part of the authorisation process for GMOs; whereas this is problematic, since the way in which complementary herbicides are broken down by the GM plant concerned, and the composition and thus toxicity of the break-down products (‘metabolites’), can be driven by the genetic modification itself<sup>(14)</sup>;

### **Bt proteins**

- N. whereas a number of studies show that side effects have been observed that may affect the immune system following exposure to Bt proteins and that some Bt proteins may have adjuvant properties<sup>(15)</sup>, meaning that they can increase the allergenicity of other proteins that they come into contact with;
- O. whereas a minority opinion adopted by a member of the EFSA GMO Panel in the process of assessing another stacked GM maize and its sub-combinations found that, while unintended effects on the immune system have never been identified in any application where Bt proteins are expressed, they could ‘not be observed by the toxicological studies [...] currently recommended and performed for the safety assessment of GM plants at EFSA because they do not include the appropriate tests for this purpose’<sup>(16)</sup>;
- P. whereas it cannot be concluded that consumption of the stacked GM maize or its sub-combinations is safe for human and animal health;
- Q. whereas a recent study has shown that a rapid rise in the use of neonicotinoid seed treatments in the United States is associated with increased planting of GM Bt maize<sup>(17)</sup>; whereas the Union has banned the outdoor use of three neonicotinoids, including as seed coatings, because of their impact on honeybees and other pollinators<sup>(18)</sup>;

<sup>(10)</sup> EFSA opinion, p. 9.

<sup>(11)</sup> The stacked GM maize contains an EPSPS modification.

<sup>(12)</sup> EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005 — revised version to take into account omitted data, *EFSA Journal* 2019;17(10):5862, p. 4, <https://www.efsa.europa.eu/en/efsajournal/pub/5862>

<sup>(13)</sup> EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, *EFSA Journal* 2015; 13 (11):4302, p. 3, <https://www.efsa.europa.eu/en/efsajournal/pub/4302>

<sup>(14)</sup> This is indeed the case for glyphosate, as stated in EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005, *EFSA Journal* 2018;16(5):5263, p. 12, <https://www.efsa.europa.eu/fr/efsajournal/pub/5263>

<sup>(15)</sup> For a review, see Rubio-Infante, N., Moreno-Fierros, L., ‘An overview of the safety and biological effects of *Bacillus thuringiensis* Cry toxins in mammals’, *Journal of Applied Toxicology*, May 2016, 36(5): pp. 630-648, <http://onlinelibrary.wiley.com/doi/10.1002/jat.3252/full>

<sup>(16)</sup> Application EFSA-GMO-DE-2010-86 (Bt11 × MIR162 × 1507 × GA21 maize and three sub combinations independently of their origin), Minority Opinion, Wal, J.M., Member of the EFSA GMO Panel, *EFSA Journal* 2018;16(7):5309, p. 34, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5309>

<sup>(17)</sup> Douglas, M.R., Tooker, J.F., ‘Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops’, *Environmental Science and Technology* 2015, 49, 8, 5088-5097, <https://pubs.acs.org/doi/10.1021/es506141g>

<sup>(18)</sup> Neonicotinoids, [https://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/approval\\_renewal/neonicotinoids\\_en](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en)

Wednesday 11 November 2020

### ***Undemocratic decision-making***

- R. whereas the vote on 15 September 2020 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003 delivered no opinion, meaning that the authorisation was not supported by a qualified majority of Member States;
- S. whereas the Commission recognises that the fact that GMO authorisation decisions continue to be adopted by the Commission without a qualified majority of Member States in favour, which is very much the exception for product authorisations as a whole but which has become the norm for decision-making on GM food and feed authorisations, is problematic;
- T. whereas, in its eighth term, Parliament adopted a total of 36 resolutions objecting to the placing on the market of GMOs for food and feed (33 resolutions) and to the cultivation of GMOs in the Union (three resolutions); whereas, to date, Parliament has adopted eight objections in its ninth term; whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas despite its own acknowledgement of the democratic shortcomings, the lack of support from Member States and the objections of Parliament, the Commission continues to authorise GMOs;
- U. whereas, under Regulation (EU) No 182/2011, the Commission may decide not to authorise a GMO when there is no qualified majority of Member States in favour in the Appeal Committee <sup>(19)</sup>; whereas no change of law is required in this respect;
1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;
  2. Considers that the draft Commission implementing decision is not consistent with Union law, in that it is not compatible with the aim of Regulation (EC) No 1829/2003, which is, in accordance with the general principles laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(20)</sup>, to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests, in relation to GM food and feed, while ensuring the effective functioning of the internal market;
  3. Calls on the Commission to withdraw its draft implementing decision;
  4. Welcomes the fact that the Commission finally recognised, in a letter of 11 September 2020 to Members, the need to take sustainability into account when it comes to authorisation decisions on GMOs <sup>(21)</sup>; expresses its strong disappointment, however, that, on 28 September 2020, the Commission authorised another GM soybean for import <sup>(22)</sup> despite objections by Parliament and a majority of Member States;
  5. Calls on the Commission to move forward with the utmost urgency concerning the development of sustainability criteria, with full involvement of Parliament; calls on the Commission to provide information on how this process will be undertaken and in what timeframe;
  6. Urges the Commission, again, to take into account the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN Convention on Biological Diversity and the UN Sustainable Development Goals;
  7. Reiterates its call on the Commission to stop authorising GMOs, whether for cultivation or for food and feed uses, when no opinion is delivered by Member States in the Appeal Committee, in accordance with Article 6(3) of Regulation (EU) No 182/2011;

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<sup>(19)</sup> The Commission 'may', and not 'shall', go ahead with authorisation if there is no qualified majority of Member States in favour at the Appeal Committee according to Article 6(3) of Regulation (EU) No 182/2011.

<sup>(20)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(21)</sup> <https://tillymetz.lu/wp-content/uploads/2020/09/Co-signed-letter-MEP-Metz.pdf>

<sup>(22)</sup> MON 87708 × MON 89788 × A5547-127, [https://webgate.ec.europa.eu/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=100](https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=100)

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8. Reiterates its call on the Commission not to authorise herbicide-tolerant GM crops until the health risks associated with the residues have been comprehensively investigated on a case-by-case basis, which requires a full assessment of the residues from spraying such GM crops with complementary herbicides, an assessment of the herbicide break-down products and any combinatorial effects;
  9. Reiterates its call on the Commission to fully integrate the risk assessment of the application of complementary herbicides and their residues into the risk assessment of herbicide-tolerant GM plants, regardless of whether the GM plant concerned is to be cultivated in the Union or is for import into the Union for food and feed uses;
  10. Reiterates its call on the Commission not to authorise any sub-combinations of stacked GM events unless they have been thoroughly evaluated by EFSA on the basis of complete data submitted by the applicant;
  11. Considers, more specifically, that to approve varieties for which no safety data have been provided, which have not been tested, or which have not even been created yet, runs contrary to the principles of general food law, as laid down in Regulation (EC) No 178/2002;
  12. Reiterates its call on EFSA to further develop and systematically use methods that permit the identification of unintended effects of stacked GM events, such as in relation to the adjuvant properties of Bt toxins;
  13. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.
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Wednesday 11 November 2020

P9\_TA(2020)0292

## Genetically modified soybean SYHT0H2 (SYN-ØØØH2-5)

**European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean SYHT0H2 (SYN-ØØØH2-5), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D068779/01 — 2020/2838(RSP))**

(2021/C 415/02)

*The European Parliament,*

- having regard to the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean SYHT0H2 (SYN-ØØØH2-5), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D068779/01,
- having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Articles 7(3) and 19(3) thereof,
- having regard to the vote of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, on 15 September 2020, at which no opinion was delivered,
- having regard to Articles 11 and 13 of 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 <sup>(2)</sup>,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 28 November 2019, and published on 20 January 2020 <sup>(3)</sup>,
- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs') <sup>(4)</sup>,

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<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> OJ L 55, 28.2.2011, p. 13.

<sup>(3)</sup> Scientific Opinion of the EFSA Panel on Genetically Modified Organisms on the assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2012-111), *EFSA Journal* 2020;18(1):5946, <https://doi.org/10.2903/j.efsa.2020.5946>

<sup>(4)</sup> In its eighth term, Parliament adopted 36 resolutions objecting to the authorisation of GMOs. Furthermore, in its ninth term Parliament has adopted the following resolutions:

- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZHGOJG (SYN-ØØØJG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0028).
- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0029).

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- having regard to Rule 112(2) and (3) of its Rules of Procedure,
  - having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas, on 8 August 2012, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, an application to the national competent authority of Germany ('the application') in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003; whereas the application covered the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean (*Glycine max* (L.) Merr.) SYHT0H2; whereas the application also covered the placing on the market of products containing or consisting of genetically modified ('GM') soybean SYHT0H2 for uses other than food and feed, with the exception of cultivation;
- B. whereas, on 28 November 2019, EFSA adopted a favourable opinion, which was published on 20 January 2020, in relation to that application;
- C. whereas GM soybean SYHT0H2 has been developed to confer tolerance to glufosinate ammonium and to the herbicidal active substances mesotrione and other p-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting herbicides<sup>(5)</sup>;

#### ***Lack of assessment of complementary herbicide residues***

- D. whereas it has been shown that the cultivation of herbicide-tolerant GM crops results in a higher use of herbicides, due in large part to the emergence of herbicide-tolerant weeds<sup>(6)</sup>; whereas, as a consequence, it is to be expected that crops of GM soybean SYHT0H2 will be exposed to both higher and repeated doses of complementary herbicides (glufosinate and HPPD-inhibiting herbicides), which will potentially lead to a higher quantity of residues in the harvest;

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— European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0030).

— European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0054).

— European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0055).

— European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0056).

— European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0057).

— European Parliament resolution of 14 May 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87708 × MON 89788 × A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2020)0069).

<sup>(5)</sup> EFSA opinion, p. 1.

<sup>(6)</sup> See, for example, Bonny, S., 'Genetically Modified Herbicide-Tolerant Crops, Weeds, and Herbicides: Overview and Impact', *Environmental Management*, January 2016, 57(1), pp. 31-48, <https://www.ncbi.nlm.nih.gov/pubmed/26296738> and Benbrook, C.M., 'Impacts of genetically engineered crops on pesticide use in the U.S. — the first sixteen years', *Environmental Sciences Europe* 24, 24 (2012), <https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24>, and Schütte, G., Eckerstorfer, M., Rastelli, V. et al., 'Herbicide resistance and biodiversity: agronomic and environmental aspects of genetically modified herbicide-resistant plants', *Environmental Sciences Europe* 29, 5 (2017), <https://link.springer.com/article/10.1186/s12302-016-0100-y>

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- E. whereas glufosinate is classified as toxic to reproduction 1B and thus meets the ‘cut-off criteria’ set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>(7)</sup>; whereas the approval of glufosinate for use in the Union expired on 31 July 2018 <sup>(8)</sup>;
- F. whereas, according to EFSA, the HPPD-inhibiting herbicide mesotrione ‘may be considered to have endocrine disrupting properties’, whilst the genotoxic potential of AMBA, a breakdown product of mesotrione, ‘could not be ruled out’ <sup>(9)</sup>;
- G. whereas only glufosinate and mesotrione were considered as complementary herbicides for the purpose of the risk assessment; whereas, however, HPPD-inhibiting herbicides include a range of herbicides, including isoxaflutole, which may therefore be used in large quantities on this GM soybean; whereas isoxaflutole is, according to the harmonised classification and labelling approved by the Union, very toxic to aquatic life and suspected of damaging the unborn child <sup>(10)</sup>;
- H. whereas, however, assessment of herbicide residues, and herbicide break-down products, found on GM plants as well as possible combinatorial (‘cocktail’) effects is considered outside the remit of the EFSA Panel on Genetically Modified Organisms and is therefore not undertaken as part of the authorisation process for GMOs; whereas this is problematic, since the way in which complementary herbicides are broken down by the GM plant concerned, and the composition and thus toxicity of the break-down products (‘metabolites’), can be driven by the genetic modification itself;
- I. whereas, under Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(11)</sup>, the residues on imported crops for food and feed of herbicides which are not authorised for use in the Union should be carefully controlled and monitored;
- J. whereas, however, under the coordinated multiannual control programme of the Union for 2020, 2021 and 2022, Member States are not obliged to measure glufosinate on soybean imports <sup>(12)</sup>; whereas it cannot be excluded that GM soybean SYHT0H2 or products derived from it for food and feed will exceed maximum residue limits, which are put in place to ensure a high level of consumer protection;
- K. whereas it, therefore, cannot be concluded that consumption of GM soybean SYHT0H2 is safe for human and animal health;
- L. whereas the conclusions of an international research project entitled ‘Risk Assessment of genetically engineered organisms in the EU and Switzerland’, presented in January 2020, found that the Union risk assessment of GMOs fails to deal in a satisfactory way with risks to public health and the environment, including in relation to the health risks associated with the consumption of products derived from herbicide-tolerant GM plants <sup>(13)</sup>;

<sup>(7)</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>(8)</sup> [https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as\\_id=79](https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=79)

<sup>(9)</sup> EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance mesotrione. *EFSA Journal* 2016;14(3):4419, p. 3, <https://doi.org/10.2903/j.efsa.2016.4419>

<sup>(10)</sup> <https://echa.europa.eu/substance-information/-/substanceinfo/100.114.433>

<sup>(11)</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

<sup>(12)</sup> Commission Implementing Regulation (EU) 2019/533 of 28 March 2019 concerning a coordinated multiannual control programme of the Union for 2020, 2021 and 2022 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin (OJ L 88, 29.3.2019, p. 28).

<sup>(13)</sup> <https://www.testbiotech.org/en/content/research-project-rages>



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**Comments from Member State competent authorities**

M. whereas Member State competent authorities submitted comments to EFSA during the three-month consultation period<sup>(14)</sup>; whereas critical comments include the lack of analysis of herbicide residues on imports of GM soybean SYHT0H2 and the potential health risks for consumers, that toxicological information is insufficient and that, therefore, the potential risk associated with the consumption of food produced from GM soybean SYHT0H2 cannot be evaluated, that information necessary to conclude on the environmental health assessment is not complete, and that a detailed monitoring plan should be provided before authorisation can be given;

**Undemocratic decision-making**

N. whereas the vote on 15 September 2020 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003 delivered no opinion, meaning that the authorisation was not supported by a qualified majority of Member States;

O. whereas the Commission recognises that the fact that GMO authorisation decisions continue to be adopted by the Commission without a qualified majority of Member States in favour, which is very much the exception for product authorisations as a whole but which has become the norm for decision-making on GM food and feed authorisations, is problematic<sup>(15)</sup>;

P. whereas, in its eighth term, Parliament adopted a total of 36 resolutions objecting to the placing on the market of GMOs for food and feed (33 resolutions) and to the cultivation of GMOs in the Union (three resolutions); whereas, to date, Parliament has adopted eight objections in its ninth term; whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas despite its own acknowledgement of the democratic shortcomings, the lack of support from Member States and the objections of Parliament, the Commission continues to authorise GMOs;

Q. whereas, under Regulation (EU) No 182/2011, the Commission may decide not to authorise a GMO when there is no qualified majority of Member States in favour in the Appeal Committee<sup>(16)</sup>; whereas no change of law is required in this respect;

**Upholding the Union's international obligations**

R. whereas Regulation (EC) No 1829/2003 provides that GM food or feed must not have adverse effects on human health, animal health or the environment, and requires the Commission to take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision; whereas such legitimate factors should include the Union's obligations under the United Nations (UN) Sustainable Development Goals ('SDGs'), the Paris Climate Agreement and the UN Convention on Biological Diversity ('UN CBD');

S. whereas a recent report by the UN's Special Rapporteur on the right to Food found that, particularly in developing countries, hazardous pesticides have catastrophic impacts on health<sup>(17)</sup>; whereas SDG Target 3.9 aims by 2030 to substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination<sup>(18)</sup>;

<sup>(14)</sup> Member State comments on GM soybean SYHT0H2 can be accessed via EFSA's register of questions: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00753>

<sup>(15)</sup> See, for example, the explanatory memorandum of the Commission's legislative proposal presented on 22 April 2015 amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of GM food and feed on their territory and the explanatory memorandum of the Commission's legislative proposal presented on 14 February 2017 amending Regulation (EU) No 182/2011.

<sup>(16)</sup> The Commission 'may, and not 'shall', go ahead with authorisation if there is no qualified majority of Member States in favour at the Appeal Committee according to Article 6(3) of Regulation (EU) No 182/2011.

<sup>(17)</sup> <https://www.ohchr.org/EN/Issues/Environment/SRToxicsandhumanrights/Pages/Pesticidesrighttofood.aspx>

<sup>(18)</sup> <https://www.un.org/sustainabledevelopment/health/>

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- T. whereas EFSA found that the estimated operator exposure to glufosinate, classified as toxic to reproduction, when used for weed control in GM maize exceeded the acceptable operator exposure level even when personal protective equipment was used<sup>(19)</sup>; whereas the risk of increased operator exposure is of particular concern in relation to herbicide-tolerant GM crops, given the higher volumes of herbicides used;
- U. whereas deforestation is a major cause of biodiversity decline; whereas emissions from land-use and land-use change, mostly due to deforestation, are the second biggest cause of climate change after burning fossil fuels<sup>(20)</sup>; whereas the Paris Climate Agreement and the Strategic Plan for Biodiversity 2011-2020 adopted under the UN CBD and the Aichi Biodiversity Targets promote sustainable forest management, protection and restoration efforts<sup>(21)</sup>; whereas SDG 15 includes the target of halting deforestation by 2020<sup>(22)</sup>; whereas forests play a multifunctional role that support the achievement of most SDGs<sup>(23)</sup>;
- V. whereas soya production is a key driver of deforestation in the Amazon, Cerrado and Gran Chaco forests in South America; whereas 97 % and 100 % of soya cultivated respectively in Brazil and Argentina is GM soya<sup>(24)</sup>;
- W. whereas the vast majority of GM soybeans authorised for cultivation in Brazil and Argentina are also authorised for import into the Union<sup>(25)</sup>; whereas GM soybean SYHT0H2 is already authorised for cultivation in Argentina<sup>(26)</sup>;
- X. whereas an analysis by the Commission found that soya has historically been the Union's number one contributor to global deforestation and related emissions, accounting for nearly half of the deforestation embodied in all Union imports<sup>(27)</sup>;

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<sup>(19)</sup> EFSA Conclusion regarding the peer review of the pesticide risk assessment of the active substance glufosinate, *EFSA Scientific Report (2005) 27*, 1-81, p. 3, <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2005.27r>

<sup>(20)</sup> Communication of the Commission of 23 July 2019, 'Stepping up EU action to Protect and Restore the World's forests', COM(2019)0352, p. 1.

<sup>(21)</sup> *Idem*, p. 2.

<sup>(22)</sup> See target 15.2: <https://www.un.org/sustainabledevelopment/biodiversity/>

<sup>(23)</sup> Communication of the Commission of 23 July 2019, 'Stepping up EU action to Protect and Restore the World's forests', COM(2019)0352, p. 2.

<sup>(24)</sup> International Service for the Acquisition of Agri-biotech Applications, 'Global status of commercialized biotech/GM crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years', *ISAAA Brief No. 53 (2017)*, pp. 16 and 21, <http://www.isaaa.org/resources/publications/briefs/53/download/isaaa-brief-53-2017.pdf>

<sup>(25)</sup> Via a cross check of two databases in October 2020 (the Community register of GM food and feed ([https://webgate.ec.europa.eu/dyna/gm\\_register/index\\_en.cfm](https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm)) and ISAAA GM approval database (<https://www.isaaa.org/gmapprovaldatabase/>)) it can be calculated how many GM soybean crops authorised for cultivation in Brazil and Argentina are also authorised for import into the Union. For Brazil: out of 17 GM soybean crops authorised for cultivation, 12 are currently authorised for import into the Union whilst authorisation for import is pending for three of the GM soybeans. For Argentina: out of a total of 15 GM soybean crops authorised for cultivation, 10 are currently authorised for import into the Union whilst authorisation for import is pending for three of the GM soybeans.

<sup>(26)</sup> <http://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=358&Event=SYHT0H2>

<sup>(27)</sup> Technical Report — 2013 — 063 of the Commission, 'The impact of EU consumption on deforestation: Comprehensive analysis of the impact of EU consumption on deforestation', study funded by the European Commission, DG ENV, and undertaken by VITO, IIASA, HIVA and IUCN NL, <http://ec.europa.eu/environment/forests/pdf/1.%20Report%20analysis%20of%20impact.pdf>, pp. 23-24: Between 1990 and 2008, the Union imported crop and livestock products embodying 90 000 km<sup>2</sup> of deforestation. Crop products accounted for 74 000 km<sup>2</sup> (82 %) of this, with oil crops having the largest share (52 000 km<sup>2</sup>). Soybeans and soya cake accounted for 82 % of this (42 600 km<sup>2</sup>), equivalent to 47 % of the Union's total import of embodied deforestation.

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Y. whereas a recent peer-reviewed scientific study found that the Union is the region with the largest carbon footprint in the world associated with soya imports from Brazil, 13,8 % larger than that of China, the largest soya importer, due to a larger share of emissions from embodied deforestation<sup>(28)</sup>; whereas another recent study found that approximately a fifth of the soya exported to the Union from Brazil's Amazon and Cerrado regions, mostly for animal feed, may be 'contaminated with illegal deforestation'<sup>(29)</sup>; whereas forest fires in the Amazon are driven by high levels of deforestation; whereas in a 2019 Communication, the Commission expressed its ambition to protect and restore the world's forests<sup>(30)</sup>; whereas the global protection of biodiversity, including forests, is a key objective of the Commission's recently published EU Biodiversity Strategy<sup>(31)</sup>;

1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;

2. Considers that the draft Commission implementing decision is not consistent with Union law, in that it is not compatible with the aim of Regulation (EC) No 1829/2003, which is, in accordance with the general principles laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>(32)</sup>, to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests, in relation to GM food and feed, while ensuring the effective functioning of the internal market;

3. Calls on the Commission to withdraw its draft implementing decision;

4. Welcomes the fact that the Commission finally recognised, in a letter of 11 September 2020 to Members, the need to take sustainability into account when it comes to authorisation decisions on GMOs<sup>(33)</sup>; expresses its deep disappointment, however, that, on 28 September 2020, the Commission authorised another GM soybean for import<sup>(34)</sup> despite objections by Parliament and a majority of Member States;

5. Calls on the Commission to move forward with the utmost urgency concerning the development of sustainability criteria, with full involvement of the Parliament; calls on the Commission to provide information on how this process will be undertaken and in what timeframe;

6. Urges the Commission, again, to take into account the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN CBD and the UN SDGs;

7. Reiterates its call on the Commission to stop authorising GMOs, whether for cultivation or for food and feed uses, when no opinion is delivered by Member States in the Appeal Committee, in accordance with Article 6(3) of Regulation (EU) No 182/2011;

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<sup>(28)</sup> Escobar, N., Tizado, E. J., zu Ermgassen, E. K., Löfgren, P., Börner, J., Godar, J., 'Spatially-explicit footprints of agricultural commodities: Mapping carbon emissions embodied in Brazil's soy exports', *Global Environmental Change*, Volume 62, May 2020, 102067, <https://www.sciencedirect.com/science/article/pii/S0959378019308623>

<sup>(29)</sup> Rajão, R., Soares-Filho, B., Nunes, F., Börner, J., Machado, L., Assis, D., Oliveira, A., Pinto, L., Ribeiro, V., Rausch, L., Gibbs, H., Figueira, D., 'The rotten apples of Brazil's agribusiness', *Science* 17 July 2020, Volume 369, Issue 6501, pp. 246-248, <https://science.sciencemag.org/content/369/6501/246>.

<sup>(30)</sup> EU Communication on Stepping up EU Action to Protect and Restore the World's Forests, <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52019DC0352&from=EN>

<sup>(31)</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: 'EU Biodiversity Strategy for 2030: Bringing nature back into our lives', May 2020, [https://eur-lex.europa.eu/resource.html?uri=cellar:a3c806a6-9ab3-11ea-9d2d-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:a3c806a6-9ab3-11ea-9d2d-01aa75ed71a1.0001.02/DOC_1&format=PDF)

<sup>(32)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(33)</sup> <https://tillymetz.lu/wp-content/uploads/2020/09/Co-signed-letter-MEP-Metz.pdf>

<sup>(34)</sup> [https://webgate.ec.europa.eu/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=100](https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=100)

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8. Reiterates its calls on the Commission not to authorise herbicide-tolerant GM crops until the health risks associated with the residues have been comprehensively investigated on a case-by-case basis, which requires a full assessment of the residues from spraying such GM crops with complementary herbicides, an assessment of the herbicide break-down products and any combinatorial effects;
9. Reiterates its call on the Commission to fully integrate the risk assessment of the application of complementary herbicides and their residues into the risk assessment of herbicide-tolerant GM plants, regardless of whether the GM plant concerned is to be cultivated in the Union or is for import into the Union for food and feed uses;
10. Reiterates its call on the Commission not to authorise the import for food or feed uses of any GM plant which has been made tolerant to a herbicide-active substance that is not authorised for use in the Union;
11. Welcomes the fact that the European Green Deal, the flagship project of the Commission, has been put forward as an integral part of the Commission's strategy to implement the UN's 2030 Agenda and the SDGs; recalls that SDGs can only be achieved if supply chains become sustainable and synergies are created between policies <sup>(35)</sup>;
12. Reiterates its consternation that the Union's high dependence on imports of animal feed in the form of soybeans causes deforestation in third countries <sup>(36)</sup>;
13. Welcomes the announcement of a legislative proposal from the Commission on 'Measures to avoid or minimise the placing of products associated with deforestation or forest degradation on the EU market' due by June 2021; in the meantime, given the urgency of tackling deforestation in the Amazon, Cerrado and Gran Chaco forests and the fact that Union demand for GM soybeans contributes to deforestation in that region, calls on the Commission to immediately suspend the import of GM soybeans cultivated in Brazil and Argentina, using Article 53 of Regulation (EC) No 178/2002 if necessary, until effective legally binding mechanisms have been put in place to prevent the placing on the Union market of products associated with deforestation and related human rights violations;
14. Reiterates its call for the implementation of a European vegetable protein production and supply strategy <sup>(37)</sup>, which would enable the Union to become less dependent on GM soybean imports and to create shorter food chains and regional markets;
15. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

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<sup>(35)</sup> European Parliament resolution of 11 September 2018 on transparent and accountable management of natural resources in developing countries: the case of forests (OJ C 433, 23.12.2019, p. 50), para. 67.

<sup>(36)</sup> Idem.

<sup>(37)</sup> European Parliament resolution of 15 January 2020 on the European Green Deal (Texts adopted, P9\_TA(2020)0005), para. 64.

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P9\_TA(2020)0293

**Genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603**

European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D068778/01 — 2020/2837(RSP))

(2021/C 415/03)

*The European Parliament,*

- having regard to the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D068778/01,
- having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Articles 7(3) and 19(3) thereof,
- having regard to the vote of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, on 15 September 2020, at which no opinion was delivered,
- having regard to Articles 11 and 13 of 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 <sup>(2)</sup>,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 3 July 2019, and published on 8 August 2019 <sup>(3)</sup>,
- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs') <sup>(4)</sup>,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> OJ L 55, 28.2.2011, p. 13.

<sup>(3)</sup> Scientific Opinion of the EFSA Panel on Genetically Modified Organisms on the assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-134), *EFSA Journal* 2019;17(8):5774, <https://doi.org/10.2903/j.efsa.2019.5774>

<sup>(4)</sup> In its eight term, Parliament adopted 36 resolutions objecting to the authorisation of GMOs. Furthermore, in its ninth term Parliament has adopted the following resolutions:

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- having regard to Rule 112(2) and (3) of its Rules of Procedure,
  - having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety;
- A. whereas, on 28 October 2016, Monsanto Europe S.A./N.V. submitted, on behalf of Monsanto company, United States, an application to the national competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 ('the stacked GM maize') in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003;
- B. whereas the application also covers the placing on the market of products containing or consisting of the stacked GM maize for uses other than food and feed, with the exception of cultivation;
- C. whereas, in addition, the application covers the placing on the market of products containing, consisting of or produced from 25 sub-combinations of those single transformation events constituting the stacked GM maize;
- D. whereas 11 sub-combinations of the stacked GM maize have already been authorised; whereas the draft Commission implementing decision covers the remaining 14 sub-combinations;
- E. whereas the stacked GM maize is derived from crossing five genetically modified ('GM') maize events (MON 87427, MON 87460, MON 89034, MIR162 and NK603), confers triple tolerance to glyphosate-containing herbicides and produces three insecticidal proteins (Cry1A.105, Cry2Ab2 and Vip3Aa20 known as 'Bt' or 'Cry' proteins) which are toxic to certain lepidopteran (butterfly) larvae <sup>(5)</sup>;

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- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0029).
  - European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0030).
  - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0054).
  - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0055).
  - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0056).
  - European Parliament resolution of 14 November 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2019)0057).
  - European Parliament resolution of 14 May 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87708 × MON 89788 × A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9\_TA(2020)0069).

<sup>(5)</sup> EFSA opinion, p. 12.

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- F. whereas, in addition, the stacked GM maize expresses a *Bacillus subtilis* modified CspB gene which aims to reduce yield loss caused by drought stress; whereas the nptII gene, conferring resistance to the antibiotics kanamycin and neomycin, was used as a selection marker in the genetic modification process <sup>(6)</sup>;
- G. whereas, on 3 July 2019, EFSA adopted a favourable opinion, which was published on 8 August 2019, in relation to that application;
- H. whereas Regulation (EC) No 1829/2003 states that GM food or feed must not have adverse effects on human health, animal health or the environment, and requires the Commission to take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision;

#### **Member State comments and lack of experimental data on sub-combinations**

- I. whereas Member States submitted many critical comments to EFSA during the three-month consultation period <sup>(7)</sup>; whereas those critical comments include the comment that potential interactions with environmental conditions, which may affect the content of transgenic proteins in the plant, are not accounted for, that unresolved questions remain regarding safety and possible toxicity, that the assessment ignores the herbicide residues and metabolites from glyphosate as well as concerns regarding the use of the antimicrobial resistant gene NPTII;
- J. whereas no experimental data were provided by the applicant for the currently unauthorised 14 sub-combinations of the stacked GM maize <sup>(8)</sup>;

#### **Lack of assessment of herbicide residues and break-down products**

- K. whereas a number of studies show that herbicide-tolerant GM crops result in a higher use of 'complementary' herbicides, due in large part to the emergence of herbicide-tolerant weeds <sup>(9)</sup>; whereas, as a consequence, it has to be expected that the stacked GM maize will be exposed to both higher and repeated doses of glyphosate, and that therefore a higher quantity of residues may be present in the harvest; whereas the stacked GM maize expresses three glyphosate-tolerant proteins, making it even more tolerant to higher dosages and repeated spraying;
- L. whereas questions concerning the carcinogenicity of glyphosate remain; whereas EFSA concluded in November 2015 that glyphosate was unlikely to be carcinogenic and the European Chemicals Agency concluded in March 2017 that no classification was warranted; whereas, on the contrary, in 2015, the International Agency for Research on Cancer, the specialised cancer agency of the World Health Organization, classified glyphosate as a probable carcinogen for humans;
- M. whereas in its scientific opinion of 3 July 2019, the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel) states that 'the assessment of herbicide residues relevant for this application has been investigated by the EFSA Pesticides Unit' <sup>(10)</sup>; whereas, according to an opinion by the EFSA Pesticides Unit however, data on glyphosate residues on GM maize with EPSPS modifications <sup>(11)</sup> are insufficient to derive maximum residue levels and risk assessment values <sup>(12)</sup>;

<sup>(6)</sup> EFSA opinion, p. 12.

<sup>(7)</sup> Member State comments: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00686>

<sup>(8)</sup> EFSA opinion, p. 4.

<sup>(9)</sup> See, for example, Bonny, S., 'Genetically Modified Herbicide-Tolerant Crops, Weeds, and Herbicides: Overview and Impact', *Environmental Management*, January 2016, 57(1), pp. 31-48, <https://www.ncbi.nlm.nih.gov/pubmed/26296738> and Benbrook, C.M., 'Impacts of genetically engineered crops on pesticide use in the U.S. — the first sixteen years', *Environmental Sciences Europe* 24, 24 (2012), <https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24>, and Schütte, G., Eckerstorfer, M., Rastelli, V. et al., 'Herbicide resistance and biodiversity: agronomic and environmental aspects of genetically modified herbicide-resistant plants', *Environmental Sciences Europe* 29, 5 (2017), <https://enveurope.springeropen.com/articles/10.1186/s12302-016-0100-y>

<sup>(10)</sup> EFSA opinion, p. 9.

<sup>(11)</sup> The stacked GM maize contains an EPSPS modification.

<sup>(12)</sup> EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005 — revised version to take into account omitted data. *EFSA Journal* 2019;17(10):5862, p. 4, <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5862>

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- N. whereas, according to the EFSA Pesticides Unit, toxicological data allowing a consumer risk assessment to be performed for several break-down products of glyphosate relevant for GM glyphosate-tolerant crops are missing <sup>(13)</sup>;
- O. whereas assessment of herbicide residues and herbicide break-down products found on GM plants, along with their potential interaction with Bt proteins, is considered outside the remit of the EFSA GMO Panel and is therefore not undertaken as part of the authorisation process for GMOs; whereas this is problematic, since the way in which complementary herbicides are broken down by the GM plant concerned, and the composition and thus toxicity of the breakdown products, can be driven by the genetic modification itself <sup>(14)</sup>;
- P. whereas it therefore cannot be concluded that consumption of the stacked GM maize or its sub-combinations is safe for human and animal health;

**Bt proteins**

- Q. whereas a number of studies show that side effects have been observed that may affect the immune system following exposure to Bt proteins and that some Bt proteins may have adjuvant properties <sup>(15)</sup>, meaning that they can increase the allergenicity of other proteins that they come into contact with;
- R. whereas a minority opinion adopted by a member of the EFSA GMO Panel in the process of assessing another stacked GM maize and its sub-combinations found that, while unintended effects on the immune system have never been identified in any application where Bt proteins are expressed, they could 'not be observed by the toxicological studies [...] currently recommended and performed for the safety assessment of GM plants at EFSA because they do not include the appropriate tests for this purpose' <sup>(16)</sup>;
- S. whereas a recent study has shown that a rapid rise in the use of neonicotinoid seed treatments in the United States coincides with increased planting of GM Bt maize <sup>(17)</sup>; whereas the Union has banned the outdoor use of three neonicotinoids, including as seed coatings, because of their impact on honeybees and other pollinators <sup>(18)</sup>;

**Inclusion of antibiotic resistance marker gene**

- T. whereas the stacked GM maize produces the protein NPTII that confers resistance to a range of antibiotics including neomycin and kanamycin which are classified as 'critically important for human and veterinary use' by the WHO <sup>(19)</sup>; whereas NPTII was used as a marker to facilitate the selection process of transformed cells;

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<sup>(13)</sup> EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, *EFSA Journal* 2015; 13 (11):4302, p. 3, <https://www.efsa.europa.eu/en/efsajournal/pub/4302>

<sup>(14)</sup> This is indeed the case for glyphosate, as stated in EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005, *EFSA Journal* 2018;16(5):5263, p. 12, <https://www.efsa.europa.eu/fr/efsajournal/pub/5263>

<sup>(15)</sup> For a review, see Rubio-Infante, N., Moreno-Fierros, L., 'An overview of the safety and biological effects of *Bacillus thuringiensis* Cry toxins in mammals', *Journal of Applied Toxicology*, May 2016, 36(5): pp. 630-648, <http://onlinelibrary.wiley.com/doi/10.1002/jat.3252/full>

<sup>(16)</sup> Application EFSA-GMO-DE-2010-86 (Bt11 × MIR162 × 1507 × GA21 maize and three sub combinations independently of their origin), Minority Opinion, Wal, J.M., Member of the EFSA GMO Panel, *EFSA Journal* 2018;16(7):5309, p. 34, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5309>

<sup>(17)</sup> Douglas, M.R., Tooker, J.F., 'Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops', *Environmental Science and Technology* 2015, 49, 8, 5088-5097, <https://pubs.acs.org/doi/10.1021/es506141g>

<sup>(18)</sup> Neonicotinoids, [https://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/approval\\_renewal/neonicotinoids\\_en](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en)

<sup>(19)</sup> <http://apps.who.int/iris/bitstream/handle/10665/255027/9789241512220-eng.pdf;jsessionid=11933F77EEEE4-D6E7BD574889996C4E6?sequence=1>, p. 21.



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- U. whereas Article 4(2) of Directive 2001/18/EC of the European Parliament and of the Council <sup>(20)</sup> requires that GMOs which contain genes expressing resistance to antibiotics which are used for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment and that the overall aim is to identify and phase out GMO antibiotic resistance marker genes (ARMGs) which may have adverse effects on human health or on the environment;
- V. whereas recital 17 of Commission Implementing Regulation (EU) No 503/2013 <sup>(21)</sup> states that ‘it is now possible to develop GMOs without the use of antibiotic resistance marker genes [...] the applicant should therefore aim to develop GMOs without the use of antibiotic resistance marker genes’;
- W. whereas Austria has formally objected to the placing on the market of the stacked GM maize due to the inclusion of NPTII, ‘which may facilitate the dissemination of antimicrobial resistance in soil and gut bacteria’, and ‘[c]onsidering the current crisis in antibiotic resistance’, Austria ‘cannot support a deliberate fuelling of the environmental antibiotic resistance gene pool by this product’; whereas Austria goes onto saying that ‘[b]y not removing this resistance gene from the commercialized product — although technically possible [...] — the applicant is violating Commission Implementing Regulation [(EU) No 503/2013] on the “insertion of marker genes and other nucleic acid(s) sequences not essential to achieve the desired trait” and Directive 2001/18/EC on phasing out of antibiotic resistance genes’ <sup>(22)</sup>;

### ***Drought trait***

- X. whereas the stacked GM maize expresses a *Bacillus subtilis* modified CspB gene, which helps to reduce yield loss caused by drought stress; whereas, however, no field trials of the GM stacked maize took place under drought conditions; whereas, however, stress conditions, such as drought, are likely to impact plant composition and biological characteristics crucial for the assessment of food and feed safety;

### ***Undemocratic decision-making***

- Y. whereas the vote on 15 September 2020 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003 delivered no opinion, meaning that the authorisation was not supported by a qualified majority of Member States;
- Z. whereas the Commission recognises that the fact that GMO authorisation decisions continue to be adopted by the Commission without a qualified majority of Member States in favour, which is very much the exception for product authorisations as a whole but which has become the norm for decision-making on GM food and feed authorisations, is problematic;
- AA. whereas, in its eighth term, Parliament adopted a total of 36 resolutions objecting to the placing on the market of GMOs for food and feed (33 resolutions) and to the cultivation of GMOs in the Union (three resolutions); whereas, to date, Parliament has adopted eight objections in its ninth term; whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas despite its own acknowledgement of the democratic shortcomings, the lack of support from Member States and the objections of Parliament, the Commission continues to authorise GMOs;

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<sup>(20)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>(21)</sup> Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1).

<sup>(22)</sup> Summary report of the Standing Committee on Plants, Animals, Food and Feed Section Genetically Modified Food and Feed, 15 September 2020, [https://ec.europa.eu/food/sites/food/files/plant/docs/sc\\_modif-genet\\_20200915\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/sc_modif-genet_20200915_sum.pdf)

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- AB. whereas, under Regulation (EU) No 182/2011, the Commission may decide not to authorise a GMO when there is no qualified majority of Member States in favour in the Appeal Committee <sup>(23)</sup>; whereas no change of law is required in this respect;
1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;
  2. Considers that the draft Commission implementing decision is not consistent with Union law, in that it is not compatible with the aim of Regulation (EC) No 1829/2003, which is, in accordance with the general principles laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(24)</sup>, to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests, in relation to GM food and feed, while ensuring the effective functioning of the internal market;
  3. Calls on the Commission to withdraw its draft implementing decision;
  4. Welcomes the fact that the Commission finally recognised, in a letter of 11 September 2020 to Members, the need to take sustainability into account when it comes to authorisation decisions on GMOs <sup>(25)</sup>; expresses its strong disappointment, however, that, on 28 September 2020, the Commission authorised another GM soybean for import <sup>(26)</sup> despite an objection by Parliament and a majority of Member States voting against;
  5. Calls on the Commission to move forward with the utmost urgency concerning the development of sustainability criteria, with full involvement of Parliament; calls on the Commission to provide information on how this process will be undertaken and in what timeframe;
  6. Urges the Commission, again, to take into account the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN Convention on Biological Diversity and the UN Sustainable Development Goals;
  7. Reiterates its call on the Commission to stop authorising GMOs, whether for cultivation or for food and feed uses, when no opinion is delivered by Member States in the Appeal Committee, in accordance with Article 6(3) of Regulation (EU) No 182/2011;
  8. Reiterates its calls on the Commission not to authorise herbicide-tolerant GM crops until the health risks associated with the residues have been comprehensively investigated on a case-by-case basis, which requires a full assessment of the residues from spraying such GM crops with complementary herbicides, an assessment of the herbicide break-down products and any combinatorial effects;
  9. Reiterates its call on the Commission to fully integrate the risk assessment of the application of complementary herbicides and their residues into the risk assessment of herbicide-tolerant GM plants, regardless of whether the GM plant concerned is to be cultivated in the Union or is for import into the Union for food and feed uses;
  10. Calls on the Commission not to authorise any sub-combinations of stacked GM events unless they have been thoroughly evaluated by EFSA on the basis of complete data submitted by the applicant;
  11. Considers, more specifically, that to approve GM crop varieties for which no safety data have been provided, which have not been tested, or which have not even been created yet, runs contrary to the principles of general food law, as laid down in Regulation (EC) No 178/2002;
  12. Calls on EFSA to further develop and systematically use methods that permit the identification of unintended effects of stacked GM events, such as in relation to the adjuvant properties of Bt toxins;

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<sup>(23)</sup> The Commission 'may, and not 'shall', go ahead with authorisation if there is no qualified majority of Member States in favour at the Appeal Committee, according to Article 6(3) of Regulation (EU) No 182/2011.

<sup>(24)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(25)</sup> <https://tillymetz.lu/wp-content/uploads/2020/09/Co-signed-letter-MEP-Metz.pdf>

<sup>(26)</sup> MON 87708 × MON 89788 × A5547-127, [https://webgate.ec.europa.eu/dyna/gm\\_register/gm\\_register\\_auth.cfm?pr\\_id=100](https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=100)

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13. Reiterates its call on the Commission not to authorise, the placing on the market of any GM plants containing genes which confer antimicrobial resistance; notes that authorisation would be in violation of Article 4(2) of Directive 2001/18/EC which calls for a phase out of GMO ARMGs which may have adverse effects on human health or on the environment;
  14. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.
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## **Sustainable Europe Investment Plan — How to finance the Green Deal**

### **European Parliament resolution of 13 November 2020 on the Sustainable Europe Investment Plan — How to finance the Green Deal (2020/2058(INI))**

(2021/C 415/04)

*The European Parliament,*

- having regard to the Commission communication of 14 January 2020 entitled ‘Sustainable Europe Investment Plan — European Green Deal Investment Plan’ (COM(2020)0021),
- having regard to the Commission communication of 11 December 2019 entitled ‘The European Green Deal’ (COM(2019)0640), and to its resolution thereon of 15 January 2020 <sup>(1)</sup>,
- having regard to the Commission proposal of 2 May 2018 for a Council regulation laying down the multiannual financial framework (MFF) for the years 2021 to 2027 (COM(2018)0322) and to the amended proposal of 28 May 2020 (COM(2020)0443), together with the amended proposal of 28 May 2020 for a decision on the system of Own Resources of the European Union (COM(2020)0445),
- having regard to its interim report of 14 November 2018 on the Multiannual Financial Framework 2021-2027 — Parliament’s position with a view to an agreement <sup>(2)</sup>,
- having regard to its resolution of 10 October 2019 on the 2021-2027 multiannual financial framework and own resources: time to meet citizens’ expectations <sup>(3)</sup>,
- having regard to its resolution of 15 May 2020 on the new multiannual financial framework, own resources and the recovery plan <sup>(4)</sup>,
- having regard to the final report and recommendations of the High Level Group on Own Resources of December 2016,
- having regard to its legislative resolution of 16 September 2020 on the draft Council decision on the system of own resources of the European Union <sup>(5)</sup>,
- having regard to the Commission communication of 27 May 2020 entitled ‘Europe’s moment: Repair and Prepare for the Next Generation’ (COM(2020)0456) and its accompanying legislative proposals,
- having regard to Directive (EU) 2018/410 of the European Parliament and of the Council of 14 March 2018 amending Directive 2003/87/EC to enhance cost-effective emission reductions and low-carbon investments, and Decision (EU) 2015/1814 of the European Parliament and of the Council of 6 October 2015 concerning the establishment and operation of a market stability reserve for the Union greenhouse gas emission trading scheme and amending Directive 2003/87/EC,

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<sup>(1)</sup> Texts adopted, P9\_TA(2020)0005.

<sup>(2)</sup> Texts adopted, P8\_TA(2018)0449.

<sup>(3)</sup> Texts adopted, P9\_TA(2019)0032.

<sup>(4)</sup> Texts adopted, P9\_TA(2020)0124.

<sup>(5)</sup> Texts adopted, P9\_TA(2020)0220.

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- having regard to its resolution of 18 December 2019 on fair taxation in a digitalised and globalised economy: BEPS 2.0 <sup>(6)</sup>,
  - having regard to its resolution of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences <sup>(7)</sup>,
  - having regard to the final report by the High Level Expert Group on Sustainable Finance (HLEG) of 31 January 2018,
  - having regard to the Commission communication of 8 March 2018 entitled ‘Action plan: Financing Sustainable Growth’ (COM(2018)0097),
  - having regard to its resolution of 29 May 2018 on sustainable finance <sup>(8)</sup>,
  - having regard to its resolution of 23 July 2020 on the conclusions of the extraordinary European Council meeting of 17-21 July 2020 <sup>(9)</sup>,
  - having regard to Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088, and Regulation (EU) 2019/2088 of the European Parliament and of the Council of 27 November 2019 on sustainability-related disclosures in the financial sector,
  - having regard to the Commission’s quarterly European Economic Forecasts,
  - having regard to the United Nations Framework Convention on Climate Change (UNFCCC), to the Kyoto Protocol thereto and to the Paris Agreement,
  - having regard to United Nations-supported Principles for Responsible Investment, Principles for Responsible Banking and Principles for Sustainable Insurance,
  - having regard to the European Pillar of Social Rights, the International Bill of Human Rights, the OECD Guidelines for Multinational Enterprises, the UN Guiding Principles on Business and Human Rights, the UN Sustainable Development Goals and the International Labour Organisation’s declaration on Fundamental Rights and Principles at Work and the eight ILO core conventions,
  - having regard to the statutes of the European Central Bank (ECB),
  - having regard to the Treaty on the Functioning of the European Union (TFEU),
  - having regard to the joint deliberations of the Committee on Budgets and the Committee on Economic and Monetary Affairs under Rule 58 of its Rules of Procedure,
  - having regard to Rule 54 of its Rules of Procedure,
  - having regard to the opinions of the Committee on the Environment, Public Health and Food Safety, the Committee on Transport and Tourism, the Committee on Agriculture and Rural Development and the Committee on Culture and Education,
  - having regard to the report of the Committee on Budgets and the Committee on Economic and Monetary Affairs (A9-0198/2020),
- A. whereas the necessary investments for climate change adaptation have not yet been assessed and incorporated into MFF climate figures;

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<sup>(6)</sup> Texts adopted, P9\_TA(2019)0102.

<sup>(7)</sup> Texts adopted, P9\_TA(2020)0054.

<sup>(8)</sup> OJ C 76, 9.3.2020, p. 23.

<sup>(9)</sup> Texts adopted, P9\_TA(2020)0206.

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- B. whereas the path to climate neutrality by 2050 will boost the competitiveness of the Union economy, and result in a surplus of sustainable, high quality jobs;
- C. whereas the 2019 International Panel on Climate Change (IPCC) special report on global warming of 1,5 °C makes it clear that policies adopted so far are insufficient to prevent global warming from exceeding 1,5 °C, biodiversity loss, and the disturbance of biogeochemical flows;
- D. whereas the EU climate law will set in stone the EU's commitment to climate neutrality by 2050, including ambitious intermediary steps needed to achieve this objective;
- E. whereas the Commission has estimated the investment needed at EU level to achieve the current 2030 climate objectives at EUR 240 billion per year<sup>(10)</sup> plus additional amounts of EUR 130 billion per year for environmental objectives, EUR 192 billion per year for social infrastructure and EUR 100 billion per year for Europe's wider transport infrastructure; whereas this adds up to a total of at least EUR 662 billion of investment needs per year; whereas these figures are based on a 2030 climate objective of lowering greenhouse gas (GHG) emissions by 40 %; whereas now that the Parliament has agreed on more ambitious objectives, the investment gap is even higher; whereas it is essential to mobilise all available funds to close the investment gap;
- F. whereas Article 2(1) of the Paris Agreement calls for 'making finance flows consistent with a pathway towards low greenhouse gas emissions and climate-resilient development';
- G. whereas the European Green Deal is a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy, where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use, and which should also contribute to ensuring the strategic autonomy of the EU;
- H. whereas the COVID-19 pandemic underlines the importance of investments in a socially and environmentally sustainable economy, in particular investments promoting cutting edge R&D, a competitive industrial sector, a deeper and stronger single market, strong SMEs, healthcare, a robust welfare system and social wellbeing;
- I. whereas the spending required to support European economies raises the question of how debt incurred will be repaid; whereas it is important to prevent an increase in inequalities, as occurred following the previous crisis;
- J. whereas creating a sustainable economic system is central to developing the long-term strategic autonomy of the EU and to increase the EU's resilience;
- K. whereas trade policy has an impact on greenhouse gas (GHG) emissions;
- L. whereas GHG emissions from transport represent 27 % of global EU emissions and are the only ones still increasing; whereas transport must contribute in a technologically neutral way to reaching the EU emissions reduction targets of the EU that aim for climate neutrality by 2050, while making sure that transport remains affordable and competitive; whereas reduction of transport sector emissions can be accelerated for both infrastructure and the vehicle fleet by developing and strengthening synergies with other sectors, such as digital or energy;
- M. whereas tax exemptions for the aviation and maritime sectors may also distort competition between industrial sectors, and may promote inefficient and polluting modes of transport;
- N. whereas Article 2 of the Statutes of the ECB provides that, if the objective of price stability is achieved and is not called into question, the ECB's monetary policy must be conducted with a view to furthering the objectives of the EU laid down in Article 3 of the Treaty on European Union (TEU), which provides among other objectives for the protection of the quality of the environment;

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<sup>(10)</sup> [https://ec.europa.eu/info/sites/info/files/economy-finance/assessment\\_of\\_economic\\_and\\_investment\\_needs.pdf](https://ec.europa.eu/info/sites/info/files/economy-finance/assessment_of_economic_and_investment_needs.pdf)

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- O. whereas in the context of its monetary policy strategy review, the ECB will assess whether and how, acting within its mandate, it can take into account sustainability considerations, and in particular risks related to environmental sustainability;
- P. whereas the activation of the general escape clause aims to allow Member States to pursue a fiscal policy that will facilitate the implementation of all measures necessary to adequately deal with the crisis while remaining within the rules-based framework of the Stability and Growth Pact (SGP); whereas the general escape clause stipulates that its application should not endanger fiscal sustainability;
1. Welcomes the Sustainable Europe Investment Plan (SEIP) as central to ensuring the success of the Green Deal and the transition towards a more sustainable, competitive, circular and resilient economy, in line with Union's environmental commitments, including climate commitments under the Paris Agreement and the EU climate law; stresses that the plan should be at the heart of a coordinated and inclusive Union response to building a more resilient economy and society after the COVID-19 pandemic, and should foster territorial, social and economic cohesion; points out that sustainability must be in compliance with financial stability considerations;
  2. Welcomes the Commission's Recovery Plan for Europe, which has the European Green Deal and Digitalisation Strategy at its heart; endorses the underlying principle that public investments will respect the 'do no significant harm' (DNSH) principle, and highlights that this principle applies to both social and environmental objectives; emphasises that national recovery and resilience plans should put the EU on the path to climate neutrality by 2050, as enshrined in the EU climate law, including the 2030 intermediate targets, thus ensuring Member States' transition towards a circular and climate neutral economy, based on science and timebound climate targets;
  3. Recalls that investments under the Recovery and Resilience Facility must respect the 'do no harm' principle; stresses that climate-relevant investments should be in line with the EU Taxonomy and that national recovery plans should be aligned with the National Energy and Climate Plans (NECPs);
  4. Considers that achieving a fair transition to climate neutrality is a major responsibility for the EU; calls for the implementation of appropriate measures and policies to make this transformation a success, involving the public and private sectors, regions, cities and Member States; calls for investments to be prioritised to support a sustainable transition, the digital agenda and European sovereignty in strategic sectors by means of a consistent industrial strategy; believes that digitalisation of the public and private sectors will help in reaching climate neutrality;
  5. Stresses that the success of the EU's aim to achieve climate neutrality and be a circular economy by 2050 will depend, among other factors, on adequate financing and coherent integration of sustainability into public and private finance; underlines the fact that public financing alone will not be sufficient to reach the aforementioned goals and contribute to the transition; stresses that substantial additional amounts of sustainable public and private investments will be needed; calls on the Commission, therefore, to encourage public and private investments when developing the SEIP; underlines the fact that, even with ambitious funding, available funds will not be unlimited; considers it essential for the SEIP to provide for and enable additional investment with real added value and that does not crowd out market financing; calls on the Commission to establish a robust framework for reporting and monitoring to ensure that spending has a real impact; insists that the link between expenditure and revenue, particularly through the creation of new own resources, will be key to the implementation of the Green Deal;
  6. Notes that all sectors of the EU economy will be impacted by the transition towards a green economy, and insists that the path to climate neutrality should boost the competitiveness of the European economy and result in a net surplus of sustainable, high quality jobs in the Union; underlines the fact that the green transition should be inclusive and in line with the principles of economic, social and environmental sustainability; considers that the SEIP should leave nobody behind and focus, where necessary, on reducing disparities between Member States and regions in achieving climate neutrality objectives; recalls that saving and creating jobs, as well as additional training and reskilling, are of utmost importance in the sustainable energy transition;
  7. Stresses also that in order for the European Green Deal to be successful, European producers of sustainable products and services need to see its advantages;

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8. Calls on the Commission and Member States to make sure that the SEIP is adequately financed to ensure that future programmes, such as the Renovation Wave Strategy, will have a sufficient impact on every building in the EU, are made acceptable to all Union citizens, and are welcomed by them;

9. Questions whether the SEIP, in its current form, will enable the mobilisation of EUR 1 trillion by 2030, given the negative economic outlook following the COVID-19 pandemic; requests the Commission ensures full transparency on financing issues, such as the optimistic leverage effect, potential double-counting of certain investments, or the lack of clarity over the extrapolations of certain amounts; questions, further, how the new MFF proposed by the Commission and agreed in the European Council's Conclusions would enable the achievement of the SEIP targets; is concerned that by frontloading EU programmes, a green investment gap might arise at the end of the next MFF period; calls on the Commission and Member States to come forward with plans that explain how they will bridge the considerable investment gap by means of both private and public investments, including an assessment of the new economic outlook resulting from the current crisis and the expected increased ambition of the climate, energy and environmental goals for 2030; underlines the fact that the SEIP is an EU long-term goal and cannot be undermined by lower MFFs in the future which allocate a large proportion of money to the repayment of long-term debt;

10. Notes that the Commission, in its SEIP Communication of 14 January 2020, has estimated EU level investment needs for achieving the current 2030 climate objectives to be of at least EUR 662 billion per year; calls on the Commission to reflect these new figures in a revised SEIP architecture;

11. Calls on the Commission to disclose the exposure of all MFF and Next Generation EU funds to the different EU taxonomy objectives and categories;

12. Wishes to see it ensured that funding from the SEIP, at EU, national and regional level, goes towards the policies and programmes with the highest potential to contribute to the fight against climate change and other environmental objectives, including the transition of EU companies, in particular SMEs, to a more competitive Union and to job creation, while adapting to different national, regional and local needs; looks forward to the Commission's publication, before the start of the next MFF, of a framework for tracking climate, biodiversity and other sustainable spending using, as appropriate, the criteria established by the Taxonomy Regulation; calls for this framework to include, inter alia, a monitoring methodology, together with corresponding corrective measures, and a sustainability-proofing and tracking mechanism to identify harmful impacts in accordance with the DNSH principle and commitments under the Paris Agreement;

13. Highlights that the success of the SEIP depends on the adequacy of the public and private financing, and on the coherence of EU policies; underlines therefore the need for harmonised sustainability indicators and a methodology for measuring impact; insists that in the light of the SEIP, impact assessments should be initiated in relation to other pieces of legislation, whether they are still at the legislative stage or have already been adopted, to evaluate the compatibility of existing EU legislation with EU environmental goals;

14. Emphasises that one of the SEIP's objectives should be to ensure a shift from unsustainable to sustainable economic activities;

15. Believes that public and private finance should take into account the Taxonomy Regulation and adhere to the DNSH principle in order to ensure that EU policies and financing, including the EU budget, the programmes financed through Next Generation EU (NGEU), the European Semester, and European Investment Bank (EIB) financing do not contribute to projects and activities that significantly harm social or environmental objectives, and do not undermine economic competitiveness or result in job losses; stresses that public budgets and public banks will not be able to bridge the investment gaps alone; recalls that every year 10 major European banks still invest more than EUR 100 billion in fossil fuels; recalls that under the Taxonomy Regulation, the Commission must adopt by the end of 2020 a delegated act containing technical screening criteria for activities which substantially contribute to climate change mitigation and adaptation;



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16. Calls on the Commission to ensure that the new MFF does not support or invest in activities which would lead to a lock-in of assets that are harmful to the climate and environmental objectives of the Union, considering the lifetime of the assets;

17. Calls on the Commission to assess options to extend the use of the EU taxonomy for tracking climate and environment spending in all EU public funding, including the new MFF, InvestEU, the Next Generation EU instrument, the Solvency Support Instrument, the Recovery and Resilience Facility and European Investment Bank (EIB) funds;

18. Calls for an operationalisation of the DNSH principle in relevant EU funding regulations, for instance through climate, environmental and social sustainability proofing; recalls that strict investment rules should not be introduced without prior consultation of local and regional public authorities, industries and SMEs;

19. Calls on the Commission to assess and identify activities that significantly harm environmental sustainability, in line with Article 26(2)(a) of Regulation (EU) 2020/852 and as recommended by the European Central Bank and the central banks' and regulators' Network for Greening the Financial System (NFGS);

20. Calls for the realistic phasing-out of public and private investments in polluting and harmful economic activities, for which economically feasible alternatives are available, while fully respecting the rights of Member States to choose their energy mix, with the objective of implementing a renewable energy system and an energy grid that is compatible with the Paris Agreement; underlines the urgency of finding these alternatives through massive investments in technological innovation and energy efficiency; insists that SEIP-funded activities must not contribute to further social inequalities and the deepening of the East-West economic and social divide in the EU; recalls in this context that between 2014 and 2016, EUR 112 billion per year were spent by 11 countries and the European Union to subsidise fossil fuels; calls on the Commission and Member States to prepare strategies to phase out all environmentally harmful subsidies in order to improve the consistency and credibility of the EU in preserving biodiversity and natural ecosystems, and to boost the transition towards clean energy systems and a climate neutral and circular economy;

21. Considers that the transition to climate neutrality should preserve a level playing field for EU companies and their competitiveness, particularly in the case of unfair competition from third countries; believes that to achieve its aims, the SEIP should also contribute to sustainable European production, and reduce global emissions through trade policy; calls for trade agreements not to guarantee investor protection at the expense of environmental, social or health standards; underlines the importance of enforceable climate and other environmental standards being included in trade agreements entered into by the EU with third countries, also in order to ensure a level playing field for European companies; calls for it to be ensured that third countries are eligible for cross-border projects that contribute to the objectives of the Paris Agreement;

22. Underlines that Erasmus+, the European Solidarity Corps and Creative Europe, as the EU's main education, volunteering and culture programmes, constitute an essential tool in the global response to climate change, and play a key role in fostering education in the skills needed for the green transition, raising awareness of environmental and climate change issues, especially among young people volunteering to protect the environment, and developing creative, inclusive and accessible solutions to tackle environmental challenges; stresses that these programmes contribute to achieving the EU's sustainable development goals; highlights in this regard the importance of agricultural internships supported by Erasmus+;

### ***The EU budget: targeting, triggering and catalysing financial resources***

23. Stresses the central role of the EU budget in delivering the SEIP; reiterates its long-standing position that new initiatives should always be subject to sustainability assessment and proofing, should be financed through additional appropriations, and should not negatively affect other policies; highlights the importance of long-standing EU policies, such as cohesion or agriculture, together with other key policy areas, such as research, innovation or climate change adaptation and mitigation; calls on the Commission and Member States to deliver on their political commitments, and equip the Union with a future-oriented MFF that is capable of responding to citizens' expectations;

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24. Underlines the importance of sustainable private investments and their role in achieving the objectives of the SEIP, and believes that private financing needs to be facilitated; stresses further that technical support should be enhanced through local and national incubators and project nurseries that bring together financiers and project promoters;

25. Welcomes the European Council's acceptance of the European Union Recovery Instrument as an emergency instrument to support investments and reforms; deplores, however, the proposal to significantly reduce top-ups to several EU programmes, and to cancel them altogether for other programmes; believes that the proposed cuts to programmes supporting the transition of carbon-dependent regions run counter to the EU's Green Deal agenda, and will ultimately also affect the financing of the SEIP;

26. Underlines the fact that, in order to meet its obligations under the Paris Agreement, the EU's contribution to the climate objectives should be underpinned by an ambitious share of climate- and biodiversity-related expenditure in the EU budget; aims, therefore, to achieve as soon as possible a legally binding spending target of 30 % for climate mainstreaming and 10 % for biodiversity; stresses that the climate spending target should apply to the MFF as a whole; underlines the fact that a 37 % climate target should also be applicable to NGEU expenditure; urges the Commission to establish a meaningful and transparent tracking and monitoring framework for climate-related expenditure in the EU budget; stresses the essential role of new own resources in enabling the EU budget to reach a higher level of climate financing in the future;

27. Welcomes the proposal to top up the Just Transition Fund (JTF), with additional funds from NGEU, but regrets the Council's proposal to reduce these top-ups, and stresses that additional support will be needed to make sure that workers affected directly and indirectly by the transition receive adequate assistance; reiterates that resources from the JTF may complement the resources available under cohesion policy, and points out that the new proposal should not be to the detriment of cohesion policy through mandatory transfers from the national envelopes of the Member States and should not lead to distortions of competition;

28. Believes that the principle of a just transition should be mainstreamed throughout the Green Deal, and that the JTF should in particular focus on the regions most heavily dependent on fossil fuels; emphasises that projects receiving the funds must be environmentally, socially and economically sustainable and viable in the long term; calls therefore for a comprehensive EU strategy for the development and modernisation of the regions benefitting from the JTF;

29. Stresses that the drafting of the just transition plans should involve all relevant stakeholders; believes that just transition plans should take into account the different starting points of Member States and regions in the transition to climate neutrality; notes that there should be greater clarity on the eligibility criteria for funding; believes that the programmes financed by the JTF should also be assessed using climate tracking, natural capital accounting and life cycle methodologies;

30. Welcomes the two additional pillars of the Just Transition Mechanism, in particular a dedicated scheme under InvestEU and a public sector loan facility, which, together with the JTF will create new economic opportunities and contribute to alleviating the socio-economic effects of the transition to climate neutrality and the implementation of the circular economy in the EU in the most vulnerable and carbon-intensive regions and cities, and help address energy affordability challenges faced by citizens during the transition process; considers that, for these pillars to be a success, it is essential to guarantee sufficient technical assistance for Member States, regions and cities;

31. Stresses that a socially just transition will not be possible without a massive contribution by metropolitan areas; considers, therefore, that resources from the second and third pillars of the Just Transition Mechanism should be easily available for cities, in order to develop a large scale financial mechanism to help city-level climate and social efforts; points out that this may include directly accessible funds for, among others, housing policies, building renovation, retrofit and insulation programmes, public transport projects, improving cities' green infrastructure, the introduction of circular economy instruments or sustainable water management projects;

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32. Welcomes InvestEU's role in the implementation and functioning of the SEIP, and considers that it should play a key role in the Union's green, fair and resilient recovery; deplores the fact that the proposed financing of InvestEU, both through the MFF and NGEU, was significantly reduced compared to the latest Commission proposal; welcomes the proposal to create a Strategic Investment Facility, particularly the addition of a fifth window — the European investment window — within InvestEU to promote sustainable investments in key technologies and value chains; stresses that projects financed under InvestEU should be consistent with the Union's 2030 climate and environment commitments;

33. Underlines the fact that the revised Commission proposal already integrates the preliminary agreement on InvestEU reached between Parliament and Council in May 2019; recalls that in addition to a privileged position for the EIB Group, this agreement also provides for an important role for other implementing partners, such as national promotional banks or other international financial institutions; recalls, moreover, that InvestEU is a demand-driven instrument, and that for this reason excessive sectoral or geographical concentration should be avoided; stresses that it is necessary to ensure that adequate technical assistance is available on the ground in order for projects to be financed where they are most needed, and in a way that provides genuine additionality; highlights, in this respect, the vital contribution of the Advisory Hub, for which an adequate financial allocation needs to be ensured;

34. Reaffirms the EU's responsibility, as global leader in the fight against climate change, to encourage other international partners to follow a similar approach; believes that the resources that the EU Budget grants to third countries should not be spent in any way that runs counter to the objectives of the Green Deal, and should aim to facilitate the achievement of its objectives, taking into account the different level of development of every country, and their varying investment needs; considers that the pandemic has demonstrated that action to protect the environment and biodiversity outside the Union is inseparably linked with health at home, and that such action is cost-effective when compared with the impacts of the pandemic;

35. Notes that the Innovation Fund and the Modernisation Fund should make a significant contribution to the sustainable transition towards net zero GHG emissions by 2020, and welcomes in particular the fact that the Modernisation Fund is designed to support investments to improve energy efficiency in 10 lower income Member States, and is therefore an important tool for ensuring a just transition; highlights nonetheless the need for heightened scrutiny of the Fund, as investments into activities which significantly harm social and environmental objectives should not be eligible under the Modernisation Fund;

36. Considers it necessary to avoid any overlap with related activities funded through the Union budget, and believes that the existence of these Funds outside the Union budget could be to the detriment of budgetary oversight; urges the Commission to keep the budgetary authority properly informed of the Funds' implementation;

37. Welcomes the Commission's intention to review both the Modernisation Fund and the Innovation Fund as part of its revision of the Emissions Trading Scheme (ETS); reiterates its long-standing demand to classify a significant proportion of ETS revenues as own resources;

38. Stresses the important role that the Common Agricultural Policy (CAP) and the Common Fisheries Policy will have to play in achieving the objectives of the SEIP; notes that on the path of the EU agricultural and fisheries sectors towards a more sustainable management of natural resources and preservation of biodiversity, the CAP should maintain its objectives of supporting the provision of a high-quality food supply, guaranteeing food sovereignty for Europeans, contributing to stable and acceptable earnings for farmers and fishers, and contributing to the sustainable development of rural areas; highlights the need to ensure that the CAP contributes to the EU's climate and sustainability goals, as underlined by the European Court of Auditors' report of 7 November 2018;

39. Underlines the importance of facilitating access to public and private finance to support increased green investment, the development of, and access to, digitalisation tools, modernisation and innovation, which will enable the agricultural sector, the fisheries sector and rural areas to meet the challenges and opportunities of realising the objectives and ambition of the Green Deal;

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40. Stresses that cohesion policy, as the main EU investment policy, will play a crucial role in supporting the transition to climate neutrality; draws attention to the fact that, in the aftermath of the COVID-19 pandemic, cohesion policy will be one of the decisive instruments in the sustainable economic recovery, and should keep its long-standing role of contributing to the promotion of social, economic and territorial cohesion, as laid down in the EU Treaties; insists that cohesion policy should be reinforced to allow it to meet its main objectives and contribute to the success of the European Green Deal;

41. Supports the Commission's innovative approach reflected in its statement that the EU budget will contribute to achieving climate and environmental objectives through its revenue side as well; recalls Parliament's position in favour of introducing new own resources that can generate added value and substantially support the European Green Deal;

42. Reaffirms its previous position regarding the list of potential candidates for new own resources, as set out in its interim report on the MFF, which should correspond to essential EU objectives including the fight against climate change and the protection of the environment; asks, therefore, for the introduction, without creating any additional burden on citizens, of new own resources, which could, for example, include resources for which the Commission gave figures in 2018 based on:

- (i) the auction revenues of the ETS, which could raise between EUR 3 and 10 billion per year,
- (ii) a contribution on non-recycled plastic packaging waste, which could raise between EUR 3 and 10 billion per year,
- (iii) the future carbon border adjustment mechanism, which could raise between EUR 5 and 14 billion per year,
- (iv) a common consolidated corporate tax base, which could raise more than EUR 12 billion per year,
- (v) a tax on large digital companies, which could raise between EUR 750 million and 1,3 billion per year, and,
- (vi) a financial transaction tax (FTT), which, based on the original Commission proposal from 2012 and taking into account Brexit and economic growth, could raise up to EUR 57 billion per year, depending on the scope of the tax;

reiterates, in this regard, its call to all Member States to join the enhanced cooperation framework on the FTT; calls on the Commission to provide details about the own resources presented in its Communication of 27 May 2020 on the Recovery Plan as soon as possible, including on the levy based on the operations of large enterprises and the possible extension of the ETS to the maritime and aviation sectors;

43. Insists that a basket of new own resources should be included in the EU budget as of 2021, while a legally binding calendar should also be established to propose and introduce new own resources in the course of the next MFF; calls for the proceeds from the new own resources to be sufficient to cover at least the repayment obligations under the Recovery Instrument; expects that any revenue beyond that level should flow into the EU budget to bridge, inter alia, the funding gap in the Green Deal, without affecting the principle of universality;

44. Underlines the fact that both types of revenue, environmental and non-specifically environmental, will be indispensable for the establishment of a reliable basket of genuine new own resources, since the income produced by environmental revenues could proportionally decrease over time as the EU advances towards climate neutrality;

***Financial institutions — enabling the implementation of the Green Deal***

45. Welcomes the EIB's decision to revise its energy lending policy and climate strategy, and to devote 50 % of its operations to climate action and environmental sustainability from 2025 onwards with the aim of achieving the EU's obligations under the Paris Agreement; calls on the EIB to also revise its transport lending policy, and to commit to the sustainable transition towards climate neutrality and a circular economy while taking into account the different energy

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mixes of Member States, and devoting particular attention to the sectors and regions most affected by the transition; calls in particular for new policies to be implemented in the carbon-intensive industrial sectors in which the EIB is active in order to support the transition of these sectors with a view to aligning all new sectoral loans to the goal of achieving climate neutrality by 2050 at the latest; commends the EIB's commitment to ending financing of fossil fuel energy projects by 2021; requires the adoption and publication of verifiable transition plans to reach climate neutrality objectives;

46. Stresses that the EIB's response to the COVID-19 pandemic should be consistent with the objectives of the SEIP; notes, however, that not all projects financed can contribute to achieving the EU's climate objectives, and insists that this should not prevent their financing; is of the opinion, however, that the EIB's portfolio must be aligned with EU sustainability goals and the DNSH principle; calls on the EIB to establish a concrete roadmap for reaching the 50 % granular target by 2025, and to disclose annually the share of its assets that finances activities that qualify as environmentally sustainable according to the EU Taxonomy; recalls that the Bank's response to the COVID-19 pandemic should generate EUR 240 billion of investments, and was made possible in a matter of weeks;

47. Considers that for the EIB to play a successful role in financing the Green Deal, a bottom-up and participatory approach is crucial, and that the EIB should promote specific dialogues between the public and private sectors, and better coordinate with various stakeholders, such as local and regional authorities, and representatives from civil society; stresses furthermore the EIB's independence, while underlining the importance of ensuring democratic scrutiny of investments;

48. Recalls that the EIB is the world's largest issuer of green bonds, having raised more than EUR 23 billion over 11 years; notes that a major challenge has been to set common standards so as to avoid greenwashing; welcomes the EIB's new Sustainability Awareness Bonds, launched in 2018 and designed to support investment related to the UN Sustainable Development Goals; underlines the importance of setting common standards for these new bonds to ensure that projects are transparent, verifiable and measurable; calls on the EIB to continue this activity and to expand the issuance of green bonds and sustainability awareness bonds, which can facilitate the implementation of the SEIP and help develop the market for social and environmental sustainability bonds, building on work under the EU Action Plan on Financing Sustainable Growth and the EU Taxonomy;

49. Encourages the EIB to play an active role in supporting projects that contribute to a just transition, such as research, innovation and digitalisation, SME access to finance, and social investment and skills;

50. Notes that the EIB President, Werner Hoyer, has emphasised the need to strengthen the EIB's capital base in order to allow it to carry on with the ambitious projects underpinning the transition to a sustainable economy;

51. Recognises the important role of the national promotional banks and institutions (NPBIs) and of international financial institutions (IFIs), including the European Bank for Reconstruction and Development and the World Bank, in the financing of sustainable projects, thereby contributing to the achievement of the Paris Agreement goals; stresses that given their experience and capabilities at national and regional level, NPBIs can be instrumental in maximising the impact of public funds, including through partnerships under InvestEU, thereby helping to achieve the Union's climate objectives; underlines the fact that the financing of SMEs is key to the successful implementation of the SEIP;

52. Underlines also the fact that NPBIs are well versed in the conception, management and financing of relatively small projects, because of their experience in this field; welcomes, therefore, their involvement in various aspects of the SEIP, as the bodies best suited to channel European level investments to the real economy and at local scale; underlines the importance of ensuring local technical support for project promoters and innovation, and highlights the role of project nurseries in helping projects to mature sufficiently to receive financing; calls for State aid reforms that will allow NPBIs to provide preferential loans to promote sustainability;

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53. Notes that public and private investment can help sustainable recovery and resilience where finance is directed to green investments, such as electricity grids, supergrids and smart grids, railway networks, energy efficiency, and circular economy projects;

54. Emphasises that environmental and climate disasters pose increasing financial stability risks, and that, therefore, prudential regulation and supervision should better incorporate those long-term risks in their assessments; considers that the fight against climate change and the promotion of sustainability should be taken account of more in ECB policies, while fully respecting its mandate and independence, and without jeopardising its role as a guardian of financial and monetary stability; recalls the statement of its President that the ECB is supporting the development of a taxonomy as a way of facilitating the incorporation of environmental considerations in central bank portfolios; notes the ambition displayed in the recent Eurosystem reply to the Commission's public consultations on the Renewed Sustainable Finance Strategy and the revision of the Non-Financial Reporting Directive (NFRD), which stated that market forces can and should be a key driver of the redirection of financial flows towards sustainable economic activities; welcomes the calls from the ECB and the Central Banks and Regulators' Network for Greening the Financial System (NGFS) for financial regulators to better assess sustainability-related financial risks;

55. Encourages the ECB to move forward with its monetary policy strategy in full respect of the ECB's price stability mandate enshrined in the TFEU; notes that as part of its monetary policy strategy review, the ECB will assess, in line with the Paris Agreement, whether and how, acting within its mandate, it can take sustainability considerations — and in particular risks related to environmental sustainability — into account in its collateral framework and annual stress testing exercise, while keeping a separation between monetary policy and prudential supervision roles; encourages, furthermore, the ECB to disclose the level of alignment of monetary policy with the Paris Agreement, while setting a roadmap for future alignment, using the EU taxonomy for these actions appropriately; invites the ECB to look at further ways of supporting the EIB in order to increase the EIB's financing capacity without creating market distortions;

56. Suggests the ECB should assess the rebalancing of its carbon-intensive bond portfolio in the context of the Corporate Sector Purchase Programme (CSPP) in the light of the EIB's climate commitments;

57. Calls on the European Supervisory Authorities (ESAs), together with national competent authorities (NCAs), to develop annual climate stress tests on the financial institutions under their supervision, as currently discussed in particular in the NGFS, in order to understand where climate-related financial risks lie in the portfolios of relevant EU financial institutions, and the extent of those risks;

58. Believes that public transport is central to achieving sustainable urban mobility; stresses the need to increase support for public transport networks and fleets at a local and regional level as an effective tool for the transition and towards low-emission mobility, while promoting modal shift, especially in metropolitan centres, and connectivity in rural areas to promote territorial cohesion; considers a stronger articulation of urban transport financing with the Sustainable Urban Mobility Plans (SUMPs) to be essential to boosting the transformation of urban mobility; calls on the Commission to cooperate with the Member States in developing sustainable urban mobility plans and policies, including support for efficient public transport systems and active mobility solutions, such as walking and cycling, and the promotion of accessibility and multimodality among different modes of transport;

### ***Mobilising private investments for a sustainable recovery***

59. Supports a renewed sustainable finance strategy; underlines the need for an evolving EU eco-label for financial products, for an EU Green Bond Standard (EU GBS), and for more reliable, comparable and accessible sustainability data obtained by harmonising sustainability indicators; recalls the considerable importance of green finance to the international role of the EU and the euro in the next decade; highlights the importance for SMEs of simplified reporting standards that allow them to fully participate in capital markets;

60. Insists that more reliable, comparable and accessible sustainability data is indispensable to making the EU's sustainable finance system work in practice; welcomes the idea of the High Level Forum on the Capital Markets Union to establish a European single access point (ESAP) to aggregate information about companies in the EU through the

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interconnection of existing national and EU registers and company databases as a way to help companies, in particular in smaller Member States, to attract investors; stresses that companies should be able to control the availability of their data in the ESAP; calls on the Commission to submit a legislative proposal for a European single access point for financial and non-financial information on listed and unlisted EU companies, while also respecting the proportionality principle where appropriate; calls on the Commission to streamline the transparency requirements under the NFRD and bring them into line with those under the Taxonomy Regulation and the Sustainable Finance Disclosure Regulation; calls for transparent methodologies in the gathering and publishing of data; calls on the Commission to put in place effective data monitoring and reporting of the SEIP's implementation, making it available to the public so as to guarantee full transparency for EU green transition spending; deems that a significant share of the EU Bonds to be issued in the context of the Recovery plan are issued based on the EU GBS as proposed by the Commission;

61. Commends the progress made on the basis of the initiatives included in the 2018 Sustainable Finance Action Plan; calls for the adoption of the delegated acts provided for in the Taxonomy Regulation, taking into account the range of sustainability criteria and indicators; calls specifically for a swift implementation of the DNSH principle as outlined in the Sustainable Finance and Disclosure and Taxonomy Regulations; highlights the importance of ambitious disclosure requirements for all financial products and entities;

62. Considers that the future renewed EU sustainable finance strategy is a major opportunity to accelerate the transition towards more sustainable retail investment; calls on the Commission to propose the measures needed to incentivise sustainable retail investment;

63. Takes note of Article 26(2) of the Taxonomy Regulation, which mandates the Commission to publish by 31 December 2021 a report describing the provisions that would be required to extend the scope of that Regulation beyond environmentally sustainable economic activities, including other sustainability objectives, such as social objectives;

64. Endorses the call by the High Level Expert Group on Sustainable Finance for new measures to foster long-termism, which benefits people and the planet; invites the Commission to analyse and propose how a long-term perspective can be better incorporated in the corporate governance regime and rules; welcomes the preparation of a sustainable corporate governance initiative;

65. Calls on the Commission to consider a revision of the NFRD, which could incorporate the disclosure of the impact of corporate activities on environmental, social and governance sustainability;

66. Insists that in mobilising finance for the Green Deal, public and private investment must complement each other where possible; stresses that private sector investment should not be crowded out so that funding for the SEIP can be maximised;

67. Recalls that investments and lending in unsustainable economic activities may lead to stranded assets or sunk investments, with lock-in effects; points out that this risk needs to be sufficiently integrated in credit ratings and prudential frameworks, including the Basel framework; calls on the Commission, therefore, to examine ways of improving the inclusion of sustainability risks and the prudential treatment of long-term investments and lending, including in the EU Banking Rule Book, which will additionally promote overall financial systemic stability, and to further seek to promote reliability, comparability and transparency of sustainability factors in credit ratings; believes that the latter could be addressed in forthcoming reviews of the Credit Rating Agencies Regulation, the Capital Requirements Directive Regulation/Directive and the Solvency frameworks;

68. Recalls that sustainable investments do not necessarily come with a lower risk-profile than other types of investments;

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69. Believes that it should be made easier for SMEs in the Union to access public and private financing under the SEIP; highlights the need for additional efforts to inform SMEs about the new financing opportunities under the SEIP;

***Promoting sustainable public investment in times of crisis***

70. Calls for the creation of an instrument for sustainable investments to achieve the goals set out in the European Green Deal, but stresses that whatever financing model is chosen, increased levels of public investment should contribute to the sustainability of public finance in the EU; considers that a possible review of the EU's economic governance framework should consider the recommendations of the independent European Fiscal Board and should stimulate Member States to bring their economies and public expenditure into line with the goals of the European Green Deal; supports the Commission's pledge to explore other enabling frameworks, such as Green Bond Standards, and encourages the Commission to map best practices on green budgeting;

71. Calls for public support for the transport sector, especially airlines, the tourism sector and the automobile sector, to be used in a sustainable and efficient manner; calls for transitional activities defined in the Taxonomy Regulation to be eligible to receive funding under the SEIP, and calls for special attention to be paid to access to funding and other forms of support for micro-enterprises and SMEs;

72. Calls for the mainstreaming of sustainable public procurement and tendering, and increased European coordination in this regard;

73. Welcomes the fact that recovery and resilience plans will be based on shared EU priorities; highlights in this regard the European Green Deal and the European Pillar of Social Rights, as well as the Digital Agenda and the strategic aim of achieving European sovereignty in strategic sectors, with a sustainable industrial base; recalls the need for green recovery investment and the need to increase convergence among Member States in implementing the SEIP, which could help to speed up economic recovery; calls for the inclusion of priorities in areas such as employment, skills, education, digital entrepreneurship, research and innovation, and health, but also in areas related to business and the non-profit sector, including public administration and the financial sector; calls on the Commission to provide technical assistance to public authorities in drafting transition plans so as to avoid stranded assets; calls on the Commission to monitor the implementation of the recovery and resilience plans, and to ensure that serious breaches lead to the recovery of allocations paid; stresses the importance of respect for the rule of law and our democratic values by the Member States issuing the plans;

74. Insists that the European Green Deal's 'do no harm' principle applies to all recovery plans;

75. Regrets the decision by the European Council to remove the Solvency Support Instrument from the NGEU programme; sees it as an important tool to level the playing field in the single market;

76. Calls for companies benefitting from public support to commit to public country-by-country reporting, while respecting the possibility for temporary derogations provided for to protect commercially sensitive information; calls for these companies to also ensure fair competition, reduce the gender pay gap, respect their non-financial reporting obligations, guarantee jobs, disclose any beneficial treatment received, and strictly refrain from engaging in any tax avoidance strategies via subsidiaries in non-cooperative jurisdictions for tax purposes without substantial economic activity; insists that these companies should contribute fairly to the recovery efforts by paying their fair share of taxes; seeks in this context a new social contract for business, harmonising profit aims with considerations for people and the planet;

77. Calls on the Commission to revise the rules on State aid, including the Temporary Framework introduced as a response to the COVID-19 pandemic, as needed in order to obtain greater public support for the European Green Deal and ensure that State aid support is conditional on meeting the Union's climate and environmental objectives; notes that any revision of State aid rules should be carefully designed to prevent distortions of competition in the internal market, and ensure its integrity and a level playing field in any future revision;



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78. Calls on the Commission, when approving a State aid request by a Member State in accordance with Article 108 TFEU, to include in its decision provisions requiring beneficiaries in carbon-intensive sectors to adopt climate targets and green transition roadmaps, and demonstrate the alignment of their business model and activities with the objectives set out in Chapter 2 of Regulation (EU) 2018/1999;

79. Welcomes the planned revision of the Energy Taxation Directive for 2021, and calls on the Commission to present legislative proposals to bring VAT rates in line with environmental considerations, introduce a single-use plastic levy, and increase relevant minimum excise duties that have lost their effect due to inflation; seeks to pair these reforms with efforts to maintain purchasing power for those with the lowest income levels in the European Union;

80. Recalls the increasing investment needs related to the green transition, and that corporate tax evasion and tax avoidance cause potential lost resources for national and EU budgets quantified as ranging from EUR 50-70 billion to EUR 160-190 billion which could be used for investment in the SEIP; calls on Member States to mobilise resources to finance the sustainable and just transition by implementing any potential OECD inclusive framework agreement, including Pillar 2 thereunder; calls for an intensified fight against tax fraud, tax evasion, tax avoidance and aggressive tax planning; calls for EU-level coordination to detect, investigate and avoid aggressive tax planning schemes by individuals and corporations; calls for an ambitious strategy on business taxation for the 21st century; calls on the Council to update the criteria on the definition of harmful tax regimes in the Code of Conduct on Business Taxation, and reiterates its position of 26 March 2019 on Member States facilitating aggressive tax planning; encourages the Commission to establish criteria to assess Member States' tax practices; reminds the Commission of Article 116 TFEU in the context of tax-related dossiers, and encourages the Commission to make use of that provision in order to avoid distortions of competition within the single market;

81. Wishes it to be ensured that everybody contributes equitably to the post-COVID-19 recovery and the transition towards a competitive and sustainable economy, while taking into account the different capacities of Member States; considers that, as highlighted by ECB President Christine Lagarde on 7 July 2020, the vulnerable often 'are the most affected' by the COVID-19 pandemic, while asset prices have so far gone up throughout the crisis; encourages Member States and the Commission to look into new resources to fund the economic recovery that take this into account;

82. Stresses that the increased financing of the Green Deal will imply a significant degree both of budgetary discipline and of scrutiny in order to prevent fraud and the diversion of funds; notes that the European Anti-Fraud Office (OLAF) lacks capacity to prevent financial fraud on its own; calls therefore on all Member States to join the European Public Prosecutor's Office (EPPO);

83. Believes that the combination of the proposals in this report can raise the EUR 660 billion per year needed to win the battle for climate and jobs;

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84. Instructs its President to forward this resolution to the Commission and the governments and Parliaments of the Member States.

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P9\_TA(2020)0307

## **The impact of COVID-19 measures on democracy, the rule of law and fundamental rights**

### **European Parliament resolution of 13 November 2020 on the impact of COVID-19 measures on democracy, the rule of law and fundamental rights (2020/2790(RSP))**

(2021/C 415/05)

*The European Parliament,*

- having regard to the Universal Declaration of Human Rights (UDHR) and other UN human rights treaties and instruments, particularly the International Covenant on Civil and Political Rights,
- having regard to the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) and the protocols thereto,
- having regard to the Treaty on European Union (TEU), the Treaty on the Functioning of the European Union (TFEU) and the Charter of Fundamental Rights of the European Union,
- having regard to the European Charter of Patients' Rights,
- having regard to the declarations of the UN Secretary General, the UN High Commissioner for Human Rights, the UN special rapporteurs, the UN Refugee Agency (UNHCR) and other UN bodies on the impact of COVID-19 measures on democracy, rule of law and fundamental rights,
- having regard to the UN Sustainable Development Goals (SDGs),
- having regard to the declarations of and documents produced by the representatives and bodies of the Council of Europe, notably its Secretary General, the president and rapporteurs of its Parliamentary Assembly (PACE), the Commissioner for Human Rights, the Commission for the Efficiency of Justice (CEPEJ), the Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), the Congress of Local and Regional Authorities and the Group of States against Corruption (GRECO) on the impact of COVID-19 measures on democracy, rule of law and fundamental rights,
- having regard to the Council of Europe publication of 7 April 2020 entitled 'Respecting democracy, rule of law and human rights in the framework of the COVID-19 sanitary crisis — A toolkit for member states',
- having regard to the relevant documents of the Venice Commission of the Council of Europe, including the compilation of Venice Commission opinions and reports on states of emergency<sup>(1)</sup>, published on 16 April 2020, the report of 26 May 2020 entitled 'Respect for democracy, human rights and the rule of law during states of emergency — Reflections'<sup>(2)</sup>, the Observatory of situations of emergency in Venice Commission member states<sup>(3)</sup>, its 2011 report on the rule of law<sup>(4)</sup> and its 2016 rule of law checklist<sup>(5)</sup>,

<sup>(1)</sup> Compilation of Venice Commission opinions and reports on states of emergency, 16 April 2020, CDL-PI(2020)003.

<sup>(2)</sup> Respect for democracy, human rights and the rule of law during states of emergency — Reflections (CDL-PI(2020)005rev).

<sup>(3)</sup> Observatory of situations of emergency in Venice Commission member states.

<sup>(4)</sup> Report on the rule of law (CDL-AD(2011)003rev).

<sup>(5)</sup> Rule of law checklist (CDL-AD(2016)007).

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- having regard to the request by its President to the Venice Commission of 1 July 2020, following the proposal of the Committee on Civil Liberties, Justice and Home Affairs (LIBE), and the subsequent interim report of 8 October 2020 on the measures taken in the EU Member States as a result of the COVID-19 crisis and their impact on democracy, the rule of law and fundamental rights <sup>(6)</sup>,
- having regard to the PACE resolutions of 13 October 2020 on democracies facing the COVID-19 pandemic <sup>(7)</sup> and on the impact of the COVID-19 pandemic on human rights and the rule of law <sup>(8)</sup>,
- having regard to the opinion of the Organization for Security and Co-operation in Europe (OSCE) of 27 April 2020 on the Draft Act on Special Rules for Conducting the General Election of the President of the Republic of Poland Ordered in 2020 (Senate Paper No.99) and to the declarations by the OSCE Representative on Freedom of the Media,
- having regard to the statement on Hungary by the Spokesperson for the UN High Commissioner for Human Rights, Rupert Colville, of 27 March 2020,
- having regard to the joint statement on Bulgaria of the UN Special Rapporteurs on contemporary forms of racism and on minority issues of 13 May 2020,
- having regard to the publications of the International Institute for Democracy and Electoral Assistance (International IDEA) of 11 May 2020 entitled 'Parliaments in Crisis: Challenges and Innovations' <sup>(9)</sup> and of 26 March 2020 entitled 'Elections and COVID-19' <sup>(10)</sup>,
- having regard to the wide debate that has taken place on the impact of COVID-19 measures on democracy, rule of law and fundamental rights, involving citizens, the academic community, civil society and society at large <sup>(11)</sup>,
- having regard to the Commission's actions in relation to COVID-19, across all fields of its competence, and its efforts to coordinate a European response to the pandemic in domains ranging from the Schengen area to disinformation on the virus, and from data protection and apps to asylum, return and resettlement procedures,
- having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) <sup>(12)</sup>,

<sup>(6)</sup> Venice Commission, Interim report on the measures taken in the EU Member States as a result of the COVID-19 crisis and their impact on democracy, the rule of law and fundamental rights, 8 October 2020 (CDL-AD(2020)018).

<sup>(7)</sup> PACE, Resolution 2337 (2020).

<sup>(8)</sup> PACE, Resolution 2338 (2020).

<sup>(9)</sup> International IDEA, Parliamentary Primer No. 1, 11 May 2020. <https://www.idea.int/publications/catalogue/parliaments-and-crisis-challenges-and-innovations>

<sup>(10)</sup> International IDEA, Technical Paper 1/2020, 26 March 2020. <https://www.idea.int/publications/catalogue/elections-and-covid-19>

<sup>(11)</sup> See for example Verfassungsblog academic articles on COVID-19 and states of emergency, Michael Meyer-Resende, The Rule of Law Stress Test: EU Member States' Responses to COVID-19, with Table and Map, Joelle Grogan, States of emergency; Fondation Robert Schuman, Le contrôle parlementaire dans la crise sanitaire Impacts of COVID-19 — The Global Access to Justice Survey: <https://verfassungsblog.de/impacts-of-covid-19-the-global-access-to-justice-survey/>; Oxford COVID-19 Government Response Tracker (OxCGRT) measuring the stringency of restrictive measures; ICNL COVID-19 Civic Freedom Tracker; Grogan, Joelle & Weinberg, Nyasha (August 2020) Principles to Uphold the Rule of Law and Good Governance in Public Health Emergencies. RECONNECT Policy Brief; International Appeal 'A Call to Defend Democracy', an Open Letter.

<sup>(12)</sup> OJ L 119, 4.5.2016, p. 1.

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- having regard to Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector <sup>(13)</sup>,
- having regard to Guidelines 04/2020 of the European Data Protection Board (EDPB) on the use of location data and contact tracing tools in the context of the COVID-19 outbreak and to Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak,
- having regard to the Commission communication of 16 April 2020 entitled ‘Guidance on Apps supporting the fight against COVID-19 pandemic in relation to data protection’ (C(2020)2523),
- having regard to the Commission communication of 30 September 2020 entitled ‘2020 Rule of Law Report — The rule of law situation in the European Union’ (COM(2020)0580) and its 27 accompanying country chapters on the rule of law in the Member States (SWD(2020)0300-0326), which address the impact of the COVID-19 measures taken by the Member States on democracy, the rule of law and fundamental rights,
- having regard to the statement of 1 April 2020 by 19 Member States in which they expressed deep concern ‘about the risk of violations of the principles of rule of law, democracy and fundamental rights arising from the adoption of certain emergency measures’ <sup>(14)</sup>,
- having regard to its resolution of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences <sup>(15)</sup>,
- having regard to its resolution of 19 June 2020 on the situation in the Schengen area following the COVID-19 outbreak <sup>(16)</sup>,
- having regard to its resolution of 19 June 2020 on European protection of cross-border and seasonal workers in the context of the COVID-19 crisis <sup>(17)</sup>,
- having regard to its resolution of 10 July 2020 on the EU’s public health strategy post-COVID-19 <sup>(18)</sup>,
- having regard to its resolution of 17 September 2020 entitled ‘COVID-19: EU coordination of health assessments and risk classification, and the consequences for Schengen and the single market’ <sup>(19)</sup>,
- having regard to its resolution of 17 September 2020 on the proposal for a Council decision on the determination of a clear risk of a serious breach by the Republic of Poland of the rule of law <sup>(20)</sup>,
- having regard to its resolution of 7 October 2020 on the establishment of an EU Mechanism on Democracy, the Rule of Law and Fundamental Rights <sup>(21)</sup>,

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<sup>(13)</sup> OJ L 201, 31.7.2002, p. 37.

<sup>(14)</sup> Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, Bulgaria, Cyprus, Estonia, Latvia, Lithuania and Romania:

<https://www.government.nl/documents/diplomatic-statements/2020/04/01/statement-by-belgium-denmark-finland-france-germany-greece-ireland-italy-luxembourg-the-netherlands-portugal-spain-sweden>

<sup>(15)</sup> Texts adopted, P9\_TA(2020)0054.

<sup>(16)</sup> Texts adopted, P9\_TA(2020)0175.

<sup>(17)</sup> Texts adopted, P9\_TA(2020)0176.

<sup>(18)</sup> Texts adopted, P9\_TA(2020)0205.

<sup>(19)</sup> Texts adopted, P9\_TA(2020)0240.

<sup>(20)</sup> Texts adopted, P9\_TA(2020)0225.

<sup>(21)</sup> Texts adopted, P9\_TA(2020)0251.

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- having regard to its resolution of 8 October 2020 on the rule of law and fundamental rights in Bulgaria <sup>(22)</sup>,
  
- having regard to the briefing published by its Policy Department for Citizens' Rights and Constitutional Affairs on 23 April 2020 entitled 'The Impact of COVID-19 Measures on Democracy, the Rule of Law and Fundamental Rights in the EU' <sup>(23)</sup>, summarising the main findings of the monitoring exercise launched through the weekly overviews of the COVID-19 measures taken by the Member States,
  
- having regard to the briefings of the European Centre for Parliamentary Research and Documentation on parliamentary activity during the COVID-19 outbreak <sup>(24)</sup>,
  
- having regard to the European Parliamentary Research Service (EPRS) briefings linked to the state of emergency in response to the coronavirus crisis in several Member States and other relevant briefings on this topic <sup>(25)</sup>,
  
- having regard to the five bulletins of the EU Agency for Fundamental Rights (FRA) on the fundamental rights implications of the coronavirus pandemic in the EU <sup>(26)</sup>,
  
- having regard to the statement of the Vice-President of the Commission / High Representative of the Union for Foreign Affairs and Security Policy (VP/HR), Josep Borrell, of 18 June 2020 on tackling COVID-19 disinformation and the impact on freedom of expression,
  
- having regard to the Europol Internet Organised Crime Threat Assessment (IOCTA) 2020, published on 5 October 2020,

<sup>(22)</sup> Texts adopted, P9\_TA(2020)0264.

<sup>(23)</sup> [https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/651343/IPOL\\_BRI\(2020\)651343\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/651343/IPOL_BRI(2020)651343_EN.pdf)

<sup>(24)</sup> Briefing N° 27 — March 2020, Adjustment of Parliamentary Activity to COVID-19 Outbreak and the prospect of remote sessions and voting; Briefing N° 28 — March 2020, Preventive and sanitary measures in Parliaments; Briefing N°29 — July 2020, Emergency Laws and Legal measures against Covid-19.

<sup>(25)</sup> EPRS, States of emergency in response to the coronavirus crisis: Situation in certain Member States (Belgium, France, Germany, Hungary, Italy, Poland, Spain), 4 May 2020; EPRS, States of emergency in response to the coronavirus crisis: Situation in certain Member States II (Bulgaria, Estonia, Latvia, Malta, Austria, Romania, and Slovenia), 13 May 2020; EPRS, Tracking mobile devices to fight coronavirus, 2 April 2020; EPRS, Tackling the coronavirus outbreak: Impact on asylum-seekers in the EU, 22 April 2020; EPRS, The impact of coronavirus on Schengen borders, 27 April 2020; EPRS, The impact of coronavirus on media freedom, 8 May 2020; EPRS, Coronavirus and elections in selected Member States, 17 June 2020; EPRS, States of emergency in response to the coronavirus crisis: Situation in certain Member States IV, 7 July 2020. EPRS, Coronavirus and prisons in the EU: Member-State measures to reduce spread of the virus, 22 June 2020; EPRS, States of emergency in response to the coronavirus crisis: Situation in certain Member States IV, 7 July 2020.

<sup>(26)</sup> FRA, Coronavirus pandemic in the EU — Fundamental Rights Implications — Bulletin 1 and Country research, 7 April 2020; FRA, Coronavirus pandemic in the EU — Fundamental Rights Implications — Bulletin 2: With a focus on contact-tracing apps, and Country research, 28 May 2020; FRA, Coronavirus pandemic in the EU — Fundamental rights Implications — Bulletin 3: With a focus on older people and Country research, 30 June 2020; FRA, Coronavirus pandemic in the EU — Fundamental Rights Implications — Bulletin 4, 30 July 2020, focusing on racism, asylum and migration, disinformation, privacy and data protection; FRA, Coronavirus pandemic in the EU — Impact on Roma and Travellers — Bulletin 5, 29 September 2020.

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- having regard to the Europol report of 19 June 2020 entitled ‘Exploiting Isolation: Offenders and victims of online child sexual abuse during the COVID-19 pandemic’,
  - having regard to the Europol report of 30 April 2020 entitled ‘Beyond the pandemic — How COVID-19 will shape the serious and organised crime landscape in the EU’,
  - having regard to the preparatory work undertaken for this resolution by the Democracy, Rule of Law and Fundamental Rights Monitoring Group (DRFMG) of the Committee on Civil Liberties, Justice and Home Affairs (LIBE), including its report to the LIBE Committee of 10 July 2020 <sup>(27)</sup>,
  - having regard to the question to the Commission on the impact of COVID-19 measures on democracy, rule of law and fundamental rights (O-000065/2020 — B9-0023/2020),
  - having regard to Rules 136(5) and 132(2) of its Rules of Procedure,
  - having regard to the motion for a resolution of the Committee on Civil Liberties, Justice and Home Affairs,
- A. whereas the COVID-19 pandemic has created distress across the entire EU and has deeply affected the population; whereas many areas of the world, including the EU, are experiencing a second wave of COVID-19 cases and governments are adopting new restrictive measures to address the spike in cases, including the reintroduction of lockdowns and sanitary measures, the use of masks and harsher fines for non-compliance;
- B. whereas government-led emergency measures that respect the rule of law, fundamental rights and democratic accountability are needed to combat the pandemic and should be the cornerstone of all efforts to control the spread of COVID-19; whereas emergency powers require additional scrutiny to ensure that they are not used as a pretext for changing the balance of powers more permanently; whereas measures taken by governments should be necessary, proportional and temporary; whereas emergency powers carry a risk of abuse of power by the executive and of remaining in the national legal framework once the emergency is over, and consequently appropriate parliamentary and judicial oversight, both internal and external, and counterbalances have to be ensured to limit this risk;
- C. whereas the COVID-19 crisis is unprecedented; whereas in the future we need to rethink our crisis management methods at both Member State and EU levels;
- D. whereas a number of EU countries have declared a state of emergency <sup>(28)</sup> on the basis of their constitutions <sup>(29)</sup> which have in some cases caused legal concerns, while others have resorted to emergency powers provided for under ordinary law <sup>(30)</sup> or to normal legislation <sup>(31)</sup> to urgently adopt restrictive measures in order to counter the COVID-19 epidemic; whereas these measures have an impact on democracy, the rule of law and fundamental rights as they affect the exercise of individual rights and freedoms, such as freedom of movement, freedom of assembly and of association, freedom of expression and information, freedom of religion, the right to family life, the right of asylum, the principle of equality and non-discrimination, the right to privacy and data protection, the right to education and the right to work; whereas these measures also have an impact on the economies of Member States;

<sup>(27)</sup> LIBE/9/02808 report of 10 July 2020.

<sup>(28)</sup> Compilation of Venice Commission opinions and reports on states of emergency, CDL-PI(2020)003.

<sup>(29)</sup> De jure constitutional state of emergency, spring 2020: Bulgaria, the Czech Republic, Finland, Estonia, Hungary, Latvia, Luxembourg, Romania, Portugal and Spain.

<sup>(30)</sup> Germany, Latvia, France, Italy and Slovakia.

<sup>(31)</sup> De facto state of emergency based on ordinary legislation: 13 Member States have not declared a de jure state of emergency during the COVID-19 crisis, notably: Austria, Belgium, Croatia, Cyprus, Denmark, Greece, Ireland, Lithuania, Malta, Netherlands, Poland, Slovenia and Sweden, plus the UK.

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- E. whereas the functioning of democracies and the checks and balances to which they are subject are impacted when a health emergency situation causes shifts in the distribution of powers such as allowing the executive to acquire new powers to limit individual rights and to exercise competences usually reserved for the legislature and local authorities, while imposing constraints on the role of parliaments, the judiciary, civil society and the media, as well as the activities and involvement of citizens; whereas in most Member States there are no specific restrictions on the judiciary, but lockdown measures have made it near impossible for courts to operate in a normal manner;
- F. whereas internal judicial oversight, complemented by external oversight, continues to be fundamental, as the rights to a fair trial and to effective legal remedies continue to apply during a state of emergency so that individuals affected by emergency measures have effective recourse in the event that state authorities interfere with their fundamental rights and to guarantee that the executive does not exceed its powers;
- G. whereas the Venice Commission supports the constitutional *de jure* state of emergency, rather than the *de facto* state of emergency based on ordinary legislation, as ‘a system of *de jure* constitutional emergency powers can provide better guarantees for fundamental rights, democracy and the rule of law, and better serve the principle of legal certainty, deriving therefrom’<sup>(32)</sup>;
- H. whereas the COVID-19 crisis has been and continues to be a stress test for democracies and the resilience of national safeguards for the rule of law and fundamental rights;
- I. whereas trust in the actions of governments and states is paramount to ensure support for and implementation of the emergency measures adopted; whereas in order to achieve this in a democracy, transparent, science-based and democratic decisions, as well as dialogue with and the involvement of the opposition, civil society and stakeholders, are fundamental;
- J. whereas the Commission has monitored the emergency measures taken by the governments of the Member States throughout the crisis; whereas Commission President Ursula von der Leyen stated on 31 March 2020 that ‘any emergency measures must be limited to what is necessary and strictly proportionate. They must not last indefinitely. Moreover, governments must make sure that such measures are subject to regular scrutiny. The European Commission will closely monitor, in a spirit of cooperation, the application of emergency measures in all Member States’<sup>(33)</sup>, and whereas Commissioner Didier Reynders made a similar statement on 26 March 2020;
- K. whereas ‘nearly all EU Member States have introduced temporary (i.e. with a time limit) emergency measures to deal with the COVID-19 crisis<sup>(34)</sup> [...] mainly through ordinary legislation’; whereas ‘the first emergency measures were generally introduced for a period of 15 days to approximately one month across all EU Member States’ and were then renewed at least once; whereas according to the Venice Commission ‘only a few EU Member States did not prescribe a time limit for the application of emergency measures’<sup>(35)</sup>;
- L. whereas the Venice Commission recommends that ‘declarations or measures that have no specific time limit, including those whose suspension is made conditional upon overcoming the exceptional situation, should not be considered as lawful if there is no regular review of the situation’<sup>(36)</sup>;

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<sup>(32)</sup> Venice Commission, Interim report on the measures taken in the EU member States as a result of the Covid-19 crisis and their impact on democracy, the Rule of Law and Fundamental Rights, 8 October 2020 (CDL-AD(2020)018), paragraph 57.

<sup>(33)</sup> [https://ec.europa.eu/commission/presscorner/detail/en/statement\\_20\\_567](https://ec.europa.eu/commission/presscorner/detail/en/statement_20_567)

<sup>(34)</sup> Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden; Venice Commission opinion, Interim Report on the measures taken in the EU member States as a result of the Covid-19 crisis and their impact on democracy, the rule of law and fundamental rights, Opinion No. 995/2020 (CDL-AD(2020)018), paragraph 46.

<sup>(35)</sup> Croatia, Hungary; Venice Commission, Interim Report, paragraph 47.

<sup>(36)</sup> Venice Commission, Interim Report, paragraph 48.

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- M. whereas emergency measures must be non-discriminatory and governments must not take advantage of emergency legislation to push through restrictions on fundamental rights; whereas governments must also undertake a range of additional actions to reduce the potential negative impact that such measures might have on people's lives;
- N. whereas the state of emergency has been prolonged at least once in almost all the Member States in which it has been declared; whereas the Venice Commission underlined that the review of the declaration and prolongation of the state of emergency, as well as of the activation and application of emergency powers, is vital and that parliamentary and judicial control should be possible <sup>(37)</sup>;
- O. whereas parliamentary scrutiny has been limited in most Member States owing to the use of exceptional executive powers, while parliaments in some Member States have been relegated to a secondary role, allowing governments to rapidly introduce emergency measures without sufficient scrutiny;
- P. whereas the European Parliament, in particular the LIBE Committee and its Democracy, Rule of Law and Fundamental Rights Monitoring Group, has continuously monitored the situation within the EU since March 2020 and has held regular exchanges with stakeholders, as reflected in the DRFMG working document on the impact of COVID-19 on democracy, the rule of law and fundamental rights <sup>(38)</sup>;
- Q. whereas ombudsman institutions and National Human Rights Institutions play an important role in detecting fundamental rights problems and in providing scrutiny, oversight and redress, and therefore in protecting citizens in relation to emergency measures;
- R. whereas freedom of movement has been restricted across the Member States through obligatory or recommended self-isolation and bans on non-essential movement; whereas as a response to the COVID-19 pandemic, most Schengen area states have reintroduced internal border controls or have closed such borders, whether partially, totally, or to certain types of travellers, including EU citizens and their family members or third-country nationals residing on their territory or that of another Member State; whereas there was a clear lack of coordination among Member States and with the Union institutions when these measures were introduced <sup>(39)</sup>; whereas some Member States have introduced unlawful and discriminatory restrictions by not allowing residents of another EU nationality to enter their territory;
- S. whereas freedom of assembly and of association are important cornerstones of democracy; whereas the ability to exercise these rights has been restricted due to the necessary social distancing rules and public health precautions in the majority of Member States; whereas some Member States have decided to allow assemblies in compliance with social distancing rules while others have banned them altogether; whereas in some Member States, controversial laws and measures unrelated to the state of emergency have been examined without the possibility for citizens to demonstrate freely;
- T. whereas freedom of expression has been restricted in some Member States on the pretext of fighting disinformation; whereas arrests have been made for 'fearmongering' or 'endangering the public' following the publishing of critical thoughts on social media; whereas the coronavirus pandemic has been accompanied by a wave of false and misleading information, hoaxes, consumer fraud, cybercrime and conspiracy theories, as well as targeted disinformation campaigns by foreign actors, or even Member State public authorities, which pose numerous potential threats to EU citizens, their health and their trust in public institutions;
- U. whereas law enforcement authorities have in recent months seen a global increase in the amount of child sexual exploitation material shared online;

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<sup>(37)</sup> Venice Commission, Interim Report, paragraph 49.

<sup>(38)</sup> LIBE/9/02808 report of 10 July 2020.

<sup>(39)</sup> Texts adopted, P9\_TA(2020)0175.



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- V. whereas serious and organised crime is benefiting from the changing circumstances brought about by the pandemic; whereas the important role of Europol in monitoring the impact of the COVID-19 pandemic on serious and organised crime and terrorism in the EU from the outset of the pandemic must be acknowledged;
- W. whereas the media play a fundamental role in scrutiny and oversight, as well as being citizens' main sources of information; whereas media freedom has come under pressure as live press conferences have been cancelled without alternatives, and as some Member States have restricted access to public health information and limited the freedom to publish about public health policy; whereas there have been numerous accounts of questions from media outlets to governments being rejected or ignored; whereas journalists and media workers need to be protected when covering demonstrations and protests; whereas some Member States have restricted access to information by either extending or suspending deadlines for authorities to respond to freedom of information (FOI) requests;
- X. whereas Member States should ensure the protection of whistleblowers during the COVID-19 crisis, and beyond, as it has proven to be a powerful tool to fight and prevent actions that undermine the public interest<sup>(40)</sup>;
- Y. whereas some Member States have resorted to disproportionately repressive measures to enforce restrictions, such as the criminalisation of the violation of lockdown and quarantine rules resulting in high fines and lasting criminal records<sup>(41)</sup>;
- Z. whereas justice systems have been impacted by the general restrictions, with the temporary closing of many courts or reductions to their activity, sometimes resulting in backlogs and longer waiting times for hearings; whereas the procedural rights of suspects and the right to a fair trial are under pressure as access to lawyers has become more difficult due to the general restrictions and as courts are making increased use of online hearings;
- AA. whereas measures to combat the pandemic that restrict the right to privacy and data protection should always be necessary, proportionate and temporary in nature, with a solid legal basis; whereas new technologies have played an important part in the fight against the pandemic, but at the same time bring significant new challenges and have raised concerns; whereas the governments of some Member States have resorted to extraordinary surveillance of their citizens through the use of drones, police surveillance cars with cameras, tracking by means of location data from telecommunications providers, police and military patrols, monitoring of mandatory quarantines via house calls by the police or mandatory reporting via an app; whereas some Member States have introduced contact tracing apps, even though there is no consensus about their effectiveness and the most privacy-friendly, decentralised system is not always used; whereas in some Member States the reopening of public spaces has been accompanied by the collection of data through mandatory temperature checks and questionnaires and the obligation to share contact details, sometimes without due regard for the obligations that stem from the General Data Protection Regulation;
- AB. whereas lockdown measures and the closing of borders have had a profound impact on access to asylum procedures; whereas many Member States temporarily limited or even put on hold the processing of asylum requests, and most suspended Dublin transfers, returns and resettlement; whereas some Member States have declared their ports unsafe or not allowed the disembarkation of migrants rescued in search and rescue operations, leaving them in limbo for an unlimited period of time at sea and putting their lives at risk; whereas most Member States have now recommenced these activities; whereas outbreaks of COVID-19 have been reported in several asylum reception centres, resulting in vulnerable groups being put directly at risk, and whereas overcrowded camps at the EU's external borders continue to pose a particular risk of a massive outbreak as social distancing rules cannot be applied, while shelter and access to food, water, sanitation facilities, and mental and physical healthcare, including for those who have contracted COVID-19, are very limited;

<sup>(40)</sup> <https://www.ecpmf.eu/coalition-to-make-whistleblowing-safe-during-covid-19/>

<sup>(41)</sup> LIBE/9/02808 report of 10 July 2020.

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- AC. whereas prisons are at particularly high risk of COVID-19 outbreaks as social distancing and sanitation rules are often impossible to enforce, and sanitary measures have led to the limiting of time in the open air as well as bans on visitors which affect prisoners' right to communicate with their families; whereas the health of prison officers has been particularly at risk during this pandemic; whereas in some Member States, some specific categories of prisoners have been released with a view to decreasing health risks during the pandemic;
- AD. whereas the enforcement of COVID-19 restrictions should be proportionate and non-discriminatory in order to avoid targeting people belonging to ethnic minorities and marginalised groups; whereas the pandemic affects Romani people disproportionately, with women and children often being the most vulnerable groups, and particularly those living in socially excluded and marginalised settings with no access to drinking water or sanitary services where it is nearly impossible to follow social distancing rules or to comply with strict hygiene measures; whereas there have been reports of incidents of racism and xenophobia in several Member States where discrimination has taken place against people of a certain background or nationality; whereas persons of Asian descent and Romani people have been the targets of hate speech and attacks; whereas certain politicians in some Member States have used media reports of mass returns of Romani migrant workers from countries with a high prevalence of COVID-19 to fan fears about the spread of the virus, reinforcing negative attitudes and stereotypes;
- AE. whereas children are at a disproportionate risk of social and economic exclusion due to the lockdown measures and are facing increased risk of violation of their fundamental rights owing to abuse, violence, exploitation, and poverty; whereas many Member States have seen an increase in domestic violence due to the lockdown measures; whereas women and girls<sup>(42)</sup>, children and LGBTI+ persons are disproportionately at risk during lockdowns, as they can be exposed to abusers for long periods of time and can be cut off from social and institutional support; whereas community support for these vulnerable groups has been dramatically restricted given the measures taken in response to the pandemic;
- AF. whereas equal access to healthcare, a right enshrined in Article 35 of the Charter of Fundamental Rights, is potentially at risk due to measures taken to stop the spread of COVID-19, in particular for groups of people in vulnerable situations such as elderly or chronically ill persons, persons with disabilities, LGBTI+ persons, children, parents, pregnant women, homeless persons, all migrants including undocumented migrants, asylum seekers, refugees, and ethnic and other minorities; whereas sexual and reproductive health and rights services, have been negatively affected during the health crisis; whereas in some Member States access to reproductive health and rights, including the right to abortion, has been heavily restricted, resulting in a de facto ban that has forced demonstrators to take to the streets in the middle of a pandemic; whereas medicine shortages, the diversion of resources from other health issues and the abrupt cancellation of certain treatments, including IVF and transitioning treatments, may present risks to patients suffering from other illnesses<sup>(43)</sup>; whereas bereavement, isolation, the additional strain on work-life balance for parents and frontline workers, loss of income and fear are triggering mental health conditions or exacerbating existing ones, leading to an increased demand for mental health services and resulting in an urgent need to increase funding for these services;
- AG. whereas many Member States postponed elections<sup>(44)</sup>, and one a referendum<sup>(45)</sup>, owing to lockdowns imposed in the first phase of the health crisis; whereas elections have been taking place again since the pandemic entered its second phase; whereas the issue of holding or postponing elections is a delicate balancing exercise, on which the Venice Commission has developed reflections and guidelines<sup>(46)</sup>; whereas universal, free, secret and direct suffrage is only possible when open and fair electoral campaigning, freedom of expression, media freedom and freedom of assembly and association for political purposes, are guaranteed;

<sup>(42)</sup> <https://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=26083&LangID=E>

<sup>(43)</sup> [https://fra.europa.eu/sites/default/files/fra\\_uploads/fra-2020-coronavirus-pandemic-eu-bulletin\\_en.pdf](https://fra.europa.eu/sites/default/files/fra_uploads/fra-2020-coronavirus-pandemic-eu-bulletin_en.pdf), Bulletin No 1, p. 26.

<sup>(44)</sup> Germany, France, Italy, Spain, Austria, the Czech Republic, Poland and Latvia (extraordinary elections of Riga city council).

<sup>(45)</sup> Italy.

<sup>(46)</sup> Compilation of Venice Commission opinions and reports on states of emergency, CDL-PI(2020)003.

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AH. whereas the provisions of the Treaties in the area of freedom, security and justice must not affect the exercise of the responsibilities incumbent upon Member States with regard to the maintenance of law and order and the safeguarding of internal security, within the boundaries of the Union's values of democracy, the rule of law and fundamental rights, as stipulated in Article 2 of the TEU;

AI. whereas, according to the Treaties, limits on the Union's competences are governed by the principle of conferral and the use of Union competences is governed by the principles of subsidiarity and proportionality;

1. Recalls that, even in a state of public emergency, the fundamental principles of the rule of law, democracy and respect for fundamental rights must prevail, and that all emergency measures, derogations and limitations are subject to three general conditions, those of necessity, proportionality in the narrow sense and temporariness, conditions which have been regularly applied and interpreted in the case law of the European Court of Human Rights (ECtHR), the Court of Justice of the EU (CJEU) and various constitutional (and other) courts of the Member States<sup>(47)</sup>;

2. Believes that reactions to the crisis have, on the whole, shown the strength and resilience of national democratic systems; stresses that extraordinary measures should be matched by more intense communication between governments and parliaments; calls for a more intense dialogue with stakeholders including citizens, civil society and political opposition in order to build broad support for extraordinary measures and ensure that they are implemented as efficiently as possible, while avoiding repressive measures and ensuring unimpeded access to information for journalists;

3. Calls on the Member States to ensure that, when measures that could restrict the functioning of democratic institutions, the rule of law or fundamental rights are adopted, assessed or reviewed, those measures observe the recommendations of international bodies such as the UN and the Council of Europe, including the Venice Commission, and of the Commission's report on the rule of law situation in the EU; reiterates its call on the Member States not to abuse emergency powers to pass legislation unrelated to the COVID-19 health emergency objectives in order to surpass parliamentary oversight;

4. Calls on the Member States:

— to consider exiting the state of emergency or otherwise limiting their impact on democracy, the rule of law and fundamental rights,

— to evaluate the constitutional and institutional rules in force in their domestic orders in the light of the Venice Commission recommendations, for instance by moving from a *de facto* state of emergency based on ordinary legislation to a *de jure* constitutional state of emergency, hence providing for better guarantees of democracy, the rule of law and fundamental rights in the event of an emergency<sup>(48)</sup>; to explicitly define in a legislative act, where a *de facto* state of emergency is maintained, the objectives, content, and scope of the delegation of power from the legislature to the executive,

— to ensure that both the declaration and possible prolongation of the state of emergency, on the one hand, and the activation and application of emergency powers, on the other hand, are subject to effective parliamentary and judicial control, both internal and external, and to ensure that parliaments are entitled to discontinue the state of emergency<sup>(49)</sup>,

— to ensure that, if legislative powers are transferred to the executive, any legal acts issued by the executive be subject to subsequent parliamentary approval and cease to produce effects if they do not secure such approval within a certain period of time<sup>(50)</sup>; to address the excessive use of accelerated and emergency legislation, an issue also pointed out by the Commission in its 2020 Rule of Law Report (COM(2020)0580),

<sup>(47)</sup> Venice Commission, Interim report of 8 October 2020 (CDL-AD(2020)018), paragraphs 19 and 21.

<sup>(48)</sup> Venice Commission, Interim report of 8 October 2020 (CDL-AD(2020)018), paragraphs 29-31.

<sup>(49)</sup> Venice Commission, Interim report of 8 October 2020 (CDL-AD(2020)018), paragraphs 59-62.

<sup>(50)</sup> Venice Commission, Interim report of 8 October 2020 (CDL-AD(2020)018), paragraph 63.

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- to examine how better to guarantee the central role of parliaments in situations of crisis and emergency, in particular their role in monitoring and controlling the situation at national level,
  - to consider the Venice Commission's view that parliaments need to hold their plenary sessions and that they should not allow the temporary replacement of members or reduce their attendance (even if proportionally) <sup>(51)</sup>;
  - to examine the Venice Commission's reflections on elections and look into the possibility of using remote voting methods such as postal voting, internet voting, mobile ballot boxes and proxy voting, as well as early voting, in particular in the event of a pandemic;
5. Calls on the Member States to enforce the COVID-19 related measures with due regard to the proportionality of the enforcement measures; affirms that the enforcement of COVID-19 related measures needs to respect EU fundamental rights and the rule of law and considers that equal treatment of persons is crucial in that regard;
6. Calls on the Member States to evaluate the measures they have implemented which have restricted freedom of movement and to exercise the utmost restraint and ensure full respect for EU law, in particular the Schengen Borders Code and the Free Movement Directive, when considering imposing new restrictions on freedom of movement; recalls that, according to the Schengen Borders Code, the assessment of the necessity for internal border control and its prolongation when introduced as an immediate action should be monitored at Union level; calls on the Commission in that respect to exercise appropriate scrutiny over the application of the Schengen acquis, and in particular to assess the measures already taken by Member States, as well as the timeliness and quality of notifications made by the Member States, to closely monitor developments and, where necessary, to remind Member States of their legal obligations and adopt opinions; encourages the Commission to make use of its prerogatives to request additional information from Member States; calls on the Commission to enhance its reporting to Parliament on how it exercises its prerogatives under the Treaties; recalls the importance of further integration of the Schengen area, based on the Commission's evaluations and recommendations;
7. Calls on the Member States to respect the right to family life, in particular of families living and working across different Member States and beyond, and only to allow for restrictions where strictly necessary and proportionate; calls on the Member States to allow for the reunification of couples and families separated by COVID-19 related measures, regardless of their marital status, and to refrain from imposing unnecessarily high standards of proof of the relationship;
8. Calls on the Member States to restrict the freedom of assembly only where strictly necessary and justifiable in the light of the local epidemiological situation and where proportionate, and not to use the banning of demonstrations to adopt controversial measures, even if unrelated to COVID-19, that would merit a proper public and democratic debate;
9. Insists that Member States refrain from adopting measures that would have a profound impact on fundamental rights, such as women's sexual and reproductive rights, especially in a situation where public health concerns do not allow for due democratic debate and safe protest, forcing protestors to endanger their health and lives in order to defend their rights;
10. Encourages the Member States to take measures aimed at ensuring the right to education during this pandemic; calls on the Member States, in the light of the resurgent waves of the pandemic, to provide the means for and a safe framework within which to guarantee the continuation of classes, and to ensure that every student has effective access;
11. Calls on the Member States to respect the right to privacy and data protection and to make sure that all new surveillance or tracking measures, adopted in full consultation with data protection authorities, are strictly necessary and proportionate, have a solid legal basis, are limited as to their purposes and are of a temporary nature; calls on the Commission to monitor these measures, especially in the light of its own Recommendation (EU) 2020/518 of 8 April 2020 on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymised mobility data <sup>(52)</sup>;

<sup>(51)</sup> Venice Commission, Interim report of 8 October 2020 (CDL-AD(2020)018), paragraph 75.

<sup>(52)</sup> OJ L 114, 14.4.2020, p. 7.

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12. Recalls that the best way to fight disinformation is to protect and ensure the right to information and freedom of expression, providing support to ensure media pluralism and independent journalism; calls on the Member States, in this context, to ensure transparency when adopting measures and to provide their citizens with comprehensive, up-to-date, precise and objective information and data concerning the public health situation and measures taken to control it, to fight disinformation that aims to discredit or distort scientific knowledge about health risks and that concerns government measures that are justified in the fight against the spread of COVID-19, in a balanced way and taking great care not to create a chilling effect on freedom of expression and on journalists, healthcare workers or others by resorting to criminalisation or disproportionate sanctioning; stresses that the pandemic has increased the stigmatisation of migrants and led to a rise in instances of discrimination which has been exacerbated by misinformation and fake news<sup>(53)</sup>, including racist and xenophobic incidents against people belonging to ethnic minorities, and hate speech against persons with disabilities and refugees<sup>(54)</sup>; stresses that disinformation is an evolving challenge with the potential to negatively influence democratic processes and societal debates affecting all policy areas, to undermine citizens' trust in democracy and to discourage European cooperation and solidarity; recalls that Parliament is already working on a set of possible measures through its Special Committee on Foreign Interference in all Democratic Processes in the European Union, including Disinformation (INGE);

13. Calls for further significant investments in the EU's strategic communication capabilities, in line with the Action Plan against Disinformation, for the stepping up of cooperation and coordination with Member States and for the full use of existing mechanisms in order to facilitate concrete cooperation with Member States and international partners on strategic communication;

14. Considers that the work of journalists has become more difficult as a result of measures related to the COVID-19 pandemic, owing, for example, to the limiting of physical access to press conferences, lacking or inadequate replies to questions from public authorities, and cancelled or delayed deadlines for freedom of information requests or access to documents; regrets that while quality journalism is needed more than ever, particularly given its role in the fight against increasingly prevalent disinformation, the economic fallout of this crisis also affects the financial viability of media outlets, and in particular of independent media and journalists, thereby further undermining media pluralism in the EU; is concerned about the lack of transparency in some Member States regarding the placing of advertisements and the distribution of subsidies to the media, and about the increasing concentration of media ownership in some Member States; underlines that substantive changes in the media sector should not be brought in during a de facto or de jure state of emergency;

15. Calls on the Member States to guarantee the rights of defendants, including their unfettered access to a lawyer, and to evaluate the possibility of online hearings as a solution and an alternative to hearings in court or to the transfer of suspects to other EU Member States under the European Arrest Warrant; calls on the Member States to ensure adherence to all governing principles of judicial proceedings, including the right to a fair trial; calls on the Member States to safeguard the rights and health of all persons in prisons, in particular their rights to medical assistance, visitors, time in the open air and educational, professional or leisure activities;

16. Acknowledges that most Member States have recommenced their asylum procedures and that some have made use of the recent period of lower numbers of new applications to reduce the backlog of pending applications; calls on the Member States to fully guarantee access to an asylum procedure and to preserve the individual right to asylum, as enshrined in the Charter of Fundamental Rights, and to carry out resettlement and dignified return procedures with full respect for international law; calls, furthermore, for access to translators to be provided, or reinstated, as soon as possible for those applying for asylum; urges the Member States to provide adequate physical and mental health facilities in reception centres, given the poor sanitary conditions, the high-risk environment and the vulnerability of refugee populations during the COVID-19 pandemic; calls on the Commission and the Member States to draw up an effective plan, with a public health focus, to comprehensively address their situation, including at external borders, by guaranteeing the right to asylum and providing adequate reception conditions for refugees and asylum seekers; recalls that COVID-19 measures should never lead to detention; calls for urgent family reunification, the immediate evacuation of the camps on the Greek islands and the

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<sup>(53)</sup> International Organization for Migration, COVID-19 Analytical Snapshot #19: Misinformation on migration & migrants, 20 April 2020.

<sup>(54)</sup> FRA, Coronavirus pandemic in the EU — Fundamental Rights implications — Bulletin No 1, 8 April 2020.

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relocation of asylum seekers to other Member States, giving priority to the most vulnerable, unaccompanied minors and families with children; calls on the Member States to allow disembarkation and to ensure that disembarkation takes place only in a place of safety, in accordance with the relevant international and Union law, and as quickly as possible;

17. Considers that discrimination has increased during the pandemic and that certain groups have been the target of hate speech and discriminatory measures; calls on the Member States to counter such hate speech and to end and remedy such discriminatory measures; calls on national and in particular local authorities to redouble their efforts to combat antigypsyism, deconstruct negative stereotypes and involve people with a Romani background themselves in identifying and implementing measures to tackle the pandemic; calls on the Member States, furthermore, to continue their efforts to combat homophobia and transphobia, as the pandemic has exacerbated the discrimination and inequalities of which LGBTI + people are victims;

18. Calls on the Member States to effectively guarantee safe and timely access to sexual and reproductive health and rights (SRHR) and the necessary healthcare services for all women and girls during the COVID-19 pandemic, especially access to contraception, including emergency contraception, and to abortion care; highlights the importance of continuing best practices and finding innovative ways to provide SRHR services, including telemedicine, online consultations and access to early medical abortion from home; calls on the Commission to organise forums for the exchange of best practices among Member States and stakeholders in this regard, and to support actions that ensure access to SRHR in Member States;

19. Calls on the Member States to include independent experts on democracy, the rule of law and fundamental rights in decision making wherever necessary; calls on the Member States to draw on the expertise of and proactively consult a broad range of experts and stakeholders, including National Human Rights Institutions, ombudsman institutions and civil society, when taking new measures;

20. Calls on the Member States to uphold the right to free and fair elections; recalls the Venice Commission's recommendation that the adoption of reforms to electoral codes during this period should only take place following a wide debate and with a large consensus as a guarantee against abuses and of trust in the electoral process and its legitimacy; underlines that parties competing for voter support must have equal rights to campaign, and that the fairness of elections held during states of emergency might be in doubt<sup>(55)</sup>; calls on the Member States to consider the institutional consequences of any decision to postpone elections; stresses that, according to the Venice Commission, the specific rules on the postponement of elections should not be adopted by the executive branch of power nor by a simple majority in parliament, but should be laid down in the constitution or an organic law, and that the decision to postpone elections should preferably be taken by parliament in reasonable time before the election, if possible before the opening of the official campaign<sup>(56)</sup>;

21. Calls on the Commission to urgently commission an independent and comprehensive evaluation of the measures taken during the 'first wave' of the COVID-19 pandemic in order to generate lessons learned, share best practices and enhance cooperation, and to ensure that measures taken during subsequent waves of the pandemic are effective, targeted, well justified on the basis of the specific epidemiological situation, strictly necessary and proportionate, and to limit their impact on democracy, the rule of law and fundamental rights; welcomes the fact that a first such assessment of Member States' COVID-19 measures is included in the Commission's first annual Rule of Law Report; calls on the Commission and the Council to engage in the negotiation of an interinstitutional agreement on an effective monitoring mechanism on rule of law, democracy and fundamental rights, as called for in its resolution of 7 October 2020 on the establishment of an EU Mechanism on Democracy, the Rule of Law and Fundamental Rights, which would assess the situation in all Member States diligently and fairly, as well as contribute to the better protection of the rule of law and the Union's values during extraordinary situations such as the ongoing pandemic;

<sup>(55)</sup> Venice Commission, Report on respect for democracy, human rights and the rule of law during states of emergency: Reflections, 19 June 2020 (CDL-AD(2020)014), paragraph 96.

<sup>(56)</sup> Venice Commission, Interim report of 8 October 2020 (CDL-AD(2020)018), paragraphs 101, 114, 119, 122, 123.

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22. Reiterates its call on the EU institutions and the Member States to draw the right lessons from the COVID-19 crisis and to engage in far stronger cooperation in the area of health, given the huge burdens citizens have faced in trying to manage their physical and mental health during this pandemic, including through the creation of a European Health Union, as put forward in its resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 <sup>(57)</sup>;

23. Calls on the Commission to continue its monitoring of the measures taken, step up its activities to coordinate the Member States, proactively guide authorities in their handling of the pandemic in line with democratic rule of law and fundamental rights, take legal action and use other tools available whenever necessary and consider options available to safeguard respect for the Union's fundamental values, as well as taking the lead to ensure that restrictive measures are lifted as soon as possible; calls on the FRA to continue reporting on the impact of COVID-19 measures on fundamental rights;

24. Instructs its President to forward this resolution to the Commission, the Council, the governments and parliaments of the Member States, the Council of Europe, the Organization for Security and Co-operation in Europe and the United Nations.

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<sup>(57)</sup> Texts adopted, P9\_TA(2020)0205.

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### III

(Preparatory acts)

## EUROPEAN PARLIAMENT

P9\_TA(2020)0290

### **Introducing exceptional trade measures for countries and territories participating in or linked to the European Union's Stabilisation and Association process \*\*\*I**

**European Parliament legislative resolution of 11 November 2020 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1215/2009 introducing exceptional trade measures for countries and territories participating in or linked to the European Union's Stabilisation and Association process (COM(2020)0135 — C9-0099/2020 — 2020/0051(COD))**

**(Ordinary legislative procedure: first reading)**

(2021/C 415/06)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2020)0135),
  - having regard to Article 294(2) and Article 207(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0099/2020),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the undertaking given by the Council representative by letter of 7 October 2020 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the report of the Committee on International Trade (A9-0175/2020),
1. Adopts its position at first reading hereinafter set out;
  2. Instructs its President to forward its position to the Council, the Commission and the national parliaments;

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### **P9\_TC1-COD(2020)0051**

**Position of the European Parliament adopted at first reading on 11 November 2020 with a view to the adoption of Regulation (EU) 2020/... of the European Parliament and of the Council amending Council Regulation (EC) No 1215/2009 introducing exceptional trade measures for countries and territories participating in or linked to the European Union's Stabilisation and Association process**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2020/2172.)*

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P9\_TA(2020)0294

**EU/Senegal Fisheries Partnership Agreement: implementation of the Agreement. Protocol \*\*\*****European Parliament legislative resolution of 11 November 2020 on the draft Council decision on the conclusion of the Protocol on the implementation of the Agreement on a Sustainable Fisheries Partnership between the European Union and the Republic of Senegal (13484/2019 — C9-0178/2019 — 2019/0226(NLE))****(Consent)**

(2021/C 415/07)

*The European Parliament,*

- having regard to the draft Council decision (13484/2019),
  - having regard to the Protocol on the implementation of the Agreement on a Sustainable Fisheries Partnership between the European Union and the Republic of Senegal (13483/2019),
  - having regard to the request for consent submitted by the Council in accordance with Article 43 and Article 218(6), second subparagraph, point (a)(v), and Article 218(7) of the Treaty on the Functioning of the European Union (C9-0178/2019),
  - having regard to its non-legislative resolution of 11 November 2020 <sup>(1)</sup> on the draft decision,
  - having regard to Rule 105(1) and (4) and Rule 114(7) of its Rules of Procedure,
  - having regard to the opinions of the Committee on Budgets and the Committee on Development ,
  - having regard to the recommendation of the Committee on Fisheries (A9-0180/2020),
1. Gives its consent to the conclusion of the protocol;
  2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Republic of Senegal.

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<sup>(1)</sup> Texts adopted, P9\_TA(2020)0295.

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P9\_TA(2020)0295

## **EU/Senegal Fisheries Partnership Agreement: implementation of the Agreement. Protocol (Resolution)**

**European Parliament non-legislative resolution of 11 November 2020 on the draft Council decision on the conclusion of the Protocol on the implementation of the Agreement on a Sustainable Fisheries Partnership between the European Union and the Republic of Senegal (13484/2019 — C9-0178/2019 — 2019/0226M(NLE))**

(2021/C 415/08)

*The European Parliament,*

- having regard to the draft Council decision (13484/2019),
  - having regard to the Sustainable Fisheries Partnership Agreement (SFPA) between the European Union and the Republic of Senegal which entered into force on 20 November 2014,
  - having regard to the retrospective and prospective assessment of the Protocol to the SFPA between the European Union and Senegal,
  - having regard to the Protocol on the implementation of the Agreement on a Sustainable Fisheries Partnership between the European Union and the Republic of Senegal (13483/2019),
  - having regard to the request for consent submitted by the Council in accordance with Article 43(2), Article 218(6), second subparagraph, point (a)(v), and Article 218(7) of the Treaty on the Functioning of the European Union (TFEU) (C9-0178/2019),
  - having regard to its legislative resolution of 11 November 2020 <sup>(1)</sup> on the draft decision,
  - having regard to Article 31(4) of the Common Fisheries Policy <sup>(2)</sup>,
  - having regard to its resolution of 12 April 2016 on common rules in respect of application of the external dimension of the CFP, including fisheries agreements <sup>(3)</sup>,
  - having regard to Senegal's Country Strategic Plan (2019–2023),
  - having regard to Senegal's National Strategy for the Promotion of Green Jobs (2015–2020),
  - having regard to the increase in the size of the Asian fleet operating in Senegalese waters,
  - having regard to Rule 105(2) of its Rules of Procedure,
  - having regard to the opinion of the Committee on Development,
  - having regard to the report of the Committee on Fisheries (A9-0182/2020),
- A. whereas the Sustainable Fisheries Partnership Agreement between the European Union and the Republic of Senegal entered into force on 20 November 2014; whereas the current Protocol implementing the Agreement expired on 19 November 2019 and whereas a new Protocol was initialled on 19 July 2019;

<sup>(1)</sup> Texts adopted, P9\_TA(2020)0294.

<sup>(2)</sup> Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy (OJ L 354, 28.12.2013, p. 22).

<sup>(3)</sup> OJ C 58, 15.2.2018, p. 93.

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- B. whereas the forward-looking assessment of the most recent protocol (2014-2019) concludes that it has generally been effective in helping ensure the sustainable exploitation of resources in the Senegalese fishing zone and recommends the renewal of the protocol to meet both parties' needs;
- C. whereas the effectiveness of the last Protocol is satisfactory in relation to tuna fisheries, and whereas Community vessels have not, however, used part of the fishing opportunities for deep-sea demersal species; whereas catches of black hake in Senegalese waters represent less than 10 % of Community catches in the subregion;
- D. whereas the development of deep-sea demersal fisheries targeting black hake, as well as additional catches of black hake in the Senegalese fishing zone and in the fishing zones of neighbouring countries, have contributed to increasing the fishing pressure on these stocks;
- E. whereas the Union's fishing vessels are limited to fishing areas on the high seas, which means they rarely interact with Senegalese small-scale fishing vessels and thus have minimal impact on their livelihood;
- F. whereas the new Protocol covers a period of five years and provides for fishing opportunities for Union vessels (28 tuna freezer seiners, 10 pole-and-line vessels, five longliners and two trawlers) for a reference tonnage of 10 000 tonnes per year for tuna and an authorised volume of catches of black hake of 1 750 tonnes per year;
- G. whereas the financial compensation is EUR 3 050 750 per year, broken down as follows: EUR 800 000 per year for access to resources, EUR 900 000 per year for the implementation of the sectoral policy and EUR 1 350 750 per year for the estimated amount of fees to be paid by shipowners;
- H. whereas the new Protocol provides fishing opportunities for the Union vessels in Senegalese waters, on the basis of the best available scientific advice and following the recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT);
- I. whereas the reform of the Common Fisheries Policy contains a chapter on the external dimension with the aim of promoting the principles of sustainable fishing; whereas bilateral agreements establish a stable legal, economic and environmental framework for the access of the EU fleet to third-country waters and provide for 'sectoral support' to strengthen local administrative capacities and improve sustainable fisheries management standards in the partner country;
- J. whereas under the Common Fisheries Policy the European fleet will only capture the surplus of permitted catches, in compliance with Article 62 of the 1982 United Nations Convention on the Law of the Sea;
- K. whereas Senegal has ratified most international instruments on international fisheries governance and is a cooperating party of the relevant regional fisheries management bodies regarding the fisheries exploited by Senegalese vessels;
- L. whereas the new Protocol to the Fisheries Partnership Agreement with Senegal forms part of the EU's external action in relation to African, Caribbean and Pacific (ACP) countries and takes into account, in particular, Union objectives on respecting democratic principles and human rights;
- M. whereas the EU compromises with international agreements, in particular the United Nations Sustainable Development Goals (SDGs) and specifically SDG 14, should also be supported under this agreement, and all EU actions, such as this SFPA, must contribute to those objectives;
- N. whereas the European Union and Senegal maintain cooperation within the general framework of the Cotonou Agreement and whereas financial support measures as regards fisheries are implemented through the PESCAO programme aimed at improving the governance of the fisheries sector and the fight against illegal, unreported and unregulated (IUU) fishing, with a budget of EUR 15 million for the period 2018-2024;

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- O. whereas IUU fishing not only depletes the natural resource base and lowers natural productivity, but also negatively affects fishers' livelihoods and national revenues;
- P. whereas Parliament must be immediately and fully informed, at all stages, of the procedures concerning the Protocol or its renewal;
- Q. whereas small pelagic stocks are shared by a number of neighbouring countries in the Northwest African region with which the EU has fisheries partnership agreements giving access to these stocks; whereas the Commission should encourage the Senegalese authorities to initiate consultations with neighbouring countries on common binding management rules based on scientific advice to ensure sustainable fishing, especially for the small pelagic stocks, even though the agreement between the EU and Senegal does not give access;
- R. whereas the strategic objectives under Senegal's Country Strategic Plan (2019–2023) include the sustainable management and improved productivity of fisheries and an overall increase in market access and competitiveness for the fishing industry;
- S. whereas the fisheries sector provides employment for over 600 000 Senegalese, which is about 17 % of the working population;
1. Affirms that the Protocol will enable continued close cooperation between the European Union and Senegal to ensure the responsible exploitation of fishery resources in Senegalese waters and to support the efforts of Senegal to develop sustainable resource management and the protection of marine biodiversity;
  2. Supports the EU strategy of being able to maintain a network of agreements in the region in order to complement actions to promote the sustainability of stocks within regional fisheries organisations (RFOs);
  3. Notes that, in line with the conclusions of the assessment report, the new Protocol entails a reduction in the tonnage of black hake (from 2 000 to 1 750 tonnes per year) and an increase in the financial contribution for sectoral support (EUR 150 000) and in the estimated amount of fees to be paid by shipowners;
  4. Notes the reduction in the fishing opportunities for deep-sea trawlers (black hake) in line with the scientific opinion of the Fishery Committee for the Eastern Central Atlantic (CECAF) in order to reduce mortality;
  5. Welcomes the fact that the Protocol takes into account sensitive species that are caught as by-catch; stresses the need to further enhance measures to protect the marine ecosystem; emphasises the central role of trained scientific observers in the monitoring of by-catches;
  6. Stresses that the Agreement contains a chapter on scientific cooperation in order to ensure better monitoring of the state of marine biological resources in Senegalese waters; takes note of the existing difficulties in the scientific monitoring of the exploitation of deep-sea demersal resources and urges that the evaluation also take into account the fishing pressure exerted by third-country fleets in the waters of other coastal countries (Mauritania, Morocco, Guinea Bissau and Gambia), considering that the fishing opportunities available in Senegalese waters for EU vessels are relatively limited;
  7. Considers that, in order to guarantee access to the existing surpluses in Senegalese waters, knowledge of the overall fishing effort — including the Senegalese and third-country fleets — is necessary and calls on the Commission to ensure that the article on transparency is applied in the context of the current protocol, as well as in the deliberations within the competent RFOs;
  8. Notes the possibility of reviewing fishing opportunities and of agreeing exploratory fishing surveys in Senegalese fishing zones; welcomes the conditions set out in the Protocol regarding sustainability and adherence to scientific recommendations, and calls on the Commission to keep Parliament informed in the event that such modifications were to be approved by the Joint Committee; welcomes the inclusion of monitoring of catches through the Electronic Reporting System (ERS); calls on the Commission to ensure that the system is operational as soon as possible;

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9. Welcomes the adoption of new technical measures to reduce incidental catches of protected species (sea birds, turtles, sharks and marine mammals), and urges the Commission to monitor the adoption of the necessary measures to improve the selectivity of fishing gear in line with the scientific recommendations and legislation derived from RFOs;

10. Underlines that the Agreement establishes a legal framework for cooperation in the field of surveillance and the fight against illegal, unreported and unregulated fishing (IUU), and welcomes Senegal's ratification of the FAO Port State Measures Agreement in 2017, which constituted a positive step given the importance of the port of Dakar for landings of fishery products caught in several areas of the subregion by vessels flying different third-country flags;

11. Takes a positive view of the signing-on of Senegalese seamen on European Union vessels and underlines the good results achieved in implementing the previous Protocol; welcomes Senegal's ratification of ILO Convention C188 on Work in Fishing and calls on the Senegalese authorities to implement its provisions; calls on the Commission to assess regularly its effective implementation, in particular as regards working conditions and pay, which are also referred to in the Protocol, in the meetings of the Joint Committee;

12. Considers that the Member States can play a key role and be an active part in capacity-building and training efforts in order to achieve this;

13. Recommends, in order to ensure compliance with the sectoral support objectives set out in Article 5 and without prejudice to other activities, the following priority and strategic actions:

- improving monitoring, control and surveillance through the rapid modernisation of the Fisheries Monitoring Centre (FMC), namely the need to update tracking software for vessel locations in Senegal's fishing zone via satellite (inter alia VMS) under appropriate technical conditions, and to be able to receive electronic fishing logbooks;
- supporting Senegal's efforts in the fight against IUU fishing by means of a monitoring mechanism for vessels calling at the port of Dakar;
- developing scientific capacity and the collection of scientific data so as to enable Senegalese authorities to take decisions based on the best available scientific stock assessment, as well as the imminent launching of planned oceanographic surveys with a view to strengthening the scientific monitoring of the deep-sea demersal fisheries and the knowledge of marine and coastal ecosystems;
- supporting decent working conditions for all fishers and fisheries-related activities, in particular for women, by developing the collection of data identifying gender gaps and by fostering empowerment and improving their role and leadership in fisheries and aquaculture organisations;
- actions to support the generation of added value for fishery products by means of a horizontal capacity building programme for operators in the sector;
- supporting Senegalese small-scale coastal fisheries and communities, including job generation and the development of fisheries-related infrastructure supporting artisanal fishing activity and facilitating the development of the fisheries sector;
- establishing basic and vocational training programmes for scientific observers and seamen (training in fishing techniques, but also safety on board, etc.), with particular emphasis on the training of young fishers and women who play an important role in marketing and processing and whose livelihoods and work depend on the fisheries sector;
- in the framework of the Sectoral Policy Charter for the Development of Fisheries and Aquaculture for the period 2016-2023 adopted by Senegal, an annual joint review with partners, including the Union, to ensure the implementation of the planned sector policy reforms;

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- increased efforts to prevent delayed implementation of the sectoral support owing to difficulties on the part of the Senegalese side in implementing the administrative mechanisms to dispose of the funds;
- ensuring greater visibility for actions financed by the Union and promoting proper understanding by the fishing communities and civil society of the specific contribution made by the Protocol to the development of the sector;
- strengthening measures to encourage young people to engage in fishing;

14. Calls on the Commission to carry out a global study on the impact of EU bilateral fisheries agreements and, in particular, on the benefits arising from sectoral support and the activity of the European fleet in third country waters to local economies (development of sustainable fishing, local employment, infrastructure, social improvements, etc.), adopting a unified and consistent approach towards all Western African countries;

15. Expresses its concerns about the growing number of fish meal and fish oil plants on the West African coast which are supplied with small pelagic stocks from Senegalese waters but also from neighbouring countries caught by foreign (non-EU) fleets; criticises in this respect the contradiction of sustainability in terms of providing the local population with valuable protein resources;

16. Considers that, in view of a possible closure of fisheries or the setting of restrictions on fisheries in order to ensure that resources are sustainable, local fishing needs should be addressed first, on the basis of sound scientific advice;

17. Appreciates the efforts made at EU level in terms of transparency in the texts of the protocols and of the joint scientific committees now available; stresses the need to increase transparency and the participation of coastal community associations in the management of the sectoral support; calls on the Commission to provide regular public reports on the use of the sectoral support, and to forward to Parliament the conclusions of the meetings of the Joint Committee and the results of its annual evaluations; calls on the Commission to facilitate the participation of Parliament representatives as observers in the meetings of the Joint Committee and to improve the participation of Senegalese fishing associations and communities; stresses the need for transparency on the part of the Senegalese Government regarding fishing partnerships with other countries;

18. Recommends that stakeholders participate in the preparation, implementation, monitoring and evaluation of operational programmes through involving local fishing communities and consulting with them in accordance with Senegalese law;

19. Calls for greater clarity and harmonisation of reporting in marine protected areas (MPAs) and for an agreed holistic management plan which allocates roles and determines the body responsible for the overall coordination of management activities;

20. Notes that landlocked countries such as Mali depend on fishery exports from Senegal which accounts for more than 40 % of their fishery imports; notes that Senegalese exports contribute to the nutrition of landlocked countries;

21. Notes that more than one fifth of Senegalese exports go to landlocked countries, in particular to Mali, Burkina Faso and Niger, and contribute to the economic integration of the African continent;

22. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States and the Republic of Senegal.

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P9\_TA(2020)0296

**EU/Seychelles Sustainable Fisheries Partnership Agreement and Implementation. Protocol (2020-2026) \*\*\***

**European Parliament legislative resolution of 11 November 2020 on the draft Council decision on the conclusion, on behalf of the European Union, of the Sustainable Fisheries Partnership Agreement between the European Union and the Republic of Seychelles and its implementing protocol (2020-2026) (05243/2020 — C9-0073/2020 — 2020/0002(NLE))**

**(Consent)**

(2021/C 415/09)

*The European Parliament,*

- having regard to the draft Council decision (05243/2020),
  - having regard to the draft Sustainable Fisheries Partnership Agreement between the European Union and the Republic of Seychelles and its implementing protocol (2020-2026) (05246/2020),
  - having regard to the request for consent submitted by the Council in accordance with Article 43(2) and Article 218(6), second subparagraph, point (a)(v), and Article 218(7), of the Treaty on the Functioning of the European Union (C9-0073/2020),
  - having regard to its non-legislative resolution of 12 November 2020 <sup>(1)</sup> on the draft decision,
  - having regard to Rule 105(1) and (4) and Rule 114(7) of its Rules of Procedure,
  - having regard to the opinion of the Committee on Budgets,
  - having regard to the letter from the Committee on Development,
  - having regard to the recommendation of the Committee on Fisheries (A9-0185/2020),
1. Gives its consent to the conclusion of the agreement and of the protocol;
  2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Republic of Seychelles.

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<sup>(1)</sup> Texts adopted, P9\_TA(2020)0303.

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P9\_TA(2020)0297

## **EU/China Agreement: cooperation on and protection of geographical indications \*\*\***

**European Parliament legislative resolution of 11 November 2020 on the draft Council decision on the conclusion of the agreement between the European Union and the government of the People's Republic of China on cooperation on, and protection of, geographical indications (08359/2020 — C9-0298/2020 — 2020/0089(NLE))**

(Consent)

(2021/C 415/10)

*The European Parliament,*

- having regard to the draft Council decision (08359/2020),
  - having regard to the draft Agreement between the European Union and the government of the People's Republic of China on cooperation on, and protection of, geographical indications (08361/2020),
  - having regard to the request for consent submitted by the Council in accordance with Article 207(4), first subparagraph and Article 218(6), second subparagraph, point (a)(v), and Article 218(7) of the Treaty on the Functioning of the European Union (C9-0298/2020),
  - having regard to its non-legislative resolution of 11 November 2020 <sup>(1)</sup> on the draft decision,
  - having regard to Rule 105(1) and (4) and Rule 114(7) of its Rules of Procedure,
  - having regard to the opinion of the Committee on Fisheries,
  - having regard to the recommendation of the Committee on International Trade (A9-0199/2020),
1. Gives its consent to the conclusion of the agreement;
  2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the People's Republic of China.

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<sup>(1)</sup> Texts adopted, P9\_TA(2020)0298.



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P9\_TA(2020)0298

**EU/China Agreement: cooperation on and protection of geographical indications (Resolution)****European Parliament non-legislative resolution of 11 November 2020 on the draft Council decision on the conclusion of the agreement between the European Union and the Government of the People's Republic of China on cooperation on, and protection of, geographical indications (08359/2020 — C9-0298/2020 — 2020/0089M (NLE))**

(2021/C 415/11)

*The European Parliament,*

- having regard to the draft Council decision (08359/2020),
- having regard to the draft agreement between the European Union and the government of the People's Republic of China on cooperation on, and protection of, geographical indications (08361/2020),
- having regard to the request for consent submitted by the Council in accordance with Articles 207(3) and 207(4), first subparagraph, in combination with Article 218(6), second subparagraph, point (a)(v), and Article 218(7) of the Treaty on the Functioning of the European Union (TFEU),
- having regard to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),
- having regard to the Commission communication of 14 October 2015 entitled 'Trade for all — Towards a more responsible trade and investment policy' (COM(2015)0497),
- having regard to the Commission communication of 1 July 2014 entitled 'Trade, growth and intellectual property — Strategy for the protection and enforcement of intellectual property rights in third countries'(COM(2014)0389),
- having regard to the Commission staff working document entitled 'Report on the protection and enforcement of intellectual property rights in third countries' (SWD(2019)0452),
- having regard to the joint statements of the 20<sup>th</sup> EU-China Summit of 16 July 2018 and of the 21<sup>st</sup> EU-China Summit of 9 April 2019,
- having regard to the joint communication of 12 March 2019 entitled 'EU-China — A strategic outlook' (JOIN(2019)0005),
- having regard to its resolution of 9 June 2015 on Strategy for the protection and enforcement of intellectual property rights in third countries <sup>(1)</sup>,
- having regard to its resolution of 12 September 2018 on the state of EU-China relations <sup>(2)</sup>,
- having regard to its legislative resolution of 11 November 2020 <sup>(3)</sup> on the draft decision,
- having regard to the Treaty on European Union (TEU), and in particular Title V thereof on the Union's external action,
- having regard to the TFEU, and in particular to Articles 91, 100, 168 and 207 thereof, in conjunction with Article 218 (6)(a)(v) and 218(7),

<sup>(1)</sup> OJ C 407, 4.11.2016, p. 18.

<sup>(2)</sup> OJ C 433, 23.12.2019, p. 103.

<sup>(3)</sup> Texts adopted, P9\_TA(2020)0297.

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- having regard to Rule 105(2) of its Rules of Procedure,
  - having regard to the opinion of the Committee on Fisheries,
  - having regard to the letter from the Committee on Agriculture and Rural Development,
  - having regard to the report of the Committee on International Trade (A9-0202/2020),
- A. whereas the protection of geographical indications at international level is a key element of EU trade policy;
- B. whereas the EU is the largest agri-food exporter in the world, achieving a record agri-food trade surplus of EUR 39 billion in 2019;
- C. whereas the average value of products with a geographical indication is twice as high as that of products without such a quality label;
- D. whereas EU agri-food exports to China have grown massively in the last decade, with an annual growth rate of more than 20 % over the period 2009-2019; whereas this has turned the EU's agri-food trade deficit of EUR 1 billion in 2009 into a trade surplus of more than EUR 9 billion in 2019, making China the third destination for EU agri-food exports, after the UK and the US; whereas Chinese imports of agri-food products are expected to grow further in the next decade;
- E. whereas the worldwide sales value of products protected by EU geographical indications, covering wines, agri-food products and spirit drinks, represents EUR 74,76 billion<sup>(4)</sup>, accounting for a 6,8 % share of EU agri-food sector sales and a 15,4 % share of EU agri-food exports;
- F. whereas the EU is globally reputed for its know-how and for the production of high value and quality agri-food products;
- G. whereas all imported agri-food products must be checked and meet the health, safety and animal welfare requirements that apply to EU producers across the agri-food supply chain, thus contributing to their value and quality;
- H. whereas many EU geographical indications are faced with considerable challenges in China, causing significant economic losses for EU producers;
- I. whereas the agreement builds on the experience gained through the EU-China pilot project on cooperation in geographical indications, which ran from 2007 to 2012;
- J. whereas a substantial proportion of future global economic growth is expected to be generated outside Europe;
- K. whereas agri-food producers and exporters have to operate in a difficult international trade environment;
- L. whereas this agreement is important in view of the global recognition that it offers for geographical indications;
- M. whereas this agreement is an important first step and should be extended as soon as possible to protect many EU GIs that are still excluded;
- N. whereas the conclusion of this agreement demonstrates that the EU and China are able to reach bilateral deals as long as common interests are well taken into account;

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<sup>(4)</sup> Commission study, published April 2020 [https://ec.europa.eu/commission/presscorner/detail/en/IP\\_20\\_683](https://ec.europa.eu/commission/presscorner/detail/en/IP_20_683)

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1. Welcomes the conclusion of this agreement on cooperation on and protection of geographical indications (GIs) between the EU and the People's Republic of China; welcomes the protection of European GIs on the Chinese market; considers the effective implementation of the agreement an important confidence building exercise for the two parties and a major signal that China is willing to engage with the EU; expects that there will also be progress in other areas of cooperation with regard to fair trade;
2. Underlines the importance of the EU strategic relationship with China and calls on the EU's Member States and institutions to address China with one voice and in a coordinated way; highlights that trade and investment should be rules-based and value-based, with a multilateral trade system at its core; calls on China to play a more active part in the WTO and other multilateral initiatives and to fully comply with its WTO obligations, matching its acquired economic power with its level of development; stresses that respect for human rights is a pre-requisite for engaging in trade and investment relations with the EU and urges China to comply with international obligations and commit to respecting human rights, in particular in view of the ongoing negotiation of the bilateral investment agreement; is deeply concerned by the reported exploitation and detention of Uighur people in factories in China;
3. Calls for financial penalties to be introduced for companies that disregard geographical indications and counterfeit products covered by a geographical indication;
4. Points out that the agreement is a positive signal to the international community, including towards multilateral institutions; welcomes the high level of protection for a list of 100 European and 100 Chinese geographical indications under the agreement, which goes beyond the current level of protection granted under the WTO TRIPS agreement, in particular for foodstuffs but also for wines and spirits; takes note of the fact that the protection of another 175 geographical indications from the EU and China respectively is envisaged within four years of the entry into force of the agreement; notes that the EU protects more than 3 300 GIs; calls on the Commission to swiftly proceed with the extension of this agreement to protect in the coming years as many GIs as possible that meet the criteria, including fisheries and aquaculture GIs; calls on the Commission, furthermore, to keep Parliament duly informed on the progress of the negotiations towards the extension of the agreement; recalls that the agreement was finalised before the EU treaties ceased to apply in the United Kingdom of Great Britain and Northern Ireland and that there are eight products from the UK on the agreed lists; urges the Commission to consult the Member States and to replace these products with products from EU Member States as soon as possible after the transition period ends;
5. Welcomes the provision that producers of protected GI products can apply directly to the Joint Committee envisioned in this agreement if their product is not included on the initially agreed lists, and also if their product subsequently acquires protection after the agreement enters into force; calls on current and potential stakeholders, including in the EU fisheries and aquaculture sectors, to explore this provision;
6. Notes that the EU has a large trade deficit with China, but recalls that in the area of agri-food products the EU has a trade surplus;
7. Recalls the importance of promoting the EU's GI protection model as a vital tool for safeguarding the authenticity and unique characteristics of registered EU products, as a useful marketing instrument for business opportunities and a symbol of cultural heritage; recognises the rich European and Chinese heritage in traditional quality food products and the importance of GI protection in this regard; calls on the Commission, the Member States and the Chinese Government to commit to the protection of this heritage and ensure that it is recognised in both societies in order to facilitate the identification and origin protection of the products concerned, as well as to promote cultural exchange and openness;
8. Regrets the fact that despite protection under the agreement, some of the EU GIs cannot be exported to China owing to Chinese food import standards; asks the Commission to continue its dialogue with China on recognising EU food safety standards, which are among the highest in the world; calls on China to remove unjustified barriers to EU agri-food exports, to ensure reciprocity in the overall commercial relationship and to comply with, improve and strictly implement and enforce sanitary and phytosanitary (SPS) standards in order to avoid unfair competition;

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9. Calls on China, furthermore, to support the existing multilateral framework protecting GIs by becoming a member of the WIPO Lisbon Agreement and the Geneva Act, in force since 26 February 2020;

10. Stresses the importance of geographical indications within the broader framework of intellectual property rights and efforts to fight the counterfeiting of products; emphasises that the agreement needs to ensure the full protection of the intellectual property rights of products in order to safeguard the value and quality of the local environment, including infrastructure, employment and biodiversity, to improve regional development and to enhance traceability, transparency and consumer information;

11. Welcomes, in this regard, the approval of the new Chinese legislation on the protection of intellectual property rights (IPR); calls on the Commission to closely monitor the implementation of this agreement and asks for swift ratification; calls on the Commission, moreover, to continue cooperation with China to make progress towards the implementation of a more ambitious agreement in the area of IPR, with a view to extending the list of protected EU geographical indications; urges the Commission to monitor the GI registration process in China; asks the Commission to keep offering support to EU companies through the IPR helpdesk; highlights the added value of cooperating with bodies such as the EU Intellectual Property Office on correct monitoring and enforcement;

12. Notes that, according to the latest report on the protection and enforcement of intellectual property rights, more than 80 % of counterfeit and pirated goods seized in the EU in 2018 and 2019 originate from China, accounting for a loss of some EUR 60 billion for EU Member States; underlines the continued importance of strict controls and testing on all imported products in order to detect counterfeit and fraudulent food products; recalls, therefore, the need for deep and effective customs cooperation between the EU and China in order to ensure fair competition in the light of increased trade flows, and as a tool in the fight against counterfeit goods;

13. Underlines the importance of effective implementation and proper enforcement in the market place of the provisions of the agreement; reiterates its determination to monitor and scrutinise the correct application of the agreement; calls on the Commission, in this regard, to inform Parliament annually about the implementation of the agreement, beginning one year after its entry into force; welcomes the appointment of a new Chief Trade Enforcement Officer (CTEO) and highlights the crucial role that he will play in monitoring and improving compliance with this agreement; calls on the CTEO to react immediately in the event that the agreement is not implemented correctly;

14. Is concerned about the impact that the Economic and Trade Agreement between the United States and China (the so-called US-China Phase One Deal), which entered into force on 14 February 2020, could have on the EU-China agreement on GIs and underlines that it must be implemented in a non-discriminatory manner, in full compliance with WTO rules and without any disruptive impact on the enforcement of the commitments taken in the EU-China agreement on GIs; stresses that the EU must also closely monitor the implementation of the second list of 175 EU geographical indications with regard to possible overlaps with the US-China Phase One Deal; expects EU exporters to see immediate benefits from trade facilitation measures in the agri-food sector;

15. Expresses deep concern for the many barriers that EU businesses and farmers face in accessing and operating in the Chinese market, owing to China's state-led system; considers that fair competition between EU and Chinese companies would lead to more opportunities and greater innovation, and urges the Commission to continue working with the Chinese authorities to dismantle those barriers;

16. Stresses the longstanding need for a level playing field between the EU and China regarding trade and investment, with a particular attention to reciprocity in market access, public procurement and financial services; urges both parties to cooperate constructively in that regard to pursue market-based reforms and make meaningful progress, in particular on the ongoing negotiation of the bilateral investment agreement but also on corporate social responsibility, the achievement of the Sustainable Development Goals, and the fight against climate change in line with the Paris Agreement; reiterates its call on China to move forward on an ambitious reform of the WTO, including comprehensive rules on industrial subsidies; reiterates its concerns regarding the market distorting practices of Chinese state-owned enterprises, forced technology transfers and data localisation, industrial overcapacity and the related dumping of exports, and other unfair trading

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practices; reiterates the need to improve bilateral and multilateral cooperation for sustainable development and a fair trade system, while promoting social and environmental standards based on respect for and the implementation of international conventions and agreements; is concerned about China's poor performance in illegal, unreported and unregulated (IUU) fishing; highlights the lack of transparency in the registration of vessels and fishing fleets globally and stresses that Chinese subsidies in this area are creating unfair competition for the EU fishing sector; calls on China to make every effort to step up its legal framework for IUU fishing and to enforce it more strictly;

17. Recalls the need for significant and ambitious progress in the negotiations on the EU-China Comprehensive Agreement on Investment, in order to address the current market asymmetries; underlines the importance of including an ambitious chapter on trade and sustainable development to protect human rights, including core labour standards, promote sustainable development and fight against climate change in line with the Paris Agreement; emphasises that ensuring the level playing field, reciprocity and non-discriminatory treatment of the respective parties and their business communities, citizens and civil society are key; urges the parties to improve transparency and to establish a parliamentary dimension with regard to the implementation of the agreement; highlights that the EU market for public procurement is open to Chinese companies, including state-owned enterprises, while European companies often encounter difficulties in gaining access to procurement opportunities on Chinese markets; calls on the Commission and China to boost EU-China cooperation to achieve environmental goals;

18. Stresses that EU commercial relations require harmonious regional relations between China and its neighbouring countries, and its cordial coexistence with all territories which have had a special relationship with Europe; underlines that China's full respect for previous international commitments in the region will pave the way for the proper implementation of this agreement;

19. Instructs its President to forward this resolution to the Council, the Commission, the governments and parliaments of the Member States and the Government of the People's Republic of China and the National People's Congress.

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P9\_TA(2020)0299

**Common system of value added tax: identification of taxable persons in Northern Ireland \***

**European Parliament legislative resolution of 11 November 2020 on the proposal for a Council directive amending Directive 2006/112/EC on the common system of value added tax as regards the identification of taxable persons in Northern Ireland (COM(2020)0360 — C9-0279/2020 — 2020/0165(CNS))**

**(Special legislative procedure — consultation)**

(2021/C 415/12)

*The European Parliament,*

- having regard to the Commission proposal to the Council (COM(2020)0360),
  - having regard to Article 113 of the Treaty on the Functioning of the European Union, pursuant to which the Council consulted Parliament (C9-0279/2020),
  - having regard to Rule 82 of its Rules of Procedure,
  - having regard to the report of the Committee on Economic and Monetary Affairs (A9-0200/2020),
1. Approves the Commission proposal;
  2. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
  3. Asks the Council to consult Parliament again if it intends to substantially amend the text approved by Parliament;
  4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.
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P9\_TA(2020)0300

**Introduction of capacity limits for Eastern Baltic cod, data collection and control measures in the Baltic Sea and permanent cessation for fleets fishing for Eastern Baltic cod \*\*\*I**

European Parliament legislative resolution of 11 November 2020 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2016/1139 as regards the introduction of capacity limits for Eastern Baltic cod, data collection and control measures in the Baltic Sea, and Regulation (EU) No 508/2014 as regards permanent cessation for fleets fishing for Eastern Baltic cod (COM(2019)0564 — C9-0161/2019 — 2019/0246(COD))

(Ordinary legislative procedure: first reading)

(2021/C 415/13)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2019)0564),
  - having regard to Article 294(2) and Article 43(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0161/2019),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 23 January 2020 <sup>(1)</sup>,
  - having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 30 September 2020 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the report of the Committee on Fisheries (A9-0093/2020),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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**P9\_TC1-COD(2019)0246**

**Position of the European Parliament adopted at first reading on 11 November 2020 with a view to the adoption of Regulation (EU) 2020/... of the European Parliament and of the Council amending Regulation (EU) 2016/1139 as regards fishing capacity reduction in the Baltic Sea, and Regulation (EU) No 508/2014 as regards permanent cessation of fishing activities for fleets fishing for Eastern Baltic cod, Western Baltic cod and Western Baltic herring**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2020/1781.)*

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<sup>(1)</sup> OJ C 106, 31.3.2020, p. 10.

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P9\_TA(2020)0301

## **Enhanced cooperation between Public Employment Services (PES) \*\*\*I**

**European Parliament legislative resolution of 11 November 2020 on the proposal for a decision of the European Parliament and of the Council amending Decision No 573/2014/EU on enhanced cooperation between Public Employment Services (PES) (COM(2019)0620 — C9-0117/2019 — 2019/0188(COD))**

**(Ordinary legislative procedure: first reading)**

(2021/C 415/14)

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2019)0620),
  - having regard to Article 294(2) and Article 149 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0117/2019),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 30 October 2019 <sup>(1)</sup>,
  - after consulting the Committee of the Regions,
  - having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 7 October 2020 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the report of the Committee on Employment and Social Affairs (A9-0128/2020),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

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## **P9\_TC1-COD(2019)0188**

**Position of the European Parliament adopted at first reading on 11 November 2020 with a view to the adoption of Decision (EU) 2020/... of the European Parliament and of the Council amending Decision No 573/2014/EU on enhanced cooperation between Public Employment Services (PES)**

*(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision (EU) 2020/1782.)*

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<sup>(1)</sup> Not yet published in the Official Journal



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P9\_TA(2020)0302

**General budget of the European Union for the financial year 2021 — all sections****European Parliament resolution of 12 November 2020 on the Council position on the draft general budget of the European Union for the financial year 2021 (11072/1/2020 — C9-0314/2020 — 2020/1998(BUD))**

(2021/C 415/15)

*The European Parliament,*

- having regard to Article 314 of the Treaty on the Functioning of the European Union,
- having regard to Article 106a of the Treaty establishing the European Atomic Energy Community,
- having regard to Council Decision 2014/335/EU, Euratom of 26 May 2014 on the system of own resources of the European Union <sup>(1)</sup>,
- having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014 and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 <sup>(2)</sup>,
- having regard to Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014–2020 <sup>(3)</sup>,
- having regard to Commission Amended proposal of 28 May 2020 laying down the multiannual financial framework for the years 2021 to 2027 (COM(2020)0443);
- having regard to 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 <sup>(4)</sup>,
- having regard to its interim report of 14 November 2018 on the multiannual financial framework 2021–2027 — Parliament’s position with a view to an agreement <sup>(5)</sup> and to its resolution of 23 July 2020 on the conclusions of the extraordinary European Council meeting of 17–21 July 2020;
- having regard to its resolution of 19 June 2020 on general guidelines for the preparation of the 2021 budget Section III — Commission <sup>(6)</sup>,
- having regard to its resolution of 14 May 2020 on Parliament’s estimates of revenue and expenditure for the financial year 2021 <sup>(7)</sup>,
- having regard to the draft general budget of the European Union for the financial year 2021, which the Commission adopted on 27 July 2020 (COM(2020)0300) (the ‘DB’),
- having regard to the position on the draft general budget of the European Union for the financial year 2021, which the Council adopted on 28 September 2020 and forwarded to Parliament on 1 October 2020 (11072/1/2020 — C9-0314/2020),

<sup>(1)</sup> OJ L 168, 7.6.2014, p. 105.

<sup>(2)</sup> OJ L 193, 30.7.2018, p. 1.

<sup>(3)</sup> OJ L 347, 20.12.2013, p. 884.

<sup>(4)</sup> OJ C 373, 20.12.2013, p. 1.

<sup>(5)</sup> Texts adopted, P8\_TA(2018)0449.

<sup>(6)</sup> Texts adopted, P9\_TA(2020)0166.

<sup>(7)</sup> Texts adopted, P9\_TA(2020)0123.

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- having regard to its legislative resolution of 16 September 2020 on the draft Council decision on the system of own resources of the European Union <sup>(8)</sup>,
- having regard to Rule 94 of its Rules of Procedure,
- having regard to the opinions of the committees concerned,
- having regard to the report of the Committee on Budgets (A9-0206/2020),

### **Section III**

#### ***General overview***

1. Recalls that 2021 should be the first year of the new Multiannual Financial Framework (MFF); regrets that because of the delays in the MFF/Own Resources (MFF/OR) negotiations, for which Parliament has been ready since November 2018 and which could not start before the European Council's 21 July 2020 conclusions, as well as because of the coronavirus (COVID-19) outbreak, the budgetary procedure for 2021 could not build so far on a solid and ambitious MFF agreement;
2. Notes that the Commission presented a draft budget (DB) for 2021 based on its own MFF proposals which were updated in May 2020, while the Council limited its reading, with the exception of Heading 7, to an arithmetic translation of the European Council's conclusions, awaiting the Amending letter which the Commission will use to update its proposal after a political agreement has been reached on the MFF/OR;
3. Takes note of the Council's position on the DB, including the importance it attaches to the Amending letter; concurs with the Council on the Amending letter, while wanting to present a reading which follows Parliament's priorities on the MFF/OR and the 2021 Budget in a coordinated manner; notes that this approach is also motivated by the limited time that will be left following the presentation of the Amending letter;
4. Recalls that in its abovementioned resolution of 19 June 2020 on general guidelines for the preparation of the 2021 Budget, Parliament stressed that the primary focus of the 2021 Budget should be to mitigate the effects of the COVID-19 outbreak and support a recovery built on the European Green Deal and digital transformation, in order to promote fair, inclusive and sustainable growth, high-quality job creation and its long-term goal of socioeconomic convergence;
5. Welcomes the EU Recovery Plan; insists, however, on the need to clearly enshrine the role of the budgetary authority in authorising external assigned revenue, notably of the Next Generation EU (NGEU) recovery instrument, under the annual budgetary procedure;
6. Recalls its position that the 2021-2027 MFF climate and biodiversity mainstreaming targets must go beyond the levels of targeted spending shares set out in its interim report; aims, therefore, to achieve a biodiversity spending level of at least 10 % and a climate mainstreaming spending level of at least 30 % for 2021; reiterates its demand for a gender mainstreaming concept that draws together gender-specific information on objectives, inputs, outputs, results, including financing commitments for gender equality and the methodology for tracking and reporting gender equality expenditure;
7. Reiterates its call on the Commission to lay down clear eligibility criteria for a new stringent and comprehensive methodology for both climate and biodiversity related expenditure, in the form of Framework Regulations ensuring that only projects meeting the relevant technical screening criteria developed under Regulation (EU) 2020/852 <sup>(9)</sup> shall be accounted for when contributing to those spending targets, together with the corresponding corrective measures, where relevant, and the full implementation of the principle of 'do no significant harm' referred to in Article 17 of Regulation (EU) 2020/852 to ensure that the Union fulfils its commitments under the Paris Agreement and its call for phase-out of indirect fossil fuel subsidies and a ban on direct ones in the entire Union budget;

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<sup>(8)</sup> Texts adopted, P9\_TA(2020)0220.

<sup>(9)</sup> Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (OJ L 198, 22.6.2020, p. 13).

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8. Decides to increase to the levels set out in the MFF interim report of 14 November 2018 the fifteen flagship programmes identified in its resolution of 23 July 2020 on the conclusions of the extraordinary European Council meeting of 17-21 July 2020 <sup>(10)</sup> (Horizon Europe, InvestEU, Erasmus+, the Child Guarantee, the Just Transition Fund, Digital Europe, the Connecting Europe Facility, LIFE, EU4health, the Integrated Border Management Fund, Creative Europe, the Right and Values programme, the European Defence Fund, the Neighbourhood, Development and International Cooperation Instrument (NDICI) and humanitarian aid, as well as relevant EU agencies and the European Public Prosecutor's Office); decides further to base its reading on the MFF ceilings proposed by the Commission in the DB; considers that any increase for the flagship programmes should be accompanied by a corresponding rise in the ceiling of the relevant MFF heading; decides to reinforce funding for Parliament's priorities *inter alia* in the fields of climate change, energy, digital and transport interconnectivity, space, SMEs, tourism, security, migration, fundamental rights and external action;
9. Accepts the Council's increases in Headings 1, 2a and 3, with the exception of the lines where it decides on a higher amount of appropriations; accepts further the moving of the Resilience cluster from Heading 5 to Heading 2b;
10. Reaffirms its previous commitments to make full use of the possibility to re-use de-commitments for research laid down in Article 15(3) of the Financial Regulation;
11. Insists on the need of a more detailed budgetary nomenclature allowing the budgetary authority to fully exercise its decision-making role in the annual budgetary procedure and scrutiny over the implementation of the budget in Headings 2b, 4 and 6;
12. As a general rule, decides to restore DB levels on all lines cut by the Council and not reinforced in its reading, with the exception of Heading 7;
13. Points to the importance of ensuring that sufficient financial resources and adequate human resources capacities are allocated to Union agencies enabling them to fulfil their mandate, execute their tasks and respond optimally to the consequences of the COVID-19 outbreak; underlines the fact that proper coordination and synergies between agencies are needed to increase the effectiveness of their work, especially where there is convergence towards specific policy objectives, in order to allow for the fair and efficient use of public money; insists that the Commission ensure optimal allocation of personnel among its Directorates-General reflecting urgent needs and long-term priorities related to the response to the COVID-19 crisis and the European Green Deal in particular;
14. Notes that the updated pragmatic calendar of the budgetary procedure does not allow for a timely agreement on a possible second DB proposal; deems it crucial, therefore, to fully exploit the whole period of the budgetary conciliation in order to achieve an ambitious agreement;
15. Sets the overall level of appropriations for the 2021 Budget (all sections) at EUR 181 762 377 716 in commitment appropriations, representing an increase of EUR 15 016 195 740 compared to the DB; decides in addition to make available an amount of EUR 1 631 420 001 in commitment appropriations further to de-commitments under Article 15(3) of the Financial Regulation; recalls however that that level should be adjusted after the publication of the Amending letter and as the negotiations and conciliation advance;
16. Recalls that, as expressed in its abovementioned legislative resolution of 16 September 2020, in order to finance 2021 Budget, the new categories of own resources should be introduced as of 2021 and that any amounts generated by new own resources beyond the level necessary to cover the repayment obligations of the NGEU in a given year should remain in the Union budget as general revenue notably to top-up the 15 EU flagship programmes as of 2021 accompanied by the corresponding rise of the MFF ceilings;

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<sup>(10)</sup> Text adopted, P9\_TA(2020)0206.

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### Heading 1

17. Highlights that Horizon Europe provides very strong European added value and stresses the importance of the programme for significant areas of European research essential to making the European Green Deal a success, and contributing to the transition towards a climate-neutral economy and society by 2050, and in supporting the digital transformation, which is vital for the Union's future prosperity; stresses also that the COVID-19 outbreak has demonstrated the need to invest in health research; proposes therefore to significantly increase Horizon Europe, in line with its long-held position calling for an overall budget of EUR 120 billion over the 2021-2027 MFF period; considers, furthermore, that the full amount of decommitments made over the whole of the current MFF should be made available, in accordance with Article 15(3) of the Financial Regulation, to support the climate and digital transitions and health research;

18. Is convinced that the fight against cancer should be a priority for the Union, and that efforts need to be significantly stepped up in that regard; underlines the fact that cancer research is an important pillar in that fight; stresses that research intensifies in this field without any delay;

19. Calls for the 2021 Union budget to ensure that the InvestEU Programme is sufficiently funded and delivers on both its long-term objectives and participates in the rebuilding of European long-term competitiveness by providing more investment capacity aimed at supporting sustainable infrastructure, research, innovation, digitalisation, SMEs, and social investments and its new short term objective of supporting a sustainable economic recovery via strategic sustainable investments; notes with deep regret that the European Council has rejected the Commission proposal on a Solvency Support Instrument (SSI); supports the line envisaged in Parliament's preparatory works on the SSI to transfer the appropriations foreseen for the SSI to the InvestEU Programme to the benefit of companies established in Member States and operating in the Union;

20. Stresses the crucial role of the Connecting Europe Facility in fostering the development of a high-performance trans-European network and interconnectivity across Member States in particular those Member States that support a sustainable and cross-border mobility as well as modal shift, with the aim of reducing greenhouse gas emissions by 60 % by 2030, supporting energy and transport projects in the shift towards a climate-neutral economy with security of supply taking into consideration the special situation of European insular and peripheral regions, and stressing the need for a digital transition, including the up-skilling and re-skilling of workers in the Union; proposes therefore major increases;

21. Underlines that the COVID-19 crisis has showed the increasing importance of digitalisation for the daily functioning of the economy; recognises the importance of the Digital Europe Programme in shaping and supporting the digital transition; proposes increases that go beyond its interim position on the MFF, to take account of needs revealed by the pandemic;

22. Recalls the fundamental value of the European Space programme, in particular the contribution of Copernicus and Galileo to the European Green Deal and consequently requests targeted reinforcements to ensure the programmes can support the Union's environmental goals; stresses the importance of independence of the European space industry in the global competition and highlights the added-value of these programmes for job growth, competitiveness, and the development of SMEs;

23. Considers that it is also necessary to strengthen further important priorities in the heading; calls, inter alia, for a substantial increase in the amount dedicated to SME objectives which are a cornerstone of the Union economy and play a crucial role in delivering excellent quality investment and job creation in all Member States, also with the aim of supporting and increasing the participation of women in SMEs and their access to markets; furthermore, strengthens key programmes of the Space Cluster; recalls the important role that Union agencies play in helping to achieve Union policy objectives; calls therefore for sufficient funding and staffing for the EU-Agency for Cybersecurity (ENISA), the European Union Agency for Railway (ERA), the European Banking Authority (EBA), the European Securities and Markets Authority (ESMA), the European Union for the Space Programme and the Body of European Regulators for Electronic Communications (BEREC) in line with their tasks and responsibilities;

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24. Reiterates its demand for support to SMEs, in particular in the tourism sector, the creative industry and the transport sector so as to build up their capacity to recover from the consequences of the COVID-19 outbreak; moreover, reiterates Parliament's request, stemming from the 2018 interim report on the Multiannual Financial Framework 2021-2027 <sup>(1)</sup>, for the creation of a new specific budget line in order to take into consideration the tourism sector, which is of paramount importance for the whole Union economy, competitiveness, employment (it ensures 23 million direct and indirect jobs in the Union, especially for young people) and social development, has been particularly hard hit by the COVID-19 crisis and is experiencing a rapid and sharp drop in demand and a surge in job losses, putting many European SMEs at risk;

25. Regrets that the Commission did not propose the creation of a dedicated line for tourism due to the current situation; calls for quick direct and indirect support for that sector, in particular for SMEs;

26. Increases therefore the level of commitment appropriations for Heading 1 by EUR 6 313 980 774 above the DB (excluding pilot projects and preparatory actions), of which EUR 5 996 664 225 for flagship programmes; in addition, makes available to the heading an amount of EUR 1 631 420 001 in commitment appropriations further to de-commitments under Article 15(3) of the Financial Regulation;

### **Heading 2a**

27. Decides to take over the Council's reading of Heading 2a;

### **Heading 2b**

28. Emphasises the urgent need to allocate additional resources to the EU4Health Programme, contributing in particular to address the significant structural needs identified during the COVID-19 crisis, setting out key action areas such as the improvement of national health systems and reduction of health inequalities, ensuring the availability and affordability of medicines and other crisis-relevant products, to ensure continued and timely provision of accessible and safe sexual and reproductive health and rights (SRHR) services and to strengthen *inter alia* the Union fight against cancer;

29. Emphasises the importance of Erasmus+ as a key flagship programme and one of the most successful Union programmes with strategic investment in the future of the Union and of its citizens; recalls that insufficient funding for the Erasmus+ programme would endanger the continued creation of new opportunities for and the increased employability of young people, as well as the capacity of the programme to reach its new objectives and to uphold the challenges of becoming more inclusive and ecological; decides therefore to substantially increase the funding for Erasmus+ in line with its position to triple its budget;

30. Recalls that the cultural and creative sector is one of the most hit by the COVID-19 outbreak and calls for adequate answers and financing to reduce continuing substantive losses of the sector due to the unforeseeable closure of venues during the COVID-19 crisis; proposes therefore to substantially increase the respective budget lines of Creative Europe to support the sectors affected by the crisis;

31. Insists on the need for more transparency in the allocation of funds under the various programme components and sub-programmes of Erasmus+, by restoring its previous nomenclature, and of Citizens, Equality, Rights and Values Programme by creating a new budget line for the Union values strand; reiterates its request to the Commission to increase transparency in its use of the budget assigned to multimedia activities, in particular by creating a series of new budget lines in connection with the measures;

32. Decides to create new budget line 07 06 04 'Protect and promote Union values' in order to reinforce the funding focus on protecting and promoting democracy, the rule of law and fundamental rights including supporting activities by civil society organisations in this area;

33. Echoes the Commission prediction that, in the context of recovery from the COVID-19 outbreak, fighting against extreme poverty, and especially tackling child poverty will become even more important in the coming years; consequently, insists that a separate budget line under ESF+ needs to be created for the European Child Guarantee with an allocation of EUR 1 billion for the year 2021; recalls the importance of a sufficient Fund for European Aid to the Most Deprived (FEAD), especially in the context of the COVID-19 outbreak;

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<sup>(1)</sup> Texts adopted, P8\_TA(2018)0449.

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34. Recalls that the COVID-19 crisis affects women, groups of people who are subject to systematic gender-based discrimination and other vulnerable groups disproportionately and calls for the reinforcement of the Employment and Social Innovation strand to support programmes and trainings targeted at advancing their participation and tackling their precarity on the labour market;

35. Stresses the crucial role of the Citizens, Equality, Rights and Values Programme to protect and promote the rights and values enshrined in the Treaties and the EU Charter of Fundamental Rights and insists that additional appropriations are required for each stand and notably for the Daphne strand to fight violence against women and for the strand promoting citizens engagement and participation in the life of the Union;

36. Emphasises the importance of the Justice Programme in contributing to the further development of a European area of justice based on rule of law, mutual recognition and mutual trust and decides to reinforce that programme;

37. Calls for an increase in appropriations in the Culture, Creativity and Inclusive Society Cluster to better integrate a gender perspective in each of the programmes, as well as to support and promote gender studies and research in the Union;

38. Deems it necessary to increase appropriations for the Turkish Cypriot Community budget line for the purpose of contributing decisively to the continuation and intensification of the mission of the Committee on Missing Persons in Cyprus and supporting the bi-communal Technical Committee on Cultural Heritage, thereby promoting trust and reconciliation between the two communities;

39. Deeply regrets that the Commission still has not responded to Parliament's call for a comprehensive review of the budget line for multimedia measures, particularly with regard to the framework contract with Euronews; decides to put its budgetary allocation in reserve until the Commission has answered the concerns raised by the Court of Auditors; notes however that the Court of Auditors does not point to any shortcomings on Euronews' part in its contractual reporting duties under the current framework;

40. Recalls the important role played by the decentralised agencies active under this heading; demands to provide the EU Agency for Fundamental Rights (FRA) with sufficient financial and human resources to perform its tasks, considering the additional projects which have been identified through the agency's consultation process with stakeholders; asks to provide the European Institute for Gender Equality (EIGE) and the European Labour Authority (ELA) with adequate budgetary resources, taking into account the relevance of their mission, as well as the expected role of ELA in ensuring fair labour mobility in the context of the COVID-19 crisis; calls in addition for sufficient funding and staffing, for further important priorities, to be allocated to the European Union Agency for Criminal Justice Cooperation (Eurojust), the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA);

41. Decides to apply targeted reinforcements to the European Public Prosecutors Office (EPPO) to allow the body to take up its duties without delay and in line with the requirements to fulfil its mandate; believes that its nature requires a stronger guarantee of independence, and its budget should therefore be presented under Heading 7, as an independent entity organism rather than assimilated to an agency; underlines that the establishment of the EPPO must not result in a deterioration of capacity of the European Anti-Fraud Office (OLAF) to function properly;

42. Rejects the Commission proposal to merge different budget lines linked to social policy objectives; believes that separate budget lines as was the case in the past would guarantee the necessary transparency and resources for each of those key areas;

43. Decides to transfer the budget line 06 04 01 (EU Recovery Instrument — Payment of periodic coupon and redemption at maturity) to Chapter 17, as all financing costs of NGEU-related spending should be counted over and over the MFF ceilings;

44. Reinforces Heading 2b overall by EUR + 5 894 270 074 above the DB in commitment appropriations (excluding pilot projects and preparatory actions), EUR 6 041 509 293 of which is for flagship programmes;

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**Heading 3**

45. Reminds that the European Council, in its position on the European Recovery Instrument, did not retain the level of support for the Just Transition Fund as foreseen by the Commission proposal; expresses its concerns that these cuts will seriously undermine the recovery efforts; re-iterates that the Just Transition Fund is a vital and indispensable building block in the architecture of the European Green Deal; proposes therefore an increase of EUR 500 million in commitment appropriations for that flagship programme in 2021;

46. In line with the overall priority to tackle climate change and prevent biodiversity loss, focuses substantial increases worth EUR 237 million in commitment appropriations on budget lines pertaining to LIFE programme; notes that that increase is intended to contribute to the main objectives such as preservation of nature and biodiversity, the circular economy and quality of life, climate change mitigation and adaptation as well as the clean energy transition; expects the Commission to warrant the necessary absorption capacity for an effective use of these additional means;

47. Reminds that a number of agricultural sectors have been hard hit by the COVID-19 outbreak and therefore supports targeted reinforcements on budget lines for market support measures under the European Agricultural Guarantee Fund (EAGF) which aim at mitigating the effects of the crisis caused by that outbreak, notably for organic farms and small-scale farmers; expects the Amending letter to adjust further the level of appropriations of EAGF by taking into account the assigned revenue expected to be available in 2021 and other parameters such as the impact of the COVID-19 outbreak on agricultural sectors;

48. Considers that any appropriations, especially from the Common Agricultural Policy, shall not be used for supporting breeding or rearing of bulls used for lethal bull fighting activities.

49. Highlights the particularly difficult socio-economic circumstances in the Union's outermost regions, compounded by the impact of the COVID-19 crisis; against that background, proposes a top-up for the budget line covering the POSEI programme for the maintenance of the agricultural activity and for the supply of food and agricultural products in the outermost regions, which must be provided with adequate resources; furthermore, underlines the importance of taking into account the special characteristics and constraints of the outermost regions when designing Union programmes and funds in the Multiannual Financial Framework 2021- 2027 and in the NGEU.

50. Reinforces the European Maritime and Fisheries Fund by EUR 19,6 million; recognises that 2021 will be a key year for the fisheries sector, which will have to face simultaneously the challenges of the adaptation to European Green Deal objectives, the risks associated with the COVID 19-crisis and Brexit;

51. Stresses the importance of ensuring sufficient financial resources for the collection, management, use and exchange of data in the fisheries sector;

52. Intends to support the European Environment Agency (EEA) with additional financial and human resources, considering that the agency is expected to play a fundamental role in supporting Green Deal related actions, by monitoring and reporting on the Union biodiversity strategy, circular economy, climate change adaptation and zero pollution initiatives.

53. Overall, reinforces Heading 3 by EUR 867 937 490 above DB in commitment appropriations (excluding pilot projects and preparatory actions), EUR 739 100 000 of which is for flagship programmes;

**Heading 4**

54. Increases funding for Parliament's priorities in the fields of migration and border management, most prominently the Integrated Border Management Fund and the Asylum and Migration Fund; at the same time, aims to enhance budgetary transparency by reflecting both Funds' specific objectives into the budget structure, so that the budgetary authority can track expenditure more closely;

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55. Underlines that it is of paramount importance to invest in adequate funding and staffing levels for all agencies operating in the fields of migration, asylum and border management; requests additional staff resources for the European Asylum Support Office (EASO), which will be necessary for the agency to properly implement its field operations, training development, analytical activities and governance framework, as well as for the European Union Agency for the Operational Management of Large-Scale IT-Systems in the Area of Freedom, Security and Justice (eu-Lisa); requests additional financial and staff resources for the European Border and Coast Guard Agency (Frontex);

56. Is deeply concerned by the continuing loss of lives in the Mediterranean; is of the opinion that a more long-term approach to search and rescue (SAR) operations is necessary as SAR cannot be exclusively left to non-state actors; considers that the Commission should present a legislative proposal to set up a Search and Rescue Fund to support SAR missions in the Mediterranean; proposes, therefore, the creation of a new budget line for that fund to encourage the saving of lives and to show solidarity among Member States in the carrying out of SAR operations in accordance with international law and fundamental rights, including the right to life and the principle of non-refoulement;

57. In sum, reinforces Heading 4 by EUR 710 251 000 in commitment appropriations above DB levels, EUR 500 251 000 of which is for flagship programmes;

**Heading 5**

58. Stresses the importance of a progressive framing of the Union's common security and defence policy; underlines the importance of enhancing European cooperation in defence matters since it not only makes Europe and its citizens safer, but also leads to a cost reduction; calls for increased funding for the European Defence Fund in order to fully foster an innovative and competitive defence industrial base that will contribute to the much-needed strategic autonomy of the Union;

59. Calls for increased funding for military mobility with the aim of helping Member States act faster and more effectively; notes that sufficient funding is needed to support missions and operations under the common security and defence policy, including by measures such as funding dual-use transport infrastructure and simplifying diplomatic clearances and customs rules;

60. Recalls that the important role played by decentralised agencies operating in the field of security and law enforcement, in particular with regard to European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the European Union Agency for Law Enforcement Cooperation (Europol), to ensure its important activity in the areas of fight against terrorism and organised crime, and proposes targeted increases to allow them to properly perform their tasks;

61. Reinforces Heading 5 overall by EUR 372 320 760 above the DB (excluding pilot projects and preparatory actions), EUR 312 829 132 of which is for flagship programmes;

**Heading 6**

62. Emphasises that at a time when external challenges and matters of international relations are gaining importance and are dominating international politics, the external dimension of the Union budget must be appropriately funded and prepared to respond without delay to current, emerging, as well as future challenges; notes that the bulk of external action spending is concentrated in NDICI, on which inter-institutional legislative negotiations are still ongoing;

63. Regrets that the new nomenclature for external action as proposed by the Commission is much less detailed than the previous one, reducing transparency, predictability, accountability, scrutiny, and limiting the budgetary authority's capacity to make choices reflecting political priorities; insists, therefore, that a more differentiated budget structure, with dedicated lines for the most important beneficiaries, policy areas and sub-regions, is needed, in order to enhance the clarity and readability of the budget; proposes therefore a revised nomenclature for NDICI, adapted to the new instruments, while introducing a higher level of detail;



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64. Calls for increased funding levels for all geographic and thematic programmes under the NDICI, in line with its first-reading position on the latter; reiterates its position that the thematic programmes within the NDICI should be reinforced in order to allow the Union to maintain its strong role in these priority areas; underlines that its position on the allocations for the NDICI is fully aligned with the amounts laid down in Parliament's first-reading position on the NDICI;

65. Proposes the creation of a dedicated budget line for 'the support to the political process in Libya' with the objective of contributing to a peaceful resolution to the Libyan conflict;

66. Points to the persistent challenges in the Union's Eastern and Southern neighbourhood, the dedicated budget for which should therefore be reinforced, as well as the importance of endowing the United Nations Relief and Works Agency for Palestine Refugees in the Near East with increased financial support to fulfil its mandate, in view of the growing needs of Palestinian refugees and as an investment towards stability and development in the region; recalls the importance of developing stable relations and strong cooperation between the Union and Africa and considers it appropriate that sufficient financial resources be dedicated to the development of that continent, which would contribute inter alia to mitigating the root causes of forced migration;

67. Emphasises the urgent need to step up development cooperation on health, remote and inclusive high-quality learning programmes, and climate change adaptation and mitigation, as well as on biodiversity, nutrition, sustainable agriculture and food security, as the COVID-19 crisis worsens the upward trend in global hunger; points out that in that regard support to institution building and strengthening and education to enlarge the skilled labour force are of great importance; affirms that a much higher sum is essential for the people, planet, prosperity and partnership lines than the figure set out for the Global Challenges line in the DB;

68. Underlines the need for meaningful financing of the Western Balkans with a view to the accession process as well as numerous challenges that the Union and the candidate countries need to face; deems it essential that the new nomenclature for the IPA III instrument comprises separate budget lines for the Western Balkans and Turkey, in view of the highly sensitive nature of Union funding for Turkey;

69. Denounces Turkey's continuous violations of international and Union law, and Union principles and values; demands that the funding for political reforms in Turkey be exclusively dedicated to fostering dialogue and providing support to civil society, non-state actors and people-to-people contacts, as long as the country does not make any progress with regard to democracy, rule of law and human rights; strongly condemns Turkey's repeated provocations and violations of Greek and Cypriot sovereignty;

70. Insists, even more so in the current COVID-19 climate and following the unfortunate decision of the European Council to discard the external pillar of NGEU, on the need to increase the humanitarian aid chapter and the need for safeguards against the crowding out of internal or external use of the Solidarity and Emergency Aid Reserve; underlines the need to ensure the continuing financing of the EU Aid Volunteers initiative, in the event of a possible impasse in the ongoing negotiations on the European Solidarity Corps programme;

71. Following the recent worrying developments in Belarus, calls for Union support through the European External Action Service and the High Representative of the Union for Foreign Affairs and Security Policy (HR/VP), as well as through the creation of a new Special Representative for Belarus, to support the process for a peaceful transition of power in accordance with a UN- or alternatively an OSCE-led dialogue based on the protection of human rights and the will of the Belarusian people;

72. In light of threats related to cybersecurity as well as the spreading of fake news, highlights the need for the Union budget to better address and respond to them on a horizontal level, both at the headquarters and at Union delegations around the world; deems it necessary therefore to reinforce lines dedicated to strategic communication for external action;

73. Reinforces Heading 5 overall by EUR 698 781 256 above the DB (excluding pilot projects and preparatory actions), EUR 583 041 792 of which is for flagship programmes;

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### **Heading 7**

74. Decides not to restore, at this stage, the Council's cuts in Heading 7;
75. Deeply regrets that the Commission still has not responded to Parliament's call for full access to contracts and information regarding the COVID-19 vaccines-related contract covered by Draft amending budget No 8/2020; demands that the Commission grant the budgetary authority access to the COVID-19 vaccines-related contract before the end of 2020;

### **Pilot projects and preparatory actions (PP-PAs)**

76. Recalls the importance of pilot projects and preparatory actions (PP-PAs) as tools for the formulation of political priorities and the introduction of new initiatives that have the potential to turn into standing Union activities and programmes; having carried out a careful analysis of all the proposals submitted adopts a balanced package of PP-PAs that reflects Parliament's political priorities; calls on the Commission to swiftly implement PP-PAs, in close cooperation with Members, and provide feedback on their performance and results delivered on the ground;

### **Payments**

77. Underlines the necessity to provide a sufficient level of payment appropriations in the 2021 Budget that will take into account the volume of outstanding commitments at the end of 2020 in order to avoid the accumulation of unpaid claims from MFF 2014-2020 and to finance the frontloading of expenditure related to the COVID-19 crisis; notes that, due to delays in the implementation of the 2014-2020 programming period, most of the relevant payments will be settled in 2021 and 2022; underlines the increased accuracy of the Member State forecasts which need to be fully taken into account in the 2021 Budget; stresses therefore that a credible payments plan for the whole MFF 2021-2027 is needed, providing for sufficient payments in its first years with a possibility to carry unused payments forward to the next years with the help of special instruments over and above the MFF payments ceilings;
78. Recalls that several legislative measures have been adopted in the course of 2020 aimed at facilitating absorption, cutting red tape and accelerating the actual disbursement of funds under several programmes in order to provide cash-flow and liquidity in a context of severe economic depression; judges that this approach would be severely and unjustifiably compromised if not underpinned by a sufficient level of payment appropriations in 2021; calls therefore for adequate means to be made available as of the adoption of the 2021 Budget; commits to take any steps necessary to adjusting of payment appropriations in the course of execution throughout 2021;
79. Reiterates Parliament's position of 4 April 2019 on the proposal for a regulation of the European Parliament and of the Council on the protection of the Union's budget in the case of generalised deficiencies as regards the rule of law in Member States<sup>(12)</sup>; underlines the importance of having a mechanism in place to protect the Union budget where there is a systemic threat to values enshrined in Article 2 of the Treaty on European Union, and where the financial interests of the Union are at stake; stresses that Parliament will not accept an agreement on a mechanism which does not protect the Union budget against general deficiencies in the rule of law;

### **Other Sections**

#### **Section I — European Parliament**

80. Expresses its surprise and deep concern at the Commission's proposed cuts to Parliament's budget, which break once more the tradition of good cooperation between the two institutions; restores the appropriations established in the estimates on the basis of a careful and responsible analysis of the needs of Parliament for 2021 and adopted by plenary in its abovementioned resolution on 14 May 2020 with a large majority. and adjusts those to take into account the setting-up

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<sup>(12)</sup> Texts adopted, P9\_TA(2019)0349.

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of five new parliamentary committees when restoring the appropriations; highlights that, in the course of 2021, the 2021 Budget might need to be adjusted in order to take account of the evolution of the COVID-19 crisis;

81. Notes the ongoing negotiations on the new Multiannual Financial Framework 2021-2027 and the uncertainty regarding the funding level of the new Heading 7 — European Public Administration; stresses that Parliament has fulfilled the 5 % staff reduction objective and actually saw an overall cut of 6 %; highlights the fact that, since the adoption of the Lisbon Treaty, Parliament has had to cope with an increased amount of tasks; notes that synergies and re-prioritisation were achieved in the last legislative term; stresses that the functioning of Parliament depends on the fulfilment of its political, legislative and administrative tasks, which require adequate staffing levels; is deeply concerned by the serious and structural understaffing in many committees' secretariats in contradiction with the important increase of their workload and invites the Bureau and the Secretary-General to urgently provide solutions to adequately staff the committees' secretariats;

82. Reiterates Parliament's priorities for the forthcoming financial year, namely, focusing Parliament's budget on its core functions of legislating, acting as one arm of the budgetary authority, representing citizens and scrutinising the work of other institutions, as well as providing the resources for priority projects on engaging with citizens, green Parliament promoting the saving of resources, accessible Parliament, fully respecting gender issues, building security, cyber-security and IT development, and multiannual building projects;

83. In line with the estimates adopted by Parliament:

- (a) welcomes the measures taken by Parliament regarding the COVID-19 outbreak, including new temporary working methods and the provision of a COVID-19 screening test centre for Members and staff; reiterates its request to the Secretary-General to evaluate the financial consequences of those measures on Parliament's budgets for 2020 and 2021 and present it to Parliament's Committee on Budgets in November 2020; calls on the Secretary-General to elaborate detailed guidelines to better prepare for any future *force majeure* events in order to ensure the continued fulfilment of Parliament's legislative functions if orderly functioning cannot be upheld;
- (b) reiterates its call on the Bureau for a detailed roadmap on achieving the ambitious environmental targets and reducing its carbon footprint as set in the Bureau decision of 16 December 2019 and for an annual review of results to be presented to Parliament's Committee on Budgets;
- (c) recalls its request to align the accredited parliamentary assistants (APAs) mission allowances for the missions they carry out between the three places of work of Parliament to the level of allowance for civil servants and other agents; calls again for the revision of the Implementing provisions governing the work of delegations and missions outside the Union to consider the possibility for APAs, subject to certain conditions, to accompany Members on official Parliament delegations and missions;
- (d) reiterates its request to the Bureau to establish full flexibility of presence for Members during green weeks;
- (e) underlines the need for Parliament's Committee on Budgets to receive all relevant information relating to Parliament's budget in a timely and intelligible manner to be able to take informed decisions; strongly reiterates its requests for:
  - a detailed analysis and justification of the costs and savings relating to the withdrawal of the United Kingdom from the Union and that the exact figures be communicated to Parliament's Committee on Budgets in November 2020;
  - a detailed breakdown of expenditure for the establishment of the new Europa Experience centres for 2021 while taking into consideration the potential consequences of the COVID-19 outbreak on local market prospects and the roll out of Europa experiences spaces;

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- a detailed breakdown of expenditure for the new visitor strategy and the four-year information campaign, as well as a thorough evaluation of the communication campaign undertaken before and during the 2019 European elections; is of the opinion that any new communication measures should be based on an objective and factual analysis of that evaluation;
  - a detailed and thorough analysis of the representation costs of diplomatic presence beyond the borders of the Union in Indonesia (Jakarta), Ethiopia (Addis Ababa) and the United States (New York);
  - further details regarding the expenditure for the project management of the construction of the west wing of the Konrad Adenauer building;
  - an overview of all other currently rented Parliament buildings in the three places that will remain occupied in 2021 as well as a detailed projection of the energy costs; calls in that regard for green energy savings;
  - an analysis of the impact on human resources, especially on translators and interpreters, of the Directorate-General for Translation project in the event of a tool being deployed that is able to automatically transcribe and translate parliamentary multilingual debates in real time;
  - a transparent decision-making process in the field of buildings policy;
- (f) asks the Bureau to make known its decision on the future of the Spaak building in Brussels and a detailed breakdown of the costs at the end of the architectural competition launched by Parliament in 2020 for its renovation or replacement; recalls that the 2021 Budget includes items for the preparation of the works in the Spaak building;
- (g) recalls the recommendations contained in Parliament's resolutions of 26 October 2017 <sup>(13)</sup>, 11 September 2018 <sup>(14)</sup> and 15 January 2019 <sup>(15)</sup> on combating sexual harassment and abuse in the Union as well as measures to prevent and combat mobbing and sexual harassment; acknowledges the measures taken by the Secretary-General to prevent and combat such events; demands that the Secretary-General provide all information on the programme for the near future; asks the Secretary-General to provide an assessment of the new harassment procedures before presenting the 2022 estimates to the Bureau; is of the opinion that staff as well as Members should be encouraged to participate in training courses to minimise the occurrence of such events inside Parliament;
- (h) recalls the request from the Bureau to the Secretary-General to investigate as soon as legally possible ways to ensure the sustainable financing of the Voluntary Pension Fund;
- (i) recalls its request to the Secretary-General to verify that the highest standards of labour law are being upheld by external contractors with respect to cleaning workers in the Parliament, as well as for the workers in the self-service restaurants, in particular as regards psychological pressure and working conditions arising from the COVID-19 crisis;

**Other sections (Sections IV-X)**

84. Notes that, in the main, the DB reflects the estimates of the various institutions falling within the other sections of the budget and therefore matches, with some exceptions, their financial requirements; considers that the horizontal and systematic cuts proposed by the Council would therefore have a deleterious effect on the working of the institutions concerned and consequently on the vital contribution they make to the functioning of the Union; on that account, proposes to restore the levels of the DB in almost all cases, including with regard to the establishment plans of the Court of Justice, the Economic and Social Committee, the Committee of the Regions (CoR), the Ombudsman and the EEAS; in line with the gentlemen's agreement, does not modify the Council's reading concerning the Council and the European Council;

<sup>(13)</sup> Texts adopted, P8\_TA(2017)0417.

<sup>(14)</sup> Texts adopted, P8\_TA(2018)0331.

<sup>(15)</sup> Texts adopted, P8\_TA(2019)0010.

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85. Considers that, in a limited number of cases and taking into account the institutions' estimates, it is necessary to increase lines above the DB; proposes therefore:

- (a) in relation to the European Economic and Social Committee and the CoR, to increase the appropriations above the DB for a few lines, so as to maintain a level of appropriations in line with their estimates;
- (b) in relation to the European External Action Service to increase the appropriations above the DB for the line 2214 'Strategic Communication Capacity' and the line 3001 'External staff and outside services';

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86. Instructs its President to forward this resolution, together with the amendments to the draft general budget, to the Council, the Commission, the other institutions and bodies concerned and the national parliaments.

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P9\_TA(2020)0303

## **EU/Seychelles Sustainable Fisheries Partnership Agreement and Implementation. Protocol (2020-2026) (Resolution)**

**European Parliament non-legislative resolution of 12 November 2020 on the draft Council decision on the conclusion, on behalf of the European Union, of the Sustainable Fisheries Partnership Agreement between the European Union and the Republic of Seychelles and its implementing protocol (2020-2026) (05243/2020 — C9-0073/2020 — 2020/0002M(NLE))**

(2021/C 415/16)

*The European Parliament,*

- having regard to the draft Council decision (05243/2020),
- having regard to the Sustainable Fisheries Partnership Agreement between the European Union and the Republic of Seychelles (05246/2020),
- having regard to the Protocol on the implementation of the Sustainable Fisheries Partnership Agreement between the European Union and the Republic of Seychelles (2020-2026),
- having regard to the request for consent submitted by the Council in accordance with Article 43, Article 218(6), second subparagraph, point (a)(v), and Article 218(7) of the Treaty on the Functioning of the European Union (TFEU) (C9-0073/2020),
- having regard to its legislative resolution of 11 November 2020 <sup>(1)</sup> on the draft Council decision,
- having regard to Article 208 of the TFEU on policy coherence for development,
- having regard to Article 31(4) of Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy (CFP) <sup>(2)</sup>,
- having regard to its resolution of 12 April 2016 on common rules in respect of application of the external dimension of the CFP, including fisheries agreements <sup>(3)</sup>,
- having regard to the report of 29 April 2019 entitled 'Ex-post and ex-ante evaluation study of the Sustainable Fisheries Partnership Agreement between the European Union and the Republic of Seychelles and of its Implementing Protocol',
- having regard to the Seychelles Blue Economy Strategic Policy Framework and Roadmap: Charting the Future (2018-2030),
- having regard to the report of the 18th Session of the Indian Ocean Tuna Commission (IOTC) Scientific Committee of November 2015, in particular its recommendation regarding yellowfin tuna,
- having regard to the report of the 21st Session of the IOTC Scientific Committee of December 2018, in particular its assessment of stocks in the Indian Ocean,
- having regard to the report of the 21st Session of the IOTC Working Party on Tropical Tuna, held in Donostia-San Sebastian, Spain, from 21 to 26 October 2019,
- having regard to Rule 105(2) of its Rules of Procedure,
- having regard to the letter of the Committee on Development,
- having regard to the report of the Committee on Fisheries (A9-0184/2020),

<sup>(1)</sup> Texts adopted, P9\_TA(2020)0296.

<sup>(2)</sup> OJ L 354, 28.12.2013, p. 22.

<sup>(3)</sup> OJ C 58, 15.2.2018, p. 93.

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- A. whereas the Commission and the Government of Seychelles have negotiated a new sustainable fisheries partnership agreement (EU-Seychelles SFPAs), together with an implementing protocol, for a six-year period; whereas the SFPAs with Seychelles is the most important tuna agreement for the Union in terms of catch volume, as it grants access to Seychelles waters to 40 purse seiners, 8 surface longliners, and support vessels, in accordance with the relevant Indian Ocean Tuna Commission (IOTC) resolutions;
- B. whereas the overall aim of the EU-Seychelles SFPAs is to promote sustainable fishing and to define the rules that govern access for Union fishing vessels to the fishing zone of Seychelles;
- C. whereas the new protocol grants fishing opportunities to EU vessels in the Seychelles fishing zone, giving them access to an appropriate share of the surplus of living marine resources, in accordance with the best available scientific advice and the resolutions and recommendations of the IOTC, within the limits of the available surplus;
- D. whereas the EU's commitments under international agreements, notably the UN Sustainable Development Goals (SDGs), have overall been supported and should still be supported under the SFPAs, in particular SDGs 14 and 10; whereas all EU actions, including the conclusion of the SFPAs, must contribute to those objectives;
- E. whereas SFPAs are among the most transparent and sustainable fisheries agreements in the world and provide a sophisticated and robust legal framework and promote high social, environmental and compliance standards;
- F. whereas the agreement promotes the stepping up of economic, financial and scientific cooperation between the EU and Seychelles with the aim of achieving sustainable fisheries;
- G. whereas when the EU is not present in a third country's exclusive economic zone (EEZ), the surplus of stocks are exploited by other fleets that often have lower social or environmental sustainability standards, whose low-cost and unsustainable products end up on the EU market;
- H. whereas the principle of non-discrimination between the different fleets fishing in the waters of the third country with which the EU has concluded an agreement is a fundamental principle contributing to sustainable fishing;
- I. whereas SFPAs also ensure consistency between the principles governing the common fisheries policy and commitments made under other European policies (sustainable use of third-country resources, combating illegal, unreported and unregulated (IUU) fishing, integration of partner countries into the global economy, contribution to sustainable development in all its dimensions, and better political and financial governance of fisheries);
- J. whereas the aim is also to enhance cooperation between the European Union and the Republic of Seychelles in order to promote a sustainable fisheries policy and sound exploitation of fisheries resources in the Seychelles fishing zone and in the Indian Ocean, in the interest of both parties; whereas, in addition, this cooperation will also help to promote decent working conditions in fisheries activities;
- K. whereas the renewal of the protocol would help strengthen monitoring, control and surveillance and would contribute to improved governance of the fisheries in the region;
- L. whereas Seychelles is the operational and logistical centre for tuna fishing activity in the Indian Ocean, and whereas it is important for the EU to maintain an instrument allowing deep sectoral cooperation with a major player in ocean governance at the sub-regional level because of the extent of its fishing area under its jurisdiction; whereas strengthening the relationship with Seychelles also serves to build alliances within the framework of the IOTC.

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- M. whereas Seychelles benefits from dedicated sectoral support that provides for multi-year funding opportunities;
- N. whereas the fisheries sector, including tuna fishing and EU vessels under this agreement, is of great importance to the Seychelles economy, as it is essential for the country's economic development, job creation and food security, and whereas sustainable fish stocks are key to its long-term stability;
- O. whereas the SFPA has contributed overall to the sustainable development of the Seychelles fisheries sector, and should continue to do so, in particular as regards artisanal fisheries, with the aim of ensuring long-term food security and food sovereignty for the country's population;
- P. whereas it is important that the SFPA contributes to improving working conditions in the fisheries sector;
- Q. whereas, under the previous agreement, the overall utilisation rate was 7 % for surface longliners and 69 % for tuna purse seiners, meaning that an average of 27 EU seiners drew authorisation, when up to 40 could have done so;
- R. whereas EU tuna vessels operating under the agreement in the period between 2014 and 2017 landed approximately 22 % of their regional tuna catch at the Indian Ocean tuna cannery (at the international market price);
- S. whereas one of the basic preconditions for achieving sustainable fisheries is having access to accurate and reliable data;
- T. whereas the IOTC stock assessments indicate that skipjack and bigeye tuna are exploited at sustainable levels but that yellowfin tuna stocks are overfished and are subject to excessive fishing effort in the region;
- U. whereas climate change is expected to have a negative impact on the different populations of tuna in the Indian Ocean;
- V. whereas in 2015 the Scientific Committee of the IOTC recommended reducing yellowfin tuna catches by 20 %, but this recommendation was not adequately followed up; whereas in 2018 the Scientific Committee reiterated its recommendation to reduce yellowfin tuna catches in order to allow the recovery of the biomass to sustainable levels;
- W. whereas the Seychelles 2018-2030 Blue Economy Strategic Policy Framework highlights the country's priorities on food security, professional training, marine protected areas and strengthening regional partnerships;
- X. whereas combating illegal, unreported and unregulated fishing is one of the basic preconditions for achieving sustainable fisheries;
- Y. whereas the Union's financial contribution to Seychelles under the SFPA is EUR 5,3 million per year; including EUR 2,8 million for sectoral support; whereas the total contribution of the EU budget is EUR 31,8 million over six years; whereas the fee to be paid by ship-owners per tonne of tuna caught was increased from EUR 55 to EUR 75 under the previous protocol, and whereas the new protocol provides for an increase from EUR 80 per tonne in 2020 to EUR 85 per tonne for the six years; whereas the total contribution by ship-owners is estimated to be EUR 26,4 million over the full duration of the protocol; whereas this amounts to a total financial contribution from the European Union over the entire duration of the protocol of EUR 58,2 million, or EUR 9,7 million per year;
- Z. whereas since 2018 the EU has, via the European Investment Bank, invested EUR 17,5 million in loans and grants for the alteration and extension of Port Victoria, the largest commercial harbour in Seychelles; whereas that investment has been beneficial in terms of the economic competitiveness of Seychelles, job creation and the sustainable growth of all sectors of the local economy;



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AA. whereas a number of Seychelles-flagged vessels are owned by EU citizens or companies;

AB. whereas Parliament must be immediately and fully informed, at all stages, of the procedures relating to the SFPA, its protocol and, if applicable, their renewal;

1. Stresses that the EU-Seychelles SFPA, while providing fishing opportunities for EU vessels and promoting scientific cooperation, has overall ensured that the fishing activity of the EU fleet adheres to sustainability objectives and should keep ensuring that it adheres to environmental protection objectives and does not harm marine biodiversity, meaning that EU vessels fish an appropriate share of the surplus of living marine resources, as calculated on the basis of the best available scientific knowledge and advice;

2. Stresses the need to foster scientific cooperation and to exchange biological conservation and environmental statistical data necessary for the management and conservation of living marine resources so that both Union and other fishing vessels fishing in Seychelles waters can operate in line with sustainability criteria;

3. Stresses that the fisheries sector is an important sector for the Seychelles economy and is essential to the country's economic development, employment and food security;

4. Stresses the importance for the SFPA to be fully in line with and contribute to the conservation and management measures introduced on the basis of the resolutions and recommendations adopted by the regional organisations to which the Republic of Seychelles belongs, notably the IOTC;

5. Welcomes the fact that Seychelles and the EU intend to strengthen their cooperation in the IOTC and to contribute to its resolutions and recommendations; encourages the Commission to put forward joint proposals on strengthening monitoring and controls, as well as on the impact of climate change on tuna populations in the Indian Ocean, including by promoting scientific cooperation;

6. Considers that the EU-Seychelles SFPA should continue to promote further economic, financial, technical and scientific cooperation between the EU and Seychelles in the field of sustainable fisheries and sound exploitation of fishery resources in the Seychelles fishing zone, including support for the control, surveillance and inspection of fishing activities;

7. Takes note of the fact that the Seychelles fisheries sector, including its artisanal component, has not been sufficiently involved throughout the negotiations; calls for the participation of and dialogue with local communities and fisheries stakeholders to be improved, as much as possible, by keeping them informed and through their systematic inclusion in the implementation of the SFPA, its protocol and future renewal, with a view to ensuring that the interests and the development of the Seychelles fisheries sector are not undermined by the EU-Seychelles SFPA and to avoid a disruption in the activities of artisanal local fisheries;

8. Takes note that the protocol to the EU-Seychelles SFPA could potentially lead to an increase in fishing capacity, with a stable number of authorised purse seiners and an increased number of longliners, as all the possibilities were not used under the previous agreement, despite scientific recommendations to reduce the catch of yellowfin tuna, and despite calls from the Seychelles fishers' union to reduce fishing effort in the region;

9. Calls for the implementation of the measures recommended by the IOTC, particularly those concerning the restoration of yellowfin tuna stocks; urges the Commission, together with the Seychelles authorities, to take all necessary measures, in line with the IOTC, to stop the overfishing of yellowfin tuna by the EU fleet, including introducing catch limits for yellowfin tuna and stepping up the fight against IUU fishing; asks the Commission and the Seychelles authorities to promote among other contracting parties the implementation of such measures by all fleets operating in Seychelles waters;

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10. Emphasises the need to improve selectivity with a view to strongly reducing bycatch and the unwanted catch of all species, in particular of sensitive species and juveniles, in order to ensure the long-term sustainability of stocks;
11. Welcomes the fact that the protocol requirement for EU tuna seiners to undertake to supply tuna canning plants and/or the Seychelles local processing industry has been met;
12. Welcomes the introduction of measures to limit the number of support vessels and the use of fish aggregating devices (FADs) in order to reduce their negative impact on juveniles and marine litter; welcomes the obligation to use biodegradable FADs, which must be recovered when they are no longer operational; stresses that these measures should be closely monitored and evaluated; considers, however, that these measures are not sufficient to limit the negative impact of FADS on biodiversity and marine litter and that their use must be quickly and drastically cut back;
13. Welcomes the fact that, for the purposes of environmental management and the observation of marine ecosystems, the Seychelles authorities are envisaging the establishment of a specific fund to which the owners of EU purse seiners will contribute;
14. Stresses the importance of strengthening measures for the prevention and collection of plastic waste in order to reduce marine litter;
15. Welcomes the establishment of marine protected areas by Seychelles in its waters over recent years; expresses concern over the lack of effective management; recalls that they must be managed in line with environment protection objectives, and warns of the negative effects that allowing other economic activities such as oil exploration and exploitation or maritime transport could have on these protected areas; recalls the importance of surveillance and monitoring of these areas so as to have the best scientific knowledge for supporting their management;
16. Stresses that the collection of accurate and reliable data, the exchange and processing of data and effective surveillance, monitoring and control of fisheries are key to ensuring sustainable fish stocks in the long term, and that the EU-Seychelles SFPAs must reinforce cooperation in these fields; welcomes the possibility of carrying out risk-based joint inspection programmes on EU vessels, monitoring, control and surveillance programmes and the transition to an electronic reporting system (ERS) as soon as possible, once agreed by the Joint Committee.
17. Stresses the need to strengthen EU-Seychelles cooperation in the fight against IUU fishing, including through training Seychelles officials in monitoring and inspection;
18. Welcomes the fact that the Seychelles Government undertakes to make public and to exchange information relating to any agreement authorising foreign vessels in its fishing zone and the resulting fishing effort, in particular the number of fishing authorisations issued and the catches reported, as foreign fleets are currently fishing under unpublished agreements in Seychelles waters; reiterates the importance for the Seychelles authorities to only sign fisheries agreements with countries that are committed to combating IUU fishing and with fleets that follow strict sustainable fisheries management rules;
19. Warmly welcomes the Seychelles authorities' undertaking not to agree to conditions more favourable than those set out in the agreement for other foreign fleets fishing in the Seychelles fishing zone that have the same characteristics and catch the same species as those covered by this agreement and its implementing protocol;
20. Invites the Commission to ensure that the reflagging of EU vessels is in compliance with Regulation (EU) 2017/2403 on the sustainable management of external fishing fleets, including by promoting a mandatory International Maritime Organization (IMO) number that would be attached to a vessel for its entire lifetime;
21. Stresses the importance for sectoral support to be targeted more precisely so as to finance measures that actually support the sustainable development of the local fishing sector, in particular its artisanal segment, and that contribute to efficient fisheries management, paying special attention to crew safety training, the improvement of monitoring, control and surveillance (MCS) and training for women and young people, building on the positive aspects of sectoral support under the previous agreement; calls for the publication of the detailed list of projects being funded by the sectoral support provided under this SFPAs and for improved communication on the outcomes of the programmes;

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22. Welcomes the fact that the parties have undertaken to promote economic, trade, scientific and technical cooperation in the fisheries sector and in activities relating thereto, and to encourage human and institutional capacity-building in the fisheries sector to improve skills development and enhance training capacities so as to contribute to sustainable fishing activities in Seychelles and the development of the blue economy;
  23. Calls on the Commission to ensure the necessary oversight of the contribution made by EU ship-owners to the fund created by the Seychelles authorities, for the purpose of environmental management and observation of marine ecosystems in their waters, including in the Joint Committee;
  24. Calls for a detailed evaluation of the effects of the SFPA on local economies in terms of employment, infrastructure development and social and labour conditions;
  25. Calls on the Commission to send to Parliament and make publicly available the minutes and conclusions of the meetings of the Joint Committee provided for in Article 12 of the SFPA and the findings of the annual evaluations; calls on the Commission to enable representatives of Parliament to attend Joint Committee meetings, including via teleconference, and to encourage the systematic participation of Seychelles fishing communities and associated stakeholders;
  26. Calls on the Commission and the Council, acting within the limits of their powers, to keep Parliament immediately and fully informed at every stage of the procedures relating to the agreement and its protocol and, if applicable, of its renewal, pursuant to Article 13(2) of the Treaty on European Union (TEU) and Article 218(10) of the TFEU;
  27. Draws the attention of the Commission and the Council to the fact that persistently proceeding with the provisional application of international agreements before Parliament has given its consent is not compatible with the guiding principles of the Interinstitutional Agreement on Better Law-Making, and that this practice damages the democratic credentials of the EU as a whole, and calls therefore for the procedure to be improved;
  28. Instructs its President to forward this resolution to the Council, the Commission, the governments and parliaments of the Member States, and the Government and Parliament of the Republic of Seychelles.
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P9\_TA(2020)0304

**Programme for the Union's action in the field of health for the period 2021-2027 ('EU4Health Programme') \*\*\*I**

Amendments adopted by the European Parliament on 13 November 2020 on the proposal for a regulation of the European Parliament and of the Council on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ('EU4Health Programme') (COM(2020)0405 — C9-0152/2020 — 2020/0102(COD)) <sup>(1)</sup>

(Ordinary legislative procedure: first reading)

(2021/C 415/17)

**Amendment 1**

**Proposal for a regulation**

**Recital 1 a (new)**

*Text proposed by the Commission*

*Amendment*

- (1 a) *According to Article 8 of the Treaty on the Functioning of the European Union, in all its activities, the Union shall aim to eliminate inequalities, and to promote equality, between men and women, establishing the principle of gender mainstreaming.*

**Amendment 2**

**Proposal for a regulation**

**Recital 2**

*Text proposed by the Commission*

*Amendment*

- (2) In accordance with Articles 9 **and** 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.
- (2) In accordance with Articles 9, **114**, 168 **and** **191** of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union (the Charter), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

<sup>(1)</sup> The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0196/2020).

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**Amendment 3**  
**Proposal for a regulation**

**Recital 3**

*Text proposed by the Commission*

- (3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States and promote the coordination between their programmes, in full respect of the responsibilities of *the Member States for the definition of* their health *policies and the organisation and delivery of* health services and medical care.

*Amendment*

- (3) Article 168 TFEU provides that the Union is to complement and support national health policies, encourage cooperation between Member States, **particularly in border regions**, and promote the coordination between their programmes, in full respect of the responsibilities of **each Member State to define** their **own health policy and to organise, deliver and manage** health services and medical care.

**Amendment 4**  
**Proposal for a regulation**

**Recital 5**

*Text proposed by the Commission*

- (5) On 11 March 2020 the World Health Organization (WHO) declared the novel coronavirus (**COVID-19**) outbreak a global pandemic. **That** pandemic **has** caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering.

*Amendment*

- (5) On 11 March 2020 the World Health Organization (WHO), **due to an exponential increase of cases**, declared **COVID-19 (the disease resulting from** the novel coronavirus **SARS-CoV-2), and associated respiratory disease** outbreak a global pandemic. **The COVID-19 pandemic and more specifically the moderate to severe cases of the disease that need intermediate and intensive medical care pushed several health systems to breaking point within and outside of the Union, and** caused an unprecedented worldwide health crisis with severe socio-economic consequences and human suffering, **particularly affecting people with chronic conditions, causing both premature death and chronic conditions, and hitting the most vulnerable, patients, women, children, carers and the elderly the hardest. The severity of the crisis demonstrates also the importance of Union action and of adequately responding to threats deriving from infectious diseases, and in general of strengthening the Union's actions to complement national policies in the field of public health.**

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**Amendment 5**  
**Proposal for a regulation**  
**Recital 5 a (new)**

*Text proposed by the Commission*

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*Amendment*

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- (5 a) *Health care workers, which have been essential during the COVID-19 crisis, are predominantly women, and have been exposed to greater health risks during the crisis.*

**Amendment 6**  
**Proposal for a regulation**  
**Recital 5 b (new)**

*Text proposed by the Commission*

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*Amendment*

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- (5 b) *Taking into account that the effects of diseases can be different between men and women, as it seems clear with Covid 19, which has a higher mortality rate in men, the Programme should study the causes of diseases' behaviour in order to advance as regards pathology, treatment and cures.*

Friday 13 November 2020

**Amendment 7**  
**Proposal for a regulation**  
**Recital 6**

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*Text proposed by the Commission*

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- (6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>(8)</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States **in order to** improve the prevention and control of the spread of severe human diseases across borders, to combat other serious cross-border threats to health and to safeguard the health and well-being of people in the Union.

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<sup>(8)</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)0112 of 13.03.2020.

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*Amendment*

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- (6) While Member States are responsible for their health policies, they are expected to protect public health in a spirit of European solidarity<sup>(8)</sup>. Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firm action at Union level to support cooperation and coordination among the Member States, **in particular between neighbouring border regions, as well as between authorities and relevant stakeholders. This cooperation should** improve the **preparedness**, prevention and control of the spread of severe human **infections and** diseases across borders, **to develop and make available products for the prevention and treatment of diseases**, to combat other serious cross-border threats to health, and to safeguard **and improve** the health and well-being of **all** people in the Union. **Preparedness is the key to improving resilience to future threats, and Member States, given their responsibility for the provision of healthcare, should carry out stress tests on their healthcare systems to identify weaknesses and verify that they are prepared for a possible future health crisis.**

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<sup>(8)</sup> Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak, COM(2020)0112 of 13.03.2020.

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**Amendment 8**  
**Proposal for a regulation**  
**Recital 6 a (new)**

Text proposed by the Commission

Amendment

- (6 a) *While the Union's action in the field of health is limited, the Union should follow a coherent public health strategy in order to respond to existing epidemics taking into consideration regional and national specificities and have the capacity to face future worrying realities and health threats, such as pandemics and cross-border threats, including antimicrobial resistance, environmental health and the health impacts of the climate change. The Union should support Member States in reducing health inequalities and in achieving universal health coverage, including provision of sexual and reproductive health services, addressing healthcare associated infections, addressing the challenges of vulnerable groups, such as children, infant and maternal care, an ageing population, of chronic diseases, and disease prevention, in promoting a healthy lifestyle, prevention services and preparing their health systems for emerging technologies in order to fully benefit from the digital revolution while seeking synergies with other relevant Union programmes such as Horizon Europe, Digital Europe, the Connecting Europe Facility programme or the Union's Space Programme.*

**Amendment 9**  
**Proposal for a regulation**  
**Recital 7**

Text proposed by the Commission

Amendment

- (7) It is therefore appropriate to establish a new Programme for the Union's action in the field of health, called EU4Health Programme ('the Programme') for the period 2021 -2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration **and** cooperation at **Union** level and actions with an impact on the internal market.
- (7) It is therefore appropriate to establish a new Programme for the Union's action in the field of **public** health, called EU4Health Programme ('the Programme') for the period 2021 -2027. In line with the goals of the Union action and its competences in the area of public health the Programme should place emphasis on actions in relation to which there are advantages and efficiency gains from collaboration **at Union level as well as from cross-border** cooperation at **regional** level and actions with an impact on the internal market. **A holistic approach is needed to improve health outcomes, and EU policy-makers should ensure that the principle of 'health in all policies' is applied in all policy-making.**



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**Amendment 10**  
**Proposal for a regulation**  
**Recital 10**

*Text proposed by the Commission*

- (10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage health **crisis** the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>(10)</sup> and other relevant mechanisms and structures established at Union level. This could include **strategic stockpiling of essential medical supplies or** capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the ‘One Health’ **approach**. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis — prevention, preparedness and response.

<sup>(10)</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

*Amendment*

- (10) Due to the serious nature of cross-border health threats, the Programme should support coordinated public health measures at Union level, **as well as between neighbouring regions** to address different aspects of such threats. With a view to strengthen the capability in the Union to prepare for, respond to and manage **any future** health **crises**, the Programme should provide support to the actions taken in the framework of the mechanisms and structures established under Decision No 1082/2013/EU of the European Parliament and of the Council<sup>(10)</sup> and other relevant mechanisms and structures established at Union level. This could include capacity building in crisis response, preventive measures related to vaccination and immunisation, strengthened surveillance programmes, **health information, and platforms to share best practices**. In this context the Programme should foster Union-wide and cross-sectoral crisis prevention, preparedness, surveillance, management and response capacity of actors at the Union, national, regional and local level, including contingency planning and preparedness exercises, in keeping with the ‘One Health’ **and ‘Health in all policies’ approaches**. It should facilitate the setting up of an integrated cross-cutting risk communication framework working in all phases of a health crisis — prevention, preparedness and response.

<sup>(10)</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

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**Amendment 11**  
**Proposal for a regulation**  
**Recital 11**

*Text proposed by the Commission*

(11) As in the **time of** health **crisis emergency** health technology assessment **as well as** clinical trials can contribute to the rapid development of medical countermeasures **the Programme should provide support to facilitate such actions**. The Commission has adopted a proposal<sup>(11)</sup> on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level.

<sup>(11)</sup> Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM(2018)0051 of 31.01.2018.

*Amendment*

(11) In the **context of public** health **crises**, Health Technology Assessment (**HTA**) **and** clinical trials can contribute to the rapid development, **identification and availability** of medical countermeasures. The Commission has adopted a proposal<sup>(11)</sup> on Health Technology Assessment (HTA) to support cooperation on health technology assessment at Union level. **The Programme should provide support to facilitate such actions**.

<sup>(11)</sup> Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM(2018)0051 of 31.01.2018.

**Amendment 12**  
**Proposal for a regulation**  
**Recital 12**

*Text proposed by the Commission*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses and chronic diseases, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups.

*Amendment*

(12) With a view to protect people in vulnerable situations, including those suffering from mental illnesses, **living with or most affected by communicable or non-communicable diseases** and chronic diseases, **such as obesity, cancer, diabetes, cardiovascular disease and neurological disorders**, the Programme should also promote actions which address the collateral impacts of the health crisis on people belonging to such vulnerable groups. **With a view to guaranteeing continued high standards of essential healthcare services, including prevention, the Programme should, in particular in times of crisis and pandemics, encourage a transition to accessible and affordable telemedicine, at-home administration of medication and implementation of preventative and self-care plans, where possible and appropriate, while ensuring that access to healthcare and prevention services is provided to chronic patients and patients at risk.**

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**Amendment 13**  
**Proposal for a regulation**  
**Recital 13**

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*Text proposed by the Commission*

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- (13) The COVID-19 crisis has highlighted many challenges in ensuring the supply of medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which **foster** the production, procurement and management of crisis relevant products ensuring complementarity with other Union instruments.

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*Amendment*

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- (13) The COVID-19 crisis has highlighted many challenges **including the Union's dependency on third countries** in ensuring the supply of **chemical raw and starting materials, active pharmaceutical ingredients**, medicines, medical devices as well as personal protective equipment needed in the Union during the pandemics. The Programme therefore should provide support to actions which **will increase the security of production, procurement, management and distribution of medicinal products and medical devices in the Union and reduce dependency on third countries by encouraging the diversification of supply chains, fostering the production in the Union and joint** procurement and management of crisis relevant products ensuring complementarity with other Union instruments, **to mitigate the risk of shortages, especially in periods of health crises**.

**Amendment 14**  
**Proposal for a regulation**  
**Recital 14**

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*Text proposed by the Commission*

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- (14) In order to minimise the public health consequences of serious cross-border threats to health it should be possible for actions supported under the Programme to cover coordination of the activities which strengthen the interoperability and coherence of Member States' health-systems through benchmarking, cooperation and exchange of best practices and ensure their capability to respond to health emergencies, that includes contingency planning, preparedness exercises and the upskilling of health care and public health staff and the establishment of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in time of crisis.

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*Amendment*

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- (14) In order to minimise the public health consequences of serious cross-border threats to health it should be possible for actions supported under the Programme to cover coordination of the activities which strengthen the interoperability and coherence of Member States' health-systems through benchmarking, cooperation and exchange of best practices **also via an increased number of joint actions** and ensure their capability to respond to health emergencies, that includes contingency planning, preparedness exercises and the upskilling of health care and public health staff and the establishment of mechanisms for the efficient monitoring and needs-driven distribution or allocation of goods and services needed in time of crisis, **which would be particularly beneficial in a cross-border context**.

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**Amendment 15**  
**Proposal for a regulation**  
**Recital 14 a (new)**

Text proposed by the Commission

Amendment

- (14a) *The establishment of a communication portal for the public would allow the Union to share validated information, send alerts to European citizens and fight against disinformation. It could include a wide range of information, prevention campaigns and youth education programs. This portal could also be used to promote, in cooperation with the European Centre for Disease Control ('ECDC'), strong immunization coverage at European level.*

**Amendment 16**  
**Proposal for a regulation**  
**Recital 15**

Text proposed by the Commission

Amendment

- (15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster disease prevention and health promotion, to provide new care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs and ensure an efficient public health workforce equipped with the right skills, including digital skills. The development of a European health data space would provide health care systems, researchers and public authorities with means to improve the availability and quality of healthcare. Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006 <sup>(12)</sup> the Programme should support actions ensuring the universality and inclusivity of health care,

- (15) Experience from the COVID-19 crisis has indicated that there is a general need for the support to structural transformation of and systemic reforms of health systems across the Union to improve their effectiveness, accessibility, **sustainability** and resilience. In the context of such transformation and reforms, the Programme should promote, in synergy with the Digital Europe Programme, actions which advance digital transformation of health services and increase their interoperability, contribute to the increased capacity of health systems to foster **primordial, primary, secondary, tertiary and quaternary** disease prevention and health promotion, to provide new **outcome-based** care models and to deliver integrated services, from the community and primary health care to the highly specialised services, based on people's needs **enhancing citizens' levels of health literacy and digital health literacy**, and ensure an efficient public health workforce equipped with the right skills, including digital skills, **regularly updated in the light of scientific and technological progress, as provided for in Directive 2005/36/EC of the European Parliament and of the Council <sup>(11a)</sup>. The synergy between the European Health Programme and the Digital Europe Programme should contribute to the implementation and expansion of e-health, reducing unnecessary travel and unmet healthcare needs.** The development of a European health

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*Text proposed by the Commission*

meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected.

<sup>(12)</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

*Amendment*

data space **and of a European electronic health record** would provide health care systems, researchers and public authorities with means to improve the **accessibility, affordability,** availability and quality of healthcare, **increasing the amount of data available to patients and health workers, and thereby improving the quality of healthcare and the patient's freedom of movement around the Union.** Given the fundamental right to access to preventive healthcare and medical treatment enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in view to the common values and principles in European Union Health Systems as set out in the Council Conclusions of 2 June 2006 <sup>(12)</sup> the Programme should support actions ensuring the universality and inclusivity of health care, meaning that no-one is barred access to health care, and those ensuring that patients' rights, including on the privacy of their data, are duly respected. **The Programme should support access to and sharing of personal health data, without prejudice to the application of GDPR and increase the digital skills of patients.**

<sup>(11a)</sup> *Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).*

<sup>(12)</sup> Council Conclusions on Common values and principles in European Union Health Systems (OJ C 146, 22.6.2006, p. 1).

#### Amendment 17

#### Proposal for a regulation

#### Recital 15 a (new)

*Text proposed by the Commission**Amendment*

**(15 a) Gender and sex sensitivity and knowledge need to be improved in the education of health care professionals, the research, diagnosis, treatment and impact of medicines and therapeutics to better understand and treat both sexes.**

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**Amendment 18**  
**Proposal for a regulation**  
**Recital 15 b (new)**

*Text proposed by the Commission*

*Amendment*

**(15 b) Under Article 153 TFEU, the Union is to support and complement the activities of Member States concerning improvement of the working environment, and protection of workers' health, safety and working conditions. It is important to take account of the large amount of time that workers spend in their workplaces and the potential health risk they could be exposed to, such as health hazard substances and carcinogens and to repeated movements, leading to a high burden as regards incapacity and number of work days lost, which in turn has consequences for the individual, family and society. The Programme should also reflect the importance of occupational health and its impact on health workers and societies. The Commission should work with Member States to create new legislation to improve workers' health conditions, improve their working conditions, the balance between work and life, promote wellbeing and better mental health, prevent early-retirement due to ill health and poor health management.**

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**Amendment 19**  
**Proposal for a regulation**  
**Recital 15 c (new)**

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*Text proposed by the Commission*

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*Amendment*

(15c) *The programme should facilitate the revision of the EU-OSHA's mandate to promote healthy and safe workplaces across the Union and to support the Agency's activities and analysis regarding occupational safety and health. The Commission should propose a new Union strategic framework on occupational safety and health for the period 2021 — 2027 and continue updating Directive 2004/37/EC of the European Parliament and of the Council<sup>(12a)</sup>. The programme should also support actions to facilitate people's return to the workplace after long-term sick leave and to better include people who are chronically sick or have a disability in the workforce.*

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<sup>(12a)</sup> *Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).*

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**Amendment 20**  
**Proposal for a regulation**  
**Recital 16**

*Text proposed by the Commission*

- (16) Keeping people healthy and active longer and empowering them to take an active role in managing their health will have positive effects on health, health inequalities, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national budgets. The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 'Ensure healthy lives and promote well-being for all at all ages' <sup>(13)</sup>. The Programme therefore should contribute to the actions taken towards reaching **these** goals.

<sup>(13)</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM(2016)0739 of 22.11.2016.

*Amendment*

- (16) **Health is an investment and the Programme should have this concept at its core.** Keeping people healthy and active longer and empowering them to take an active role in managing their health, **by improving their health literacy**, will have positive effects on health, health inequalities, **health inequities**, quality of life, productivity, competitiveness and inclusiveness, while reducing pressures on national **health systems and** budgets. **The Programme should also support action to reduce inequalities in the provision of healthcare, in rural and remote areas including in the outermost regions, for the purposes of achieving inclusive growth.** The Commission has committed to help Member States to reach the sustainable development targets set in the 'UN 2030 Agenda for Sustainable Development' in particular Sustainable Development Goal 3 'Ensure healthy lives and promote well-being for all at all ages' <sup>(13)</sup>. The Programme therefore should contribute to the actions taken towards reaching **the SDGs goals, and consequently improve the social determinants of health and enhance the health of the Union's citizens.**

<sup>(13)</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Next steps for a sustainable European future. European action for sustainability COM(2016)0739 of 22.11.2016.



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**Amendment 21**  
**Proposal for a regulation**  
**Recital 17**

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*Text proposed by the Commission*

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(17) Non-communicable diseases are a result of a combination of genetic, physiological, environmental **and behavioural factors**. Such non-communicable diseases as cardiovascular diseases, cancer, chronic respiratory diseases, **and** diabetes, represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, resulting in considerable social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on prevention across sectors **and policy fields**, combined with efforts to strengthen health systems.

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*Amendment*

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(17) Non-communicable diseases are a result of a combination of genetic **and health determinants** (physiological, **behavioural, and** environmental) Such non-communicable diseases, as cardiovascular diseases, cancer, **obesity**, chronic respiratory diseases, diabetes, **mental health illness and neurological disorders** represent major causes of disability, ill-health, health-related retirement, and premature death in the Union, **while non-communicable diseases were responsible for 87% of Disability-Adjusted Life Years (DALYs) in the Union in 2017**, resulting in considerable **affective**, social and economic impacts. To decrease the impact of non-communicable diseases on individuals and society in the Union and reach goal 3 of the Sustainable Development Goals, **particularly but not exclusively** Target 3.4, to reduce premature mortality from non-communicable diseases by one third by 2030, it is key to provide an integrated response focusing on **health promotion and** prevention across sectors, **specialities and policy-fields, taking into account the interrelated nature of most non-communicable diseases**, combined with efforts to strengthen health systems **and the supply of appropriate medicines., on strengthening the implementation of the WHO Framework Convention on Tobacco Control is crucial to achieving an effective, sustainable reduction in preventable non-communicable diseases. The Program should support actions aimed at integrating mental health into all areas, including in the workspace and in schools, and promote actions to combat depression and suicide and to implement integrative mental health care.**

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**Amendment 22**  
**Proposal for a regulation**  
**Recital 18**

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*Text proposed by the Commission*

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(18) **The Programme** therefore should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing health risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of **illicit** drugs. The Programme should also contribute to the reduction of drugs-related health damage, unhealthy dietary habits **and** physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. The Programme should also **therefore** contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy.

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*Amendment*

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(18) **Health promotion and health prevention are vastly more cost-efficient than treatment, both in terms of money and of quality-adjusted life years, therefore the Programme** should contribute to disease prevention throughout the lifetime of an individual and to health promotion by addressing **determinants of health, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, an unhealthy food environment, and the consumption of illicit drugs and psychoactive substances. To achieve the best health status possible, the Programme should tackle all health determinants. Health promotion, health protection and disease prevention throughout the lifetime of an individual should be at the core of the programme by addressing health and mental** risk factors, such as the use of tobacco and related products and exposure to their emissions, the harmful use of alcohol, and the consumption of drugs **and other addictive behaviours**. The Programme should also contribute to the reduction of drugs-related health damage, **obesity and** unhealthy dietary habits, physical inactivity, and exposure to environmental pollution, and foster supportive environments for healthy lifestyles in order to complement Member States action in these areas. **The Programme therefore should contribute to a high level of human health protection and prevention, throughout the entire lifetime of an individual, including through the promotion of physical activity, nutritional care and promotion of health education. The Programme should also strengthen and support the implementation of the Union's health-related legislation, including in the area of environmental health, and foster the 'Health in All Policies' approach.** The Programme should also contribute to the objectives of the European Green Deal, the Farm to Fork Strategy and the Biodiversity Strategy **and the Chemicals strategy for sustainability.**

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**Amendment 23**  
**Proposal for a regulation**  
**Recital 18 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (18a) *The Programme should continue supporting actions in the area of reducing and preventing alcohol related harm in the perspective of a revised Union alcohol strategy. Protecting children from alcohol should be one of the Programme's priorities.*

**Amendment 24**  
**Proposal for a regulation**  
**Recital 18 b (new)**

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*Text proposed by the Commission*

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*Amendment*

- (18 b) *The burden of chronic diseases is still significant in the Union. Chronic diseases develop slowly, are long-lasting and often incurable. Chronic diseases are, in many cases, associated with more than one comorbidity, which makes them even more difficult to treat and manage. They have caused great human suffering and also placed an enormous burden on health systems. However, many chronic diseases, such as cardiovascular diseases and type 2 diabetes, could be prevented by healthy lifestyle choices, while other illnesses, for instance neurological diseases, can be managed to slow the onset if detected early, or helping patients feel their best and remain active for longer. The Union and the Member States can therefore greatly reduce the burden of Member States by working together to achieve a better and more effective management of diseases, and the Programme should support actions in this area. The Programme should support the development of specific European preventive and disease management guidelines in the area of both communicable and non-communicable diseases, such as cardiovascular diseases, neurodegenerative diseases, respiratory diseases and diabetes.*

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**Amendment 25**  
**Proposal for a regulation**  
**Recital 19**

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*Text proposed by the Commission*

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(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. It is also one of non-communicable diseases that share common risk factors and the prevention and control of which would benefit the majority of citizens. In 2020 the Commission announced the 'Europe's Beating Cancer Plan' which would cover **the entire cycle** of the disease **starting from prevention and early diagnosis to treatment and quality of life of patients and survivors**. The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer.

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*Amendment*

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(19) Cancer is the second leading cause of mortality in the Member States after cardiovascular diseases. **Cancer is caused by many factors and therefore requires a new prevention paradigm that addresses individual health determinants (genetic, lifestyle) and wider (populations) determinants related to occupational, environmental and social exposure factors.** It is also one of non-communicable diseases that share common risk factors **with others** and the prevention and control of which would benefit the majority of citizens. **Poor nutrition, physical inactivity, obesity, tobacco and alcohol are risk factors common to other chronic diseases, such as cardiovascular diseases, and therefore cancer prevention programmes should be implemented within the context of an integrated chronic disease prevention programme.** In 2020 the Commission announced the 'Europe's Beating Cancer Plan' which would cover **every key stage** of the disease: prevention, diagnosis, treatment, **life as a cancer survivor, reinsertion and palliative care and pain management.** **The programme should promote actions to complement the 'Europe's Beating Cancer Plan' and thus improve cancer patients' quality of life.** The measures should benefit from the Programme and from Horizon Europe's Mission on Cancer **in particular by initiatives which support the mid- and long-term goals of the Plan, and address cancer's common risk factors and synergies with other major non-communicable diseases.**

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**Amendment 26**  
**Proposal for a regulation**

**Recital 20**

*Text proposed by the Commission*

(20) The Programme will work in synergy and complementarity with other EU policies, programmes and funds such as actions implemented under the Digital Europe Programme, Horizon Europe, rescEU reserve under the Union Civil Protection Mechanism, Emergency Support Instrument, European Social Fund+ (ESF+, including as regards synergies on better protecting the health and safety of millions of workers in the EU), including the Employment and Social Innovation Strand (EaSI), the InvestEU fund, Single Market Programme, European Regional Development Fund (ERDF), Recovery and Resilience Facility including the Reform Delivery Tool, Erasmus, European Solidarity Corps, Support to mitigate Unemployment Risks in an Emergency (SURE), and EU external action instruments, such as the Neighbourhood, Development and International Cooperation Instrument and the Instrument for Pre-accession Assistance III. Where appropriate, common rules will be established in view of ensuring consistency and complementarity between funds, while making sure that specificities of these policies are respected, and in view of aligning with the strategic requirements of these policies, programmes and funds, such as the enabling conditions under ERDF and ESF+.

*Amendment*

(20) The Programme will work in synergy and complementarity with other EU policies, programmes and funds such as actions implemented under the Digital Europe Programme, Horizon Europe, rescEU reserve under the Union Civil Protection Mechanism, Emergency Support Instrument, European Social Fund+ (ESF+, including as regards synergies on better protecting the health and safety of millions of workers in the EU), including the Employment and Social Innovation Strand (EaSI), the InvestEU fund, Single Market Programme, European Regional Development Fund (ERDF), **including Interreg**, Recovery and Resilience Facility including the Reform Delivery Tool, Erasmus, European Solidarity Corps, Support to mitigate Unemployment Risks in an Emergency (SURE), and EU external action instruments, such as the Neighbourhood, Development and International Cooperation Instrument and the Instrument for Pre-accession Assistance III. Where appropriate, common rules will be established in view of ensuring consistency and complementarity between funds, **avoiding any overlap or duplication of financing**, while making sure that specificities of these policies are respected, and in view of aligning with the strategic requirements of these policies, programmes and funds, such as the enabling conditions under ERDF and ESF+.

**Amendment 249**

**Proposal for a regulation**

**Recital 20 a (new)**

*Text proposed by the Commission*

*Amendment*

(20a) ***The Programme should contribute to the establishment of a reserve of health crisis relevant products, such as essential medicines, vaccines and medical devices, in synergy and complementarity with rescEU, the Emergency Support Instrument, the Resilience Instrument and with other Union policies, programmes and funds.***

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**Amendment 27**  
**Proposal for a regulation**  
**Recital 21**

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*Text proposed by the Commission*

(21) 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. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a considerable body of Union acquis was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to high quality healthcare products and can fully benefit from them.

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*Amendment*

(21) 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. On the basis of Article 114 TFEU and point (c) of Article 168(4) TFEU, a considerable body of Union acquis was developed which guarantees the high standards of quality and safety for medicinal products and medical devices. Given the rising healthcare demand, Member States' healthcare systems face challenges in the availability and affordability of medicines and medical devices. To ensure a better public health protection as well as the safety and empowerment of patients in the Union, it is essential that patients and health systems have access to **sustainable, efficient, equitable, affordable and** high quality healthcare products, **including in a cross-border context**, and can fully benefit from them, **based on transparent, consistent, patient-oriented medical information**.

Friday 13 November 2020

**Amendment 28**  
**Proposal for a regulation**  
**Recital 22**

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*Text proposed by the Commission*

- (22) The Programme should **therefore** support **actions to monitor** shortages of medicines, medical devices and other healthcare products and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. In particular, in order to address unmet medical needs, the Programme should provide support to clinical **trials so as to speed up** the development, authorisation and access to **innovative and** effective medicines, promote incentives to **develop such medicinal products as** antimicrobials and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines.

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*Amendment*

- (22) The Programme should support **the development of a European monitoring, reporting and notification system for** shortages of medicines, medical devices, **vaccines, diagnostic tools,** and other healthcare products, **to avoid fragmentation of the single market** and to ensure greater availability and affordability of those products while limiting the dependency of their supply chains on third countries. **The Programme should, therefore encourage the production of medicinal products and medical devices within the Union.** In particular, in order to address unmet medical needs, the Programme should provide support to clinical **and real world evidence generation to enable** the development, authorisation, **evaluation of** and access to effective medicines, **including generics and biosimilars, medical devices, and treatment, promote research and the development of new medicinal products, with particular attention to be given to antimicrobials and vaccines to tackle AMR and vaccine-preventable diseases,** promote incentives to **boost the production capacity for** antimicrobials, **personalized treatment and vaccination,** and foster the **digital** transformation of healthcare products and platforms for monitoring and collecting information on medicines. **The Programme should also strengthen decision-making on medicines by enabling access to and analysis of real-world healthcare data by regulators and health technology assessments ('HTA'), bodies.** The Programme should also help to ensure best use of research results and facilitate the uptake, scaling-up and deployment of health innovation in healthcare systems and clinical practice.

Friday 13 November 2020

**Amendment 29**  
**Proposal for a regulation**  
**Recital 22 a (new)**

Text proposed by the Commission

Amendment

(22 a) *A harmonised definition should be laid down at Union level for the terms ‘shortage’, ‘tension’, ‘supply disruptions’, ‘stock-out’ and ‘overstocking’. The Commission should work towards developing such harmonised definitions in close cooperation with the Member States and all the relevant stakeholders, including patient organisations. Moreover, the Commission should, in particular, reinforce the definition of ‘shortage’ proposed by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) joint Task Force in 2019.*

**Amendment 30**  
**Proposal for a regulation**  
**Recital 23**

Text proposed by the Commission

Amendment

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance <sup>(14)</sup>, adopted in June 2017 following the request from Member States, and given **the experience with the bacterial secondary infections related to COVID 19**, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, in the framework of an integrated policy on patient safety and prevention of medical errors.

<sup>(14)</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 of 29.6.2017.

(23) As the optimal use of medicines and antimicrobials in particular yields benefits for individuals and health systems, the Programme should promote their prudent and efficient use. In line with the European One Health Action Plan against Antimicrobial Resistance <sup>(14)</sup>, adopted in June 2017 following the request from Member States, and given **that infections and sepsis caused by antibiotic-resistant bacteria are responsible for a high number of deaths in the Union**, it is essential that the Programme supports actions aimed at the prudent use of antimicrobials in humans, animals and crops, **and actions including the use of non-antibiotic integrative treatments**, in the framework of an integrated policy on patient safety and prevention of medical errors. **The Programme should support the monitoring and surveillance programmes on the usage of antimicrobials and AMR, and the support to the implementation of local, regional and national plans to fight against AMR, supported by evidence-based strategies and the sharing of good practices within the Union.**

<sup>(14)</sup> Communication from the Commission to the Council and the European Parliament ‘A European One Health Action Plan against Antimicrobial Resistance (AMR)’, COM(2017)0339 of 29.6.2017.



Friday 13 November 2020

**Amendment 31**  
**Proposal for a regulation**

**Recital 24**

*Text proposed by the Commission*

(24) Since **environmental** pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment <sup>(15)</sup>.

<sup>(15)</sup> Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee 'European Union Strategic Approach to Pharmaceuticals in the Environment', COM(2019)0128 of 11.03.2019.

*Amendment*

(24) Since **the** pollution caused by human and veterinary pharmaceutical substances is an emerging environmental problem that can impact on public health, the Programme should foster measures to strengthen the assessment and appropriate management of environmental risks associated with the production, use and disposal of medicinal products, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment <sup>(15)</sup>.

<sup>(15)</sup> Communication of the Commission to the European Parliament, the Council and the European economic and Social Committee 'European Union Strategic Approach to Pharmaceuticals in the Environment', COM(2019)0128 of 11.03.2019.

**Amendment 32**  
**Proposal for a regulation**

**Recital 25**

*Text proposed by the Commission*

(25) The Union health legislation has an immediate impact on public health, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and provide high quality, comparable and reliable data to underpin policymaking and monitoring.

*Amendment*

(25) The Union health legislation has an immediate impact on public health **and safety**, the lives of citizens, the efficiency and resilience of the health systems and the good functioning of the internal market. The regulatory framework for medical products and technologies (medicinal products, medical devices and substances of human origin), as well as for tobacco legislation, patients' rights in cross-border healthcare and serious cross-border threats to health is essential to health protection in the Union. The Programme therefore should support the development, implementation and enforcement of Union health legislation and, **in conjunction with key partners such as EMA and ECDC**, provide high quality, **unbiased**, comparable and reliable data, **including real-world healthcare data collected locally across Europe, through a well-defined homogeneous methodology**, to underpin policymaking and monitoring, **set targets and develop tools to measure progress**.

Friday 13 November 2020

**Amendment 33**  
**Proposal for a regulation**  
**Recital 26**

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*Text proposed by the Commission*

(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore **support activities to enable** such integrated and coordinated work, **which also serves** to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the **concerned** population and areas so as to maximise their impact.

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*Amendment*

(26) Cross-border cooperation in the provision of healthcare to patients moving between Member States **or living in border regions**, collaboration on health technology assessments (HTA), and European Reference Networks (ERNs) are examples of areas where integrated work among Member States has shown to have strong added value and great potential to increase the efficiency of health systems and thus health in general. The Programme should therefore **be aimed at ensuring that** such integrated and coordinated work **is developed and implemented to its full potential in areas such as HTA and ERNs. That work would serve** to foster the implementation of high-impact practices that are aimed at distributing in the most effective way the available resources to the **relevant groups of the** population and areas so as to maximise their impact.

**Amendment 34**  
**Proposal for a regulation**  
**Recital 26 a (new)**

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*Text proposed by the Commission*

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*Amendment*

(26 a) **Solidarity and unity are principles of the Union and the programme should ensure that the Union has a coherent approach to combating cross-border health-threats. In order to respond to public health threats, the Programme should under Article 168 TFEU support the creation of a European Health Response Mechanism, coordinated by the ECDC and led by the Commissioner for Health and the Commissioner for Crisis Management, fully articulated with the other EU health agencies. This Mechanism with its own medical resources under a strengthened Union Civil Protection Mechanism should be prepared with a pandemic emergency plan, in order to have a coordinated response and the capacity to rapidly scale up the response to future health crises, based on standardised information.**

Friday 13 November 2020

**Amendment 35**  
**Proposal for a regulation**  
**Recital 27**

*Text proposed by the Commission*

- (27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>(16)</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider **the extension of ERNs beyond rare diseases to communicable and non-communicable diseases such as cancer.**

<sup>(16)</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

*Amendment*

- (27) The ERNs, established pursuant to Directive 2011/24/EU of the European Parliament and the Council<sup>(16)</sup> are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources. **ERNs are a ground-breaking platform that represents a unique opportunity and which, based on the innovative use and sharing of knowledge and health data across borders, aims to improve diagnosis and care for people living with a rare or complex disease. The Programme should, therefore, provide adequate funding to support the coordination and collaborative activities of both existing and future ERNs through grants or other instruments that are fit for purpose. It should increase upscale current funding to ensure that ERNs fulfil the objectives set out in their mission.** As the Networks can improve the access to diagnosis and the provision of high-quality healthcare to patients with rare conditions and can be focal points for medical training and research and dissemination of information, the Programme should **also** contribute to the upscaling of networking through the ERNs, and other transnational networks. It should consider **reinforcing ERNs, supporting the creation of new ERNs to cover infectious diseases, complex pregnancies and rare and complex mental health diseases. The reinforcement of ERNs can play a key role in supporting the adoption of a common newly developed screening framework at Union level, starting from disease selection criteria and mechanisms, with the aim of overcoming existing inequalities in terms of screening coverage across Member States. The Programme should also consider the development of excellence networks in the field of communicable and non-communicable diseases, including cancer and paediatric cancer, cardiovascular disease, chronic respiratory disease, diabetes, mental health conditions, neurodegenerative diseases and other major chronic diseases, and in the field of health crisis management.**

<sup>(16)</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

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**Amendment 36**  
**Proposal for a regulation**  
**Recital 27 a (new)**

Text proposed by the Commission

Amendment

*(27 a) The ERNs face significant challenges as regards ensuring they are financially sustainable and are able to operate effectively within and across national healthcare systems, as highlighted by the European Court of Auditors, in their ‘Special report no 07/2019: EU actions for cross-border healthcare’<sup>(16a)</sup>.*

<sup>(16a)</sup> OJ C 192, 7.6.2019, p. 5.

**Amendment 37**  
**Proposal for a regulation**  
**Recital 30**

Text proposed by the Commission

Amendment

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union’s action in the field of health and other Union programmes, including those under shared-management. To maximise those synergies, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union’s action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union’s action in the field of health and another Union programme.

(30) In order to optimise the added value and impact from investments funded wholly or in part through the budget of the Union, synergies should be sought in particular between the Programme for the Union’s action in the field of health and other Union programmes, including those under shared-management, **in particular the Interreg programme, which already addresses cross-border cooperation in the field of health and helps to facilitate the cross-border mobility of patients and health professionals, and to develop access to high quality healthcare through the use of common equipment, shared services and joint facilities in cross-border areas.** To maximise those synergies, **and avoid duplications**, key enabling mechanisms should be ensured, including cumulative funding in an action from the Programme for the Union’s action in the field of health and another Union programme, as long as such cumulative funding does not exceed the total eligible costs of the action. For that purpose, this Regulation should set out appropriate rules, in particular on the possibility to declare the same cost or expenditure on a pro-rata basis to Programme for the Union’s action in the field of health and another Union programme, **guaranteeing detailed and transparent reporting.**

Friday 13 November 2020

**Amendment 38**  
**Proposal for a regulation**

**Recital 31**

*Text proposed by the Commission*

- (31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals.

*Amendment*

- (31) Given the specific nature of the objectives and actions covered by the Programme, the respective competent authorities of the Member States are best placed in some cases to implement the related activities. Those authorities, designated by the Member States themselves, should therefore be considered to be identified beneficiaries for the purpose of Article 195 of the Financial Regulation and the grants be awarded to such authorities without prior publication of calls for proposals. ***Investments from the Programme should be implemented in close cooperation with Member States especially in areas falling under national competences.***

**Amendment 39**  
**Proposal for a regulation**

**Recital 31 a (new)**

*Text proposed by the Commission*

- (31 a) *In order to ensure that each of these objectives is implemented at Union level, the Commission should increase the budget and should submit a proposal to strengthen the mandates of the ECDC and of EMA, which are already pursuing some of the EU4Health objectives at their level, and should have a greater role in the implementation of the Programme.*

*Amendment*

- (31 a) ***In order to ensure that each of these objectives is implemented at Union level, the Commission should increase the budget and should submit a proposal to strengthen the mandates of the ECDC and of EMA, which are already pursuing some of the EU4Health objectives at their level, and should have a greater role in the implementation of the Programme.***

**Amendment 40**  
**Proposal for a regulation**

**Recital 33**

*Text proposed by the Commission*

- (33) Given the common agreed values of solidarity towards equitable and universal coverage of quality health services as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges<sup>(19)</sup>, the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

<sup>(19)</sup> Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010.

*Amendment*

- (33) Given the common agreed values of solidarity towards ***accessible***, equitable and universal coverage of quality health services, ***including in a cross-border context***, as a basis for the Union's policies in this area and that the Union has a central role to play in accelerating progress on global health challenges<sup>(19)</sup>, the Programme should support the Union's contribution to international and global health initiatives with a view to improve health, address inequalities and increase protection against global health threats.

<sup>(19)</sup> Council conclusions on the EU role in Global Health, 3011th Foreign Affairs Council meeting, Brussels, 10 May 2010.

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**Amendment 41**  
**Proposal for a regulation**  
**Recital 34**

*Text proposed by the Commission*

(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU<sup>(20)</sup>, persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.

<sup>(20)</sup> Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ('Overseas Association Decision') (OJ L 344, 19.12.2013, p. 1).

*Amendment*

(34) In order to maximise the effectiveness and efficiency of actions at Union and international level, cooperation should be developed **with the Member States and** with relevant international organisations such as the United Nations and its specialised agencies, in particular the WHO, the World Bank, as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) to implement the Programme. Pursuant to Article 94 of Council Decision 2013/755/EU<sup>(20)</sup>, persons and entities established in Overseas Countries and Territories (OCTs) are eligible for funding subject to the rules and objectives of the Programme and possible arrangements applicable to the Member State to which the relevant OCTs are linked.

<sup>(20)</sup> Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European Union ('Overseas Association Decision') (OJ L 344, 19.12.2013, p. 1).

**Amendment 42**  
**Proposal for a regulation**  
**Recital 34 a (new)**

*Text proposed by the Commission*

*Amendment*

**(34 a) *The programme should guarantee that there is strong involvement of civil society, in particular patients' associations, and academics, in particular healthcare professionals' societies, to ensure a balanced representation and participation in achieving public health goals. European health organisations should contribute to the implementation and the evaluation of the programme.***

**Amendment 43**  
**Proposal for a regulation**  
**Recital 34 b (new)**

*Text proposed by the Commission*

*Amendment*

**(34 b) *To achieve a coherent implementation of the actions included in the Programme, a EU4Health Steering Group should be established.***

Friday 13 November 2020

**Amendment 44**  
**Proposal for a regulation**  
**Recital 39 a (new)**

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*Text proposed by the Commission*

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*Amendment*

- (39a) *According to the WHO, climate change affects the social and environmental determinants of health, including clean air, safe drinking water, sufficient food and secure shelter, and that 250 000 additional deaths, from malnutrition, malaria, diarrhoea and heat stress, are expected every year between 2030 and 2050, with extreme high air temperatures contributing directly to deaths particularly amongst the elderly and vulnerable individuals. Through flood, heatwaves, drought and fires, climate change has a considerable impact on human health, including under nutrition, cardiovascular and respiratory diseases, and vector-borne infections.*

**Amendment 45**  
**Proposal for a regulation**  
**Recital 40**

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*Text proposed by the Commission*

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*Amendment*

- (40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of **25** % of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.

- (40) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement and the United Nations Sustainable Development Goals, this Programme will contribute to mainstream climate action in the Union's policies and to the achievement of an overall target of **30** % of the EU budget expenditures supporting climate objectives. Relevant actions will be identified during the Programme's preparation and implementation, and reassessed in the context of its mid-term evaluation.

Friday 13 November 2020

**Amendment 46**  
**Proposal for a regulation**  
**Recital 40 a (new)**

Text proposed by the Commission

Amendment

- (40 a) **Recognising the importance of achieving gender equality, this Programme should contribute to mainstream gender equality in the Union's policies. It should use gender mainstreaming and gender budgeting tools to ensure that health crises are responded to in a gender-sensitive and transformative manner and that women's and girls' specific health needs are addressed during and in the aftermath of a health crisis.**

**Amendment 47**  
**Proposal for a regulation**  
**Recital 43**

Text proposed by the Commission

Amendment

- (43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level **can** also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability and affordability in the Union of medicines, medical devices and other crisis relevant products, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States, and to address inequalities in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

- (43) Given the nature and potential scale of cross-border threats to human health, the objective of protecting people in the Union from such threats and to increase crisis prevention and preparedness cannot be sufficiently achieved by the Member States acting alone. In accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union, action at Union level **should** also be taken to support Member States' efforts in the pursuit of a high level of protection of public health, to improve the availability, **sustainability, acceptability, accessibility, safety** and affordability in the Union of medicines, medical devices and other **health** crisis relevant products **and services**, to support innovation and to support integrated and coordinated work and implementation of best practices among Member States **and among their regions**, and to address inequalities **and inequities** in access to health throughout the EU in a manner that creates efficiency gains and value-added impacts that could not be generated by action taken at national level while respecting the Member States' competence and responsibility in the areas covered by the Programme. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.



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**Amendment 49****Proposal for a regulation****Article 2 — paragraph 1 — point 3***Text proposed by the Commission*

- 3) 'health crisis' means any crisis or serious incident arising from a threat of human, animal, plant, food **or environment** origin, having a health dimension and which requires urgent action by authorities;

*Amendment*

- (3) 'health crisis' means any crisis or serious incident arising from a threat of human, animal, plant, food, **chemical, biological, radiological, nuclear, environmental or unknown** origin, having a health dimension and which requires urgent action by authorities;

**Amendment 50****Proposal for a regulation****Article 2 — paragraph 1 — point 4***Text proposed by the Commission*

- (4) 'crisis relevant products' means products and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, **included** but not limited to: medicinal products — including vaccines — and their intermediates, active pharmaceutical ingredients and raw materials; medical devices; hospital and medical equipment (such as ventilators, protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);

*Amendment*

- (4) 'crisis relevant products' means products, **tools** and substances necessary, in the context of a health crisis, to prevent, diagnose or treat a disease and its consequences, **and for the monitoring and the epidemiological surveillance of diseases and infections, including** but not limited to: medicinal products — including vaccines — and their intermediates, active pharmaceutical ingredients and raw materials; medical devices; hospital and medical equipment (such as ventilators, protective clothing and equipment, diagnostic materials and tools); personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production);

**Amendment 48****Proposal for a regulation****Article 2 — paragraph 1 — point 5***Text proposed by the Commission*

- (5) 'One Health approach' means an approach which recognises **that** human **and** animal **health are interconnected**, that diseases may be transmitted from **humans to animals and vice versa** and must therefore be tackled in **both, and that the environment links humans and animals**;

*Amendment*

- (5) 'One Health approach' means an approach which recognises **the interconnection between the** human, animal **and environmental spheres**, that diseases may be transmitted from **one pillar to another** and must therefore be tackled in **a holistic approach**;

Friday 13 November 2020

## Amendment 51

## Proposal for a regulation

## Article 2 — paragraph 1 — point 9

*Text proposed by the Commission*

(9) 'serious cross-border threat to health' means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

*Amendment*

(9) 'serious cross-border threat to health' means a life-threatening or otherwise serious hazard to health of biological, chemical, **radiological, nuclear**, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

## Amendment 52

## Proposal for a regulation

## Article 2 — paragraph 1 — point 9 a (new)

*Text proposed by the Commission**Amendment*

**(9a) 'Health in all policies' means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies, and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;**

## Amendment 53

## Proposal for a regulation

## Article 2 — paragraph 1 — point 9 b (new)

*Text proposed by the Commission**Amendment*

**(9b) 'Health determinants' means a range of factors, such as behaviour-related, biological, socio-economic and environmental factors, that influence the health status of a person;**

## Amendment 54

## Proposal for a regulation

## Article 3 — paragraph 1 — introductory part

*Text proposed by the Commission*

The Programme shall pursue the following general objectives, in keeping with the 'One Health' approach where relevant:

*Amendment*

The Programme shall pursue the following general objectives, in keeping with the **'Health in all policies' approach where applicable**, and with the 'One Health' approach:

Friday 13 November 2020

## Amendment 55

## Proposal for a regulation

## Article 3 — paragraph 1 — point 1

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*Text proposed by the Commission*

1) **protect people** in the Union **from serious cross-border threats** to health;

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*Amendment*

(1) **improve and foster health** in the Union, **by supporting health promotion and disease prevention, reducing health inequalities and ensuring equal and full access** to health;

## Amendment 56

## Proposal for a regulation

## Article 3 — paragraph 1 — point 1 a (new)

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*Text proposed by the Commission*

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*Amendment*

(1a) **protect people in the Union from any serious cross-border threats to health; support the development and implementation of better preparedness and coordination within and between Member States as regards health emergencies;**

## Amendment 57

## Proposal for a regulation

## Article 3 — paragraph 1 — point 2

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*Text proposed by the Commission*

(2) improve the availability **in the Union of medicines, medical devices and other crisis relevant products, contribute to their** affordability, and support innovation;

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*Amendment*

(2) **supporting existing and future Union legislation and policies, in order to, inter alia, restore pharmaceutical independence and address shortages,** improve the availability, **accessibility and affordability of health care and services in the Union,** and support **research and innovation as well as development in health and healthcare without duplicating efforts under other programmes, including Horizon Europe;**

Friday 13 November 2020

**Amendment 58****Proposal for a regulation****Article 3 — paragraph 1 — point 3***Text proposed by the Commission*

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best **practice and** data sharing, to increase the general level of public health.

*Amendment*

(3) strengthen health systems and **their sustainability, as well as** the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, **including at national, regional and local level, by** sustained implementation of best **practices, and by sharing of comparable and interoperable** data, **with the aim** of increasing the general level of public health, **health literacy and make health systems more resilient and responsive.**

**Amendment 59****Proposal for a regulation****Article 4 — paragraph 1 — introductory part***Text proposed by the Commission*

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, **in keeping with the ‘One Health’ approach** where relevant:

*Amendment*

The general objectives referred to in Article 3 shall be pursued through the following specific objectives, in keeping with the **‘Health in all policies’ approach where applicable**, and with the ‘One Health’ approach:

**Amendment 226****Proposal for a regulation****Article 4 — paragraph 1 — point 1***Text proposed by the Commission*

(1) strengthen the capability of the Union for prevention, preparedness and response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance;

*Amendment*

(1) strengthen the capability of the Union for prevention, preparedness and **rapid** response to serious cross-border threats to health, and the management of health crises, including through coordination, provision and deployment of emergency health care capacity, data gathering and surveillance, **the coordination of stress testing of national healthcare systems and the development of quality healthcare standards;**

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**Amendment 250****Proposal for a regulation****Article 4 — paragraph 1 — point 2***Text proposed by the Commission*

- (2) **ensure the availability in the Union of reserves or stockpiles of crisis relevant products, and a reserve of** medical, healthcare and support staff to be mobilised in case of a crisis;

*Amendment*

- (2) **In synergy with other Union instruments, programmes and funds, support actions to allow** medical, healthcare and support staff to be mobilised in case of a crisis, **such as staff of the European Medical Corps, including by improving the staff's training and updating their knowledge, and support action to contribute to the availability in the Union, during a crisis, of health crisis relevant products such as essential medicines, vaccines and medical devices;**

**Amendment 62****Proposal for a regulation****Article 4 — paragraph 1 — point 3***Text proposed by the Commission*

- (3) **support actions** to ensure **appropriate** availability, accessibility and affordability of **crisis relevant** products and other necessary health supplies;

*Amendment*

- (3) **strengthen the European Medicines Market,** to ensure **in a sustainable manner the** availability, accessibility and affordability of **medicinal** products, **e-health solutions, medical devices** and other necessary health **related** supplies **and crisis relevant medical products;**

**Amendment 222****Proposal for a regulation****Article 4 — paragraph 1 — point 4***Text proposed by the Commission*

- (4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, **the uptake of digital tools and services,** systemic reforms, implementation of new care models **and** universal health coverage, **and address** inequalities in health;

*Amendment*

- (4) strengthen the effectiveness, accessibility, sustainability and resilience of health systems, including by supporting digital transformation, **including the creation and implementation of a European Health Data Space** systemic reforms, implementation of new care models, **enhance the equal and timely access to quality, sustainable, affordable, person-centred, outcome-based healthcare and related care services, the achievement of** universal health coverage, **encompassing access to sexual and reproductive health and rights, and reduce** inequalities **and inequities** in health;

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**Amendment 64****Proposal for a regulation****Article 4 — paragraph 1 — point 4 a (new)***Text proposed by the Commission**Amendment*

(4a) *strengthen the Union's innovation to ensure the development and uptake of the next generation of medicines, vaccines and medical devices to meet increasing health-care challenges and expectations that arise;*

**Amendment 65****Proposal for a regulation****Article 4 — paragraph 1 — point 5***Text proposed by the Commission**Amendment*

(5) support actions aimed at strengthening health system's ability to foster disease prevention **and** health promotion, patient rights and cross-border healthcare, **and promote the excellence of medical and healthcare professionals;**

(5) support actions aimed at strengthening health system's ability to foster disease prevention, **screening and early diagnosis, and implement** health promotion, **address health determinants, improve health literacy,** patient rights **and safety** and cross-border healthcare;

**Amendment 245****Proposal for a regulation****Article 4 — paragraph 1 — point 6***Text proposed by the Commission**Amendment*

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, and notably of cancer;

(6) support action for the surveillance, prevention, diagnosis and treatment and care of non-communicable diseases, **the early diagnosis of neurodegenerative disorders and other brain diseases,** and notably of cancer;

**Amendment 66****Proposal for a regulation****Article 4 — paragraph 1 — point 6 a (new)***Text proposed by the Commission**Amendment*

(6a) *strengthen the Union fight against cancer in synergy with the Europe's Beating Cancer Plan, including by supporting actions for the surveillance, prevention, early diagnosis and treatment and care of cancer, including paediatric cancer, and by supporting the establishment of the European Cancer Institute;*

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**Amendment 67****Proposal for a regulation****Article 4 — paragraph 1 — point 6 b (new)**

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*Text proposed by the Commission*

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*Amendment*

(6b) **strengthen the fight against communicable diseases and health threats;**

**Amendment 68****Proposal for a regulation****Article 4 — paragraph 1 — point 6 c (new)**

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*Text proposed by the Commission*

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*Amendment*

(6c) **address vaccine hesitancy, and support action for the elimination of vaccine preventable diseases, including cancers;**

**Amendment 69****Proposal for a regulation****Article 4 — paragraph 1 — point 7**

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*Text proposed by the Commission*

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*Amendment*

(7) foster and support the prudent and efficient use of medicines, and in particular of antimicrobials, **and** more environmentally friendly production **and** disposal of **medicines** and medical devices;

(7) foster and support the **informed**, prudent and efficient use of medicines, and in particular of antimicrobials, **the development of medicines that are intrinsically less harmful for the environment**, more environmentally friendly production **of medicines and environmentally sound** disposal of **medicinal products** and medical devices;

**Amendment 70****Proposal for a regulation****Article 4 — paragraph 1 — point 8**

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*Text proposed by the Commission*

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*Amendment*

(8) support the development, implementation and enforcement of Union health legislation and provide high-quality, comparable and reliable data to underpin policy making and monitoring, and promote the use of health impact assessments of relevant policies;

(8) support the development, implementation and enforcement **and, when necessary, the revision**, of Union health legislation, and provide high-quality, comparable, and reliable, data to underpin policy making and monitoring, **support the delivery of care and respond to unmet medical needs**, and promote the use of health impact assessments of **other** relevant **Union** policies;

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## Amendments 246 and 71

## Proposal for a regulation

## Article 4 — paragraph 1 — point 9

*Text proposed by the Commission*

(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, and scaling up networking through the **European Reference** Networks and other transnational networks;

*Amendment*

(9) support integrated work among Member States, and in particular their health systems, including the implementation of high-impact prevention practices, **support the identification of health technologies that are required to undergo a Union assessment, and strengthening** and scaling up networking through the ERNs, **develop and implement excellence** networks for high prevalence communicable and non-communicable diseases and other transnational networks, **including the Orphanet network, in full synergy with Horizon Europe and its Missions and Partnerships, and aim to to increase the coverage of patients and the response to diseases, and health problems, in greater numbers;**

## Amendment 223

## Proposal for a regulation

## Article 4 — paragraph 1 — point 10

*Text proposed by the Commission*

(10) support the Union's contribution to international and global health initiatives.

*Amendment*

(10) support the Union's contribution to international and global health **commitments and** initiatives, **including access to sexual and reproductive health and rights.**

## Amendment 73

## Proposal for a regulation

## Article 5 — paragraph 1

*Text proposed by the Commission*

1. The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR **1 946 614 000** in current prices.

*Amendment*

1. The financial envelope for the implementation of the Programme for the period 2021-27 shall be EUR **10 398 000 000** in current prices (**EUR 9 370 000 000 in constant prices**).



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**Amendment 74**  
**Proposal for a regulation**  
**Article 5 — paragraph 2**

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*Text proposed by the Commission*

2. The amount referred to in paragraph 1 may be used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems.

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*Amendment*

2. The amount referred to in paragraph 1 may be **also** used for technical and administrative assistance for the implementation of the Programme, such as preparatory, monitoring, control, audit and evaluation activities including corporate information technology systems. **The administrative expenses related to indirect actions shall not exceed 5 % of the total amount under the Programme.**

**Amendment 75**  
**Proposal for a regulation**  
**Article 6**

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*Text proposed by the Commission*

**Article 6**

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*Amendment*

**deleted**

***Resources from the European Union Recovery Instrument***

***Measures referred to in Article 2 of Regulation [European Union Recovery Instrument] shall be implemented under the Programme through an amount of up to EUR 8 451 000 000 in current prices referred to in point (iii) of Article 3(2)(a) of that Regulation, subject to its Article 5(4) and (8).***

***These amounts shall constitute external assigned revenue in accordance with Article 21(5) of Regulation (EU, Euratom) 2018/1046.***

**Amendment 76**  
**Proposal for a regulation**  
**Article 7 — paragraph 1 — point 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(1 a) The contributions of all associated countries shall be included in the relevant parts of the Programme. The Commission shall report to the Council and the Parliament during the annual budgetary procedure the total budget of each part of the Programme, identifying each of the associated countries, individual contributions and their financial balance.**

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**Amendment 77****Proposal for a regulation****Article 8 — paragraph 1***Text proposed by the Commission*

1. The Programme shall be implemented in direct management in accordance with Regulation (EU, Euratom) 2018/1046 or in indirect management with the bodies referred to in Article 62(1) (c) of Regulation (EU, Euratom) 2018/1046.

*Amendment*

1. The Programme shall be implemented in direct management in accordance with Regulation (EU, Euratom) 2018/1046 or in indirect management with the bodies referred to in Article 62(1) (c) of Regulation (EU, Euratom) 2018/1046, **to ensure there is no overlap or duplication with other funding programmes at the Union level.**

**Amendment 78****Proposal for a regulation****Article 8 — paragraph 2***Text proposed by the Commission*

2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, in particular grants, prizes and procurement.

*Amendment*

2. The Programme may provide funding in any of the forms laid down in Regulation (EU, Euratom) 2018/1046, in particular grants, prizes and procurement. **The Commission shall seek to achieve effective and balanced geographical coverage across the Union, including by supporting Member States to increase the quality of the projects through capacity building.**

**Amendment 79****Proposal for a regulation****Article 8 — paragraph 4 a (new)***Text proposed by the Commission**Amendment*

**4 a. The Commission shall facilitate the consistent implementation of the Programme while seeking maximal administrative simplification. The Commission and the Member States shall, commensurate to their respective responsibilities, foster synergies and ensure effective coordination between the Programme and the other Union programmes and funds.**

**For that purpose, they shall:**

**(a) ensure that there is complementarity, synergy, coherence and consistency among different instruments at Union, national and, where appropriate, regional levels, in particular in relation to measures financed by Union funds, both in the planning phase and during implementation;**

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Text proposed by the Commission

Amendment

- (b) *optimise coordination mechanisms to avoid duplication of effort;*
- (c) *ensure that close cooperation exists between those responsible for implementation at Union, national and, where appropriate, regional levels to deliver coherent and streamlined support actions under the instrument.*

**Amendment 80****Proposal for a regulation****Article 8 — paragraph 4 b (new)**

Text proposed by the Commission

Amendment

**4b.** *The Commission shall develop cooperation with relevant international organisations such as the United Nations and its specialised agencies, in particular the World Health Organisation (WHO), as well as with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) when implementing the Programme, in order to maximise the effectiveness and efficiency of actions at Union and international level.*

**Amendment 81****Proposal for a regulation****Article 8 — paragraph 4 c (new)**

Text proposed by the Commission

Amendment

**4c.** *The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases or in other relevant Commission expert groups as well as stakeholders, in particular professional bodies in the health sector and NGOs active in the field, at all stages of the implementation of the Programme .*

**Amendment 82****Proposal for a regulation****Article 9 a (new)**

Text proposed by the Commission

Amendment

**Article 9a****Award criteria**

*The award criteria shall be defined in the work programmes referred to in Article 18 and in the calls for proposals taking into account, to the extent applicable, the following elements:*

- (a) *consistency with the specific objectives provided for in Article 4;*

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Text proposed by the Commission

Amendment

- (b) *contribution to the accessibility and affordability of the health system;*
- (c) *cross-border dimension;*
- (d) *contribution to digital transformation;*
- (e) *social impact (benefits and costs);*
- (f) *consistency with the provisions of Annex 1;*
- (g) *contribution to the prevention of diseases and notably of cancer;*
- (h) *contribution to access to medicine;*
- (i) *maturity of the action in the project development;*
- (j) *soundness of the implementation plan proposed.*

**Amendment 83****Proposal for a regulation****Article 12 — paragraph 3 a (new)**

Text proposed by the Commission

Amendment

*A reliable and efficient mechanism shall be created in order to avoid any duplication of funding and to ensure synergies between the different Union programmes and policies that are pursuing health objectives. All data on funding operations and actions financed under different Union programmes and funds shall be centralised under this mechanism. It shall follow the principles of transparency and accountability and shall allow better monitoring and evaluation of actions pursuing health objectives.*

**Amendment 84****Proposal for a regulation****Article 14 — paragraph 1 — point b**

Text proposed by the Commission

Amendment

(b) any legal entity created under Union law or any international organisation;

(b) any legal entity created under Union law or any **relevant** international organisation **such as public authorities, public sector bodies, health establishments, research institutes, universities and higher education establishments, patient associations;**

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**Amendment 85****Proposal for a regulation****Article 14 — paragraph 3**

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*Text proposed by the Commission*

3. Legal entities established in a third country which is not associated to the Programme should **in principle** bear the cost of their participation.

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*Amendment*

3. Legal entities established in a third country which is not associated to the Programme should bear the cost of their participation.

**Amendment 86****Proposal for a regulation****Article 14 — paragraph 5**

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*Text proposed by the Commission*

5. Under the Programme, direct grants may be awarded without a call for proposals to fund 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 associated to the Programme, relevant international health organisations or by public sector bodies and non-governmental bodies, acting individually or as a network, mandated by those competent authorities.

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*Amendment*

5. Under the Programme, direct grants may be awarded without a call for proposals to fund actions **if such grants are duly justified, if they have** a clear Union added value co-financed by the **local, regional or national** competent authorities that are responsible for health in the Member States or in the third countries associated to the Programme, relevant international health organisations or by **Interreg programmes**, public sector bodies and non-governmental bodies, acting individually or as a network, mandated by those competent authorities.

**Amendment 87****Proposal for a regulation****Article 14 — paragraph 6**

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*Text proposed by the Commission*

6. Under the Programme, direct grants **may** be awarded without a call for proposals to **European Reference Networks**. Direct grants may also be awarded to other transnational networks set out in accordance with **EU rules**.

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*Amendment*

6. Under the Programme, direct grants **shall** be awarded without a call for proposals to **ERNs with a simplified financial and technical reporting system**. Direct grants may also be awarded to other transnational networks, **including to Interreg programmes**, set out in accordance with **Union law**.

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### Amendment 88

#### Proposal for a regulation

#### Article 14 — paragraph 6 a (new)

*Text proposed by the Commission*

*Amendment*

**6a. Adequate funding shall be ensured to consolidate and expand the ERN model of cross-border healthcare by securing the provision of a range of clinical services through different channels, including online second opinions and specialist advice for patients on treatment and management and ‘online out-patient’ clinics.**

### Amendment 89

#### Proposal for a regulation

#### Article 16 — paragraph 1

*Text proposed by the Commission*

*Amendment*

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the work plans established for the Programme and its priorities and strategic orientations and its implementation.

The Commission shall consult the health authorities of the Member States in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases on the **annual** work plans established for the Programme and its priorities and strategic orientations and its implementation **and on possible synergies with Member States’ own resources to ensure long-term effectiveness and sustainability of actions.**

### Amendment 90

#### Proposal for a regulation

#### Article 16 — paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

**The Commission shall consult the EU4Health Steering Group on the annual work plans established for the Programme and on the Programme’s priorities, strategic orientations and implementation, and on possible synergies with European funds to ensure the long-term effectiveness and sustainability of actions.**

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**Amendment 91****Proposal for a regulation****Article 16 — paragraph 1 b (new)***Text proposed by the Commission**Amendment*

*The Commission shall also consult relevant Union decentralised agencies and stakeholders, such as representatives of civil society organisations, in particular patients' organisations, on the annual work plans established for the Programme and the Programme's priorities, strategic orientations and implementation.*

**Amendment 92****Proposal for a regulation****Article 16 — paragraph 1 c (new)***Text proposed by the Commission**Amendment*

*The Commission shall adopt the annual work plans by means of delegated acts. Those delegated acts shall be adopted in accordance with Article 24 of this Regulation.*

**Amendment 93****Proposal for a regulation****Article 16 a (new)***Text proposed by the Commission**Amendment***Article 16 a****Establishment of EU4Health Steering Group**

1. *The Commission shall establish a EU4Health Steering Group ('the Steering Group').*
2. *The Steering Group shall:*
  - (i) *provide input, in the form of a comprehensive strategy and steering, and contribute to the annual work plans for the Programme;*
  - (ii) *elaborate a blueprint for steering coordination, cooperation and synergies between the Programme and other Programmes in which a health dimension is integrated;*
  - (iii) *provide value-oriented health actions, sustainability, better health solutions, foster access to health and reduce health inequalities, promote engagement by patients and society.*

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Text proposed by the Commission

Amendment

3. *The Steering Group shall be an independent stakeholder group, composed of actors in the field of public health, such as representatives of the European Parliament, independent health experts and patient representatives.*

4. *The Steering Group shall be composed of 20 high-level individuals respecting the principle of geographical and gender balance, drawn from various disciplines and activities referred to in paragraph 3.*

5. *The members of the Steering Board shall be appointed by the Commission in consultation with the Parliament, following an open call for nominations or for expression of interest.*

*The members shall be appointed for the period referred to in Article 1(2). The Commission shall also appoint a Chair from among its members.*

6. *The Steering Group shall meet at least three times a year, which allows regular and transparent exchanges of views.*

*The blueprint for steering coordination, cooperation and synergies shall facilitate ensuring visibility and coordination of all the existing financial mechanisms relevant to health, and shall help to steer coordination and cooperation.*

*The Commission may consult the Steering Group on matters other than those referred to in paragraph 2.*

Amendment 94

Proposal for a regulation

Article 18 — paragraph 1

Text proposed by the Commission

Amendment

The Programme shall be implemented by work programmes referred to in Article 110 of Regulation (EU, Euratom) 2018/1046. Work programmes shall set out, where applicable, the overall amount reserved for blending operations.

The Programme shall be implemented by **annual** work programmes referred to in Article 110 of Regulation (EU, Euratom) 2018/1046. Work programmes shall set out, where applicable, the overall amount reserved for blending operations.

Amendment 95

Proposal for a regulation

Article 18 — paragraph 1 a (new)

Text proposed by the Commission

Amendment

*The work programmes shall be informed by a gender impact assessment.*



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**Amendment 96**  
**Proposal for a regulation**  
**Article 19 — paragraph 1**

*Text proposed by the Commission*

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1. Indicators to report on progress of the Programme towards the achievement of the general and specific objectives set out in Articles 3 and 4 are set out in Annex II.

*Amendment*

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1. Indicators, **including programme- and action-specific indicators**, to report on progress of the Programme towards the achievement of the general and specific objectives set out in Articles 3 and 4 are set out in Annex II.

**Amendment 97**  
**Proposal for a regulation**  
**Article 19 — paragraph 1 a (new)**

*Text proposed by the Commission*

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*Amendment*

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**1 a. The Commission shall monitor continuously the management and implementation of the Programme. In order to enhance transparency, the constantly updated data on the management and implementation shall be made publicly available in an accessible manner on the Commission's website.**

**In particular, data for projects funded shall be included in the same database. Those data shall include:**

- (a) information on the types of financing and the types of beneficiaries, that allows for a transparent tracking of the financial allocations; a detailed overview of the synergies with other Union programmes, including the activities implemented by Union agencies, that allows for a proper analysis of the complementarity between different activities to be carried out.**
- (b) the levels of expenditure disaggregated at project level in order to allow for specific analysis, including per intervention area as defined in Article 13 and Annex I.**

**Amendment 98**  
**Proposal for a regulation**  
**Article 19 — paragraph 2**

*Text proposed by the Commission*

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2. The Commission is empowered to adopt delegated acts in accordance with Article 24 concerning amendments to Annex II to amend and supplement the indicators where considered necessary.

*Amendment*

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2. The Commission is empowered to adopt delegated acts in accordance with Article 24 concerning amendments to Annex II to amend and supplement the indicators, **including programme- and action-specific ones**, where considered necessary.

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**Amendment 99****Proposal for a regulation****Article 19 — paragraph 2 a (new)***Text proposed by the Commission**Amendment*

**2 a. Indicators shall be collected, where relevant, disaggregated by gender.**

**Amendment 100****Proposal for a regulation****Article 19 — paragraph 3***Text proposed by the Commission**Amendment*

3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner. To that end, proportionate reporting requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.

3. The performance reporting system shall ensure that data for monitoring programme implementation and results are collected efficiently, effectively, and in a timely manner **without increasing the administrative burden for beneficiaries**. To that end, proportionate reporting requirements shall be imposed on recipients of Union funds and, where relevant, on Member States.

**Amendment 101****Proposal for a regulation****Article 20 — paragraph 4***Text proposed by the Commission**Amendment*

4. The Commission shall communicate the conclusions of the evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

4. The Commission shall **publish**, communicate **and present** the conclusions of **both the interim and final** evaluations accompanied by its observations, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

**Amendment 102****Proposal for a regulation****Article 21 — paragraph 1 a (new)***Text proposed by the Commission**Amendment*

**The audit system for the Programme shall ensure an appropriate balance between trust and control, taking into account administrative and other costs of controls at all levels, especially for beneficiaries. Audit rules shall be clear, consistent and coherent throughout the Programme.**

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**Amendment 103****Proposal for a regulation****Article 21 — paragraph 1 b (new)**

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*Text proposed by the Commission*

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*Amendment*

*The audit strategy for the Programme shall be based on the financial audit of a representative sample of expenditure across the Programme as a whole. The representative sample shall be complemented by a selection based on an assessment of the risks related to expenditure. Actions that receive joint funding from different Union programmes shall be audited only once, covering all programmes involved and their respective applicable rules.*

**Amendment 104****Proposal for a regulation****Article 21 — paragraph 1 c (new)**

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*Text proposed by the Commission*

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*Amendment*

*The Commission or the funding body may rely on combined system reviews at beneficiary level. Such combined reviews shall be optional for certain types of beneficiaries and shall consist in a systems and process audit, complemented by an audit of transactions, carried out by a competent independent auditor qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC <sup>(1a)</sup>. They may be used by the Commission or funding body to verify overall assurance on the sound financial management of expenditure and for reconsideration of the level of ex-post audits and certificates on financial statements.*

<sup>(1a)</sup> Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directive 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87)

**Amendment 105****Proposal for a regulation****Article 21 — paragraph 1 d (new)**

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*Text proposed by the Commission*

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*Amendment*

*Audits may be carried out up to two years after the payment of the balance.*

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**Amendment 106****Proposal for a regulation****Article 21 — paragraph 1 e (new)***Text proposed by the Commission**Amendment*

*The Commission shall publish audit guidelines with the aim of ensuring that there is reliable and uniform application and interpretation of the audit procedures and rules throughout the duration of the programme.*

**Amendment 107****Proposal for a regulation****Article 24 — paragraph 2***Text proposed by the Commission**Amendment*

2. The power to adopt delegated acts referred to in Article 19 (2) shall be conferred on the Commission **until 31 December 2028**.

2. The power to adopt delegated acts referred to in Article 19 (2) shall be conferred on the Commission **for a period of three years from [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the three-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**

**Amendment 108****Proposal for a regulation****Annex I — point a — point ii***Text proposed by the Commission**Amendment*

(ii) **Critical health infrastructure** relevant in the context of health crises, tools, structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks.

(ii) **Coordinated action** relevant in the context of health crises, tools, **mechanisms**, structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks.

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**Amendment 109**  
**Proposal for a regulation**  
**Annex I — point b**

*Text proposed by the Commission*

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- (b) Transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value between Member States, and country-specific tailor made support to countries, or groups of countries, with the highest needs, through the funding of specific projects including twinning, expert advice and peer support.

*Amendment*

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- (b) Transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value between Member States **or regions**, and country-specific tailor made support to **regions or** countries, or groups of **regions or** countries, with the highest needs, through the funding of specific projects including twinning, expert advice and peer support.

**Amendment 110**  
**Proposal for a regulation**  
**Annex I — point c — point i**

*Text proposed by the Commission*

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- (i) Surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations, indicators, knowledge brokering and benchmark exercises;

*Amendment*

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- (i) Surveys, studies, collection of **comparable** data and statistics, **where relevant including disaggregated data by gender and age**, methodologies, classifications, microsimulations, **pilot studies**, indicators, knowledge brokering and benchmark exercises;

**Amendment 111**  
**Proposal for a regulation**  
**Annex I — point c — point iii**

*Text proposed by the Commission*

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- (iii) Expert groups and panels providing advice, data and information to support health policy development and implementation;

*Amendment*

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- (iii) Expert groups and panels, **including representatives of relevant stakeholders where applicable**, providing advice, **evaluation**, data and information to support health policy development and implementation, **including follow-up evaluations of the implementation of health policies**;

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**Amendment 112****Proposal for a regulation****Annex I — point c — point iv***Text proposed by the Commission*


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(iv) Studies and analysis, and scientific advice to support policymaking, and support to the scientific committees on 'Consumer Safety' and on 'Health, Environmental and Emerging Risks'.

*Amendment*


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(iv) Studies and analysis, **systematic health impact assessment of other Union policy actions** and scientific advice to support **evidence-based** policymaking, and support to the scientific committees on 'Consumer Safety' and on 'Health, Environmental and Emerging Risks', **as well as the expert group on 'Health Systems Performance Assessment'**.

**Amendment 113****Proposal for a regulation****Annex I — point d — introductory part***Text proposed by the Commission*


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(d) Development **and** implementation of Union health legislation and action, in particular through support to:

*Amendment*


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(d) Development, implementation, **and evaluation**, of Union health legislation and action, in particular through support to:

**Amendment 114****Proposal for a regulation****Annex I — point d — point i***Text proposed by the Commission*


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(i) Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;

*Amendment*


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(i) Implementation, enforcement, monitoring of Union health legislation and action, **including promotion of health**; and technical support to the **full** implementation of legal **and operational** requirements **throughout Member States**;

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**Amendment 115****Proposal for a regulation****Annex I — point d — point iv***Text proposed by the Commission*


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(iv) Development **and** operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based;

*Amendment*


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(iv) Development, operation **and maintenance** of databases and digital tools and their interoperability, including **already established projects**, where appropriate with other sensing technologies, such as space-based **and artificial intelligence**;

**Amendment 116****Proposal for a regulation****Annex I — point d — point v***Text proposed by the Commission*


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(v) Auditing **and** assessment work in accordance with Union legislation;

*Amendment*


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(v) Auditing, assessment **and inspection** work in accordance with Union legislation;

**Amendment 117****Proposal for a regulation****Annex I — point d — point x***Text proposed by the Commission*


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(x) National contact points providing guidance, information and assistance related **the** implementation of Union health legislation and of the Programme;

*Amendment*


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(x) National contact points providing guidance, information and assistance related **to the promotion and** implementation of Union health legislation and of the Programme;

**Amendment 118****Proposal for a regulation****Annex I — point d — point xi***Text proposed by the Commission*


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(xi) Stakeholders in view of transnational cooperation.

*Amendment*


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(xi) Stakeholders in view of transnational **and regional** cooperation.

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**Amendment 119**  
**Proposal for a regulation**  
**Annex I — point e**

Text proposed by the Commission

Amendment

*(e) Structural stockpile and crisis preparation:**deleted*

- (i) Establishment and support of a mechanism to develop, procure and manage crisis relevant products;*
- (ii) Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with other Union instruments;*
- (iii) Establishment and support of mechanisms for the efficient monitoring and allocation of available care facilities (such as hospital beds and places in ICUs), for the distribution or allocation of goods and services needed in the case of a health crisis, and to ensure the supply and safe use of medicines, investigational medicines and medical devices;*
- (iv) Procurement of goods and services necessary for the prevention and management of health crises and action to secure access to those essential goods and services;*
- (v) Establishment and operation of a Union reserve of medical and healthcare staff and experts and of a mechanism to deploy such staff and experts as necessary to prevent or respond to a health crisis throughout the Union; establishment and operation of a Union Health Emergency team to provide expert advice and technical assistance on request by the Commission in the case of a health crisis;*

**Amendment 227**  
**Proposal for a regulation**  
**Annex I — point f — point i**

Text proposed by the Commission

Amendment

(i) Actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and response capacity of actors at Union, national, regional and local level, including contingency planning and preparedness exercises and the upskilling of medical, healthcare and public health staff;

(i) Actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and **the** response capacity of actors at Union, national, regional and local level, including **stress tests**, contingency planning and preparedness exercises, **development of quality healthcare standards** and the upskilling of medical, healthcare and public health staff;



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**Amendment 121****Proposal for a regulation****Annex I — point f — point i a (new)***Text proposed by the Commission**Amendment*

**(i a) Establishment of a European Health Response Mechanism (EHRM) to respond to all types of health threats and crises and to strengthen operational coordination at European level, coordinated by ECDC with the assistance of relevant agencies;**

**Amendment 251****Proposal for a regulation****Annex I — point f — point i b (new)***Text proposed by the Commission**Amendment*

**(ib) Contribute to the establishment of the reserve of health crisis relevant products in complementarity with rescEU, the Emergency Support Instrument, the Resilience Instrument and other Union instruments, programmes and funds, and ensure the availability of such products in times of crisis;**

**Amendment 122****Proposal for a regulation****Annex I — point f — point iii***Text proposed by the Commission**Amendment*

**(iii) Support and/or procure emergency production of medical countermeasures, including essential chemicals and active substances, and the financing of cooperation on emergency health technology assessments and clinical trials;**

**deleted****Amendment 123****Proposal for a regulation****Annex I — point f — point iv***Text proposed by the Commission**Amendment*

**(iv) Preventive actions to protect vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups;**

**(iv) Preventive actions to protect *all citizens, in particular* vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups, *such as securing basic care for chronic disease patients in need of palliative care and pain management treatment;***

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**Amendment 124****Proposal for a regulation****Annex I — point f — point iv a (new)***Text proposed by the Commission**Amendment*

- (iv a) Actions to support e-health, such as the transition to telemedicine, at-home administration of medication and implementation of preventative / self-care plans, where possible and appropriate;*

**Amendment 125****Proposal for a regulation****Annex I — point f — point iv b (new)***Text proposed by the Commission**Amendment*

- (iv b) Actions to support cross-border cooperation to ensure access to rapid treatment for all patients across the Union, particularly for those who suffer from a rare disease;*

**Amendment 126****Proposal for a regulation****Annex I — point f — point v***Text proposed by the Commission**Amendment*

- (v) Actions to address the collateral health consequences of a health crisis, in particular those on mental health, on patients suffering from chronic diseases and other vulnerable **groups**;

- (v) Actions to address **and manage** the collateral health consequences of a health crisis, in particular those on mental health, on patients suffering from chronic diseases and other vulnerable **situations, including people living with addiction, with HIV/AIDS, or suffering from tuberculosis**;

**Amendment 127****Proposal for a regulation****Annex I — point f — point viii a (new)***Text proposed by the Commission**Amendment*

- (viii a) Support action regarding epidemiological surveillance, focusing on national health entities, thus contributing to assessment of factors that affect or determine the health of citizens;*

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**Amendment 128**  
**Proposal for a regulation**  
**Annex I — point f — point viii b (new)**

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*Text proposed by the Commission*

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*Amendment*

(viii b) **Actions to ensure that access to medicines is undisrupted, and that there is continuity of care and treatment, in particular for patients suffering from chronic conditions;**

**Amendment 129**  
**Proposal for a regulation**  
**Annex I — point g — introductory part**

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*Text proposed by the Commission*

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*Amendment*

(g) Strengthen national health systems:

(g) Strengthen national health systems, **promote and protect health and prevent diseases:**

**Amendment 130**  
**Proposal for a regulation**  
**Annex I — point g — point i**

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*Text proposed by the Commission*

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*Amendment*

(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare;

(i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, **while linking available Union funding**, in particular to address the challenges identified by the European Semester **and Country Specific Recommendations on health**, and to strengthen primary care, reinforce the integration of care, aim at universal health coverage and **reach** equal access to **good quality** healthcare;

**Amendment 131**  
**Proposal for a regulation**  
**Annex I — point g — point i a (new)**

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*Text proposed by the Commission*

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*Amendment*

(i a) **Support implementing policies and actions to reduce health inequalities and inequities in relation to health-care;**

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**Amendment 132****Proposal for a regulation****Annex I — point g — point ii***Text proposed by the Commission*

(ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;

*Amendment*

(ii) **Support in synergy with other Programmes** training, **educational and mobility** programmes for medical and healthcare staff, **including online programmes**, and programmes for temporary exchanges of staff, **in particular with the aim of improving their curricula and digital skills**;

**Amendment 133****Proposal for a regulation****Annex I — point g — point iii***Text proposed by the Commission*

(iii) Support to improve the geographical distribution of healthcare workforce **and avoidance of** 'medical deserts';

*Amendment*

(iii) Support **in synergy with other Programmes** to improve the geographical distribution of **the** healthcare workforce, **while ensuring that such distribution of the workforce is also proportionate to the population of the area or region in question, and thus avoiding** 'medical deserts' **and promote and implement retention policies**;

**Amendment 134****Proposal for a regulation****Annex I — point g — point iv***Text proposed by the Commission*

(iv) Support the establishment **and** coordination of Union Reference Laboratories and Centres, **and of** Centres of excellence;

*Amendment*

(iv) Support the establishment, coordination **and deployment** of Union Reference Laboratories and Centres, Centres of Excellence **and EU disease-specific platforms for the exchange, comparison and benchmarking of best practices between Member States**;

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**Amendment 135****Proposal for a regulation****Annex I — point g — point v***Text proposed by the Commission*

- 
- (v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);

*Amendment*

- 
- (v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination) **and the implementation of their health promotion and disease prevention national strategies or programmes;**

**Amendment 136****Proposal for a regulation****Annex I — point g — point viii a (new)***Text proposed by the Commission*

- 
- (viii a) Support the establishment and implementation of **national and European** programmes, **including digital and evidence-based programmes**, assisting Member States and their action to improve health promotion, **health literacy** and disease prevention (for communicable and non-communicable diseases) **in health units and communities, and mitigate the main risk factors of chronic diseases;**

*Amendment*

- 
- (viii a) **Support a Union framework and the related interoperable digital tools to strengthen health technology assessment cooperation among Member States and in networks, including networks needed in order to enable Member States to deliver and exchange timely, reliable and high quality joint clinical assessments, and joint scientific consultations and other relevant activities to support decision-makers to exchange outcomes of cooperation regarding HTA;**

**Amendment 137****Proposal for a regulation****Annex I — point g — point ix***Text proposed by the Commission*

- 
- (ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);

*Amendment*

- 
- (ix) Support the establishment and implementation of **national and European** programmes, **including digital and evidence-based programmes**, assisting Member States and their action to improve health promotion, **health literacy** and disease prevention (for communicable and non-communicable diseases) **in health units and communities, and mitigate the main risk factors of chronic diseases;**

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## Amendment 138

## Proposal for a regulation

## Annex I — point g — point ix a (new)

Text proposed by the Commission

Amendment

- (ix a) *Support the establishment and functioning of disease-specific Union platforms for the exchange, comparison and benchmarking of best practices between Member States, in the form of excellence networks in the field of communicable and non-communicable diseases, in particular in the area of chronic diseases;*

## Amendment 139

## Proposal for a regulation

## Annex I — point g — point ix b (new)

Text proposed by the Commission

Amendment

- (ix b) *Support the development of guidelines for preventing and managing diseases in the area of both communicable and non-communicable diseases;*

## Amendment 140

## Proposal for a regulation

## Annex I — point g — point x

Text proposed by the Commission

Amendment

- (x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and promote healthy diets taking into account the needs of **vulnerable groups**;

- (x) Support Member States' actions to put in place healthy and safe urban, work and school environments, to **promote mental health, health education**, enable healthy life choices and promote **regular physical activity and** healthy diets taking into account the needs of **people at every stage of their life with the aim of promoting life-long health**;

## Amendment 141

## Proposal for a regulation

## Annex I — point g — point x a (new)

Text proposed by the Commission

Amendment

- (x a) *Support Member States actions to address health determinants, including reducing alcohol related harm and tobacco use;*

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**Amendment 142**  
**Proposal for a regulation**  
**Annex I — point g — point x b (new)**

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*Text proposed by the Commission*

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*Amendment*

*(x b) Support Member States' actions to ensure access to sexual and reproductive health services and related medicinal products, and support integrated and intersectional approaches to prevention, diagnosis, treatment and care;*

**Amendment 143**  
**Proposal for a regulation**  
**Annex I — point g — point x c (new)**

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*Text proposed by the Commission*

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*Amendment*

*(x c) Actions promoting care and support for victims of gender-based violence;*

**Amendment 144**  
**Proposal for a regulation**  
**Annex I — point g — point x d (new)**

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*Text proposed by the Commission*

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*Amendment*

*(x d) Actions promoting equal access to health services and related facilities and care for people with disabilities;*

**Amendment 145**  
**Proposal for a regulation**  
**Annex I — point g — point xi a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(xi a) Support Member States in the revision of their rare disease national plans to put in place the necessary financial and organisational arrangements to integrate effectively the European Reference Networks system into the national health systems by also supporting the development and implementation of the set of policies, rules and procedures required to anchor the ERN system to the national level;*

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**Amendment 146****Proposal for a regulation****Annex I — point g — point xi b (new)**

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*Text proposed by the Commission*

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*Amendment*

*(xi b) Support the implementation of the ERNs' system for continuous assessment, monitoring, evaluation and quality improvement;*

**Amendment 147****Proposal for a regulation****Annex I — point g — point xi c (new)**

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*Text proposed by the Commission*

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*Amendment*

*(xi c) Earmark funding to create effective and permanent mechanisms for the collaboration of ERNs to address the multi-systemic needs arising from low prevalence diseases and rare diseases and to facilitate diagonal networking between different specialities and disciplines;*

**Amendment 148****Proposal for a regulation****Annex I — point g — point xi d (new)**

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*Text proposed by the Commission*

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*Amendment*

*(xi d) Support Member States in strengthening their Centres of Expertise for rare diseases to increase the capacities of national health systems to diagnose, treat and manage such diseases, transnational cooperation on codification, information and knowledge in the field of rare diseases, in particular the Orphanet database;*

**Amendment 149****Proposal for a regulation****Annex I — point g — point xii a (new)**

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*Text proposed by the Commission*

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*Amendment*

*(xii a) Support cooperation and coordination between Member States for the creation of a European Network for Hospitals Excellence, improving the cross-border treatment for rare diseases and increasing access to treatment for all Union citizens;*



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**Amendment 150**  
**Proposal for a regulation**  
**Annex I — point h — introductory part**

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*Text proposed by the Commission*

(h) Actions on cancer:

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*Amendment*

(h) Actions on cancer, **including paediatric cancer**.

**Amendment 151**  
**Proposal for a regulation**  
**Annex I — point h — point i**

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*Text proposed by the Commission*

(i) Support Member States and NGOs in the promotion and **implementation** of the recommendations of the European Code against Cancer;

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*Amendment*

(i) Support Member States, **IARC** and NGOs in the promotion and **implementation** of the recommendations of the European Code against Cancer; **support the revision and continuous update of the current edition of the European Code against Cancer**;

**Amendment 152**  
**Proposal for a regulation**  
**Annex I — point h — point i a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(i a) Support the establishment of a European Cancer Institute (ECI) as a platform for the implementation of the European Reference Cancer Networks, the collection of clinical data among centres from all participating countries across the Union and the prioritisation of academic and clinical research programmes of excellence in the area of cancer including paediatric cancer**;

**Amendment 153**  
**Proposal for a regulation**  
**Annex I — point h — point iii**

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*Text proposed by the Commission*

(iii) Support prevention programmes on the main cancer risk factors;

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*Amendment*

(iii) Support prevention programmes on the main cancer risk factors **that are of demonstrated effectiveness and supported by established evidence**;

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**Amendment 154****Proposal for a regulation****Annex I — point h — point iv a (new)***Text proposed by the Commission**Amendment*

*(iv a) Action to support the implementation of cancer registries in all Member States;*

**Amendment 155****Proposal for a regulation****Annex I — point h — point v***Text proposed by the Commission**Amendment*

(v) Actions supporting access to cancer services and to innovative medicines for cancer;

(v) Actions supporting **implementing policies, national programmes and guidelines, in line with the Europe's Beating Cancer plan, to reduce inequalities and grant** access to cancer services, **supportive and palliative care**, and to innovative, **accessible and effective screening, treatments and medicines for cancer across all Member States, in full synergy with Horizon Europe and its missions and partnerships**;

**Amendment 156****Proposal for a regulation****Annex I — point h — point v a (new)***Text proposed by the Commission**Amendment*

*(v a) Actions supporting equal and timely access to new and innovative medicines and therapies, including for supportive and palliative care, for paediatric malignancies, across Europe, and foster the availability and affordability of such medicines and treatments in child-friendly doses and formulations;*

**Amendment 157****Proposal for a regulation****Annex I — point h — point v b (new)***Text proposed by the Commission**Amendment*

*(v b) Actions to address the unmet needs of children and adolescents with cancer, and of survivors of cancer, through dedicated programmes and plans that will enable the ERN, including those on paediatric cancer;*

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**Amendment 158****Proposal for a regulation****Annex I — point h — point vii**

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*Text proposed by the Commission*

(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment;

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*Amendment*

(vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment, **follow-up, and supportive and palliative care;**

**Amendment 159****Proposal for a regulation****Annex I — point h — point viii**

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*Text proposed by the Commission*

(viii) Actions supporting the quality of life of cancer survivors and care givers;

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*Amendment*

(viii) Actions supporting the quality of life of cancer survivors and care givers, **including provision of psychological support, pain management, and professional re-integration;**

**Amendment 160****Proposal for a regulation****Annex I — point h — point ix**

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*Text proposed by the Commission*

(ix) Support to the implementation of the Union's tobacco control policy and legislation;

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*Amendment*

(ix) Support to the implementation of the Union's tobacco control policy and legislation **and other related legislation in the area of prevention and health promotion, including aimed at reducing alcohol related harm;**

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**Amendment 161****Proposal for a regulation****Annex I — point h — point x***Text proposed by the Commission*


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(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.

*Amendment*


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(x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education **of healthcare professionals and informal carers** in the area of cancer care, **screening and early diagnosis, in particular in the area of paediatric cancer, with the aim to improve the quality of care;**

**Amendment 162****Proposal for a regulation****Annex I — point h — point x a (new)***Text proposed by the Commission*


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*Amendment*


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(x a) **Actions to support an integrative, coordinated, multi-disciplinary and patient-centred approach concerning cancer patients and survivors;**

**Amendment 163****Proposal for a regulation****Annex I — point i — point ii***Text proposed by the Commission*


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(ii) Support actions to fight vaccine hesitancy;

*Amendment*


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(ii) Support actions to fight vaccine hesitancy **and disinformation, and promote immunization throughout all stages of a person's lifetime;**

**Amendment 164****Proposal for a regulation****Annex I — point i — point ii a (new)***Text proposed by the Commission*


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*Amendment*


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(ii a) **Support tools and platforms to collect real-world evidence on the safety, effectiveness and impact of vaccines after use, without prejudice to the generation of robust evidence in the pre-approval phase;**

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**Amendment 165**  
**Proposal for a regulation**  
**Annex I — point i — point ii b (new)**

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*Text proposed by the Commission*

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*Amendment*

**(ii b) support action for the elimination of vaccine preventable diseases;**

**Amendment 166**  
**Proposal for a regulation**  
**Annex I — point i — point iii**

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*Text proposed by the Commission*

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*Amendment*

(iii) Support clinical trials to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;

(iii) Support clinical trials **and the use of real world data, including those involving increased coordination at Union level and with EMA**, to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;

**Amendment 167**  
**Proposal for a regulation**  
**Annex I — point i — point iii a (new)**

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*Text proposed by the Commission*

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*Amendment*

**(iii a) Support actions aimed at creating and developing a European digital mechanism for better reporting, notification and monitoring of potential shortages, in the form of a Union platform for shortages of medicines, vaccines and medical devices, based on one harmonised and interoperable data-collection model and national reporting systems for shortages, including the full implementation of an effective Union telematics infrastructure that will link data on medicines and supply chains;**

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## Amendment 168

## Proposal for a regulation

## Annex I — point i — point iii b (new)

Text proposed by the Commission

Amendment

(iii b) *Support actions aimed at stimulating the increase in the production of essential APIs and medicinal products in the Union, including by diversifying supply chain production of active ingredients and generics within the Union to reduce the Member States' dependence on certain third countries;*

## Amendment 169

## Proposal for a regulation

## Annex I — point i — point iv

Text proposed by the Commission

Amendment

(iv) Support action to ensure greater availability in the Union of **medicines** and medical devices and contribute to their affordability for patients and health systems;

(iv) Support action to ensure greater availability in the Union of **medicinal products** and medical devices and contribute to their affordability for patients and health systems;

## Amendment 170

## Proposal for a regulation

## Annex I — point i — point v

Text proposed by the Commission

Amendment

(v) Support action to encourage the **development** of innovative **products and of less commercially interesting products such as antimicrobials**;

(v) Support action to encourage the **discovery and development** of innovative **medicines and vaccines to meet rising healthcare challenges and patients' needs**;

## Amendment 171

## Proposal for a regulation

## Annex I — point i — point v a (new)

Text proposed by the Commission

Amendment

(v a) *Support actions to foster innovation in repurposing, reformulation and combining of off-patent medicines that deliver relevant improvements for patients, health-care professionals and healthcare systems;*

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**Amendment 172**  
**Proposal for a regulation**  
**Annex I — point i — point v b (new)**

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*Text proposed by the Commission*

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*Amendment*

(v b) *Action to address market failures with regard to antibiotics and encourage sustainable investments for the discovery and development of new antimicrobials, of medicines for rare diseases and of medicines to fight against communicable diseases, while ensuring equitable access;*

**Amendment 173**  
**Proposal for a regulation**  
**Annex I — point i — point vi**

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*Text proposed by the Commission*

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*Amendment*

(vi) Support action to monitor shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages, and to increase security of supplies;

(vi) Support action to monitor, **prevent, manage, report and notify** shortages of medicines and medical devices occurring in hospitals and community pharmacies, to **collect reported shortages in a centralized database, interoperable with databases that contained regulatory data on medicines**, to address such shortages, and to increase security of supplies;

**Amendment 174**  
**Proposal for a regulation**  
**Annex I — point i — point viii**

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*Text proposed by the Commission*

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*Amendment*

(viii) Action to strengthen the environmental risk assessment of pharmaceuticals;

(viii) Action to strengthen the environmental risk assessment of pharmaceuticals **and medical devices**;

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**Amendment 175****Proposal for a regulation****Annex I — point i — point ix***Text proposed by the Commission*


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(ix) Action to promote the prudent use and disposal of antimicrobials;

*Amendment*


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(ix) Action to promote the prudent use and disposal of **medicines, especially** antimicrobials **and to reduce the overall use of medicines, action to support the surveillance of antimicrobial use and to support the fight against antimicrobial resistance (AMR)**;

**Amendment 176****Proposal for a regulation****Annex I — point i — point x***Text proposed by the Commission*


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(x) Support action to foster international regulatory **convergence on medicines** and medical devices.

*Amendment*


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(x) Support action to foster international regulatory **convergence and reliance on medicinal products** and medical devices, **and to improve regulatory oversight by the Union**.

**Amendment 177****Proposal for a regulation****Annex I — point j — point i***Text proposed by the Commission*


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(i) Support for the deployment, operation and maintenance of mature interoperable digital service infrastructures and data **quality** assurance processes for data exchange, access, use and reuse; support for cross border networking, including through **the** use of electronic health records, registries and other databases;

*Amendment*


---

(i) Support for the deployment, operation and maintenance of mature interoperable digital service infrastructures and data **security and** quality assurance processes for data exchange, access, use and reuse; support for cross border networking, including through **improvement and better** use of electronic health records, registries and other databases;



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**Amendment 178****Proposal for a regulation****Annex I — point j — point i a (new)**

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*Text proposed by the Commission*

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*Amendment*

***(i a) Establish the European Electronic Health Record and support its implementation in the Member States in order to increase the use of e-health and improve the sustainability and resilience of healthcare systems;***

**Amendment 179****Proposal for a regulation****Annex I — point j — point i b (new)**

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*Text proposed by the Commission*

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*Amendment*

***(i b) Support Member States to improve and further develop and implement ERN registries;***

**Amendment 180****Proposal for a regulation****Annex I — point j — point ii**

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*Text proposed by the Commission*

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*Amendment*

(ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care **professionals**;

(ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies **and strengthening the safe use and re-use of health data, in line with GDPR; support and implement digital upskilling of health care professionals and citizens, through enhanced education, training and (digital) health literacy measures;**

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**Amendment 181****Proposal for a regulation****Annex I — point j — point iii***Text proposed by the Commission*

- (iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and strengthen citizens' access to and control over their health data;

*Amendment*

- (iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions, **agencies** and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and with **a view to having safe and efficient deployment of AI in health care strengthening and facilitating** citizens' access to and control over their health data; **support uptake and broader implementation of current successful initiatives and projects on person-centred digital health and health data;**

**Amendment 182****Proposal for a regulation****Annex I — point j — point iv***Text proposed by the Commission*

- (iv) Support optimal use of telemedicine/telehealth, including through satellite communication for remote areas, foster digitally-driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment and person-centred care.

*Amendment*

- (iv) Support **access to and** optimal use of telemedicine/telehealth, including through satellite communication for remote areas, foster digitally-driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment and person-centred care; **promote involvement of patients and care professionals in the co-design and co-development of user-friendly, accessible, secure and efficient telemedicine/telehealth and other digital solutions.**

**Amendment 183****Proposal for a regulation****Annex I — point k — point iii***Text proposed by the Commission*

- (iii) Communication to promote **disease prevention and** healthy lifestyles, in cooperation with all concerned actors at international, Union **and** national level.

*Amendment*

- (iii) Communication to promote **health, healthy lifestyles and disease prevention**, in cooperation with all concerned actors at international, Union, national **and regional** level;

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**Amendment 184****Proposal for a regulation****Annex I — point k — point iii a (new)**

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*Text proposed by the Commission*

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*Amendment*

***(iii a) Awareness-raising campaigns for the general population as well as for targeted groups and stakeholder-led projects, including prevention of and combating disinformation;***

**Amendment 185****Proposal for a regulation****Annex I — point k — point iii b (new)**

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*Text proposed by the Commission*

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*Amendment*

***(iii b) Communication activities aimed at fighting against misinformation and disinformation, such as fake news, regarding medicines, vaccines, health products, causes and treatment of diseases;***

**Amendment 186****Proposal for a regulation****Annex I — point k — point iii c (new)**

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*Text proposed by the Commission*

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*Amendment*

***(iii c) Communication to citizens on health risks and health determinants;***

**Amendment 187****Proposal for a regulation****Annex I — point k — point iii d (new)**

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*Text proposed by the Commission*

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*Amendment*

***(iii d) Communication, information and awareness campaigns on blood components, organs, tissues and cells donation that alert the public to the importance of such donation, in terms of solidarity, health policy and therapeutical benefits.***

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**Amendment 188****Proposal for a regulation****Annex II — part A — point I***Text proposed by the Commission*

I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health

*Amendment*

I. Quality and completeness of the preparedness and response planning of the Union and of Member States for serious cross border threats to health, **including resilience assessment indicators across the Union**

**Amendment 189****Proposal for a regulation****Annex II — part A — point II***Text proposed by the Commission*

II. Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs

*Amendment*

II. Access to centrally authorised medicines **and medical devices**, e.g. number of **existing and new** orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs

**Amendment 190****Proposal for a regulation****Annex II — part A — point III***Text proposed by the Commission*

III. Number of actions and best practices directly contributing to **the SDG 3.4/Member State**

*Amendment*

III. Number of actions and best practices directly contributing to **achieve Universal Health Coverage / Member State**

**Amendment 191****Proposal for a regulation****Annex II — part A — point IV***Text proposed by the Commission*

IV. Implementation of **best practices** by EU Member States

*Amendment*

IV. Implementation of **health programmes** by EU Member States, **that promote health, prevent diseases and address health inequalities**

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**Amendment 192**  
**Proposal for a regulation**  
**Annex II — part A — point IV a (new)**

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*Text proposed by the Commission*

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*Amendment*

***IV a. Implementation of the European Health Data Space (EHDS)***

**Amendment 193**  
**Proposal for a regulation**  
**Annex II — part B — point 1 a (new)**

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*Text proposed by the Commission*

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*Amendment*

***1a. Number of new procedures for accelerated development and assessment of medicines for major public health needs, where relevant taking into account novel technologies***

**Amendment 194**  
**Proposal for a regulation**  
**Annex II — part B — point 1b (new)**

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*Text proposed by the Commission*

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*Amendment*

***1b. Number of Member States with adequate level of digital health infrastructure***

**Amendment 195**  
**Proposal for a regulation**  
**Annex II — part B — point 1 c (new)**

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*Text proposed by the Commission*

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*Amendment*

***1c. Number of Member States that implemented the European Electronic Health Record***

**Amendment 196**  
**Proposal for a regulation**  
**Annex II — part B — point 1d (new)**

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*Text proposed by the Commission*

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*Amendment*

***1d. Proportion of Member States' population of citizens with access to their data on the EHDS, per Member State***

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**Amendment 197**  
**Proposal for a regulation**  
**Annex II — part B — point 3**

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*Text proposed by the Commission*

3. Number of vaccine doses ***distributed***

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*Amendment*

3. Number of vaccine doses ***made available by type and by Member State***

**Amendment 198**  
**Proposal for a regulation**  
**Annex II — part B — point 3 a (new)**

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*Text proposed by the Commission*

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*Amendment*

***3a. Vaccination coverage, by age, and by vaccine-preventable-disease***

**Amendment 199**  
**Proposal for a regulation**  
**Annex II — part B — point 6**

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*Text proposed by the Commission*

6. Age-standardised five-year net survival of ***cervical, breast and colorectal*** cancer

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*Amendment*

6. Age-standardised five-year net survival of cancer ***by type, age, gender and Member State***

**Amendment 200**  
**Proposal for a regulation**  
**Annex II — part B — point 6 a (new)**

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*Text proposed by the Commission*

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*Amendment*

***6a. Age-standardised five-year net survival rate for paediatric cancer by type, age, gender and Member State***

**Amendment 201**  
**Proposal for a regulation**  
**Annex II — part B — point 6 b (new)**

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*Text proposed by the Commission*

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*Amendment*

***6b. Screening coverage for breast, cervical and colorectal cancer screening programmes, by type, age, gender and Member State***

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**Amendment 202****Proposal for a regulation****Annex II — part B — point 7***Text proposed by the Commission*


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7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on ***cervical, breast, and colorectal*** cancer stage at diagnosis

*Amendment*


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7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cancer stage at diagnosis

**Amendment 203****Proposal for a regulation****Annex II — part B — point 7 a (new)***Text proposed by the Commission*


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*Amendment*


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***7a. Ratio of palliative care admissions and outcome result for cancer and paediatric cancer, by type, age, gender and Member State***

**Amendment 204****Proposal for a regulation****Annex II — part B — point 7 b (new)***Text proposed by the Commission*


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*Amendment*


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***7b. Ratio of Paediatric Cancer Registries (CRs)/Member State and number of Member States (MSs) reporting information on paediatric cancer stage at diagnosis***

**Amendment 205****Proposal for a regulation****Annex II — part B — point 7 c (new)***Text proposed by the Commission*


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*Amendment*


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***7c. Prevalence of major chronic diseases per Member State, by disease, gender and age***

**Amendment 206****Proposal for a regulation****Annex II — part B — point 7 d (new)***Text proposed by the Commission*


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*Amendment*


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***7d. Age-standardized NCD mortality rate (per 100 000 people), by disease***

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**Amendment 207****Proposal for a regulation****Annex II — part B — point 7 e (new)***Text proposed by the Commission**Amendment*

**7e. Percentage of HIV/AIDS patients with access to adequate treatment, by Member State, gender and age**

**Amendment 208****Proposal for a regulation****Annex II — part B — point 7 f (new)***Text proposed by the Commission**Amendment*

**7f. Proportion of tuberculosis patients with access to adequate treatment, by Member State, gender and age**

**Amendment 209****Proposal for a regulation****Annex II — part B — point 8***Text proposed by the Commission**Amendment*8. **Smoking** prevalence8. **Age standardized** prevalence **of tobacco use, by gender****Amendment 228****Proposal for a regulation****Annex II — part B — point 8 a (new)***Text proposed by the Commission**Amendment*

**8a. Age-standardised prevalence of harmful use of alcohol, by gender and age**

**Amendment 210****Proposal for a regulation****Annex II — part B — point 9***Text proposed by the Commission**Amendment*9. Number of shortages of medicines in the **single point of contact network**9. Number of shortages of medicines in the **Member States**



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**Amendment 211****Proposal for a regulation****Annex II — part B — point 9 a (new)***Text proposed by the Commission**Amendment***9a. Actions aimed at stimulating the production of essential APIs and medicinal products in the EU****Amendment 212****Proposal for a regulation****Annex II — part B — point 12 a (new)***Text proposed by the Commission**Amendment***12a. Antimicrobial use by ATC type and per Member States****Amendment 213****Proposal for a regulation****Annex II — part B — point 12 b (new)***Text proposed by the Commission**Amendment***12b. Attributable mortality to Healthcare Associated Infections, by age, gender and Member State****Amendment 214****Proposal for a regulation****Annex II — part B — point 12 c (new)***Text proposed by the Commission**Amendment***12c. Avoidable deaths attributed to cardiovascular disease, cancer, diabetes, DALYs attributable to the NCDs and QALYs, chronic respiratory disease, for persons aged less than 75 years, by gender and Member State****Amendment 215****Proposal for a regulation****Annex II — part B — point 13***Text proposed by the Commission**Amendment*13. Number of **hospital** units involved in ERN and of patients diagnosed and treated by the members of ERN networks13. Number of **health** units involved in ERN and of patients diagnosed and treated by the members of ERN networks

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**Amendment 216****Proposal for a regulation****Annex II — part B — point 14 a (new)**

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*Text proposed by the Commission*

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*Amendment***14a. Number of health impact assessments of Union policies****Amendment 217****Proposal for a regulation****Annex II — part B — point 14 b (new)**

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*Text proposed by the Commission*

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*Amendment***14b. Age-standardised obesity prevalence, by gender, age and Member State****Amendment 218****Proposal for a regulation****Annex II — part B — point 14 c (new)**

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*Text proposed by the Commission*

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*Amendment***14c. Maternal mortality ratio, by age and by Member State****Amendment 219****Proposal for a regulation****Annex II — part B — point 14 d (new)**

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*Text proposed by the Commission*

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*Amendment***14d. Infant mortality rate by Member State****Amendment 229****Proposal for a regulation****Annex II — part B — point 14 e (new)**

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*Text proposed by the Commission*

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*Amendment***14e. Age-standardized deaths attributable to environmental pollution (per 100 000 people), by gender and age**

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P9\_TA(2020)0306

**InvestEU Programme \*\*\*I**

**Amendments adopted by the European Parliament on 13 November 2020 on the proposal for a regulation of the European Parliament and of the Council establishing the InvestEU Programme (COM(2020)0403 — C9-0158/2020 — 2020/0108(COD))<sup>(1)</sup>**

**(Ordinary legislative procedure: first reading)**

**Amendment 1**

(2021/C 415/18)

AMENDMENTS BY THE EUROPEAN PARLIAMENT (\*)

to the Commission proposal

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
establishing the InvestEU Programme

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 173 and the third paragraph of Article 175 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee<sup>(1)</sup>,

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The Covid-19 pandemic is a major ***symmetric*** shock to the global and Union economy ***with a major asymmetric social and economic impact across Member States and regions***. Due to the necessary containment measures, economic activity in the EU dropped significantly. ***According to the Commission's Summer 2020 European Economic Forecast***, the contraction in EU GDP in 2020 is expected to be around ***8,3 %***, ***deeper even than the Commission's Spring 2020 European Economic Forecast and*** far deeper than during the financial crisis in 2009, ***with the contraction in certain sectors being greater still***. The outbreak of the pandemic has shown the interconnectivity of global supply chains and exposed some vulnerabilities such as the over-reliance of strategic industries on non-diversified external supply sources ***and a lack of critical infrastructure***. Such vulnerabilities need to be addressed, ***in particular for small and medium-sized enterprises, including micro-enterprises***, to improve the Union's emergency response as well as the resilience of the entire economy, while maintaining its openness to fair competition and fair trade in line with its rules. Investment activity is expected to have dropped significantly. Even before the pandemic, while a recovery in investment-to-GDP ratios in the Union could be observed, it remained below what might be expected in a strong recovery and was insufficient to compensate for years of underinvestment

(1) The matter was referred back for interinstitutional negotiations to the committees responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0203/2020).

(\*) Amendments: new or amended text is highlighted in bold italics; deletions are indicated by the symbol ▬.

(1) OJ C [...], [...], p. [...].

(2) OJ C [...], [...], p. [...].

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following the 2009 crisis. More importantly, the current investment levels and forecasts do not cover the Union's needs for structural investment to restart and sustain long-term growth in the face of technological change and global competitiveness, including for innovation, skills, infrastructure, small and medium-sized enterprises (SMEs) and the need to address key societal challenges such as sustainability or population ageing. Consequently, in order to achieve the Union's policy objectives, **including the communications of the Commission of 11 December 2019 on the European Green Deal and of 14 January 2020 on the Sustainable Europe Investment Plan, of 10 March 2020 on a New Industrial Strategy for Europe and of 10 March 2020 on an SME Strategy for a sustainable and digital Europe**, and to support a swift, **sustainable**, inclusive, **lasting** and healthy economic recovery, support is necessary to address market failures and sub-optimal investment situations and to reduce the investment gap in targeted sectors.

- (2) Evaluations have underlined that the variety of financial instruments delivered under the 2014-2020 Multiannual Financial Framework period has led to some overlaps in their scope. That variety has also produced complexity for intermediaries and final recipients who were confronted with different eligibility and reporting rules. The absence of compatible rules also hampered the combination of several Union funds, although such combinations would have been beneficial in order to support projects in need of different types of funding. Therefore, a single fund, the InvestEU Fund, which builds on the experience of the European Fund for Strategic Investments (EFSI) set up under the Investment Plan for Europe, should be set up in order to provide more efficiently functioning support to final recipients by integrating and simplifying the financing offered under a single budgetary guarantee scheme, thereby improving the impact of Union support while reducing the cost to the Union payable from the budget.
- (3) In the last years, the Union has adopted ambitious strategies **and texts** to complete the Single Market and to stimulate sustainable and inclusive growth and jobs, such as 'Europe 2020 — A strategy for smart, sustainable and inclusive growth' of 3 March 2010, 'Action Plan on Building a Capital Markets Union' of 30 September 2015, 'A new European Agenda for Culture' of 22 May 2018, **The Digital Education Action Plan 2021-2027**, 'Clean Energy for all Europeans' of 30 November 2016, 'Closing the loop — An EU action plan for the Circular Economy' of 2 December 2015, 'A European Strategy for Low-Emission Mobility' of 20 July 2016, 'European Defence Action Plan' of 30 November 2016, 'Launching the European Defence Fund' of 7 June 2017, 'Space Strategy for Europe' of 26 October 2016, the Interinstitutional Proclamation on the European Pillar of Social Rights of 13 December 2017, **the 2050 long-term strategy 'A Clean Planet for all' of 28 November 2018**, the 'European Green Deal' of 11 December 2019, the 'European Green Deal Investment Plan' of 14 January 2020, the 'Strong Social Europe for Just Transitions' of 14 January 2020, the 'Strategy for shaping Europe's digital future', the 'Data Strategy' and the 'Artificial Intelligence Communication' of 19 February 2020, **[Regulation establishing the framework for achieving climate neutrality and amending Regulation (EU) 2018/1999 (European Climate Law)]**, 'A New Industrial Strategy for Europe' of 10 March 2020 and 'SME Strategy for a sustainable and digital Europe' of 10 March 2020, **the EU Biodiversity Strategy for 2030 of 20 May 2020, Regulation (EU) 2020/852 of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088, the Energy System Integration Strategy and the Hydrogen Strategy of 8 July 2020**. The InvestEU Fund should exploit and reinforce synergies between those mutually reinforcing strategies through providing support to investment and access to financing.
- (4) At Union level, the European Semester of economic policy coordination is the framework to identify national reform priorities and monitor their implementation. Member States, where appropriate in cooperation with local and regional authorities, develop their own national multiannual investment strategies in support of those reform priorities. Those strategies should be presented alongside the yearly national reform programmes as a way of outlining and coordinating priority investment projects that are to be supported by national funding, Union funding, or both. Those strategies should also use Union funding in a coherent manner and maximise the added value of the financial support to be received notably from the European structural and investment funds, the Recovery and Resilience Facility and the InvestEU Programme.
- (5) The InvestEU Fund should contribute to improving the competitiveness and socio-economic convergence and cohesion of the Union, including in the fields of innovation and digitisation, to the efficient use of resources in accordance with the circular economy, to the sustainability and inclusiveness of the Union's economic growth and to

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the social resilience and integration of the Union capital markets, including through solutions that address the fragmentation of Union capital markets and that diversify sources of financing for Union enterprises. To that end, the InvestEU Fund should support projects that are technically and economically viable by providing a framework for the use of debt, risk sharing and equity **and quasi-equity instruments (such as hybrid debt, subordinated debt or convertible equity)** backed up by a guarantee from the Union budget and by financial contributions from implementing partners as relevant. The InvestEU Fund should be demand-driven, while at the same time it should focus on providing strategic, long-term benefits in relation to key areas of Union policy which otherwise would not be funded or would be insufficiently funded, thereby contributing to meeting policy objectives of the Union. Support under the InvestEU Fund should cover a wide range of sectors and regions, but should avoid excessive sectoral or geographical concentration and should facilitate **█** projects composed of partner entities **and projects that foster the development of networks, clusters and digital innovation hubs** in **█** regions across the EU.

- (6) The cultural and creative sectors are key and fast growing sectors in the Union **that can play an important part in ensuring a sustainable recovery**, generating both economic and cultural value from intellectual property and individual creativity. However, restrictions on social contacts **and the organisation of events** put in place **at the outset of** the Covid-19 crisis **continue to evolve and have** had a significantly negative economic impact on these sectors **and those working in them, with potential long-term structural damage as regards access to the Cultural and Creative Sectors Guarantee Facility established under Regulation (EU) No 1295/2013 of the European Parliament and of the Council <sup>(3)</sup> or complex financial instruments.** Moreover, the intangible nature of the assets in those sectors limits the access of SMEs and organisations from those sectors to private financing which is essential to be able to invest, scale up and compete at an international level. The InvestEU Programme should continue to facilitate access to finance for SMEs and organisations from the cultural and creative sectors. The cultural and creative, audiovisual and media sectors are essential for our cultural diversity and **for building democratic and cohesive societies** in the digital age, and an intrinsic part of our sovereignty and autonomy, and strategic investments in audiovisual and media content and technology will determine the **sectors' competitiveness and their** long-term capacity to produce and distribute **high-quality** content to wide audiences across national borders, **with respect for pluralism and freedom of speech.**
- (7) With a view to fostering sustainable and inclusive growth, investment and employment, and thereby contributing to improved well-being, to fairer income distribution and to greater economic, social and territorial cohesion in the Union, the InvestEU Fund should support investments in tangible and intangible assets, including in cultural heritage. Projects funded by the InvestEU Fund should meet Union environmental and social standards, including standards on labour rights. Interventions through the InvestEU Fund should complement Union support delivered through grants.
- (8) The Union endorsed the objectives set out in the United Nations 2030 Agenda for Sustainable Development (the '2030 Agenda'), its Sustainable Development Goals (SDGs) and the Paris Agreement adopted under the United Nations Framework Convention on Climate Change <sup>(4)</sup> ('Paris Agreement on Climate Change') as well as the Sendai Framework for Disaster Risk Reduction 2015-2030. To achieve those objectives, as well as those set out in the environmental policies of the Union, action pursuing sustainable development is to be stepped up significantly. Therefore, the principles of sustainable development should feature prominently in the design of the InvestEU Fund.
- (9) The InvestEU Programme should contribute to building a sustainable finance system in the Union which supports the reorientation of private capital towards sustainable investments in accordance with the objectives set out in the **communications** of the Commission of 8 March 2018 'Action Plan: Financing Sustainable Growth', **of 10 March 2020 on a New Industrial Strategy for Europe, of 10 March 2020 on an SME Strategy for a sustainable and digital Europe** and **█** of 14 January 2020 on the European Green Deal Investment Plan.

<sup>(3)</sup> **Regulation (EU) No 1295/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Creative Europe Programme (2014 to 2020) and repealing Decisions No 1718/2006/EC, No 1855/2006/EC and No 1041/2009/EC (OJ L 347, 20.12.2013, p. 221).**

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

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- (10) Reflecting the importance of tackling climate change in line with the Union's commitments to implement the Paris Agreement on Climate Change and the SDGs, the InvestEU Programme will contribute to mainstream climate actions and to the achievement of an overall target of at **least 30 %** of the Union budget expenditures supporting climate objectives. Actions under the InvestEU Programme are expected to contribute **at least 30 %** of the overall financial envelope of the InvestEU Programme to climate objectives. Relevant actions will be identified during the InvestEU Programme's preparation and implementation and reassessed in the context of the relevant evaluations and review processes.
- (11) The contribution of the InvestEU Fund to the achievement of the climate target will be tracked through a Union climate tracking system to be developed by the Commission in cooperation with potential implementing partners, appropriately using the criteria established by [Regulation on the establishment of a framework to facilitate sustainable investment<sup>(5)</sup>] for determining whether an economic activity is environmentally sustainable. The InvestEU Programme should also contribute to the implementation of other dimensions of the SDGs.
- (12) According to the 2018 Global Risks Report issued by the World Economic Forum, half of the ten most critical risks threatening the global economy relate to the environment. Such risks include the pollution of air, soil, inland waters and oceans, extreme weather events, biodiversity losses and failures of climate-change mitigation and adaptation. Environmental principles are strongly embedded in the Treaties and many of the Union's policies. Therefore, the mainstreaming of environmental objectives should be promoted in operations related to the InvestEU Fund. Environmental protection and the prevention and management of related risks should be integrated in the preparation and implementation of investments. The Union should also track its biodiversity-related and air pollution control-related expenditures in order to fulfil the reporting obligations under the Convention on Biological Diversity<sup>(6)</sup> and under Directive (EU) 2016/2284 of the European Parliament and of the Council<sup>(7)</sup>. Investment allocated to environmentally sustainability objectives should therefore be tracked using common methodologies that are consistent with methodologies developed under other Union programmes that apply to climate, biodiversity and air pollution management in order to allow the assessment of the individual and combined impact of investments on the key components of natural capital, including air, water, land and biodiversity.
- (13) Investment projects that receive substantial Union support, in particular in the area of infrastructure, should be screened by the implementing partner to determine whether they have an environmental, climate or social impact. Investment projects that have such an impact should be subject to sustainability proofing in accordance with guidance that should be developed by the Commission in close cooperation with potential implementing partners under the InvestEU Programme. This guidance should appropriately use the criteria established by [Regulation on establishment of a framework to facilitate sustainable investment] for determining whether an economic activity is environmentally sustainable and consistent with the guidance developed for other programmes of the Union. Consistent with the principle of proportionality, such guidance should include adequate provisions for avoiding undue administrative burdens, and projects below a certain size as to be defined in the guidance should be excluded from the sustainability proofing. Where the implementing partner concludes that no sustainability proofing is to be carried out, it should provide a justification to the Investment Committee established for the InvestEU Fund. Operations that are inconsistent with the achievement of the climate objectives should not be eligible for support under this Regulation.
- (14) Low infrastructure investment rates in the Union during the financial crisis and again during the Covid-19 crisis **have** undermined the Union's ability to boost sustainable growth, **efforts towards climate neutrality**, competitiveness, **upward convergence of living conditions in the Union, and the creation of jobs**. It also creates risk of **growing divergences and inequalities within and between Member States**, and impacts regions' development long-term, **affecting the convergence and cohesion of the Union, which is visible in particular with**

<sup>(5)</sup> COM(2018)0353.

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

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

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**regard to digital infrastructure. It is crucial to support fast and ultra-fast broadband connectivity in all rural and urban regions of the Union, provide support to digital start-ups and innovative SMEs to enable them to better compete and scale up, and accelerate the digital transformation of the entire economy in order to increase both long-term competitiveness and the resilience of the Union economy.** Sizeable investments in Union infrastructure, in particular with regard to interconnection and energy efficiency and to creating a Single European Transport Area, are essential to meeting the Union's sustainability targets, including the Union's commitments towards the SDGs, and the 2030 energy and climate targets. Accordingly, support from the InvestEU Fund should target investments into transport, energy, including energy efficiency and renewable energy sources and other safe and sustainable low-emission energy sources, environmental infrastructure, infrastructure related to climate action, maritime infrastructure and digital infrastructure. The InvestEU Programme should prioritise areas that are under-invested, and in which additional investment is required. To maximise the impact and added value of Union financing support, it is appropriate to promote a streamlined investment process that enables visibility of the project pipeline and maximises synergies across relevant Union programmes in areas such as transport, energy and digitisation. Bearing in mind threats to safety and security, investment projects receiving Union support should include measures for infrastructure resilience, including infrastructure maintenance and safety, and should take into account principles for the protection of citizens in public spaces. This should be complementary to the efforts made by other Union funds that provide support for security components of investments in public spaces, transport, energy and other critical infrastructure, such as the European Regional Development Fund.

- (15) Where appropriate, the InvestEU Programme should contribute to the objectives of Directive (EU) 2018/2001 of the European Parliament and of the Council <sup>(8)</sup> and the Governance Regulation <sup>(9)</sup>, as well as promote energy efficiency in investment decisions.
- (16) Genuine multimodality is an opportunity to create an efficient and environmentally friendly transport network that uses the maximum potential of all means of transport and generates synergy between them. The InvestEU Programme should support investments in multimodal transport hubs, which — in spite of their significant economic potential and business cases — carry a significant risk for private investors. The InvestEU Programme should also contribute to the development and deployment of Intelligent Transport Systems (ITS). The InvestEU Programme should help to boost efforts to design and apply technologies that help to improve the safety of vehicles and road infrastructure.
- (17) The InvestEU Programme should contribute to Union policies concerning seas and oceans through the development of projects and enterprises in the area of the blue economy, and the Sustainable Blue Economy Finance Principles. This may include interventions in the area of maritime entrepreneurship and industry, an innovative and competitive maritime industry, as well as renewable marine energy and circular economy.
- (18) Although the level of overall investment in the Union was increasing before the Covid-19 crisis, investment in higher-risk activities such as research and innovation was still inadequate and is now expected to have suffered a significant hit with the crisis. **Research and innovation will have a crucial role in overcoming the crisis, consolidating the resilience of the Union to tackle future challenges, and creating the necessary technologies to achieve Union policies and goals. That is why it is necessary to achieve the target of investing at least 3 % of Union GDP in research and innovation, as agreed by Member States as part of the Europe 2020 Strategy. The InvestEU Fund should help remedy inadequate levels of investment by substantially contributing to increasing public and private investment in research and innovation in Member States, thereby helping to reach the overall**

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

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

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**target of at least 3 % of Union GDP. The achievement of that target would require Member States and the private sector to complement the InvestEU Fund with their own and reinforced investment actions in research, development and innovation, to avoid** underinvestment in research and innovation, **which** is damaging to the industrial and economic competitiveness of the Union and the quality of life of its citizens. The InvestEU Fund should provide appropriate financial products to cover different stages of the innovation cycle and a wide range of stakeholders, in particular to allow the upscaling of and deployment of solutions at a commercial scale in the Union in order to make such solutions competitive on world markets and to promote Union excellence in sustainable technologies at a global level, in synergy with Horizon Europe, including the European Innovation Council. In that regard, the experience gained from the financial instruments, such as InnovFin — EU Finance for Innovators, deployed under Horizon 2020 to facilitate and accelerate access to finance for innovative businesses should serve as a strong basis to deliver this targeted support.

- (19) Tourism, **including the hospitality industry**, is an **area of strategic importance** for the Union economy and the sector **is experiencing** a particularly severe contraction as a result of **the COVID-19 pandemic and the restrictions on social contacts and closures of borders put in place. That contraction is particularly damaging for SMEs and family businesses and has caused large-scale unemployment affecting, in particular, women, young people, seasonal workers and those in vulnerable situations, and heavy losses of revenue for many businesses.** The InvestEU Programme should contribute to strengthening **the recovery**, long-term competitiveness **and sustainability of the sector, and its value chains**, by supporting operations promoting sustainable, innovative and digital tourism, **including innovative measures to reduce the climate and environment footprint of the sector, as it responds to the COVID-19 crisis. The sustainable recovery of tourism should contribute to the creation of numerous permanent, local, quality jobs, allowing regions heavily dependent on tourism and with specific challenges related to their economic development to attract investment that would not be possible without the firepower of InvestEU Programme and its capacity to attract private investors as a result of the EU guarantee and the crowding-in effect produced by it.**
- (20) A significant effort is urgently needed to invest in and boost the digital transformation and to distribute the benefits of it to all Union citizens and businesses. The strong policy framework of the Digital Single Market Strategy should now be matched by investment of a similar ambition, including in artificial intelligence in line with the Digital Europe programme.
- (21) SMEs represent over 99 % of businesses in the Union and their economic value is significant and crucial. However, they face difficulties when accessing finance because of their perceived high risk and lack of sufficient collateral. Additional challenges arise from the need for SMEs and social economy enterprises to stay competitive by engaging in digitisation, internationalisation, transformation in a logic of circular economy, innovation activities and skilling up their workforce. **SMEs have been particularly badly hit by the COVID-19 crisis, notably those in the services, manufacturing, construction, tourism, cultural and creative sectors.** Moreover, SMEs and social economy enterprises have access to a more limited set of financing sources than larger enterprises, because they typically do not issue bonds, and have only limited access to stock exchanges and large institutional investors. Innovative solutions such as the acquisition of a business or ownership stake in a business by employees are also increasingly common for SMEs and social economy enterprises. The difficulty in accessing finance is even greater for those SMEs whose activities focus on intangible assets. SMEs in the Union rely heavily on banks and on debt financing in the form of bank overdrafts, bank loans or leasing. Supporting SMEs that face the above challenges by making it easier for them to gain access to finance and by providing more diversified sources of funding is necessary to increase the ability of SMEs to finance their creation, growth, innovation and sustainable development, ensure their competitiveness and withstand economic shocks to make the economy and the financial system more resilient during economic downturns and to maintain SMEs' ability to create jobs and social well-being. This Regulation is also complementary to the initiatives already undertaken in the context of the Capital Markets Union. The InvestEU Fund should therefore build on successful Union programmes such as the Programme for the Competitiveness of enterprises and SMEs (COSME) and should provide working capital and investment throughout the life cycle of a company, should provide financing for leasing transactions and should provide an opportunity to focus on



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specific, more targeted financial products. It should also maximise firepower of public/private fund vehicles, such as the SME IPO (Initial Public Offering) Fund, seeking to support SMEs through channelling both more private and public equity in particular in strategic companies.

- (22) As set out in the Commission's Reflection paper on the social dimension of Europe of 26 April 2017, the Communication on European Pillar of Social Rights, the Union framework for the UN Convention on the Rights of Persons with Disabilities and the Communication on 'Strong Social Europe for Just Transitions' of 14 January 2020, building a more inclusive and fair Union is a key priority for the Union to tackle inequality and foster social inclusion policies in Europe. Inequality of opportunities affects in particular access to education, training, culture, employment, health and social services. Investment in the social, skills and human capital-related economy, as well as in the integration of vulnerable populations in the society, can enhance economic opportunities, especially if coordinated at Union level. **The COVID-19 crisis has demonstrated that such investment helps build societal resilience to crises and has revealed a significant need for investment in social infrastructure and projects in the fields of social services, healthcare services, education, care and social housing.** The InvestEU Fund should be used to support investment in education and training, including the re-skilling and upskilling of workers, inter alia in regions depending on a carbon intensive economy and affected by the structural transition to a low-carbon economy. It should be used to support projects that generate positive social impacts and enhance social inclusion by helping to increase employment across all regions, in particular among the unskilled and long-term unemployed, and to improve the situation with regard to gender equality, equal opportunities, non-discrimination, accessibility, intergenerational solidarity, the health and social services sector, social housing, homelessness, digital inclusiveness, community development, the role and place of young people in society as well as vulnerable people, including third country nationals. The InvestEU Programme should also support European culture and creativity that has a social goal.
- (22a) **The COVID-19 crisis has had a disproportionate impact on women, from both a social and an economic perspective, including through job losses and the unpaid care burden and a rise in domestic violence. Bearing that in mind, and taking fully into account Article 8 of the Treaty, the InvestEU Programme should contribute to the achievement of the Union's policies on gender equality and the promotion and empowerment of women, inter alia through addressing the gender digital gap, helping to encourage female creativity and entrepreneurial potential and supporting the development of care infrastructure and infrastructure for victims of violence.**
- (23) To counter the negative effects of profound transformations of societies in the Union and of the labour market in the coming decade, it is necessary to invest in human capital, social infrastructure, microfinance, ethical and social enterprise finance and new social economy business models, including social impact investment and social outcomes contracting. The InvestEU Programme should strengthen nascent social market eco-system to increase the supply of and access to finance to micro- and social enterprises and social solidarity institutions, in order to meet the demand of those who need it the most. The report of the High-Level Task Force on Investing in Social Infrastructure in Europe of January 2018 entitled 'Boosting Investment in Social Infrastructure in Europe' has identified a total investment gap of at least EUR 1,5 trillion in social infrastructure and services for the period between 2018 and 2030, including education, training, health and housing. This calls for support, including at the Union level. Therefore, the collective power of public, commercial and philanthropic capital, as well as support from foundations and from alternative types of finance providers such as ethical, social and sustainable actors, should be harnessed to support the development of the social market value chain and a more resilient Union.
- (24) In the economic crisis caused by the Covid-19 pandemic, market allocation of resources is not fully efficient and perceived risk impairs private investment flow significantly. Under such circumstances, the key feature of the InvestEU Fund of de-risking economically viable projects to crowd in private finance is particularly valuable and should be reinforced, inter alia in order to counteract the risk of an asymmetric recovery **and reduce the gaps between Member States.** The InvestEU Programme should be able to provide crucial support to companies, **especially SMEs**, in the recovery phase and at the same time ensure a strong focus of investors on the Union's

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medium- and long-term policy **and legislative** priorities such as the European Green Deal, the European Green Deal Investment Plan, **[the European Climate law]**, the Strategy on shaping Europe's digital future, **the New Industrial Strategy for Europe, Horizon Europe ambitions, the Renovation Wave, the European Pillar of Social Rights**, and the Strong Social Europe for Just Transitions, **taking account of the principle of 'do no significant harm'**. It should significantly increase the risk-taking capacity of the European Investment Bank (EIB) Group and national promotional banks and institutions and other implementing partners in support of **projects that would otherwise become missed opportunities, thereby aiding** economic recovery.

- (25) The Covid-19 pandemic is a major shock to the global and Union economy. The contraction in EU GDP is expected to be far deeper than during the financial crisis in 2009 and adverse social effects will be inevitable. The outbreak of the pandemic has shown the need for strategic vulnerabilities to be **urgently and efficiently** addressed in order to improve the Union's emergency response as well as the resilience **and sustainability** of the entire economy. Only a resilient, **sustainable**, inclusive and integrated European economy can preserve the **integrity of the** Single Market and the level playing field also to the benefit of the hardest-hit Member States **and regions**.
- (26) The InvestEU Fund should operate through **six** policy windows that mirror the key Union policy priorities, namely: sustainable infrastructure; research, innovation and digitisation; SMEs; social investment and skills; strategic European investment; **and solvency support**.
- (27) Although the SME policy window should primarily focus on benefitting SMEs, small mid-cap companies should also be eligible under this policy window. Mid-cap companies should also be eligible for support under the other **five** policy windows.
- (28) The primary focus of the strategic European investment window should be on support to those final recipients established in a Member State and operating in the Union whose activities are of strategic importance to the Union, **in line with the priorities described in the New Industrial Strategy for Europe, which aims for a globally competitive, green and digital Europe, with a development model based on industrial ecosystems. The window should also enhance the competitiveness of the Union economy, including the need to rebuild Member States' productive capacity and create future-oriented investments promoting entrepreneurship and job creation, and enhance resilience, including by decreasing dependence on vulnerable supply chains. Projects should bring Union added value and should either be cross-border or generate real added value in more than one Member State or region through spill-over effects. No support should flow directly into the national budgets or substitute national budgetary expenditure, such as social benefits. Areas of strategic importance are as follows** (i) critical healthcare provision, manufacturing and stockpiling of **medicinal products, including vaccines, and their intermediates, active pharmaceutical ingredients and raw materials**; medical devices, **hospital and medical equipment, such as ventilators, protective clothing and equipment, diagnostic materials and tools; personal protective equipment, disinfectants and their intermediary products and raw materials necessary for their production**; strengthening the **resilience of healthcare and health systems in preparation for future** crisis response capacity, **including the performance of stress tests of national and regional healthcare systems**, and of the civil protection system **based on the principles of wide availability and affordability of products vital in health emergencies** (ii) critical infrastructure, whether physical, **analogue or digital, including infrastructure elements and mobile assets identified as critical in the fields of energy, transport, including public transport and active mobility, logistics, environment, water, health, secure digital communication and networks, 5G and very high-speed electronic communication networks, internet of things, online service platforms, secure edge and cloud computing, data processing or storage, payments and financial infrastructure, aerospace, security and defence, communications, media, audio-visual, culture and creativity, education and training, electoral infrastructure and sensitive facilities, public administration, security, housing, as well as land and real estate crucial for the use of such critical infrastructure**; (iii) provision of **know-how, goods, technologies and services instrumental to the operation and maintenance of such infrastructure and mobile assets**; (iv) key enabling, transformative, green and digital technologies and game-changing innovations where the investment is strategically important for the **Union economy, and the sustainable and innovative industrial future of the Union**, including artificial intelligence, blockchain **and distributed ledger technologies**, software, robotics, semiconductors, microprocessors, edge **and** cloud technologies, high-performance computing, cybersecurity, quantum technologies, photonics, industrial

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biotechnology, **technologies for safe, sustainable, smart and automated mobility and logistics in all modes of transport**, renewable **and other** energy technologies **which contribute to the achievement of climate neutrality by 2050**, energy storage technologies including **sustainable** batteries, sustainable transport technologies, clean hydrogen and fuel cell applications, decarbonisation technologies for industry, **such as the production of CO<sub>2</sub> free steel, and infrastructure for carbon capture and storage in industrial processes, bioenergy plants and manufacturing facilities towards the energy transition**, circular economy technologies **and supply chains**, biomedicine, nanotechnologies, pharmaceuticals and advanced, **renewable and circular** materials, **space systems and technologies including critical space components, as well as space-based services and applications, and tourism** (v) **recycling and** manufacturing facilities for mass production of information Communication and Technology components and devices in the **Union, including energy or raw materials, except if already covered by legislative requirements, or food security, having regard to resource efficiency and circularity in strategic value chains and strategic eco-systems**; (vi) supply and stockpiling of critical inputs to public actors, businesses or consumers in the Union; (vii) critical technologies, inputs **and applications** for the security of the Union and its Member States, such as **security and** defence and space sectors and cybersecurity, **including 5G network security**, and dual use items as defined in point 1 of Article 2 of Council Regulation (EC) No 428/2009; (viii) **investment and technical assistance to companies, in particular SMEs, start-ups and family businesses to increase the resilience of their value chains and business models, to foster entrepreneurial skills as well as supporting the conditions for boosting entrepreneurship, including by developing networks of clusters and digital innovation hubs, and technological and sustainable sectoral development** (viib) **critical early detection, and coordinated institutional and economic response capabilities in order to react to the risk of crises, as well as advancing business and service continuity solutions for essential public and private institutions and sectors** (viic) **investment in New Space activities, both upstream and downstream, in order to bring the most promising technologies and applications to the market, thus ensuring the competitiveness of the Union space industry** (viid) **strategic investment in renewable energy and energy efficiency projects, including building renovation, with a high potential to significantly contribute to meeting the targets set out in Directives (EU) 2018/2001, (EU) 2018/2002 and (EU) 2018/844 and to contribute to achieving a climate neutral and energy efficient building sector as part of the European Green Deal as laid out in the [renovation wave strategy], or actions under the Union Renewable energy financing mechanism**. Final recipients should have their registered office in a Member State and they should be active in the Union in the sense that they have substantial activities in terms of staff, manufacturing, research and development or other business activities in the Union. **No final recipient should have a subsidiary that carries on activities with no real economic substance in a country on the Union list of non-cooperative jurisdictions for tax purposes**. Projects which contribute to diversification of strategic supply chains in the Single Market through operations in multiple locations across the **Union** should be able to benefit.

- (29) The strategic European investment window should also target suppliers established and operating in the Union whose activities are of strategic importance to the Union and that would need long term investment or are covered by the Foreign Direct Investment Screening mechanism. In addition, important projects of common European interest should in particular be able to benefit from the strategic European investment window. **The window should also support strategic collaboration between industry partners and research players, thereby reinforcing synergies between InvestEU and Horizon Europe.**
- (29a) **The purpose of the solvency support window is to help companies to overcome this difficult period so that they are in a position to carry the recovery, to safeguard employment levels, and to counter-balance the expected distortions in the single market, given that not all companies have the same level of access to market financing and certain Member States may not have sufficient budgetary means available to provide adequate support to companies in need. The possibility of national solvency support measures for companies may therefore differ substantially across Member States and lead to an uneven playing field. Furthermore, as there is a considerable risk that the impact of the COVID-19 outbreak will be long-lasting, such lack of capacity to help viable companies can lead to systemic distortions, creating new disparities or cementing existing ones. Given the strong interconnectedness of the Union economy, an economic downturn in one part of the Union would have negative spill-over effects on cross-border supply chains and the Union economy as a whole. Conversely, for the same reason, support in one part of the Union would also have positive spill-over effects on cross-border supply chains and the Union economy as a whole.**

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- (29b) *In order to avoid abuse and maximize the effect on the real economy and on employment, companies that benefit from EUR 30 million or more through the solvency support window should be subject to temporary payout limitations, such as restrictions on dividend payments, senior pay and share buy-backs during the period of the guarantee.*
- (30) *As proposed in the European Green Deal and the European Green Deal Investment Plan, a Just Transition Mechanism should be established in order to address the social, economic and environmental challenges of reaching the Union's 2030 climate target and its target of achieving climate neutrality by 2050. That mechanism which is composed of three pillars, namely a Just Transition Fund (pillar 1), a dedicated Just Transition Scheme under InvestEU (pillar 2) and a Public Sector Loan Facility (pillar 3), should focus on the regions that are most affected by the green transition and have less capacity to finance the necessary investments. As such, the InvestEU should also provide support to financing to generate investment to the benefit of just transition regions **as well as the possibility for the respective regions to benefit from dedicated technical assistance through the InvestEU Advisory Hub.***
- (30a) *To implement pillar 2 under the Just Transition Mechanism, a dedicated Just Transition Scheme under InvestEU should be established horizontally across all policy windows. That scheme should provide funding to additional investment needs to support the regions identified in the territorial just transitions plans, prepared by Member States, and approved by the Commission, in accordance with Regulation [JTF Regulation].*
- (31) Each policy window should be composed of two compartments, that is to say an EU compartment and a Member State compartment. The EU compartment should address Union-wide or Member State specific market failures or sub-optimal investment situations in a proportionate manner. Operations supported should have a clear Union added value. The Member State compartment should give Member States as well as regional authorities via their Member State the possibility of contributing a share of their resources from the funds under shared management **or contributions from recovery and resilience plans under the Recovery and Resilience Facility** to the provisioning for the EU guarantee and of using the EU guarantee for financing or investment operations in order to address specific market failures or sub-optimal investment situations in their own territories, including in vulnerable and remote areas such as the outermost regions of the Union, as to be set out in the contribution agreement, in order to achieve objectives of the funds under shared management **or of national recovery and resilience plans. In addition, recovery and resilience plans under the Recovery and Resilience Facility might include contributions to the Member States compartment. Amongst other things, this could allow support to be given for the solvency of companies established in the Member States concerned.** Operations supported by the InvestEU Fund through either EU or Member State compartments should not duplicate or crowd out private financing or distort competition in the internal market.
- (32) The Member State compartment should be specifically designed to allow the use of funds under shared management **or contributions from recovery and resilience plans under the Recovery and Resilience Facility** to provision a guarantee issued by the Union. That possibility would increase the value added of the EU guarantee by providing support under it to a wider range of financial recipients and projects and diversifying the means of achieving the objectives of the funds under shared management **or of national recovery and resilience plans**, while ensuring a consistent risk management of the contingent liabilities by implementing the EU guarantee under indirect management. The Union should guarantee the financing and investment operations provided for in the guarantee agreements concluded between the Commission and implementing partners under the Member State compartment. The funds under shared management **or the contributions from recovery and resilience plans under the Recovery and Resilience Facility** should provide the provisioning for the guarantee, following a provisioning rate determined by the Commission and set out in the contribution agreement concluded with the Member State, based on the nature of the operations and the resulting expected losses. The Member State would assume losses above the expected losses by issuing a back-to-back guarantee in favour of the Union. Such arrangements should be concluded in a single contribution agreement with each Member State that voluntarily chooses such option. The contribution agreement should encompass the one or more specific guarantee agreements to be implemented within the Member State concerned on the basis of the rules of the InvestEU Fund, and any regional ring-fencing. The setting out of the provisioning rate on a case-by-case basis requires a derogation from Article 211(1) of Regulation (EU, Euratom)

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2018/1046 of the European Parliament and of the Council<sup>(10)</sup> (the Financial Regulation). This set-up provides also a single set of rules for budgetary guarantees supported by funds that are managed centrally or by **contributions from recovery and resilience plans under the Recovery and Resilience Facility**, which would facilitate their combination.

- (33) A partnership between the Commission and the EIB Group should be established, drawing on the relative strengths of each partner to ensure maximum policy impact, deployment efficiency, and appropriate budgetary and risk management oversight, which should support effective and inclusive direct access to the EU guarantee.
- (34) In order to be able to channel support to the European economy through the European Investment Fund (EIF), the Commission should be in a position to participate in one or more possible capital increases of the EIF in order to allow it to continue supporting the European economy and its recovery. The Union should be able to maintain its overall share in the EIF capital, with due consideration of the financial implications. A sufficient financial envelope to this effect should be foreseen in the Multiannual Financial Framework for 2021-2027.
- (35) The Commission should seek the views of other potential implementing partners along with the EIB Group on investment guidelines, the climate tracking system, the sustainability proofing guidance documents and common methodologies, as appropriate, with a view to ensuring inclusiveness and operability until the governance bodies have been set up, after which the involvement of implementing partners should take place within the framework of the Advisory Board and the Steering Board of the InvestEU Programme.
- (36) The InvestEU Fund should be open to contributions from third countries that are members of the European Free Trade Association, acceding countries, candidates and potential candidates, countries covered by the European Neighbourhood Policy and other countries, in accordance with the conditions laid down between the Union and those countries. This should allow continuing cooperating with the relevant countries, where appropriate, in particular in the fields of research and innovation as well as SMEs.
- (37) This Regulation lays down a financial envelope for other measures of the InvestEU Programme than the provisioning of the EU guarantee, which is to constitute the prime reference amount, within the meaning of [*reference to be updated as appropriate according to the new inter-institutional agreement*: point 16 of the Proposal for an 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 as adopted by the said Institutions<sup>(11)</sup>], for the European Parliament and the Council during the annual budgetary procedure.
- (38) The EU guarantee of EUR **91 773 320 000** (current prices) at Union level is expected to mobilise more than EUR **1 200 000 000 000** of additional investment across the Union and should be indicatively allocated between the policy windows. However, the strategic European investment window should have a dedicated portion of the EU guarantee.
- (39) On 18 April 2019, the Commission declared that '**[w]ithout** prejudice to the prerogatives of the Council in the implementation of the Stability and Growth Pact (SGP), one-off contributions by Member States, **either** by a Member State or by national promotional banks classified in the general government sector or acting on behalf of a Member State, **into** thematic or multi-country investment platforms should in principle qualify as one-off measures within the meaning of Articles 5(1) and 9(1) of Council Regulation (EC) No 1466/97<sup>(12)</sup> and Article 3(4) of Council Regulation (EC) No 1467/97<sup>(13)</sup>. In addition, without prejudice to the prerogatives of the Council in the implementation of the SGP, the Commission **will** consider to what extent the same treatment as for the EFSI in the

<sup>(10)</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

<sup>(11)</sup> COM(2018)0323 final.

<sup>(12)</sup> Council Regulation (EC) No 1466/97 of 7 July 1997 on the strengthening of the surveillance of budgetary positions and the surveillance and coordination of economic policies (OJ L 209, 2.8.1997, p. 1).

<sup>(13)</sup> Council Regulation (EC) No 1467/97 of 7 July 1997 on speeding up and clarifying the implementation of the excessive deficit procedure (OJ L 209, 2.8.1997, p. 6).

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context of the Commission communication on flexibility can be applied to the InvestEU Programme as the successor instrument to the EFSI with regard to one-off contributions provided by Member States in cash to finance an additional amount of the EU guarantee for the purposes of the Member State compartment.'

- (40) The EU guarantee underpinning the InvestEU Fund should be implemented indirectly by the Commission relying on implementing partners with outreach to financial intermediaries, where applicable, and final recipients. The selection of the implementing partners should be transparent and free from any conflict of interest. The Commission should conclude a guarantee agreement allocating guarantee capacity from the InvestEU Fund with each implementing partner to support its financing and investment operations that meet the InvestEU Fund eligibility criteria and contribute to meeting its objectives. The management of the risk related to the EU guarantee should not hamper direct access to the EU guarantee by the implementing partners. Once the EU guarantee is granted under the EU compartment to implementing partners, they should be fully responsible for the whole investment process and the due diligence related to the financing or investment operations. The InvestEU Fund should support projects that typically have a higher risk profile than the projects supported by the normal operations of the implementing partners and that could not have been carried out during the period in which the EU guarantee could be used, or could not have been carried out to the same extent, by other public or private sources without InvestEU support. However, specific conditions may apply to the additionality criterion in relation to the financing and investment operations under the strategic European investment window stemming from its objective.
- (41) The InvestEU Fund should be provided with a governance structure, the function of which should be commensurate with its sole purpose of ensuring the appropriate use of the EU guarantee, in line with ensuring the political independence of investment decisions. That governance structure should be composed of an Advisory Board, a Steering Board and a fully independent Investment Committee. The overall composition of the governance structure should strive to achieve gender balance. The governance structure should not encroach upon or interfere with the decision-making of the EIB Group or other implementing partners, and should not be a substitute for their respective governing bodies.
- (42) An Advisory Board consisting of representatives of the implementing partners, representatives of Member States, one expert appointed by the European Economic and Social Committee and one expert appointed by the Committee of the Regions should be established in order to exchange information and exchange views on the take-up of the financial products deployed under the InvestEU Fund and to discuss evolving needs and new products, including specific territorial market gaps.
- (43) In order to be able to constitute the Advisory Board from the start, the Commission should appoint the representatives of the potential implementing partners for a temporary period of one year, thereafter the implementing partners having signed guarantee agreements would take over this responsibility.
- (44) A Steering Board composed of representatives of the Commission, representatives of implementing partners and one non-voting expert appointed by the European Parliament should determine the strategic and operational guidance for the InvestEU Fund.
- (45) The Commission should assess the compatibility of investment and financing operations submitted by the implementing partners with all Union law and policies. The decisions on financing and investment operations should ultimately be taken by an implementing partner.
- (46) An Investment Committee composed of independent experts should conclude on the granting of the support from the EU guarantee to financing and investment operations fulfilling the eligibility criteria, thereby providing external expertise in investment assessments in relation to projects. The investment committee should have different configurations to cover different policy areas and sectors in the best way possible.

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- (47) The Investment Committee should become responsible as of its constitution also for granting the benefit of the EU guarantee for financing and investment operations under Regulation (EU) 2015/1017 in order to avoid parallel similar structures assessing proposals for the use of the EU guarantee.
- (48) An independent secretariat hosted by the Commission and answerable to the chairperson of the Investment Committee should assist the investment committee.
- (49) In selecting implementing partners for the deployment of the InvestEU Fund, the Commission should consider the counterparty's ability to fulfil the objectives of the InvestEU Fund and to contribute its own resources, in order to ensure adequate geographical coverage and diversification, to crowd in private investors and to provide sufficient risk diversification and solutions to address market failures and sub-optimal investment situations. Given its role under the Treaties, its capacity to operate in all Member States and the existing experience under the current financial instruments and the EFSI, the EIB Group should remain a privileged implementing partner under the InvestEU Fund's EU compartment. In addition to the EIB Group, national promotional banks or institutions should be able to offer a complementary financial product range, given that their experience and capabilities at national and regional level could be beneficial for the maximisation of the impact of public funds on the whole territory of the Union, and for ensuring a fair geographical balance of projects. The InvestEU Programme should be implemented in such a way as to promote a level playing field for smaller and younger promotional banks and institutions. Moreover, it should be possible for other international financial institutions to become implementing partners, in particular when they present a comparative advantage in terms of specific expertise and experience in certain Member States and when they present a Union majority of shareholding. It should also be possible for other entities fulfilling the criteria laid down in the Financial Regulation to become implementing partners.
- (50) With a view to promoting improved geographic diversification, investment platforms may be established to combine the efforts and expertise of implementing partners with other national promotional banks or institutions that have limited experience in the use of financial instruments. Such structures should be encouraged, including with available support from the InvestEU Advisory Hub. It is appropriate to bring together co-investors, public authorities, experts, education, training and research institutions, relevant social partners and representatives of the civil society and other relevant actors at Union, at national and regional levels to promote the use of investment platforms in relevant sectors.
- (51) The EU guarantee under the Member State compartment should be allocated to any implementing partner eligible in accordance with point (c) of Article 62(1) of the Financial Regulation, including national or regional promotional banks or institutions, the EIB, the European Investment Fund and other international financial institutions. When selecting implementing partners under the Member State compartment, the Commission should take into account the proposals made by each Member State, as reflected in the contribution agreement. In accordance with Article 154 of the Financial Regulation, the Commission is to carry out an assessment of the rules and procedures of the implementing partner to ascertain that they provide a level of protection of the financial interest of the Union equivalent to the one provided by the Commission.
- (52) Financing and investment operations should ultimately be decided by the implementing partner in its own name, implemented in accordance with its internal rules, policies and procedures, and accounted for in its own financial statements or, where applicable, disclosed in the notes to the financial statements. Therefore, the Commission should exclusively account for any financial liability arising from the EU guarantee and should disclose the maximum guarantee amount, including all relevant information concerning the guarantee provided.
- (53) Where appropriate, the InvestEU Fund should allow for the smooth, seamless and efficient blending of grants, financial instruments or both, funded by the Union budget or by other funds, such as the EU emissions trading system (ETS) Innovation Fund with the EU guarantee in situations where this is necessary to best underpin investments to address particular market failures or sub-optimal investment situations.
- (54) Projects submitted by implementing partners for support under the InvestEU Programme, which include blending support under InvestEU Fund with support from other Union programmes, should as a whole be consistent with the objectives and eligibility criteria of the relevant other Union programmes. The use of the EU guarantee should be decided under the InvestEU Programme.

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- (55) The InvestEU Advisory Hub should support the development of a robust pipeline of investment projects in each policy window through advisory initiatives that are implemented by the EIB Group or other advisory partners, or are implemented directly by the Commission. The InvestEU Advisory Hub should promote geographic diversification with a view to contributing to the Union objectives of economic, social, and territorial cohesion and reducing regional disparities. The InvestEU Advisory Hub should pay particular attention to the aggregation of small-sized projects into larger portfolios. The Commission, the EIB Group and the other advisory partners should cooperate closely with a view to ensuring efficiency, synergies and effective geographic coverage of support across the Union, taking into account the expertise and local capacity of local implementing partners, as well as the European Investment Advisory Hub established under Regulation (EU) 2015/1017 of the European Parliament and of the Council<sup>(14)</sup>. In addition, the InvestEU Advisory Hub should provide a central entry point for project development assistance delivered under the InvestEU Advisory Hub to public authorities and for project promoters.
- (56) The InvestEU Advisory Hub should be established by the Commission with the EIB Group as the main partner, building on the experience acquired through the European Investment Advisory Hub. The Commission should be responsible for the policy steer of the InvestEU Advisory Hub and for the management of the central entry point. The EIB Group should deliver advisory initiatives under the policy windows. In addition, the EIB Group should provide operational services to the Commission, including by providing input to the strategic and policy guidelines regarding advisory initiatives, mapping existing and emerging advisory initiatives, assessing advisory needs and advising the Commission on optimal ways to address these needs through existing or new advisory initiatives.
- (57) In order to ensure a wide geographic outreach of the advisory services across the Union and to successfully leverage local knowledge about the InvestEU Fund, a local presence of the InvestEU Advisory Hub should be ensured, where needed, taking into account existing support schemes and the presence of local partners, with a view to provide tangible, proactive, tailor-made assistance on the ground. In order to facilitate the provision of advisory support at local level and to ensure efficiency, synergies and effective geographic coverage of support across the Union, the InvestEU Advisory Hub should cooperate with national promotional banks or institutions, and should benefit from and make use of their expertise.
- (58) The InvestEU Advisory Hub should provide advisory support to small-sized projects and projects for start-ups, especially when start-ups seek to protect their research and innovation investments by obtaining intellectual property titles, such as patents, taking into account the existence of other services able to cover such actions and seeking synergies with those services.
- (59) In the context of the InvestEU Fund, there is a need to provide support for project development and capacity building to develop the organisational capacities and market development activities needed to originate quality projects. Such support should also target financial intermediaries that are key to help **SMEs and other actors** access financing and realise their full potential, **and should include technical assistance**. Moreover, the aim of the advisory support is to create the conditions for the expansion of the potential number of eligible recipients in nascent market segments, in particular where the small size of individual projects considerably raises the transaction cost at the project level, such as for the social finance ecosystem, including philanthropic organisations, or for the cultural and creative sectors. The capacity-building support should be complementary and in addition to actions taken under other Union programmes that cover specific policy areas. An effort should also be made to support the capacity building of potential project promoters, in particular local organisations and authorities.
- (60) The InvestEU Portal should be established to provide for an easily accessible and user-friendly project database to promote visibility of investment projects searching for financing with enhanced focus on the provision of a possible pipeline of investment projects, compatible with Union law and policies, to the implementing partners.

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<sup>(14)</sup> Regulation (EU) 2015/1017 of the European Parliament and of the Council of 25 June 2015 on the European Fund for Strategic Investments, the European Investment Advisory Hub and the European Investment Project Portal and amending Regulations (EU) No 1291/2013 and (EU) No 1316/2013 — the European Fund for Strategic Investments (OJ L 169, 1.7.2015, p. 1).



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- (61) In accordance with Regulation [European Union Recovery Instrument] and within the limits of resources allocated therein, recovery and resilience measures under InvestEU should be carried out to address the unprecedented impact of the Covid-19 crisis **and to strengthen the Union economy in the long term**. Such additional resources should be used in such a way as to ensure compliance with the time limits provided for in Regulation [EURI]. **That requirement would be met by the conclusion of the relevant guarantee agreements with the implementing partners by 31 December 2023.**
- (62) Pursuant to paragraphs 22 and 23 of the Interinstitutional agreement for Better Law-Making of 13 April 2016 <sup>(15)</sup>, there is a need to evaluate the InvestEU Programme on the basis of information collected through specific monitoring requirements, while avoiding overregulation and administrative burdens, in particular on Member States. These requirements, where appropriate, can include measurable indicators, as a basis for evaluating the effects of the InvestEU Programme on the ground.
- (63) A solid monitoring framework that is based on output, outcome and impact indicators should be implemented to track progress towards the Union's objectives. In order to ensure accountability to the Union's citizens, the Commission should report annually to the European Parliament and the Council on the progress, impact and operations of the InvestEU Programme.
- (64) Horizontal financial rules adopted by the European Parliament and the Council on the basis of Article 322 of the Treaty on the Functioning of the European Union (TFEU) apply to this Regulation. These rules are laid down in the Financial Regulation and determine in particular the procedure for establishing and implementing the budget through grants, procurement, prizes, indirect implementation, and provide for checks on the responsibility of financial actors. Rules adopted on the basis of Article 322 TFEU also concern the protection of the Union's budget in case of generalised deficiencies as regards the rule of law in the Member States, as the respect for the rule of law is an essential precondition for sound financial management and effective EU funding.
- (65) The Financial Regulation applies to the InvestEU Programme. It lays down rules on the implementation of the Union budget, including the rules on budgetary guarantees.
- (66) In accordance with the Financial Regulation, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council <sup>(16)</sup>, Council Regulation (EC, Euratom) No 2988/95 <sup>(17)</sup>, Council Regulation (Euratom, EC) No 2185/96 <sup>(18)</sup> and Council Regulation (EU) 2017/1939 <sup>(19)</sup>, the financial interests of the Union are to be protected through proportionate measures, including the prevention, detection, correction and investigation of irregularities, including fraud, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, the imposition of administrative sanctions. In particular, in accordance with Regulation (EU, Euratom) No 883/2013 and Regulation (Euratom, EC) No 2185/96 the European Anti-Fraud Office (OLAF) may carry out administrative investigations, including on-the-spot checks and inspections, with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union. In accordance with Regulation (EU) 2017/1939, the European Public Prosecutor's Office ('the EPPO') may investigate and prosecute offences against the Union's financial interests as provided for in Directive (EU) 2017/1371 of the European Parliament and of the

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<sup>(15)</sup> OJ L 123, 12.5.2016, p. 1.

<sup>(16)</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

<sup>(17)</sup> Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

<sup>(18)</sup> Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

<sup>(19)</sup> Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p. 1).

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Council<sup>(20)</sup>. In accordance with the Financial Regulation, any person or entity receiving Union funds is to fully cooperate in the protection of the Union's financial interests, to grant the necessary rights and access to the Commission, OLAF, the EPPO in respect of those Member States participating in enhanced cooperation pursuant to Regulation (EU) 2017/1939, and the European Court of Auditors and to ensure that any third parties involved in the implementation of Union funds grant equivalent rights.

- (67) Third countries which are members of the European Economic Area (EEA) may participate in Union programmes in the framework of the cooperation established under the EEA agreement, which provides for the implementation of the programmes by a decision under that agreement. Third countries may also participate on the basis of other legal instruments. A specific provision should be introduced in this Regulation to grant the necessary rights for and access to the authorising officer responsible, the OLAF as well as the European Court of Auditors to comprehensively exert their respective competences.
- (68) Pursuant to Article 83 of the [Proposal for a Council Decision on the Association of the Overseas Countries and Territories with the European Union including relations between the European Union on the one hand, and Greenland and the Kingdom of Denmark on the other ('Overseas Association Decision')] <sup>(21)</sup>, persons and entities established in the overseas countries and territories (OCTs) are eligible for funding subject to the rules and objectives of InvestEU Programme and possible arrangements applicable to the Member State to which the relevant overseas country or territory is linked.
- (69) In order to supplement the non-essential elements of this Regulation with investment guidelines and with a scoreboard of indicators, to facilitate the prompt and flexible adaptation of the performance indicators and to adjust the provisioning rate, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of **establishing indicators to be used by the Steering Board to determine the Member States and sectors economically most hit by the COVID-19 pandemic and the Member States where the possibility of State solvency support is more limited and the methodology for the application of those indicators and drawing-up the investment guidelines for the financing and investment operations under different policy windows, the scoreboard, the amendment of Annex III to this Regulation to review or complement the indicators and the adjustment of the provisioning rate.** In line with the principle of proportionality, such investment guidelines should include adequate provisions to avoid undue administrative burden. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (69a) ***It is necessary to ensure that InvestEU is implemented as promptly as possible after its entry into force. It would therefore be appropriate to allow implementing partners to submit financing and investment operations to the Commission before the Investment Committee is up and running or before the conclusion of the relevant guarantee agreement. In such cases, the Commission should be responsible for approving the operations. It should also be possible to merge both financial instruments established by programmes referred to in Annex IV to this Regulation and the EU guarantee established by Regulation (EU) 2015/1017 with financial instruments under this Regulation, if applicable and subject to a prior evaluation.***
- (70) The InvestEU Programme should address Union-wide and Member State specific market failures and sub-optimal investment situations and should provide for Union-wide market testing of innovative financial products and systems to spread them, for addressing new or complex market failures. Therefore, action at Union level is warranted,

<sup>(20)</sup> Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

<sup>(21)</sup> SEC(2018)0310; SWD(2018)0337.

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HAVE ADOPTED THIS REGULATION:

## CHAPTER I GENERAL PROVISIONS

### *Article 1*

#### *Subject matter*

1. This Regulation establishes the InvestEU Fund, which shall provide for an EU guarantee to support financing and investment operations carried out by the implementing partners that contribute to objectives of the Union's internal policies.
2. This Regulation also establishes an advisory support mechanism to provide support for the development of investable projects and access to financing and to provide related capacity building assistance (the 'InvestEU Advisory Hub'). It further establishes a database granting visibility to projects for which project promoters seek financing and which provides investors with information about investment opportunities (the 'InvestEU Portal').
3. This Regulation establishes the objectives of the InvestEU Programme, its budget and the amount of the EU guarantee for the period 2021 to 2027, the forms of Union funding and the rules for providing such funding.

### *Article 2*

#### *Definitions*

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

- (1) 'InvestEU Programme' means the InvestEU Fund, the InvestEU Advisory Hub, the InvestEU Portal and blending operations, collectively;
- (2) 'EU guarantee' means an overall irrevocable, unconditional and on demand budgetary guarantee provided by the Union budget under which the budgetary guarantees in accordance with Article 219(1) of the Financial Regulation take effect through the entry into force of individual guarantee agreements with implementing partners;
- (3) 'policy window' means a targeted area for support by the EU guarantee as laid down in Article 7(1);
- (4) 'compartment' means a part of the EU guarantee defined in terms of the origin of the resources backing it;
- (5) 'blending operation' means an operation supported by the Union budget that combines non-repayable forms of support, repayable forms of support, or both, from the Union budget with repayable forms of support from development or other public finance institutions, or from commercial finance institutions and investors; for the purposes of this definition, Union programmes financed from sources other than the Union budget, such as the EU Emissions Trading System (ETS) Innovation Fund, may be assimilated to Union programmes financed by the Union budget;
- (6) 'EIB' means the European Investment Bank;
- (7) 'EIB Group' means the EIB, its subsidiaries and other entities established in accordance with Article 28(1) of Protocol No 5 on the Statute of the European Investment Bank, annexed to the Treaty on European Union and the TFEU (the EIB Statute);
- (8) 'financial contribution' means a contribution from an implementing partner in the form of own risk-taking capacity that is provided on a *pari passu* basis with the EU guarantee or in another form that allows an efficient implementation of the InvestEU Programme while ensuring appropriate alignment of interest;

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- (9) 'contribution agreement' means a legal instrument whereby the Commission and one or more Member States specify the conditions of the EU guarantee under the Member State compartment, as laid down in Article 9;
- (10) 'financial product' means a financial mechanism or arrangement under the terms of which the implementing partner provides direct or intermediated financing to final recipients using any of the types of financing referred to in Article 15;
- (11) 'financing and/or investment operations' means operations to provide finance directly or indirectly to final recipients through financial products, carried out by an implementing partner in its own name, provided by the implementing partner in accordance with its internal rules, policies and procedures and accounted for in the implementing partner's financial statements or, where applicable, disclosed in the notes to those financial statements;
- (12) 'funds under shared management' means funds that provide for the possibility of allocating a portion of those funds to the provisioning for a budgetary guarantee under the Member State compartment of the InvestEU Fund, namely the European Regional Development Fund (ERDF), the European Social Fund Plus (ESF+), the Cohesion Fund, the European Maritime and Fisheries Fund (EMFF), the European Agriculture Fund for Rural Development (EAFRD) and the [Just Transition Fund (JTF)] <sup>(22)</sup>;
- (13) 'guarantee agreement' means a legal instrument whereby the Commission and an implementing partner specify the conditions for proposing financing or investment operations in order for them to be granted the benefit of the EU guarantee, for providing the EU guarantee for those operations and for implementing them in accordance with the provisions of this Regulation;
- (14) 'implementing partner' means an eligible counterpart such as a financial institution or other financial intermediary with whom the Commission has concluded a guarantee agreement;
- (15) 'Important Project of Common European Interest' means a project that fulfils all the criteria laid down in Commission Communication on Criteria for the analysis of the compatibility with the internal market of State aid to promote the execution of important projects of common European interest (OJ C 188, 20.6.2014, p. 4) or any subsequent revision;
- (16) 'InvestEU Advisory Hub' means the technical assistance defined in Article 24;
- (17) 'advisory agreement' means a legal instrument whereby the Commission and the advisory partner specify the conditions for the implementation of the InvestEU Advisory Hub;
- (18) 'advisory initiative' means technical assistance and advisory services that support investment, including capacity building activities, provided by advisory partners, by external service providers contracted by the Commission or by executive agencies;
- (19) 'advisory partner' means an eligible counterpart such as a financial institution or other entity with whom the Commission has concluded an advisory agreement for the purpose of implementing one or more advisory initiatives, other than advisory initiatives implemented through external service providers contracted by the Commission or by executive agencies;
- (20) 'InvestEU Portal' means the database defined in Article 25;
- (21) 'investment guidelines' means the guidelines established by a delegated act referred to in Article 7(7);
- (22) 'investment platform' means a special purpose vehicle, managed account, contract-based co-financing or risk-sharing arrangement or an arrangement established by any other means by which entities channel a financial contribution in order to finance a number of investment projects, and which may include:
- (a) a national or sub-national platform that groups together several investment projects on the territory of a given Member State;

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<sup>(22)</sup> COM(2020)0022 final.

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- (b) a cross-border, multi-country, regional or macro-regional platform that groups together partners from several Member States, regions or third countries interested in investment projects in a given geographic area;
- (c) a thematic platform that groups together investment projects in a given sector;
- (23) 'microfinance' means microfinance as defined in Article [2(11)] of Regulation [[ESF+] number];
- (24) 'national promotional bank or institution' or 'NPBI' means a legal entity that carries out financial activities on a professional basis which has been given mandate by a Member State or a Member State's entity at central, regional or local level to carry out development or promotional activities;
- (25) 'small and medium-sized enterprise' or 'SME' means a micro, small or medium-sized enterprise within the meaning of the Annex to Commission Recommendation 2003/361/EC<sup>(23)</sup>;
- (26) 'small mid-cap company' means an entity that is not an SME and that employs up to 499 employees;
- (26a) 'companies' means, for the purposes of the solvency support window companies, project companies, public-private partnerships and other legal structures;**
- (27) 'social enterprise' means a social enterprise as defined in Article [2(15)] of Regulation [[ESF+] number];
- (28) 'third country' means a country that is not a Member State of the Union;

### Article 3

#### Objectives of the InvestEU Programme

1. The general objective of the InvestEU Programme is to support the policy objectives of the Union by means of financing and investment operations that contribute to:
- (a) the competitiveness of the Union, including research, innovation and digitisation;
- (b) growth and employment in the Union economy, the sustainability of the Union economy and its environmental and climate dimension contributing to the achievement of the SDGs and the objectives of the Paris Agreement on Climate Change and to the creation of high-quality jobs;
- (c) the social resilience, inclusiveness and innovativeness of the Union;
- (d) the promotion of scientific and technological advances, of culture, education and training;
- (e) the integration of Union capital markets and the strengthening of the Single Market, including solutions to address the fragmentation of Union capital markets, diversify sources of financing for Union enterprises and promote sustainable finance;
- (f) the promotion of economic, social and territorial cohesion; or
- (g) the sustainable and inclusive recovery of the Union economy, **and in particular of SMEs**, after the crisis caused by the Covid-19 pandemic, upholding and strengthening **existing** strategic value chains **of tangible or intangible assets, and developing new such value chains**, and maintaining and reinforcing activities of strategic importance to the Union in relation to critical infrastructure, **whether physical or virtual or based on intellectual property**, transformative technologies, game-changing innovations and inputs to businesses and consumers, **and supporting a sustainable transition in accordance with the Union's 2030 and 2050 climate targets and taking account of the principle of 'do no significant harm'**.

<sup>(23)</sup> Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

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2. The InvestEU Programme has the following specific objectives:
- (a) supporting financing and investment operations related to sustainable infrastructure in the areas referred to in point (a) of Article 7(1);
  - (b) supporting financing and investment operations related to research, innovation and digitisation, including support for the scaling up of innovative companies and the rolling out of technologies to market, in the areas referred to in point (b) of Article 7(1);
  - (c) increasing the access to and the availability of finance for SMEs and for small mid-cap companies and to enhance the global competitiveness of such SMEs;
  - (d) increasing access to and the availability of microfinance and finance for social enterprises, to support financing and investment operations related to social investment, competences and skills, and to develop and consolidate social investment markets, in the areas referred to in point (d) of Article 7(1);
  - (e) to support financing and investment operations in sectors referred to in point (e) of Article 7(1) in order to maintain and reinforce the strategic autonomy **and the sustainability** of the Union and **the inclusiveness and convergence** of its economy, **as well as to reinforce resilience to economic shocks**.

**(ea) to support the solvency of companies established in a Member State and operating in the Union.**

#### Article 4

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

1. The EU guarantee for the purposes of the EU compartment referred to in point (a) of Article 8(1) shall be EUR **91 773 320 000** (current prices). It shall be provisioned at the rate of **40 %**. The amount referred to in point (a) of the first subparagraph of Article 34(3) shall be also taken into account for contributing to the provisioning resulting from this provisioning rate.

An additional amount of the EU guarantee may be provided for the purposes of the Member State compartment referred to in point (b) of Article 8(1), subject to the allocation by Member States, pursuant to [Article 10(1)] of Regulation [[CPR] number] <sup>(24)</sup>, Article [75(1)] of Regulation [[CAP Strategic Plan] number] <sup>(25)</sup>, **and in accordance with the implementation of the relevant measures in recovery and resilience plans under Regulation [Recovery and Resilience Facility]**, of the corresponding amounts.

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

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

2. An amount of EUR **31 153 850 000** (current prices) of the amount referred to in the first subparagraph of paragraph 1 shall be allocated for operations implementing measures referred to in Article 2 of Regulation [EURI] for the objectives referred to in point (e) of Article 3(2).

An amount of EUR **19 850 000 000** (current prices) of the amount referred to in the first subparagraph of paragraph 1 shall be allocated for operations implementing measures referred to in Article 2 of Regulation [EURI] for the objectives referred to in point (a) **and (ea)** of Article 3(2).

An amount of EUR **40 769 470 000** (current prices) of the amount referred to in the first subparagraph of paragraph 1 shall be allocated for the objectives referred to in **points (a) to (d)** of Article 3(2).

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<sup>(24)</sup> ...  
<sup>(25)</sup> ...

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The amounts referred to in the first and second subparagraph shall only be available as of the date referred to in Article 4(3) of Regulation [EURI].

The indicative distribution of the EU guarantee for the purpose of the EU compartment is set out in Annex I to this Regulation. Where appropriate, the Commission may **depart from** the amounts referred to in Annex I by up to 15 % for each objective. The Commission shall inform the European Parliament and the Council of any such **departure**.

3. The financial envelope for the implementation of the measures provided in Chapters VI and VII shall be EUR **824 733 000** (current prices).

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

**4a. Where the grants referred to in Article 3(2)(a) of Regulation [EURI], have not been used in their entirety by 31 December 2023, or where the loans to Member States referred to in Article 3(2)(b) of Regulation [EURI], have not been granted by 31 December 2023, part of the unused amount or the unallocated headroom, up to a maximum amount of EUR 16 000 000 000 (in current prices), shall be made available automatically to the InvestEU Fund, for the provisioning of the EU guarantee for the period 2024–2027, in accordance with Article X of Regulation [EURI]. The amount of the EU guarantee as referred to in the first subparagraph of paragraph 1 of this Article and the distribution of the EU guarantee set out in Annex I to this Regulation shall be adjusted upwards accordingly.**

#### Article 5

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

The EU compartment of the InvestEU Fund referred to in point (a) of Article 8(1) and each of the policy windows referred to in Article 7(1), except the strategic European investment window, may receive contributions from the following third countries for the purpose of participation in certain financial products pursuant to Article 218(2) of the Financial Regulation:

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

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## Article 6

### *Implementation and forms of Union funding*

1. The EU guarantee shall be implemented in indirect management with bodies referred to in points (c)(ii), (c)(iii), (c)(v) and (c)(vi) of Article 62(1) of the Financial Regulation. Other forms of Union funding under this Regulation shall be implemented in direct or indirect management in accordance with the Financial Regulation, including grants implemented in accordance with Title VIII of the Financial Regulation and blending operations implemented in accordance with this Article as smoothly as possible, in a manner that ensures efficient and coherent support for Union policies.
2. Financing and investment operations covered by the EU guarantee which form part of the blending operation combining support under this Regulation with support provided under one or more other Union programmes or covered by the EU ETS Innovation Fund shall:
  - (a) be consistent with the policy objectives and comply with the eligibility criteria set out in the rules of the Union programme under which the support is decided;
  - (b) comply with this Regulation.
3. Blending operations that include a financial instrument that is fully financed by other Union programmes or by the EU ETS Innovation Fund without the use of the EU guarantee under this Regulation shall be consistent with the policy objectives and comply with the eligibility criteria set out in the rules of the Union programme under which the support is provided.
4. In accordance with Article 6(2), the non-repayable forms of support and financial instruments from the Union budget forming part of the blending operation referred to in paragraphs 2 and 3 of this Article shall be decided under the rules of the relevant Union programme and shall be implemented within the blending operation in accordance with this Regulation and with Title X of the Financial Regulation.

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

## CHAPTER II

### **InvestEU Fund**

## Article 7

### *Policy windows*

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



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- (c) an SME policy window which comprises access to and the availability of finance primarily for SMEs, including for innovative SMEs and SMEs operating in the cultural and creative sectors, as well as for small mid-cap companies;
- (d) a social investment and skills policy window, which comprises microfinance, social enterprise finance, social economy and measures to promote gender equality, skills, education, training and related services, social infrastructure, including health and educational infrastructure and social and student housing, social innovation, health and long-term care, inclusion and accessibility, cultural and creative activities with a social goal, and the integration of vulnerable people, including third country nationals;
- (e) a strategic European investment policy window which comprises strategic, **future-oriented** investment to support final recipients, **including SMEs and start-ups**, that are established in a Member State and that operate in the Union, and whose activities are of strategic importance to the Union, in particular in view of the **climate** and digital transitions, **in accordance with the priorities described in the New Industrial Strategy for Europe, which aims for a globally competitive, green and digital Europe, with a development model based on industrial ecosystems and the Union climate neutrality goal, [as enshrined in the European climate law] and the 2030 target. The window shall support projects that enhance the competitiveness of the Union's economy, rebuild productive capacity, decrease dependence on vulnerable supply chains, and promote entrepreneurship, job creation, and enhanced resilience**, in one of the following areas:
- i) critical healthcare provision, manufacturing and stockpiling of **medicinal products, including vaccines, and their intermediates, active pharmaceutical ingredients and raw materials**; medical devices; **hospital and medical equipment, such as ventilators, protective clothing and equipment, diagnostic materials and tools; personal protective equipment; disinfectants and their intermediary products and raw materials necessary for their production**; strengthening the resilience of healthcare and health systems in preparation for future crisis response capacity, **including the performance of stress tests of national and regional healthcare systems**, and of the civil protection system; **based on the principle of availability and affordability of products vital in health emergencies**;
  - ii) critical infrastructure, whether physical, **analogue or digital**, including infrastructure elements **and mobile assets** identified as critical in the fields of energy, transport, **including public transport and active mobility, logistics**, environment, **water**, health, secure digital communication **and networks**, 5G and very high-speed **electronic communication networks**, internet of things, online service platforms, secure **edge and cloud** computing, data processing or storage, payments and financial infrastructure, aerospace, **security and defence**, communications, media, **audio-visual, culture and creativity**, education and training, electoral infrastructure and sensitive facilities, **public administration, security, housing**, as well as land and real estate crucial for the use of such critical infrastructure;
  - iii) the provision of **know-how**, goods, **technologies** and services instrumental to the operation and maintenance of the critical infrastructure **and mobile assets** under point ii);
  - iv) key enabling, transformative, green and digital technologies and game-changing innovations where the investment is strategically important for the **Union economy, and the sustainable and innovative industrial future of the Union**, including **reindustrialisation, having regard to the principle of just transition and broad societal benefits, including**
    - (a) artificial intelligence, blockchain **and distributed ledger technologies**, software, robotics, semiconductors, microprocessors, edge cloud technologies, high-performance computing, cybersecurity, quantum technologies, photonics, industrial biotechnology, **technologies for safe, sustainable, smart and automated mobility and logistics in all modes of transport**,
    - (b) renewable **and other** energy technologies **which contribute to the achievement of climate neutrality by 2050**, energy storage technologies including **sustainable** batteries, sustainable transport technologies, clean hydrogen and fuel cell applications, decarbonisation technologies for industry, **infrastructure for carbon capture and storage in industrial processes, bioenergy plants and manufacturing facilities towards the energy transition**, circular economy technologies **and supply chains**,

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- (ba) *space systems and technologies including critical space components, as well as space-based services and applications,*
- (c) *biomedicine, nanotechnologies, **biotechnologies**, pharmaceuticals and advanced, **renewable and circular** materials;*
- (ca) *tourism;*
- v) ***recycling and** manufacturing facilities for mass production of Information Communication and Technology components and devices in the **Union**;*
- vi) *supply and stockpiling of critical inputs to public actors, businesses or consumers in the **Union**, including energy or raw materials, **except if already covered by legislative requirements**, or food security, having regard to resource efficiency and circularity in strategic value chains **and strategic eco-systems**;*
- vii) *critical technologies, inputs **and applications** for the security of the Union and its Member States, such as **security and** defence and space sectors and cybersecurity, and dual use items as defined in point 1 of Article 2 of Council Regulation (EC) No 428/2009 **and related legislation**. **Moreover, final recipients shall not export defence-related technology to third countries that threaten the territorial integrity of the Member States, systematically violate international law or undermine regional or global security and stability**;*
- (viiia) *investment and technical assistance to companies, in particular SMEs, start-ups, family businesses and communities to increase the resilience of their value chains and business models, to foster entrepreneurial skills as well as supporting the conditions for boosting entrepreneurship, including by developing networks of clusters and digital innovation hubs, and technological and sustainable sectoral development;*
- (viiib) *critical early detection, and coordinated institutional and economic response capabilities in order to react to the risk of crises, as well as advancing business and service continuity solutions for essential public and private institutions and sectors;*
- (viiic) *investment in New Space activities, both upstream and downstream, in order to bring the most promising technologies and applications to the market, thus ensuring the competitiveness of the Union space industry;*
- (viiid) *strategic investment in renewable energy and energy efficiency projects, including building renovation, with a high potential to significantly contribute to meeting the targets set out in Directives (EU) 2018/2001, (EU) 2018/2002 and (EU) 2018/844 and to contribute to achieving a climate neutral and energy efficient building sector as part of the European Green Deal as laid out in the [renovation wave strategy], or actions under the Union Renewable energy financing mechanism, eligible under the InvestEU programme.*

In addition, *final recipients that receive funding under this window* shall not be controlled by a third country or third country entities and shall have their executive management in the Union with a view to protect the security of the Union and its Member States.

The Steering Board shall set any necessary requirements relating to the control and executive management of final recipients for other areas under the strategic European investment window, and to the control of intermediaries under that window, in the light of any applicable public order or security considerations.

- (ea) *a solvency support window, which comprises solvency support for companies that were not already in difficulty in State aid terms at the end of 2019, but since then have faced significant solvency risks due to the COVID-19 crisis, or for companies created on or before 31 December 2020 that have acquired or are managing either the assets or branches of a company that was already in difficulty in State aid terms at the end of 2019, provided that their management is not the same as the management of the company in difficulty in State aid terms.*

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**The solvency support window shall be open to all Member States and to the areas referred to in Annex II. The majority of InvestEU financing under the solvency support window shall be used to support:**

- (a) eligible companies in Member States and sectors economically most hit by the Covid-19 crisis;**
- (b) eligible companies in Member States where the possibility of State solvency support is more limited.**

**The Commission shall establish, by delegated acts in accordance with Article 33, both the indicators to be used by the Steering Board to determine the Member States and sectors economically most hit by the COVID-19 crisis and the Member States where the possibility of State solvency support is more limited, and the methodology for the application of those indicators.**

**Companies receiving support under the solvency support window shall comply, to the extent possible, with minimum high-level social and environmental safeguards in line with guidance provided by the Steering Board. Such guidance shall include adequate provisions for avoiding undue administrative burdens, taking into account the size of companies and including lighter provisions for SMEs. Such companies shall be encouraged to put in place green transition plans, advance in their digital transformation and safeguard employment. Technical assistance shall be available to assist companies for the purpose of these transitions.**

**Implementing partners and financial intermediaries under the solvency support window shall be established in a Member State and operate in the Union. The Steering Board shall set any necessary requirements relating to the control of those intermediaries in the light of any applicable public order or security considerations.**

**1a. A Just Transition Scheme, the second pillar of the Just Transition Mechanism, shall be established horizontally across all policy windows. This scheme shall comprise investments which address social, economic and environmental challenges deriving from the transition process towards the achievement of the Union's 2030 climate target and its target of achieving climate neutrality by 2050.**

2. Where a financing or investment operation proposed to the Investment Committee referred to in Article 23 falls under more than one policy window, it shall be attributed to the policy window under which its main objective or the main objective of most of its sub-projects falls, unless the investment guidelines provide otherwise.

3. Financing and investment operations shall be screened to determine whether they have an environmental, climate or social impact. If those operations have such an impact they shall be subject to climate, environmental and social sustainability proofing with a view to minimising detrimental impacts and to maximising benefits to the climate, environment and social dimensions. For that purpose, project promoters that request financing shall provide adequate information based on the guidance referred to in paragraph 4. Projects below a certain size specified in the guidance shall be excluded from the proofing. Projects that are inconsistent with the climate objectives shall not be eligible for support under this Regulation. In case the implementing partner concludes that no sustainability proofing is to be carried out, it shall provide a justification to the Investment Committee.

4. The Commission shall develop sustainability guidance that, in accordance with Union environmental and social objectives and standards, allows to:

- (a) as regards adaptation, ensure resilience to the potential adverse impacts of climate change through a climate vulnerability and risk assessment, including through relevant adaptation measures, and, as regards mitigation, integrate the cost of greenhouse gas emissions and the positive effects of climate mitigation measures in the cost-benefit analysis;
- (b) account for the consolidated impact of projects in terms of the principal components of the natural capital relating to air, water, land and biodiversity;
- (c) estimate the social impact of projects, including on gender equality, on the social inclusion of certain areas or populations and on the economic development of areas and sectors affected by structural challenges such as the need to decarbonise the economy;

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- (d) identify projects that are inconsistent with the achievement of climate objectives;
  - (e) provide implementing partners with guidance for the purpose of the screening provided for under paragraph 3.
5. Implementing partners shall provide the information necessary to allow the tracking of investment that contributes to meeting the Union objectives on climate and environment, on the basis of guidance to be provided by the Commission.
6. Implementing partners shall apply a target of at least 60 % of the investment under the sustainable infrastructure policy window contributing to meeting the Union objectives on climate and environment.

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

7. The Commission is empowered to adopt delegated acts in accordance with Article 33 in order to supplement this Regulation by defining the investment guidelines for each of the policy windows. **The investment guidelines shall also set out the arrangements for the implementation of the Just Transition Scheme, as referred to in paragraph 1a.** The investment guidelines shall be prepared in close dialogue with the EIB Group and other potential implementing partners.
8. For financing and investment operations under the strategic European investment window in **security and** defence and space sectors and in cybersecurity, the investment guidelines may set out limitations with respect to transfer and licensing of intellectual property rights to critical technologies and technologies instrumental to safeguarding the security of the Union and its Member States.
9. The Commission shall make the information on the application and interpretation of the investment guidelines available to the implementing partners, the Investment Committee and the advisory partners.

#### Article 8

##### Compartments

1. The policy windows referred to in Article 7(1) shall consist of an EU compartment and a Member State compartment. Those compartments shall address market failures or sub-optimal investment situations as follows:
- (a) the EU compartment shall address any of the following situations:
    - (i) market failures or sub-optimal investment situations related to Union policy priorities;
    - (ii) Union-wide or Member State specific market failures or sub-optimal investment situations; or
    - (iii) market failures or sub-optimal investment situations, which require the development of innovative financial solutions and market structures, in particular new or complex market failures or sub-optimal investment situations;
  - (b) the Member State compartment shall address specific market failures or sub-optimal investment situations in one or several regions or Member States to deliver the policy objectives of the contributing funds under shared management or of the additional amount provided by a Member State under the third subparagraph of Article 4(1), in particular to strengthen economic, social and territorial cohesion in the Union by addressing imbalances between its regions.
2. Where appropriate, the compartments referred to in paragraph 1 shall be used in a complementary manner to support a given financing or investment operation, including by combining support from both compartments.

#### Article 9

##### Specific provisions applicable to the Member State compartment

1. Amounts allocated by a Member State on a voluntary basis under Article [10(1)] of Regulation [[CPR] number] or Article [75(1)] of Regulation [[CAP Strategic Plan] number] **or in accordance with the implementation of the relevant measures in the recovery and resilience plans established under Regulation [Recovery and Resilience Facility]** shall be used for the provisioning for the part of the EU guarantee under the Member State compartment covering financing and

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investment operations in the Member State concerned or for the possible contribution from funds under shared management **or from contributions made in accordance with the implementation of the relevant measures in the recovery and resilience plans established under Regulation [RRF]** to the InvestEU Advisory Hub. Those amounts shall be used to contribute to the achievement of the policy objectives specified in the Partnership Agreement referred to in Article 7 of Regulation [[CPR] number], in the programmes or in the CAP Strategic Plan **or in the recovery and resilience plan of the Member State concerned**, which contribute to InvestEU.

An additional amount allocated by a Member State under the third subparagraph of Article 4(1) shall be used for the provisioning for the part of the EU guarantee under the Member State compartment.

2. The establishment of the part of the EU guarantee under the Member State compartment shall be subject to the conclusion of a contribution agreement between a Member State and the Commission.

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

The provisions in this Article relating to amounts allocated under Article 10(1) of Regulation [CPR number] or Article 75 (1) of Regulation [CAP Strategic Plan] **or in accordance with the implementation of the relevant measures in the recovery and resilience plans drawn up under Regulation [RRF]** are not applicable to a contribution agreement concerning an additional amount by a Member State, referred to in the third subparagraph of Article 4(1).

The Member State and the Commission shall conclude a contribution agreement or an amendment to it within four months following the Commission Decision approving the Partnership Agreement pursuant to Article 9(4) of Regulation [CPR] or the CAP Strategic Plan under Regulation [CAP] **or a recovery and resilience plan established under Regulation [RRF]** or simultaneously to the Commission Decision amending a programme according to Article 10 of Regulation [CPR] or a CAP Strategic Plan according to Article 107 of Regulation [CAP] **or a recovery and resilience plan in accordance with Article 18 of Regulation [RRF]**.

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

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

3. The contribution agreement shall at least contain the following elements:

- (a) the overall amount of the part of the EU guarantee under the Member State compartment pertaining to the Member State, its provisioning rate, the amount of the contribution from funds under shared management **or contributions from recovery and resilience plans as established under Regulation [RRF]**, the constitution phase of the provisioning in accordance with an annual financial plan and the amount of the resulting contingent liability to be covered by a back-to-back guarantee provided by the Member State concerned;
- (b) the Member State strategy, consisting of the financial products and their minimum leverage, the geographical coverage, including regional coverage if necessary, types of projects, the investment period and, where applicable, the categories of final recipients and of eligible intermediaries;
- (c) the potential implementing partner or partners proposed in accordance with fourth subparagraph of Article 14(1) and the obligation of the Commission to inform the Member State concerned of the implementing partner or partners selected;
- (d) any contribution from funds under shared management **or contributions from recovery and resilience plans established under Regulation [RRF]** to the InvestEU Advisory Hub;

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- (e) the obligations to provide annual reports to the Member State, including reporting on the relevant indicators related to the policy objectives covered in the Partnership Agreement, programme or CAP Strategic Plan **or the recovery and resilience plan** and referred to in the contribution agreement;
- (f) provisions on the remuneration for the part of the EU guarantee under the Member State compartment;
- (g) any combination with resources under the EU compartment in accordance with Article 8(2), including in a layered structure to achieve better risk coverage.

4. The contribution agreements shall be implemented by the Commission through guarantee agreements concluded with implementing partners in accordance with Article 16 and advisory agreements concluded with advisory partners in accordance with the second subparagraph of Article 24(1).

Where no guarantee agreement has been concluded within nine months from the conclusion of the contribution agreement, the contribution agreement shall be terminated or prolonged by mutual agreement. Where the amount of a contribution agreement has not been fully committed under one or more guarantee agreements within nine months from the conclusion of the contribution agreement, that amount shall be amended accordingly. The unused amount of provisioning attributable to amounts allocated by Member States under Article [10(1) of Regulation [[CPR]] or Article [75(1)] of Regulation [[CAP]] **or in accordance with the implementation of the relevant measures in the recovery and resilience plans drawn up under Regulation [RRF]** shall be re-used in accordance with [Article 10(5) of Regulation [[CPR] number] and Article [75(5) of Regulation [[CAP Strategic Plan] number] **and Article [X] of Regulation [RRF]**. The unused amount of provisioning attributable to amounts allocated by a Member State under the third subparagraph of Article 4(1) of this Regulation shall be paid back to the Member State.

Where a guarantee agreement has not been duly implemented within a period specified in Article [10(6) of Regulation [[CPR] number] or in Article [75(6) of Regulation [[CAP Strategic Plan] number] **or in Article [X] of Regulation [RRF]**, the contribution agreement shall be amended. The unused amount of provisioning attributable to amounts allocated by Member States under Article [10(1) of Regulation [[CPR]] or Article [75(1) of Regulation [[CAP]] **or Article [X] of Regulation [RRF]** shall be re-used in accordance with [Article 10(6) of Regulation [[CPR] number] and Article [75(6) of Regulation [[CAP Strategic Plan] number] **and Article [X] of Regulation [RRF]**. The unused amount of provisioning attributable to amounts allocated by a Member State under the third subparagraph of Article 4(1) of this Regulation shall be paid back to the Member State.

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

- (a) After the constitution phase referred to in point (a) of paragraph 3 of this Article, any annual surplus of provisions, calculated by comparing the amount of provisions required by the provisioning rate set in the contribution agreement and the actual amount of provisions, shall be re-used pursuant to [Article 10(7)] of the [CPR] and to Article [75(7)] of the [[CAP Strategic Plan] number] **and to Article [X] of Regulation [RRF]**.
- (b) By way of derogation from Article 213(4) of the Financial Regulation, after the constitution phase referred to in point (a) of paragraph 3 of this Article, the provisioning shall not give rise to annual replenishments during the availability of that part of the EU guarantee under the Member State compartment.
- (c) The Commission shall immediately inform the Member State where the level of provisions for that part of the EU guarantee falls below 20 % of the initial provisioning as a result of calls on that part of the EU guarantee under the Member State compartment.
- (d) If the level of provisions for that part of the EU guarantee under the Member State compartment reaches 10 % of the initial provisioning, the Member State concerned shall provide up to 5 % of the initial provisioning to the common provisioning fund referred to in Article 212 of the Financial Regulation upon request by the Commission.

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**CHAPTER III**  
**PARTNERSHIP BETWEEN THE COMMISSION AND THE EIB GROUP**

*Article 10*

*Scope of the partnership*

1. The Commission and the EIB Group shall form a partnership under this Regulation with the objective of supporting the implementation of the InvestEU and fostering consistency, inclusivity, additionality, and efficient deployment. In accordance with this Regulation and as further specified in the agreements referred to in paragraph 3, the EIB Group:

- (a) shall implement the portion of the EU guarantee specified in Article 12(4);
- (b) shall support the implementation of the EU compartment of the InvestEU Fund, and, where applicable, the Member State compartment, in particular by:
  - (i) contributing, together with potential implementing partners, to the investment guidelines in accordance with Article 7(7), contributing to the design of the scoreboard in accordance with Article 21 and contributing to other documents that set out the operational guidance of the InvestEU Fund;
  - (ii) defining, together with the Commission and potential implementing partners, the risk methodology and risk mapping system that relate to the financing and investment operations of the implementing partners in order to allow such operations to be assessed on a common rating scale;
  - (iii) at the request of the Commission and in agreement with the potential implementing partner concerned, carrying out an assessment of the systems of that potential implementing partner and providing targeted technical advice on those systems, where and to the extent required by the conclusions of the audit of the pillar assessment in view of the implementation of the financial products envisaged by that potential implementing partner;
  - (iv) providing a non-binding opinion on the banking-related aspects, in particular on the financial risk and financial terms related to the portion of the EU guarantee to be allocated to the implementing partner, other than to the EIB Group, as defined in the guarantee agreement to be concluded with that implementing partner;
  - (v) carrying out simulations and projections of the financial risk and remuneration of the aggregate portfolio on the basis of assumptions agreed with the Commission;
  - (vi) measuring the financial risk of the aggregate portfolio and providing financial reports on the aggregate portfolio; and
  - (vii) providing restructuring and recovery services as set out in the agreement referred to in point (b) of paragraph 3 to the Commission at the request of the Commission and in agreement with the implementing partner in accordance with point (g) of Article 16(2) where that implementing partner is no longer responsible for pursuing restructuring and recovery activities under the relevant guarantee agreement;
- (c) may provide capacity building as referred to in point (h) of Article 24(2) to a national promotional bank or institution and other services, in relation to the implementation of financial products supported by the EU guarantee if requested by that national promotional bank or institution;
- (d) shall, in relation to the InvestEU Advisory Hub:
  - (i) be allocated an amount of up to EUR 525 000 000 for the advisory initiatives referred to in Article 24 and operational tasks referred to in point (ii) of this point (d) out of the financial envelope referred to in Article 4(3);
  - (ii) advise the Commission and perform operational tasks set out in the agreement referred to in point (c) of paragraph 3, by:
    - providing support to the Commission in the design, the establishment and operation of the InvestEU Advisory Hub;

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- providing an assessment of requests for advisory support that the Commission does not consider to fall under existing advisory initiatives, with a view to supporting the allocation decision of the Commission in relation to advisory requests received under the central point of entry defined in point (a) of Article 24(2);
- providing support to national promotional banks or institutions by providing capacity building referred to in point (h) of Article 24(2) in relation to the development of their advisory capabilities to enable them to participate in advisory initiatives, at the request of such banks or institutions;
- at the request of the Commission and of a potential advisory partner, and subject to the agreement of the EIB Group, concluding on behalf of the Commission an agreement with the advisory partner for the delivery of advisory initiatives.

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

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

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

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

(a) on the granting and implementation of the portion of the EU guarantee specified in Article 12(4):

(i) a guarantee agreement between the Commission and the EIB Group; or

(ii) separate guarantee agreements between the Commission and the EIB and its subsidiaries or other entities established in accordance with Article 28(1) of the EIB Statute, as applicable;

(b) an agreement between the Commission and the EIB Group in relation to points (b) and (c) of paragraph 1;

(c) an agreement between the Commission and the EIB Group in relation to the InvestEU Advisory Hub;

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

4. Without prejudice to Articles 17(3) and 24(4) of this Regulation, the costs incurred by the EIB Group in the performance of tasks referred to in points (b) and (c) of paragraph 1 of this Article shall be in accordance with the terms of the agreement referred to in point (b) of paragraph 3 of this Article and may be covered from the repayments or revenues attributable to the EU guarantee, or from the provisioning, in accordance with Article 211(4) and (5) of the Financial Regulation, or may be charged to the financial envelope referred to in Article 4(3) of this Regulation, upon justification of those costs by the EIB Group, subject to an overall cap of EUR 10 000 000.

5. The costs incurred by the EIB Group for the performance of the operational tasks referred to in point (d)(ii) of paragraph 1 shall be fully covered by and paid from the amount referred to in point (d)(i) of paragraph 1, upon justification of those costs by the EIB Group, subject to an overall cap of EUR 15 000 000.



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## Article 11

*Conflicts of interest*

1. Within the framework of the partnership as referred to in Article 10, the EIB Group shall take all necessary measures and precautions to avoid conflicts of interest with other implementing partners, including by putting in place a dedicated and independent team for the tasks referred to in points (b)(iii) to (vi) of Article 10(1). That team shall be subject to strict confidentiality rules, which shall continue to apply to members of the team after they have left the team.
2. The EIB Group and other implementing partners shall inform the Commission without delay of any situation that constitutes a conflict of interest or is likely to lead to a conflict of interest. In case of doubt, the Commission shall determine whether a conflict of interest exists and shall inform the EIB Group of its conclusion. In the event of a conflict of interest, the EIB Group shall take appropriate measures. The Steering Board shall be informed of those measures and their results.
3. The EIB Group shall take the necessary precautions to avoid situations in which a conflict of interest could arise in the implementation of the InvestEU Advisory Hub, in particular in relation to its operational tasks in its role of supporting the Commission as referred to in point (d)(ii) of Article 10(1). In the event of a conflict of interest, the EIB Group shall take appropriate measures.

## CHAPTER IV

## EU GUARANTEE

## Article 12

*EU guarantee*

1. The EU guarantee shall be granted as an irrevocable, unconditional and on demand guarantee to the implementing partners in accordance with Article 219(1) of the Financial Regulation and implemented in indirect management in accordance with Title X of that Regulation.
2. The remuneration for the EU guarantee shall be linked to the characteristics and risk profile of the financial products, taking into account the nature of the underlying financing and investment operations and the fulfilment of the policy objectives targeted by the financial products.

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

- (a) where stressed financial market conditions would prevent the realisation of a financing or investment operation under market-based pricing; or
  - (b) where necessary to catalyse financing and investment operations in sectors or areas experiencing a significant market failure or sub-optimal investment situation or to facilitate the establishment of investment platforms,
- (ba) for the solvency support window, in the Member States and sectors economically most hit and the Member States where the possibility of State solvency support is more limited,**

to the extent that the reduction of the remuneration for the EU guarantee or the coverage of the outstanding administrative costs borne by the implementing partner does not significantly impact the provisioning for the EU guarantee.

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

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

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4. 75 % of the EU guarantee under the EU compartment as referred to in **the** first subparagraph of Article 4(1), amounting to EUR **68 829 990 000**, shall be granted to the EIB Group. The EIB Group shall provide an aggregate financial contribution amounting to EUR **11 494 608 330**. **That** contribution shall be provided in a manner and form that facilitates the implementation of the InvestEU Fund and the achievement of the objectives set out in Article 14(2).

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

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

7. Support of the EU guarantee referred to in the first and second subparagraphs of Article 4(2) **may** be granted **for financing and investment operations to be carried out by an implementing partner provided that the Commission has concluded a guarantee agreement with that implementing partner by 31 December 2023, thereby meeting** the conditions set out in Article 4(6) of Regulation [EURI]. In other cases, support of the EU guarantee may be granted for financing and investment operations covered by this Regulation for an investment period ending on 31 December 2027.

Contracts **■** between the implementing partner and the final recipient or the financial intermediary or other entity referred to in point (a) of Article 15(1) shall be signed by 31 December 2028.

#### Article 13

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

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

- (a) comply with the conditions set out in points (a) to (e) of Article 209(2) of the Financial Regulation, in particular regarding market failures, sub-optimal investment situations and additionality as set out in points (a) and (b) of Article 209(2) of the Financial Regulation and in Annex V to this Regulation and, where appropriate, maximising private investment in accordance with point (d) of Article 209(2) of the Financial Regulation;
- (b) contribute to the Union policy objectives and fall within the scope of the areas eligible for financing and investment operations under the appropriate policy window in accordance with Annex II to this Regulation;
- (c) do not provide financial support to the excluded activities set out in point B of Annex V to this Regulation; and
- (d) are consistent with the investment guidelines.

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

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

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

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

Notwithstanding the first subparagraph, under the strategic European investment window final recipients and intermediaries shall be legal entities fulfilling the requirements laid down in the introductory sentence and the second subparagraph, and in accordance with the third subparagraph, of point (e) of Article 7(1).

***Notwithstanding the first subparagraph, only companies established in a Member State and operating in the Union may be supported by financing and investment operations under the solvency support window.***

***Notwithstanding the first subparagraph, under the solvency support window, final recipients of EUR 30 million or more shall not make dividend payments, non-mandatory coupon payments or buy back shares. The remuneration of any member of the management of a beneficiary that receives financing of EUR 30 million or more under the solvency support window shall not go beyond the fixed part of that members' remuneration on 31 December 2019. For a person becoming a member of the management on or after the granting of InvestEU financing under the solvency support window, the applicable limit shall be the lowest fixed remuneration of any member of the management on 31 December 2019. Bonuses or other variable or comparable remuneration elements shall not be paid under any circumstances.***

#### Article 14

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

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

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

For the EU compartment, the eligible counterparties shall have expressed their interest in relation to the portion of the EU guarantee referred to in Article 12(5). For the Member State compartment, the Member State concerned may propose one or more counterparties as implementing partners from among those counterparties that have expressed their interest. The Member State concerned may also propose the EIB Group as an implementing partner and, at its own expense, may contract the EIB Group to provide the services listed in Article 10.

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

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

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

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

*Article 15**Eligible types of financing*

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

In order to be covered by the EU guarantee, the financing referred to in points (a) and (b) of the first subparagraph of this paragraph shall be granted, acquired or issued for the benefit of financing or investment operations referred to in Article 13 (1), where the financing by the implementing partner was granted in accordance with a financing agreement or transaction signed or entered into by the implementing partner after the signature of the guarantee agreement and that has not expired or been cancelled.

2. Financing and investment operations through funds or other intermediate structures shall be supported by the EU guarantee in accordance with provisions to be laid down in the investment guidelines, even if such structures invest a minority of their invested amounts outside the Union and in third countries referred to Article 13(2) or invest a minority of their invested amounts into assets other than those eligible under this Regulation.

The investment guidelines may set out further limitations as regards the proportion of amounts invested outside the Union in financing and investment operations through funds or other intermediate structures under the strategic European investment window, including potential clauses on exit from such investments.

**2a. Eligible instruments under the solvency support window, via implementing partners, shall result in the provision of equity or quasi-equity to companies, as referred to in Article 3(2), point (ea). Hybrid instruments may be used if such instruments fulfil the purpose of the window.**

*Article 16**Guarantee agreements*

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

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

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2. The guarantee agreement shall contain:
- (a) the amount and the terms of the financial contribution which is to be provided by the implementing partner;
  - (b) the terms of the funding or the guarantees which are to be provided by the implementing partner to another legal entity participating in the implementation, whenever that is the case;
  - (c) detailed rules on the provision of the EU guarantee in accordance with Article 18, including on the coverage of portfolios of specific types of instruments and the respective events that trigger possible calls on the EU guarantee;
  - (d) the remuneration for risk-taking that is to be allocated in proportion to the respective share of the risk-taking of the Union and of the implementing partner or as adjusted in duly justified cases pursuant to Article 12(2);
  - (e) the payment conditions;
  - (f) the commitment of the implementing partner to accept the decisions by the Commission and the Investment Committee as regards the use of the EU guarantee for the benefit of a proposed financing or investment operation, without prejudice to the decision-making of the implementing partner in respect of the proposed operation without the EU guarantee;
  - (g) provisions and procedures relating to the recovery of claims that is to be entrusted to the implementing partner;
  - (h) financial and operational reporting and monitoring of the financing and investment operations under the EU guarantee;
  - (i) key performance indicators, in particular as regards the use of the EU guarantee, the fulfilment of the objectives and criteria laid down in Articles 3, 7 and 13, and the mobilisation of private capital;
  - (j) where applicable, provisions and procedures relating to blending operations;
  - (k) other relevant provisions in compliance with the requirements of Article 155(2) and Title X of the Financial Regulation;
  - (l) the existence of adequate mechanisms for addressing the potential concerns of private investors.
3. A guarantee agreement shall also provide that remuneration attributable to the Union from financing and investment operations covered by this Regulation is to be provided after the deduction of payments due upon calls on the EU guarantee.
4. In addition, a guarantee agreement shall provide that any amount due to the implementing partner that relates to the EU guarantee shall be deducted from the overall amount of remuneration, revenues and repayments due by the implementing partner to the Union from financing and investment operations covered by this Regulation. Where that amount is not sufficient to cover the amount due to the implementing partner in accordance with Article 17(3), the outstanding amount shall be drawn from the provisioning for the EU guarantee.
5. Where the guarantee agreement is concluded under the Member State compartment, it may provide for the participation of representatives from the Member State or the regions concerned in the monitoring of the implementation of that guarantee agreement.

#### Article 17

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

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

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3. No administrative costs or fees related to the implementation of financing and investment operations under the EU guarantee shall be due to the implementing partner by the Commission unless the nature of the policy objectives targeted by the financial product to be implemented and the affordability for the targeted final recipients or the type of financing provided allow the implementing partner to duly justify to the Commission the need for an exception. The coverage of such costs by the Union budget shall be limited to the amount strictly required to implement the relevant financing and investment operations, and shall be provided only to the extent to which the costs are not covered by revenues received by the implementing partners from the financing and investment operations concerned. The fee arrangements shall be laid down in the guarantee agreement and shall comply with Article 16(4) and with point (g) of Article 209(2) of the Financial Regulation.

4. In addition, the implementing partner may use the EU guarantee to meet the relevant share of any recovery costs in accordance with Article 16(4), unless those costs have been deducted from recovery proceeds.

#### Article 18

##### *Coverage and terms of the EU guarantee*

1. Remuneration for risk-taking shall be allocated between the Union and an implementing partner in proportion to their respective share of the risk-taking with respect to a portfolio of financing and investment operations or, where relevant, with respect to individual financing and investment operations. The remuneration for the EU guarantee may be reduced in duly justified cases referred to in Article 12(2).

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

2. The EU guarantee shall cover:

(a) for debt products referred to in point (a) of Article 15(1):

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

(ii) restructuring losses;

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

(b) for equity or quasi-equity investments referred to in point (a) of Article 15(1): the amounts invested and the associated funding costs and losses arising from fluctuations of currencies other than the euro;

(c) for funding or guarantees by an implementing partner to another financial institution in accordance with point (b) of Article 15(1): the amounts used and their associated funding costs.

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

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

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

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## CHAPTER V GOVERNANCE

### *Article 19*

#### *Advisory Board*

1. The Commission and the Steering Board established pursuant to Article 20 shall be advised by an Advisory Board.
2. The Advisory Board shall strive to ensure gender balance and shall comprise:
  - (a) one representative of each implementing partner;
  - (b) one representative of each Member State;
  - (c) one expert appointed by the European Economic and Social Committee;
  - (d) one expert appointed by the Committee of the Regions.
3. The Advisory Board shall be chaired by a representative of the Commission. The representative of the EIB Group shall be the vice-chair.

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

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

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

9. The NPBI's represented on the Advisory Board shall select from among themselves the representatives of the implementing partners other than the EIB Group in the Steering Board referred to in Article 20(1). The NPBI's shall aim to achieve a balanced representation in the Steering Board in terms of size and geographical location. The representatives selected shall represent the agreed common position of all implementing partners other than the EIB Group.

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Article 20

Steering Board

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

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

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

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

3. The Steering Board shall:

- (a) provide strategic and operational guidance for the implementing partners, including guidance on the design of financial products and on other operating policies and procedures necessary for the operation of the InvestEU Fund;
- (b) adopt the risk methodological framework developed by the Commission in cooperation with the EIB Group and the other implementing partners;
- (c) oversee the implementation of the InvestEU Programme;
- (d) be consulted, reflecting the views of all its member, on the shortlist of candidates for the Investment Committee before their selection in accordance with Article 23(2);
- (e) adopt the rules of procedure of the secretariat to the Investment Committee referred to in Article 23(4).
- (f) adopt the rules applicable to the operations with investment platforms;

**(fa) determine the Member States and sectors economically most hit by the COVID-19 crisis and the Member States where the possibility of State solvency support is more limited, on the basis of the indicators established by the Commission pursuant to Article 7(1)(ea).**

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

Article 21

Scoreboard

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

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



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3. The Scoreboard shall cover the following elements:
  - (a) a description of the proposed financing and investment operation;
  - (b) how the proposed operation contributes to EU policy objectives;
  - (c) a description of additionality;
  - (d) description of the market failure or sub-optimal investment situation;
  - (e) the financial and technical contribution by the implementing partner;
  - (f) the impact of the investment;
  - (g) the financial profile of the financing or investment operation;
  - (h) complementary indicators.

4. The Commission is empowered to adopt delegated acts in accordance with Article 33 in order to supplement this Regulation by establishing additional elements of the Scoreboard, including detailed rules for the Scoreboard to be used by the implementing partners.

#### *Article 22*

##### *Policy check*

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

#### *Article 23*

##### *Investment Committee*

1. A fully independent investment committee shall be established for the InvestEU Fund (the 'Investment Committee'). The Investment Committee shall:
  - (a) examine the proposals for financing and investment operations submitted by implementing partners for coverage under the EU guarantee that have passed the policy check referred to in Article 22(1) or that have received a favourable opinion within the framework of the procedure provided for in Article 19 of the EIB Statute;
  - (b) verify their compliance with this Regulation and the relevant investment guidelines;
  - (c) give particular attention to the additionality requirement set out in point (b) of Article 209(2) of the Financial Regulation and in Annex V to this Regulation and to the requirement to crowd in private investment set out in point (d) of Article 209(2) of the Financial Regulation; and
  - (d) check whether the financing and investment operations that would benefit from the support of the EU guarantee comply with all relevant requirements.
2. The Investment Committee shall meet in **six** different configurations, corresponding to the **six** policy windows referred to in Article 7(1).

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

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

The composition of the Investment Committee shall ensure that it has a wide knowledge of the sectors covered by the policy windows referred to in Article 7(1) and a wide knowledge of the geographic markets in the Union, and shall ensure that the Investment Committee as a whole is gender-balanced.

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

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

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

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

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

The documentation to be provided by the implementing partners shall comprise a standardised request form, the Scoreboard referred to in Article 21 and any other document the Investment Committee considers relevant, in particular a description of the character of the market failure or sub-optimal investment situation and how it will be alleviated by the financing or investment operation, as well as a reliable assessment of the operation that demonstrates the additionality of the financing or investment operation. The secretariat shall check the completeness of the documentation provided by implementing partners other than the EIB Group. The Investment Committee may seek clarifications from the implementing partner concerned in relation to a proposal for an investment or financing operation, including by requesting the direct presence of a representative of the implementing partner concerned during the discussion of the aforementioned operation. Any project assessment conducted by an implementing partner shall not be binding on the Investment Committee for the purposes of granting a financing or investment operation coverage by the EU guarantee.

The Investment Committee shall use the Scoreboard referred to in Article 21 in its assessment and verification of the proposed financial and investment operations.

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

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

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

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

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

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

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

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

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

8. From the date of its constitution, the Investment Committee shall also be in charge of approving the use of the EU guarantee under Regulation (EU) 2015/1017 for the remainder of the investment period under that Regulation. They shall be assessed in accordance with the criteria laid down in that Regulation. Article 22 shall not apply to such submissions.

## CHAPTER VI

### InvestEU Advisory Hub

#### Article 24

##### *InvestEU Advisory Hub*

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

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

Advisory initiatives shall be available as a component under each policy window referred to in Article 7(1), covering sectors under that window. In addition, advisory initiatives shall be available under a cross-sectoral component.

2. The InvestEU Advisory Hub shall in particular:

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

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- (c) where appropriate, assist project promoters in developing their projects so that they fulfil the objectives set out in Articles 3 and 7 and the eligibility criteria set out in Article 13, and facilitate the development of Important Projects of Common European Interest and aggregators for small-sized projects, including through investment platforms as referred to in point (f) of this paragraph, provided that such assistance does not prejudice the conclusions of the Investment Committee with respect to the coverage of the EU guarantee with respect to such projects;
- (d) support actions and leverage local knowledge to facilitate the use of InvestEU Fund support across the Union and contribute actively where possible to the objective of the sectorial and geographical diversification of the InvestEU Fund by supporting implementing partners in originating and developing potential financing and investment operations;
- (e) facilitate the establishment of collaborative platforms for peer-to-peer exchanges and the sharing of data, knowhow and best practices to support project pipeline and sector development;
- (f) provide proactive advisory support with respect to the establishment of investment platforms, including cross-border and macro-regional investment platforms and investment platforms that bundle small and medium-sized projects in one or more Member States by theme or by region;
- (g) support the use of blending with grants or financial instruments funded by the Union budget or by other sources in order to strengthen synergies and complementarities between Union instruments and to maximise the leverage and impact of the InvestEU Programme;
- (h) support capacity building actions to develop organisational capacities, skills and processes and to accelerate the investment readiness of organisations in order for public authorities and project promoters to build investment project pipelines, develop financing mechanisms and investment platforms and to manage projects and for financial intermediaries to implement financing and investment operations for the benefit of entities that face difficulties in obtaining access to finance, including through support for developing risk assessment capacity or sector specific knowledge;
- (i) providing advisory support for start-ups, especially when they seek to protect their research and innovation investments by obtaining intellectual property titles, such as patents;
- (ia) providing support to financing and investment operations under the solvency support window by covering costs, advisory services and technical and administrative assistance to set-up and manage investment platforms and having a special focus on Member States with less developed equity markets. The technical assistance shall also be available to support the green and digital transformation of companies financed under this window.**

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

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

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

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

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

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

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

Where relevant, the implementing partners and advisory partners shall also inform the project promoters of the possibility of listing their projects on the InvestEU Portal referred to in Article 25.

## CHAPTER VII

### InvestEU Portal

#### *Article 25*

##### *InvestEU Portal*

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

## CHAPTER VIII

### ACCOUNTABILITY, MONITORING AND REPORTING, EVALUATION AND CONTROL

#### *Article 26*

##### *Accountability*

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

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#### Article 27

##### *Monitoring and reporting*

1. Indicators for reporting on the progress of the InvestEU Programme towards the achievement of the general and specific objectives set out in Article 3 are set in Annex III.
2. The performance reporting system shall ensure that data for monitoring implementation and results are collected in an efficient, effective and timely manner, and that those data allow for adequate risk and guarantee portfolio monitoring. To that end, proportionate reporting requirements shall be imposed on the implementing partners, the advisory partners and other recipients of Union funds, as appropriate.
3. The Commission shall report on the implementation of the InvestEU Programme in accordance with Articles 241 and 250 of the Financial Regulation. In accordance with Article 41(5) of the Financial Regulation, the annual report shall provide information on the level of implementation of the Programme with respect to its objectives and performance indicators. For that purpose, each implementing partners shall provide on an annual basis the information necessary to allow the Commission to comply with its reporting obligations, including information on the operation of the EU guarantee.
4. Every six months, each implementing partner shall submit a report to the Commission on the financing and investment operations covered by this Regulation, broken down by EU compartment and Member State compartment, as appropriate. Each implementing partner shall also submit information on the Member State compartment to the Member State whose compartment it implements. The report shall include an assessment of compliance with the requirements on the use of the EU guarantee and with the key performance indicators laid down in Annex III to this Regulation. The report shall also include operational, statistical, financial and accounting data on each financing and investment operation and an estimation of expected cash flows, at the level of compartment, policy window and the InvestEU Fund. Once a year, the report from the EIB Group and, where appropriate, from other implementing partners, shall also include information on barriers to investment encountered when carrying out financing and investment operations covered by this Regulation. The reports shall contain the information the implementing partners have to provide under point (a) of Article 155(1) of the Financial Regulation.
5. To ensure the effective assessment of the progress of the InvestEU Programme towards the achievement of its objectives, the Commission is empowered to adopt delegated acts in accordance with Article 33 in order to amend this Regulation by reviewing or complementing the indicators set in Annex III where considered necessary and the provisions on the establishment of a monitoring and evaluation framework.

#### Article 28

##### *Evaluation*

1. Evaluations of the InvestEU Programme shall be carried out so that they feed into the decision-making process in a timely manner.
2. By 30 September 2024, the Commission shall submit to the European Parliament and to the Council an independent interim evaluation report on the InvestEU Programme, in particular on the use of the EU guarantee, on the fulfilment of the EIB Group's obligations under points (b) and (c) of Article 10(1), on the allocation of the EU guarantee provided for in Article 12(4) and (5), on the implementation of the InvestEU Advisory Hub, on the budgetary allocation provided for in point (d)(i) of Article 10(1), and on Article 7(6). The evaluation shall in particular demonstrate how the inclusion of the implementing partners and advisory partners in the implementation of the InvestEU Programme has contributed to the reaching of InvestEU Programme targets as well as EU policy goals, especially with regard to value added, geographical and sectoral balance of the supported financing and investment operations. The evaluation shall also assess the application of sustainability proofing pursuant to Article 7(3) and the focus on SMEs reached under the SME policy window referred to in point (c) of Article 7(1).
3. At the end of the implementation of the InvestEU Programme, but no later than four years after the end of the period specified in Article 1(3), the Commission shall submit to the European Parliament and to the Council an independent final evaluation report on the InvestEU Programme, in particular on the use of the EU guarantee.

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4. The Commission shall communicate the conclusions of the evaluations, accompanied by its observations, to the European Parliament, to the Council, to the European Economic and Social Committee and to the Committee of Regions.
5. The implementing partners and advisory partners shall contribute to and provide the Commission with the information necessary to perform the evaluations referred to in paragraphs 2 and 3.
6. In accordance with Article 211(1) of the Financial Regulation, every three years the Commission shall include in the annual report referred to in Article 250 of the Financial Regulation a review of the adequacy of the provisioning rate laid down in Article 4(1) of this Regulation with respect to the actual risk profile of the financing and investment operations covered by the EU guarantee. The Commission is empowered to adopt delegated acts in accordance with Article 33 of this Regulation in order to amend this Regulation by adjusting the provisioning rate laid down in Article 4(1) of this Regulation by up to 15 % on the basis of that review.

#### *Article 29*

##### *Audits*

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

#### *Article 30*

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

Where a third country participates in the InvestEU Programme by a decision under an international agreement or by virtue of any other legal instrument, the third country shall grant the necessary rights and access required for the authorising officer responsible, the European Anti-Fraud Office (OLAF), the European Court of Auditors to comprehensively exert their respective competences. In the case of OLAF, such rights shall include the right to carry out investigations, including on-the-spot checks and inspections, provided for in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council concerning investigations conducted by the European Anti-Fraud Office (OLAF).

## **CHAPTER IX**

### **TRANSPARENCY AND VISIBILITY**

#### *Article 31*

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

1. Implementing partners and advisory partners shall acknowledge the origin and ensure the visibility of the Union funding (in particular when promoting the actions and their results), by providing coherent, effective and targeted information to multiple audiences, including the media and the public.

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

2. The implementing partners and advisory partners shall inform the final recipients, including SMEs, of the existence of InvestEU Programme support, or oblige other financial intermediaries to inform such final recipients of that support, by making that information clearly visible in the relevant agreement providing InvestEU Programme support, particularly in the case of SMEs, in order to increase public awareness and improve visibility.
3. The Commission shall implement information and communication actions relating to the InvestEU Programme and its actions and results. Financial resources allocated to the InvestEU Programme shall also contribute to the corporate communication of the political priorities of the Union, insofar as those priorities are related to the objectives referred to in Article 3.

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## CHAPTER X TRANSITIONAL AND FINAL PROVISIONS

### Article 32

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

The Union shall subscribe shares in forthcoming capital increases of the European Investment Fund so that its relative share in the capital remains at current level. The subscription of the shares and the payment of up to EUR 900 000 000 of the paid-in part of the shares shall be carried out in accordance with the terms and conditions that shall be approved by the General Meeting of the Fund.

### Article 33

#### *Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. Where delegated acts concern activities to be carried out by or involving the EIB Group and other implementing partners, the Commission shall consult with the EIB Group and other potential implementing partners before preparing those delegated acts.
2. The power to adopt delegated acts referred to in Articles **7(1)(ea) and (7)**, 21(4), 27(5) and 28(6) shall be conferred on the Commission until 31 December 2028. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Articles **7(1)(ea) and (7)**, 21(4), 27(5) and 28(6) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Articles **7(1)(ea) and (7)**, 21(4), 27(5) and 28(6) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

### Article 34

#### *Transitional provisions*

1. By **way of** derogation **from** the first and **fourth** subparagraphs of Article 209(3) of the Financial Regulation, **any** revenues, repayments and recoveries from financial instruments established by programmes referred to in Annex IV to this Regulation **shall** be used for the provisioning of the EU guarantee under this Regulation ■ .



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2. By way of derogation from point (a) of Article 213(4) of the Financial Regulation, any surplus of provisions for the EU guarantee established by Regulation (EU) 2015/1017 shall be used for the provisioning of the EU guarantee under this Regulation.

3. The amount of EUR XXX (current prices) referred to in point (i) of Article 3(2)(c) of Regulation [EURI] shall be used:

- (a) for the provisioning of the EU guarantee under this Regulation with an amount of EUR XXX (current prices), in addition to the resources mentioned in the first subparagraph of Article 211(4) of the Financial Regulation,
- (b) for the implementation of the measures provided in Chapters V and VI and the measures referred to in the second sentence of Article 2(2) of Regulation [EURI], subject to Article 4(4) and (8) of that Regulation, with an amount of EUR 200 440 000 (current prices).

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

**3a.** The implementing partners may submit to the Commission financing and investment operations approved by them during the period from the conclusion of the relevant guarantee agreement and the first appointment of all the members of the Investment Committee.

**3b.** The Commission shall assess the operations referred to in paragraph 3a and shall decide whether to grant them coverage under the EU guarantee.

**3c.** The implementing partners may submit to the Commission financing and investment operations approved by them during the period from ... [date of entry into force of this Regulation] until the conclusion of the relevant guarantee agreement.

**3d.** The Commission shall assess the operations referred to in paragraph 3c and shall decide whether to grant them coverage under the EU guarantee. In the event of positive decision by the Commission, such coverage shall take effect on the date of conclusion of the relevant guarantee agreements, after which the implementing partners may sign the financing and investment operations.

**3e.** All financial instruments established by programmes referred to in Annex IV to this Regulation and the EU guarantee established by Regulation (EU) 2015/1017 may, if applicable and subject to a prior evaluation, be merged with those under this Regulation.

**3f.** By way of derogation from the second and third subparagraphs of Article 209(3) of the Financial Regulation, revenues and repayments from the financial instruments established by programmes referred to in Annex IV to this Regulation and the budgetary guarantee established under Regulation (EU) 2015/1017, which have been merged with the EU guarantee established by this Regulation in accordance with paragraph 3e of this Article, shall constitute, respectively, internal assigned revenue within the meaning of Article 21(5) of the Financial Regulation for the EU guarantee established by this Regulation and repayments for the EU guarantee established by this Regulation.

Article 35

Entry into force

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

It shall apply from 1 January 2021.

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

Done at Brussels,

For the European Parliament

The President

For the Council

The President

Friday 13 November 2020

ANNEX I

**Amounts of EU guarantee per specific objective**

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

- (a) up to EUR 20 051 970 000 for objectives referred to in point (a) of Article 3(2);
  - (b) up to EUR **11 250 000 000** for objectives referred to in point (b) of Article 3(2);
  - (c) up to EUR **12 500 000 000** for objectives referred to in point (c) of Article 3(2);
  - (d) up to EUR **5 567 500 000** for objectives referred to in point (d) of Article 3(2);
  - (e) up to EUR 31 153 850 000 for objectives referred to in point (e) of Article 3(2).
  - (ea) up to EUR 11 250 000 000 for objectives referred to in point (ea) of Article 3(2).**
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**ANNEX II****Areas eligible for financing and investment operations**

The financing and investment operations under other windows than the strategic European investment window may fall under one or more of the following areas:

The financing and investment operations under the strategic European investment window shall fall under the areas laid down in point (e) of Article 7(1). They may in particular include Important Projects of Common European Interest.

1. The development of the energy sector in accordance with the Energy Union priorities, including security of energy supply, clean energy transition and the commitments taken under the 2030 Agenda for Sustainable Development and the Paris Agreement on Climate Change, in particular through:
  - (a) the expansion of the generation, supply or use of clean and sustainable renewable and safe and sustainable other zero and low-emission energy sources and solutions;
  - (b) energy efficiency and energy savings (with a focus on reducing demand through demand side management and the refurbishment of buildings);
  - (c) the development, smartening and modernisation of sustainable energy infrastructure in particular, but not only transmission and distribution level, storage technologies, electricity interconnection between Member States and smart grids;
  - (d) the development of innovative zero- and low-emission heat supply systems and the combined production of electricity and heat;
  - (e) the production and supply of sustainable synthetic fuels from renewable/carbon-neutral sources and other safe and sustainable zero- and low-emission sources, biofuels, biomass and alternative fuels, including fuels for all modes of transport, in accordance with the objectives of Directive (EU) 2018/2001 of the European Parliament and of the Council <sup>(1)</sup>; and
  - (f) infrastructure for carbon capture, and storage in industrial processes, bioenergy plants and manufacturing facilities towards the energy transition.
2. The development of sustainable and safe transport infrastructures and mobility solutions, equipment and innovative technologies in accordance with Union transport priorities and the commitments taken under the Paris Agreement on Climate Change, in particular through:
  - (a) projects that support the development of the trans-European transport network (TEN-T) infrastructure, including infrastructure maintenance and safety, the urban nodes of TEN-T, maritime and inland ports, airports, multimodal terminals and the connection of such multimodal terminals to the TEN-T networks, and the telematic applications referred to in Regulation (EU) No 1315/2013 of the European Parliament and of the Council <sup>(2)</sup>;
  - (b) TEN-T infrastructure projects that make provision for the use of at least two different modes of transport, in particular multimodal freight terminals and passenger transport hubs;
  - (c) smart and sustainable urban mobility projects that target low-emission urban transport modes, including inland waterway solutions and innovative mobility solutions, non-discriminatory accessibility, reduced air pollution and noise, energy consumption, networks of smart cities, maintenance, and increasing safety levels and decreasing the frequency of accidents, including for cyclists and pedestrians);

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<sup>(1)</sup> Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82).

<sup>(2)</sup> Regulation (EU) No 1315/2013 of the European Parliament and of the Council of 11 December 2013 on Union guidelines for the development of the trans-European transport network and repealing Decision No 661/2010/EU (OJ L 348, 20.12.2013, p. 1).

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

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5. Research, development and innovation, in particular through:
  - (a) research and innovation projects that contribute to the objectives of Horizon Europe, including research infrastructure and support to academia;
  - (b) corporate projects, including training and promoting the creation of clusters and business networks;
  - (c) demonstration projects and programmes, as well as deployment of related infrastructures, technologies and processes;
  - (d) collaborative research and innovation projects involving academia, research and innovation organisations and industry; public-private partnerships and civil society organisations;
  - (e) knowledge and technology transfer;
  - (f) research in the field of key enabling technologies (KETs) and their industrial applications, including new and advanced materials; and
  - (g) new effective and accessible healthcare products, including pharmaceuticals, medical devices, diagnostics and advanced therapy medicinal products, new antimicrobials and innovative development process that avoid using animal testing.
6. The development, deployment and scaling-up of digital technologies and services, especially digital technologies and services that contribute to the objectives of the Digital Europe programme, in particular through:
  - (a) artificial intelligence;
  - (b) quantum technology;
  - (c) cybersecurity and network protection infrastructures;
  - (d) the internet of things;
  - (e) blockchain and other distributed ledger technologies;
  - (f) advanced digital skills;
  - (g) robotics and automation;
  - (h) photonics; and
  - (i) other advanced digital technologies and services contributing to the digitisation of the Union industry and the integration of digital technologies, services and skills in the transport sector of the Union.
7. Financial support to entities employing up to 499 employees, with a particular focus on SMEs, and small mid-cap companies, in particular through:
  - (a) the provision of working capital and investment;
  - (b) the provision of risk financing from seed to expansion stages to ensure technological leadership in innovative and sustainable sectors, including enhancing their digitisation and innovation capacity and to ensure their global competitiveness;
  - (c) the provision of financing for the acquisition of a business by employees or participation in the ownership of a business by employees.
8. Cultural and creative sectors, cultural heritage, media, the audio-visual sector, journalism and press, in particular through but not only the development of new technologies, the use of digital technologies and technological management of intellectual property rights.
9. Tourism.

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

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

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- (d) to foster Union's autonomy for safe and secure access to space, including dual use aspects.
15. Seas and oceans, through the development of projects and enterprises in the area of the blue economy, and the Sustainable Blue Economy Finance Principles, in particular through maritime entrepreneurship and industry, renewable marine energy and circular economy.
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ANNEX III

**Key performance indicators**

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



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- Number of alternative fuel supply points built or upgraded
  - Number of projects contributing to the safety of transport
- 4.8 Environment: Investment contributing to the implementation of plans and programmes required by the Union environmental acquis relating to air quality, water, waste and nature
5. Research, innovation and digitisation
- 5.1 Contribution to the objective of 3 % of the Union's gross domestic product (GDP) invested in research, development and innovation
- 5.2 Number of enterprises supported by size carrying out research and innovation projects
6. SMEs
- 6.1 Number of enterprises supported by size (micro, small, medium-sized and small mid-cap companies)
- 6.2 Number of enterprises supported by stage (early, growth/expansion)
- 6.3 Number of enterprises supported by Member State and region at NUTS 2 level
- 6.4 Number of enterprises supported by sectors by statistical classification of economic activities in the European Union (NACE) code
- 6.5 Percentage of investment volume under the SME policy window directed towards SMEs
7. Social investment and skills
- 7.1 Social infrastructure: Capacity and access to supported social infrastructure by sector: housing, education, health, other
- 7.2 Microfinance and social enterprise finance: Number of microfinance recipients and social enterprises supported
- 7.3 Skills: Number of individuals acquiring new skills or having their skills validated and certified: formal, education and training qualification
8. Strategic European investment
- 8.1 Number and volume of operations contributing to the provision of critical infrastructure, broken down by physical **and virtual** infrastructure and the associated goods and services, where applicable
- 8.2 Additional Capacity of critical infrastructure, broken down by areas, where applicable
- 8.3 Number and volume of operations contributing to the **research and** development of critical technologies and inputs for the security of the Union and its Member States, and dual use items
- 8.4 Number of enterprises supported by size developing and manufacturing critical technologies and inputs for the security of the Union and its Member States, and dual use items
- 8.4a Number of clusters and Digital Innovation Hubs supported for the creation of synergies between companies**
- 8.5 Number and volume of operations contributing to the supply, manufacturing and stockpiling of critical inputs, **unless within the limits of existing legal requirements**, including critical healthcare provisions
- 8.6 Additional critical inputs, including critical healthcare provisions, supported for supply, manufacturing and stockpiling, by type, where applicable
- 8.7 Number and volume of operations supporting key enabling and digital technologies that are strategically important for the Union's industrial future

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- 8.7a Number and volume of operations to help companies, especially SMEs, to digitalise their businesses and increase the resilience of their value chains and business models*
  - 8.7b Number of start-ups that have been supported by the InvestEU Fund, number and volume of operations to promote entrepreneurship*
  - 8.7c Number and volume of operations contributing to the reduction of greenhouse gas emissions in accordance with the Union climate targets*
  - 8.7d Number of engagements of the European Investment Advisory Hubs in regions and Member States with so far limited track record in project initiation and development and in under-invested industrial sectors that have not benefitted from the Union's investment instruments in the past*
  - 8.7e Increase of volume of private equity and venture capital investments in related projects*
  - 8.7f Regional and national breadth that indicates that Member States and regions that have benefitted are spread evenly across the Union's territory and there is no concentration of benefits to a limited number of Member States or regions.*
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ANNEX IVThe InvestEU Programme — Predecessor instruments

## A. Equity instruments:

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

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

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- Council Decision 2013/743/EU of 3 December 2013 establishing the specific programme implementing Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC (OJ L 347, 20.12.2013, p. 965)
- Cultural and Creative Sectors Guarantee Facility (CCS GF): Regulation (EU) No 1295/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Creative Europe Programme (2014 to 2020) and repealing Decisions No 1718/2006/EC, No 1855/2006/EC and No 1041/2009/EC (OJ L 347, 20.12.2013, p. 221)
- Student Loan Guarantee Facility (SLGF): Regulation (EU) No 1288/2013 of the European Parliament and of the Council of 11 December 2013 establishing 'Erasmus+': the Union programme for education, training, youth and sport and repealing Decisions No 1719/2006/EC, No 1720/2006/EC and No 1298/2008/EC (OJ L 347, 20.12.2013, p. 50)
- Private Finance for Energy Efficiency (PF4EE): Regulation (EU) No 1293/2013 of the European Parliament and of the Council of 11 December 2013 on the establishment of a Programme for the Environment and Climate Action (LIFE) and repealing Regulation (EC) No 614/2007 (OJ L 347, 20.12.2013, p. 185)

#### C. Risk-Sharing Instruments:

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

#### D. Dedicated Investment Vehicles:

- European Progress Microfinance Facility — Fonds commun de placement — fonds d'investissement spécialisé (EPMF FCP-FIS): Decision No 283/2010/EU of the European Parliament and of the Council of 25 March 2010 establishing a European Progress Microfinance Facility for employment and social inclusion (OJ L 87, 7.4.2010, p. 1)
- Marguerite:
  - Regulation (EC) No 680/2007 of the European Parliament and of the Council of 20 June 2007 laying down general rules for the granting of Community financial aid in the field of the trans-European transport and energy networks (OJ L 162, 22.6.2007, p. 1)
  - Commission Decision of 25.2.2010 on European Union participation in the 2020 European Fund for Energy, Climate Change and Infrastructure (the Marguerite Fund)
- European Energy Efficiency Fund (EEEF): Regulation (EU) No 1233/2010 of the European Parliament and of the Council of 15 December 2010 amending Regulation (EC) No 663/2009 establishing a programme to aid economic recovery by granting Community financial assistance to projects in the field of energy (OJ L 346, 30.12.2010, p. 5)

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ANNEX V

**Market failures, sub-optimal investment situations, additionality and excluded activities**

A. Market failures, sub-optimal investment situations and additionality

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

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

1. Market failures and sub-optimal investment situations

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

- (a) Have the nature of a public good for which the operator or company cannot capture sufficient financial benefits (such as education and skills, healthcare and accessibility, security and defence, and infrastructure available at no or negligible cost).
- (b) Externalities which the operator or company generally fails to internalise, such as R&D investment, energy efficiency, climate or environmental protection.
- (c) Information asymmetries, in particular in case of SMEs and small mid-cap companies, including higher risk levels related to early stage firms, firms with mainly intangible assets or insufficient collateral, or firms focusing on higher risk activities.
- (d) Cross-border infrastructure projects and related services or funds that invest on a cross-border basis to address the fragmentation of the internal market and to enhance coordination within the internal market.
- (e) Exposure to higher levels of risks in certain sectors, countries or regions beyond levels that private financial actors are able or willing to accept, including where the investment would not have been undertaken or would not have been undertaken to the same extent because of its novelty or because of risks associated with innovation or unproven technology.
- (f) In the case of support to financing and investment operations under the strategic European investment window, the investment would not have been undertaken or would not have been undertaken to the same extent through market financing by entities established and operating in the Union because of difficulties in internalising the benefits provided to the European strategic interest.
- (g) New or complex market failures or sub-optimal investment situations in accordance with point (a)(iii) of Article 8(1) of this Regulation.

2. Additionality

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

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- (1) To be considered additional to the private sources referred to in point (b) of Article 209(2) of the Financial Regulation, the InvestEU Fund shall support the financing and investment operations of the implementing partners by targeting investments which, due to their characteristics (public good nature, externalities, information asymmetries, socio-economic cohesion considerations or other), are unable to generate sufficient market-level financial returns or are perceived to be too risky (compared to the risk levels that the relevant private entities are willing to accept). Because of those characteristics, such financing and investment operations cannot access market financing at reasonable conditions in terms of pricing, collateral requirements, the type of finance, the tenor of financing provided or other conditions, and would not be undertaken in the Union at all or to the same extent without public support.
- (2) To be considered additional to existing support from other public sources referred to in point (b) of Article 209(2) of the Financial Regulation the InvestEU Fund shall only support financing and investment operations for which the following conditions apply:
  - (a) the financing or investment operations would not have been carried out or would not have been carried out to the same extent by the implementing partner without the InvestEU Fund support; and
  - (b) the financing or investment operations would not have been carried out or would not have been carried out to the same extent in the Union under other existing public instruments, such as shared management financial instruments that operate at regional or national level, although the complementary use of InvestEU and other public sources has to be possible, in particular where Union value added can be achieved and where the use of public sources to achieve policy objectives in an efficient manner can be optimised.
- (3) Financing and investment operations under the strategic European investment window may also be considered additional whenever these operations would not have been carried out, or not to the same extent, by other private and public entities established and operating in the Union without the InvestEU Fund support.

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

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

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

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

#### B. Excluded activities

The InvestEU Fund shall not support:

- (1) Activities which limit individual rights and freedoms or that violate human rights
- (2) In the area of defence activities, the use, development, or production of products and technologies that are prohibited by applicable international law
- (3) Tobacco related products and activities (production, distribution, processing, and trade)
- (4) Activities excluded from financing pursuant to Article [X] of the [Horizon Europe] Regulation <sup>(1)</sup>: research on human cloning for reproductive purposes; activities intended to modify the genetic heritage of human beings which could make such changes heritable; and activities to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer
- (5) Gambling (production, construction, distribution, processing, trade or software related activities)
- (6) Sex trade and related infrastructure, services and media
- (7) Activities involving live animals for experimental and scientific purposes insofar as compliance with the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes <sup>(2)</sup> cannot be guaranteed
- (8) Real estate development activity, such as an activity with a sole purpose of renovating and re-leasing or re-selling existing buildings as well as building new projects; however, activities in the real-estate sector that are related to the specific objectives of the InvestEU Programme as specified in Article 3(2) and to the areas eligible for financing and investment operations under Annex II, such as investments in energy efficiency projects or social housing, shall be eligible
- (9) Financial activities such as purchasing or trading in financial instruments. In particular, interventions targeting buy-out intended for asset stripping or replacement capital intended for asset stripping shall be excluded
- (10) Activities forbidden by applicable national legislation
- (11) The decommissioning, operation, adaptation or construction of nuclear power stations
- (12) Investments related to mining or to the extraction, processing, distribution, storage or combustion of solid fossil fuels and oil, as well as investments related to the extraction of gas. This exclusion does not apply to:
  - (a) projects where there is no viable alternative technology;
  - (b) projects related to pollution prevention and control;
  - (c) projects equipped with carbon capture and storage or carbon capture and utilisation installations; industrial or research projects that lead to substantial reductions of greenhouse gas emissions as compared with the applicable EU Emission Trading System benchmarks

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<sup>(1)</sup> Article 14 of the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing Horizon Europe — the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination 2018/0224(COD).

<sup>(2)</sup> OJ L 222, 24.8.1999, p. 31.



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- (13) Investments in facilities for the disposal of waste in landfill. This exclusion does not apply to investments in:
- (a) on-site landfill facilities that are an ancillary element of an industrial or mining investment project and where it has been demonstrated that landfilling is the only viable option to treat the industrial or mining waste produced by the concerned activity itself;
  - (b) existing landfill facilities to ensure the utilisation of landfill gas and to promote landfill mining and the reprocessing of mining waste
- (14) Investments in mechanical biological treatment (MBT) plants. This exclusion does not apply to investments to retrofit existing MBT plants for waste-to-energy purposes or recycling operations of separated waste such as composting and anaerobic digestion
- (15) Investments in incinerators for the treatment of waste. This exclusion does not apply to investments in:
- (a) plants exclusively dedicated to treating non-recyclable hazardous waste;
  - (b) existing plants, where the investment is for the purpose of increasing energy efficiency, capturing exhaust gases for storage or use or recovering materials from incineration ashes, provided such investments do not result in an increase of the plants' waste processing capacity

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

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