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Legislation

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⁽¹⁾ Text with EEA relevance.

I

(Legislative acts)

DECISIONS

DECISION (EU) 2021/2084 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 24 November 2021****on the participation of the Union in the European Partnership on Metrology jointly undertaken by several Member States**

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 185 and the second paragraph of Article 188 thereof,

Having regard to the proposal from the European Commission,

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

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

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

Whereas:

- (1) In order to achieve the greatest possible impact of Union funding and the most effective contribution to the Union's policy objectives, Regulation (EU) 2021/695 of the European Parliament and of the Council ⁽³⁾ established Horizon Europe – the Framework Programme for Research and Innovation, which provides for the policy and legal framework for European Partnerships with private or public sector partners, or both. European Partnerships are a key element of the policy approach of Horizon Europe. They are set up to deliver on Union commitments and priorities targeted by Horizon Europe and to ensure a clear impact for the Union, its citizens and the environment, which can be achieved more effectively in a partnership, through a strategic vision that is shared and committed to by partners, rather than by the Union alone.
- (2) In particular, European Partnerships under Horizon Europe's Pillar II, 'Global challenges and European Industrial Competitiveness' (Pillar II), are expected to play an important role in achieving the strategic objectives of accelerating the achievement of the United Nations Sustainable Development Goals (UN SDGs), the Union's commitments under the Paris Agreement, adopted under the UN Framework Convention on Climate Change ⁽⁴⁾ (the 'Paris Agreement'), as well as the transitions towards a green and digital Europe, while contributing to a socially, economically, and environmentally resilient recovery. European Partnerships are key to addressing complex cross-border challenges that require an integrated approach. They make it possible to address transformational, systematic and market failures by bringing together a broad range of players across value chains, research and innovation areas

⁽¹⁾ OJ C 341, 24.8.2021, p. 34.

⁽²⁾ Position of the European Parliament of 11 November 2021 (not yet published in the Official Journal) and decision of the Council of 18 November 2021.

⁽³⁾ Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

⁽⁴⁾ OJ L 282, 19.10.2016, p. 4.

and industrial ecosystems to work towards a common vision and translate it into concrete roadmaps and a coordinated implementation of activities. Furthermore, they make it possible to concentrate efforts and resources on common priorities to solve the complex challenges ahead, in order to benefit society.

- (3) In order to deliver on priorities and impact, European Partnerships should be developed through a broad involvement of relevant stakeholders across Europe, including industry, higher education institutions, research organisations, bodies with a public service mission at local, regional, national or international level, and civil society organisations, including foundations, that support or carry out research and innovation. European Partnerships should also be one of the measures to strengthen cooperation and synergies at international level, among private sector partners and public sector partners and between them, including by joining up research and innovation programmes and cross-border investment in research and innovation, bringing mutual benefits to people and businesses.
- (4) A European Partnership on Metrology should be established. Such a partnership is intended to be a more effective means of delivery than traditional calls for proposals or co-funded partnerships under the work programmes prepared under the related clusters of Pillar II.
- (5) The European Partnership on Metrology (the 'Metrology Partnership') should implement its mission and objectives in a clear, simple and flexible way in order to increase its attractiveness to industry, small and medium-sized enterprises (SMEs) and other relevant stakeholders.
- (6) The Metrology Partnership should promote and reward scientific excellence and support the uptake and systematic use of research and innovation results generated within the Union, including by ensuring that state-of-the-art science and fundamental research findings are taken into account in the implementation of its activities. It should also strive to ensure that the results of its actions are taken up and deployed by industry and innovators and, ultimately, in society.
- (7) In order to guarantee scientific excellence and in line with Article 13 of the Charter of Fundamental Rights of the European Union, the Metrology Partnership should promote academic freedom in all of the Participating States, in particular the freedom to conduct scientific research, and promote the highest standards of scientific integrity.
- (8) In line with the objectives of Regulation (EU) 2021/695, any Member State and any third country associated to Horizon Europe should be entitled to participate in the Metrology Partnership. In order to ensure complementarity within the European Economic Area (EEA) and with other neighbouring countries, other third countries should be able to participate in the Metrology Partnership, subject to the conclusion of a relevant international agreement for scientific and technological cooperation with the Union and the agreement of the Participating States.
- (9) Horizon Europe introduces a more strategic, coherent and impact-driven approach to European Partnerships, building on the lessons learned from the interim evaluation of Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council^(*). Regulation (EU) 2021/695 provides for the possibility to make more effective use of Institutionalised European Partnerships, in particular by focusing on clear objectives, outcomes and impacts that can be achieved by 2030, and by ensuring a clear contribution to related Union policy priorities and policies. Close collaboration, complementarity and synergies with other relevant programmes and initiatives at Union, national and regional level, including with the European Research Council and the European Innovation Council and in particular with other European Partnerships, will be key in fostering the innovation pipeline and research in other areas, achieving greater impact and ensuring that the results are used in all relevant areas where technological development is linked with metrology, such as digitalisation, artificial intelligence, energy, smart health, climate, autonomous traffic and the circular economy.

^(*) 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).

- (10) By Decision No 555/2014/EU of the European Parliament and of the Council ⁽⁶⁾, the Union made a financial contribution to the European Metrology Programme for Innovation and Research (EMPIR) matching that of the states participating in EMPIR but not exceeding EUR 300 000 000, for the duration of Horizon 2020. The interim evaluation of EMPIR in July 2017 gave rise to a new initiative being suggested.
- (11) The Union's financial contribution to the Metrology Partnership should be subject to formal commitments by the Participating States to contribute financially to the implementation of the Metrology Partnership and to fulfil those commitments. The contributions from the Participating States should include a contribution to the administrative costs pertaining to the implementation of the Metrology Partnership, subject to a ceiling of 5 % of its budget. The Participating States should commit to increasing, if necessary, their contribution to the Metrology Partnership by establishing a reserve funding capability to ensure that they are able to fund their national entities, national metrology institutes (NMIs) and designated institutes (DIs) participating in the activities of the Metrology Partnership. The joint implementation of the Metrology Partnership requires an implementation structure. The Union's financial contribution should be managed in accordance with the principle of sound financial management and with the relevant rules on indirect management laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽⁷⁾.
- (12) The Metrology Partnership, which is aligned with the political priorities of the Union, including the European Green Deal, an economy that works for people, and a Europe Fit for the Digital Age, should be implemented over a period of 10 years, from 2021 to 2031. The Metrology Partnership should include new activities compared to EMPIR, and, in particular, the development of European metrology networks, which should be established in an open and transparent manner with the aim of responding to pressing societal and environmental challenges and metrology needs from emerging technologies and innovations. The metrology capacity provided through those networks should be equivalent and comparable to other world-leading metrology systems, demonstrating world-class excellence. Calls for proposals under the Metrology Partnership should be launched during the implementation of Horizon Europe and should be open, transparent and competitive. The Metrology Partnership should promote the circulation of talent and the development of skills, including by means of skilling and re-skilling opportunities.
- (13) The activities of the Metrology Partnership should be carried out in line with the objectives and research and innovation priorities of Horizon Europe and in accordance with the general principles and conditions laid down in Article 10 of, and Annex III to, Regulation (EU) 2021/695, supporting, inter alia, the uptake of innovative solutions in European industry, in particular by SMEs and, ultimately, in society.
- (14) A ceiling should be established for the Union's financial contribution in the Metrology Partnership for the duration of Horizon Europe. Within the limits of that ceiling, the Union's financial contribution should be up to equal to the contributions from the Participating States in order to achieve a high leverage effect and ensure a stronger integration of Participating States' programmes.
- (15) The Metrology Partnership should be financed by the Union programmes under the multiannual financial framework for the years 2021 to 2027 as laid down in Council Regulation (EU, Euratom) 2020/2093 ⁽⁸⁾. In accordance with Article 10(2) point (c) of Regulation (EU) 2021/695, the Metrology Partnership should have a clear life-cycle approach. In order to adequately protect the financial interests of the Union, the Metrology Partnership should be set up for a period ending on 31 December 2031 to allow it to exercise its responsibilities with regard to grant implementation until the last indirect actions launched have been completed.

⁽⁶⁾ Decision No 555/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a European Metrology Programme for Innovation and Research (EMPIR) jointly undertaken by several Member States (OJ L 169, 7.6.2014, p. 27).

⁽⁷⁾ 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).

⁽⁸⁾ Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027 (OJ L 433 I, 22.12.2020, p. 11).

- (16) In accordance with Article 3 of Regulation (EU) 2021/695, the general objective of Horizon Europe is to deliver scientific, technological, economic and societal impact from the Union's investments in research and innovation so as to strengthen the scientific and technological bases of the Union and foster the competitiveness of the Union in all Member States, including in its industry, to deliver on the Union's strategic priorities, to contribute to the realisation of the Union's objectives and policies, to tackle global challenges, including the UN SDGs by following the principles of Agenda 2030 for Sustainable Development and in line with the Paris Agreement, and to strengthen the European Research Area.
- (17) The Participating States have agreed upon the implementation structure for the predecessor initiatives, namely, the European Metrology Research Programme (EMRP) and EMPIR. In 2007, EURAMET e.V. (EURAMET), the European Regional Metrology Organisation and a non-profit association under German law, was set up to serve as this structure. EURAMET also has tasks and obligations related to the wider European and global harmonisation of metrology. Membership in EURAMET is open to all European NMIs, as members, and to European DIs, as associates. Membership in EURAMET is not conditional upon the existence of national metrology research programmes. Given that, according to EMPIR's interim evaluation report, the governance structure of EURAMET has proved to be efficient and of high quality for the implementation of the EMRP and EMPIR, EURAMET should also be used to implement the Metrology Partnership. EURAMET should therefore manage the Union's financial contribution.
- (18) The financial contributions to the Metrology Partnership should be managed centrally by EURAMET in accordance with Article 10(1) of Regulation (EU) 2021/695. This should be without prejudice to the possibility for the Participating States to provide direct financial contributions to designated NMIs on the basis of a coordinated approach through a metrology partnership committee.
- (19) The Metrology Partnership should strive for the effective promotion of equal opportunities for all and, in particular, ensure, to the extent possible, gender balance in the relevant bodies of the Metrology Partnership, as well as in evaluation panels and in other relevant advisory bodies.
- (20) Pursuant to Article 49(4) of Regulation (EU) 2021/695 and the relevant rules on Commission expert groups, the Commission should select the members of the Metrology Partnership's Steering Group in particular by taking due account of the relevant disclosure of any conflict of interest.
- (21) In order to achieve the objectives of the Metrology Partnership, EURAMET should provide financial support mainly in the form of grants to participants in actions selected at the level of EURAMET. Those actions should be selected following open, transparent and competitive calls for proposals under the responsibility of EURAMET. The Metrology Partnership should use its best efforts to increase the visibility of the calls for proposals by publishing them on the Horizon Europe portal for participants in a timely manner and by promoting and advertising the calls for proposals widely, with a view to increasing participation of newcomers. The ranking list should be binding for the selection of proposals and the allocation of funding from the Union's financial contribution and the financial contributions from the Participating States for research projects and related activities. In accordance with Article 28(3) of Regulation (EU) 2021/695, and the Horizon Europe work programme, the annual work programme should be able to include conditions concerning the involvement of SMEs, gender and geographical diversity among the rules for dealing with *ex-aequo* proposals. For the activities funded by the contributions from the Participating States to European metrology networks, the actions funded should also be under the responsibility of EURAMET.
- (22) Participation in indirect actions funded by the Metrology Partnership is subject to Regulation (EU) 2021/695. However, due to the specific operating needs of the Metrology Partnership, in particular building and managing future European metrology networks and facilitating adequate financial participation of the Participating States, it should be possible to provide that the coordinator role in indirect actions, from the submission of the proposal until the end of the project, be limited to the NMIs and the DIs of the Participating States, where strictly necessary, and taking into account the advice of the Steering Group, if any.

- (23) The contributions from the Participating States should be ensured through institutional funding from their NMIs and their DIs. The wide variety of underlying activities should contribute to the objectives of the Metrology Partnership and be laid out in the annual work programmes, with links to operational costs and expenditure. The contributions should cover, inter alia, the costs of services that directly deliver calibrations and other services traceable to the International System of Units. The contributions from the Participating States should also include a financial contribution to the administrative costs of the Metrology Partnership.
- (24) In order to ensure the openness, transparency and accessibility of the Metrology Partnership, calls for proposals should also be published in a user-friendly manner on the single portal for participants as well as through other Horizon Europe electronic means of dissemination managed by the Commission. In order to engage with stakeholders and society and attract newcomers from a wide range of research and industry stakeholders, including SMEs, higher education institutions, research organisations and civil society organisations, the Metrology Partnership should carry out a wide range of outreach activities, including the dissemination and exploitation of results, promotional and awareness-raising activities and the promotion of the Metrology Partnership beyond the Union.
- (25) The functioning of the funding model with regard to the matching principle between Union and non-Union funds should be reassessed at the time of the interim evaluation of the Metrology Partnership in order to ensure that the matching principle for the financial contributions from the Participating States is respected.
- (26) The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties.
- (27) In order to protect the Union's financial interests, the Commission should have the right to terminate, proportionally reduce or suspend the Union's financial contribution if the Metrology Partnership is implemented inadequately, only partially or late, or if a Participating State does not contribute, or contributes only partially or late, to the financing of the Metrology Partnership. Those rights should be provided for in the contribution agreement to be concluded between the Union and EURAMET.
- (28) For the purpose of simplification, the administrative burden of all concerned should be reduced. Double audits and disproportionate documentation and reporting should be avoided. When audits are conducted, the specific characteristics of the national programmes should be taken into account, as appropriate. Audits of recipients of Union funds provided in accordance with this Decision should ensure a reduction in the administrative burden, in accordance with Regulation (EU, Euratom) 2018/1046.
- (29) EURAMET and the Participating States should, upon a request from the Commission, the European Parliament, the Council or the Court of Auditors, provide any information that the Commission is required to include in its evaluation of the Metrology Partnership.
- (30) The Commission should conduct an interim evaluation not later than 2025, assessing in particular the quality and efficiency of the Metrology Partnership, the progress made towards achieving the objectives set and a final evaluation not later than 2030 and should publish and disseminate the results and conclusions of those evaluations. In accordance with Article 10(2), point (c), of Regulation (EU) 2021/695, the Metrology Partnership should have a clear life-cycle approach, be limited in time and include the conditions for phasing-out the funding under Horizon Europe. To that end, evaluations should assess the relevance and coherence of any possible renewal.
- (31) The objective of this Decision is the participation of the Union in the Metrology Partnership in order to support its general objectives. The requirements of metrology are of such a scale and complexity that investments that go beyond the core research budgets of NMIs and DIs are needed. The excellence required for research and the development of cutting-edge metrology solutions is spread across national borders and hence cannot be attained at national level. Since the objective of this Decision cannot be sufficiently achieved by the Member States, but can rather be better achieved at Union level by integrating national efforts into a consistent European approach, by bringing together compartmentalised national research programmes, by helping design common research and funding strategies across national borders, and by achieving the critical mass of actors and investments required, the

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

- (32) In order to ensure continuity in providing support in the relevant policy areas, this Decision should enter into force as a matter of urgency,

HAVE ADOPTED THIS DECISION:

Article 1

Participation in the European Partnership on Metrology

1. The Union shall participate in the European Partnership on Metrology (the 'Metrology Partnership'), an Institutionalised European Partnership as referred to in Article 10(1), point (c), of Regulation (EU) 2021/695, jointly undertaken by Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovakia, Spain and Sweden (the 'Participating States'), in accordance with the conditions laid down in this Decision.

2. Any Member State not referred to in paragraph 1 of this Article and any third country associated to Horizon Europe may participate in the Metrology Partnership, provided that it fulfils the condition laid down in Article 4(1), point (c). Such Member States and third countries shall be considered to be Participating States for the purposes of this Decision.

3. Any third country not associated to Horizon Europe may participate in the Metrology Partnership, provided that it:

- (a) concludes an international agreement for scientific and technological cooperation with the Union setting out the terms and conditions of its participation in the Metrology Partnership;
- (b) obtains the approval of the Metrology Partnership Committee in accordance with Article 14(3), point (g); and
- (c) fulfils the condition laid down in Article 4(1), point (c).

A third country that fulfils the conditions laid down in the first subparagraph shall be considered to be a Participating State for the purposes of this Decision.

Article 2

Objectives of the Metrology Partnership

1. The Metrology Partnership shall contribute to the implementation of Regulation (EU) 2021/695, and in particular Article 3 thereof.

2. Without prejudice to paragraph 1, the Metrology Partnership shall, through the involvement and commitment of partners in designing and implementing an annual work programme as referred to in Article 7, pursue the following general objectives:

- (a) to develop a sustainable, excellent and coordinated metrology system at European level, thereby helping to bridge the investment gap between Europe and its global competitors;
- (b) to ensure that state-of-the-art metrology capabilities are widely taken up by innovators in their ecosystems and beyond;
- (c) to increase the impact of metrology on societal challenges in relation to the implementation of policies, standards and regulations, inter alia in the digital, economic, industrial and environmental areas, in order to make them fit for purpose.

3. When implementing the general objectives set out in paragraph 2, the Metrology Partnership shall pursue the following specific objectives:

- (a) to develop, by 2030, new research capabilities which are built within the framework of new European metrology networks and which perform in terms of calibration and measurement capabilities at least equally to the leading metrology institutes outside the Participating States;
- (b) to support, by 2030, sales of new innovative products and services through the use and adoption of the new metrology capabilities in key emerging and enabling technologies;
- (c) to contribute to the creation and diffusion of high-quality new knowledge, competences and skills across the Union in the context of lifelong learning and with a view to achieving societal transformation, including through enhancing capability for innovation;
- (d) to contribute fully and effectively, by 2030, to the design and implementation of specific standards and regulations that underpin public policies addressing societal, economic and environmental challenges;
- (e) to unleash the potential of metrology among end-users, including SMEs and industrial stakeholders, as an instrument which contributes to the achievement of the Union goals for the digital and green transitions.

Article 3

The Union's financial contribution to the Metrology Partnership

1. The Union's financial contribution, including EEA appropriations, to the Metrology Partnership shall be up to EUR 300 million to match the contributions from the Participating States referred to in Article 1(1). The amount of the Union's financial contribution may be increased by contributions from third countries associated to Horizon Europe, in accordance with Article 16(5) of Regulation (EU) 2021/695, provided that the total amount by which the Union's financial contribution is increased is at least matched by contributions from the Participating States referred to in Article 1(2) of this Decision.

2. For the calculation of the Union's financial contribution, any contribution from the Participating States to the administrative costs pertaining to the implementation of the Metrology Partnership that exceeds 5 % of the total combined contributions to the Metrology Partnership shall not be taken into account.

3. The Union's financial contribution shall be paid from the appropriations in the general budget of the Union allocated to the relevant parts of the Specific Programme implementing Horizon Europe, established by Council Decision (EU) 2021/764 ⁽⁹⁾.

4. EURAMET e.V. (EURAMET) shall use the Union's financial contribution to fund the activities referred to in Article 6(1), point (a).

5. The Union's financial contribution shall not be used to cover the administrative costs of the Metrology Partnership.

6. Financial contributions under the programmes co-financed by the European Regional Development Fund, the European Social Fund Plus, the European Maritime, Fisheries and Aquaculture Fund and the European Agricultural Fund for Rural Development, as well as the Recovery and Resilience Facility, may be considered to be contributions from a Member State that is a Participating State, subject to compliance with the relevant provisions of Regulation (EU) 2021/1060 of the European Parliament and of the Council ⁽¹⁰⁾ and the regulations laying down specific rules applicable to each of those funds.

⁽⁹⁾ Council Decision (EU) 2021/764 of 10 May 2021 establishing the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation, and repealing Decision 2013/743/EU (OJ L 167I, 12.5.2021, p. 1).

⁽¹⁰⁾ Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy (OJ L 231, 30.6.2021, p. 159).

*Article 4***Conditions for the Union's financial contribution**

1. The Union's financial contribution shall be conditional upon all of the following:
 - (a) the demonstration by the Participating States that the Metrology Partnership is set up in accordance with this Decision;
 - (b) the designation by the Participating States, or by the NMIs designated by them, of EURAMET as the structure responsible for implementing the Metrology Partnership and for receiving, allocating and monitoring the Union's financial contribution;
 - (c) the commitment by each Participating State to contribute to the financing of the Metrology Partnership and to establish a reserve funding capability of 50 % of the amount of the commitment;
 - (d) the demonstration by EURAMET of its capacity to implement the Metrology Partnership, including receiving, allocating and monitoring the Union's financial contribution in the framework of indirect management of the Union budget in accordance with Articles 62 and 154 of Regulation (EU, Euratom) 2018/1046;
 - (e) the establishment of a governance model for the Metrology Partnership in accordance with Articles 13 to 16.
2. During the implementation of the Metrology Partnership, the Union's financial contribution shall also be conditional upon all of the following:
 - (a) the implementation by EURAMET of the activities of the Metrology Partnership set out in Article 6 in line with the objectives set out in Article 2;
 - (b) the maintenance of an efficient governance model in accordance with Articles 13 to 16;
 - (c) the compliance by EURAMET with the reporting requirements set out in Article 155 of Regulation (EU, Euratom) 2018/1046;
 - (d) the fulfilment by the Participating States of the commitments referred to in paragraph 1, point (c).

*Article 5***Contributions from the Participating States to the Metrology Partnership**

1. The Participating States referred to in Article 1(1) shall make, or arrange for their national funding bodies to make, contributions, whether financial or in kind, of at least EUR 363 million during the period from 1 January 2021 until 31 December 2031.

A share of the contributions from the Participating States shall be in the form of financial contributions. The Participating States shall arrange among themselves their collective contributions and how they will deliver them.

2. The contributions from the Participating States shall consist of the following:
 - (a) financial or in-kind contributions to the implementing activities referred to in Article 6(1); and
 - (b) financial or in-kind contributions to cover all the administrative costs of EURAMET.
3. The financial or in-kind contributions referred to in paragraph 2, point (a), of this Article shall cover the costs incurred by the Participating States in implementing the activities referred to in Article 6(1), point (b), less any direct or indirect Union's financial contribution to those costs.
4. The financial or in-kind contributions referred to in paragraph 2, point (b), shall cover the costs incurred by the Participating States in relation to the administrative costs of EURAMET for the implementation of the Metrology Partnership. Those administrative costs shall not exceed 5 % of the total budget of the Metrology Partnership.

5. For the purpose of valuing the in-kind contributions referred to in paragraph 2, points (a) and (b), of this Article, the costs shall be determined in accordance with a harmonised approach, including criteria and processes, to be established by the Metrology Partnership Committee in accordance with Article 14. To the extent possible, the reporting of costs shall comply with the reporting procedures laid down in Regulation (EU) 2021/695, while taking into account the usual accounting practices of the Participating States or the national funding bodies concerned, the applicable accounting standards of the Participating State where the national funding bodies concerned are established, and the applicable International Accounting Standards and International Financial Reporting Standards. The costs shall be certified by an independent auditor appointed by the Participating States or the national funding bodies concerned.

6. The contributions from the Participating States shall be made after the adoption of the annual work programme.

If the annual work programme is adopted during the reference year, the contributions referred to in paragraph 2, point (b), that are included in the annual work programme may comprise contributions made as from 1 January of that year.

The contributions referred to in paragraph 2, point (b), that are made after 1 December 2021 may count as contributions from Participating States, provided that they are included in the Metrology Partnership's first annual work programme.

Article 6

Activities of EURAMET

1. The Metrology Partnership shall support a wide range of research and innovation activities by means of:
 - (a) indirect actions within the meaning of Article 2, point (43), of Regulation (EU) 2021/695 funded by EURAMET in accordance with Article 7 of this Decision, mainly in the form of grants following transnational open, transparent and competitive calls for proposals organised by EURAMET, including:
 - (i) scientific and technical actions supporting fundamental scientific metrology laying the basis for all successive steps, including applied metrology research and development and metrology-related services;
 - (ii) metrology research to provide solutions for societal, economic and environmental challenges focusing on contributions to sustainable technologies and innovations in the energy, digital and health sectors, as well as with regard to the environment and the climate, and to develop projects in specific European metrology networks addressing those challenges;
 - (iii) research to develop novel measurement instrumentation aiming to enhance the European industrial and commercial take-up of metrological technologies to stimulate innovation in industry;
 - (iv) pre-normative and co-normative metrology research and development in support of policy implementation, regulations and acceleration of the market introduction and societal uptake of sustainable innovative products and services;
 - (v) exchange of best practices on metrology research carried out at national level;
 - (b) activities funded by the Participating States without the Union's financial contribution consisting of the metrology capacity-building activities at different technological levels to achieve the widest possible, balanced and integrated metrology system in the Participating States enabling them to develop their scientific and technical capabilities in metrology, and which include activities not selected from the calls for proposals referred to in point (a), of this Article, as outlined in the annual work programmes, as well as any of the following:
 - (i) activities under the national programmes of the Participating States such as transnational projects contributing to the priorities laid out in a European metrology network and EURAMET technical committees;
 - (ii) actions for the dissemination and exploitation of results, including in industry and by SMEs, of metrology research as widely as possible in Europe, with a view to increasing the visibility of EURAMET activities to the public in a user-friendly manner;

- (iii) activities to raise awareness and promote educational and dissemination activities and campaigns and to provide appropriate information on EURAMET's website, and the publication of relevant documentation;
- (iv) actions specifically addressing metrology institutes which have no or limited scientific capabilities by supporting them in using other Union, national or regional programmes for training and mobility, cross-border cooperation or investment in metrology infrastructure;
- (v) the organisation of external dissemination and knowledge-transfer activities to promote the Metrology Partnership as widely as possible in the Union and beyond, in order to maximise its impact.

2. Before identifying the topics of each call for proposals referred to in paragraph 1, point (a), EURAMET shall publicly invite individuals or organisations, including SMEs, and the general metrology value chain to suggest potential research topics in a transparent manner.

Article 7

Annual work programme

1. The Metrology Partnership shall be implemented on the basis of annual work programmes covering activities to be undertaken for the period from 1 January to 31 December of a given year (the 'reference year').
2. The Metrology Partnership Committee referred to in Article 14 shall adopt the annual work programmes by 31 March of the reference year, after obtaining approval from the Commission. In adopting the annual work programmes, both the Metrology Partnership Committee and the Commission shall act without undue delay. The Metrology Partnership Committee shall make the annual work programme publicly available.
3. The activities referred to in Article 6(1), points (a) and (b), shall be launched only in the reference year and only after the adoption of the annual work programme for that year.
4. Activities may be funded by EURAMET only if they are set out in the annual work programme. The annual work programme shall distinguish between the activities referred to in Article 6(1), point (a), the activities referred to in Article 6(1), point (b), and the administrative costs of EURAMET. The annual work programme shall include their corresponding expenditure estimates and the budget being allocated to activities funded with the Union's financial contribution and to activities funded by the Participating States without that contribution. The annual work programme shall also include the valuation of the in-kind contributions from the Participating States referred to in Article 5(2), point (b).
5. Any amended annual work programmes for a reference year and annual work programmes for subsequent reference years shall take into account the results of previous calls for proposals. They shall endeavour to address insufficient coverage of scientific topics, in particular those initially addressed in activities under Article 6(1), point (b), that could not be adequately funded.
6. The calls for proposals under the relevant annual work programmes, shall be launched by 31 December 2027. In duly justified cases, they may be launched by 31 December 2028.
7. EURAMET shall monitor, and shall report annually to the Commission on, the implementation of all activities included in the annual work programme without increasing the administrative burden on the beneficiaries. The annual report shall be made publicly available in a timely manner on EURAMET's website.
8. Any communication or publication relating to the activities of the Metrology Partnership and performed in cooperation with the Metrology Partnership, whether undertaken by EURAMET, a Participating State or its national funding bodies, or participants in an activity, shall be labelled or co-labelled as being co-funded by the Metrology Partnership under Horizon Europe.

*Article 8***Rules for participation and dissemination**

1. EURAMET shall be considered to be a funding body within the meaning of Article 2, point 14, of Regulation (EU) 2021/695 and shall provide financial support to indirect actions referred to in Article 6(1), point (a), of this Decision in accordance with Article 6(2) of that Regulation.
2. Regulation (EU) 2021/695, in particular the rules for participation, open science and dissemination laid down therein, shall apply to the actions referred to in Article 6(1), point (a), of this Decision. In addition, in accordance with Article 17(2) of that Regulation, where strictly necessary and after consulting the Steering Group referred to in Article 15 of this Decision where the Metrology Partnership Committee requests such consultation, the annual work programme may provide for a limitation of the coordinator role in indirect actions, from submission of the proposal to the end of the project, to the NMI and the DIs of the Participating States in order to ensure that the objectives and the contribution targets of the Participating States are met.
3. EURAMET shall ensure appropriate interactions with NMIs and DIs in the indirect actions referred to in Article 6(1), point (a), in accordance with their designation by the appropriate national authority. EURAMET shall also encourage and support the participation of other entities, including SMEs, in all calls for proposals.

*Article 9***Agreements between the Union and EURAMET**

Provided that an equivalent level of protection of the financial interest of the Union is ensured, EURAMET shall be entrusted with the implementation of the Union's financial contribution in accordance with Article 62(3) and Article 154 of Regulation (EU, Euratom) 2018/1046.

*Article 10***Termination, reduction or suspension of the Union's financial contribution**

1. If the Metrology Partnership fails to meet the conditions under which the Union's financial contribution is entrusted, the Commission may terminate, proportionally reduce or suspend that contribution.
2. If a Participating State does not contribute to the financing of the Metrology Partnership, contributes only partially or does not respect the time frames for the contributions referred to in Article 5, the Commission may terminate, proportionally reduce or suspend the Union's financial contribution. The Commission's decision shall not hinder the reimbursement of eligible costs already incurred by the Participating State before the decision to terminate, proportionally reduce or suspend the Union's financial contribution is notified to the Metrology Partnership.

*Article 11***Ex post audits**

1. The *ex post* audits of expenditure on indirect actions referred to in Article 6(1), point (a), of this Decision shall be carried out by EURAMET in accordance with Article 53(3) of Regulation (EU) 2021/695.
2. The Commission may itself carry out the audits referred to in paragraph 1 of this Article. In such cases, the Commission shall carry out such audits in accordance with the applicable rules, in particular Article 53(3) of Regulation (EU) 2021/695 and Article 127 of Regulation (EU, Euratom) 2018/1046.

*Article 12***Protection of the financial interests of the Union**

1. The Commission shall take appropriate measures to ensure that, when actions financed under this Decision are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive penalties.
2. In implementing the Metrology Partnership, the Participating States shall take the legislative, regulatory, administrative and other measures necessary to protect the financial interests of the Union, in particular, to ensure full recovery of any amounts due to the Union in accordance with Regulation (EU, Euratom) 2018/1046.
3. EURAMET shall grant Commission staff and other persons authorised by the Commission, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.
4. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council ⁽¹⁾ and Council Regulation (Euratom, EC) No 2185/96 ⁽²⁾ with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with an agreement, a decision or a contract funded under this Decision.
5. The European Public Prosecutor's Office (EPPO) may carry out investigations in accordance with the provisions and procedures laid down in Council Regulation (EU) 2017/1939 ⁽³⁾, with a view to investigating criminal offences affecting the financial interests of the Union as set out in Article 4 of that Regulation.
6. Without prejudice to paragraphs 3, 4 and 5, agreements, decisions and contracts resulting from the implementation of this Decision shall contain provisions expressly empowering the Commission, EURAMET, the Court of Auditors, EPPO and OLAF to conduct such audits, on-the-spot checks and investigations in accordance with their respective competences.

*Article 13***Governance of the Metrology Partnership**

1. The bodies governing the Metrology Partnership shall include at least the following:
 - (a) a Metrology Partnership Committee;
 - (b) a Steering Group;
 - (c) the Secretariat of EURAMET.
2. The bodies referred to in paragraph 1 shall take appropriate measures to seek a balanced composition in terms of skills, experience, knowledge, geographical diversity and gender.

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

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

⁽³⁾ 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).

Article 14

Metrology Partnership Committee

1. The Metrology Partnership Committee shall manage the Metrology Partnership in a transparent way, while ensuring that the Metrology Partnership as executed meets its objectives.
2. The Metrology Partnership Committee shall be composed of one representative and one alternate representative from each Participating State. The voting weights shall be calculated on the basis of the commitments by each Participating State according to the square root of the commitment.
3. The Metrology Partnership Committee shall, in particular:
 - (a) take decisions on the strategic research and innovation agenda, and make them publicly available;
 - (b) take decisions on the planning of calls for proposals and on the evaluation review procedure as provided for in Article 30 of Regulation (EU) 2021/695;
 - (c) adopt the annual work programme after obtaining the Commission's approval and after consulting the Steering Group referred to in Article 15 and make it publicly available;
 - (d) take decisions on the selection of the proposals to be funded according to the ranking lists established after evaluations of the proposals following the calls for proposals referred to in Article 6(1), point (a) of this Decision;
 - (e) adopt measures to attract newcomers;
 - (f) monitor the progress of the activities of EURAMET referred to in Article 6;
 - (g) approve the participation in the Metrology Partnership of any third country not associated to Horizon Europe, provided that that third country fulfils the conditions referred to in Article 1(3), points (a) and (c);
 - (h) by 31 December 2021, establish a harmonised approach, including criteria and processes, for the purpose of valuing the in-kind contributions referred to in Article 5(2).

For the purpose of taking decisions in accordance with point (d) of the first subparagraph of this paragraph, the annual work programme may include rules for dealing with *ex-aequo* proposals in accordance with Article 28(3) of Regulation (EU) 2021/695 and the Horizon Europe work programme.

4. The Commission shall have observer status in the meetings of the Metrology Partnership Committee. However, the adoption of the annual work programme by the Metrology Partnership Committee shall require the Commission's prior approval. The Metrology Partnership Committee shall invite the Commission to its meetings and shall provide the Commission with all relevant documents. The Commission may take part in the Metrology Partnership Committee's discussions. The agenda, list of participants and decisions of meetings of the Metrology Partnership Committee shall be made publicly available in a timely manner on EURAMET's website.
5. The Metrology Partnership Committee shall elect its Chairperson and Deputy Chairperson according to the voting weights set out in paragraph 2. The Chairperson of the Metrology Partnership Committee shall represent EURAMET in matters related to the Metrology Partnership.

Article 15

Steering Group

1. The Commission shall set up a Steering Group. The Commission shall seek geographical and gender balanced representation among its members as well as balance in terms of the necessary competence and expertise. The Steering Group shall be an advisory body of the Metrology Partnership and shall give advice to the Metrology Partnership on the emerging priorities for metrology research at European level and on how to increase the impact of its research on European industry, economy and society. It shall in particular:

- (a) identify emerging technologies, innovations, markets and industrial applications where metrology research and innovation could become relevant in the future;
 - (b) identify research areas which contribute to the smooth functioning of the internal market and to the Union's goal of achieving climate neutrality by 2050 at the latest, including to relevant regulations and standards;
 - (c) advise the Metrology Partnership on priorities for its future work programmes.
2. The Steering Group shall be composed of 15 members:
- (a) four representatives from European standard setters and regulators designated by EURAMET;
 - (b) four representatives from different European Partnerships set up pursuant to Regulation (EU) 2021/695, which the Commission shall designate in an open and transparent manner, ensuring diversity of expertise and background;
 - (c) four representatives from the European scientific community, appointed by the Commission following an open and transparent process, based on a call for expression of interest, seeking geographical and gender balanced representation, covering the necessary competences and expertise with regard to the relevant technical domains and aiming to make independent science-based recommendations;
 - (d) the Chairperson of EURAMET;
 - (e) one representative designated by the Commission; and
 - (f) one representative from a national ministry who is not a staff member of a national metrology institute represented in EURAMET and who is appointed by the Metrology Partnership Committee.
3. The Steering Group shall provide independent advice on the scientific priorities and other relevant issues to be addressed in the Metrology Partnership's annual work programme, as well as on specific issues, as requested by the Metrology Partnership Committee, and shall monitor scientific achievements in adjacent sectors.
4. At least 50 % of the members referred in paragraph 2, points (a) and (b), of this Article shall be rotated at the latest after the interim evaluation referred to in Article 18(1).
5. The Steering Group shall be jointly chaired by the representatives referred to in paragraph 2, point (e).
6. All recommendations made by the Steering Group shall be made publicly available.

Article 16

Secretariat of EURAMET

1. The Secretariat of EURAMET, providing general administrative support for EURAMET, shall keep separate accounting and bank accounts for the Metrology Partnership.
2. A Management support unit shall be established as part of the Secretariat of EURAMET and shall be responsible for the implementation and day-to-day management of the Metrology Partnership.
3. The Secretariat shall offer support to the Participating States as regards the application of the criteria and processes of the harmonised approach referred to in Article 5(5).

Article 17

Communication of information

1. EURAMET shall, upon the Commission's request, provide the Commission with any information necessary for the preparation of the evaluations referred to in Article 18.

2. The Participating States shall submit to the Commission, through EURAMET, any information requested by the European Parliament, by the Council or by the Court of Auditors concerning the financial management of the Metrology Partnership.
3. The Commission shall include the information referred to in paragraph 2 of this Article in the evaluations referred to in Article 18.

Article 18

Evaluations

1. The Commission shall conduct an interim evaluation and a final evaluation of the Metrology Partnership in the framework of the Horizon Europe evaluations, in accordance with Article 52 of Regulation (EU) 2021/695, with the assistance of external independent experts selected on the basis of an open and transparent process.
2. The interim and final evaluations shall examine how the Metrology Partnership fulfils its mission and objectives, cover all its activities and evaluate its European added value, effectiveness, efficiency, including its openness and transparency, the relevance of the activities pursued, including in industry and by SMEs, and their consistency and complementarity with relevant regional, national and Union policies, including synergies with other parts of Horizon Europe, such as other partnerships, missions, clusters, thematic or specific programmes. The evaluations shall take into account the views of stakeholders, at both European and national level and shall, where relevant, also include an assessment of the long-term scientific, societal, economic, environmental and technological impacts of the preceding initiatives, as well as an evaluation of external partners' participation. They shall include, where relevant, an assessment of the most effective policy intervention mode for any future action, as well as the relevance and coherence of any possible renewal of the Metrology Partnership, given the overall policy priorities and the research and innovation support landscape, including the positioning against other initiatives supported through Horizon Europe. When carrying out those evaluations, the Commission shall fully consider the administrative impact on the Metrology Partnership and shall make best efforts to reduce the administrative burden and to ensure that the evaluation process is kept simple and fully transparent.
3. The Commission shall publish and disseminate the results and conclusions of the evaluations conducted under this Article.

Article 19

Access to results and information on proposals

1. EURAMET shall provide the Commission access to all information related to the indirect actions it funds. Such information shall include the results of beneficiaries' participation in indirect actions of the Metrology Partnership or any other information deemed necessary for developing, implementing, monitoring and evaluating Union policies or programmes. Such access rights are limited to a non-commercial and non-competitive use and shall comply with the applicable confidentiality rules.
2. EURAMET shall enter information on funded proposals of the Metrology Partnership in the database established pursuant to Article 50 of Regulation (EU) 2021/695.
3. For the purposes of developing, implementing, monitoring and evaluating Union policies or programmes, EURAMET shall provide the Commission with information included in submitted proposals.

Article 20

Confidentiality

Without prejudice to Article 17, EURAMET shall ensure the protection of confidential information which, if disclosed beyond the Union institutions, bodies, offices or agencies, could damage the interests of EURAMET members or of participants in the activities of the Metrology Partnership. Such confidential information includes but is not limited to personal, commercial, sensitive non-classified and classified information.

*Article 21***Conflicts of interest**

1. EURAMET, its bodies and staff, and the bodies of the Metrology Partnership shall take the appropriate measures to prevent any conflict of interest in the implementation of their activities, and shall ensure that a person faced with such a conflict of interest does not decide, give advice, or assist on the specific matter affected by that conflict of interest.
2. EURAMET shall adopt rules for the prevention, avoidance and management of conflicts of interest in respect of the staff of EURAMET, the members and other persons serving in the Metrology Partnership Committee and in the other bodies or groups of EURAMET and the Metrology Partnership, in accordance with Article 61 of Regulation (EU, Euratom) 2018/1046.
3. EURAMET shall establish a code of conduct for members of the Metrology Partnership Committee, considering the publication of declarations of professional activities, financial interests and conflicts of interest in accordance with data protection rules.

*Article 22***Entry into force**

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

*Article 23***Addressees**

This Decision is addressed to the Member States.

Done at Strasbourg, 24 November 2021.

For the European Parliament
The President
D.M. SASSOLI

For the Council
The President
A. LOGAR

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2021/2085**of 19 November 2021****establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 187 and the first subparagraph of Article 188 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

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

Whereas:

- (1) In order to achieve the greatest possible impact of Union funding and the most effective contribution to the Union's policy objectives, Regulation (EU) 2021/695 of the European Parliament and of the Council ⁽³⁾ (the 'Horizon Europe Regulation') established the policy and legal framework for European partnerships with private or public sector partners. European partnerships are a key element of the policy approach of Horizon Europe – the Framework Programme for Research and Innovation ('Horizon Europe'). They are set up to deliver on Union priorities targeted by Horizon Europe and ensure a clear impact for the Union and its people, which can be achieved more effectively in partnership, through a strategic vision that is shared and committed to by partners, rather than by the Union alone.
- (2) In particular, European partnerships in the 'Global Challenges and European Industrial Competitiveness' pillar of Horizon Europe play an important role in achieving strategic objectives such as accelerating the transitions towards sustainable development goals and a green and digital Europe, and should contribute to recovery from the unprecedented crisis brought about by the COVID-19 pandemic. European partnerships address complex cross-border challenges that require an integrated approach. They make it possible to address the transformational, systemic and market failures described in the impact assessments accompanying this Regulation by bringing together a broad range of players across the value chains and ecosystems to work towards a common vision and translating it into concrete roadmaps and coordinated implementation of activities. Furthermore, they enable efforts and resources to be concentrated on common priorities to solve the complex challenges.

⁽¹⁾ Opinion of 21 October 2021 (not yet published in the Official Journal).

⁽²⁾ OJ C 341, 24.8.2021, p. 29.

⁽³⁾ Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

- (3) To deliver on priorities and impact, European partnerships should be developed through a broad involvement of relevant stakeholders across Europe including industry, research organisations, bodies with a public service mission at local, regional, national or international level, and civil society organisations such as foundations that support or carry out research and innovation. They should also be one of the measures to strengthen cooperation between private or public sector partners at the international level, including by joining up research and innovation programmes and cross-border investment in research and innovation, bringing mutual benefits to people and businesses while ensuring that the Union can uphold its interests in strategic areas.
- (4) The interim evaluation of Horizon 2020 established by Regulation (EU) No 1291/2013 of the European Parliament and of the Council ⁽⁴⁾ revealed that a considerable repertoire of partnership instruments and initiatives have been introduced over time, with seven forms of implementation and close to 120 partnership initiatives running under Horizon 2020. In addition to the complexity generated by the proliferation of instruments and initiatives, it has been assessed that their ability to contribute to related policies at Union and national level as a whole is not sufficient despite the fact that they deliver positive impact in progressing towards their objectives, for example by setting long-term agendas, structuring research and innovation cooperation between otherwise dispersed actors, and leveraging additional investments. The impact assessment of Horizon Europe identifies therefore the need to address and to rationalise the Union research and innovation funding landscape, in particular with respect to partnerships, as well as to re-orient partnerships towards more impact and delivery on Union priorities.
- (5) To address such concerns and to achieve the higher ambition for European investments, Horizon Europe should put forward a major simplification and reform for the Commission's policy on research and innovation partnerships. In order to reflect its systemic nature that aims to contribute to Union-wide 'transformations' towards the sustainability objectives, Horizon Europe should make more effective use of those partnerships with a more strategic, coherent and impact-driven approach.
- (6) Regulation (EU) 2020/852 of the European Parliament and of the Council ⁽⁵⁾ establishes the general framework for determining whether an economic activity qualifies as environmentally sustainable for the purposes of defining sustainable investments. It creates a common reference that investors, banks, industry and researchers can use when investing in projects and economic activities that have a substantial positive impact on climate and environment and cause no significant harm to either of them. It is the reference for green investments in the Union.
- (7) Where relevant, European partnerships should consider technical screening criteria referred to in Article 3 and the 'do no significant harm' principle set out in Article 17 of Regulation (EU) 2020/852 as an instrument to improve their projects' readiness and access to green financing that will be crucial for market uptake and wider deployment of the innovative technologies and solutions they will deliver. Scientific evidence is at the core of those technical screening criteria. Research and innovation, pursued by European partnerships, should play an important role in helping economic operators to reach or go beyond the standards and thresholds set in that Regulation, and to keep those technical screening criteria up-to-date and consistent with the objectives set out in the Commission Communication of 11 December 2019 on 'The European Green Deal'.
- (8) On the basis of the Horizon Europe Regulation, it should be possible for the European partnerships to be set up using three different forms, namely 'co-funded', 'co-programmed' and 'institutionalised'. The setting-up of institutionalised European partnerships that are joint undertakings between private and public sector partners should involve new Union legislation and the establishment of dedicated implementing structures pursuant to Article 187 of the Treaty on the Functioning of the European Union (TFEU).

⁽⁴⁾ 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).

⁽⁵⁾ 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).

- (9) The Horizon Europe Regulation defines eight priority areas, in which institutionalised European partnerships established under Article 185 or 187 TFEU could be proposed. Across those priority areas, several initiatives for such institutionalised European partnerships are put forward and nine of them are covered by this Regulation.
- (10) The research and innovation activities undertaken by joint undertakings should be funded from Horizon Europe as provided in Articles 12 and 13 of the Horizon Europe Regulation. To achieve maximum impact, the joint undertakings should develop close synergies with other Horizon Europe initiatives and other Union programmes and funding instruments, particularly with those supporting the deployment of innovative solutions, education and regional development, in order to increase economic and social cohesion and reduce imbalances.
- (11) The new policy approach for European partnerships, and in particular institutionalised European partnerships, calls for a novel way of establishing the legal framework under which they would operate. While the setting-up of joint undertakings on the basis of Article 187 TFEU for the purpose of Horizon 2020 has proven to be effective as far as the implementation is concerned, it is necessary to step it up. Therefore, this Regulation aims to increase the coherence, efficiency, openness, effectiveness and impact-orientation of implementation by translating the Horizon Europe Regulation and the experience gained from programme implementation under Horizon 2020 into common provisions across the joint undertakings in a harmonised way. It aims to facilitate the creation of collaboration and synergies between European partnerships, thereby making full use of their interconnections at the organisational level. Joint undertakings should seek opportunities to involve representatives of other European partnerships in discussions during the drafting of their work programmes, identify the areas in which complementary or joint activities would address the challenges more effectively and efficiently, avoid overlaps, align timing of their activities and ensure access to results and other relevant means of knowledge exchange.
- (12) Following the identification of synergies between them, joint undertakings should aim to determine budget shares which should be used for complementary or joint activities between joint undertakings. Moreover, this Regulation aims to improve efficiencies and harmonisation of the rules through intensified operational collaboration and by exploring economies of scale, including the establishment of back office arrangements which should provide horizontal support functions to the joint undertakings. Those back office arrangements should make it easier to achieve greater impact and harmonisation on common points while retaining a certain degree of flexibility to meet the specific needs of each joint undertaking. The structure should be established using service level agreements to be concluded by the joint undertakings. The back office arrangements should cover coordination and administrative support functions in areas where their screening has proved efficient and cost-effective and should take into account as far as possible compliance with the requirement of accountability of each individual authorising officer and harmonisation of the rules, including intellectual property rights. The legal set-up should be designed to best serve the common needs of the joint undertakings, to ensure their close collaboration and to explore all possible synergies among the European partnerships and, as a consequence, between the various parts of Horizon Europe as well as between the other programmes managed by the joint undertakings.
- (13) The impact assessments regarding each joint undertaking accompanying the proposal for this Regulation have provided evidence that justifies the implementation of European partnerships in accordance with the Horizon Europe Regulation only where other parts of Horizon Europe, including other forms of European partnership, would not achieve the objectives or would not generate the necessary expected impacts, and whereby such implementation is justified by a long-term perspective and high degree of integration.
- (14) Horizon Europe introduces a more strategic, coherent and impact-driven approach to European partnerships, building on the lessons learned from the Horizon 2020 interim evaluation. In line with the new ambition, this Regulation aims to achieve a more effective use of institutionalised European partnerships, in particular by focusing on clear objectives, outcomes and impact that can be achieved by 2030, and by ensuring a clear contribution to the related Union policy priorities and policies. Close collaboration and synergies with other relevant initiatives at Union, national and regional level, in particular with other European partnerships, are key to achieving greater scientific, socioeconomic and environmental impact and ensuring uptake of results. For this purpose, the joint undertakings may apply Horizon Europe provisions enabling different types of synergies, such as alternative, cumulative or combined funding and transfer of resources. In assessing the overall impact, broader investments beyond the contributions from partners and triggered by the joint undertakings that contribute to achieving their objectives should be taken into account to facilitate the acceleration of market uptake of innovative solutions.

- (15) In order to ensure a coherent approach and capture the scientific, technological, economic, societal and environmental impacts of European partnerships in relation to the objectives of Horizon Europe and Union priorities, this Regulation should set out collective general and common specific objectives that should be delivered by all joint undertakings. All joint undertakings contribute collectively to achieving those objectives by reaching their individual objectives. In addition, the common parts of this Regulation define common operational objectives derived from the objectives set for the Specific Programme implementing Horizon Europe, established by Council Decision (EU) 2021/764 ⁽⁶⁾ (the 'Specific Programme implementing Horizon Europe'). All joint undertakings should carry out their tasks in order to fulfil the principles and criteria set out for European partnerships in the Horizon Europe Regulation (Article 10 and Annex III) and deliver European added value compared to calls under the main Horizon Europe work programme. The objectives and tasks of the joint undertakings are complemented by additional ones specific to each joint undertaking. While taking into account their specificities and policy contexts, the alignment of the intervention logics of individual joint undertakings with Horizon Europe should support the coordinated assessment of progress of the joint undertakings as part of Horizon Europe monitoring and evaluation activities.
- (16) This Regulation is based on the principles and criteria set out in the Horizon Europe Regulation, including openness and transparency, a strong leverage effect and long-term commitments of all the involved parties. One of the objectives of this Regulation is to ensure the openness of the joint undertakings and their actions to a broad range of entities, including newcomers who will be monitored also within the framework of the strategic coordinating process for European partnerships provided under Article 6(5) of the Specific Programme implementing Horizon Europe. Such partnerships should be open to any entity that is willing and able to work towards the common goal, should promote broad and active participation of stakeholders in their activities, membership and governance, and should ensure that the results would be for the benefit of all Europeans, in particular through a broad dissemination of results and pre-deployment activities across the Union. As regards private members and their constituent or affiliated entities established in third countries, the interests of the Union and the joint undertaking on the grounds of security or public order should be safeguarded. To that end, the Commission should be able to request private members to take appropriate measures. Such measures could include the appropriate handling of confidential information or limitation of certain entities in specific operational activities of the private member.
- (17) To ensure the coherent application of Article 22(5) of the Horizon Europe Regulation, the joint undertakings should ensure coherence with the approach taken for actions funded under the Horizon Europe work programme regarding the application of that Article, as well as Union legislation and guidance relevant for its application in similar topics in the work programme of the joint undertaking concerned.
- (18) Where the Commission or the Member States consider limiting participation in specific actions of the joint undertaking in accordance with Article 22(5) of the Horizon Europe Regulation, the Commission and the Member States in the states' representatives group should seek an agreed position on a case-by-case basis before the adoption of the work programme. In the case of joint undertakings with a Public Authorities Board, the application of that Article should be approved by the Public Authorities Board, following the request by the Commission, before the adoption of the work programme. Furthermore, following an invitation from the Chair, the Executive Director should inform regularly the relevant configuration of the Horizon Europe Programme Committee, further to the Commission's responsibility to inform the Programme Committee under Article 14(7) and Annex III of the Specific Programme implementing Horizon Europe, and in particular before the adoption of the work programme of the joint undertaking concerned, in relation to the application of Article 22(5) of the Horizon Europe Regulation.
- (19) Annex III of the Horizon Europe Regulation requires that the financial or in-kind contributions from members other than the Union should be at least equal to 50 % and may reach up to 75 % of the aggregated joint undertaking budgetary commitments. Conversely, the Union contribution, including any additional funds from associated countries, should not exceed 50 % of the aggregated budgetary commitments of each joint undertaking. Consequently, this Regulation should set the required contribution from members other than the Union at the same level or higher than the Union contribution. The Union should be in a position to reduce its contribution if members other than the Union fail to fulfil their commitments.

⁽⁶⁾ Council Decision (EU) 2021/764 of 10 May 2021 establishing the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation, and repealing Decision 2013/743/EU (OJ L 167 I, 12.5.2021, p. 1).

- (20) In accordance with Article 10(1), point (c), of the Horizon Europe Regulation, the joint undertakings are to implement a central management of all financial contributions through a coordinated approach. Accordingly, each participating state should conclude one or more administrative agreements with the joint undertaking laying down the coordination mechanism for the payment of and reporting on contributions to applicants established in that participating state. In order to ensure coherence with their national strategic priorities, participating states should be provided with a right of veto over the use of their national financial contributions for applicants established in those participating states. In order to minimise the administrative burden for beneficiaries, achieve simplification and ensure a more efficient implementation, each participating state should strive to synchronise its payment schedule, reporting and audits with those of the joint undertakings and to converge its cost eligibility with the Horizon Europe Regulation. Beneficiaries established in participating states that entrusted the payment activities to the joint undertaking should sign a single grant agreement with the joint undertaking following Horizon Europe Regulation.
- (21) In line with the ambitions set out in the Horizon Europe Regulation, one of the preconditions of setting up institutionalised European partnerships is ensuring partners' contributions throughout the lifetime of the joint undertakings. In this context, private partners should deliver a significant part of their contributions in the form of in-kind contributions to operational costs of the joint undertaking. Joint undertakings should be able to identify measures to facilitate those contributions through their work programmes, in particular by reducing funding rates. Those measures should be based on the specific needs of a joint undertaking and the underlying activities. In duly justified cases, it should be possible to introduce additional conditions that require the participation of a member of the joint undertaking or their constituent or affiliated entities, targeting activities where the industrial partners of the joint undertaking can play a key role such as large-scale demonstrations and flagship projects closer to the market, and contribute more via lower funding rates. The level of participation of members should be monitored by the executive director in order to empower the governing board to take appropriate actions, ensuring a balance between commitment from partners and openness. In duly justified cases, the capital expenditure for, for example, large-scale demonstrations or flagship projects may be considered as an eligible cost in line with the applicable legal framework.
- (22) It should be possible that, in accordance with Article 15(3) of the Horizon Europe Regulation, contributions from programmes co-financed by the European Regional Development Fund established by Regulation (EU) 2021/1058 of the European Parliament and of the Council ⁽⁷⁾ (ERDF), the European Social Fund Plus established by Regulation (EU) 2021/1057 of the European Parliament and of the Council ⁽⁸⁾ (ESF+), the European Maritime, Fisheries and Aquaculture Fund established by Regulation (EU) 2021/1139 of the European Parliament and of the Council ⁽⁹⁾ (EMFAF) and the European Agricultural Fund for Rural Development established by Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽¹⁰⁾ (EAFRD) be considered to be a contribution of the participating states that are Member States to the joint undertakings, provided that Regulation (EU) 2021/1060 of the European Parliament and of the Council ⁽¹¹⁾ and the fund-specific regulations are complied with. In addition, it should be
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- ⁽⁷⁾ Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60).
- ⁽⁸⁾ Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21).
- ⁽⁹⁾ Regulation (EU) 2021/1139 of the European Parliament and of the Council of 7 July 2021 establishing the European Maritime, Fisheries and Aquaculture Fund and amending Regulation (EU) 2017/1004 (OJ L 247, 13.7.2021, p. 1).
- ⁽¹⁰⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).
- ⁽¹¹⁾ Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy (OJ L 231, 30.6.2021, p. 159).

possible that contributions from the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council ⁽¹²⁾ (the 'Facility') be considered to be a contribution of the Member States that are participating states to the joint undertakings, provided that the provisions of the Facility and commitments set in the national recovery and resilience plans are complied with.

- (23) In line with the principle of fair sharing of contributions among the members of joint undertakings, financial contributions to the administrative costs of the joint undertakings should be divided equally between the Union and the members other than the Union. Deviations from that principle should only be considered in exceptional and duly justified cases such as where the size or the membership structure of a member of the joint undertaking other than the Union would result in contributions per constituent or affiliated entity, in particular small and medium-sized enterprises (SMEs), of such a high level as to seriously jeopardise the incentive to become or remain a constituent or affiliated entity of the member of the joint undertaking. In such cases, the minimum percentage of annual financial contribution to the administrative costs of the joint undertaking from members other than the Union should be 20 % of the total annual administrative costs and the contributions from SMEs should be significantly lower than those from larger constituent or affiliated entities. Once a critical mass of membership that allows for a contribution higher than 20 % of the total annual administrative costs is reached, annual contributions per constituent or affiliated entity should be maintained or increased with the aim of gradually increasing the share of the members other than Union in the overall contribution to the annual administrative costs of the joint undertaking. The members of the joint undertaking other than the Union should endeavour to increase the number of constituent or affiliated entities in order to increase their contribution to 50 % of the administrative costs of the joint undertaking over its lifetime.
- (24) The Horizon Europe Regulation requires the partners to show their long term commitment, including through a minimum share of public or private investments. Consequently, it is necessary for the Union to identify in this Regulation founding members established in the Member States, countries associated to Horizon Europe or international organisations. However, where necessary it should be possible to expand the membership base of joint undertakings after they are established with associated members selected following open and transparent procedures, taking into account in particular the new technological developments or the association of additional countries to Horizon Europe.
- (25) Legal entities interested in supporting the joint undertakings' objectives in their specific areas of research, without becoming a member, should also be offered the possibility to become contributing partners of those joint undertakings.
- (26) In accordance with Article 16(5) of the Horizon Europe Regulation, the allocation of the financial contributions from third countries associated to Horizon Europe should take into account the level of participation of the legal entities of the associated third countries. Accordingly, the Union contribution to the joint undertakings may be increased with contributions from third countries associated to Horizon Europe, taking into account the level of participation of such legal entities and provided that the total amount by which the Union contribution is increased is at least matched by the contribution of members other than the Union, or their constituent or affiliated entities.
- (27) The establishment of a joint undertaking ensures a mutually beneficial public-private partnership for the members involved, including by promoting certainty on major budget allocations for the relevant industries over a period of seven years. Becoming a founding member or associated member, or one of their constituent or affiliated entities, enables members to gain influence, either directly or through the industry representatives, in the governing board of the joint undertaking. The governing board is the decision-making body of the joint undertaking that decides on the long-term strategic orientation of the partnership, as well as its annual priorities. The Union, the participating states where relevant, the founding members and associated members should therefore be able to contribute to the joint undertaking's agenda and priority-setting through the adoption and possible amendment of the Strategic Research and Innovation Agenda, as well as the adoption of the annual work programme, including the content of the calls for proposals, the applicable funding rate per call topic, and the related rules for submission, evaluation, selection, award and review procedures.

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

- (28) It is appropriate that the members other than the Union commit to the implementation of this Regulation by means of a letter of commitment, or a joint letter of commitment indicating the total amount of their contributions where appropriate, without imposing conditions regarding their accession. Such letters of commitment should be legally valid throughout the lifetime of the joint undertaking and closely monitored by the joint undertaking and the Commission. Joint undertakings should create a legal and organisational environment that enables members to deliver on their commitments, while ensuring attractiveness for all stakeholders, continuous openness of the joint undertakings and transparency during their implementation, in particular for priority setting and for participation in calls for proposals.
- (29) Further simplification is a cornerstone of Horizon Europe. In that context, there should be a simplified reporting mechanism for partners, who are no longer required to report on non-eligible costs. In-kind contributions to operational activities should be accounted for solely on the basis of eligible costs and should be reported and audited in accordance with the mechanism applicable to the specific grant agreement. Such accounting on the basis of eligible costs only allows for the automated calculation of in-kind contributions to operational activities via the Horizon Europe IT tools, lowers the administrative burden for partners and makes the reporting mechanism for contributions more effective. In-kind contributions to operational activities should be closely monitored by the joint undertakings and regular reports should be prepared and made public by the executive director in order to establish whether the progress towards reaching the in-kind contributions targets is sufficiently satisfactory. The governing board should assess both the efforts made and the results achieved by the members contributing to operational activities, as well as other factors such as the level of participation of SMEs and attractiveness of the joint undertakings to newcomers. Where necessary it should take appropriate remedial and corrective measures, taking into account the principles of openness and transparency.
- (30) The joint undertakings should provide a systematic opportunity and incentive for members other than the Union to combine their research and innovation activities with those of the joint undertaking. Additional activities should not receive financial support from the joint undertaking. However, they can be accounted for as members' in-kind contributions to additional activities when they contribute to the objectives of the joint undertaking and are directly linked to its activities, including non-eligible costs of indirect actions funded by the joint undertaking where this is provided for in the annual additional activities plan. That link can be established through the uptake of results from indirect actions funded by the joint undertaking or its preceding initiatives, or by demonstrating a significant Union added value. The respective costs should be certified by an independent audit body appointed by the entity concerned subject to the valuation method being open to verification by the joint undertaking in the event of uncertainty. This Regulation should lay down more specific provisions concerning the scope of additional activities for each joint undertaking, to the extent that it is necessary to achieve the desired directionality and impact. It should be further decided by joint undertakings' governing boards whether, for the purposes of valuing these contributions, the use of simplifying methods such as lump sums or unit costs is necessary to achieve simplification, cost effectiveness and an appropriate level of protection of confidential commercial data.
- (31) The governance of joint undertakings should ensure that their decision-making processes are fit to keep pace with a fast-changing socioeconomic and technological environment and global challenges. Joint undertakings should benefit from expertise, advice and support from all relevant stakeholders, in order to effectively implement their tasks and ensure synergies at Union and national level. Therefore, joint undertakings should be empowered to set up advisory bodies with a view to providing them with expert advice and carrying out any other task of an advisory nature that is necessary for the achievement of the joint undertakings' objectives. In setting up the advisory bodies, joint undertakings should ensure a balanced representation of experts within the scope of the activities of the joint undertaking, including with respect to gender balance. The advice provided by those bodies should bring in scientific perspectives, as well as those of national and regional authorities and of other stakeholders of joint undertakings.
- (32) Joint undertakings should ensure that Member States are sufficiently informed of the joint undertakings' activities, can provide timely information on activities undertaken in the Member States and have the opportunity to contribute to the preparatory and decision-making processes. Such dialogue with Member States is particularly important in the context of synergies and the need to ensure the alignment of efforts and activities at national, regional, Union and European level to create more impact. Joint undertakings without the direct or indirect involvement of Member States as members or constituent entities should establish a state representatives group with the aim of aligning the joint undertakings' activities with the policies and actions taken at national and regional level.

- (33) Joint undertakings should be able to set up an advisory body with a scientific advisory function. That body or its members should be in a position to provide independent scientific advice and support to the respective joint undertaking. The scientific advice should concern, in particular, annual work programmes and additional activities, as well as any other aspect of the joint undertakings' tasks, as necessary.
- (34) With a view to ensuring that joint undertakings are aware of the positions and views of stakeholders from the entire value chain in their respective fields, joint undertakings should be able to set up their respective advisory stakeholders groups, to be consulted on horizontal issues or specific questions, as per the needs of each joint undertaking. Such groups should be open to public and private stakeholders, including organised interest groups and international interest groups from the Member States, associated countries or other countries, active in the field of the joint undertaking.
- (35) The joint undertakings should operate in an open and transparent way, providing all relevant information in a regular and timely manner to their appropriate bodies as well as promoting their activities, including information and dissemination activities, to the wider public. This includes timely information, subject to confidentiality rules and broken down by country on the application and participation in indirect actions funded by the joint undertaking, on the evaluation results of each call for proposals and project implementation, on synergies with other relevant Union programmes and other European partnerships, on additional activities, on committed and actually provided financial and in-kind contributions, on the execution of the budget of the joint undertaking, and on the link between the objectives of the joint undertaking and in-kind contributions to additional activities.
- (36) The joint undertakings should be implemented using a structure and rules that enhance efficiency and ensure simplification. To that effect, the joint undertakings should adopt financial rules specific to their needs in accordance with Article 71 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽¹³⁾.
- (37) The implementation of the joint undertakings should be based on the criteria set out for institutionalised European partnerships in the Horizon Europe Regulation. It should be supported by the use of electronic means managed by the Commission. Information related to indirect actions funded by the joint undertakings, including results, is essential for the purposes of developing, implementing, monitoring and evaluating Union policies or programmes. Therefore, joint undertakings should ensure that Union institutions and Union bodies, offices or agencies have access to all information related to the indirect actions they fund, including contributions and results of beneficiaries participating in indirect actions. Such access rights should be limited to non-commercial and non-competitive use and should comply with applicable confidentiality rules. Staff of the Union institutions and Union bodies, offices or agencies should be granted access to this information subject to adequate IT security and information security standards and in accordance with the principles of necessity and proportionality.
- (38) Participation in indirect actions funded by the joint undertakings under Horizon Europe should comply with the rules set out in the Horizon Europe Regulation. The joint undertakings should ensure consistent application of those rules based on relevant measures adopted by the Commission. The joint undertakings should use the corporate model grant agreement prepared by the Commission. In relation to the period to object to transfers of ownership of results referred to in Article 40(4) of the Horizon Europe Regulation, the duration of innovation cycles in the areas covered by the respective joint undertakings should be taken into account.
- (39) One of the main purposes of joint undertakings is to foster the Union's economic capacities and in particular its scientific and technological leadership. Moreover, the post-COVID-19 recovery highlights the need to invest in key technologies such as 5G, artificial intelligence (AI), cloud, cybersecurity and green tech and to valorise those technologies in the Union. The joint undertakings should contribute to fostering open science in accordance with Articles 14 and 39 of the Horizon Europe Regulation. Results generated by all participants will play an important role in this respect and all participants will benefit from Union funding through the results generated in the project

⁽¹³⁾ 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).

and access rights thereto, even those participants not having received Union funding. Therefore, to protect Union interests, the right for joint undertakings to object to transfers of ownership of results or to grants of an exclusive licence regarding results should also apply to participants not having received Union funding. In exercising this right to object and in accordance with the principle of proportionality, the joint undertaking should strike a fair balance between Union interests and protection of fundamental rights as regards the results of the participants not having received Union funding, taking into account that those participants did not receive any Union funding for the action from which the results were generated.

- (40) The Union financial contribution should be managed in accordance with the principle of sound financial management and with the rules on indirect management set out in Regulation (EU, Euratom) 2018/1046.
- (41) For the purpose of simplification, the administrative burden should be reduced for all parties. Double audits and disproportionate amounts of documentation and reporting should be avoided. Audits of recipients of Union funds under this Regulation should be carried out in compliance with the Horizon Europe Regulation and other relevant Union funding programmes.
- (42) The financial interests of the Union and of the other members of the joint undertakings should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties in accordance with Regulation (EU, Euratom) 2018/1046. In view of the specific nature of the actions implemented by some of the joint undertakings requiring them to be phased out over several years, it should be possible to split multiannual budgetary commitments by the Commission and the relevant joint undertaking into annual instalments. In this respect, budgetary commitments of the Clean Aviation Joint Undertaking, of the Europe's Rail Joint Undertaking and of the Single European Sky ATM Research 3 Joint Undertaking may be divided into annual instalments. Until 31 December 2024, the cumulative amount of those budgetary commitments should not exceed 50 % of the respective maximum Union contribution. From 1 January 2025, at least 20 % of the cumulative budget of the residual years should not be covered by annual instalments.
- (43) In view of the specific nature and the current status of the joint undertakings, they should continue to be subject to a separate discharge. The auditing of accounts and of the legality and regularity of the underlying transactions should be undertaken by the Court of Auditors.
- (44) In accordance with Article 10(2), point (c), of the Horizon Europe Regulation, joint undertakings should have a clear life cycle approach. In order to adequately protect the financial interests of the Union, joint undertakings should be set up for a period ending 31 December 2031 to allow them to exercise their responsibilities with regard to grant implementation until the last indirect actions launched have been completed. The joint undertakings should be financed by the Union programmes under the multiannual financial framework for 2021-2027 ('MFF 2021-2027'). The joint undertakings should be able to launch calls for proposals by 31 December 2028, in duly justified cases related to availability of remaining budget stemming from the MFF 2021-2027.
- (45) In the context of the Commission's priority of the European Green Deal supported by the communications from the Commission of 11 October 2018 on A sustainable Union Bioeconomy for Europe: Strengthening the connection between economy, society and the environment, of 28 November 2018 on A Clean Planet for All: A European strategic long-term vision for a prosperous, modern, competitive and climate neutral economy, of 11 March 2020 on A new Circular Economy Action Plan: For a cleaner and more competitive Europe, of 20 May 2020 on EU Biodiversity Strategy for 2030: Bringing nature back into our lives, of 20 May 2020 on A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system and of 17 October 2020 on the Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment, the European bio-based sector, including SMEs, regions and primary producers, should become climate neutral, more circular and more sustainable while remaining competitive on the global scale. A strong, resource-efficient and competitive bio-based innovation ecosystem can

decrease dependency on and accelerate the substitution of non-renewable fossil raw materials and mineral resources. It can develop renewable bio-based products, materials, processes and nutrients from waste and biomass through sustainability and circularity-driven innovation. Such ecosystem can also create value from local feedstock, including waste, residues and side-streams, to deliver jobs, economic growth and development throughout the Union, not only in urban areas but also in rural and coastal territories where biomass is produced and which are often peripheral regions that rarely benefit from industrial development.

- (46) The Bio-based Industries Joint Undertaking established under Horizon 2020 has focused on sustainable resource use, especially in resource-intensive and high-impact sectors such as agriculture, textiles manufacturing and construction, in particular aiming at local operators, manufacturers, plants and factories. Its interim evaluation published in October 2017 included a strong set of 34 recommendations that are reflected in the design of the Circular Bio-based Europe Joint Undertaking established by this Regulation. The Circular Bio-based Europe Joint Undertaking is not a direct continuation of the Bio-Based Industries Joint Undertaking but rather a programme that builds on the achievements of the preceding initiative and addresses its shortcomings. In line with the recommendations, the Circular Bio-based Europe Joint Undertaking should involve a wider range of stakeholders including the primary sector (namely agriculture, aquaculture, fisheries and forestry) as well as providers of waste, residues and side streams, regional authorities and investors to prevent market failures and unsustainable bio-based processes. To deliver on its objectives, it should only fund projects that respect principles of circularity, sustainability and planetary boundaries.
- (47) The Circular Bio-based Europe Joint Undertaking should establish Deployment Groups that should serve as advisory bodies and actively participate in the strategic discussions that are to set the agenda for the partnership. It is crucial to include those advisory bodies in the governance structure to ensure wider participation and higher private investment in the circular bio-based sector. The Deployment Groups should in particular provide support to the strategic Governing Board meetings where industrial leaders and the stakeholders' representatives together with high-level Commission representatives join the permanent Governing Board to discuss and set the strategic direction of the partnership.
- (48) The main objective of the Clean Aviation Joint Undertaking should be to contribute to reducing the ecological footprint of aviation by accelerating the development of climate neutral aviation technologies for their earliest possible deployment, therefore significantly contributing to the ambitious environment impact mitigation goals of the European Green Deal and Regulation (EU) 2021/1119 of the European Parliament and of the Council ⁽¹⁴⁾ ('European Climate Law'), that is to say a 55 % emissions reduction by 2030 compared to 1990 levels, and climate neutrality at the latest by 2050 in line with the Paris Agreement adopted under the United Nations Framework Convention on Climate Change ⁽¹⁵⁾. This objective can only be achieved through accelerating and optimising the research and innovation processes in aeronautics and by improving the global competitiveness of the Union aviation industry. The Clean Aviation Joint Undertaking should also ensure that cleaner aviation remains safe, secure and efficient for the transportation of passengers and goods by air.
- (49) The Clean Aviation Joint Undertaking builds on the experience gained from the Clean Sky and Clean Sky 2 Joint Undertakings. The new European partnership should be more ambitious by focusing on developing breakthrough demonstrators. In line with the findings of the interim evaluation of the Clean Sky 2 Joint Undertaking, a new initiative should ensure that every demonstrator is on the critical path for the development of the next aircraft programmes in order for the technologies developed to really serve the key priority of earliest possible deployment. Therefore, the new joint undertaking should focus on increasing the visibility of its individual exploitation objectives and strengthening the monitoring, management and reporting capabilities of the joint undertaking to reflect the complexity of the research and innovation effort required for the European partnership to reach its objectives.

⁽¹⁴⁾ Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law') (OJ L 243, 9.7.2021, p. 1).

⁽¹⁵⁾ OJ L 282, 19.10.2016, p. 4.

- (50) The Clean Aviation Joint Undertaking should build on a strong leadership from the European aviation industry and a diverse membership base, bringing together a broad spectrum of stakeholders and ideas across Europe. With a view to identifying the most promising approaches and entities capable of pursuing them, the Commission launched a call for expression of ideas and potential members. The Governing Board should be allowed to select associated members based on the results of that call and future calls in order to provide for a swift expansion of the group of members.
- (51) In order to maximise and accelerate the impact of the research and innovation activities undertaken by the Clean Aviation and Single European Sky ATM Research 3 Joint Undertakings on effective emission reduction and the digitalisation of the aviation industry, those joint undertakings should seek close collaboration with the European Union Aviation Safety Agency (EASA) in the work of the European partnership, ensuring an early exchange of knowledge on new technologies developed. That collaboration will be crucial to accelerate market uptake, by facilitating the certification process of resulting products and services as required by Regulation (EU) 2018/1139 of the European Parliament and of the Council ⁽¹⁶⁾.
- (52) In order to maximise synergies between programmes at Union, national and regional level, the members of the states' representatives group of the Clean Aviation Joint Undertaking should explore possibilities to provide financial support at national level to excellent proposals that were not selected for funding by the Clean Aviation Joint Undertaking due to oversubscription.
- (53) Europe faces the challenge of having to play a leading role in accelerating the environmental transformation of the next generation of aircraft and internalising the societal costs of greenhouse gas emissions in the air transport business model while continuing to ensure a level playing field for European products in the global market. Therefore, the Clean Aviation Joint Undertaking should support the European representatives in international standardisation and international legislative efforts.
- (54) Interest in hydrogen has evolved dramatically in the last five years, with all Member States having signed and ratified the United Nations Framework Convention on Climate Change (Paris Agreement) at the 21st Conference of the Parties (COP21). The European Green Deal aims to transform the Union into a fair and prosperous society with a modern, resource-efficient and competitive economy, where there are no net emissions of greenhouse gases at the latest by 2050. Priority areas include clean hydrogen, fuel cells, other alternative fuels and energy storage. Hydrogen is prominent in the communications from the Commission of 8 July 2020 on A hydrogen strategy for a climate-neutral Europe and on Powering a climate-neutral economy: EU Strategy for Energy System Integration, as well as for the launch of the European Clean Hydrogen Alliance that brings all stakeholders together to identify technology needs, investment opportunities and regulatory barriers to build a clean hydrogen ecosystem in the Union contributing to reducing the current dependence on fossil fuels and greenhouse gases emissions in relevant sectors. The Clean Hydrogen Joint Undertaking may enable the uptake of research and innovation (R&I) results by investment frameworks, such as the European Clean Hydrogen Alliance and Important Projects of Common European Interest (IPCEI) on Hydrogen.
- (55) Dedicated research and innovation activities related to hydrogen applications have been supported since 2008, mainly through the Fuel Cell and Hydrogen Joint Undertakings, namely FCH Joint Undertaking and FCH 2 Joint Undertaking, under the Seventh Framework Programme established by Decision No 1982/2006/EC of the European Parliament and of the Council ⁽¹⁷⁾ and Horizon 2020 as well as by traditional collaborative projects, covering all stages/fields of the hydrogen value chain. The Clean Hydrogen Joint Undertaking should strengthen and

⁽¹⁶⁾ Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).

⁽¹⁷⁾ Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).

integrate Union scientific capacity to accelerate the development and improvement of advanced clean hydrogen applications ready for market, across energy, transport, building and industrial end-uses. That will only be possible if combined with strengthening competitiveness of the Union clean hydrogen value chain, and in particular SMEs.

- (56) To achieve the scientific objectives of the Clean Hydrogen Joint Undertaking, all sectors concerned by the hydrogen economy should be given the possibility to get involved in preparing and implementing its Strategic Research and Innovation Agenda. Actions undertaken by the Clean Hydrogen Joint Undertaking should take into account disruptive technological trajectories alternative to mainstream technologies. The public sector should be involved, especially regional and national authorities, the latter being responsible for setting up climate policies and measures related to market mechanisms, to fill in the gaps between ready-to-market technology development and large-scale uptake.
- (57) The Clean Hydrogen Joint Undertaking includes the research community as a member of the Hydrogen Europe Research association, and thus a body providing scientific advice should not be established.
- (58) Since hydrogen can be deployed as a fuel or an energy carrier and for storing energy, it is essential that the clean hydrogen partnership establishes structured collaboration with many other European partnerships, in particular for end-use. The clean hydrogen European partnership should interact in particular with the zero emission road and waterborne transport, Europe's railway, clean aviation, processes for the planet and clean steel European partnerships. For that purpose, a structure should be set up reporting to the Governing Board in order to ensure the cooperation and synergies between those partnerships in the domain of hydrogen. The Clean Hydrogen Joint Undertaking would be the only partnership focused on addressing hydrogen production technologies. Collaboration with end-use partnerships should in particular focus on demonstrating the technology and co-defining specifications.
- (59) Railways contribute to the Single European Transport Area (SETA) and represent a fundamental element of the Union long-term sustainable development strategy policy. In terms of economic size, the direct gross added value of the European rail sector is EUR 69 billion and the indirect value amounts to EUR 80 billion. 1,3 million persons are directly employed in the rail sector and more than one million indirectly.
- (60) The communication from the Commission of 10 March 2020 on a New Industrial Strategy for Europe underlines that sustainable and smart mobility industries, such as the rail industry, have both the responsibility and the potential to drive the digital and green transition, support Europe's industrial competitiveness and improve connectivity. Therefore road, rail, aviation and waterborne transport should all contribute to a 90 % reduction in transport emissions by 2050. As a matter of priority, a substantial part of the 75 % of inland freight carried today by road should shift onto rail and inland waterways.
- (61) The Shift2Rail Joint Undertaking was established in 2014 to manage the research, development and validation activities of the Shift2Rail preceding initiative by combining public and private sector funding provided by its members and by drawing on internal and external technical resources. It established new forms of collaboration, consistent with competition rules, between stakeholders from the entire rail value chain and from outside the traditional rail sector, and brought in the experience and expertise of the European Union Agency for Railways on issues relating to interoperability and safety.
- (62) The objective of Europe's Rail Joint Undertaking should be to deliver a high capacity integrated European railway network by eliminating barriers to interoperability and providing solutions for full integration, covering traffic management, vehicles, infrastructure and services, aiming to achieve faster uptake and deployment of projects and innovations. That should exploit the huge potential for digitalisation and automation to reduce rail's costs, increase its capacity and enhance its flexibility and reliability, and should be based upon a solid reference functional system architecture shared by the sector, in coordination with the European Union Agency for Railways.

- (63) The Europe's Rail Joint Undertaking should define in its Master Plan its priority research and innovation activities, and overall system architecture and harmonised operational approach, including large-scale demonstration activities and flagship areas, required to accelerate the penetration of integrated, interoperable and standardised technological innovations necessary to support the Single European Railway Area.
- (64) Rail is a complex system, with very close interactions between infrastructure managers, rail undertakings (train operators) and their respective equipment (infrastructure and rolling stock). It is impossible to deliver innovation without common specifications and strategy across the rail system. Therefore, the System Pillar of the Europe's Rail Joint Undertaking, which will gather input from relevant stakeholders from both outside and within the joint undertaking, should enable the sector to converge on a single operational concept and system architecture, including the definition of the services, functional blocks and interfaces, which form the basis of rail system operations. It should provide the overall framework to ensure that research targets customer requirements and operational needs that are commonly agreed and shared. The output of the System Pillar should support interoperability for the whole railway network, including TEN-T core and comprehensive network, and main lines and regional lines not included in the TEN-T. The governance model and the decision-making process of the Europe's Rail Joint Undertaking should reflect the Commission's leading role in unifying and integrating Europe's railway system, especially in rapidly and effectively delivering the single operational concept and system architecture, while involving the private partners in advisory and technical support roles.
- (65) To ensure that the results of low technology readiness levels (TRLs) research are effectively used at higher TRLs, and in particular by the Europe's Rail Joint Undertaking, the Europe's Rail Joint Undertaking's programme office should implement such activities.
- (66) Where necessary, in order to ensure swift transition and expansion of membership, the Governing Board of the Europe's Rail Joint Undertaking should be allowed to select associated members on the basis of the results of a call for expression of interest launched by the Commission.
- (67) In the context of the Commission's priorities of the United Nations Sustainable Development Goals, in particular Sustainable Development Goal 3, and the joint communication from the Commission of 9 March 2020 entitled 'Towards a Comprehensive Strategy with Africa', the Union is committed to contribute to ensuring healthy lives and promoting well-being for all, to building an even stronger partnership between the two continents and to supporting the development of research and innovation capacities within Africa. The Global Health EDCTP3 Joint Undertaking should address the lack of appropriate diagnostics, treatments and vaccines, among other so-called health technologies, to address infectious diseases, such as HIV, malaria and tuberculosis but also other poverty-related and neglected infectious diseases, that are prevalent in Africa, especially in sub-Saharan Africa. The COVID-19 pandemic has revealed that, with the increased connectivity of different regions in the world, through world trade and tourism, infectious diseases can rapidly spread all over the world. Developing health technologies is therefore crucial to limit the spread of infectious diseases, as well as to fight them once they have spread, to protect the health of citizens in the countries concerned and in the Union. In order to achieve a stronger global health leadership than the preceding EDCTP2 initiative, the scope of the partnership should be extended to cover response to emerging infectious diseases threats, the increasing problems of antimicrobial resistance and non-communicable diseases co-morbidities.
- (68) Tackling infectious diseases affecting sub-Saharan Africa with modern technology tools requires the involvement of a large set of actors and long-term commitments. The Global Health EDCTP3 Joint Undertaking should broker productive and sustainable North-South and South-South networking and cooperation, building relationships with multiple private and public sector organisations to strengthen project and institutional collaborations. The programme should also help to establish new North-South and South-South collaborations to conduct multi-country, multi-site studies in sub-Saharan Africa. In addition, a regular international conference, the European and Developing Countries Clinical Trials Partnership (EDCTP) Forum, should provide a platform for scientists and relevant networks from Europe, Africa and elsewhere to share findings and ideas, and to establish collaborative links.

- (69) The Global Health EDCTP3 Joint Undertaking should build on the experience gained during the EDCTP and EDCTP2 programmes, achieving results by harnessing investments of the Union, the Member States, associated countries and African countries which could not have been achieved by individual countries or by the Union research framework programme alone. The EDCTP Association, representing the states participating in the programme, should contribute with additional activities and may contribute financially to the EDCTP3 Programme and its implementation. It should provide meaningful participation and involvement of the sub-Saharan countries in the decision-making process, which is essential for tackling the burden of diseases in sub-Saharan countries. The joint undertaking should include other international research funders, such as philanthropists, the pharmaceutical industry and other third countries, that should contribute to the partnership as contributing partners on an ad hoc basis. Furthermore, to increase the impact of the programme, the Global Health EDCTP3 Joint Undertaking should have, for specific calls, the possibility to identify legal entities that could participate in indirect actions. It should be possible to provide in the work programme that such legal entities would not be eligible for funding by the joint undertaking.
- (70) The Global Health EDCTP3 Joint Undertaking includes Member States and associated countries as members of the EDCTP Association, and thus a states' representatives group should not be established.
- (71) It is essential that the research activities funded by Global Health EDCTP3 Joint Undertaking, or otherwise covered by its work programme, are in full compliance with the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and its Supplementary Protocols, ethical principles included in the World Medical Association's Declaration of Helsinki of 2008, the standards of good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, relevant Union legislation and local ethics requirements of the countries where the research activities are to be conducted. Furthermore, the Global Health EDCTP3 Joint Undertaking should require that the innovations and interventions developed based on results of the indirect actions supported by the programme be affordable and accessible for vulnerable populations.
- (72) For the Global Health EDCTP3 Joint Undertaking to succeed and incentivise participation in the partnership, the joint undertaking funding should be restricted to legal entities established in Member States or associated countries or established in constituent states of the EDCTP Association, in accordance with the Horizon Europe Regulation. The entities established in sub-Saharan African and other third countries should still be able to participate in the calls without receiving funding. Additionally it should also be possible for entities established in other countries than members of the EDCTP3 Association to be eligible for funding in specific call topics or in the event of a call addressing a public health emergency, where it is provided for in the work programme. The Global Health EDCTP3 Joint Undertaking should take all appropriate measures, including contractual, to protect the financial interests of the Union. The conclusion of science and technology agreements with third countries should be sought. Before their conclusion, where entities established in a third country without such an agreement participate with funding in an indirect action, alternative measures to safeguard Union interests should be applied by the Global Health EDCTP3 Joint Undertaking, namely the financial coordinator of the action should be established in a Member State or associated country and the amount of pre-financing as well as liability provisions of the grant agreement should be adapted to adequately take the financial risks into account.
- (73) In the context of the Commission's priorities of 'An economy that works for people' and 'A Europe fit for the digital age', the European industry, including SMEs, should become greener, more circular and more digital while remaining competitive on the global scale. The Commission has emphasised the role of medical devices and digital technologies addressing emerging challenges and the use of e-health services to provide high-quality health care, along with a call for ensuring the supply of affordable medicines to meet the Union's needs, whilst supporting an innovative and world-leading European pharmaceutical industry. The Innovative Health Initiative Joint Undertaking aims to contribute to strengthening the competitiveness of the Union's health industry, a cornerstone of the Union's knowledge-based economy, to an increased economic activity in the development of health technologies, in particular of integrated health solutions, and thus serve as a tool for increasing technological leadership and fostering the digital transformation of our societies. Such political priorities can be achieved by bringing together the crucial players, namely academia, companies of various sizes and end-users of health innovations, under the umbrella of a public-private partnership in health research and innovation. The Innovative Health Initiative Joint Undertaking should help reach the objectives of the 'Europe's Beating Cancer Plan' and the 'European One Health

Action Plan against Antimicrobial Resistance'. The Innovative Health Initiative Joint Undertaking should be in line with the communications from the Commission 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 25 November 2020 on the Pharmaceutical Strategy for Europe.

- (74) The Innovative Health Initiative Joint Undertaking builds on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 Joint Undertaking) including the work done by that preceding initiative to combat the COVID-19 pandemic. In line with the recommendations of the interim evaluation of the IMI2 Joint Undertaking, a successor initiative needs to enable the active engagement of other industry sectors with the pharmaceutical industry to capitalise on their expertise in the development of new health care interventions. Therefore, the industry sectors need to cover the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area. The scope of the joint undertaking should cover prevention, diagnosis, treatment and disease management and must be established taking due account of the high burden for patients or society or both due to the severity of the disease or the number of people affected, as well as the high economic impact of the disease for patients and for health care systems. The funded actions must respond to the Union public health needs, supporting the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems.
- (75) To ensure the best opportunity for generating new scientific ideas and successful research and innovation activities, the key actors in Innovative Health Initiative Joint Undertaking should be researchers from various types of entities, public and private. At the same time, end-users such as Union citizens, health care professionals and health care providers should provide input into the strategic design and activities of the joint undertaking, ensuring that it addresses their needs. Furthermore, Union-wide and national regulatory authorities, health technology assessment bodies and health care payers should also provide early input to the partnership's activities, while ensuring the absence of any conflicts of interest, in order to increase the likelihood that the results of funded actions meet the requirements necessary for uptake and thus achieve the expected impacts. All such input should help better target research efforts towards areas of unmet need.
- (76) Current health challenges and threats are global. Therefore, the Innovative Health Initiative Joint Undertaking should be open to participation by international academic, industrial and regulatory actors, in order to benefit from wider access to data and expertise, to respond to emerging health threats and to achieve the necessary societal impact, in particular improved health outcomes for Union citizens. At the same time, most of the partnership's activities should be conducted in the Member States and in Horizon Europe associated countries.
- (77) The partnership's objectives should focus on the pre-competitive area, thereby creating a safe space for efficient collaboration between companies active in different health technologies. To reflect the integrative nature of the Innovative Health Initiative Joint Undertaking, help break the silos between health industry sectors and strengthen industry-academia collaborations, the majority of the projects funded by the Joint Undertaking should be cross-sectoral.
- (78) The term Key Digital Technologies refers to electronic components and systems that underpin all major economic sectors. The Commission highlighted the need to master such technologies in Europe, in particular in the context of delivering on European policy priorities such as digital leadership. The importance of the area and the challenges faced by the stakeholders in the Union require urgent action in order to leave no weak link in Europe's innovation and value chains. A mechanism at Union level should therefore be set up to combine and focus the provision of support to research and innovation in electronic components and systems by the Member States, the Union and the private sector.

- (79) The Key Digital Technologies Joint Undertaking should address clearly defined topics that would enable European industries at large to design, manufacture and use the most innovative technologies in electronic components and systems. Structured and coordinated financial support at European level is necessary to help research teams and European industries maintain their current strengths at the leading edge in a highly competitive international context and close the gap in technologies that are critical for a digital transformation in Europe that reflects core Union values including privacy and trust, security and safety. Collaboration among stakeholders of the ecosystem, representing all segments of the value chains, is essential for the development of new technologies and the fast market uptake of innovation. Openness and flexibility to integrate relevant stakeholders, including in particular SMEs, in emerging or adjacent areas of technology or in both, is also vital.
- (80) The Key Digital Technologies Joint Undertaking should combine the financial and technical means that are essential to master the escalating pace of innovation in this area, to generate important spill-overs for society, and to share risk-taking by aligning strategies and investments towards a common European interest. Therefore, the members of the Key Digital Technologies Joint Undertaking should be the Union, Member States and associated countries to Horizon Europe on a voluntary basis, and associations as private members representing their constituent entities. Participation of Member States will furthermore facilitate a coherent alignment with national programmes and strategies, reducing overlap and fragmentation of efforts while ensuring synergies across stakeholders and activities.
- (81) In implementing the contributions of the participating states to their national participants in indirect actions, the Key Digital Technologies Joint Undertaking should take into account that the participating states have to abide by strict national budgetary rules. In that respect, participating states should give indicative financial commitments prior to the adoption of each annual work programme and should conclude legally binding agreements with the joint undertaking, committing participating states to the payment arrangements of their contribution to indirect actions throughout the lifetime of the joint undertaking. Such agreements should be concluded in the context of the annual budgetary procedure and programming of the joint undertaking. The Governing Board should adopt the annual work programme taking due account of those indicative commitments. The Public Authorities Board should select proposals. Only after those steps, and in line with the joint undertaking's financial rules, the authorising officer should make the budgetary and legal commitments for those indirect actions.
- (82) As a continuation of the practice established in the ECSEL Joint Undertaking, a derogation from Article 34 of the Horizon Europe Regulation is necessary in order to allow different funding rates depending on the type of participant, in particular SMEs and non-profit legal entities, and the type of action, to be applied invariably across beneficiaries from all participating states. That should ensure the right balance of stakeholder participation in the actions funded by the Key Digital Technologies Joint Undertaking and foster a higher level of involvement of SMEs as recommended in the ECSEL Joint Undertaking interim evaluation.
- (83) The Key Digital Technologies Joint Undertaking includes Member States and associated countries as members of the Public Authorities Board, and thus a state representative group should not be established.
- (84) The Union's Single European Sky legal framework established by Regulation (EC) No 549/2004 of the European Parliament and of the Council⁽¹⁸⁾ seeks to reform the European air traffic management (ATM) system through institutional, operational, technological and regulatory actions with the aim of improving its performance in terms of capacity, safety, efficiency and environmental impact.

⁽¹⁸⁾ Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European Sky (OJ L 96, 31.3.2004, p. 1).

- (85) The Single European Sky ATM Research and Development project (the 'SESAR project') established by Council Regulation (EC) No 219/2007 ⁽¹⁹⁾ aims to modernise ATM and to bundle technological and operational innovation in support of the Single European Sky. It aims to provide the technological solutions for a highly performing ATM by 2035 to enable an uncongested, even safer and more environmentally and climate friendly functioning of the air transport sector, in line with the European Green Deal and the European Climate Law. The SESAR project comprises three interrelated, continuous and evolving collaborative processes that define, develop and deploy innovative technological systems and operational procedures underlying the digital European sky defined in the European ATM Master Plan referred to in Council Decision 2009/320/EC ⁽²⁰⁾.
- (86) The European ATM Master Plan is the planning tool for ATM modernisation across Europe, connecting ATM research and innovation activities with deployment activities scenarios to achieve the Single European Sky performance objectives.
- (87) The SESAR Joint Undertaking was established with the objective of managing the definition and development phases of the SESAR project, by combining public and private sector funding provided by its members and by drawing on internal and external technical resources, as well as to execute and update, when necessary, the European ATM Master Plan. It established a new and efficient form of collaboration between stakeholders in a sector where progress is only possible when all stakeholders implement new solutions in a synchronised manner. Given the successful establishment of the SESAR brand name, the new Single European Sky ATM Research 3 Joint Undertaking should continue to make use of it.
- (88) The Single European Sky ATM Research 3 Joint Undertaking should build on the experience of the SESAR Joint Undertaking and continue its coordination role for ATM research in the Union. The main objectives of the Single European Sky ATM Research 3 Joint Undertaking should be to strengthen and further integrate the research and innovation capacity in Europe, helping to accelerate the digitalisation of the sector and rendering it more resilient and scalable to fluctuations in traffic. It should strengthen, through innovation, the competitiveness of manned and unmanned air transport and ATM services, to support economic recovery and growth. It should develop and accelerate the market uptake of innovative solutions to establish the Single European Sky airspace as the most efficient and environmentally friendly sky to fly in the world.
- (89) The new Single European Sky ATM Research 3 Joint Undertaking should be able to develop and validate technical input assisting the Commission with regulatory activities in ATM, for example preparing all the technical documentation for the common projects established under a Regulation of the European Parliament and of the Council on the implementation of the Single European Sky, conducting technical studies or supporting standardisation activities. It should also ensure the stewardship of the European ATM Master Plan endorsed by Decision 2009/320/EC, including its monitoring, reporting and updating. In addition, the Commission should have votes in proportion to the Union contribution to the budget, and at least 25 % of votes. This set-up ensures that the Commission retains a strong ability to steer, from a policy perspective, the work carried out by the Joint Undertaking in relation to those tasks through the strengthened supervision mechanisms established for such bodies.
- (90) Participation in the Single European Sky ATM Research 3 Joint Undertaking should be open to the widest possible range and representation of stakeholders from all Member States and countries associated to Horizon Europe, including SMEs, through different forms of participation. In particular, participation should ensure a proper balance between equipment manufacturers for both manned and unmanned aviation, airspace users, air navigation service providers, airports, military and professional staff associations, and offer opportunities to SMEs, academia and research organisations. With a view to identifying the most promising approaches and entities capable of pursuing them, the Commission launched a call for expression of interest for potential members. The Governing Board should be allowed to select associated members on the basis of the results of that call in order to provide for a swift expansion of the group of members.

⁽¹⁹⁾ Council Regulation (EC) No 219/2007 of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) (OJ L 64, 2.3.2007, p. 1).

⁽²⁰⁾ Council Decision 2009/320/EC of 30 March 2009 endorsing the European Air Traffic Management Master Plan of the Single European Sky ATM Research (SESAR) project (OJ L 95, 9.4.2009, p. 41).

- (91) Route charges are entirely borne by airspace users, who contribute indirectly to the research and development efforts financed by major ATM stakeholders like air navigation service providers or the manufacturing industry building and equipping the aircrafts used by the airspace users. Therefore, airspace users should be given appropriate representation within the Single European Sky ATM Research 3 Joint Undertaking's Governing Board.
- (92) To ensure that the results of ATM exploratory (low TRLs) research are effectively used at higher TRLs, and in particular by the Single European Sky ATM Research 3 Joint Undertaking, the joint undertaking's programme office should manage such activities.
- (93) The Eurocontrol Agency possesses an appropriate infrastructure and the necessary administrative, IT, communications and logistics support services. The Single European Sky ATM Research 3 Joint Undertaking should benefit from such infrastructure and services from Eurocontrol. In this context, there are few potential synergies that could be gained from pooling administrative resources with other Joint Undertakings through a common back office. For this reason, the Single European Sky ATM Research 3 Joint Undertaking should opt out from the back office arrangements established by this Regulation.
- (94) With the purpose of creating a broad stakeholder base for ensuring the Smart Networks and Services partnership's objectives, the 6G Smart Networks and Services Industry Association (6G-IA) has been established building on the predecessor association. While the new industry association, in the first years following its establishment, is expected to have only a limited number of constituent and affiliated entities, it has the objective to include new members from stakeholder constituencies active in the Smart Network and Services value chain. Considering its expected modest size and the impact on its SMEs constituent entities, it is not sustainable for the association to contribute to 50 % of the administrative costs of the Smart Networks and Services Joint Undertaking over its lifetime, in particular in the first years following its establishment. Additionally, the crisis brought about by the COVID-19 pandemic and its impact on the economy has posed challenges for the European economic actors including in the field of information and communications technology. Therefore it should be ensured that the private partners of the joint undertaking are able to fulfil their commitments, while the conditions remain attractive and incentivise new partners to join the association. The minimum percentage of annual financial contribution to the administrative costs from members other than the Union should therefore be 20 % of the total annual administrative costs. In particular, it should be possible that SMEs constituent entities contribute less than bigger enterprises. The members of the joint undertaking other than the Union should endeavour to increase the number of constituent or affiliated entities in order to increase their contribution to 50 % of the administrative costs of the joint undertaking over its lifetime.
- (95) In the context of Commission priorities for 2019-2024 'A Europe fit for the digital age', 'An economy that works for people' and the policy objectives set out in the context of its communication on 'Shaping Europe's digital future', Europe needs to develop critical digital infrastructures based on 5G networks and build its technological capacities towards 6G with a time horizon of 2030. In this context, the Commission has emphasised the strategic importance of a European partnership for Smart Networks and Services to provide secure connectivity-based services to consumers and businesses. Those priorities can be achieved by bringing together the key players, namely industry, academia and public authorities, under the umbrella of a European partnership that builds on the achievements of the 5G Infrastructure Public Private Partnership preceding initiative, which successfully developed 5G technology and standards.
- (96) The Smart Networks and Services Joint Undertaking is designed to address policy issues in the field of digital infrastructure, to support 5G infrastructure deployment within the scope of the Connecting Europe Facility 2 (CEF2) Digital programme established by Regulation (EU) 2021/1153 of the European Parliament and of the Council ⁽²¹⁾ and to extend the technology scope of research and innovation for 6G networks. It should, with close involvement of the Member States, strengthen the response to Union policy and social needs regarding network

⁽²¹⁾ Regulation (EU) 2021/1153 of the European Parliament and of the Council of 7 July 2021 establishing the Connecting Europe Facility and repealing Regulations (EU) No 1316/2013 and (EU) No 283/2014 (OJ L 249, 14.7.2021, p. 38).

energy efficiency, cybersecurity, technological leadership, privacy and ethics and should extend the research and innovation scope from networks to cloud-based service provisioning as well as components and devices enabling services for citizens and a broad range of economic sectors such as health care, transport, manufacturing and media.

- (97) The public policy objectives related to Smart Networks and Services cannot be addressed solely by the industry and the Commission. Addressing them from a holistic and coordinated perspective requires in particular the strategic involvement of the Member States as part of the governance structure. Therefore, the Governing Board should take utmost account of the opinions of the states' representatives group, in particular as regards strategic guidance concerning work programmes and funding decisions.
- (98) Advanced 5G infrastructures will be the basis for developing the ecosystems for the digital and green transitions and, in the next step, for Europe's position to adopt 6G technology. The CEF2 Digital programme as well as the Digital Europe Programme (DEP) established by Regulation (EU) 2021/694 of the European Parliament and of the Council ⁽²²⁾ and InvestEU established by Regulation (EU) 2021/523 of the European Parliament and of the Council ⁽²³⁾ offer opportunities for the development of 5G- and later 6G-based digital ecosystems. Taking into account the broad set of public and private stakeholders involved in such deployment projects, it is essential to coordinate the setting-up of a strategic agenda, the contribution to the programming and the stakeholder information and engagement related to such programmes. As a strategic basis for those tasks, the Smart Networks and Services Joint Undertaking should coordinate the development of Strategic Deployment Agendas for the relevant areas of deployment, such as 5G systems along roads and along railways. Those agendas should, inter alia, support setting out deployment roadmaps, the main options for cooperation models and other strategic issues.
- (99) Article 20(3) of the Horizon Europe Regulation provides that, where appropriate, the Commission or funding body has to carry out a security scrutiny for proposals raising security issues.
- (100) Pursuant to the Council Conclusions of 3 December 2019 and the Recommendation of 26 March 2019 on Cybersecurity of 5G networks for coordinated action at Union level, the Member States' Cooperation Group on Network and Information Security published the EU toolbox of risk mitigating measures concerning cyber-security of 5G networks of January 2020 (the 'toolbox'). The toolbox includes a set of strategic and technical measures as well as supporting actions in order to mitigate the main cybersecurity risks of 5G networks, which have been identified in the Union coordinated risk assessment report, and to provide guidance for the selection of measures that should be prioritised in mitigation plans at national and at Union level. The Commission Communication of 29 January 2020 on Implementing the EU toolbox endorses all measures and guidance set out in the toolbox and emphasises the need for restrictions, including necessary exclusions, concerning suppliers considered to be high risk based on the factors specified in the Union coordinated risk assessment as well as measures to avoid dependency on those suppliers. It also identifies a set of specific actions for the Commission, in particular to ensure that participation in Union funding programmes in relevant technology domains will be conditional on compliance with security requirements, by making full use of and further implementing security conditions. Therefore, the implementation of this Regulation should introduce appropriate provisions to reflect the security measures through actions funded by the SNS Joint Undertaking and, on the basis of its recommendations, by other funding bodies implementing other Union programmes in the area of smart networks and services.

⁽²²⁾ Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240 (OJ L 166, 11.5.2021, p. 1).

⁽²³⁾ Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017 (OJ L 107, 26.3.2021, p. 30).

- (101) The joint undertakings under Horizon 2020 were set up for a period up to 31 December 2024. The joint undertakings should provide continued support to the respective research programmes by implementing the remaining actions initiated or continued under Council Regulations (EC) No 219/2007, (EU) No 557/2014 ⁽²⁴⁾, (EU) No 558/2014 ⁽²⁵⁾, (EU) No 559/2014 ⁽²⁶⁾, (EU) No 560/2014 ⁽²⁷⁾, (EU) No 561/2014 ⁽²⁸⁾ and (EU) No 642/2014 ⁽²⁹⁾ and in accordance with those Regulations until their winding-up. In the interest of legal certainty and clarity those Regulations should therefore be repealed.
- (102) The Union should act only where there is a demonstrable advantage that action at Union level is more effective than action taken at national, regional or local level. The joint undertakings focus on areas where there is a demonstrable added value in acting at the Union level due to the scale, speed and scope of the efforts needed for the Union to meet its long-term TFEU objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed joint undertakings should be seen as complementary to and should reinforce national and sub-national activities in the same area.
- (103) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, but can rather, by reason of avoiding unnecessary duplication, retaining critical mass and ensuring that public financing is used in an optimal way, be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union (TEU). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (104) In order to ensure continuity in providing support in the relevant policy areas, this Regulation should enter into force as a matter of urgency on the day of its publication,

HAS ADOPTED THIS REGULATION:

PART ONE

COMMON PROVISIONS

TITLE I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation sets up nine joint undertakings within the meaning of Article 187 TFEU for the implementation of institutionalised European partnerships referred to in Article 10(1), point (c), of the Horizon Europe Regulation. It determines their objectives and tasks, membership, organisation and other operating rules.

⁽²⁴⁾ Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (OJ L 169, 7.6.2014, p. 54).

⁽²⁵⁾ Council Regulation (EU) No 558/2014 of 6 May 2014 establishing the Clean Sky 2 Joint Undertaking (OJ L 169, 7.6.2014, p. 77).

⁽²⁶⁾ Council Regulation (EU) No 559/2014 of 6 May 2014 establishing the Fuel Cells and Hydrogen 2 Joint Undertaking (OJ L 169, 7.6.2014, p. 108).

⁽²⁷⁾ Council Regulation (EU) No 560/2014 of 6 May 2014 establishing the Bio-based Industries Joint Undertaking (OJ L 169, 7.6.2014, p. 130).

⁽²⁸⁾ Council Regulation (EU) No 561/2014 of 6 May 2014 establishing the ECSEL Joint Undertaking (OJ L 169, 7.6.2014, p. 152).

⁽²⁹⁾ Council Regulation (EU) No 642/2014 of 16 June 2014 establishing the Shift2Rail Joint Undertaking (OJ L 177, 17.6.2014, p. 9).

*Article 2***Definitions**

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

1. 'member other than the Union' means any participating state, private member or international organisation that is a member of a joint undertaking;
2. 'founding member' means any legal entity established in a Member State, a country associated to Horizon Europe, or an international organisation that is identified as a member of a joint undertaking in this Regulation or in one of its Annexes;
3. 'associated member' means any legal entity established in a Member State, a country associated to Horizon Europe, or an international organisation that accedes to a joint undertaking by signing a letter of commitment in accordance with Article 6(3) and subject to an approval in accordance with Article 7;
4. 'participating state' means any Member State or country associated to Horizon Europe upon notification of its participation in the activities of the relevant joint undertaking by means of a letter of commitment;
5. 'private member' means any legal entity established under public or private law that is a member of a joint undertaking other than the Union, participating states or international organisations;
6. 'constituent entities' means the entities that constitute a private member of a joint undertaking, where the private member is an association according to that member's statutes;
7. 'contributing partner' means any country, international organisation or legal entity other than a member of a joint undertaking, or a constituent entity of a member or an affiliated entity of either, that supports the objectives of a joint undertaking in its specific area of research and whose application has been approved in accordance with Article 9;
8. 'in-kind contributions to operational activities' means contributions by private members, constituent entities or the affiliated entities of either, by international organisations and by contributing partners, consisting of the eligible costs incurred by them in implementing indirect actions less the contribution of that joint undertaking and of the participating states of that joint undertaking to those costs;
9. 'additional activity' means an activity, included in the annual additional activities plan annexed to the main part of the work programme, that does not receive financial support from the joint undertaking but contributes to its objectives and is directly linked to the uptake of results from projects under that joint undertaking or its preceding initiatives or that has a significant Union added value;
10. 'in-kind contributions to additional activities' means contributions by the private members, constituent entities or the affiliated entities of either, and by international organisations, consisting of the costs incurred by them in implementing additional activities less any contribution to those costs from the Union and from the participating states of that joint undertaking;
11. 'preceding initiative' means any partnership in one of the areas covered by a joint undertaking that received financial support from one of the previous Union framework programmes for research;
12. 'Strategic Research and Innovation Agenda' means the document covering the duration of Horizon Europe that identifies the key priorities and the essential technologies and innovations required to achieve the objectives of a joint undertaking;
13. 'work programme' means the document referred to in Article 2, point (25), of the Horizon Europe Regulation;

14. 'conflict of interest' means a situation involving a financial actor or other person as referred to in Article 61 of Regulation (EU, Euratom) 2018/1046;
15. 'newcomer' means an entity that is, for the first time, a beneficiary of a grant awarded by an individual joint undertaking or its preceding initiative and that is not a founding member of that joint undertaking or its preceding initiative.

Article 3

Establishment

1. The following joint undertakings are set up as Union bodies for a period ending on 31 December 2031 and financed under the MFF 2021-2027:
 - (a) the Circular Bio-based Europe Joint Undertaking;
 - (b) the Clean Aviation Joint Undertaking;
 - (c) the Clean Hydrogen Joint Undertaking;
 - (d) the Europe's Rail Joint Undertaking;
 - (e) the Global Health EDCTP3 Joint Undertaking;
 - (f) the Innovative Health Initiative Joint Undertaking;
 - (g) the Key Digital Technologies Joint Undertaking;
 - (h) the Single European Sky ATM Research 3 Joint Undertaking;
 - (i) the Smart Networks and Services Joint Undertaking.
2. The Union bodies referred to in paragraph 1 shall be collectively referred to as the 'joint undertakings'.
3. In order to take into account the duration of Horizon Europe, calls for proposals under the joint undertakings shall be launched at the latest by 31 December 2027. In duly justified cases, calls for proposals may be launched by 31 December 2028, at the latest.
4. The joint undertakings shall have legal personality. In each of the Member States, they shall enjoy the most extensive legal capacity accorded to legal persons under the laws of that Member State. They may, in particular, acquire or dispose of movable and immovable property and may be a party to legal proceedings.
5. The seat of the joint undertakings shall be in Brussels, Belgium.
6. Unless specified otherwise, the provisions set out in Part One and Part Three shall apply to all joint undertakings. The provisions set out in Part Two shall apply to individual joint undertakings, as appropriate.
7. For the purposes of Parts One and Three and unless specified otherwise, a reference to an individual joint undertaking or body shall denote a reference to each joint undertaking or each equivalent body of the individual joint undertakings and its competences in relation to other bodies of the same joint undertaking.

TITLE II

FUNCTIONING OF THE JOINT UNDERTAKINGS

CHAPTER 1

Objectives and tasks*Article 4***Objectives and principles**

1. The joint undertakings referred to in Article 3 of this Regulation shall contribute to the general and specific objectives of the Horizon Europe Regulation as set out in Article 3 thereof.
2. The joint undertakings shall, through the involvement and commitment of partners in designing and implementing a programme of research and innovation activities with European added value, deliver collectively on the following general objectives:
 - (a) strengthening and integrating the scientific, innovation and technological capacities and facilitating collaborative links across the Union to support the creation and diffusion of high-quality new knowledge and skills, in particular with a view to delivering on global challenges, securing and enhancing Union competitiveness, European added value, resilience and sustainability and contributing to a reinforced European Research Area (ERA);
 - (b) securing sustainability-driven global leadership and resilience of Union value chains in key technologies and industries in line with the industrial and SMEs strategies for Europe, the European Green Deal, the European Recovery Plan and other relevant Union policies;
 - (c) developing and accelerating the uptake of innovative solutions throughout the Union addressing climate, environmental, health, digital and other global challenges contributing to Union strategic priorities, accelerating the economic growth of the Union and fostering the innovation ecosystem, while reaching the United Nations Sustainable Development Goals and achieving climate neutrality in the Union at the latest by 2050, in line with the Paris Agreement, thereby improving the quality of life of European citizens.
3. The joint undertakings shall deliver on the following specific objectives:
 - (a) enhance the critical mass and scientific and technological capabilities and competences in collaborative, cross-sectoral, cross policy, cross-border and interdisciplinary research and innovation across the Union as well as facilitate their integration into European ecosystems;
 - (b) accelerate the green and digital transitions as well as economic, social and societal transformations in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas emissions by 2030 in accordance with the climate and energy targets set in line with the European Green Deal and the European Climate Law;
 - (c) enhance the research and innovation capabilities and performance of existing and new European innovation ecosystem and economic value chains, including in start-ups and SMEs;
 - (d) accelerate the deployment, uptake and diffusion of innovative solutions, technologies, services and skills in reinforced European research and innovation ecosystems and industrial ecosystems, including through wide and early engagement and co-creation with end-users, including SMEs and start-ups, citizens and regulatory and standardisation bodies;
 - (e) deliver environmental, energy, resource-saving, societal, circularity and productivity improvements in new products, technologies, applications and services by exploiting Union capabilities and resources.
4. The joint undertakings shall also have the additional objectives set out in Part Two.

5. In the implementation of the Horizon Europe Regulation, the joint undertakings shall respect the principles set out in Article 7 of that Regulation.

6. The joint undertakings shall adhere to the conditions and criteria for European partnerships set out in Article 10 of and Annex III to the Horizon Europe Regulation.

Article 5

Operational objectives and tasks

1. The joint undertakings shall adhere to the following operational objectives in accordance with the criteria set out in Annex III to the Horizon Europe Regulation, and contribute to the operational objectives of Horizon Europe set out in the Specific Programme implementing Horizon Europe:

- (a) reinforce and spread excellence, including by fostering wider participation and boosting collaborative links throughout the Union;
- (b) strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities;
- (c) stimulate research and innovation activities in SMEs and contribute to the creation and scaling-up of innovative companies, in particular start-ups, SMEs and, in exceptional cases, small mid-caps;
- (d) reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities;
- (e) strengthening gender mainstreaming, including the integration of gender dimension in the research and innovation content;
- (f) increase collaboration links in European research and innovation and across sectors and disciplines, including social sciences and humanities;
- (g) strengthen international cooperation in support of Union policy objectives and international commitments;
- (h) increase public awareness and acceptance, respond to demand and encourage the diffusion and uptake of new solutions by involving, where appropriate, citizens and end-users in co-design and co-creation processes;
- (i) encourage exploitation of research and innovation results and actively disseminate and exploit results, in particular for leveraging private investments and for policy development;
- (j) accelerate industrial transformation and resilience across the value chains, including through improving skills for innovation and advancing digital technology;
- (k) support the scientific evidence-based implementation of related Union policies, as well as regulatory, standardisation and sustainable investment activities at national, European and global levels.

2. The joint undertakings shall carry out the following tasks by adopting a systemic approach in achieving the objectives:

- (a) provide financial support, mainly in the form of grants, to research and innovation indirect actions, selected following open, transparent and competitive calls except in duly justified cases specified in their work programme in order to set additional conditions requiring the participation of members of the joint undertaking or their constituent or affiliated entities;
- (b) develop close cooperation and ensure coordination with other European partnerships, including by dedicating, where appropriate, a part of the joint undertaking's budget to joint calls;
- (c) seek and maximise synergies with and, where appropriate, possibilities for further funding from relevant activities and programmes at Union, national and regional level, in particular with those supporting the deployment and uptake of innovative solutions, training, education and regional development, such as Cohesion Policy Funds, or the national Recovery and Resilience Plans;

- (d) ensure their operations contribute towards the strategic multiannual planning, reporting, monitoring and evaluation and other requirements of Horizon Europe set out in Articles 50 and 52 of the Horizon Europe Regulation, such as the implementation of the common policy feedback framework;
- (e) promote the involvement of SMEs and start-ups in their activities and ensure the provision of timely information to them, in line with the objectives of Horizon Europe;
- (f) develop a targeted approach within their Strategic Research and Innovation Agenda to implement measures for attracting newcomers, in particular SMEs, higher education institutions and research organisations, for expanding collaborative networks;
- (g) mobilise the public and private sector resources needed to achieve the objectives set out in this Regulation;
- (h) monitor progress towards the achievement of the objectives set out in this Regulation, as well as in accordance with the provisions set out in Article 50 of and Annexes III and V to the Horizon Europe Regulation;
- (i) define and implement their work programme;
- (j) liaise with the most extensive range of stakeholders including, but not limited to, decentralised agencies, research organisations and higher education institutions, end users and public authorities, in particular for the purpose of defining the priorities and activities of each joint undertaking as well as to ensure transparency, openness and inclusiveness, and benefits to society;
- (k) engage in information, communication, publicity and dissemination and exploitation activities by applying *mutatis mutandis* Article 51 of the Horizon Europe Regulation, including by making the detailed and coherent information on results from funded research and innovation activities available and accessible in a common Horizon Europe e-database, in a timely manner;
- (l) provide the Commission with the necessary technical, scientific and administrative support to carry out its tasks for the purposes of ensuring the proper functioning and development in the Union of the specific areas addressed by the joint undertaking;
- (m) contribute to developing a more effective science-policy interface, to fostering open science by ensuring better use of results and to addressing policy needs, as well as to promoting faster exploitation, dissemination and uptake of results in accordance with Articles 14 and 39 of the Horizon Europe Regulation;
- (n) identify and report, in line with the common policy feedback framework and with strategies and actions to support the European Green Deal objectives, the relevant knowledge acquired from the management of research and innovation projects and their results to the Commission to serve as input for monitoring, evaluating and rectifying, where necessary, existing policy measures or shaping new policy initiatives and decisions;
- (o) support the Commission in the development and implementation of robust science-based technical screening criteria pursuant to Article 3 of Regulation (EU) 2020/852 on sustainable investments, by monitoring and assessing their implementation within the economic sector in which they operate, in order to provide ad hoc feedback to policy-making, when needed;
- (p) consider the 'do no significant harm' principle pursuant to Article 17 of Regulation (EU) 2020/852 for activities of the joint undertakings falling within the scope of that Regulation and take into account the provisions of that Regulation to improve access to sustainable finance, where relevant;
- (q) perform any other task necessary to achieve the objectives set out in this Regulation.

3. In addition to the tasks set out in this Article and in Part Two, the joint undertakings may be entrusted with the implementation of additional tasks requiring cumulative, complementary or combined funding between Union programmes.

CHAPTER 2

Members, contributing partners and contributions*Article 6***Members**

1. The members of the joint undertakings referred to in Article 3 shall be the Union, represented by the Commission, and any of the following, as specified in Part Two:
 - (a) participating states;
 - (b) founding members;
 - (c) associated members.
2. Membership of a joint undertaking may not be transferred to a third party without the prior agreement of the governing board referred to in Chapter 3, Section 1 of this Title.
3. A letter of commitment shall be signed by founding members and associated members and shall detail the scope of the membership in terms of content, activities and its duration, as well as the founding members' and associated members' contributions to the joint undertaking, including an indication of the envisaged additional activities referred to in Article 11(1), point (b).

*Article 7***Selection of associated members**

1. Joint undertakings may launch open and transparent calls for expression of interest with a view to selecting associated members with the potential to contribute to the achievement of the objectives of the joint undertakings. Joint undertakings whose founding members are listed in Annexes I, II and III shall launch such calls. The call for expression of interest shall set out the key capacities needed in order to achieve the objectives of the joint undertaking and may request applicants to provide an indication of their potential contributions. All calls shall be published on the joint undertaking's website and communicated through all appropriate channels including, where applicable, the states' representatives group, in order to ensure the widest possible participation in the interest of achieving the objectives of the joint undertaking.
2. The executive director shall assess the applications for membership with the assistance of independent experts and, where appropriate, of relevant bodies of the joint undertaking, on the basis of documented knowledge, experience and added value of the applicant in achieving the objectives of the joint undertaking, the applicant's financial soundness and long-term commitment for financial and in-kind contributions to the joint undertaking, and taking into account potential conflicts of interest.
3. The governing board shall assess and approve or reject applications for membership.

*Article 8***Changes to or termination of membership**

1. Any member of a joint undertaking may terminate its membership of that joint undertaking. The termination shall become effective and irrevocable six months after notification to the executive director of the joint undertaking, who shall inform the other members. As from the date of termination, the member shall be discharged from any obligations other than those approved or incurred by the joint undertaking prior to terminating the membership, unless mutually agreed otherwise.
2. Each private member shall inform in a timely manner the joint undertaking of any merger or acquisition between members likely to affect the joint undertaking or any takeover of a member by an entity that is not a member of the joint undertaking.

3. The governing board shall decide whether to terminate the membership of any member referred to in paragraph 2, with a view to ensuring business continuity and protecting the Union's or the joint undertaking's interest. The termination shall become effective and irrevocable no later than six months from the decision of the governing board or on the date specified in that decision, whichever is earlier. The member or members concerned shall not participate in the vote of the governing board.
4. Each private member shall inform in a timely manner the joint undertaking of any other significant changes in its ownership, control or composition. Where the Commission considers that the change is likely to affect the Union's or the joint undertaking's interest on grounds of security or public order, it may propose to the governing board to terminate the membership of the concerned private member. The governing board shall decide on a termination of the membership of the private member concerned. The private member concerned shall not participate in the vote of the governing board.
5. The termination shall become effective and irrevocable not later than six months from the decision of the governing board or on the date specified in that decision, whichever is earlier.
6. The governing board may terminate the membership of any member that fails to fulfil its obligations pursuant to this Regulation. The procedure set out in Article 28(6) applies *mutatis mutandis*.
7. Where appropriate, the Commission may request private members to take appropriate measures to ensure that the Union's and the joint undertaking's interest on grounds of security or public order are safeguarded.
8. Where there is a change to membership or termination, the joint undertaking shall immediately publish on its website an updated list of its members, together with the date when such change shall take effect.
9. Where appropriate and subject to Article 16(3), the governing board shall decide on a redistribution of the voting rights in the governing board due to the change to membership or due to termination.

Article 9

Contributing partners

1. Any candidate contributing partner as defined in Article 2, point (7), shall submit a letter of endorsement to the governing board. The letter of endorsement shall specify the scope of the partnership in terms of subject matter, activities and their duration and detail the applicant's contribution to the joint undertaking.
2. The governing board shall assess the letter of endorsement and shall approve or reject the application.
3. Contributing partners shall not have voting rights in the governing board of a joint undertaking.

Article 10

Union financial contribution

1. The Union financial contribution to the joint undertakings, including European Economic Area (EEA) appropriations, shall cover administrative and operational costs up to the maximum amounts specified in Part Two, provided that that amount is at least matched by the contribution of members other than the Union or their constituent or affiliated entities.
2. The amount of the Union contribution specified in Part Two may be increased with contributions from third countries associated to Horizon Europe in line with Article 16(5) of the Horizon Europe Regulation and provided that the total amount by which the Union contribution is increased is at least matched by the contribution of members other than the Union, or their constituent or affiliated entities.

3. The Union contribution shall be paid from the appropriations in the general budget of the Union allocated to the Specific Programme implementing Horizon Europe, in accordance with Article 62(1), point (c)(iv), and Article 154 of Regulation (EU, Euratom) 2018/1046 in the case of bodies referred to in Article 71 of that Regulation.
4. Additional Union funds complementing the contribution referred to in paragraph 3 of this Article may be entrusted to the joint undertakings in accordance with Article 62(1), point (c)(iv), and Article 154 of Regulation (EU, Euratom) 2018/1046.
5. For contributions corresponding to additional tasks entrusted to a Joint Undertaking in accordance with paragraph 4 of this Article or Article 5(3) of this Regulation, the requirements of Article 155 of Regulation (EU, Euratom) 2018/1046 are applicable.
6. Additional contributions from Union programmes corresponding to additional tasks entrusted to a joint undertaking pursuant to paragraph 4 of this Article or Article 5(3) shall not be accounted for in the calculation of the Union maximum financial contribution specified in Part Two.

Article 11

Contributions from members other than the Union and contributing partners

1. Unless specified otherwise in Part Two, the contributions of private members shall consist of financial contributions and of any of the following:
 - (a) in-kind contributions to operational activities;
 - (b) in-kind contributions to additional activities, approved by the governing board in accordance with Article 17(2), point (n).
2. Unless specified otherwise in Part Two, the private members shall report by 31 May each year at the latest to their respective governing board on the value of the contributions referred to in paragraph 1, point (b), made in each of the previous financial years. For the purpose of valuing these contributions, the costs shall be determined in accordance with the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where the entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards. The costs shall be certified by an independent audit body appointed by the entity concerned and shall not be audited by the joint undertaking concerned or any Union body. The valuation method may be verified by the joint undertaking concerned should there be any uncertainty arising from the certification. In duly specified cases, the governing board may authorise the use of lump sums or unit costs for valuing those contributions.
3. The contributions from participating states shall consist of financial contributions. The participating states shall report by 31 January of each year to the governing board on the financial contributions made in the previous financial year.
4. The contributions from international organisations shall consist of financial contributions and in-kind contributions to operational activities, unless specified otherwise in Part Two.
5. The contributions from contributing partners shall correspond to the amounts they have committed in the letter of endorsement when becoming a contributing partner and shall consist of financial contributions and in-kind contributions to operational activities.
6. The Commission may terminate, proportionally reduce or suspend the Union financial contribution to a joint undertaking or trigger the winding-up procedure referred to in Article 45 in any of the following cases:
 - (a) where the joint undertaking concerned fails to meet the conditions for the entrustment of the Union contribution;
 - (b) where the members other than the Union or their constituent or affiliated entities fail to contribute, contribute only partially, do not respect the time limits set out in paragraph 2 with regard to the contribution referred to in paragraphs 1, 4 and 5 of this Article;
 - (c) as a result of the evaluations referred to in Article 171(2).

7. The Commission's decision to terminate, proportionally reduce or suspend the Union financial contribution shall not hinder the reimbursement of eligible costs already incurred by the members other than the Union before the decision is notified to the joint undertaking.

8. Following the procedure set out in Article 28(6), any member of the joint undertaking other than the Union that fails to meet their commitments concerning the contributions referred to in this Regulation shall be disqualified from voting in the governing board until their obligations have been met. Where any such member fails to meet their obligations upon expiry of an additional six-month period, their membership shall be revoked, unless the governing board decides otherwise in duly justified cases. The entity concerned shall not participate in the vote of the governing board.

Article 12

Management of contributions from the participating states

1. Each participating state shall make an indicative commitment of the amount of their national financial contributions to the joint undertaking. Such commitment shall be made prior to the adoption of the work programme.

In addition to criteria set out in Article 22 of the Horizon Europe Regulation, the work programme may include, as an annex, eligibility criteria regarding national legal entities.

Each participating state shall entrust the joint undertaking with the evaluation of the proposals according to the Horizon Europe Regulation.

The selection of proposals shall be based on the ranking list provided by the evaluation committee. The body responsible for selection may deviate from that list in duly justified cases as set out in the work programme to ensure the overall consistency of the portfolio approach.

Each participating state shall have a right of veto on all issues concerning the use of its own national financial contributions to the joint undertaking for applicants established in those participating states, on the basis of national strategic priorities.

2. Each participating state shall conclude one or more administrative agreements with the joint undertaking laying down the coordination mechanism for the payment of and reporting on contributions to applicants established in that participating state. This agreement shall include the schedule, conditions of payment, reporting and audit requirements.

Each participating state shall strive to synchronise its payment schedule, reporting and audits with those of the joint undertaking and to converge its cost eligibility rules with Horizon Europe's rules.

3. In the agreement referred to in paragraph 2, each participating state may entrust the joint undertaking with the payment of its contribution to its beneficiaries. After the selection of proposals, the participating state shall commit the amount necessary for payments. The audit authorities of the participating state may audit the respective national contributions.

CHAPTER 3

Organisation of the joint undertakings

Article 13

Synergies and efficiencies in back office arrangements

1. Joint undertakings shall, within one year following the date of entry into force of this Regulation, operate back office arrangements by concluding service level agreements, unless specified otherwise in Part Two and subject to the need to guarantee an equivalent level of protection of the Union's financial interest when entrusting budgetary implementation tasks to joint undertakings. Such arrangements shall include at least the following areas, subject to confirmation of viability and following screening of resources:

(a) human resource support;

- (b) legal support;
- (c) information and communication technologies;
- (d) accounting (excluding treasury);
- (e) communication;
- (f) logistics, events and meeting room management;
- (g) support for audit and anti-fraud strategy.

2. The back office arrangements referred to in paragraph 1 shall be provided by one or more selected joint undertakings to all others. Interrelated arrangements shall be kept within the same joint undertaking to the extent appropriate for efficient and effective implementation of the tasks concerned in order to ensure a coherent organisational structure.

3. The service level agreements referred to in paragraph 1 shall enable the transfer of appropriations or the recovery of costs for the provision of the common services between the joint undertakings.

4. Without prejudice to the reassignment to other tasks within the joint undertaking, or to other administrative arrangements, which do not impact contracts of employment, staff assigned to the functions transferred for the purpose of the back office arrangements, hosted by another joint undertaking, may be transferred to that joint undertaking. Where a member of the staff concerned expresses his or her refusal in writing, the contract of that member of staff may be terminated by the joint undertaking under the conditions referred to in Article 47 of the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68 ⁽³⁰⁾ (CEOS).

5. Staff referred to in paragraph 4, who are transferred to the joint undertaking hosting the back office arrangements, shall keep the same type of contract and function group and grade, and shall be deemed to have served their entire service in that joint undertaking.

Article 14

Bodies of the joint undertakings

1. Each joint undertaking shall have a governing board, an executive director and, except in joint undertakings where states are represented in the Governing Board, a states' representatives group.

2. A joint undertaking may also have a scientific advisory body and a stakeholders group and any other body in accordance with the provisions in Part Two.

3. When carrying out its tasks, each body of the joint undertakings shall only pursue the objectives set out in this Regulation and shall only act within the scope of the activities of the joint undertaking for the purpose of which it was established.

4. Without prejudice to paragraph 3, bodies of two or more joint undertakings may decide to establish a structured cooperation, including through regular meetings or joint committees.

⁽³⁰⁾ OJ L 56, 4.3.1968, p. 1.

Section 1

Governing Board

Article 15

Composition of the governing board

1. The governing board shall be composed of at least two representatives of the Commission on behalf of the Union and of the number of representatives from each of the members of the joint undertaking other than the Union as set out in Part Two in relation to each joint undertaking.
2. Where, in accordance with Article 6(1), point (b), the members of the joint undertaking include participating states, one representative of each participating state shall be appointed to the governing board.

Article 16

Functioning of the governing board

1. The representatives of the members in the governing board shall make every effort to adopt decisions by consensus. Failing consensus a vote shall be held. A decision shall be deemed adopted by a majority of at least 75 % of the votes including the votes of representatives who are absent, but excluding abstentions.

Adoption of decisions by the governing board may also be subject to any relevant specific rules set out in Part Two.

2. The presence of the Commission, of at least 50 % of the private members and, if applicable, of at least 50 % of participating states' delegates is required to enable the governing board to vote.
3. The Union shall hold 50 % of the voting rights, unless specified otherwise in Part Two. The voting rights of the Union shall be indivisible.

The voting rights of the members other than the Union shall be subject to the specific rules set out in Part Two. Unless specified otherwise in Part Two, each of the representatives of the members other than the Union shall hold an equal number of votes.

4. The chairperson of the governing board shall be appointed on a rotating annual basis by the Union and by the other representatives, in turn, unless otherwise provided in Part Two.

5. The governing board shall hold ordinary meetings at least twice a year. Extraordinary meetings may be convened at the request of the chairperson, the executive director, the Commission or a majority of the representatives of the members other than the Union or of the participating states. The meetings of the governing board shall be convened by the chairperson and shall take place at the seat of the joint undertaking concerned, unless decided otherwise by the governing board in duly justified cases. The agenda of meetings and decisions shall be made publicly available in a timely manner on the website of the respective joint undertaking.

6. The executive director shall attend the meetings and shall have the right to take part in the deliberations but shall have no voting rights.

7. The chairperson and vice-chairperson of the states' representatives group shall have observer status in the governing board meetings. The chairpersons of the other bodies of the joint undertaking concerned shall have the right to attend meetings of the governing board as observers whenever issues falling within the scope of their tasks are discussed. Observers may take part in deliberations but shall have no voting rights.

8. Other persons, in particular representatives of other European partnerships, executive or regulatory agencies, regional authorities within the Union and European technology platforms may also be invited to attend by the chairperson as observers on a case-by-case basis subject to the rules on confidentiality and conflict of interest.

9. The representatives of the members shall not be personally liable for actions they have taken in their capacity as representatives on the governing board except in cases of gross negligence or wilful misconduct.
10. The governing board shall adopt its own rules of procedure.
11. The representatives of the members and observers shall be bound by the provisions of a code of conduct which shall establish their obligations to safeguard the integrity and reputation of the joint undertaking concerned and of the Union.

Article 17

Tasks of the governing board

1. The governing board is the decision-making body of each joint undertaking. It shall have overall responsibility for the strategic orientation, coherence with relevant Union objectives and policies, and operations of that joint undertaking and shall supervise the implementation of its activities.

The Commission, in its role in the governing board, shall seek to ensure coordination and coherence between the activities of the joint undertakings and the relevant activities of Union funding programmes with a view to promoting synergies and complementarities while avoiding duplications when identifying priorities covered by collaborative research.

2. The governing board shall carry out the following tasks:
 - (a) take measures to implement the joint undertaking's general, specific and operational objectives, assess their effectiveness and impact, ensure close and timely monitoring of the progress of the joint undertaking's research and innovation programme and individual actions in relation to the priorities of the Union and the Strategic Research and Innovation Agenda, including in relation to complementarity with regional or national programmes, and take corrective measures where needed to ensure that the joint undertaking meets its objectives;
 - (b) assess, accept or reject applications for membership in accordance with Article 7;
 - (c) assess, accept or reject applications of prospective contributing partners in accordance with Article 9;
 - (d) decide on the termination of the membership in the joint undertaking with regard to any member that does not fulfil its obligations pursuant to this Regulation or in accordance with Article 8(2) and (3);
 - (e) adopt the financial rules of the joint undertaking in accordance with Article 27;
 - (f) adopt the annual budget and the staff establishment plan including the number of permanent and temporary posts by function group and by grade as well as the number of contract staff and seconded national experts expressed in full-time equivalents;
 - (g) decide on the distribution of administrative costs among the members other than the Union, where these members fail to reach an agreement in accordance with Article 28(2), taking into account possible imbalances in their administrative commitments compared to their participation;
 - (h) exercise, in accordance with paragraph 4 of this Article and with regard to the staff of the joint undertaking, the powers conferred by the Staff Regulations of Officials of the European Union laid down in Regulation (EEC, Euratom, ECSC) No 259/68 (the 'Staff Regulations') on the Appointing Authority and by the CEOS on the Authority Empowered to Conclude a Contract of Employment (the 'appointing authority powers');
 - (i) appoint, dismiss, extend the term of office, provide guidance and monitor the performance of the executive director;
 - (j) adopt the Strategic Research and Innovation Agenda at the beginning of the joint undertaking and update it throughout the duration of Horizon Europe, where necessary. The Strategic Research and Innovation Agenda shall identify the partnership's targeted impact, foreseen portfolio of activities, measurable expected outcomes, resources, deliverables and milestones within a defined timeframe. It shall also identify the other European partnerships with

which the joint undertaking shall establish a formal and regular collaboration and the possibilities for synergies between the joint undertaking's actions and national or regional initiatives and policies based on information received by the participating states or the states' representatives group as well as synergies with other Union programmes and policies;

- (k) adopt the work programme and corresponding expenditure estimates as proposed by the executive director, after taking into consideration the states' representatives group's opinion, to implement the Strategic Research and Innovation Agenda, including the administrative activities, the content of the calls for proposals, possible conditions for dealing with ex aequo proposals in accordance with Article 28(3) of Horizon Europe and its work programmes, the research areas subject to joint calls and cooperation with other partnerships and synergies with other Union programmes, the applicable funding rate, and the related rules for submission, evaluation, selection, award and review procedures with particular attention to the feedback to policy requirements;
- (l) where appropriate, limit the participation in specific actions in the work programme in accordance with Article 22(5) of the Horizon Europe Regulation and in accordance with the position agreed on a case-by-case basis between the Commission and the Member States in the states' representatives group, unless specified otherwise in Part Two;
- (m) adopt measures for attracting newcomers, in particularly SMEs, higher education institutions and research organisations, into the activities and actions of the joint undertaking, including where applicable by encouraging them to become private members or constituent entities of the private members;
- (n) approve the annual additional activities plan, set out in an annex to the main part of the work programme, on the basis of a proposal from the members other than the Union and after having consulted the scientific advisory body or such body as set out in Part Two and after taking into consideration the states' representatives group's opinion;
- (o) provide strategic orientation as regards the collaboration with other European partnerships in accordance with the Strategic Research and Innovation Agenda;
- (p) assess and approve the consolidated annual activity report, including the corresponding expenditure and the budget dedicated to joint calls with other European partnerships;
- (q) deliver an opinion on the joint undertaking's final accounts;
- (r) make arrangements, as appropriate, for the establishment of an internal audit capability of the joint undertaking;
- (s) approve the organisational structure of the programme office upon recommendation of the executive director;
- (t) approve the joint undertaking's communication policy upon recommendation by the executive director;
- (u) unless specified otherwise in Part Two, approve the list of actions selected for funding;
- (v) adopt implementing rules for giving effect to the Staff Regulations and the CEOS in accordance with Article 110(2) of the Staff Regulations;
- (w) adopt rules on the secondment of national experts to the joint undertakings or the use of trainees;
- (x) set up, as required, advisory or working groups, including in collaboration with other joint undertakings, in addition to the bodies of the joint undertaking referred to in Article 14, for a determined period of time and to fulfil a specific purpose;
- (y) submit to the Commission, where appropriate, requests to amend this Regulation;
- (z) request scientific advice or analysis on specific issues to the joint undertaking's scientific advisory body or its members, including as regards developments in adjacent sectors;
- (a1) adopt by the end of 2023 a plan for the phasing-out of the joint undertaking from Horizon Europe funding upon recommendation of the executive director;
- (b1) ensure the performance of any task that is not specifically assigned to a particular body of a joint undertaking, subject to the possibility that the governing board may assign such task to another body of the joint undertaking concerned.

3. The governing board of a joint undertaking may also be subject to specific rules set out in Part Two.
4. The governing board shall adopt, in accordance with Article 110(2) of the Staff Regulations, a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the CEOS, delegating relevant appointing authority powers to the executive director and defining the conditions under which that delegation of powers can be suspended. The executive director shall be authorised to sub-delegate those powers.
5. The governing board shall take the utmost account of the states' representatives group's opinions, recommendations or proposals, if any, before voting. The governing board shall inform without undue delay the states' representatives group of the follow-up it has given to such opinions, recommendations or proposals, or it shall give reasons if they are not followed up.

Section 2

Executive Director

Article 18

Appointment, dismissal and extension of the term of office of the executive director

1. The Commission shall propose a list of candidates, preferably at least three, for executive director after consultation with the members other than the Union of the joint undertaking. For the purpose of such consultation, each type of members other than the Union of the joint undertaking shall appoint one representative as well as one observer on behalf of the governing board.
2. The executive director shall be appointed by the governing board on the basis of merit and skills, from the list of candidates proposed by the Commission, following an open and transparent selection procedure, which shall respect the principle of gender balance.
3. The executive director shall be a member of staff and shall be engaged as a temporary agent of the joint undertaking under Article 2, point (a), of the CEOS.

For the purpose of concluding the contract of the executive director, the joint undertaking shall be represented by the chairperson of the governing board.

4. The term of office of the executive director shall be four years. By the end of that period, the Commission after consulting the members other than the Union shall carry out an assessment of the performance of the executive director and the future tasks and challenges of the joint undertaking.
5. The governing board of the joint undertaking, acting on a proposal from the Commission which takes into account the assessment referred to in paragraph 4, may extend the term of office of the executive director once, for a period of not more than three years.
6. An executive director whose term of office has been extended may not participate in another selection procedure for the same post.
7. An executive director may be dismissed only upon a decision of the governing board acting on a proposal from the Commission, after consulting the states' representatives group and the members other than the Union of the joint undertaking.

Article 19

Tasks of the executive director

1. The executive director shall be the chief executive responsible for the day-to-day management of the joint undertaking in accordance with the decisions of the governing board. He or she shall provide the governing board with all information necessary for the performance of its functions. Without prejudice to the respective competencies of the Union institutions and the governing board, the executive director shall neither seek nor take instructions from any government or from any other body.

2. The executive director shall be the legal representative of the joint undertaking. He or she shall be accountable to the governing board of the joint undertaking.
3. The executive director shall implement the budget of the joint undertaking and shall ensure coordination between the different bodies and services of the joint undertaking.
4. The executive director shall carry out the following tasks for the joint undertaking:
 - (a) ensure sustainable and efficient management of the joint undertaking and efficient implementation of the work programme;
 - (b) prepare and submit for adoption to the governing board the draft annual budget and the staff establishment plan;
 - (c) prepare and, after having taken into account the opinion of the states' representatives group or the Public Authorities Board as appropriate, submit for adoption to the governing board the work programme and the corresponding expenditure estimates for the joint undertaking, to implement the Strategic Research and Innovation Agenda;
 - (d) submit for opinion to the governing board the annual accounts for the joint undertaking;
 - (e) prepare and submit for assessment and approval to the governing board the consolidated annual activity report, including information on the corresponding expenditure and contributions from members other than the Union referred to in Article 11(1);
 - (f) monitor the contributions referred to in Article 11(1), report to the governing board regularly on the progress in achieving the targets and propose remedial or corrective measures, where necessary;
 - (g) monitor the implementation of measures for attracting newcomers, in particularly SMEs, higher education institutions and research organisations;
 - (h) establish a formal and regular collaboration with the European partnerships identified in the Strategic Research and Innovation Agenda and in accordance with the strategic orientation provided by the governing board;
 - (i) following an invitation from the Chair, inform regularly the relevant configuration of the Horizon Europe Programme Committee, further to the Commission responsibility to inform the Programme Committee under Article 14(7) and Annex III to the Specific Programme implementing Horizon Europe, and in particular, before adoption of the work programme of the joint undertaking, in relation to the application of Article 22(5) of the Horizon Europe Regulation;
 - (j) submit for approval to the governing board or to the Public Authorities Board as appropriate the list of actions to be selected for funding by the joint undertaking;
 - (k) assess applications for associated members to the joint undertaking following an open call for expression of interest and submit proposals for associated members to the governing board;
 - (l) inform regularly the other bodies of the joint undertaking on all matters relevant to their role;
 - (m) sign individual grant agreements and decisions in his or her remit on behalf of the joint undertaking;
 - (n) sign procurement contracts on behalf of the joint undertaking;
 - (o) ensure the programme's monitoring and assessment of the progress compared to relevant impact indicators and the joint undertaking's specific objectives as defined in Part Two, under the supervision of the governing board and in coordination with advisory bodies where relevant, and in accordance with Article 171;
 - (p) implement the communications policy of the joint undertaking;
 - (q) organise, direct and supervise the operations and the staff of the joint undertaking within the limits of the delegations by the governing board;
 - (r) establish and ensure the functioning of an effective and efficient internal control system and report any significant change to it to the governing board;

- (s) protect the financial interests of the Union and of other members by applying preventive measures against fraud, corruption and any other illegal activities by means of effective checks and, if irregularities are detected, by recovering amounts that were wrongly paid and, where appropriate, imposing effective, proportionate and dissuasive administrative and financial penalties;
 - (t) ensure the carrying out of risk assessments and risk management for the joint undertaking;
 - (u) take any other measures necessary for assessing the progress of the joint undertaking towards achieving its objectives;
 - (v) prepare and submit for adoption to the governing board a plan for the phasing out of the joint undertaking from Horizon Europe funding;
 - (w) perform any other tasks entrusted or delegated to him or her by the governing board or as may be required by this Regulation;
 - (x) have the power to delegate his or her powers to other staff members subject to rules to be adopted in accordance with Article 17(4).
5. The executive director may also be subject to any specific rules set out in Part Two.
6. The executive director shall set up a programme office for the execution, under his or her responsibility, of all support tasks of the joint undertaking deriving from this Regulation. The programme office shall be composed of the staff of the joint undertaking and shall in particular carry out the following tasks:
- (a) provide support in establishing and managing an appropriate accounting system in accordance with the financial rules for the joint undertaking;
 - (b) manage the implementation of the work programme of the joint undertaking throughout the implementation cycle;
 - (c) provide to the members of the joint undertaking and its bodies all relevant and timely information and support necessary for them to perform their duties;
 - (d) act as the secretariat of the bodies of the joint undertaking and provide support to advisory groups set up by the governing board, if any.

Section 3

Advisory bodies

Article 20

The states' representatives group

1. Except in cases where Member States and associated countries participate in a joint undertaking as members or constituent entities of members, joint undertakings shall establish a states' representatives group as specified in Part Two subject to the provisions in this Article.
2. The states' representatives group shall consist of up to two representatives and up to two alternates from each Member State and from each associated country. The states' representatives group shall elect a chairperson and vice-chairperson from among its members.
3. The states' representatives group shall meet at least twice a year. The meetings shall be convened by the chairperson or by at least one third of the states' representatives group members. The chairperson of the governing board and the executive director or their representatives shall attend the meetings as observers upon request of the chairperson of the states' representatives group for the purpose of delivering information on specific matters.
4. The meetings of the states' representatives group may be regulated by any relevant specific provisions set out in Part Two.

5. The chairperson of the states' representatives group may invite other persons to attend its meetings as observers, in particular representatives of relevant federal or regional authorities within the Union, representatives of higher education institutions and research performing organisations, SME associations or industry associations and representatives of other bodies of the joint undertaking.

6. The agenda and supporting documents of the state representatives group's meetings shall be circulated sufficiently in advance to ensure appropriate representation by each Member State and associated country. The agenda shall also be circulated for information to the governing board in a timely manner.

7. The states' representatives group shall be consulted and, in particular, it shall review information and provide opinions on the following matters:

- (a) programme progress of the joint undertaking and achievement of its targets and expected impacts as part of Horizon Europe, including the information on calls for proposals and proposals received as well as on the proposal evaluation process;
- (b) updating of the Strategic Research and Innovation Agenda or equivalent in line with the Horizon Europe strategic planning and with other Union and Member States funding instruments;
- (c) links to Horizon Europe and other Union, national and, where relevant, regional initiatives, including cohesion policy funds in line with smart specialisation strategies;
- (d) draft work programmes, including the content of calls for proposals, especially on lower TRL research topics included in the draft work programme and on the application of eligibility criteria;
- (e) involvement of SMEs, start-ups, higher education institutions and research organisations, and measures taken for promoting participation of newcomers;
- (f) actions taken for dissemination and exploitation of results along the value chain;
- (g) annual activity report.

8. For the purpose of seeking the agreed position referred to in Article 17(2), point (l), the states' representatives group shall solely include Member States. The rules of procedure of the states' representatives group shall further specify the procedure for agreeing that position.

9. Where applicable, the states' representatives group shall also regularly report to the governing board, and act as an interface with the joint undertaking on the following matters:

- (a) the status of relevant national or regional research and innovation programmes and identification of potential areas of cooperation, including concrete actions taken or envisaged for the deployment and uptake of relevant technologies and innovative solutions;
- (b) specific measures taken at national level or regional level with regard to dissemination events, dedicated technical workshops and communication activities;
- (c) specific measures at national or regional level with regard to deployment activities in relation to each respective joint undertaking;
- (d) national or regional policies and initiatives with a view to ensuring complementarities with regard to the joint undertaking's Strategic Research and Innovation Agenda and annual work programmes.

10. The states' representatives group shall submit, at the end of each calendar year, a report describing the national or regional policies in the scope of the joint undertaking and identifying specific ways of cooperation with the actions funded by the joint undertaking.

11. The states' representatives group may issue, on its own initiative, opinions, recommendations or proposals to the governing board or the executive director on technical, managerial and financial matters as well as on work programmes and other documents, in particular when those matters affect national or regional interests.

12. The states' representatives group shall receive timely and relevant information on a regular basis, including a breakdown by country, among other data on the application and participation in indirect actions funded by the joint undertaking, on the evaluation results of each call for proposals and project implementation, on synergies with other relevant Union programmes and other European partnerships, on additional activities, on committed and actually provided financial and in-kind contributions and on the execution of the budget of the joint undertaking.

13. The states' representatives group shall adopt its own rules of procedure with due consideration to Articles 33 and 42.

14. One or more joint undertakings may establish a joint state representatives group in accordance with the relevant provisions set out in Part Two.

Article 21

Scientific advice

1. Unless specified otherwise in Part Two, joint undertakings shall seek independent scientific advice by means of:

- (a) a scientific advisory body to be set up by the joint undertaking in accordance with the relevant provisions set out in Part Two, and subject to the provisions in this Article; or
- (b) ad hoc requests for independent expertise by the governing board to the joint undertaking on specific questions.

2. There shall be a balanced representation of experts among the members of the scientific advisory body, within the scope of the activities of the joint undertaking, including with respect to gender and geographical balance. Collectively, the members of the scientific advisory body shall have the necessary competences and expertise covering the technical domain in order to make science-based recommendations to the joint undertaking, taking into account the climate, environmental and socioeconomic impact of such recommendations and the objectives of the joint undertaking.

3. The members of the scientific advisory body, as well as invited observers, shall be subject to the obligation of professional secrecy which, by virtue of the Treaties and the rules implementing them, applies to all members of the institutions and their staff, as well as to the Commission's rules on security regarding the protection of sensitive non-classified and Union classified information, laid down in Commission Decisions (EU, Euratom) 2015/443 ⁽³¹⁾ and (EU, Euratom) 2015/444 ⁽³²⁾ respectively.

4. The governing board shall establish an open selection process including specific criteria for the composition of the scientific advisory body of the joint undertaking and shall appoint its members. The governing board shall take into consideration the potential candidates proposed by the states' representatives group.

5. The scientific advisory body shall elect its chair from among its members.

6. The scientific advisory body shall meet at least twice a year and meetings shall be convened by the chairperson. The chairperson may invite other persons to attend its meetings as observers. The scientific advisory body shall adopt its own rules of procedure. The agenda of meetings shall be made publicly available in a timely manner on the website of the respective joint undertaking.

7. The scientific advisory body shall carry out the following tasks:

- (a) advise on the scientific priorities to be addressed in the work programmes including on scope of calls for proposals, in line with the Strategic Research and Innovation Agenda and the Horizon Europe strategic planning;
- (b) advise on the scientific achievements to be described in the annual activity report;

⁽³¹⁾ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

⁽³²⁾ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

- (c) suggest, in view of the progress of the Strategic Research and Innovation Agenda and individual actions, corrective measures or re-orientations to the governing board, where necessary;
- (d) provide independent advice and scientific analysis on specific issues as requested by the governing board, in particular as regards developments in adjacent sectors or to support the assessment of applications of potential associated members and contributing partners;
- (e) where specified in Part Two, evaluate the results from technology and innovation actions that are funded by the joint undertaking and report to the governing board;
- (f) where specified in Part Two, participate in sector integration committees specifically set up between European partnerships under Horizon Europe to enable synergies;
- (g) carry out any other task, as specified in Part Two.

8. After each meeting of the scientific advisory body, its chairperson shall submit to the governing board a report outlining the body's and its members' opinions on the matters discussed during the meeting. To the extent possible, the report shall be made publicly available on the website of the respective joint undertaking.

9. The scientific advisory body may, of its own initiative, advise the governing board to consult it on specific points not covered by the tasks set out in paragraph 7. To the extent possible, the report shall be made publicly available on the website of the respective joint undertaking.

10. The scientific advisory body shall be informed of the reasons in the event that its advice on the work programme and the Strategic Research and Innovation Agenda is not followed.

Article 22

The stakeholders group

1. Joint undertakings may establish a stakeholders group in accordance with the relevant provisions in Part Two and subject to this Article.
2. The stakeholders group shall be open to all public and private stakeholders, including organised groups, active in the field of the joint undertaking, international interest groups from Member States, associated countries or other countries.
3. The governing board shall establish the specific criteria and selection process for the composition of the stakeholders group and shall aim to balance representation in terms of geographical distribution, gender, sector and stakeholders' expertise. Where relevant, the governing board shall take into account the potential candidates proposed by the states' representatives group.
4. The stakeholders group shall be regularly informed of the activities of the joint undertaking and shall be invited to provide comments on the joint undertaking's planned initiatives.
5. The meetings of the stakeholders group shall be convened by the executive director.
6. The executive director may advise the governing board to consult the stakeholders group on specific questions. Where such consultation takes place, a report shall be submitted to the governing board and to the states' representatives group after the relevant discussion in the stakeholders group and be made publicly available on the website of the respective joint undertaking.

CHAPTER 4

Financial and operational provisions

Section 1

General provisions

Article 23

Coherent application of limitation to participation

The joint undertakings shall ensure coherence with the approach taken for actions funded under the Horizon Europe work programme adopted in accordance with Article 13(2), point (b), of the Specific Programme implementing Horizon Europe regarding the application of Article 22(5) of the Horizon Europe Regulation, as well as Union legislation and guidance relevant for its application in similar topics in the work programme of the joint undertaking concerned.

Article 24

Rules applicable to the activities funded by the joint undertakings

1. The Horizon Europe Regulation shall apply to the actions funded by the joint undertakings under Horizon Europe. In accordance with that Regulation, each joint undertaking shall be considered as a funding body and shall provide financial support to indirect actions pursuant to Article 6 of that Regulation.
2. Actions funded by the joint undertakings under Horizon Europe may also be subject to any specific provisions set out in Part Two.
3. By way of derogation from Article 40(4), point (a), of the Horizon Europe Regulation, the right to object shall also apply to participants generating the results that have not received funding from a joint undertaking.

Article 25

Operational and financial planning

1. The executive director shall submit for adoption to the governing board a draft work programme.
2. The work programme shall be adopted by the end of the year prior to its implementation. The work programme and the calls for proposals shall be published on the website of the joint undertaking and on the Horizon Europe website, and, to support the coordination with the overall strategy of Horizon Europe, be shared with the relevant configuration of the Programme Committee for information.
3. The executive director shall prepare a draft annual budget for the following year and submit it to the governing board for adoption.
4. The annual budget for a particular year shall be adopted by the governing board by the end of the year prior to its implementation.
5. The annual budget shall be adapted in order to take into account the amount of the Union financial contribution as set out in the Union budget and, where applicable, the amounts of the financial contributions from members other than the Union and from contributing partners, if any.

*Article 26***Operational and financial reporting**

1. The executive director shall provide the governing board with a consolidated annual activity report on the performance of his or her duties in accordance with the financial rules of the joint undertaking. The consolidated annual activity report shall be made public in a timely manner on the website of the respective joint undertaking.
2. The consolidated annual activity report shall include, among other things, information on the following matters:
 - (a) research, innovation and other actions carried out and the corresponding expenditure;
 - (b) the proposals submitted, including a breakdown by country where the legal entity is established, and by participant type, in particular SMEs and newcomers;
 - (c) the indirect actions selected for funding, including a breakdown by participant type, including SMEs, and by country and indicating the contribution of the respective joint undertaking to the individual participants and actions;
 - (d) information regarding the openness of the joint undertakings, including monitoring of collaborative links;
 - (e) the additional activities undertaken by the members other than the Union, including a breakdown by country where the private members, their constituent entities or the affiliated entities of either is established;
 - (f) the collaboration with other European partnerships, including joint calls, and synergies between the joint undertaking's actions and national or regional initiatives and policies.
3. The accounting officer of the joint undertaking shall send the provisional accounts to the Commission's accounting officer and the Court of Auditors in accordance with the financial rules of the joint undertaking.
4. The executive director shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors in accordance with the financial rules of the joint undertaking.
5. The discharge procedure shall be carried out in accordance with the financial rules of the joint undertaking.

*Section 2***Financial provisions***Article 27***Financial rules**

1. The joint undertakings shall adopt their financial rules in accordance with Article 71 of Regulation (EU, Euratom) 2018/1046.
2. The financial rules shall be published on the website of the respective joint undertaking.

*Article 28***Sources of financing**

1. Each joint undertaking shall be jointly funded by the Union, the members other than the Union and the contributing partners through financial contributions and in-kind contributions to operational activities.
2. The members other than the Union shall agree on how to share their collective contribution among them in accordance with the applicable financial rules.
3. The operational costs of a joint undertaking shall be covered by means of the:
 - (a) financial contribution by the Union;
 - (b) financial contributions by the private members or their constituent or affiliated entities, by contributing partners or by an international organisation that is a member of a joint undertaking;
 - (c) where applicable, financial contributions by the participating states;
 - (d) in-kind contributions defined in Article 2, point (8).
4. In accordance with Articles 10 and 11, the resources of a joint undertaking entered in its budget shall be composed of the following contributions:
 - (a) members' financial contributions to the joint undertaking for the administrative costs, divided equally on an annual basis between the Union and the members other than the Union, unless specified otherwise in Part Two due to the specific membership nature of a joint undertaking;
 - (b) members' or contributing partners' financial contributions to the joint undertaking for the operational costs;
 - (c) any revenue generated by the joint undertaking;
 - (d) any other financial contributions, resources and revenues.

Any interest yielded by the contributions referred to in this paragraph shall be considered to be its revenue.
5. Any unused part of the contribution for administrative costs may be made available to cover the operational costs of the joint undertaking concerned.
6. Should a member other than the Union of the joint undertaking be in default of its commitment concerning its contribution, the executive director shall inform it in writing and shall set a reasonable period within which such default should be remedied. Where, on the expiry of that period, the member other than the Union concerned is still in default, the executive director shall inform the Commission and the participating states, where applicable, in view of potential measures pursuant to Article 11(8) and inform the member concerned that it is disqualified from voting in the governing board in line with that Article.
7. The resources of the joint undertaking and its activities shall be used for the fulfilment of its objectives and tasks.
8. The joint undertaking shall own all assets generated by it or transferred to it for the fulfilment of its objectives and tasks.
9. Except where the joint undertaking is wound up, any excess revenue over expenditure shall not be paid to the members of that joint undertaking, unless decided otherwise by the governing board.

*Article 29***Financial commitments**

1. The financial commitments of a joint undertaking shall not exceed the amount of financial resources available or committed to its budget by its members and contributing partners.
2. Budgetary commitments of the joint undertakings referred to in Article 3(1), points (b), (d) and (h), may be divided into annual instalments. Until 31 December 2024, the cumulative amount of those budgetary commitments in instalments shall not exceed 50 % of the maximum Union contribution set out in Article 10. From January 2025, at least 20 % of the cumulative budget of the residual years shall not be covered by annual instalments.

*Article 30***Protection of the financial interests of the members**

1. The joint undertaking shall grant Commission staff and other persons authorised by the respective joint undertaking or the Commission, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.
2. The European Anti-Fraud Office (OLAF) has the power to carry out administrative investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Council Regulation (Euratom, EC) No 2185/96 ⁽³³⁾ and Regulation (EC, Euratom) No 883/2013 of the European Parliament and of the Council ⁽³⁴⁾ and with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with an agreement, a decision or a contract funded under this Regulation.
3. The European Public Prosecutor's Office (EPPO) is empowered, in accordance with Council Regulation (EU) 2017/1939 ⁽³⁵⁾, to investigate and prosecute criminal offences affecting the financial interests of the Union as set out in Article 4 of that Regulation.
4. Notwithstanding paragraphs 1 to 3, agreements, decisions and contracts resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the respective joint undertaking, the Court of Auditors, the EPPO and OLAF to conduct such audits, on-the spot checks and investigations in accordance with their respective competences.
5. Each joint undertaking shall ensure that the financial interests of its members are adequately protected by carrying out or commissioning appropriate internal and external controls.
6. Each joint undertaking shall accede to the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council and the Commission concerning internal investigations by the European Anti-Fraud Office (OLAF) ⁽³⁶⁾. Each joint undertaking shall adopt the necessary measures needed to facilitate internal investigations conducted by OLAF.
7. The joint undertaking shall grant each national court of auditors on their request access to all the information related to the national contributions of the respective participating state, including information in electronic format, needed in order to conduct their audits.

⁽³³⁾ 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).

⁽³⁴⁾ 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).

⁽³⁵⁾ 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).

⁽³⁶⁾ OJ L 136, 31.5.1999, p. 15.

*Article 31***Ex post audits**

Audits of expenditure on indirect actions shall be carried out in accordance with Article 53 of the Horizon Europe Regulation as part of the Horizon Europe indirect actions, in particular in line with the audit strategy referred to in Article 53(2) of that Regulation.

*Article 32***Internal audit**

1. The Commission's internal auditor shall exercise the same powers over the joint undertakings as those exercised in respect of the Commission and shall endeavour to reduce the administrative burden of the joint undertaking.
2. The governing board may establish an internal audit capability in accordance with the financial rules of the joint undertaking concerned.

*Section 3***Operational provisions***Article 33***Confidentiality**

Without prejudice to Articles 34 and 36, each joint undertaking shall ensure the protection of confidential information the disclosure of which beyond Union institutions and other Union bodies, offices or agencies could damage the interests of its members or of participants in the activities of the respective joint undertaking. Such confidential information includes but is not limited to personal, commercial, sensitive non-classified and classified information.

*Article 34***Transparency**

Regulation (EC) No 1049/2001 of the European Parliament and of the Council ⁽³⁷⁾ shall apply to documents held by a joint undertaking.

*Article 35***Processing of personal data**

Where the implementation of this Regulation requires the processing of personal data, this shall be processed in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽³⁸⁾.

⁽³⁷⁾ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

⁽³⁸⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

*Article 36***Access to results and information on proposals**

1. The joint undertaking shall provide the Union institutions and Union bodies, offices or agencies, as well as the authorities of the participating states where applicable, access to all information related to the indirect actions it funds. Such information shall include contributions and results of beneficiaries participating in indirect actions of the joint undertaking, or any other information deemed necessary for developing, implementing, monitoring and evaluating Union or where applicable participating states' policies or programmes. Such access rights are limited to non-commercial and non-competitive use and shall comply with applicable confidentiality rules.
2. For the purposes of developing, implementing, monitoring and evaluating Union policies or programmes, the joint undertaking shall provide the Commission with the information included in submitted proposals. This shall apply *mutatis mutandis* to participating states where applicable regarding proposals which include applicants established in their territories, limited to non-commercial and non-competitive use and in accordance with applicable confidentiality rules.

CHAPTER 5

Staff and liability

Section 1

Staff, privileges and immunities*Article 37***Staff**

1. The Staff Regulations and the CEOS and the rules adopted jointly by the institutions of the Union for the purpose of applying the Staff Regulations and the CEOS shall apply to the staff of the joint undertakings.
2. The staff resources shall be determined in the staff establishment plan of each joint undertaking indicating the number of temporary posts by function group and by grade and the number of contract staff expressed in full-time equivalents, in line with its annual budget.
3. The staff of the joint undertaking shall consist of temporary staff and contract staff.
4. All costs related to staff shall be borne by the joint undertaking.

*Article 38***Seconded national experts and trainees**

1. A joint undertaking may make use of seconded national experts and trainees not employed directly by it. The number of seconded national experts expressed in full-time equivalents shall be added to the information on staff resources as referred to in Article 37(2) in accordance with the annual budget of the joint undertaking concerned.
2. The governing board of the joint undertaking concerned shall adopt a decision laying down rules on the secondment of national experts to the respective joint undertaking and on the employment of trainees.

*Article 39***Privileges and Immunities**

Protocol No 7 on the privileges and immunities of the European Union, annexed to the TEU and the TFEU, shall apply to the joint undertakings and their staff.

*Section 2***Liability***Article 40***Liability of the joint undertakings**

1. The contractual liability of a joint undertaking shall be governed by the relevant contractual provisions and by the law applicable to the agreement, decision or contract in question.
2. Where liability is of a non-contractual nature, a joint undertaking shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its staff in the performance of their duties.
3. Any payment by a joint undertaking in respect of the liability referred to in paragraphs 1 and 2 and the costs and expenses incurred in connection therewith shall be considered as expenditure of the joint undertaking and shall be covered by its resources.
4. Joint undertakings shall be solely responsible for meeting their obligations.

*Article 41***Liability of members and insurance**

1. The financial liability of the members of a joint undertaking for its debts shall be limited to their financial contributions made to the joint undertaking.
2. The joint undertakings shall take out and maintain appropriate insurance.

*Article 42***Conflicts of interest**

1. The joint undertaking, its bodies and staff shall avoid any conflict of interest in carrying out their activities.
2. The governing board shall adopt rules for the prevention, avoidance and management of conflicts of interest in respect of the staff of the joint undertaking, the members and other persons serving the governing board and in the other bodies or groups of the joint undertaking, in accordance with the financial rules of the joint undertaking and with the Staff Regulations in respect of staff.

*CHAPTER 6****Dispute resolution****Article 43***Jurisdiction of the Court of Justice and applicable law**

1. The Court of Justice of the European Union shall have jurisdiction:
 - (a) pursuant to any arbitration clause contained in agreements or contracts concluded by a joint undertaking, or in its decisions;

- (b) in disputes relating to compensation for damage caused by the staff of the joint undertaking in the performance of their duties;
 - (c) in any dispute between the joint undertaking and its staff within the limits and under the conditions laid down in the Staff Regulations and the CEOS.
2. Regarding any matter not covered by this Regulation or by other Union legal acts, the law of the state where the seat of the joint undertaking is located shall apply.

Article 44

Complaints to the Ombudsman

Decisions taken by a joint undertaking in the implementation of this Regulation may form the subject of a complaint to the Ombudsman in accordance with Article 228 of the TFEU.

CHAPTER 7

Winding up

Article 45

Winding up

1. Joint undertakings shall be wound up at the end of the period laid down in Article 3.
2. In addition to paragraph 1, the winding-up procedure of a joint undertaking shall be automatically triggered where the Union or all members other than the Union withdraw from the joint undertaking.
3. For the purpose of conducting the winding-up proceedings of a joint undertaking, the governing board shall appoint one or more liquidators, who shall comply with the decisions of the governing board.
4. During the winding-up procedure, the assets of the joint undertaking shall be used to cover its liabilities and the expenditure relating to its winding up. Any surplus shall be distributed among the members of the joint undertaking at the time of the winding up in proportion to their financial contribution to the joint undertaking. Any such surplus distributed to the Union shall be returned to the Union budget.
5. An ad hoc procedure shall be set up to ensure the appropriate management of any agreement concluded or decision adopted by the joint undertaking being wound up as well as any procurement contract the duration of which extends beyond the duration of the joint undertaking.

PART TWO

SPECIFIC PROVISIONS OF INDIVIDUAL JOINT UNDERTAKINGS

TITLE I

CIRCULAR BIO-BASED EUROPE JOINT UNDERTAKING

Article 46

Additional objectives of the Circular Bio-based Europe Joint Undertaking

1. In addition to the objectives set out in Articles 4 and 5, the Circular Bio-based Europe Joint Undertaking shall have the following general objectives:
 - (a) accelerate the innovation process and development of bio-based innovative solutions;

- (b) accelerate market deployment of the existing mature and innovative bio-based solutions;
 - (c) ensure a high level of environmental performance of bio-based industrial systems.
2. The Circular Bio-based Europe Joint Undertaking shall also have the following specific objectives:
- (a) increase the intensity of cross-disciplinary research and innovation activities to reap the benefits of the advancement in life sciences and in other scientific disciplines for the development and demonstration of sustainable bio-based solutions;
 - (b) increase and integrate the research and innovation capacity of stakeholders across the Union to exploit the local bioeconomy potential, including in regions with underdeveloped capacity;
 - (c) increase the research and innovation capacity for addressing environmental challenges and development of more sustainable bio-based innovations by ensuring that sustainability issues and environmental performance are integrated throughout the whole innovation chain and in future innovative solutions;
 - (d) reinforce the integration of bio-based research and innovation in the Union bio-based industry and increase the involvement of R&I actors including feedstock providers in the bio-based value chains;
 - (e) reduce the risk for research and innovation investment in bio-based companies and projects;
 - (f) ensure that circularity and environmental considerations, including contributions to climate neutrality and zero pollution objectives, are taken into account in the development and implementation of research and innovation bio-based projects and facilitate societal acceptance.

Article 47

Additional tasks of the Circular Bio-Based Europe Joint Undertaking

In addition to the tasks set out in Article 5, the Circular Bio-based Europe Joint Undertaking shall carry out the following tasks:

- (a) ensure that its objectives are reached through the programming of research and innovation activities of the public and private partners;
- (b) mobilise public and private funding for its research and innovation activities;
- (c) support high impact multidisciplinary research and innovation projects that enhance the industrial bio-based innovation to deliver on its objectives;
- (d) intensify its research and innovation activities along the whole innovation chain from low to high TRLs;
- (e) mobilise and integrate research and innovation actors including feedstock providers from rural, coastal, urban areas and regions with unexploited potential for bio-based value chain development to cooperate in project activities;
- (f) ensure that research and innovation activities under it focus on issues of public interest, specifically on the environmental and climate performance of the bio-based industry, both in terms of understanding the relevant problems and developing solutions to them;
- (g) promote communication and collaboration between research and innovation actors and industrial stakeholders under it to raise awareness about rapidly evolving knowledge and technology, facilitate cross-disciplinary and cross-sectorial collaboration and facilitate market uptake of innovative bio-based solutions;
- (h) mobilise national and regional authorities that are able to create more favourable conditions for market uptake of bio-based innovations;

- (i) support the reflection towards the development of standards in order to facilitate the market uptake of bio-based innovations;
- (j) set scientifically robust sustainability criteria and performance benchmarks, apply and monitor them in all its research and innovation activities, and promote them beyond the initiative to the bio-based industry;
- (k) communicate and promote innovative bio-based solutions towards policy makers, industry, NGOs, civil society and consumers at large.

Article 48

Members

The members of the Circular Bio-based Europe Joint Undertaking shall be:

- (a) the Union, represented by the Commission;
- (b) the Bio-based Industries Consortium, a non-profit organisation registered under Belgian law, upon notification of its decision to accede to the Circular Bio-based Europe Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding its accession other than those set out in this Regulation;
- (c) the associated members selected in accordance with Article 7, subject to a decision of the governing board.

Article 49

Union financial contribution

The Union financial contribution to the Circular Bio-based Europe Joint Undertaking, including EEA appropriations, to cover administrative and operational costs shall be up to EUR 1 000 000 000, including up to EUR 23 500 000 for administrative costs.

Article 50

Contributions from members other than the Union

The members of the Circular Bio-based Europe Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 1 000 000 000, including up to EUR 23 500 000 for administrative costs, over the period set out in Article 3.

Article 51

Scope of additional activities

1. Notwithstanding the Governing Board's power of decision concerning the additional activities plan pursuant to Article 17(2), point (n), and within the scope of Article 2, points (9) and (10), the Bio-based Industries Consortium or their constituent or affiliated entities shall each year make a proposal for the additional activities. The additional activities are those directly linked to projects and activities of the Circular Bio-based Europe Joint Undertaking, including in particular:

- (a) investments in new facilities demonstrating a new value chain, including investments in durable equipment, tools and accompanying infrastructure, in particular related to regional deployment and its sustainability verification;
- (b) investments in a new innovative and sustainable production plant or flagship;
- (c) investments in new research and innovation and justified infrastructure, including facilities, tools, durable equipment or pilot plants (research centres);

- (d) standardisation activities;
 - (e) communication, dissemination and awareness-raising activities.
2. The investments directly linked to projects are in particular:
- (a) non-eligible investments needed for the implementation of a Circular Bio-based Europe Joint Undertaking project during the duration of that project;
 - (b) investment made in parallel with a Circular Bio-based Europe Joint Undertaking project, complementing the results of the project and bringing it to a higher TRL;
 - (c) investments needed for the deployment of a Circular Bio-based Europe Joint Undertaking project's results following the closure of the project until the winding up of the Circular Bio-based Europe Joint Undertaking. In justified cases, the investment related to deployment of results of projects from the preceding initiative (BBI Joint Undertaking) may be taken into account.

Article 52

Bodies of the Circular Bio-based Europe Joint Undertaking

The bodies of the Circular Bio-based Europe Joint Undertaking shall be:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the states' representatives group;
- (d) the Scientific Committee;
- (e) the Deployment Groups.

Article 53

Composition of the Governing Board

The Governing Board shall be composed as follows:

- (a) five representatives of the Commission, on behalf of the Union; and
- (b) five representatives of the members other than the Union, at least one of which should represent SMEs.

Article 54

Functioning of the Governing Board

1. The members other than the Union shall collectively hold 50 % of the voting rights.
2. By derogation from Article 16(4), the Governing Board shall elect its chairperson for a period of two years.
3. The Governing Board shall hold its ordinary meetings four times a year.
4. In addition to the meetings referred to in paragraph 2, the Governing Board shall also convene a strategic meeting at least once a year, with the primary objectives of identifying challenges and opportunities for sustainable bio-based industry and providing additional strategic orientation for the Circular Bio-based Europe Joint Undertaking.
5. Additional chief executive officers or officers with decision-making power of leading European bio-based companies and the Commission shall be invited to the strategic meeting.

*Article 55***The Scientific Committee**

1. The Scientific Committee shall be the scientific advisory body of the Circular Bio-based Europe Joint Undertaking referred to in Article 21(1).
2. The Scientific Committee shall have no more than 15 permanent members.
3. The chairperson of the Scientific Committee shall be elected for a period of two years.
4. The Scientific Committee shall set up a task force composed of experts with the appropriate profiles to contribute to ensuring sufficient focus on all sustainability aspects of the work programme. Whenever possible, advice of the Scientific Committee on the work programme shall include aspects related to circularity, environmental sustainability, biodiversity preservation and enhancement, as well as broader aspects of sustainability of the bio-based systems and related value chains.

*Article 56***The Deployment Groups**

1. One or more Deployment Groups shall be established pursuant to Article 22. The role of the Deployment Groups is to advise the Governing Board on issues critical to market uptake of bio-based innovation and to promote deployment of sustainable circular bio-based solutions.
2. The composition of the Deployment Groups shall ensure appropriate thematic focus and representativeness of a broad range of the bio-based innovation stakeholders. Any stakeholder other than the members of the Bio-Based Industries Consortium, their constituents or their affiliated entities may express its interest in becoming a member of a Deployment Group. The Governing Board shall set out the envisaged size and composition of the Deployment Groups, the duration of the mandates and the possibility of renewal of its members, and select their members.
3. The Deployment Groups shall meet at least once per year. At the first meeting, the Deployment Groups shall adopt their rules of procedure. Those rules of procedure shall be approved by the Governing Board. Extraordinary meetings of the Deployment Groups shall be called upon a request from the Governing Board, the chairperson or a majority of the relevant Deployment Group.
4. The Deployment Groups shall elect a chairperson, and a vice-chair per thematic focus, for a period of two years. The chairperson coordinates activities and represents the Deployment Group. The chairperson may be invited as an observer to meetings of the Scientific Committee and the states' representatives group.
5. The Deployment Groups shall provide recommendations on the issues related to the deployment of bio-based innovation upon request from the Governing Board. The Deployment Groups can also issue recommendations to the Governing Board at any time on their own initiative.

TITLE II

CLEAN AVIATION JOINT UNDERTAKING*Article 57***Additional objectives of the Clean Aviation Joint Undertaking**

1. In addition to the objectives set out in Articles 4 and 5, the Clean Aviation Joint Undertaking shall have the following general objectives:
 - (a) to contribute to reducing the ecological footprint of aviation by accelerating the development of climate neutral aviation technologies for earliest possible deployment, therefore significantly contributing to the achievement of the general goals of the European Green Deal, in particular in relation to the Union-wide net greenhouse gas emissions reduction target of at least 55 % by 2030, compared to 1990 levels, and to a pathway towards reaching climate neutrality at the latest by 2050;

- (b) to ensure that aeronautics-related research and innovation activities, with particular focus on breakthrough technology initiatives, contribute to the global sustainable competitiveness of the Union aviation industry, and to ensure that climate-neutral aviation technologies meet the relevant aviation safety and security requirements, and that aviation remains a secure, reliable, cost-effective and efficient means of passenger and freight transportation;
 - (c) to advance the European aviation research and innovation capacity.
2. The Clean Aviation Joint Undertaking shall also have the following specific objectives:
- (a) to integrate and demonstrate disruptive aircraft technological innovations able to decrease net emissions of greenhouse gases by no less than 30 % by 2030, compared to 2020 state-of-the-art technology, while paving the ground towards climate-neutral aviation by 2050;
 - (b) to ensure that the technological and the potential industrial readiness of innovations can support the launch of disruptive new products and services by 2035, with the aim of replacing 75 % of the operating fleet by 2050 and developing an innovative, reliable, safe and cost-effective European aviation system that is able to meet the objective of climate neutrality at the latest by 2050;
 - (c) to expand and foster integration of the climate-neutral aviation research and innovations value chains, including academia, research organisations, industry and SMEs, also by benefiting from exploiting synergies with other national and European related programmes and by supporting the uptake of industry-related skills across the value chain.

Article 58

Additional tasks of the Clean Aviation Joint Undertaking

In addition to the tasks set out in Article 5, the Clean Aviation Joint Undertaking shall carry out the following tasks:

- (a) publish on its website and on relevant Commission websites all the information necessary for the preparation and submission of proposals to open calls of the Clean Aviation Joint Undertaking;
- (b) monitor and assess technological progress towards the achievement of the general and specific objectives set out in Article 57;
- (c) facilitate full access to data and information for the independent impact monitoring of aviation research and innovation, carried out under the supervision of the Commission;
- (d) assist the Commission upon its request with the establishment and development coordination of regulations and standards supporting market uptake of clean aviation solutions, in particular by conducting studies, simulations and providing technical advice, while taking into account the need to eliminate barriers to market entry.

Article 59

Members

1. The members of the Clean Aviation Joint Undertaking shall be:
- (a) the Union, represented by the Commission;
 - (b) the founding members listed in Annex I, upon notification of their decision to accede to the Clean Aviation Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding their accession other than those set out in this Regulation;
 - (c) the associated members to be selected in accordance with Article 7 subject to a decision of the Governing Board.

2. In addition to Article 7(1), the Governing Board may, during the first six months following the establishment of Clean Aviation Joint Undertaking, select associated members from a list drawn up after an open call for expression of interest launched by the Commission prior to its establishment. The conditions of Article 7(2) shall apply *mutatis mutandis*.

Article 60

Union financial contribution

The Union financial contribution to the Clean Aviation Joint Undertaking, including EEA appropriations, to cover administrative costs and operational costs shall be up to EUR 1 700 000 000, including up to EUR 39 223 000 for administrative costs.

Article 61

Contributions from members other than the Union

The members of the Clean Aviation Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 2 400 000 000, including up to EUR 39 223 000 for administrative costs, over the period set out in Article 3.

Article 62

Scope of additional activities

1. For the purpose of Article 11(1), point (b), additional activities may include:
 - (a) activities covered under the indirect actions of the Clean Aviation Joint Undertaking but not funded under such indirect actions;
 - (b) activities directly linked to the Clean Aviation Joint Undertaking work programme;
 - (c) research and innovation activities building on activities funded by the Clean Aviation Joint Undertaking or its preceding initiative;
 - (d) the research and innovation activities of projects with a clear link to the Strategic Research and Innovation Agenda, and co-funded under national or regional programmes within the Union;
 - (e) private research and innovation projects complementing projects on the Strategic Research and Innovation Agenda as well as activities contributing to the uptake of industry-specific skills across the value chain;
 - (f) activities leading to the deployment or uptake of project results from the Clean Aviation Joint Undertaking or its preceding initiatives, or from both, that have not received any Union funding;
 - (g) European standardisation and certification activities related to clean aviation solutions from the Clean Aviation Joint Undertaking projects or its preceding initiatives.
2. Additional activities shall have clearly defined deliverables.

Article 63

Bodies of the Clean Aviation Joint Undertaking

The bodies of the Clean Aviation Joint Undertaking shall be:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the states' representatives group;

- (d) the Technical Committee;
- (e) the European Clean Aviation Scientific Advisory Body.

Article 64

Composition of the Governing Board

The Governing Board shall be composed as follows:

- (a) two representatives of the Commission on behalf of the Union;
- (b) fifteen representatives of the members other than the Union chosen by and from the founding members and associated members ensuring a balanced representation of the aeronautical value chain such as aircraft integrators, engine manufacturers and equipment manufacturers. The governing board shall establish in its rules of procedure a rotation mechanism for the allocation of the seats of the members other than the Union taking into account gender balance. The selected representatives shall include at least one representative of the European SMEs, at least two representatives of the research organisations and at least one representative of the higher education institutions.

Article 65

Functioning of the Governing Board

1. The members other than the Union shall collectively hold 50 % of the voting rights.
2. By derogation from Article 16(4), the Governing Board shall be chaired by the Commission on behalf of the Union and co-chaired by a representative from the members other than the Union.
3. The chairpersons of the European Clean Aviation Scientific Advisory Body, of the Technical Committee and of the states' representatives group and one representative from EASA shall attend the meetings of the Governing Board as observers.
4. The Governing Board shall ensure a direct link and coordination between the activities of the states' representatives group or other advisory bodies. To that effect, the Governing Board may also delegate a member to follow activities of those bodies.

Article 66

Additional tasks of the Governing Board

1. In addition to the tasks listed in Article 17, the Governing Board of the Clean Aviation Joint Undertaking shall carry out the following tasks:
 - (a) oversee the relevance for clean aviation of the strategies for additional activities of the members other than the Union;
 - (b) promote the market uptake of technologies and solutions for contributing to achieving the European Green Deal's objectives and ensure the achievement of the Joint Undertaking's specific objectives set out in Article 57;
 - (c) pursue synergies between research and demonstration activities at regional, national or Union level that relate to the Strategic Research and Innovation Agenda and the Clean Aviation Joint Undertaking's work programme;
 - (d) supervise the programme's monitoring and assessment of the progress compared to impact indicators and the Clean Aviation Joint Undertaking's specific objectives set out in Article 57(2);
 - (e) ensure the continued steering and management of the transition of the Clean Sky 2 programme technical priorities and research and innovation activities until their completion, in line with the objectives of the Clean Aviation Joint Undertaking and ensure, where relevant, the transfer of results to the Clean Aviation programme.

2. The Governing Board shall assess and decide in relation to the implementation of the programme and to the delivery on the Clean Aviation Joint Undertaking objectives, including on:
- (a) the strategic multiannual planning of Clean Aviation calls and their alignment with the objectives of Horizon Europe and the related work programmes and the technical priorities and research actions;
 - (b) revisions or optimisation of the technical scope of the programme to align the work programme and the objectives of the Clean Aviation Joint Undertaking with the overall Horizon Europe and other European partnership' related work programmes;
 - (c) the recommendations by advisory bodies and specific actions set out in Article 58 to increase market penetration and impact of clean aviation solutions in line with the European Green Deal and related policy actions to improve it.

Article 67

Additional tasks of the Executive Director

In addition to the tasks set out in Article 19, the Executive Director of the Clean Aviation Joint Undertaking shall carry out the following tasks:

- (a) take appropriate action to manage interactions between projects supported by the joint undertaking, avoiding undue overlaps between them and boosting synergies across the whole programme;
- (b) ensure that deadlines are met for the transmission of necessary information to the various bodies of the Clean Aviation Joint Undertaking;
- (c) facilitate coordination by the Commission in accordance with the advice of the advisory bodies between the activities of the Clean Aviation Joint Undertaking and the relevant research and innovation activities within Horizon Europe with a view to avoiding overlaps and promoting synergies;
- (d) ensure that the Joint Undertaking facilitates full access to data and information for the independent impact monitoring of aviation research and innovation carried out under the direct supervision of the Commission and takes any appropriate action needed to ensure the independence of that process from the Clean Aviation Joint Undertaking itself, such as by means of public procurement, independent evaluations, reviews or ad-hoc analysis. The programme's monitoring and assessment report shall be presented to the Governing Board once a year;
- (e) assist the Governing Board adaptations of the technical content and budget allocations of the work programme during the implementation of the Strategic Research and Innovation Agenda in order to maximise the achievements of the Clean Aviation Joint Undertaking.

Article 68

The states' representatives group

1. The states' representatives group shall hold coordination meetings with the states' representatives group of other relevant joint undertakings, such as the Single European Sky ATM Research 3 Joint Undertaking, at least twice a year, with the aim of creating an interface between the national and regional authorities and the Clean Aviation Joint Undertaking and providing advice to the Clean Aviation Joint Undertaking on this basis.
2. In addition to Article 20, the states' representatives group shall also have the following additional tasks:
- (a) propose measures to improve the complementarity between the Clean Aviation Research and Innovation actions and national research programmes contributing to the objectives of the Strategic Research and Innovation Agenda, as well as with international and other national initiatives and projects;

- (b) promote specific measures at national or regional level that aim to increase the involvement of SMEs in Clean Aviation Research and Innovation, including through dissemination events, dedicated technical workshops and communication, and any other actions that aim to promote cooperation and deployment of aeronautical technologies;
- (c) promote research and innovation investment from Cohesion Policy funds such as the European Regional Development Funds, the European Social funds, the Just Transition Funds and Next Generation EU Funds into the context of the Clean Aviation Joint Undertaking.

Article 69

The Technical Committee

1. The Technical Committee shall be composed as follows:
 - (a) up to four Commission representatives and Union bodies, as decided by the representatives of the Union in the Governing Board;
 - (b) one representative from each member other than the Union;
 - (c) one representative of the EASA.
2. The Technical Committee shall be co-chaired by a representative of the founding members, rotating on a two-yearly basis, and the Commission. It shall report to the Governing Board and its secretariat shall be provided by the Clean Aviation Joint Undertaking.
3. The Executive Director shall be a permanent observer in the Technical Committee. Representatives of the states' representatives group and the European Clean Aviation Scientific Advisory Body may attend as observers upon invitation of the chair, or on their own request, in which case their attendance shall be subject to the agreement of the chair and the Joint Undertaking's representatives.
4. The Technical Committee shall propose its rules of procedure and shall submit them for adoption by the Governing Board.
5. The Technical Committee shall develop and maintain the technological roadmap and strategy of the programme. It shall propose and prepare for adoption by the Governing Board, as appropriate, the scope and programming of the research actions, the technical strategy and the overall research roadmap of the Clean Aviation Joint Undertaking. A Governing Board member may be delegated to follow the activities therein.
6. The Technical Committee shall carry out the following tasks:
 - (a) prepare proposals for the amendment of the Strategic Research and Innovation Agenda as needed for deliberation and final decision by the Governing Board;
 - (b) prepare proposals for the technical priorities and research actions to be included in the work programme and the research topics for open calls for proposals;
 - (c) provide information on research actions planned or in progress at national, regional or other non-Union levels and make recommendations on the actions necessary to maximise possible synergies of the Clean Aviation Joint Undertaking's programme;
 - (d) propose for deliberation and final decision by the Governing Board revisions or optimisation of the technical scope of the programme in order to align the work programme and the objectives of the Clean Aviation Joint Undertaking with the overall Horizon Europe and other European partnerships' related work programmes, as identified in the Strategic Research and Innovation Agenda;
 - (e) make recommendations on maximising the impact in line with the European Green Deal objectives and the potential market uptake of the programme's results from indirect actions funded by the Joint Undertaking.

*Article 70***The European Clean Aviation Scientific Advisory Body**

1. The European Clean Aviation Scientific Advisory Body shall be the scientific advisory body of the Clean Aviation Joint Undertaking set up in accordance with Article 21(1), point (a), and with Article 21(4).
2. The European Clean Aviation Scientific Advisory Body shall have no more than 15 permanent members and those members shall not be members of any other body under this Joint Undertaking.
3. The chairperson of the European Clean Aviation Scientific Advisory Body shall be elected for the duration of two years.
4. A representative of the EASA shall be a permanent member of the European Clean Aviation Scientific Advisory Body.
5. In carrying out its tasks the European Clean Aviation Scientific Advisory Body shall cooperate with relevant European aviation stakeholders' fora, such as the Advisory Council for Aeronautics Research in Europe (ACARE).
6. The European Clean Aviation Scientific Advisory Body shall, pursuant to Article 21(7), point (f), hold coordination meetings with the advisory bodies of other relevant joint undertakings such as the Single European Sky ATM Research 3 Joint Undertaking, with the aim of promoting synergies and cooperation among relevant Union research and innovation initiatives in aviation and providing advice to that effect to the Clean Aviation Joint Undertaking on this basis.
7. The European Clean Aviation Scientific Advisory Body shall also advise and support the Commission and the Clean Aviation Joint Undertaking on initiatives that promote aviation research in the European education systems, and provide recommendations on aeronautical skills and competences development and updated aeronautical engineering curricula.

*Article 71***Certification of new technologies**

1. The EASA may be invited by applicants, beneficiaries or the Executive Director to advise on individual projects and demonstration activities on issues related to compliance with aviation safety, interoperability and environmental standards, to ensure that these lead to timely development of relevant standards, testing capacity and regulatory requirements for product development and deployment of new technologies.
2. Certification activities and services provided shall be subject to the provisions regarding fees and charges set out in Regulation (EU) 2018/1139.

*Article 72***Derogation from the rules for participation**

Where it is duly justified in the description of relevant topics in the work programme, a single legal entity established in a Member State or associated country or consortia not meeting the condition laid down in Article 22(2) of the Horizon Europe Regulation shall be eligible to participate in indirect actions funded by the Clean Aviation Joint Undertaking.

TITLE III

CLEAN HYDROGEN JOINT UNDERTAKING*Article 73***Additional objectives of the Clean Hydrogen Joint Undertaking**

1. In addition to the objectives set out in Articles 4 and 5, the Clean Hydrogen Joint Undertaking shall have the following general objectives:
 - (a) to contribute to the objectives set out in the communication from the Commission of 17 September 2020 on Stepping up Europe's 2030 climate ambition: Investing in a climate-neutral future for the benefit of our people, the European Green Deal and the European Climate Law by raising the Union's ambition on reducing greenhouse gas emissions to at least 55 % below 1990 levels by 2030, and climate neutrality at the latest by 2050;
 - (b) to contribute to the implementation of the 2020 Commission's Hydrogen Strategy for a climate neutral Europe;
 - (c) to strengthen the competitiveness of the Union clean hydrogen value chain, with a view to supporting, in particular for SMEs, the acceleration of the market entry of innovative competitive clean solutions;
 - (d) to stimulate research and innovation on clean hydrogen production, distribution, storage and end use applications.
2. The Clean Hydrogen Joint Undertaking shall also have the following specific objectives:
 - (a) improve through research and innovation, including activities related to lower TRLs, the cost-effectiveness, efficiency, reliability, quantity and quality of clean hydrogen solutions, including production, distribution, storage and end uses developed in the Union;
 - (b) strengthen the knowledge and capacity of scientific and industrial actors along the Union's hydrogen value chain while supporting the uptake of industry-related skills;
 - (c) carry out demonstrations of clean hydrogen solutions with a view to local, regional and Union-wide deployment, aiming to involve stakeholders in all Member States and addressing renewable production, distribution, storage and use for transport and energy-intensive industries as well as other applications;
 - (d) increase public and private awareness, acceptance and uptake of clean hydrogen solutions, in particular through cooperation with other European partnerships under Horizon Europe.

*Article 74***Additional tasks of the Clean Hydrogen Joint Undertaking**

In addition to the tasks set out in Article 5, the Clean Hydrogen Joint Undertaking shall carry out the following tasks:

- (a) assess and monitor technological progress and technological, economic and societal barriers to market entry, including in emerging hydrogen markets;
- (b) notwithstanding the Commission's policy prerogatives, under the Commission's policy guidance and supervision, contribute to the development of regulations and standards with the view to eliminating barriers to market entry and to supporting interchangeability, inter-operability and trade across the internal market and globally;
- (c) support the Commission, including through technical expertise, in its international initiatives on the hydrogen strategy, such as the International Partnership on the Hydrogen Economy (IPHE), Mission Innovation and the Clean Energy Ministerial Hydrogen Initiative.

*Article 75***Members**

The members of the Clean Hydrogen Joint Undertaking shall be:

- (a) the Union, represented by the Commission;
- (b) the Hydrogen Europe AISBL, a non-profit organisation registered under Belgian Law (the 'Industry Grouping'), upon notification of its decision to accede to the Clean Hydrogen Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding its accession other than those set out in this Regulation;
- (c) the Hydrogen Europe Research AISBL, a non-profit organisation registered under Belgian Law (the 'Research Grouping'), upon notification of its decision to accede to the Clean Hydrogen Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding its accession other than those set out in this Regulation.

*Article 76***Union financial contribution**

The Union financial contribution to the Clean Hydrogen Joint Undertaking, including EEA appropriations, to cover administrative and operational costs shall be up to EUR 1 000 000 000, including up to EUR 30 193 000 for administrative costs.

*Article 77***Contributions from members other than the Union**

The members of the Clean Hydrogen Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 1 000 000 000, including up to EUR 30 193 000 for administrative costs, over the period set out in Article 3.

*Article 78***Scope of additional activities**

1. For the purpose of Article 11(1), point (b), additional activities may include activities directly linked to the activities of the Clean Hydrogen Joint Undertaking and contributing to its objectives, including the following:

- (a) pre-commercial trials and field tests;
- (b) proof of concept;
- (c) improvement of existing production lines for up-scaling;
- (d) large scale case studies;
- (e) awareness-raising activities on hydrogen technologies and safety measures;
- (f) uptake of results from projects into products, further exploitation and activities within the research chain either at higher TRLs or in parallel strands of activity;
- (g) the research and innovation activities of projects with a clear link to the Strategic Research and Innovation Agenda, and co-funded under national or regional programmes within the Union.

2. Additional activities of the Clean Hydrogen Joint Undertaking shall aim to ensure synergies with the Clean Hydrogen Alliance, Mission Innovation Challenge 'Renewable and Clean Hydrogen', the European Union Innovation Fund, the H2 Regions Smart Specialisation Strategy (S3) platform and the ERA pilot on green hydrogen.

*Article 79***Bodies of the Clean Hydrogen Joint Undertaking**

The bodies of the Clean Hydrogen Joint Undertaking shall be the following:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the states' representatives group; and
- (d) the stakeholders group.

*Article 80***Composition of the Governing Board**

The Governing Board shall be composed of the following:

- (a) representatives of the Commission on behalf of the Union;
- (b) six representatives of the Industry Grouping, having regard to geographical, gender, company size and sector representation;
- (c) one representative of the Research Grouping.

*Article 81***Functioning of the Governing Board**

1. In addition to the voting rules set out in Article 16(3), the Industry Grouping shall hold 43 % of the voting rights and the Research Grouping 7 % of the voting rights in the Governing Board.
2. The chairperson of the Governing Board shall be a representative of the private members and shall be appointed by the Governing Board.

*Article 82***Additional tasks of the Governing Board**

In addition to the tasks set out in Article 17, the Governing Board of the Clean Hydrogen Joint Undertaking shall carry out the following tasks:

- (a) foster synergies with relevant activities and programmes at Union, national or regional level, in particular with those supporting the deployment of research and innovation solutions, infrastructure, education and regional development on the use of clean hydrogen;
- (b) provide pursuant to Article 5(2), point (b), and Article 17(n) strategic orientation as regards the collaboration with other European partnerships, including the partnerships towards zero emission road transport, zero emission waterborne, Europe's rail, clean aviation, processes for the planet and clean steel in accordance with their respective Strategic Research and Innovation Agendas or other equivalent document;
- (c) encourage market uptake of technologies and solutions for achieving the European Green Deal's objectives;
- (d) ensure that independent opinions and advice of the wider scientific community on the Strategic Research and Innovation Agenda, work programmes and developments in adjacent sectors are gathered through an independent scientific advisory workshop as part of the European Clean Hydrogen partnership forum.

*Article 83***Additional tasks of the Executive Director**

In addition to the tasks set out in Article 19, the Executive Director of the Clean Hydrogen Joint Undertaking shall carry out the following tasks:

- (a) propose and implement activities that boost synergies with relevant activities and programmes at Union, national or regional level;
- (b) support and contribute to other Union initiatives related to hydrogen, subject to approval by the Governing Board;
- (c) convene, subject to approval by the Governing Board, an annual European Clean Hydrogen partnership forum, including the independent scientific advisory workshop referred to in Article 82(d); the partnership forum, where possible, shall be held jointly and in parallel with the European Hydrogen Forum of the Clean Hydrogen Alliance.

*Article 84***The stakeholders group**

1. The stakeholders group shall consist of representatives of sectors which generate, distribute, store, need or use clean hydrogen across the Union, including the representatives of other relevant European partnerships, as well as representatives of the European Hydrogen Valleys Interregional Partnership and of the scientific community.
2. In addition to the tasks set out in Article 22, the stakeholders group shall have the following tasks:
 - (a) provide input on the strategic and the technological priorities to be addressed by the Clean Hydrogen Joint Undertaking as laid down in the Strategic Research and Innovation Agenda or any other equivalent document and associated detailed technological roadmaps, taking due account of the progress and needs in adjacent sectors;
 - (b) provide suggestions to enable concrete synergies to take place between the Clean Hydrogen Joint Undertaking and the adjacent sectors or any sector with which synergies are deemed of added value;
 - (c) provide input to the European Clean Hydrogen partnership forum and to the European Hydrogen Forum of the Clean Hydrogen Alliance.

TITLE IV

EUROPE'S RAIL JOINT UNDERTAKING*Article 85***Additional objectives of the Europe's Rail Joint Undertaking**

1. In addition to the objectives set out in Articles 4 and 5, the Europe's Rail Joint Undertaking shall have the following general objectives:
 - (a) contribute towards the achievement of the Single European Railway Area;
 - (b) ensure a fast transition to more attractive, user-friendly, competitive, affordable, easy to maintain, efficient and sustainable European rail system, integrated into the wider mobility system;
 - (c) support the development of a strong and globally competitive European rail industry.

2. In addition to the objectives set out in paragraph 1, the Europe's Rail Joint Undertaking shall have the following specific objectives:

- (a) facilitate research and innovation activities to deliver an integrated European railway network by design, eliminating barriers to interoperability and providing solutions for full integration, covering traffic management, vehicles, infrastructure also including integration with national gauges, such as 1 520, 1 000 or 1 668 mm railway, and services, and providing the best answer to the needs of passengers and businesses, accelerating uptake of innovative solutions to support the Single European Railway Area, while increasing capacity and reliability and decreasing costs of railway transport;
- (b) deliver a sustainable and resilient rail system by developing a zero-emission, silent rail system and climate resilient infrastructure, applying circular economy to the rail sector, piloting the use of innovative processes, technologies, designs and materials in the full life-cycle of rail systems and developing other innovative solutions to guided surface transport;
- (c) develop through its System Pillar a unified operational concept and a functional, safe and secure system architecture, with due consideration of cyber-security aspects, focused on the European railway network to which Directive (EU) 2016/797 of the European Parliament and of the Council ⁽³⁹⁾ applies, for integrated European rail traffic management, command, control and signalling systems, including automated train operation which shall ensure that research and innovation is targeted on commonly agreed and shared customer requirements and operational needs and is open to evolution;
- (d) facilitate research and innovation activities related to rail freight and intermodal transport services to deliver a competitive green rail freight fully integrated into the logistic value chain, with automation and digitalisation of freight rail at the core;
- (e) develop demonstration projects in interested Member States;
- (f) contribute to the development of a strong and globally competitive European rail industry;
- (g) enable, promote and exploit synergies with other Union policies, programmes, initiatives, instruments or funds in order to maximise its impact and added value.

3. In carrying out its activities, the Europe's Rail Joint Undertaking shall seek a geographically balanced involvement of members and partners in its activities. It shall also establish the necessary international connections in relation to rail research and innovation, in line with the Commission priorities.

Article 86

Additional tasks of the Europe's Rail Joint Undertaking

1. In addition to the tasks set out in Article 5, the Europe's Rail Joint Undertaking together with the Commission shall prepare and, after consultation of the states' representatives group, submit for adoption by the Governing Board the Master Plan, developed in consultation with all relevant stakeholders in the railway system and rail supply industry.

2. The Commission may start the preparation of the Master Plan prior to the establishment of the Europe's Rail Joint Undertaking, in consultation with Member States' representatives and all relevant stakeholders.

3. The Master Plan shall constitute a common, forward-looking roadmap based on a system view. It shall identify the areas of intervention within the scope of the Europe's Rail Joint Undertaking. The objectives set out in the Master Plan shall be performance driven and structured around the objectives set out in Article 85.

4. The Master Plan shall be adopted by the Governing Board and endorsed by the Commission in accordance with Article 16 with the exception of the section of the Master Plan relating to the System Pillar that shall be adopted in accordance with Article 93(4). Before endorsement, the Commission shall present the Master Plan to the Council and to the European Parliament. Subsequently, any modification shall be communicated to the Council and the European Parliament.

⁽³⁹⁾ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

5. The Master Plan shall constitute the Europe's Rail Joint Undertaking's Strategic Research and Innovation Agenda within the meaning of Article 2, point (12). It shall provide guidance for the Europe's Rail Joint Undertaking's more specific tasks, namely:

- (a) develop in its System Pillar a system view that reflects the needs of the rail manufacturing industry, the rail operating community, Member States and other rail private and public stakeholders, including bodies representing customers, such as passengers and freight and staff, as well as relevant actors outside the traditional rail sector. The 'system view' shall encompass:
 - (i) the development of the operational concept and system architecture, including the definition of the services, functional blocks, and interfaces which form the basis of rail system operations;
 - (ii) the development of associated specifications including interfaces, functional requirement specifications and system requirement specifications to feed into Technical Specifications for Interoperability (TSI) established pursuant to Directive (EU) 2016/797 or standardisation processes to lead to higher levels of digitalisation and automation;
 - (iii) ensuring the system is maintained, error-corrected and able to adapt over time and ensure migration considerations from current architectures;
 - (iv) ensuring that the necessary interfaces with other modes, as well as with metro and trams or light rail systems, are assessed and demonstrated, in particular for freight and passenger flows;
- (b) facilitate the research and innovation activities necessary to achieve the objectives of the Europe's Rail Joint Undertaking, including low TRLs rail-focused research and innovation activities. In that respect, the Europe's Rail Joint Undertaking shall:
 - (i) define and organise the research, innovation, demonstration, validation and study activities to be carried out under its authority, while avoiding fragmentation of such activities;
 - (ii) exploit standardisation and modularity opportunities, and facilitate the interfaces with other modes and systems;
 - (iii) develop demonstration projects;
 - (iv) develop close cooperation and ensure coordination with related European, national and international research and innovation activities in the rail sector and beyond as necessary, in particular under Horizon Europe, thereby enabling the Europe's Rail Joint Undertaking to play a major role in rail-related research and innovation while also benefiting from scientific and technological advances reached in other sectors;
 - (v) ensure, through the cooperation referred to in point (iv), the translation of research into effective development effort and development of pioneering innovations and ultimately into market focused innovation through demonstration and deployment;
- (c) perform any tasks necessary to achieve the objectives set out in Articles 4 and 85.

Article 87

Members

1. The members of the Europe's Rail Joint Undertaking shall be:
 - (a) the Union, represented by the Commission;
 - (b) the founding members listed in Annex II, upon notification of their decision to accede to the Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding their accession other than those set out in this Regulation;
 - (c) the associated members to be selected in accordance with Article 7. The list of the associated members shall be endorsed by the Commission.

2. In addition to Article 7(1), the Governing Board may, during the first six months following the establishment of the Europe's Rail Joint Undertaking, select associated members from a list drawn up after an open call for expression of interest launched by the Commission prior to its establishment. The conditions of Article 7(2) shall apply *mutatis mutandis*.

Article 88

Union financial contribution

The Union financial contribution to the Europe's Rail Joint Undertaking, including EEA appropriations, to cover administrative costs and operational costs shall be up to EUR 600 000 000, including at least EUR 50 000 000 for the System Pillar and up to EUR 24 000 000 for administrative costs.

Article 89

Contributions from members other than the Union

The members of the Europe's Rail Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 600 000 000, including up to EUR 24 000 000 for administrative costs, over the period set out in Article 3.

Article 90

Scope of additional activities

1. For the purposes of Article 11(1), point (b), additional activities may include:
 - (a) activities covered under the indirect actions of the Europe's Rail Joint Undertaking but not funded under such indirect actions;
 - (b) activities directly linked to the Europe's Rail Joint Undertaking work programme;
 - (c) research and innovation activities building on activities funded by the Europe's Rail Joint Undertaking or Shift2Rail Joint Undertaking;
 - (d) complementary research and innovation activities funded by the members other than the Union, having a clear Union added value and contributing to achieving the objectives of the Europe's Rail Joint Undertaking;
 - (e) activities funded by the members other than the Union in projects funded by national programmes or by regional programmes which complement activities funded by the Europe's Rail Joint Undertaking;
 - (f) uptake of results of activities funded under the Shift2Rail and Europe's Rail Joint Undertakings, further exploitation, demonstration activities, standardisation and development of recommendations for seamless transition strategies, migration paths and updates of TSI, and European authorisation and certification activities not linked to wider deployment.
2. With regard to activities funded by the members other than the Union in projects funded by other European partnerships or by other Union programmes or by other research and innovation efforts and investments that have a significant Union added value and contribute to achieving the objectives of the Europe's Rail Joint Undertaking and its complement activities funded by it, the value of such activities shall be reported, indicating the type, level and source of Union funding to avoid double counting.

Article 91

Bodies of the Europe's Rail Joint Undertaking

1. The bodies of the Europe's Rail Joint Undertaking shall be:
 - (a) the Governing Board;

- (b) the Executive Director;
- (c) the states' representatives group;
- (d) the System Pillar steering group;
- (e) the Deployment Group.

2. The Europe's Rail Joint Undertaking may set up a scientific steering group or seek scientific advice from independent academic experts or from shared scientific advisory bodies.

Article 92

Composition of the Governing Board

The Governing Board shall be composed as follows:

- (a) two representatives from the Commission on behalf of the Union;
- (b) one representative from each of the members other than the Union.

Article 93

Functioning of the Governing Board

1. By derogation from Article 16(4), the Governing Board shall be chaired by the Commission on behalf of the Union.
2. The members other than the Union shall collectively hold 50 % of the voting rights.
3. Representatives of the European Union Agency for Railways and of the European Rail Research Advisory Council (ERRAC) shall be invited to attend meetings of the Governing Board as observers and take part in its deliberation, but shall have no voting rights.
4. By derogation from Article 16(1) with regard to activities to be performed under the System Pillar, a decision shall be deemed adopted by a majority of at least 55 % of the votes including the votes of representatives who are absent.
5. In addition to Article 16(5), the Governing Board shall meet once a year in a general assembly and all participants to the research and innovation activities of the Europe's Rail Joint Undertaking shall be invited to attend. The assembly shall stimulate reflection on the overall direction of the activities of the Europe's Rail Joint Undertaking while conducting an open and transparent discussion on the progress of the Master Plan implementation.

Article 94

Additional tasks of the Governing Board

In addition to the tasks set out in Article 17, the Governing Board of the Europe's Rail Joint Undertaking shall carry out the following tasks:

- (a) adopt the Master Plan and any proposal for its modification;
- (b) adopt the work programmes, including the budget and implementation plan, of the System Pillar and their amendments based on recommendations made by the System Pillar steering group and on the proposals of the Executive Director.

Article 95

The states' representatives group

In addition to Article 20, the Member States shall ensure that their respective representatives present a coordinated position that reflects their Member State's views expressed in:

- (a) the committee established by Article 51 of Directive (EU) 2016/797;

- (b) the Programme Committee under Horizon Europe configuration 'Climate, Energy and Mobility';
- (c) the Single European Rail Area Committee, established by Article 62 of Directive 2012/34/EU of the European Parliament and of the Council ⁽⁴⁰⁾.

Article 96

The System Pillar steering group

1. The System Pillar steering group shall be an advisory body of the Europe's Rail Joint Undertaking in charge of providing advice on System Pillar issues.
2. The System Pillar steering group shall be composed of representatives of the Commission, representatives of the rail and mobility sector and of relevant organisations, the Executive Director of the Europe's Rail Joint Undertaking, the chairperson of the states' representatives group and representatives of the European Union Agency for Railways and of the ERRAC. The Commission shall take the final decision on the composition of the Group. When justified, the Commission may invite additional relevant experts and stakeholders to attend the meetings of the System Pillar steering group as observers. The System Pillar steering group shall regularly report to the states' representatives group on its activities.
3. The System Pillar Steering group shall be chaired by the Commission.
4. The recommendations of the System Pillar steering group shall be adopted by consensus. Where no consensus is reached, the Executive Director of the Europe's Rail Joint Undertaking shall prepare a report for the Governing Board, in consultation with the European Union Agency for Railways and the Commission, outlining the key common points and diverging views. In this case, the states' representatives group shall also prepare an opinion for the Governing Board.
5. The System Pillar steering group shall adopt its own rules of procedure.
6. The System Pillar steering group shall be responsible for providing advice to the Executive Director and Governing Board on any of the following:
 - (a) the approach to operational harmonisation and the development of system architecture, including on the relevant part of the Master Plan;
 - (b) delivering on the specific objective set out in Article 85(2), point (c);
 - (c) carrying out the task set out in Article 86(5), point (a);
 - (d) the detailed annual implementation plan for the System Pillar in line with the work programmes adopted by the Governing Board in accordance with Article 94, point (b);
 - (e) monitoring the progress of the System Pillar.

Article 97

The Deployment Group

1. The Deployment Group shall be established pursuant to Article 22. The role of the Deployment Group shall be to advise the Governing Board on the market uptake of rail innovation developed in the Europe's Rail Joint Undertaking and to support deployment of the innovative solutions.
2. The Deployment Group shall be open to all stakeholders. The composition of the Deployment Group shall ensure appropriate thematic focus and representativeness. The Commission shall take the final decision on the composition of the Group. The list of members shall be published on the website of the Europe's Rail Joint Undertaking.

⁽⁴⁰⁾ Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (OJ L 343, 14.12.2012, p. 32).

3. The Deployment Group shall provide recommendations on issues related to the deployment of rail innovative solutions upon request of the Governing Board. The Deployment Group may also issue recommendations on its own initiative.

Article 98

Collaboration with the European Union Agency for Railways

The Europe's Rail Joint Undertaking shall ensure a close collaboration with the European Union Agency for Railways, in particular with regard to the implementation of the Master Plan. Pursuant to Article 40 of Regulation (EU) 2016/796 of the European Parliament and of the Council ⁽⁴¹⁾, that collaboration shall consist of the following advisory tasks:

- (a) input on research needs relating to the realisation of the Single European Railway Area for consideration by the Europe's Rail Joint Undertaking in the Master Plan and its amendments as well as in the work programmes;
- (b) feedback and advice on interoperability and safety to be considered in the research innovation activities and, more specifically, in the context of project activities and results for the objectives identified in Article 86(5), point (a);
- (c) support to the Europe's Rail Joint Undertaking in identifying needs for any additional specific validation or studies to be performed by it, including via the involvement of national safety authorities;
- (d) provide advice as regards the System Pillar;
- (e) ensure that the development of specifications including interfaces, functional requirement specifications, and system requirement specifications takes into consideration the experience and feedback on TSI or standards.

TITLE V

GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING

Article 99

Additional objectives of the Global Health EDCTP3 Joint Undertaking

1. In addition to the objectives set out in Articles 4 and 5, the Global Health EDCTP3 Joint Undertaking shall have the following general objectives:

- (a) to contribute to the reduction of the socioeconomic burden of infectious diseases in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies;
- (b) to contribute to the increase of health security in sub-Saharan Africa and globally by strengthening the research- and innovation-based capacities for preparedness and response to control infectious diseases.

2. The Global Health EDCTP3 Joint Undertaking shall also have the following specific objectives:

- (a) to advance the development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the clinical trials, in sub-Saharan Africa;
- (b) to strengthen research and innovation capacity and the national health research systems in sub-Saharan Africa for tackling infectious diseases;

⁽⁴¹⁾ Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (OJ L 138, 26.5.2016, p. 1).

- (c) to facilitate better alignment of Member States, associated countries and sub-Saharan countries around a common Strategic Research and Innovation Agenda in the field of global health to increase the cost-effectiveness of European public investment;
- (d) to strengthen capacity in sub-Saharan Africa for epidemic preparedness through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of emerging diseases of epidemic potential;
- (e) to promote productive and sustainable networking and partnerships in the area of global health research building North–South and South–South relationships with multiple private and public-sector organisations.

Article 100

Additional tasks of the Global Health EDCTP3 Joint Undertaking

In addition to the tasks set out in Article 5, the Global Health EDCTP3 Joint Undertaking shall carry out the following tasks:

- (a) fostering productive relationships between European and African individuals, groups and institutions;
- (b) raising awareness of common interests and shared goals between institutions and research groups to facilitate and strengthen project and institutional collaborations;
- (c) contributing to facilitating alignment of global health strategies of European and African funders, institutions and authorities;
- (d) attracting additional investment involving partners from the private, public, and charitable sectors;
- (e) promoting synergies, collaboration and joint actions with the Neighbourhood, Development and International Cooperation Instrument established by Regulation (EU) 2021/947 of the European Parliament and of the Council ⁽⁴²⁾, in particular for capacity building and sharing facilities and infrastructures.

Article 101

Members

The members of the Global Health EDCTP3 Joint Undertaking shall be:

- (a) the Union, represented by the Commission;
- (b) the EDCTP Association, a non-profit organisation registered under Dutch law, upon notification of its decision to accede to the Global Health EDCTP3 joint undertaking by means of a letter of commitment, which shall not contain conditions regarding its accession other than those set out in this Regulation.

Article 102

Union financial contribution

The Union financial contribution to the Global Health EDCTP3 Joint Undertaking, including EEA appropriations, to cover administrative costs and operational costs shall be up to EUR 800 000 000, including up to EUR 59 756 000 for administrative costs, and shall consist of the following:

- (a) up to EUR 400 000 000 provided that the contribution of members other than the Union, or its constituent or affiliated entities, is at least equal to this amount;
- (b) up to EUR 400 000 000 provided that the contributions from contributing partners, or from their constituent or affiliated entities, are at least equal to this amount.

⁽⁴²⁾ Regulation (EU) 2021/947 of the European Parliament and of the Council of 9 June 2021 establishing the Neighbourhood, Development and International Cooperation Instrument – Global Europe, amending and repealing Decision No 466/2014/EU and repealing Regulation (EU) 2017/1601 and Council Regulation (EC, Euratom) No 480/2009 (OJ L 209, 14.6.2021, p. 1).

In the event that the condition under point (b) is not met, the amount under point (a) shall be increased by up to EUR 400 000 000, provided that the total amount by which it is increased shall be at least matched by the contribution of members other than the Union, or their constituent or affiliated entities, as set out in Article 103(1).

Article 103

Contributions from members other than the Union

1. The members of the Global Health EDCTP3 Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 439 878 000 over the period set out in Article 3.
2. The contributions referred to in paragraph 1 of this Article shall consist of contributions to the Global Health EDCTP3 Joint Undertaking as laid down in Article 11(1). By derogation from Article 11(1), those contributions may consist of financial contributions.

Article 104

Scope of additional activities

1. Additional activities of the Global Health EDCTP3 Joint Undertaking shall be developed and implemented in an aligned, integrated and coherent manner by the EDCTP Association and its constituent or affiliated entities and shall follow the Global Health EDCTP3 Strategic Research and Innovation Agenda.
2. For the purpose of Article 11(1), point (b), additional activities may include activities directly linked to the activities of the Global Health EDCTP3 Joint Undertaking and contributing to its objectives, including the following:
 - (a) activities of constituent or affiliated entities of the EDCTP Association aligned with similar activities from other constituent or affiliated entities of the EDCTP Association and independently managed in accordance with national funding rules;
 - (b) activities implemented by sub-Saharan African governmental research organisations;
 - (c) activities which promote networking and partnerships building relationships with multiple private and public-sector organisations;
 - (d) support for the development of research infrastructures such as clinical trial networks or cohorts related to the scope of the Global Health EDCTP3 Joint Undertaking, and support for strengthening health systems' preparedness for carrying out research activities within the scope of the Global Health EDCTP3 Joint Undertaking.

Article 105

Bodies of the Global Health EDCTP3 Joint Undertaking

The bodies of the Global Health EDCTP3 Joint Undertaking shall be:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the Scientific Committee;
- (d) the stakeholders group.

Article 106

Composition of the Governing Board

The Governing Board shall be composed of the following:

- (a) six representatives of the Commission on behalf of the Union;
- (b) six representatives of the EDCTP Association.

*Article 107***Functioning of the Governing Board**

The EDCTP Association shall hold 50 % of the voting rights.

*Article 108***The Scientific Committee**

1. Pursuant to Article 21(1), point (a), the Scientific Committee shall be the scientific advisory body of the Global Health EDCTP3 Joint Undertaking.
2. In addition to Article 21(2), the Scientific Committee shall ensure the inclusion of scientific expertise from African countries.
3. In addition to the tasks listed in Article 21, the Scientific Committee shall perform the following tasks:
 - (a) assist in the design of the strategic and scientific planning of the activities of the Global Health EDCTP3 Joint Undertaking;
 - (b) advise on strategies to foster synergies and partnerships with all stakeholders;
 - (c) contribute to the preparation of strategic and scientific documents relevant to the Global Health EDCTP3 Joint Undertaking, as required;
 - (d) provide strategic and scientific advice to the Global Health EDCTP3 Joint Undertaking and ensure the successful completion of on-going projects;
 - (e) identify strategic needs and priorities for accelerating the development of new or improved clinical interventions, including the required training, networking and capacity building to be undertaken to achieve those objectives;
 - (f) review the landscape of poverty-related and neglected diseases to identify the Global Health EDCTP3 Joint Undertaking's role in partnership with other stakeholders to accelerate the development or improvement of interventions against those diseases;
 - (g) assess the state of global product development pathways and the critical path opportunities for future product development;
 - (h) provide advice on the review of any calls for proposals and other programmes;
 - (i) provide support and input on the monitoring and evaluation framework of the Global Health EDCTP3 Joint Undertaking, as well as in the monitoring of scientific outcomes and strategic impacts of the grants funded by the Global Health EDCTP3 Joint Undertaking;
 - (j) advise, assist and participate in Global Health EDCTP3 Joint Undertaking working groups, stakeholder meetings, EDCTP Forum and other relevant events.
4. The chairperson shall prepare an annual report on the previous year's activities and achievements of the Scientific Committee and submit it for approval by the Governing Board.

*Article 109***The stakeholders group**

1. The stakeholders group shall have a balanced representation of stakeholders from a geographic, thematic and gender perspective, including in particular African expertise.
2. In addition to the tasks set out in Article 22, the Stakeholders' Group shall also perform the following tasks:
 - (a) provide input on the scientific, strategic and the technological priorities to be addressed by the Global Health EDCTP3 Joint Undertaking as laid down in the Strategic Research and Innovation Agenda or any other equivalent document taking account the progress and needs of the Global Health and adjacent sectors;

- (b) provide suggestions to enable concrete synergies to take place between the Global Health EDCTP3 Joint Undertaking and the adjacent sectors or any sector with which synergies will be deemed of added value;
- (c) provide input to the EDCTP Forum.

Article 110

Eligibility for funding

1. In accordance with Article 17(2) of the Horizon Europe Regulation and by derogation from Article 23(1) thereof, funding from the Global Health EDCTP3 Joint Undertaking shall be restricted to legal entities established in Member States or associated countries or in the constituent states of the EDCTP Association. Exceptionally and if provided for in the work programme, entities established in other states may be eligible for funding from the Global Health EDCTP3 Joint Undertaking in specific call topics or in the event of a call addressing a public health emergency.
2. The Union shall seek to conclude agreements with third countries that allow the protection of the financial interest of the Union. Before their conclusion and in order to safeguard Union financial interests, where entities established in a third country without such an agreement participate with funding in an indirect action, the financial coordinator of the indirect action shall be established in a Member State or associated country, the amount of pre-financing shall be adequately adapted and liability provisions of the grant agreement shall take due account of the financial risks.

Article 111

Identified participants

The participation of entities identified by the Global Health EDCTP3 Joint Undertaking may be an eligibility criterion in the call for proposals. It shall be duly justified in the work programme which may also provide that such identified participants shall not be eligible for funding from the Global Health EDCTP3 Joint Undertaking under the selected indirect actions.

Article 112

Ethical principles

The clinical trials and implementation research conducted under the Global Health EDCTP3 Joint Undertaking shall be implemented in compliance with fundamental ethical principles, recognised international regulatory standards and good participatory practices.

Article 113

Collaboration with the European Medicines Agency and European Centre for Disease Prevention and Control

The Global Health EDCTP3 Joint Undertaking shall ensure a close collaboration with the European Medicines Agency and European Centre for Disease Prevention and Control, as well as with relevant African agencies and organisations.

Article 114

Affordable access

Participants to indirect actions funded by the Global Health EDCTP3 Joint Undertaking shall ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken as part of an indirect action are affordable, available and accessible to the public at fair and reasonable conditions. For that purpose, where relevant, the work programme shall specify additional exploitation obligations applicable to specific indirect actions.

TITLE VI

INNOVATIVE HEALTH INITIATIVE JOINT UNDERTAKING

*Article 115***Additional objectives of the Innovative Health Joint Undertaking**

1. In addition to the objectives set out in Articles 4 and 5, the Innovative Health Initiative Joint Undertaking shall reach the following general objectives by 2030:
 - (a) contribute towards the creation of a Union-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, in particular by launching at least 30 large-scale cross-sectoral projects, focusing on health innovations;
 - (b) foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least five examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment or management of diseases affecting the Union population, including contribution to Europe's Beating Cancer Plan;
 - (c) drive cross-sectoral health innovation for a globally competitive European health industry, and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.
2. The Innovative Health Initiative Joint Undertaking shall also have the following specific objectives:
 - (a) contribute towards a better understanding of the determinants of health and priority disease areas;
 - (b) integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users;
 - (c) demonstrate the feasibility of people-centred integrated health care solutions;
 - (d) exploit the full potential of digitalisation and data exchange in health care;
 - (e) enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions.

*Article 116***Additional tasks of the Innovative Health Initiative Joint Undertaking**

In addition to the tasks set out in Article 5, the Innovative Health Initiative Joint Undertaking shall carry out the following tasks:

- (a) foster close and long-term cooperation between the Union, other members, contributing partners, and other stakeholders involved in health care such as other relevant industries, health care authorities (such as regulatory bodies, health technology assessment bodies and payers), patient organisations, health care professionals and providers, as well as academia;
- (b) effectively support pre-competitive health research and innovation, especially actions that bring together entities of several health care industry sectors to work jointly on areas of unmet public health need;
- (c) ensure that all stakeholders have the possibility of proposing areas for future calls for proposals;
- (d) regularly review and make any necessary adjustments to the Strategic Research and Innovation Agenda of the Innovative Health Initiative Joint Undertaking in light of scientific developments occurring during its implementation or emerging public health needs;

- (e) publish information on the projects, including participating entities and the amount of the financial contribution of the Innovative Health Initiative Joint Undertaking and committed in-kind contributions per participant;
- (f) organise regular communication, including at least one annual meeting with interest groups and with its stakeholders to ensure openness and transparency of the research and innovation activities of the Innovative Health Initiative Joint Undertaking;
- (g) any other task necessary to achieve the objectives referred to in Article 115.

Article 117

Members

The members of the Innovative Health Initiative Joint Undertaking shall be:

- (a) the Union, represented by the Commission;
- (b) the European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR) registered under Belgian law, the European Federation of Pharmaceutical Industries and Associations, including its subgroup Vaccines Europe, registered under Luxemburgish law, EuropaBio registered under Belgian law and MedTech Europe registered under Belgian law, upon notification of their respective decisions to accede to the Innovative Health Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding their accession other than those set out in this Regulation;
- (c) the associated members to be selected in accordance with Article 7.

Article 118

Union financial contribution

The Union financial contribution to the Innovative Health Initiative Joint Undertaking, including EEA appropriations, to cover administrative costs and operational costs shall be up to EUR 1 200 000 000, including up to EUR 30 212 000 for administrative costs, and shall consist of the following:

- (a) up to EUR 1 000 000 000 provided that that amount is matched by the contribution of members other than the Union, or its constituent or affiliated entities;
- (b) up to EUR 200 000 000 provided that that amount is matched by the additional contributions from contributing partners, or from their constituent or affiliated entities.

Article 119

Contributions from members other than the Union

1. The members of the Innovative Health Initiative Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 1 000 000 000, including up to EUR 30 212 000 for administrative costs, over the period set out in Article 3.
2. In-kind contributions to additional activities shall not constitute more than 40 % of in-kind contributions of members other than the Union, at the level of the Innovative Health Initiative Joint Undertaking.
3. Contributions provided by participants to indirect actions funded by the Innovative Health Initiative Joint Undertaking shall amount to at least 45 % of an indirect action's eligible costs and costs of its related additional activities. When justified, the work programme may exceptionally allow a lower proportion of contributions at the level of an individual indirect action and its related additional activities.

4. Costs incurred in indirect actions in third countries other than countries associated to Horizon Europe shall be justified and relevant to the objectives set out in Article 115. They shall not exceed 20 % of the in-kind contributions to operational costs provided by members other than the Union and by contributing partners at the level of the Innovative Health Initiative Joint Undertaking. Costs in excess of 20 % of the in-kind contributions to operational costs at the level of the Innovative Health Initiative Joint Undertaking shall not be considered as in-kind contributions to operational costs.

5. In duly justified cases, work programmes of the Innovative Health Initiative Joint Undertaking may set out specific limits for in-kind contributions to operational costs incurred in third countries other than countries associated with Horizon Europe at an indirect action level. The decisions on such specific limits shall take into account in particular the objectives and the impact sought by the actions concerned and shall not result in an excess of the ceiling set out in paragraph 4 at the Innovative Health Initiative Joint Undertaking level.

Article 120

Conditions related to additional activities

1. For the purpose of Article 11(1), point (b), additional activities shall be carried out in the Union or countries associated with Horizon Europe and may include:

- (a) activities contributing towards the achievement of objectives of indirect actions funded by the Innovative Health Initiative Joint Undertaking;
- (b) activities contributing towards the dissemination, sustainability or exploitation of results of indirect actions funded by the Innovative Health Initiative Joint Undertaking.

2. Where relevant, project proposals shall include a plan for their related additional activities. Costs associated to such project-specific additional activities must be incurred between the date of submission of the proposal and up to two years after the end date of the indirect action.

3. In order for the costs to be accounted for as in-kind contributions referred to in Article 11(1), point (b), the underlying additional activities shall be carried out within the Union or countries associated to Horizon Europe.

Article 121

Bodies of the Innovative Health Initiative Joint Undertaking

The bodies of the Innovative Health Initiative Joint Undertaking shall be:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the states' representatives group;
- (d) the Science and Innovation Panel.

Article 122

Composition of the Governing Board

The Governing Board shall be composed of the following:

- (a) four representatives of the Commission on behalf of the Union;
- (b) one representative per member other than the Union.

*Article 123***Functioning of the Governing Board**

The members other than the Union shall collectively hold 50 % of the voting rights.

*Article 124***The Science and Innovation Panel**

1. The Science and Innovation Panel shall advise the Governing Board on matters relevant to the research and innovation activities of the Innovative Health Initiative Joint Undertaking in accordance with Article 21.

2. The Science and Innovation Panel shall be composed of the following permanent panellists:

- (a) two representatives of the Commission on behalf of the Union;
- (b) four representatives of the members other than the Union;
- (c) two representatives of the states' representatives group;
- (d) four representatives of the scientific community, appointed by the Governing Board following an open selection process in accordance with Article 21(4);
- (e) up to six other permanent panellists, appointed by the Governing Board following an open selection process in application of Article 21(4), ensuring in particular appropriate representation of stakeholders involved in health care, covering in particular the public sector, including regulatory bodies, patients and end-users in general.

3. The permanent panellists referred to in paragraph 2, points (a), (b) and (c), may invite ad hoc panellists where appropriate to discuss specific subjects. They may jointly invite a maximum of six ad hoc panellists for each meeting.

Such ad hoc panellists shall be invited based on their scientific or technical expertise on the subjects to be discussed at given meetings or taking into account the need to create synergies with other research programmes.

The permanent panellists referred to in paragraph 2, points (a), (b) and (c), shall invite ad hoc panellists consensually. They shall communicate their decisions to the Governing Board, the states' representatives group and the other permanent panellists.

4. In addition to Article 21(7), the Science and Innovation Panel shall provide advice to the Governing Board, at its request or on its own initiative, on scientific and technological matters related to the Innovative Health Initiative Joint Undertaking's objectives, in particular about:

- (a) scientific priorities, including in the context of updating the Strategic Research and Innovation Agenda;
- (b) the draft work programme, including the content of calls for proposals;
- (c) the planning of additional activities of members other than the Union referred to in Article 120;
- (d) the set-up of advisory groups focused on specific scientific priorities in accordance with Article 17(2), point (x), and following an open selection process for their members in accordance with Article 21(4);
- (e) creation of synergies with other Horizon Europe activities, including other European partnerships, as well as other Union funding programmes and national funding programmes.

5. In addition to Article 21(5), the Science and Innovation Panel shall elect its chair among the representatives provided in paragraph 2, point (d), of this Article.

*Article 125***Conditions applicable to indirect actions**

1. For the purpose of this Regulation, an unmet public health need shall be defined as a need currently not addressed by the health care systems for availability or accessibility reasons, for example where there is no satisfactory method of diagnosis, prevention or treatment for a given health condition or if people's access to health care is limited because of cost, distance to health facilities or waiting times. People-centred care refers to an approach to care that consciously adopts individuals', carers', families' and communities' perspectives and considers them as participants as well as beneficiaries of health care systems that are organised around their needs and preferences rather than individual diseases.
2. Indirect actions funded by the Innovative Health Initiative Joint Undertaking may include clinical studies where the targeted area or the intended use represents an unmet public health need, significantly affecting or threatening the Union's population.
3. Participants to indirect actions funded by the Innovative Health Initiative Joint Undertaking must ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken as part of an indirect action are affordable, available and accessible to the public at fair and reasonable conditions. For that purpose, where relevant, the work programme shall specify additional exploitation obligations applicable to specific indirect actions.
4. Where provided for in the work programme and in addition to Article 5(2), point (a), legal entities identified by the Innovative Health Initiative Joint Undertaking may be required to participate in specific indirect actions. Those entities shall not be eligible for funding from the Innovative Health Initiative Joint Undertaking.
5. Any legal entities participating in specific indirect actions with the identified legal entities referred to in paragraph 4 shall not be eligible for funding where:
 - (a) they are for-profit legal entities with an annual turnover of EUR 500 million or more;
 - (b) they are under the direct or indirect control of a legal entity described in point (a), or under the same direct or indirect control as a legal entity described in point (a);
 - (c) they are directly or indirectly controlling a legal entity referred to in point (a).

TITLE VII

KEY DIGITAL TECHNOLOGIES JOINT UNDERTAKING*Article 126***Additional objectives of the Key Digital Technologies Joint Undertaking**

1. In addition to the objectives set out in Articles 4 and 5, the Key Digital Technologies Joint Undertaking shall have the following general objectives:
 - (a) reinforce the Union's strategic autonomy in electronic components and systems to support future needs of vertical industries and the economy at large. The overall target is to contribute towards doubling the value of the design and production of electronic components and systems in Europe by 2030, in line with the weight of the Union in products and services;
 - (b) establish Union scientific excellence and innovation leadership in emerging components and systems technologies, including in activities related to lower TRLs; and promote the active involvement of SMEs, which shall represent at least one third of the total number of participants in indirect actions and at least 20 % of public funding should go to them;
 - (c) ensure that components and systems technologies address Europe's societal and environmental challenges. The target is to align with the Union policy on energy efficiency and contribute towards the reduction of energy consumption by 32,5 % in 2030.

2. In addition to the objectives set out in paragraph 1, the Key Digital Technologies Joint Undertaking shall have the following specific objectives:

- (a) support research and development for establishing design and production capabilities in Europe for strategic application areas;
- (b) launch a balanced portfolio of large and small projects supporting the fast transfer of technologies from the research to the industrial environment;
- (c) foster a dynamic Union-wide ecosystem based on digital value-chains with simplified access to newcomers;
- (d) support research and development for enhancing component technologies that guarantee security, trust and energy-efficiency for critical infrastructures and sectors in Europe;
- (e) foster mobilisation of national resources and ensure coordination of Union and national research and innovation programmes in the field of electronic components and systems;
- (f) establish coherence between the Strategic Research and Innovation Agenda of the Key Digital Technologies Joint Undertaking and Union policies so that electronics components and systems technologies contribute efficiently.

Article 127

Members

1. The members of the Key Digital Technologies Joint Undertaking shall be:

- (a) the public authorities consisting of:
 - (i) the Union, represented by the Commission;
 - (ii) the following participating states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden;
- (b) the private members consisting of the following industrial associations: the AENEAS Association registered under French law; the Inside Industry Association (INSIDE) registered under Dutch law; the EPoSs e.V. Association registered under German law.

2. Each participating state shall appoint its representatives in the bodies of the Key Digital Technologies Joint Undertaking and shall designate the national entity or entities responsible for fulfilling its obligations with respect to the activities of the Key Digital Technologies Joint Undertaking.

Article 128

Union financial contribution

The Union financial contribution to the Key Digital Technologies Joint Undertaking, including EEA appropriations, to cover administrative costs and operational costs shall be up to EUR 1 800 000 000, including up to EUR 26 331 000 for administrative costs.

Article 129

Contributions from members other than the Union

1. Over the period set out in Article 3, the participating states of the Key Digital Technologies Joint Undertaking shall make a total contribution that is commensurate to the amount of the Union contribution to operational costs referred to in Article 128. The participating states shall arrange among them their collective contributions and how they will deliver those. This shall not affect the ability of each participating state to define its national financial contribution in accordance with Article 12. By derogation from Article 28(4), point (a), the participating states shall not make a contribution to administrative costs.

2. Over the period set out in Article 3, the private members of the Key Digital Technologies Joint Undertaking shall make or arrange for their constituent or affiliated entities to make contributions of at least EUR 2 511 164 000 to the Key Digital Technologies Joint Undertaking.
3. In line with Article 28(4), the private members shall make or arrange for their constituent and affiliated entities to make a financial contribution of up to EUR 26 331 000 for administrative costs of the Key Digital Technologies Joint Undertaking.
4. The contributions referred to in paragraph 1 shall consist of contributions laid down in Article 11(3). The contributions referred to in paragraph 2 of this Article shall consist of contributions laid down in Article 11(1), including at least 90 % of contributions laid down in Article 11(1), point (a).

Article 130

Scope of additional activities

1. The Governing Board of the Key Digital Technologies Joint Undertaking may approve where necessary the additional activities plan referred to in Article 11(1), point (b), following a proposal by the Private Members Board, taking into account the opinion of the Public Authorities Board.
2. For the purpose of Article 11(1), point (b), additional activities may include:
 - (a) investment aiming to industrialise the Key Digital Technologies, ECSEL, ARTEMIS and ENIAC Joint Undertakings' projects' results;
 - (b) pilots, demonstrators, applications, deployments, industrialisation, including relevant capital expenditure, including projects under the IPCEIs on microelectronics;
 - (c) related research and development activities that are not publicly funded;
 - (d) activities financed by loans of the European Investment Bank and not funded under a grant by the Union;
 - (e) activities to develop the ecosystem supporting the cooperation of technology users and suppliers.

Article 131

Bodies of the Key Digital Technologies Joint Undertaking

The bodies of the Key Digital Technologies Joint Undertaking shall be:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the Public Authorities Board;
- (d) the Private Members Board.

Article 132

Composition of the Governing Board

Each member of the Key Digital Technologies Joint Undertaking shall appoint its representatives and a lead delegate who shall hold the voting rights of the member in the Governing Board.

Article 133

Functioning of the Governing Board

1. The voting rights in the Governing Board shall be distributed as follows:
 - (a) one third for the Commission;

(b) one third for the private members collectively; and

(c) one third for the participating states collectively.

2. For the first two financial years following the establishment of the Key Digital Technologies Joint Undertaking, the voting rights of the participating states shall be distributed as follows:

(a) 1 % for each participating state;

(b) the remaining percentage distributed annually among the participating states in proportion to their actual financial contributions to the Key Digital Technologies Joint Undertaking or to its preceding initiative over the past two years.

3. For the subsequent financial years, the distribution of the voting rights of the participating states shall be established annually and in proportion to the funds they have committed to indirect actions over the past two financial years.

4. The voting rights of the private members shall be distributed equally amongst the industrial associations unless decided otherwise by the Private Members Board.

5. Voting rights for any new member of the Key Digital Technologies Joint Undertaking that is not a Member State or an associated country shall be determined by the Governing Board before that member joins the Key Digital Technologies Joint Undertaking.

Article 134

Limitation to participation in specific actions

By derogation from Article 17(2), point (l), where the Commission so requests, following approval of the Public Authorities Board, participation in specific actions shall be limited in accordance with Article 22(5) of the Horizon Europe Regulation.

Article 135

Composition of the Public Authorities Board

The Public Authorities Board shall be composed of representatives of the public authorities of the Key Digital Technologies Joint Undertaking.

Each public authority shall appoint its representatives and a lead delegate who shall hold the voting rights in the Public Authorities Board.

Article 136

Functioning of the Public Authorities Board

1. The voting rights in the Public Authorities Board shall be assigned to the public authorities on an annual basis in proportion to their financial contribution to the activities of the Key Digital Technologies Joint Undertaking for that year in accordance with Article 12, and with an upper limit for any given member of 50 % of the total voting rights in the Public Authorities Board.

2. For the purpose of Article 134, the Public Authorities Board shall solely include public authorities that are Member States. Paragraph 1 shall apply *mutatis mutandis*.

3. If fewer than three participating states have communicated to the Executive Director their financial contribution according to Article 12(3), the Commission shall hold 50 % of the voting rights and the remaining 50 % shall be distributed equally amongst the participating states until such time as more than three Key Digital Technologies participating states have communicated their contribution.

4. The public authorities shall make every effort to adopt decisions by consensus. Failing consensus, a vote shall be held. A decision shall be adopted by a majority of at least 75 % of the votes including the votes of the participating states who are absent, but excluding abstentions.
5. The Public Authorities Board shall elect its chairperson from among its members for a period of at least two years.
6. The chairperson may invite other persons to attend its meetings as observers, in particular representatives of regional authorities within the Union, representatives of SME associations and representatives of other bodies of the Key Digital Technologies Joint Undertaking.
7. The Public Authorities Board shall hold its ordinary meetings at least twice a year. It may hold extraordinary meetings at the request of the Commission or of a majority of the representatives of the participating states, or at the request of the chairperson. The meetings of the Public Authorities Board shall be convened by its chairperson and shall normally take place at the seat of the Key Digital Technologies Joint Undertaking.
8. The quorum of the Public Authorities Board shall be constituted by the Commission and at least three participating states' lead delegates.
9. The Executive Director shall attend the meetings of the Public Authorities Board meetings, unless decided otherwise by the Public Authorities Board, but shall have no voting rights.
10. Upon invitation from the Public Authorities Board, any Member State or associated country that is not a member of the Key Digital Technologies Joint Undertaking may participate in the Public Authorities Board meetings as an observer. Observers shall receive all relevant documents and may give advice on any decision taken by the Public Authorities Board. All such observers will be bound by the confidentiality rules applying to the Public Authorities Board members.
11. The Public Authorities Board may appoint working groups where necessary under the overall coordination of one or more public authorities.
12. The Public Authorities Board shall adopt its own rules of procedure.
13. Articles 11(8) and 28(6) shall also apply *mutatis mutandis* to the Public Authorities Board.

Article 137

Tasks of the Public Authorities Board

The Public Authorities Board shall:

- (a) contribute to the drafting of the Strategic Research and Innovation Agenda;
- (b) provide input to the draft work programme, in particular the calls for proposals, including the rules for evaluation, selection and monitoring of indirect actions;
- (c) approve the launch of calls for proposals, in accordance with the work programme;
- (d) select proposals in accordance with Articles 12(1) and 17(2), point (s);
- (e) provide an opinion on the draft additional activities plan referred to in Article 11(1), point (b).

Article 138

Composition of the Private Members Board

1. The Private Members Board shall be composed of representatives of the private members of the Key Digital Technologies Joint Undertaking.
2. Each private member shall appoint its representatives and a lead delegate who shall hold the voting rights in the Private Members Board.

*Article 139***Functioning of the Private Members Board**

1. The Private Members Board shall meet at least twice a year.
2. The Private Members Board may appoint working groups where necessary under the overall coordination of one or more members.
3. The Private Members Board shall elect its chairperson from among its members.
4. The Private Members Board shall adopt its rules of procedure.

*Article 140***Tasks of the Private Members Board**

The Private Members Board shall:

- (a) draw up and regularly update the draft Strategic Research and Innovation Agenda for achieving the objectives of the Key Digital Technologies Joint Undertaking set out in Articles 4 and 126 taking into account the input of the Public Authorities Board;
- (b) submit to the Executive Director the draft Strategic Research and Innovation Agenda within the deadlines set by the Governing Board;
- (c) organise an advisory Stakeholder Forum that is open to all public and private stakeholders having an interest in the field of key digital technologies to inform them about and collect feedback on the draft Strategic Research and Innovation Agenda for a given year;
- (d) where appropriate, and taking into account Article 130, draw up and submit for approval to the Governing Board the draft additional activities plan referred to in Article 11(1), point (b), taking into account the opinion of the Public Authorities Board.

*Article 141***Funding rates**

In accordance with Article 17(2) of the Horizon Europe Regulation and by way of derogation from Article 34 of that Regulation, the Key Digital Technologies Joint Undertaking may apply different funding rates for the Union funding within an action depending on the type of participant, in particular SMEs and non-profit legal entities, and the type of action. The funding rates shall be indicated in the work programme.

TITLE VIII

SINGLE EUROPEAN SKY ATM RESEARCH 3 JOINT UNDERTAKING*Article 142***Additional objectives of the Single European Sky ATM Research 3 Joint Undertaking**

1. In addition to the objectives set out in Articles 4 and 5, the Single European Sky ATM Research 3 Joint Undertaking shall have the following general objectives:
 - (a) strengthen and integrate the Union's research and innovation capacity in the ATM sector, making it more resilient and scalable to fluctuations in traffic while enabling the seamless operation of all aircraft;
 - (b) strengthen, through innovation, the competitiveness of manned and unmanned air transport in the Union, and ATM services' markets to support economic growth in the Union;
 - (c) develop and accelerate the market uptake of innovative solutions to establish the Single European Sky airspace as the most efficient and environmentally friendly sky to fly in the world.

2. The Single European Sky ATM Research 3 Joint Undertaking shall also have the following specific objectives:

- (a) develop a research and innovation ecosystem covering the entire ATM and U-space airspace value chains allowing to build the Digital European Sky defined in the European ATM Master plan, enabling the collaboration and coordination needed between air navigation services providers and airspace users to ensure a single harmonised Union ATM system for both manned and unmanned operations;
- (b) develop and validate ATM solutions supporting high levels of automation;
- (c) develop and validate the technical architecture of the Digital European Sky;
- (d) support an accelerated market deployment of innovative solutions through demonstrators;
- (e) coordinate the prioritisation and planning for the Union's ATM modernisation efforts, based on a consensus-led process among the ATM stakeholders;
- (f) facilitate the development of standards for the industrialisation of SESAR solutions.

3. For the purpose of the Single European Sky ATM Research 3 Joint Undertaking, the following definitions apply:

- (a) 'U-space airspace' means an unmanned airborne system (UAS) geographical zone designated by Member States, where UAS operations are only allowed to take place with the support of U-space services provided by a U-Space service provider;
- (b) 'Digital European Sky' refers to the vision of the European ATM Master Plan, seeking to transform Europe's aviation infrastructure enabling it to handle the future growth and diversity of air traffic safely and efficiently, while minimising environmental impact;
- (c) 'architecture of the Digital European Sky' refers to the vision of the European ATM Master Plan, seeking to address the current inefficient airspace architecture in the medium to long term by combining airspace configuration and design with technologies to decouple service provision from local infrastructure and progressively increase the levels of collaboration and automation support;
- (d) 'SESAR definition phase' means the phase comprising the establishment and updating of the long-term vision of the SESAR project, of the related concept of operations enabling improvements at every stage of flight, of the required essential operational changes within the European ATM Network and of the required development and deployment priorities;
- (e) 'SESAR deployment phase' means the successive phases of industrialisation and implementation, during which the following activities are conducted: standardisation, production and certification of ground and airborne equipment and processes necessary to implement SESAR solutions (industrialisation); and procurement, installation and putting into service of equipment and systems based on SESAR solutions, including associated operational procedures (implementation).

Article 143

Additional tasks of the Single European Sky ATM Research 3 Joint Undertaking

In addition to the tasks set out in Article 5, the Single European Sky ATM Research 3 Joint Undertaking shall carry out the following tasks:

- (a) coordinate the tasks of the Single European Sky ATM Research definition phase, monitor the implementation of the SESAR project and amend, where necessary, the European ATM Master Plan;
- (b) implement the research and development aspects of the European ATM Master Plan, in particular by:
 - (i) organising, coordinating and monitoring the work of the SESAR development phase in accordance with the European ATM Master Plan, including low TRLs (0 to 2) research and innovation activities;
 - (ii) delivering SESAR solutions, which are deployable outputs of the SESAR development phase introducing new or improved standardised and interoperable operational procedures or technologies;

- (iii) ensuring the involvement of the civil and military stakeholders of the aviation sector, in particular air navigation service providers, airspace users, professional staff associations, airports, manufacturing industry and the relevant scientific institutions and scientific community;
- (c) facilitate an accelerated market uptake of SESAR solutions by:
 - (i) organising and coordinating large-scale demonstrations activities;
 - (ii) coordinating closely with EASA in order to enable timely development by EASA of regulatory measures that fall under Regulation (EU) 2018/1139 and the relevant implementing rules;
 - (iii) supporting the related standardisation activities, in close cooperation with standardisation bodies and EASA, as well as with the entity established to coordinate the tasks of the SESAR deployment phase in line with Commission Implementing Regulation (EU) No 409/2013 ⁽⁴³⁾.

Article 144

Members

1. The members of the Single European Sky ATM Research 3 Joint Undertaking shall be:
 - (a) the Union, represented by the Commission;
 - (b) the European Organisation for the Safety of Air Navigation (Eurocontrol), represented by its Agency, upon notification of its decision to accede to the Single European Sky ATM Research 3 Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding its accession other than those set out in this Regulation;
 - (c) the founding members listed in Annex III to this Regulation, upon notification of their decision to accede to the Single European Sky ATM Research 3 Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding its accession other than those set out in this Regulation;
 - (d) the associated members to be selected in accordance with Article 7.
2. In addition to Article 7(1), the Governing Board may, during the first six months following the establishment of the Single European Sky ATM Research 3 Joint Undertaking, select associated members from a list drawn up after an open call for expression of interest launched by the Commission prior to its establishment. The conditions of Article 7(2) shall apply *mutatis mutandis*.
3. In selecting associated members, the Governing Board shall seek to ensure the proper representation of the entire ATM value chain and, where necessary, the selection of relevant players from outside the sector. Any public or private entity or body including those from third countries that have concluded at least one agreement with the Union in the field of air transport may be selected as associated members of the Single European Sky ATM Research 3 Joint Undertaking.

Article 145

Union financial contribution

The Union financial contribution to the Single European Sky ATM Research 3 Joint Undertaking, including EEA appropriations, to cover administrative costs and operational costs shall be up to EUR 600 000 000, including up to EUR 30 000 000 for administrative costs.

⁽⁴³⁾ Commission Implementing Regulation (EU) No 409/2013 of 3 May 2013 on the definition of common projects, the establishment of governance and the identification of incentives supporting the implementation of the European Air Traffic Management Master Plan (OJ L 123, 4.5.2013, p. 1).

*Article 146***Contributions from members other than the Union**

1. The private members of the Single European Sky ATM Research 3 Joint Undertaking shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 500 000 000, including up to EUR 25 000 000 for administrative costs, over the period set out in Article 3.
2. Eurocontrol shall make a total contribution of up to EUR 500 000 000, including up to EUR 25 000 000 for administrative costs, over the period set out in Article 3. In addition to Article 11(4), the contribution shall also consist of in-kind contributions to additional activities.

*Article 147***Scope of additional activities**

For the purposes of Article 11(1), point (b), additional activities may include:

- (a) activities covering all the non-Union funded part of the Single European Sky ATM Research projects that contribute to the achievement of the agreed work programme of the Joint Undertaking;
- (b) industrialisation activities, including standardisation, certification and production, related to SESAR Solutions from the Single European Sky ATM Research 3 Joint Undertaking or the preceding initiative, the SESAR Joint Undertaking;
- (c) communication and outreach activities related to SESAR Solutions from the Single European Sky ATM Research 3 Joint Undertaking or the preceding initiative, the SESAR Joint Undertaking;
- (d) activities ensuring the global ATM harmonisation based on SESAR Solutions from the Single European Sky ATM Research 3 Joint Undertaking or the preceding initiative, the SESAR Joint Undertaking;
- (e) deployment or uptake of results from projects under the Single European Sky ATM Research 3 Joint Undertaking or the preceding initiative, the SESAR Joint Undertaking, which have not received any Union funding.

*Article 148***Bodies of the Single European Sky ATM Research 3 Joint Undertaking**

The bodies of the Single European Sky ATM Research 3 Joint Undertaking shall be:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the states' representatives group;
- (d) the Scientific Advisory Body.

*Article 149***Composition of the Governing Board**

The Governing Board shall be composed as follows:

- (a) two representatives of the Commission on behalf of the Union;
- (b) one representative from each of the members other than the Union.

*Article 150***Functioning of the Governing Board**

1. By derogation to Article 16(4), the Governing Board shall be chaired by the Commission on behalf of the Union.
2. The Governing Board shall have the following permanent observers:
 - (a) a representative of the European Defence Agency;
 - (b) a representative of civil users of airspace, designated by their representative organisation at European level;
 - (c) an air navigation service providers' representative, designated by their representative organisation at European level;
 - (d) an equipment manufacturers' representative, designated by their representative organisation at European level;
 - (e) an airports' representative, designated by their representative organisation at European level;
 - (f) a representative from the bodies representing staff in the ATM sector, designated by their representative organisation at European level;
 - (g) a representative of the relevant scientific institutions or the relevant scientific community, designated by their representative organisation at European level;
 - (h) a representative of the EASA;
 - (i) a representative of the European standardisation organisation in aviation;
 - (j) a representative of the unmanned aerial vehicle industry, designated by their representative organisation at European level.
3. The number of votes of the members of the Single European Sky ATM Research 3 Joint Undertaking shall be in proportion to their contribution to the budget of the joint undertaking. However, the Union and Eurocontrol shall each have at least 25 % of the total number of votes and the representative of the civil users of airspace referred to in paragraph 2, point (b), shall have at least 10 % of the total number of votes.
4. Decisions of the Governing Board shall be adopted by a simple majority of the votes cast. Where the votes are evenly divided, the Union shall have the deciding vote.
5. Decisions relating to the revision of the European ATM Master Plan shall require the positive votes of the Union and Eurocontrol. Such decisions shall take into account the opinions expressed by all permanent observers referred to in paragraph 2 and the states' representatives group.

*Article 151***Additional tasks of the Governing Board**

In addition to the tasks listed in Article 17, the Governing Board of the Single European Sky ATM Research 3 Joint Undertaking shall supervise the delivery of the research and development components identified in the European ATM Master Plan.

*Article 152***Additional tasks of the Executive Director**

In addition to the tasks listed in Article 19, the Executive Director of the Single European Sky ATM Research 3 Joint Undertaking shall carry out the following tasks:

- (a) direct the execution of the definition and development phases of the SESAR project within the guidelines established by the Governing Board;
- (b) submit to the Governing Board any proposal involving changes in the design of the development phase of the SESAR project.

*Article 153***The states' representatives group**

In addition to Article 20, the Member States shall ensure that their respective representatives present a coordinated position that reflects their Member State's views expressed in:

- (a) the Single Sky Committee, established by Article 5 of Regulation (EC) No 549/2004;
- (b) the Programme Committee under Article 14 of the Specific Programme implementing Horizon Europe.

*Article 154***The Scientific Committee**

1. The scientific advisory body of the Single European Sky ATM Research 3 Joint Undertaking referred to in Article 21(1), point (a), shall be the Scientific Committee.
2. The Scientific Committee shall have no more than 15 permanent members.
3. The chairman of the Scientific Committee shall be elected for a period of two years.
4. The Scientific Committee may advise on request of the Governing Board and other bodies of the Single European Sky ATM Research 3 Joint Undertaking, or on its own initiative, in particular on activities related to low TRLs (0 to 2).
5. The Scientific Committee shall collaborate with the relevant advisory bodies set up under Horizon Europe.

*Article 155***Implementing acts to establish the position of the Union concerning the amendment of the European ATM Master Plan**

1. The Commission shall adopt implementing acts with the view to establishing the position of the Union concerning the amendment of the European ATM Master Plan. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽⁴⁴⁾.
2. The Commission shall be assisted by the Single Sky Committee established by Regulation (EC) No 549/2004. The Single Sky Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

*Article 156***Certification of new technologies**

1. The EASA may be invited by applicants, participants or the Executive Director to advise on individual projects and demonstration activities on issues related to compliance with aviation safety, interoperability and environmental standards, to ensure that those lead to timely development of relevant standards, testing capacity and regulatory requirements for product development and deployment of new technologies.
2. Certification activities and services provided shall be subject to the provisions regarding fees and charges set out in Regulation (EU) 2018/1139.

⁽⁴⁴⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

*Article 157***Agreement with Eurocontrol**

As founding member of the Single European Sky ATM Research 3 Joint Undertaking, Eurocontrol's role and contribution shall be set out in an administrative agreement between the two parties, the Single European Sky ATM Research 3 Joint Undertaking and Eurocontrol. That agreement shall describe Eurocontrol's tasks, responsibilities and contribution to the activities of the Single European Sky ATM Research 3 Joint Undertaking as regards the following:

- (a) organising Eurocontrol's research, development and validation activities in accordance with the work programme of the Single European Sky ATM Research 3 Joint Undertaking;
- (b) providing specialist support and advice to the Single European Sky ATM Research 3 Joint Undertaking on its request;
- (c) supporting and advising on the common developments for the future European ATM systems, in particular related to the future airspace architecture;
- (d) supporting the monitoring of the implementation of SESAR Solutions in line with the European ATM Master Plan;
- (e) engaging with Eurocontrol Member States to secure wide support for the Union's policy objectives and results of research, validation and demonstration activities amongst pan-European network partners;
- (f) providing support to programme management;
- (g) contributing to the administrative costs of the Single European Sky ATM Research 3 Joint Undertaking and providing information technology, communications and logistics support to the Single European Sky ATM Research 3 Joint Undertaking.

*Article 158***Back office arrangements**

Article 13 shall not apply to the Single European Sky ATM Research 3 Joint Undertaking. The back office arrangement shall be provided by Eurocontrol.

TITLE IX

SMART NETWORKS AND SERVICES JOINT UNDERTAKING*Article 159***Additional objectives of the Smart Networks and Services Joint Undertaking**

1. In addition to the objectives set out in Articles 4 and 5, the Smart Networks and Services Joint Undertaking shall have the following general objectives:

- (a) foster Europe's technological leadership in future smart networks and services by reinforcing current industrial strengths and by extending the scope from 5G connectivity to the broader strategic value chain including cloud-based service provisioning as well as components and devices;
- (b) align strategic roadmaps of a wider range of industrial players, including not only the telecommunication industry, but also actors from the internet of Things, cloud, and components and devices;
- (c) advance European technological and scientific excellence to support European leadership to shape and master 6G systems by 2030;
- (d) strengthen the deployment of digital infrastructures and uptake of digital solutions in the European markets, in particular by ensuring a strategic coordination mechanism for the CEF2 Digital programme as well as synergies within CEF2, and with DEP and InvestEU as part of the scope and governance of the Smart Networks and Services Joint Undertaking;

- (e) prepare the European smart networks and services supply industry for the longer term opportunities emerging from the development of vertical markets for 5G and later 6G infrastructures and services in Europe;
- (f) facilitate digital innovation, by 2030, meeting European market needs and public policy requirements, including the most demanding requirements of vertical industries, as well as societal requirements in fields including security, energy efficiency and electromagnetic fields;
- (g) support the alignment of future smart networks and services with Union policy objectives including European Green Deal, network and information security, ethics and privacy, as well as a human-centric and sustainable internet.

2. The Smart Networks and Services Joint Undertaking shall also have the following specific objectives:

- (a) facilitate the development of technologies able to meet advanced communication requirements while supporting European excellence in smart networks and services technologies and architectures and their evolution towards 6G, including strong European positions on standards, essential patents, and key requirements such as requirements for spectrum bands needed for future advanced smart network technologies;
- (b) accelerate the development of energy-efficient network technologies with the aim of significantly reducing the energy and resource consumption of the whole digital infrastructure by 2030 and decreasing the energy consumption of key verticals industries supported by smart networks and services technologies;
- (c) accelerate the development and widespread deployment of 5G by 2025 and later 6G infrastructure in Europe by, in particular, promoting the coordination and strategic support of 5G deployment for Connected and Automated Mobility along cross-border corridors, by using the CEF2 Digital programme and by promoting deployment under CEF2, DEP and InvestEU;
- (d) foster a sustainable and diverse supply and value chain in line with the 5G Cybersecurity toolbox;
- (e) strengthen the positioning of the Union's industry in the global smart network and services value chain by creating a critical mass of public and private actors, in particular by increasing the contribution from software and internet of Things actors, leveraging national initiatives and supporting the emergence of new actors;
- (f) support alignment with ethical and security requirements, including them in the Strategic Research and Innovation Agendas and providing input to the Union's legislative process as appropriate.

Article 160

Additional tasks of the Smart Networks and Services Joint Undertaking

In addition to the tasks set out in Article 5, the Smart Networks and Services Joint Undertaking shall carry out the following tasks:

- (a) contribute to the work programmes of other Union programmes, such as CEF2 Digital programme, DEP and InvestEU that are implementing activities in the area of smart networks and services;
- (b) coordinate Union trialling, piloting and deployment initiatives in the field of smart networks and services, such as pan-European 5G corridors for connected and automated mobility under CEF2 Digital programme, in liaison with the Commission and competent relevant funding bodies;
- (c) promote synergies among relevant Union-funded trials, pilots and deployment activities in the area of smart networks and services, such as those funded under CEF2 Digital programme, DEP and InvestEU, and ensure effective dissemination and leveraging of the knowledge and know-how gathered in the context of those activities;

- (d) develop and coordinate the strategic deployment agendas for pan-European 5G corridors for connected and automated mobility with the involvement of stakeholders. Those agendas shall provide strategic non-binding guidance covering the duration of CEF2 Digital programme by defining a common vision for the development of 5G-enabled ecosystems and the underpinning network and services requirements, and identifying deployment objectives and roadmaps as well as potential cooperation models.

Article 161

Members

The members of the Smart Networks and Services Joint Undertaking shall be:

- (a) the Union, represented by the Commission;
- (b) the 6G-IA registered under Belgian law, upon notification of its decision to accede to the Smart Networks and Services Joint Undertaking by means of a letter of commitment, which shall not contain conditions regarding its accession other than those set out in this Regulation.

Article 162

Union financial contribution

The Union financial contribution to the Smart Networks and Services Joint Undertaking, including EEA appropriations, to cover administrative costs and operational costs shall be up to EUR 900 000 000, including up to EUR 18 519 000 for administrative costs.

Article 163

Contributions from members other than the Union

1. The members of the Smart Networks and Services Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make a total contribution of at least EUR 900 000 000 over the period set out in Article 3.
2. The members of the Smart Networks and Services Joint Undertaking other than the Union shall make or arrange for their constituent or affiliated entities to make an annual financial contribution to the administrative costs of the Smart Networks and Services Joint Undertaking of at least 20 % of the total administrative costs. They shall endeavour to increase their number of constituent or affiliated entities in order to increase their contribution to 50 % of the administrative costs of the Smart Networks and Services Joint Undertaking over its lifetime, taking due account of constituent and affiliated entities that are SMEs.

Article 164

Scope of additional activities

For the purpose of Article 11(1), point (b), additional activities may include:

- (a) spin-off research and development activities;
- (b) contributions to standardisation;
- (c) contributions to consultations in the context of Union regulatory processes;
- (d) activities financed by loans of the European Investment Bank and not funded under a grant by the Union;
- (e) contributions to activities of the members other than the Union and any other group or association of stakeholders in the area of the Smart Networks and Services Joint Undertaking, not funded under a grant by the Union;
- (f) activities to develop the ecosystem including building cooperation with verticals;

- (g) dissemination activities of results globally to achieve consensus on supported technologies as preparation of future standards;
- (h) trials, demos, pilots, go to market and early deployment of technologies;
- (i) international cooperation not funded under a grant by the Union;
- (j) activities related to the preparation of, and participation in, research and innovation projects funded by private or public bodies other than the Union.

Article 165

Bodies of the Smart Networks and Services Joint Undertaking

The bodies of the Smart Networks and Services Joint Undertaking shall be:

- (a) the Governing Board;
- (b) the Executive Director;
- (c) the states' representatives group;
- (d) the stakeholders group.

Article 166

Composition of the Governing Board

1. The Governing Board shall be composed of the following:
 - (a) two representatives of the Commission on behalf of the Union;
 - (b) five representatives of the 6G-IA.
2. Notwithstanding Article 42, the representatives of the private members shall disclose immediately to the Governing Board their involvement in professional activities with entities that are not established in the Union, or with entities that are not controlled by legal persons or entities established in the Union. In such a case, the representatives of the Union may decide to request the member concerned to appoint another representative.

Article 167

Functioning of the Governing Board

The 6G-IA shall hold 50 % of the voting rights.

Article 168

Additional tasks of the Governing Board

In addition to the tasks listed in Article 17, the Governing Board of the Smart Networks and Services Joint Undertaking shall carry out the following tasks:

- (a) adopt strategic deployment agendas as non-binding contributions under CEF2 Digital programme with regard to 5G corridors and, if appropriate, amend them throughout the duration of CEF2 Digital programme;
- (b) ensure that Union cybersecurity legislation and Member States' existing and future coordinated guidance are taken into consideration in all the activities of the Smart Network and Services Joint Undertaking;
- (c) promote synergies and complementarities between the digital, transport and energy sectors of CEF2 Digital programme through the identification of intervention areas and contribution to the work programmes, as well as synergies and complementarities with the other relevant Union programmes.

*Article 169***The states' representatives group**

In addition to Article 20, the representatives shall ensure that they present a coordinated position that reflects their state's views expressed in any of the following:

- (a) the research and innovation matters related to Horizon Europe;
- (b) the strategic deployment agenda and the deployment activities related to other Union programmes, in particular CEF2 Digital programme, but also activities under DEP and InvestEU that are in scope of the Smart Networks and Services Joint Undertaking.

*Article 170***Security**

1. When deemed relevant, the Governing Board may mandate that an action funded by the Smart Networks and Services Joint Undertaking shall ensure that network elements deployed for large-scale experimentation or piloting follow security scrutiny assessments. The assessments shall reflect Union cybersecurity legislation and policies, as well as Member States' existing and future coordinated guidance.

2. In relation to its task referred to in Article 160, point (a), the Governing Board shall advise that other funding bodies apply paragraph 1 of this Article and Article 17(2), point (l), to their actions *mutatis mutandis*, where it deems it appropriate and where this is authorised by the basic act of the respective Union funding programme.

PART THREE

FINAL PROVISIONS*Article 171***Monitoring and evaluation**

1. The activities of the joint undertakings shall be subject to continuous monitoring and periodic reviews in accordance with their financial rules, to ensure the highest impact, scientific excellence and the most effective and efficient use of resources. The outcomes of monitoring and periodic reviews shall feed into the monitoring of European partnerships and evaluations of the joint undertakings as part of Horizon Europe evaluations, as specified in Articles 50 and 52 of the Horizon Europe Regulation.

2. The joint undertakings shall organise the continuous monitoring and reporting of the management and implementation of their activities and periodic reviews of the outputs, results and impacts of the funded indirect actions implemented in accordance with Article 50 of and Annex III to the Horizon Europe Regulation. That monitoring and reporting shall include:

- (a) time-bound indicators for the purpose of reporting on an annual basis on the progress of their activities towards the achievement of the general, specific and operational objectives, including joint undertakings' additional objectives laid down in Part Two, as well as along impact pathways set out in Annex V to the Horizon Europe Regulation;
- (b) information on synergies between the joint undertaking's actions and national or regional initiatives and policies based on information received by the participating states or the states' representatives group as well as on synergies with other Union programmes and other European partnerships;
- (c) information on the level of mainstreaming social sciences and humanities, the ratio between lower and higher TRLs in collaborative research, the progress on widening countries' participation, the geographical composition of consortia in collaborative projects, the use of two-stage submission and evaluation procedure, the measures that aim to facilitate collaborative links in European research and innovation, the use of the evaluation review and the number and types of

complaints, the level of climate mainstreaming and related expenditures, SME participation, private sector participation, gender participation in funded actions, evaluation panels, boards and advisory groups, the co-funding rate, the complementary and cumulative funding from other Union funds, the time-to-grant, the level of international cooperation, engagement of citizens' and civil society participation;

- (d) the levels of expenditure disaggregated at project level in order to allow for specific analysis, including per intervention area;
- (e) the level of oversubscription, in particular the number of proposals and for each call for proposals, the average score, the share of proposals above and below quality thresholds;
- (f) information on quantitative and qualitative leverage effects, including on committed and actually provided financial and in-kind contributions, visibility and positioning in the international context, impact on research and innovation related risks of private sector investments;
- (g) information on measures for attracting newcomers, in particularly SMEs, higher education institutions and research organisations, and for expanding collaborative networks.

3. Evaluations of the joint undertakings' operations shall be carried out in a timely manner to feed into the overall interim and final evaluations of Horizon Europe and the related decision-making process on Horizon Europe, its successor and other initiatives relevant to research and innovation, referred to in Article 52 of the Horizon Europe Regulation.

4. The Commission shall carry out an interim and a final evaluation of each Joint Undertaking feeding into the Horizon Europe evaluations, as specified in Article 52 of the Horizon Europe Regulation. The evaluations shall examine how each joint undertaking fulfils its mission and objectives, cover all activities of the joint undertaking and evaluate the joint undertaking's concerned European added value, effectiveness, efficiency, including its openness and transparency, the relevance of the activities pursued and their coherence and complementarity with relevant regional, national and Union policies, including synergies with other parts of Horizon Europe, such as missions, clusters or thematic or specific programmes. The evaluations shall take into account the views of stakeholders, at both European and national level and shall, where relevant, also include an assessment of the long-term scientific, societal, economic and technological impacts of the joint undertakings referred to in Article 174(3) to (9). The evaluations shall also include, where relevant, an assessment of the most effective policy intervention mode for any future action, as well as the relevance and coherence of any possible renewal of each joint undertaking given the overall policy priorities and the research and innovation support landscape, including its positioning against other initiatives supported through the Framework Programme, in particular European partnerships or missions. The evaluations shall also take due account of the phasing-out plan adopted by the Governing Board in accordance with Article 17(2), point (a1).

5. On the basis of the conclusions of an interim evaluation referred to in paragraph 2 of this Article, the Commission may act in accordance with Article 11(6) or take any other appropriate action.

6. The Commission may carry out further evaluations of themes or topics of strategic relevance, with the assistance of external independent experts selected on the basis of a transparent process, to examine the progress made by a joint undertaking towards the objectives set, identify the factors contributing to the implementation of the activities and identify best practices. By carrying out those further evaluations, the Commission shall fully consider the administrative impact on the joint undertaking.

7. Joint undertakings shall perform periodic reviews of their activities to serve as a basis for their interim and final evaluations as part of Horizon Europe evaluations referred to in Article 52 of the Horizon Europe Regulation.

8. Periodic reviews and evaluations shall be taken into consideration in the winding up or phasing out of the joint undertaking referred to in Article 45 of this Regulation, in line with Annex III to the Horizon Europe Regulation. Within six months after the winding up of a joint undertaking, but no later than four years after the triggering of the winding-up procedure referred to in Article 45 of this Regulation, the Commission shall conduct a final evaluation of that joint undertaking in line with the final evaluation of Horizon Europe.

9. The Commission shall publish and communicate the results of the evaluations of the joint undertakings, which shall include conclusions of the evaluation and observations by the Commission, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions as part of the Horizon Europe evaluations referred to in Article 52 of the Horizon Europe Regulation.

Article 172

Support from the host state

An administrative agreement may be concluded between a joint undertaking and the Member State where its seat is located concerning privileges and immunities and other support to be provided by that Member State to the joint undertaking concerned.

Article 173

Initial actions

1. The Commission shall be responsible for the establishment and initial operation of the Global Health EDCTP3 Joint Undertaking and the Smart Networks and Services Joint Undertaking until they have the operational capacity to implement their own budget. The Commission shall carry out all necessary actions in collaboration with the other members and with the involvement of the competent bodies of those joint undertakings.

2. For the purpose of paragraph 1:

- (a) until the Executive Director takes up his or her duties following his or her appointment by the Governing Board in accordance with Article 18(2), the Commission may designate a Commission official to act as interim Executive Director and exercise the duties assigned to the Executive Director;
- (b) by derogation from Article 17(2), point (h), the interim Executive Director shall exercise the relevant appointing authority powers in respect of any staff positions that need to be filled before the Executive Director takes up his or her duties in accordance with Article 18(2);
- (c) the Commission may assign a limited number of its officials on an interim basis.

3. The interim Executive Director may authorise all payments covered by the appropriations provided in the annual budget of the Joint Undertakings referred to in paragraph 1 after they are approved by the Governing Board and may conclude agreements, decisions and contracts, including staff employment contracts, following the adoption of the staff establishment plan of those joint undertakings.

4. The interim Executive Director shall, with the agreement of the incoming Executive Director and subject to the approval of the Governing Board, determine the date on which the joint undertaking concerned will be deemed to have the capacity to implement its own budget. From that date, the Commission shall abstain from making commitments and executing payments for the activities of that joint undertaking.

Article 174

Repeal and transitional provisions

1. Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014 are repealed.

2. Actions initiated or continued under the Regulations referred to in paragraph 1 and the financial obligations related to such actions shall continue to be governed by those Regulations until their completion.

3. The Circular Bio-based Europe Joint Undertaking shall be the legal and universal successor in respect of all contracts, including employment contracts and grant agreements, liabilities and acquired property of the Bio-based Industries Joint Undertaking established by Regulation (EU) No 560/2014, which it shall replace and succeed.
4. The Clean Aviation Joint Undertaking shall be the legal and universal successor in respect of all contracts, including employment contracts and grant agreements, liabilities and acquired property of the Clean Sky 2 Joint Undertaking established by Regulation (EU) No 558/2014, which it shall replace and succeed.
5. The Clean Hydrogen Joint Undertaking shall be the legal and universal successor in respect of all contracts, including employment contracts and grant agreements, liabilities and acquired property of the Fuel Cells and Hydrogen 2 Joint Undertaking established by Regulation (EU) No 559/2014, which it shall replace and succeed.
6. The Europe's Rail Joint Undertaking shall be the legal and universal successor in respect of all contracts, including employment contracts and grant agreements, liabilities and acquired property of the Shift2Rail joint undertaking established by Regulation (EU) No 642/2014, which it shall replace and succeed.
7. The Innovative Health Initiative Joint Undertaking shall be the legal and universal successor in respect of all contracts, including employment contracts and grant agreements, liabilities and acquired property of the Innovative Medicines Initiative 2 Joint Undertaking established by Regulation (EU) No 557/2014, which it shall replace and succeed.
8. The Key Digital Technologies Joint Undertaking shall be the legal and universal successor in respect of all contracts, including employment contracts and grant agreements, liabilities and acquired property of the ECSEL joint undertaking established by Regulation (EU) No 561/2014, which it shall replace and succeed.
9. The Single European Sky ATM Research 3 Joint Undertaking shall be the legal and universal successor in respect of all contracts, including employment contracts and grant agreements, liabilities and acquired property of the SESAR Joint Undertaking established by Regulation (EC) No 219/2007, which it shall replace and succeed.
10. This Regulation does not affect the rights and obligations of staff engaged under the Regulations referred to in paragraph 1.
11. The Executive Directors appointed under the Regulations referred to in paragraph 1 of this Article shall, for their remaining term of office, be assigned to the functions of Executive Director as provided for in this Regulation with effect from the date of entry into force of this Regulation. The other conditions of the contract shall remain unchanged.
12. In its first meeting, the Governing Board of each joint undertaking shall adopt a list of decisions adopted by the Governing Board of the preceding joint undertakings referred to in paragraphs 3 to 9 that shall continue to apply for the joint undertaking concerned established by this Regulation.
13. The interim evaluations referred to in Article 171(2) shall include a final evaluation of the preceding joint undertakings referred to in paragraphs 3 to 9 of this Article.
14. Any unused appropriations under the Regulations referred to in paragraph 1 shall be transferred to the corresponding joint undertaking established by this Regulation. Any unused operational appropriations so transferred shall first be used to provide financial support to indirect actions initiated under Horizon 2020. Remaining operational appropriations may be used for indirect actions initiated under this Regulation. Where such operational appropriations are used for indirect actions initiated under this Regulation, they shall count against the financial contribution to be provided by the Union to the respective joint undertaking under this Regulation.

*Article 175***Entry into force**

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

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

Done at Brussels, 19 November 2021.

For the Council

The President

J. BORRELL FONTELLES

ANNEX I

Founding members of the Clean Aviation Joint Undertaking

- (1) Aciturri Aeronáutica S.L.U., registered under Spanish law (registration number: BU12351), with its registered office in P.I. Bayas, calle Ayuelas, 22, 09200, Miranda de Ebro (Burgos), Spain;
- (2) Aernnova Aerospace SAU, registered under Spanish law (registration number: VI6749), with its registered office in Parque Tecnológico de Álava, C/Leonardo da Vinci num. 13, Miñano (Álava), Spain;
- (3) Airbus SAS, registered under French law (registration number: 383 474 814), with its registered office in 2 Rond-Point Emile Dewoitine, 31707 Blagnac, France;
- (4) Centro Italiano Ricerche Aerospaziali SCPA (CIRA), registered under Italian law (registration number: 128446), with its registered office in Via Maiorise 1, Capua-Caserta 81043, Italy;
- (5) Dassault Aviation SA, registered under French law (registration number: 712042456), with its registered office in 9, Rond-Point des Champs-Élysées Marcel-Dassault, 78008 Paris, France;
- (6) Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR), registered under German law (registration number: VR2780), with its registered office in Linder Höhe, 51147 Köln, Germany;
- (7) Fraunhofer-Gesellschaft zur Förderung der Angewandten Forschung e.V., registered under German law (registration number: VR4461), with its registered office in 27C, Hansastrasse, 80686 München, Germany;
- (8) Fokker Technologies Holding BV, registered under Dutch law (registration number: 50010964), with its registered office in Industrieweg 4, 3351 LB Papendrecht, The Netherlands;
- (9) GE Avio S.r.l., registered under Italian law (registration number: 1170622CF10898340012), with its registered office in Rivalta di Torino (TO), Via I Maggio no. 99, Italy;
- (10) GKN Aerospace, Sweden AB, registered under Swedish law (registration number: 5560290347), with its registered office in Flygmotorvägen 1, SE-461 81 Trollhättan, Sweden;
- (11) Honeywell International s.r.o., registered under Czech law (registration number: 27617793), with its registered office in V Parku 2325/18, 148 00 Praha 4 – Chodov, Prague, Czech Republic;
- (12) Industria de Turbo Propulsores S.A.U., registered under Spanish law (registration number: BI5062), with its registered office in Parque Tecnológico, Edificio 300, 48170 Zamudio, Spain;
- (13) Leonardo SpA, registered under Italian law (registration number: 7031), with its registered office in Piazza Monte Grappa 4, 00195 Rome, Italy;
- (14) Liebherr-Aerospace & Transportation SAS, registered under French law (registration number: 552016834), with its registered office in 408 avenue des Etats-Unis, 31016 Toulouse Cedex 2, France;
- (15) Lufthansa Technik AG, registered under German law (registration number: HRB 56865), with its registered office in Weg beim Jäger 193, 22335 Hamburg, Germany;
- (16) Łukasiewicz Research Network – Institute of Aviation, registered under Polish law (registration number: 387193275), with its registered office in Al. Krakowska 110/114, 02-256 Warsaw, Poland;
- (17) MTU Aero Engines AG, registered under German law (registration number: HRB 157206), with its registered office in Dachauer Str. 665, 80995 München, Germany;
- (18) National Institute for Aerospace Research (INCAS), registered under Romanian law (registration number: J40649215071991), with its registered office in B-dul Iuliu Maniu no. 220, sect 6, 061126 Bucharest, Romania;
- (19) Office National d'Etudes et de Recherches Aéropatiales (ONERA), registered under French law (registration number: 775722879), with its registered office in BP 80100 – 91123 Palaiseau, France;

- (20) Piaggio Aero Industries, registered under Italian law (registration number: 903062), with its registered office in Viale Generale Disegna, 1, 17038 Villanova d'Albenga, Savona, Italy;
 - (21) Pipistrel Vertical Solutions d.o.o., registered under Slovenian law (registration number: 7254466000), with its registered office in Vipavska cesta 2, SI-5270 Ajdovščina, Slovenia;
 - (22) Rolls-Royce Deutschland Ltd & Co KG, registered under German law (registration number: HRA 2731P), with its registered office in Eschenweg 11, Dahlewitz, 15827 Blankenfelde-Mahlow, Germany;
 - (23) Safran, registered under French law (registration number: 562 082 909), with its registered office in 2, Bvd. du General Martial-Valin, 75015 Paris, France;
 - (24) Stichting Nationaal Lucht- en Ruimtevaartlaboratorium, registered under Dutch law (registration number: 41150373), with its registered office in Anthony Fokkerweg 2, 1059 CM Amsterdam, The Netherlands;
 - (25) Thales AVS France SAS, registered under French law (registration number: 612039495), with its registered office in 75-77 Avenue Marcel Dassault, 33700 Mérignac, France;
 - (26) United Technologies Research Centre Ireland, Ltd, registered under Irish law (registration number: 472601), with its registered office in Fourth Floor, Penrose Business Centre, Penrose Wharf, Cork T23 XN53, Ireland;
 - (27) University of Patras, registered under Greek law (registration number: EL998219694 (VAT)), with its registered office in University Campus, 26504 Rio Achaia, Greece.
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ANNEX II

Founding members of the Europe's Rail Joint Undertaking

- (1) Administrador de Infraestructuras Ferroviarias (ADIF), Entidad Pública Empresarial, a public corporate company registered under Spanish law (registration number: Q2801660H), with its registered office at Calle Sor Ángela de la Cruz, 3, 28020 Madrid, Spain;
- (2) Alstom Transport SA, registered under French law (registration number 389 191 982), with its registered office in 48, rue Albert Dhalenne, 93482 Saint-Ouen, France;
- (3) ANGELRAIL consortium led by MER MEC S.p.A., registered under Italian law (registration number: 05033050963), with its registered office in Monopoli (BA) 70043 Via Oberdan, 70 Italy;
- (4) AŽD Praha s.r.o., registered under Czech law (registration number: 48029483), with its registered office in Žirovnická 3146/2, Záběhlce, 106 00, Praha 10, Czech Republic;
- (5) Construcciones y Auxiliar de Ferrocarriles, S.A. (CAF), registered under Spanish law (registration number: Volume 983, Folio 144, Sheet number SS-329, entry 239^a), with its registered office in calle José Miguel Iturriz n° 26, 20200, Beasain (Gipuzkoa), Spain;
- (6) Asociación Centro Tecnológico CEIT, registered under Spanish law (registration number: 28/1986 Registry of Associations of the government of the autonomous community of the Basque Country), with its registered office in Paseo Manuel Lardizabal, n° 15. Donostia-San Sebastián, Spain;
- (7) České dráhy, a.s., registered under Czech law (registration number: 70994226, entered in the Commercial Register kept by the Municipal Court in Prague, section B, insert 8039), with its registered office in Prague 1, Nábřeží L. Svobody 1222, postal code 110 15, Czech Republic;
- (8) Deutsche Bahn AG, Germany;
- (9) Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR), registered under German law (registration number: VR 2780 at Amtsgericht Bonn), with its registered office in Linder Höhe, 51147 Cologne, Germany;
- (10) European Smart Green Rail Joint Venture (eSGR JV), represented by Centro de Estudios de Materiales y Control de Obra S.A (CEMOSA), registered under Spanish law (registration number: A-29021334), with its registered office in Benaque 9, 29004 Málaga, Spain;
- (11) Faiveley Transport SAS, registered under French law (registration number 323 288 563 RCS Nanterre), with its registered office in 3, rue du 19 mars 1962, 92230 Gennevilliers, France;
- (12) Ferrovie dello Stato Italiane S.p.A. (FSI), registered under Italian law (registration number: R.E.A. 962805), with its registered office in piazza della Croce Rossa 1 – 00161 Roma, Italy;
- (13) Hitachi Rail STS S.p.A., registered under Italian law, registration number R.E.A. GE421689, with its registered office in Genova, Italy;
- (14) INDRA SISTEMAS S.A & PATENTES TALGO S.L.U.

INDRA SISTEMAS S.A., registered under Spanish law (registration number: A-28599033), with its registered office in Avenida de Bruselas n° 35, 28108 Alcobendas, Madrid, Spain;

PATENTES TALGO S.L.U., registered under Spanish law (registration number: B-84528553), with registered office in Paseo del tren Talgo, n° 2, 28290 Las Rozas de Madrid, Madrid, Spain;
- (15) Jernbanedirektoratet (Norwegian Rail Directorate), Oslo, Norway;
- (16) Knorr-Bremse Systems für Schienenfahrzeuge GmbH, registered under German law (registration number: HRB91181), with its registered office in Moosacher Str. 80, 80809 München, Germany;
- (17) Österreichische Bundesbahnen-Holding Aktiengesellschaft (ÖBB-Holding AG), registered under Austrian law (registration number: FN 247642f), with its registered office in Am Hauptbahnhof 2, 1100 Vienna, Austria;

- (18) Polskie Koleje Państwowe Spółka Akcyjna (PKP), registered under Polish law (registration number: 0000019193), with its registered office Al. Jerozolimskie 142A, 02-305 Warszawa, Poland;
 - (19) ProRail B.V. & NS Groep N.V.
ProRail B.V., registered under Dutch law (registration number: 30124359), with its registered office in Utrecht (PIC-nr.: 998208668), The Netherlands;
NS Groep N.V., registered under Dutch law (registration number: 30124358), with its registered office in Utrecht (PIC-nr.: 892354217), The Netherlands;
 - (20) Siemens Mobility GmbH, registered under German law (registration number HRB 237219), with its registered office in Otto-Hahn-Ring 6, Munich, Germany;
 - (21) Société nationale SNCF, société anonyme, registered under French law (registration number: 552 049 447), with its registered office in 2 Place aux Étoiles, 93200 Saint-Denis, France;
 - (22) Strukton Rail Nederland B.V., registered under Dutch law (registration number: 30139439 Chamber of commerce Utrecht), The Netherlands;
 - (23) THALES SIX GTS France SAS, registered under French law (registration number: 383 470 937), with its registered office in 4 Avenue des Louvresses – 92230 Gennevilliers, France;
 - (24) Trafikverket, a Public Sector Body, registered under Swedish law (registration number: 202100-6297), with its registered office in 781 89 Borlänge, Sweden;
 - (25) voestalpine Railway Systems GmbH, registered under Austrian law (registration number: FN 126714w), with its registered office in Kerpelystrasse 199, 8700 Leoben, Austria.
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ANNEX III

Founding members of the Single European Sky Research 3 Joint Undertaking

- (1) Aeroporti di Roma SpA, a company incorporated under Italian law, subject to the management and coordination of Atlantia SpA, with registered office at Via Pier Paolo Racchetti 1, Fiumicino (Rome), Italy, Tax Code and Rome Business and Trade Registry number 13032990155;
- (2) AENA Sociedad Mercantil Estatal, Sociedad Anónima (AENA S.M.E.S.A), registered under Spanish law (official registration C.I.F Tax identification certificate.: A-86212420), with its legal address at Calle Peonías 12, 28042, Madrid, Spain. Telephone number +34 913 211 000;
- (3) AEROPORTS DE PARIS, Société Anonyme, registered under French law (official registration RCS Bobigny B 552 016 628), with its registered office in 1 rue de France, 93290 Tremblay-en-France, France;
- (4) Société Air France SA, registered under French law, 420 495 178 RCS Bobigny, 45 rue de Paris, 95747 Roissy-CDG, France, FR 61 420 495 178;
- (5) Air Navigation Services of the Czech Republic (ANS CR), state enterprise, established and organised under the laws of the Czech Republic, with its registered office at Navigační 787, 252 61 Jeneč, Czech Republic, Company Identification Number: 497 10 371, VAT Identification Number: CZ699004742, registered in the Commercial Register administered by the Municipal Court in Prague, under Section A, Insert 10771;
- (6) Airbus SAS, registered under French law (registration number: 383 474 814 R.C.S. Toulouse), with its registered office in 2 Rond Point Émile Dewoitine, 31700 Blagnac, France;
- (7) Airtel ATN Limited, registered under Irish law (registration number: 287698), with its registered office in 2 Harbour Square, Crofton Road, Dun Laoghaire, County Dublin, A96 D6RO, Ireland;
- (8) Alliance for New Mobility Europe (AME), a non-profit organisation ('Association sans but lucratif / Vereniging zonder winstoogmerk'), registered under Belgian law with registration number 0774.408.606, with its registered office in 227, rue de la Loi, 1000 Brussels, Belgium;
- (9) Athens International Airport S.A, registered under Greek Law (official registration: General Electronic Commercial Registry under G.E.MI. number 2229601000), with its registered premises at Spata Attica, Greece, postal code 19019;
- (10) Austro Control Österreichische Gesellschaft für Zivilluftfahrt mit beschränkter Haftung, a company with limited liability, registered under the Laws of Austria (registration number 71000m), with its registered office at Wagramer Strasse 19, A-1220 Vienna, Austria;
- (11) Brussels Airport Company NV/SA, a limited liability company incorporated and existing under the laws of Belgium, registered with the Crossroads Bank of Enterprises under number 0890.082.292 and with its registered offices in Auguste Reyerslaan 80, 1030 Brussels, Belgium;
- (12) Boeing Aerospace Spain, SL, registered under Spanish law, VAT number: B-83053835, with its registered office in Avenida Sur del Aeropuerto de Barajas 38, Madrid, 28042, Spain;
- (13) State enterprise "Air traffic services authority" (BULATSA), state enterprise, registered under Bulgarian law (registration number 000697179), with its registered office in Bulgaria, 1 Brussels blvd, 1540 Sofia;
- (14) Centro Italiano Ricerche Aerospaziali C.I.R.A. SCpA, registered under Italian law (registration number: CE-128446), with its registered office in Via Maiorise snc – 81043 Capua (CE) – Italy;
- (15) Croatia Control Ltd, (CCL), registered under the Laws of Croatia (registration number 080328617), with its registered office at Rudolfa Fizira 2, Velika Gorica, Croatia;
- (16) Deutsche Lufthansa AG; registered under German law, District Court of Cologne HRB 2168, Venloer Str. 151-153, D-50672 Cologne, Germany, DE 122 652 565;
- (17) Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR), registered under German law (registration number: VR 2780 at Amtsgericht Bonn), with its registered office in Linder Höhe, 51147 Cologne, Germany;

- (18) DFS Deutsche Flugsicherung GmbH, registered under the Private Law (Registration number: HRB 34977), with its registered office in Langen (Hessen), Germany;
- (19) The French State – Ministry for an ecological transition, Direction générale de l'aviation civile (DGAC), Direction des services de la navigation aérienne DSNA, registered under French law (registration number: SIREN 120 064 019 00074), with its registered office at 50 rue Henry Farman 75 720 Paris Cedex 15, France;
- (20) Drone Alliance Europe, non-profit organisation ('Association sans but lucratif / Vereniging zonder winstoogmerk'), registered under Belgian law with registration number 0693.860.794, with its registered office in rue Breydel 34 – 36, 1040 Brussels, Belgium;
- (21) Droniq GmbH, registered under German law, Ginnheimer Stadtweg 88, 60431 Frankfurt, Germany, Amtsgericht Frankfurt am Main, HRB 115576, DE324815501;
- (22) easyJet Europe Airline GmbH, registered under the Laws of Austria (registration number FN 452433 v), with its registered office at Wagramer Strasse 19, IZD Tower, 11. Stock, 1220 Vienna, Austria;
- (23) Ecole Nationale de l'Aviation Civile (ENAC), registered under French law registration number: n°193 112 562 00015, with its registered office on 7 avenue Edouard Belin, CS 54005 – 31055 TOULOUSE cedex 4, France;
- (24) ENTIDAD PUBLICA EMPRESARIAL ENAIRE, a public business entity registered under the law 4/1990 of June 29th and Law 18/2014 of October 15th, VAT number: Q2822001J, and with its registered office in Parque Empresarial las Mercedes. Edificio n°2 Avda. de Aragón, 330. 28022 Madrid, Spain;
- (25) ENAV S.p.A., a Joint-Stock Company registered under the laws of Italy, registration number: R.E.A. 965162, with its registered office in Via Salaria, 716 – 00138, Rome, Italy;
- (26) Flughafen München GmbH, registered under German law (registration number: HRB 5448, Munich local court), with its registered office at Nordallee 25, 85356 Munich-Airport, Germany;
- (27) Frequentis AG, registered under Austrian law (registration number: FN 72115 b), with its registered office in Innovationsstraße 1, 1100 Vienna, Austria;
- (28) Honeywell International s.r.o., registered under Czech law, ID No.: 276 17 793, with its registered office in V Parku 2325/16, 148 00 Prague 4, Czech Republic;
- (29) HungaroControl Hungarian Air Navigation Services Private Limited Company, registered under Hungarian law (registration number: 01-10-045570), with its registered office in Igló utca 33-35, 1185 Budapest, Hungary;
- (30) Indra Sistemas, S.A., registered under Spanish law, with Tax Identification Code A-28599033, registered in the Mercantile Registry of Madrid in Volume 5465 general, 4554 of section 3 of the Corporate Ledger, Folio 80, Sheet number 43677, 1st entry, with its registered office at Avenida de Bruselas, NUM 35, 28108 Alcobendas – Madrid;
- (31) Irish Aviation Authority (IAA), registered under the Laws of Ireland (registration number 211082), with its registered office at The Times Building, 11-12 D'Olier Street, Dublin 2, Ireland;
- (32) Københavns Lufthavne A/S, registered under Danish law (official registration CVR 14707204), with its registered office in Lufthavnsboulevarden 6, 2770 Kastrup;
- (33) L'OFFICE NATIONAL D'ÉTUDES ET DE RECHERCHES AÉROSPATIALES (ONERA), a French agency (Établissement public à caractère industriel et commercial), registered under French Law with the Évry commercial and companies registry (number 775 722 879), having its head office at: BP 80100 – FR-91123 Palaiseau Cedex – France;
- (34) Leonardo Società per azioni; Short name: Leonardo S.p.A. – registered under the Italian Law (Fiscal Code and Registration number: 00401990585), with its registered office in Piazza Monte Grappa n. 4, 00195 Roma, Italy;
- (35) Letiště Praha, a. s. („Prague Airport“), a Joint-Stock Company registered under the law of Czech Republic, registration number: 28244532, with its registered office in K Letišti 6/1019, Prague 6, Czech Republic;

- (36) Luftfartsverket (LFV), registered under the Laws of Sweden (registration number 202195-0795) with its registered office at Hospitalsgatan 30, S-601 79 Norrköping – Sweden;
- (37) Luchtverkeersleiding Nederland (LVNL) a public body established by the Dutch Aviation Act, registered under Dutch law (registration number: 34367959), with its registered office at Stationsplein ZuidWest 1001, 1117 CV Schiphol, The Netherlands;
- (38) NAVEGAÇÃO AÉREA DE PORTUGAL – NAV Portugal E.P.E, registered under the Laws of Portugal (registration number 504448064) with its registered office at Rua D, Edifício 121, Aeroporto de Lisboa, 1700-008 Lisboa, Portugal;
- (39) NAVIAIR, registered under the Laws of Denmark, including the law on Naviar of 26 May 2010, (registration number 26059763) with its registered office is at Naviar Allé 1 2770 Kastrup, Denmark;
- (40) Stichting Koninklijk Nederlands Lucht- en Ruimtevaartcentrum (NLR), a foundation under Dutch law with Chamber of Commerce registration number: 41150373, with its registered office in Amsterdam, The Netherlands, with address at Anthony Fokkerweg 2, 1059 CM Amsterdam, The Netherlands;
- (41) Pipistrel Vertical Solutions d.o.o., registered under Slovenian law (registration number: 7254466000), with its registered office in Ajdovščina, Slovenia;
- (42) Polish Air Navigation Services Agency PANSA, state legal entity, organised and operating under the Act of 8 December, 2006 on Polish Air Navigation Services Agency, National Business Registry Number: 140886771, tax identification number: 5222838321, located at Wieżowa 8 street, 02-147 Warszawa, Poland;
- (43) Régie autonome "Romanian Air Traffic Services Administration" – ROMATSA, state legal entity registered under Romanian Trade Register's Office No. J40/1012/1991, Tax Code No. RO1589932, located at 10, Ion Ionescu de la Brad Blvd., 013813, Bucharest, Romania;
- (44) Ryanair Holdings plc, registered under Irish law, Ryanair Dublin Office, Airside Business Park, Swords, County Dublin, Ireland, Company No 249885;
- (45) Saab AB (publ), registered under Swedish law (registration number 556036-0793), with its registered office 581 88 Linköping, Sweden;
- (46) SAFRAN, registered under French law (Registration number: 562 082 909 R.C.S. Paris), with its registered office in Paris, France;
- (47) SINTEF AS, a non-profit Research and Technology Organisation, registered under Norwegian law (registration number: 919 303 808), with its registered office in Strindvegen 4 7034 TRONDHEIM, Norway;
- (48) SCHIPHOL NEDERLAND BV, registered under Dutch law (Chambers of Commerce number: 34166584), with its registered office in SHG, Evert van de Beekstraat 202, 1118 CP Schiphol, The Netherlands;
- (49) Societa per Azioni Esercizi Aeroportuali (S.E.A), official registration No: 00826040156, with its registered office at Aeroporto Milano Linate, Segrate, 20090, Italy, VAT number: 00826040156;
- (50) SWEDAVIA AB, a public limited company, registered under Swedish law on 14 December 2009 with the official registration number 556797-0818, having its registered office in Sigtuna with the address 190 45 Stockholm-Arlanda;
- (51) THALES AVS SAS FRANCE, Société simplifiée par actions, registered under THALES AVS law of France registration number RCS Bordeaux 612 039 495, with its registered office in 73-75 Avenue Marcel Dassault 33700 Mérignac, France;
- (52) THALES LAS FRANCE SAS, registered under French law (registration number: 319 159 877), with its registered office in 2, Avenue Gay Lussac, 78990 Elancourt, France;
- (53) United Technologies Research Centre Ireland Limited, registered under Irish laws (registration number: 472601), with its registered office in Penrose Business Centre, Penrose Wharf, Cork, Ireland;

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- (54) Volocopter GmbH registered under German law (registration number HRB 702987), with its registered office in Zeiloch 20, 76646 Bruchsal, Germany;
- (55) VTT Technical Research Centre of Finland Ltd, registered under Finnish law (registration number: 2647375-4), with its registered office in Espoo, Finland and registered address P.O. Box 1000, FI-02044 VTT, Finland.
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COMMISSION DELEGATED REGULATION (EU) 2021/2086**of 5 July 2021****amending Annexes II and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding precipitated phosphate salts and derivatives as a component material category in EU fertilising products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 ⁽¹⁾, and in particular Article 42(1) thereof,

Whereas:

- (1) Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. EU fertilising products contain component materials of one or more of the categories listed in Annex II to that Regulation.
- (2) Article 42(2) of Regulation (EU) 2019/1009 read in conjunction with Article 42(1), first subparagraph, point (b), of that Regulation requires the Commission to assess struvite without undue delay after 15 July 2019, and to include it in Annex II to that Regulation if that assessment concludes that EU fertilising products containing that material do not present a risk to human, animal or plant health, to safety or to the environment, and ensure agronomic efficiency.
- (3) Struvite can be waste, and can in accordance with Article 19 of Regulation (EU) 2019/1009 cease to be waste if it is contained in a compliant EU fertilising product. Pursuant to Article 42(3) of that Regulation read in conjunction with Article 6 of Directive 2008/98/EC of the European Parliament and of the Council ⁽²⁾, the Commission may therefore include struvite in Annex II to Regulation (EU) 2019/1009 only if recovery rules in that Annex ensure that the material is to be used for specific purposes, that a market or demand exists for it, and that its use will not lead to overall adverse environmental or human health impacts.
- (4) The Commission's Joint Research Centre ("JRC") began its assessment of struvite in anticipation of the adoption of Regulation (EU) 2019/1009, and concluded it in 2019. Throughout the assessment, the scope was widened to include the broad spectrum of precipitated phosphate salts, as well as their derivatives.
- (5) JRC's assessment report ⁽³⁾ concludes that precipitated phosphate salts and derivatives, if produced following the recovery rules suggested in the report, provide plants with nutrients or improve their nutrition efficiency and therefore ensure agronomic efficiency.

⁽¹⁾ OJ L 170, 25.6.2019, p. 1.

⁽²⁾ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

⁽³⁾ Huygens D, Saveyn HGM, Tonini D, Eder P, Delgado Sancho L, Technical proposals for selected new fertilising materials under the Fertilising Products Regulation (Regulation (EU) 2019/1009) – Process and quality criteria, and assessment of environmental and market impacts for precipitated phosphate salts & derivatives, thermal oxidation materials & derivatives and pyrolysis & gasification materials, EUR 29841 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-09888-1, doi:10.2760/186684, JRC117856.

- (6) JRC's assessment report furthermore concludes that there is an existing and growing market demand for precipitated phosphate salts and derivatives, and that those materials are likely to be used to provide nutrient inputs to European agriculture. It further concludes that the use of precipitated phosphate salts and derivatives produced following the recovery rules suggested in the report does not lead to overall adverse environmental or human health impacts.
- (7) The recovery rules suggested in JRC's assessment report include measures to limit the risks of recycling or producing contaminants, such as creating an exhaustive list of eligible input materials and excluding, for example, mixed municipal waste, and laying down specific processing conditions and product quality requirements. That assessment report also concludes that the conformity assessment rules applicable to fertilising products containing precipitated phosphate salts and derivatives should include a quality system assessed and approved by a notified body.
- (8) Based on the above, the Commission concludes that precipitated phosphate salts and derivatives, if produced in accordance with the recovery rules suggested in JRC's assessment report, ensure agronomic efficiency within the meaning of Article 42(1), first subparagraph, point (b)(ii), of Regulation (EU) 2019/1009. Furthermore, they comply with the criteria laid down in Article 6 of Directive 2008/98/EC. Finally, if compliant with the other requirements laid down in Regulation (EU) 2019/1009 in general and in Annex I to that Regulation in particular, they would not present a risk to human, animal or plant health, to safety or to the environment within the meaning of Article 42(1), first subparagraph, point (b)(i), of Regulation (EU) 2019/1009. Therefore, precipitated phosphate salts and derivatives should be included in Annex II to Regulation (EU) 2019/1009 subject to those recovery rules.
- (9) In particular, animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009 of the European Parliament and of the Council (*) should only be allowed as input materials for precipitated phosphate salts and derivatives governed by Regulation (EU) 2019/1009, if and when their end points in the manufacturing chain have been determined in accordance with Article 5(2), third subparagraph, of Regulation (EC) No 1069/2009 and will be reached at the latest by the end of the production process of the EU fertilising product containing the precipitated phosphate salts or derivatives.
- (10) Furthermore, given the fact that precipitated phosphate salt and derivatives can be considered to be recovered waste or by-products within the meaning of Directive 2008/98/EC, such materials should be excluded from component material categories 1 and 11 of Annex II to Regulation (EU) 2019/1009 pursuant to Article 42(1), third subparagraph, of that Regulation.
- (11) It is important to ensure that when fertilising products contain precipitated phosphate salts and derivatives, they are subject to an appropriate conformity assessment procedure including a quality system assessed and approved by a notified body. Therefore, it is necessary to amend Annex IV to Regulation (EU) 2019/1009 to provide for a conformity assessment appropriate for such fertilising products.
- (12) Given that the requirements set out in Annex II to Regulation (EU) 2019/1009 and the conformity assessment procedures set out in Annex IV to that Regulation are to apply as of 16 July 2022, it is necessary to defer the application of this Regulation to the same date,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/1009 is amended as follows:

- (1) Annex II is amended in accordance with Annex I to this Regulation;
- (2) Annex IV is amended in accordance with Annex II to this Regulation.

(*) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

Article 2

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

It shall apply from 16 July 2022.

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

Done at Brussels, 5 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex II to Regulation (EU) 2019/1009 is amended as follows:

(1) In Part I, the following point is added:

“CMC 12: Precipitated phosphate salts and derivatives”.

(2) Part II is amended as follows:

(a) In CMC 1, point 1 is amended as follows:

- (i) in sub-point (g), “or” is deleted;
- (ii) in sub-point (h), “.” is replaced by “, or”;
- (iii) the following sub-point (i) is added:

“(i) precipitated phosphate salts or derivatives, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.”.

(b) In CMC 11, point 1 is amended as follows:

- (i) in sub-point (c), “or” is deleted;
- (ii) in sub-point (d), “.” is replaced by “, or”;
- (iii) the following sub-point (e) is added:

“(e) precipitated phosphate salts or derivatives, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.”.

(c) The following CMC 12 is added:

“CMC 12: PRECIPITATED PHOSPHATE SALTS AND DERIVATES

1. An EU fertilising product may contain precipitated phosphate salts obtained through precipitation exclusively from one or more of the following input materials:

- (a) wastewaters and sewage sludge from municipal wastewater treatment plants, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (b) wastewaters and sludge from processing of foods, beverages, pet foods, animal feeds, or dairy products, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, unless processing steps involved contact with biocidal products within the meaning of Article 3(1), point (a), of Regulation (EU) No 528/2012 of the European Parliament and of the Council (*) other than those defined as product-type 4 of main group 1 of Annex V to that Regulation;
- (c) bio-waste within the meaning of Article 3, point 4, of Directive 2008/98/EC resulting from separate bio-waste collection at source, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (d) processing residues within the meaning of Article 2, point (t), of Directive 2009/28/EC of the European Parliament and of the Council (**) from the production of bioethanol and biodiesel derived from materials referred to in this point, sub-points (b), (c) and (e);
- (e) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water, or which are extracted from air by any means, except (***):
 - materials originating from mixed municipal waste,
 - sewage sludge, industrial sludge or dredging sludge,
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

- (f) substances and mixtures, other than (***):
- those referred to in sub-points (a) to (e),
 - waste within the meaning of Article 3, point 1, of Directive 2008/98/EC,
 - substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,
 - substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,
 - non-biodegradable polymers,
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

In addition, precipitated phosphate salts shall be obtained through precipitation from any input material referred to in sub-points (a) to (f), or a combination thereof, processed by manual, mechanical or gravitational means, solid-liquid fractionation using biodegradable polymers, dissolution in water, flotation, extraction with water, steam distillation or heating solely to remove water, thermal hydrolysis, anaerobic digestion or composting. The temperature under such processes shall not be raised above 275 °C.

2. The precipitation process shall take place under controlled conditions in a reactor. In addition, only input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been unintentionally contaminated with other material streams in a one-off incident resulting only in trace levels of exogenous compounds shall be used.

In the plant where the precipitation takes place, physical contacts between input and output materials shall be avoided after the precipitation process, including during storage.

3. The precipitated phosphate salts shall contain:
- (a) a minimum phosphorus pentoxide (P_2O_5) content of 16 % of the dry matter content;
 - (b) a maximum organic carbon (C_{org}) content of 3 % of the dry matter content;
 - (c) no more than 3 g/kg dry matter of macroscopic impurities above 2 mm in any of the following forms: organic matter, glass, stones, metal and plastics;
 - (d) no more than 5 g/kg dry matter of the sum of the macroscopic impurities referred to in sub-point (c).
4. An EU fertilising product may contain derivatives from precipitated phosphate salts produced through one or more chemical manufacturing steps that react the precipitated phosphate salts with materials referred to in sub-point 1(f) that are consumed in or used for chemical processing.

The derivative manufacturing process shall be executed so as to intentionally modify the chemical composition of the precipitated phosphate salts.

5. The precipitated phosphate salts used for the derivatives shall comply with points 1, 2 and 3.
6. Notwithstanding point 1, an EU fertilising product may contain precipitated phosphate salts obtained through precipitation from Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:
- (a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph, of Regulation (EC) No 1069/2009;
 - (b) the conditions in points 2 and 3 are met.

An EU fertilising product may also contain derivatives from such precipitated phosphate salts, obtained in accordance with the conditions set out in point 4.

7. In the plant where the precipitation takes place, the production lines for the processing of input materials allowed for the precipitated phosphate salts and derivatives referred to in points 1, 4 and 6 shall be clearly separated from production lines for the processing of other input materials.
8. Where for the PFC of an EU fertilising product containing or consisting of precipitated phosphate salts or derivatives or both there are no requirements regarding *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* in Annex I, those pathogens shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
<i>Salmonella</i> spp.	5	0	0	Absence in 25 g or 25 ml
<i>Escherichia coli</i> or <i>Enterococcaceae</i>	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

9. Pathogens in an EU fertilising product containing or consisting of precipitated phosphate salts obtained from materials referred to in sub-point 1(a) or derivatives from such precipitated phosphate salts or both shall not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
<i>Clostridium perfringens</i>	5	5	0	100 CFU in 1 g or 1 ml
<i>Ascaris</i> sp. viable eggs	5	0	0	Absence in 25 g or 25 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in CFU is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

10. The requirements set out in points (8) and (9), as well as the requirements for *Salmonella* spp., *Escherichia coli* or *Enterococcaceae* set in the corresponding PFC of an EU fertilising product consisting only of precipitated phosphate salts or derivatives or both shall not apply when those precipitated phosphate salts or all of the biogenic input materials used in the precipitation process have undergone one of the following processes:
 - (a) pressure sterilisation through the heating to a core temperature of more than 133 °C for at least 20 minutes at an absolute pressure of at least 3 bars, whereby the pressure must be produced by the evacuation of all air in the sterilisation chamber and the replacement of the air by steam ('saturated steam');

- (b) processing in a pasteurisation or hygienisation unit that reaches a temperature of 70 °C for at least one hour.
11. Precipitated phosphate salts obtained from materials referred to in sub-point 1(a) and derivatives obtained from such precipitated phosphate salts shall have no more than 6 mg/kg dry matter of PAH₁₆ (****)
 12. The sum of aluminium (Al) and iron (Fe) in precipitated phosphate salts or derivatives shall not exceed 10 % of the dry matter of the precipitated phosphate salts or the derivatives.
 13. Precipitated phosphate salts or derivatives shall have been registered pursuant to Regulation (EC) No 1907/2006 with a dossier containing:
 - (a) the information provided for by Annexes VI, VII and VIII of Regulation (EC) No 1907/2006; and
 - (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product, unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8, or 9 of Annex V to that Regulation.
 14. For the purposes of points 3, 11 and 12, the dry matter of precipitated phosphate salts and derivatives shall be measured using vacuum drying at 40 °C until constant weight to avoid the loss of crystal-bound water.

(*) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

(**) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140 5.6.2009, p. 16).

(***) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.

(****) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.”.

ANNEX II

In Annex IV, Part II, of Regulation (EU) 2019/1009, Module D1 (Quality assurance of the production process) is amended as follows:

(1) In point 2.2, sub-point (d) is replaced by the following:

“(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product, and, in relation to materials belonging to CMCs 3, 5 and 12 as defined in Annex II, a written description and a diagram of the production process, where each treatment, storage vessel and area is clearly identified.”.

(2) The introductory wording in point 5.1.1.1 is replaced by the following:

“5.1.1.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, senior management of the manufacturer's organisation shall.”.

(3) Point 5.1.2.1 is replaced by the following:

“5.1.2.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the quality system shall ensure compliance with the requirements specified in that Annex.”.

(4) Point 5.1.3.1 is amended as follows:

(a) The introductory wording is replaced by the following:

“5.1.3.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the examinations and tests shall comprise the following elements:”.

(b) Sub-points (b) and (c) are replaced by the following:

“(b) Qualified staff shall carry out a visual inspection of each consignment of input materials and verify compatibility with the specifications of input materials in CMCs 3, 5 and 12 laid down in Annex II.

(c) The manufacturer shall refuse any consignment of any given input material where visual inspection raises any suspicion of any of the following:

— the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product;

— incompatibility with the specifications of CMCs 3, 5 and 12 in Annex II, in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.”.

(c) Sub-point (e) is replaced by the following:

“(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5 and 12, as defined in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product's compliance with the relevant requirements laid down in Annex I.”.

(d) In subpoint (f), the introductory wording is replaced by the following:

“(f) For materials belonging to CMCs 3 and 5, the output material samples shall be taken on a regular basis with at least the following frequency:”.

(e) The following sub-points are inserted:

“(fa) For materials belonging to CMC 12, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled if triggered by any significant change that may affect the quality of the EU fertilising product:

Annual output (tonnes)	Samples/year
≤ 3 000	4
3 001 – 10 000	8
10 001 – 20 000	12
20 001 – 40 000	16
40 001 – 60 000	20
60 001 – 80 000	24
80 001 – 100 000	28
100 001 – 120 000	32
120 001 – 140 000	36
140 001 – 160 000	40
160 001 – 180 000	44
> 180 000	48

Manufacturers may reduce the default frequency of testing for contaminants as indicated above by considering the distribution of historical samples. After a minimum monitoring period of one year and a minimum number of 10 samples showing compliance with the requirements in Annex I and II, the manufacturer may reduce the default sampling frequency for that parameter by a factor 2 in case the greatest contaminant level recorded from the last 10 samples is smaller than half of the limit value for that parameter laid down in Annexes I and II.

(fb) For materials belonging to CMC 12, each batch or portion of production shall be assigned a unique code for quality management purposes. At least one sample per 3 000 tonnes of these materials or one sample per two months, whichever occurs soonest, shall be stored in good condition for a period of at least 2 years.”.

(f) In sub-point (g) (iii), “.” is replaced by “,” and the following sub-point (iv) is added:

“(iv) for materials belonging to CMC 12, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of that material.”.

(5) In point 5.1.4.1, the introductory wording is replaced by the following:

“5.1.4.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the quality records shall demonstrate effective control of input materials, production, storage and compliance of input and output materials with the relevant requirements of this Regulation. Each document shall be legible and available at its relevant place(s) of use, and any obsolete version shall be promptly removed from all places where it is used, or at least identified as obsolete. The quality management documentation shall contain at least the following information:”.

(6) In point 5.1.5.1, the introductory wording is replaced by the following:

“5.1.5.1. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the manufacturer shall establish an annual internal audit program in order to verify the compliance of the quality system, with the following components:”.

(7) Point 6.3.2 is replaced by the following:

“6.3.2. For materials belonging to CMCs 3, 5 and 12, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and those audits shall be carried out with the following frequency:

- (a) during the notified body's first year of surveillance of the plant in question: the same frequency as the sampling frequency indicated in the tables included in points 5.1.3.1(f) and, respectively, 5.1.3.1(fa); and
 - (b) during the following years of surveillance: half the sampling frequency indicated in the table included in point 5.1.3.1(f) and, respectively, 5.1.3.1(fa).”.
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COMMISSION DELEGATED REGULATION (EU) 2021/2087**of 6 July 2021****amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding thermal oxidation materials and derivatives as a component material category in EU fertilising products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 ⁽¹⁾, and in particular Article 42(1) thereof,

Whereas:

- (1) Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. EU fertilising products contain component materials of one or more of the categories listed in Annex II to that Regulation.
- (2) Article 42(2) of Regulation (EU) 2019/1009 read in conjunction with Article 42(1), first subparagraph, point (b) of that Regulation requires the Commission to assess ash-based products without undue delay after 15 July 2019, and to include it in Annex II to that Regulation if that assessment concludes that EU fertilising products containing that materials do not present a risk to human, animal or plant health, to safety or to the environment, and ensure agronomic efficiency.
- (3) Ash-based products can be waste, and can in accordance with Article 19 of Regulation (EU) 2019/1009 cease to be waste if it is contained in a compliant EU fertilising product. Pursuant to Article 42(3) of Regulation (EU) 2019/1009 read in conjunction with Article 6 of Directive 2008/98/EC of the European Parliament and of the Council ⁽²⁾, the Commission may therefore include ash-based products in Annex II to Regulation (EU) 2019/1009 only if recovery rules in that Annex ensure that the materials are to be used for specific purposes, that a market or demand exists for them, and that their use will not lead to overall adverse environmental or human health impacts.
- (4) The Commission's Joint Research Centre ("JRC") began its assessment of ash-based products in anticipation of the adoption of Regulation (EU) 2019/1009, and concluded it in 2019. Throughout the assessment, the scope was widened to include the broad spectrum of thermal oxidation materials, as well as their derivatives.
- (5) JRC's assessment report ⁽³⁾ concludes that thermal oxidation materials and derivatives, if produced following the recovery rules suggested in the report, provide plants with nutrients or improve their nutrition efficiency and therefore ensure agronomic efficiency.
- (6) JRC's assessment report furthermore concludes that there is an existing and growing market demand for thermal oxidation materials and derivatives, and that those materials are likely to be used to provide nutrient inputs to European agriculture. It further concludes that the use of thermal oxidation materials and derivatives produced following the recovery rules suggested in the report does not lead to overall adverse environmental or human health impacts.

⁽¹⁾ OJ L 170, 25.6.2019, p. 1.

⁽²⁾ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

⁽³⁾ Huygens D, Saveyn HGM, Tonini D, Eder P, Delgado Sancho L, Technical proposals for selected new fertilising materials under the Fertilising Products Regulation (Regulation (EU) 2019/1009) – Process and quality criteria, and assessment of environmental and market impacts for precipitated phosphate salts & derivatives, thermal oxidation materials & derivatives and pyrolysis & gasification materials, EUR 29841 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-09888-1, doi:10.2760/186684, JRC117856.

- (7) The recovery rules suggested in JRC's assessment report include measures to limit the risks of recycling or producing contaminants, such as creating an exhaustive list of eligible input materials and excluding, for example, mixed municipal waste, and laying down specific processing conditions and product quality requirements. That assessment report also concludes that fertilising products containing thermal oxidation materials and derivatives should follow specific labelling rules and that the conformity assessment rules applicable to such products should include a quality system assessed and approved by a notified body.
- (8) Based on the above, the Commission concludes that thermal oxidation materials and derivatives, if produced following the recovery rules suggested in JRC's assessment report, ensure agronomic efficiency within the meaning of Article 42(1), first subparagraph, point (b)(ii) of Regulation (EU) 2019/1009. Furthermore, they comply with the criteria laid down in Article 6 of Directive 2008/98/EC. Finally, if compliant with the other requirements laid down in Regulation (EU) 2019/1009 in general and in Annex I to that Regulation in particular, they would not present a risk to human, animal or plant health, to safety or to the environment within the meaning of Article 42(1), first subparagraph, point (b)(i) of Regulation (EU) 2019/1009. Therefore, thermal oxidation materials and derivatives should be included in Annex II to Regulation (EU) 2019/1009 subject to those recovery rules.
- (9) In particular, animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009 of the European Parliament and of the Council (*) should only be allowed as input materials for thermal oxidation materials and derivatives governed by Regulation (EU) 2019/1009, if and when their end points in the manufacturing chain have been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009 and will be reached at the latest by the end of the production process of the EU fertilising product containing the thermal oxidation materials or derivatives.
- (10) Furthermore, given the fact that thermal oxidation materials and derivatives can be considered to be recovered waste or by-products within the meaning of Directive 2008/98/EC, such materials should be excluded from the component material categories 1 and 11 of Annex II to Regulation (EU) 2019/1009 pursuant to Article 42(1), third subparagraph of that Regulation.
- (11) It is important to ensure that fertilising products containing thermal oxidation materials and derivatives will follow additional labelling rules and will be subject to a conformity assessment procedure including a quality system assessed and approved by a notified body. It is therefore necessary to amend Annex III and Annex IV to Regulation (EU) 2019/1009 to provide for labelling requirements and for a conformity assessment appropriate for such fertilising products.
- (12) Given that the requirements set out in Annexes II and III to Regulation (EU) 2019/1009 and the conformity assessment procedures set out in Annex IV to that Regulation are to apply as of 16 July 2022, it is necessary to defer the application of this Regulation to the same date,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/1009 is amended as follows:

- (1) Annex II is amended in accordance with Annex I to this Regulation;
- (2) Annex III is amended in accordance with Annex II to this Regulation;
- (3) Annex IV is amended in accordance with Annex III to this Regulation.

(*) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

Article 2

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

It shall apply from 16 July 2022.

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

Done at Brussels, 6 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex II to Regulation (EU) 2019/1009 is amended as follows:

(1) In Part I, the following point is added:

‘CMC 13: Thermal oxidation materials and derivatives’;

(2) Part II is amended as follows:

(a) In CMC 1, point 1, the following sub-point (j) is added:

‘(j) thermal oxidation materials or derivatives which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC, or’;

(b) In CMC 11, point 1, the following sub-point (f) is added:

‘(f) thermal oxidation materials or derivatives, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC, or’;

(c) The following CMC 13 is added:

‘CMC 13: THERMAL OXIDATION MATERIALS OR DERIVATES

1. An EU fertilising product may contain thermal oxidation materials obtained through thermochemical conversion under non-oxygen-limiting conditions exclusively from one or more of the following input materials:

(a) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except (*):

- materials originating from mixed municipal waste,
- sewage sludge, industrial sludge or dredging sludge, and
- animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(b) vegetable waste from the food processing industry and fibrous vegetable waste from virgin pulp production and from production of paper from virgin pulp, if not chemically modified;

(c) bio-waste fraction resulting from subsequent treatment operations of bio-waste separately collected for recycling within the meaning of Directive 2008/98/EC, for which incineration delivers the best environmental outcome in accordance with Article 4 of that Directive other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(d) materials resulting from a controlled microbial or thermochemical conversion process using exclusively the input materials referred to in sub-points (a), (b), and (c);

(e) sewage sludge from municipal wastewater treatment plants, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(f) materials from the independently operated treatment of waste water not covered by Council Directive 91/271/EEC (**) from food processing, pet food, feed, milk and drink industries, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(g) waste within the meaning of Directive 2008/98/EC with the exception (*) of:

- input materials referred to in sub-points (a) to (f),
- hazardous waste within the meaning of Article 3, point 2 of Directive 2008/98/EC,

- materials originating from mixed municipal waste,
 - bio-waste within the meaning of Article 3, point 4 of Directive 2008/98/EC resulting from separate bio-waste collection at source, and
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;
- (h) auxiliary fuels (natural gas, liquefied gas, natural gas condensate, process gases and components thereof, crude-oil, coal, coke as well as their derived materials), when used to process input materials referred to in sub-points (a) to (g);
- (i) substances which are used in production processes of the iron and steel industry; or
- (j) substances and mixtures, with the exception (*) of:
- input materials referred to in sub-points (a) to (i),
 - waste within the meaning of Article 3, point 1 of Directive 2008/98/EC,
 - substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,
 - substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances, and
 - animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.
2. Notwithstanding point 1, an EU fertilising product may contain thermal oxidation materials obtained through thermochemical conversion under non-oxygen-limiting conditions from Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:
- (a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009;
- (b) the conditions in points 3, 4, and 5 are met.
3. The thermal oxidation shall take place under non-oxygen limiting conditions in such a way that the gas resulting from the thermochemical conversion process is raised, after the last injection of combustion air, in a controlled and homogeneous fashion and even under the most unfavourable conditions to a temperature of at least 850 °C for at least 2 seconds. These conditions shall apply to all input materials, with the exemption of:
- (a) the input materials referred to in points 1(a), (b) and (h), or resulting from a controlled microbial or thermochemical conversion process using exclusively those materials, and
- (b) input materials referred to in point 2,
- for which a temperature of at least 450 °C for at least 0,2 seconds shall apply;
4. The thermal oxidation shall take place in an incineration or combustion chamber. The chamber may only process input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been contaminated with other material streams unintentionally in a one-off incident resulting only in trace levels of exogenous compounds.

All of the following conditions shall be met in the plant, where the thermal oxidation takes place:

- (a) the production lines for the processing of input materials referred to in points 1 and 2 shall be clearly separated from production lines for the processing of other input materials,

- (b) the input material shall be oxidised in such a way that the total organic carbon (C_{org}) content of the resulting slags and bottom ashes is less than 3 % by dry matter of the material,
 - (c) physical contact between input and output materials shall be avoided after the thermochemical conversion process, including during storage.
5. The thermal oxidation materials shall be ashes or slags, and have no more than:
- (a) 6 mg/kg dry matter of PAH₁₆ (**),
 - (b) 20 ng WHO toxicity equivalents (****) of PCDD/F (****)/kg dry matter.
6. An EU fertilising product may contain derivatives from thermal oxidation materials that have been produced from the input materials referred to in points 1 and 2 that meet the conditions of point 5 and that have been manufactured by a thermochemical conversion process in accordance with points 3 and 4.

The derivative manufacturing process shall be executed so as to intentionally modify the chemical composition of the thermal oxidation material.

The derivative manufacturing process shall be of the following nature:

- (a) chemical manufacturing: derivatives are produced through one or more chemical manufacturing steps that react thermal oxidation materials with input materials referred to in sub-point 1(j) that are consumed in or used for chemical processing whereas non-biodegradable polymers shall not be used;
- (b) thermochemical manufacturing: derivatives are produced through one or more manufacturing steps that thermochemically react thermal oxidation materials with reactants referred to in points 1 and 2 that are consumed in or used for chemical processing.

Thermal oxidation materials that display one or more of the hazardous properties listed in Annex III to Directive 2008/98/EC shall not be mixed or reacted, either with waste, substances or materials with the intention of reducing hazardous substances to levels below the limit values for the hazardous property as laid down in Annex III to that Directive. Using a mass balance approach, manufacturers that use thermal oxidation materials with hazardous properties must demonstrate the removal or transformation of the contaminants to levels below the limit values laid down in Annex III to Directive 2008/98/EC.

7. Contaminants in an EU fertilising product containing or consisting of thermal oxidation materials or derivatives must not exceed the following limit values:
- (a) total chromium (Cr): 400 mg/kg dry matter, if the thermal oxidation materials or derivatives are from input materials referred to in sub-points 1(e), (g) or (i);
 - (b) thallium (Tl): 2 mg/kg dry matter, if the thermal oxidation materials or derivatives are from input materials referred to in sub-points 1(e), (g), (h) or (i);

The chlorine (Cl) content shall not be higher than 30 g/kg of dry matter. However, this limit value shall not apply to EU fertilising products produced through a manufacturing process where a Cl⁻ containing compound has been added with the intention of producing alkali metal salts or alkaline earth metal salts, and is declared in accordance with Annex III;

The vanadium (V) content shall not be higher than 600 mg/kg dry matter if the thermal oxidation materials or derivatives are from input materials referred to in sub-points 1(g) or (i).

8. The thermal oxidation materials or derivatives shall have been registered pursuant to Regulation (EC) No 1907/2006, in a dossier containing:
- (a) the information provided for by Annexes VI, VII and VIII of Regulation (EC) No 1907/2006, and
 - (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8 or 9 of Annex V to that Regulation.

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- (*) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.
 - (**) Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40).
 - (***) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.
 - (****) van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. *Toxicological sciences: an official journal of the Society of Toxicology* 93:223-241. doi:10.1093/toxsci/kfl055.
 - (*****) Polychlorinated dibenzo-p-dioxins and dibenzofurans.'
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ANNEX II

In Annex III, Part I to Regulation (EU) 2019/1009, the following point is inserted:

- ‘7a. Where the EU fertilising product contains or consists of thermal oxidation materials or derivatives referred to in CMC 13 in Part II of Annex II and has a manganese (Mn) content above 3,5 % by mass, the manganese content shall be declared.’
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ANNEX III

In Annex IV, Part II of Regulation (EU) 2019/1009, Module D1 (Quality assurance of the production process) is amended as follows:

(1) Point 2.2 is amended as follows:

(a) sub-point (d) is replaced by the following:

‘(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product, and, in relation to materials belonging to CMCs 3, 5, 12 or 13 as defined in Annex II, a written description and a diagram of the production process, where each treatment, storage vessel and area is clearly identified;’

(b) the following sub-point (ga) is inserted:

‘(ga) hazardous waste calculations for EU fertilising products containing or consisting of CMC 13; the testing referred to in point 6 in CMC 13 in Part II of Annex II shall be carried out at least every year, or sooner than scheduled in case of any significant change that may affect the safety or quality of the EU fertilising product (for example processing of input material batches of different composition, modification of process conditions). For a representative input material batch that is processed at the plant, the hazardous property identified (in accordance with point 5.1.3.1) and the total mass shall be measured on the different input materials (1, ..., n) and on the output material that will be incorporated in the EU fertilising product. The incorporation rate of the hazardous property into the output material shall then be calculated as follows:

$$\text{incorporation rate (\%)} = \frac{HPC_{\text{output material}} \times M_{\text{output material}}}{\sum_{i=1}^n (HPC_{\text{input material},i} \times M_{\text{input material},i})}$$

Where:

HPC = the concentration of the hazardous property (mg/kg),

M = the total mass (kg), and

i(1-n) = the different input materials used in the production process.

The removal of the hazardous property during the production process shall be such that the incorporation rate multiplied by the concentration of the hazardous property of each individual input material is below the limit values laid down in Annex III to Directive 2008/98/EC for that hazardous property.’

(2) The introductory wording in point 5.1.1.1 is replaced by the following:

‘5.1.1.1. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, senior management of the manufacturer’s organisation shall.’

(3) Point 5.1.2.1 is replaced by the following:

‘5.1.2.1. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, the quality system shall ensure compliance with the requirements laid down in that Annex.’

(4) Point 5.1.3.1 is amended as follows:

(a) The introductory wording is replaced by the following:

‘5.1.3.1. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, the examinations and tests shall comprise the following elements:’

(b) Sub-points (b) and (c) are replaced by the following:

‘(b) Qualified staff shall carry out a visual inspection of each consignment of input materials and verify compatibility with the specifications of input materials in CMCs 3, 5, 12 and 13 laid down in Annex II.

- (c) The manufacturer shall refuse any consignment of any given input material where visual inspection raises any suspicion of any of the following:
 - (i) the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product;
 - (ii) incompatibility with the specifications of CMCs 3, 5, 12 and 13 in Annex II, in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.’;
 - (c) Sub-point (e) is replaced by the following:
 - ‘(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5, 12 and 13, as defined in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product’s compliance with the relevant requirements laid down in Annex I.’;
 - (d) In sub-point (fa), the introductory wording is replaced by the following:
 - ‘(fa) For materials belonging to CMCs 12 and 13, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in case of any significant change that may affect the quality of the EU fertilising product.’;
 - (e) Sub-point (fb) is replaced by the following:
 - ‘(fb) For materials belonging to CMCs 12 and 13, each batch or portion of production shall be assigned a unique code for quality management purposes; at least one sample per 3000 tonnes of these materials or one sample per two months, whichever occurs sooner, shall be stored in good condition for a period of at least two years.’;
 - (f) Sub-point (g)(iv) is replaced by the following:
 - ‘(iv) for materials belonging to CMCs 12 and 13, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of that material.’.
 - (5) In point 5.1.4.1, the introductory wording is replaced by the following:
 - ‘5.1.4.1. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, the quality records shall demonstrate effective control of input materials, production, storage and compliance of input and output materials with the relevant requirements of this Regulation. Each document shall be legible and available at its relevant place(s) of use, and any obsolete version shall be promptly removed from all places where it is used, or at least identified as obsolete. The quality management documentation shall at least contain the following information.’.
 - (6) In point 5.1.5.1, the introductory wording is replaced by the following:
 - ‘5.1.5.1. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, the manufacturer shall establish an annual internal audit program in order to verify the compliance of the quality system, with the following components.’.
 - (7) In point 6.3.2, the introductory wording is replaced by the following:
 - ‘6.3.2. For materials belonging to CMCs 3, 5, 12 and 13, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and those audits shall be carried out with the following frequency.’.
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COMMISSION DELEGATED REGULATION (EU) 2021/2088**of 7 July 2021****amending Annexes II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council for the purpose of adding pyrolysis and gasification materials as a component material category in EU fertilising products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 ⁽¹⁾, and in particular Article 42(1) thereof,

Whereas:

- (1) Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. EU fertilising products contain component materials of one or more of the categories listed in Annex II to that Regulation.
- (2) Article 42(2) of Regulation (EU) 2019/1009 read in conjunction with Article 42(1), first subparagraph, point (b) of that Regulation requires the Commission to assess biochar without undue delay after 15 July 2019, and to include it in Annex II to that Regulation if that assessment concludes that EU fertilising products containing that material do not present a risk to human, animal or plant health, to safety or to the environment, and ensure agronomic efficiency.
- (3) Biochar can be waste, and can in accordance with Article 19 of Regulation (EU) 2019/1009 cease to be waste if it is contained in a compliant EU fertilising product. Pursuant to Article 42(3) of Regulation (EU) 2019/1009 read in conjunction with Article 6 of Directive 2008/98/EC of the European Parliament and of the Council ⁽²⁾, the Commission may therefore include biochar in Annex II to Regulation (EU) 2019/1009 only if recovery rules in that Annex ensure that the material is to be used for specific purposes, that a market or demand exists for it, and that its use will not lead to overall adverse environmental or human health impacts.
- (4) The Commission's Joint Research Centre ('JRC') began its assessment of biochar in anticipation of the adoption of Regulation (EU) 2019/1009, and concluded it in 2019. Throughout the assessment, the scope was widened to include the broad spectrum of pyrolysis and gasification materials.
- (5) JRC's assessment report ⁽³⁾ concludes that pyrolysis and gasification materials, if produced following the recovery rules suggested in the report, provide plants with nutrients or improve their nutrition efficiency and therefore ensure agronomic efficiency.
- (6) JRC's assessment report furthermore concludes that there is an existing and growing market demand for pyrolysis and gasification materials, and that those materials are likely to be used to provide nutrient inputs to European agriculture. It further concludes that the use of pyrolysis and gasification materials produced following the recovery rules suggested in the assessment report does not lead to overall adverse environmental or human health impacts.

⁽¹⁾ OJ L 170, 25.6.2019, p. 1.

⁽²⁾ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

⁽³⁾ Huygens D, Saveyn HGM, Tonini D, Eder P, Delgado Sancho L, Technical proposals for selected new fertilising materials under the Fertilising Products Regulation (Regulation (EU) 2019/1009) – Process and quality criteria, and assessment of environmental and market impacts for precipitated phosphate salts & derivatives, thermal oxidation materials & derivatives and pyrolysis & gasification materials, EUR 29841 EN, Publications Office of the European Union, Luxembourg, 2019, ISBN 978-92-76-09888-1, doi:10.2760/186684, JRC117856.

- (7) The recovery rules suggested in the JRC's assessment report include measures to limit the risks of recycling or producing contaminants, such as creating an exhaustive list of eligible input materials and excluding, for example, mixed municipal waste, and laying down specific processing conditions and product quality requirements. That assessment report also concludes that the fertilising products containing pyrolysis and gasification materials should follow specific labelling rules and that the conformity assessment rules applicable to such products should include a quality system assessed and approved by a notified body.
- (8) Based on the above, the Commission concludes that pyrolysis and gasification materials, if produced following the recovery rules suggested in JRC's report, ensure agronomic efficiency within the meaning of Article 42(1), first subparagraph, point (b)(ii) of Regulation (EU) 2019/1009. Furthermore, they comply with the criteria laid down in Article 6 of Directive 2008/98/EC. Finally, if compliant with the other requirements laid down in Regulation (EU) 2019/1009 in general and in Annex I to that Regulation in particular, they would not present a risk to human, animal or plant health, to safety or to the environment, within the meaning of Article 42(1), first subparagraph, point (b)(i) of Regulation (EU) 2019/1009. Therefore, pyrolysis and gasification materials should be included in Annex II to Regulation (EU) 2019/1009 subject to those recovery rules.
- (9) In particular, animal by-products or derived products within the meaning of Regulation (EC) No 1069/2009 of the European Parliament and of the Council (*) should only be allowed as input materials for pyrolysis and gasification materials governed by Regulation (EU) 2019/1009, if and when their end points in the manufacturing chain have been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009 and will be reached at the latest by the end of the production process of the EU fertilising product containing the pyrolysis or gasification materials.
- (10) Furthermore, given the fact that pyrolysis and gasification materials can be considered to be recovered waste or by-products within the meaning of Directive 2008/98/EC, such materials should be excluded from component material categories 1 and 11 of Annex II to Regulation (EU) 2019/1009 pursuant to Article 42(1), third subparagraph of that Regulation.
- (11) It is important to ensure that fertilising products containing pyrolysis and gasification materials follow specific labelling rules and are subject to a conformity assessment procedure including a quality system assessed and approved by a notified body. It is therefore necessary to amend Annex III and Annex IV to Regulation (EU) 2019/1009 to provide for labelling requirements and for a conformity assessment appropriate for such fertilising products.
- (12) Given that the requirements set out in Annexes II and III to Regulation (EU) 2019/1009 and the conformity assessment procedures set out in Annex IV to that Regulation are to apply as of 16 July 2022, it is necessary to defer the application of this Regulation to the same date,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/1009 is amended as follows:

- (1) Annex II is amended in accordance with Annex I to this Regulation;
- (2) Annex III is amended in accordance with Annex II to this Regulation;
- (3) Annex IV is amended in accordance with Annex III to this Regulation.

(*) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

Article 2

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

It shall apply from 16 July 2022.

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

Done at Brussels, 7 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex II to Regulation (EU) 2019/1009 is amended as follows:

(1) In Part I, the following point is added:

‘CMC 14: Pyrolysis and gasification materials’;

(2) Part II is amended as follows:

(a) In CMC 1, point 1, the following sub-point (k) is added:

‘(k) pyrolysis and gasification materials, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.’;

(b) In CMC 11, point 1, the following sub-point (g) is added:

‘(g) pyrolysis and gasification materials, which are recovered from waste or are by-products within the meaning of Directive 2008/98/EC.’;

(c) The following CMC 14 is added:

‘CMC 14: PYROLYSIS AND GASIFICATION MATERIALS

1. An EU fertilising product may contain pyrolysis or gasification materials obtained through the thermochemical conversion under oxygen-limiting conditions of exclusively one or more of the following input materials:

(a) living or dead organisms or parts thereof, which are unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, extraction with water, by steam distillation or by heating solely to remove water, or which are extracted from air by any means, except (*):

- materials originating from mixed municipal waste,
- sewage sludge, industrial sludge or dredging sludge, and
- animal by-products or derived products within the scope of Regulation (EC) No 1069/2009;

(b) vegetable waste from the food processing industry and fibrous vegetable waste from virgin pulp production and from production of paper from virgin pulp, if not chemically modified;

(c) processing residues within the meaning of Article 2, point (t) of Directive 2009/28/EC from the production of bioethanol and biodiesel, derived from materials referred to in sub-points (a), (b) and (d);

(d) bio-waste within the meaning of Article 3, point 4 of Directive 2008/98/EC resulting from separate bio-waste collection at source, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009 or

(e) pyrolysis or gasification additives which are necessary to improve the process performance or the environmental performance of the pyrolysis or gasification process, provided that those additives are consumed in chemical processing or used for such processing and that total concentration of all additives do not exceed 25 % of the fresh matter of the total input material, with the exception (*) of:

- input materials referred to in sub-points (a) to (d),
- waste within the meaning of Article 3, point 1 of Directive 2008/98/EC,
- substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,
- substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,

- non-biodegradable polymers, and
- animal by-products or derived products within the scope of Regulation (EC) No 1069/2009.

An EU fertilising product may contain pyrolysis or gasification materials obtained through thermochemical conversion under oxygen-limiting conditions of any input material referred to in sub-points (a) to (e), or combination thereof, processed by manual, mechanical or gravitational means, by solid-liquid fractionation using biodegradable polymers, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, by composting or by anaerobic digestion.

2. The thermochemical conversion process shall take place under oxygen-limiting conditions in such a way that a temperature of at least 180 °C for at least two seconds is reached in the reactor.

The pyrolysis or gasification reactor may only process input materials, which are not contaminated with other material streams, or input materials, other than animal by-products or derived products within the scope of Regulation (EC) No 1069/2009, which have been contaminated with other material streams unintentionally in a one-off incident resulting only in trace levels of exogenous compounds.

In the plant where the pyrolysis or gasification takes place, physical contacts between input and output materials shall be avoided after the thermochemical process, including during storage.

3. The pyrolysis and gasification materials shall have a molar ratio of hydrogen (H) to organic carbon (H/C_{org}) of less than 0,7, with testing to be performed in the dry and ash-free fraction for materials that have an organic carbon (C_{org}) content of less than 50 %. They shall have no more than:

- (a) 6 mg/kg dry matter of PAH₁₆ (**),
- (b) 20 ng WHO toxicity equivalents (***) of PCDD/F (****)/kg dry matter,
- (c) 0,8 mg/kg dry matter of ndl-PCB (*****),

4. Notwithstanding point 1, an EU fertilising product may contain pyrolysis or gasification materials obtained through the thermochemical conversion under oxygen-limiting conditions of Category 2 or Category 3 materials or derived products thereof, in accordance with the conditions set out in Article 32(1) and (2) of Regulation (EC) No 1069/2009 and in the measures referred to in Article 32(3) of that Regulation, alone or mixed with input materials referred to in point 1, provided that both of the following conditions are fulfilled:

- (a) the end point in the manufacturing chain has been determined in accordance with Article 5(2), third subparagraph of Regulation (EC) No 1069/2009;
- (b) the conditions in points 2 and 3 are met.

5. In the plant where the pyrolysis or gasification takes place, the production lines for the processing of input materials referred to in points 1 and 4 shall be clearly separated from production lines for the processing of other input materials.

6. In an EU fertilising product containing or consisting of pyrolysis and gasification materials:

- (a) the chlorine (Cl) content shall not be higher than 30 g/kg dry matter and
- (b) the thallium (Tl) content shall not be higher than 2 mg/kg dry matter, in case more than 5 % of pyrolysis or gasification additives relative to the fresh weight of total input material have been applied.

7. The pyrolysis and gasification material shall have been registered pursuant to Regulation (EC) No 1907/2006, in a dossier containing:

- (a) the information provided for by Annex VI, VII and VIII of Regulation (EC) No 1907/2006, and
- (b) a chemical safety report pursuant to Article 14 of Regulation (EC) No 1907/2006 covering the use as a fertilising product,

unless explicitly covered by one of the registration obligation exemptions provided for by Annex IV to Regulation (EC) No 1907/2006 or by points 6, 7, 8 or 9 of Annex V to that Regulation.

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- (*) The exclusion of an input material from a sub-point does not prevent it from being an eligible input material by virtue of another sub-point.
 - (**) Sum of naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.
 - (***) van den Berg M., L.S. Birnbaum, M. Denison, M. De Vito, W. Farland, et al. (2006) The 2005 World Health Organization Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds. *Toxicological sciences: an official journal of the Society of Toxicology* 93:223-241. doi:10.1093/toxsci/kfl055.
 - (****) Polychlorinated dibenzo-p-dioxins and dibenzofurans.
 - (*****) Sum of congeners PCB 28, 52, 101, 138, 153, 180.'
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ANNEX II

In Annex III, Part I to Regulation (EU) 2019/1009, the following point is inserted:

‘7a. Where the EU fertilising product contains or consists of thermal oxidation materials and derivatives as referred to in CMC 13 in Part II in Annex II or pyrolysis or gasification materials as referred to in CMC 14 in Part II of that Annex and has a manganese (Mn) content above 3,5 % by mass, the manganese content shall be declared.’

ANNEX III

In Annex IV, Part II of Regulation (EU) 2019/1009, Module D1 (Quality assurance of the production process) is amended as follows:

(1) In point 2.2, sub-point (d) is replaced by the following:

‘(d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product, and, in relation to materials belonging to CMCs 3, 5, 12, 13 or 14 as defined in Annex II, a written description and a diagram of the production process, where each treatment, storage vessel and area is clearly identified;’

(2) In point 5.1.1.1, the introductory wording is replaced by the following:

‘5.1.1.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, senior management of the manufacturer’s organisation shall;’

(3) Point 5.1.2.1 is replaced by the following:

‘5.1.2.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the quality system shall ensure compliance with the requirements specified in that Annex.’

(4) Point 5.1.3.1 is amended as follows:

(a) The introductory wording is replaced by the following:

‘5.1.3.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the examinations and tests shall comprise the following elements;’

(b) Sub-points (b) and (c) are replaced by the following:

‘(b) Qualified staff shall carry out a visual inspection of each consignment of input materials and verify compatibility with the specifications of input materials in CMCs 3, 5, 12, 13 and 14 laid down in Annex II.

(c) The manufacturer shall refuse any consignment of any given input material where visual inspection raises any suspicion of any of the following:

- the presence of hazardous or damageable substances for the process or for the quality of the final EU fertilising product,
- incompatibility with the specifications of CMCs 3, 5, 12, 13 and 14 in Annex II, in particular by presence of plastics leading to exceedance of the limit value for macroscopic impurities.’

(c) Sub-point (e) is replaced by the following:

‘(e) Samples shall be taken on output materials, to verify that they comply with the specifications laid down in CMCs 3, 5, 12, 13 and 14, as defined in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product’s compliance with the relevant requirements laid down in Annex I.’

(d) In sub-point (fa), the introductory wording is replaced by the following:

‘(fa) For materials belonging to CMCs 12, 13 and 14, the output material samples shall be taken with at least the following default frequency, or sooner than scheduled in case of any significant change that may affect the quality of the EU fertilising product;’

(e) Sub-point (fb) is replaced by the following:

‘(fb) For materials belonging to CMCs 12, 13 and 14, each batch or portion of production shall be assigned a unique code for quality management purposes. At least one sample per 3 000 tonnes of these materials or one sample per two months, whichever occurs sooner, shall be stored in good condition for a period of at least two years.’

(f) Sub-point (g)(iv) is replaced by the following:

‘(iv) for materials belonging to CMCs 12, 13 and 14, measure retainer samples referred to in sub-point (fb) and take the necessary corrective actions to prevent possible further transport and use of that material.’

(5) In point 5.1.4.1, the introductory wording is replaced by the following:

‘5.1.4.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the quality records shall demonstrate effective control of input materials, production, storage and compliance of input and output materials with the relevant requirements of this Regulation. Each document shall be legible and available at its relevant place(s) of use, and any obsolete version shall be promptly removed from all places where it is used, or at least identified as obsolete. The quality management documentation shall at least contain the following information:’.

(6) In point 5.1.5.1, the introductory wording is replaced by the following:

‘5.1.5.1. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the manufacturer shall establish an annual internal audit program in order to verify the compliance of the quality system, with the following components:’;

(7) In point 6.3.2, the introductory wording is replaced by the following:

‘6.3.2. For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and those audits shall be carried out with the following frequency:’.

COMMISSION DELEGATED REGULATION (EU) 2021/2089**of 21 September 2021****amending Delegated Regulation (EU) 2019/2122 as regards certain categories of goods posing low risk, goods that form part of passengers' personal luggage and pet animals exempted from official controls at border control posts and amending that Delegated Regulation and Delegated Regulation (EU) 2019/2074 as regards references to certain repealed legislation****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 48 (b), (c), (d), (e), (f) and (h), Article 53(1)(d)(ii) and Article 77(1)(h) and (k) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 establishes rules on the performance of official controls by the competent authorities of the Member States on animals and goods entering the Union in order to verify the compliance with Union agri-food chain legislation.
- (2) Commission Delegated Regulation (EU) 2019/2122 ⁽²⁾ lays down rules for when and the conditions under which certain categories of animals and goods are exempted from official controls at border control posts and for when and the conditions under which specific control tasks may be performed by customs authorities or other public authorities, insofar as those tasks are not already falling under the responsibility of those authorities, on passengers' personal luggage.
- (3) Samples of products of animal origin and of composite products for product analysis and quality testing, including organoleptic analysis, that are used for testing and analysis by an operator in the Member State of destination pose a low risk to public health, as they do not enter the food chain. Therefore, the competent authority of the Member State of destination should be able to grant an authorisation to exempt those samples from official controls at border control posts.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2019/2122 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers' personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending Commission Regulation (EU) No 142/2011 (OJ L 321, 12.12.2019, p. 45).

- (4) In order to prevent risks to animal health, the competent authority of the Member State of destination should issue the authorisation for samples of products of animal origin and of composite products in accordance with the animal health requirements laid down in rules established in, or pursuant to, Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽³⁾ or by the Member States. The competent authority of the Member State of destination should specify in the authorisation the public health conditions for entry into the Union and for the use of the samples.
- (5) In order to prevent the placing on the market of samples of products of animal origin and of composite products for product analysis and quality testing, the competent authority should specify in the authorisation the obligations of operators to keep records of the use of the samples for product analysis and quality testing, and to dispose of the samples after use in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽⁴⁾.
- (6) To avoid any misuse of this exemption, the competent authority that authorises the entry of research or diagnostic samples and of samples of products of animal origin and of composite products for product analysis and quality testing should specify in the authorisation issued to operators the maximum amount of the samples.
- (7) The quantity of certain goods that form part of passengers' personal luggage, are intended for personal consumption or use and are exempted from official controls at border control posts, should be clarified.
- (8) In order to ensure coherence with the relevant lists of third countries in Regulation (EU) No 576/2013 of the European Parliament and of the Council ⁽⁵⁾ from where pet animals may be moved into a Member, the exemption for pet animals that enter the Union from third countries, not listed in Part 1 of Annex II to Commission Implementing Regulation (EU) No 577/2013 ⁽⁶⁾ should be corrected.
- (9) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (Withdrawal Agreement), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EU) 2017/625, as well as the Commission acts based on it, apply in the United Kingdom in respect of Northern Ireland. Consequently, the posters in Annex II to Delegated Regulation (EU) 2019/2122 and the leaflet in Annex III thereto concerning the introduction of products that form part of passengers' personal luggage, should be amended to include references to the United Kingdom in respect of Northern Ireland.

⁽³⁾ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law) (OJ L 84, 31.3.2016, p. 1).

⁽⁴⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

⁽⁵⁾ Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1).

⁽⁶⁾ Commission Implementing Regulation (EU) No 577/2013 of 28 June 2013 on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council (OJ L 178, 28.6.2013, p. 109).

- (10) Commission Decision 2007/275/EC ⁽⁷⁾ is repealed by Commission Implementing Regulation (EU) 2021/632 ⁽⁸⁾. In the interest of legal certainty, references to Commission Decision 2007/275/EC in Annex III to Delegated Regulation (EU) 2019/2122 should be replaced by references to Commission Delegated Regulation (EU) 2021/630 ⁽⁹⁾.
- (11) Delegated Regulation (EU) 2019/2122 should therefore be amended accordingly.
- (12) Commission Implementing Regulation (EU) 2019/2007 ⁽¹⁰⁾ is repealed by Implementing Regulation (EU) 2021/632. In the interest of legal certainty, the references to Implementing Regulation (EU) 2019/2007, and to Decision 2007/275/EC in Commission Delegated Regulation (EU) 2019/2074 ⁽¹¹⁾ should be replaced by references to Commission Implementing Regulation (EU) 2021/632.
- (13) Delegated Regulation (EU) 2019/2074 should be amended accordingly.
- (14) In Delegated Regulation (EU) 2019/2074, references to the same repealed legal acts as in Delegated Regulation (EU) 2019/2122 should be corrected. The rules in those Delegated Regulations are substantively linked and are intended to be applied in tandem. In the interests of simplicity and transparency, as well as to facilitate their application and to avoid a multiplication of rules, they should be laid down in a single act rather than in a number of separate acts with many cross-references and the risk of duplication. In conclusion, the amendment to Delegated Regulation (EU) 2019/2074 should be included into this Regulation together with the amendment to Delegated Regulation (EU) 2019/2122,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2019/2122 is amended as follows:

- (1) in Article 3(1), point (b) is replaced by the following:

‘(b) their entry into the Union is authorised in advance for that purpose by the competent authority of the Member State ^(*)of destination;

^(*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation, references to Member States include the United Kingdom in respect of Northern Ireland.’;

⁽⁷⁾ Commission Decision 2007/275/EC of 17 April 2007 concerning lists of composite products to be subject to controls at border control posts (OJ L 116, 4.5.2007, p. 9).

⁽⁸⁾ Commission Implementing Regulation (EU) 2021/632 of 13 April 2021 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Implementing Regulation (EU) 2019/2007 and Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 24).

⁽⁹⁾ Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC [C(2021)899] (OJ L 132, 19.4.2021, p. 17).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2019/2007 of 18 November 2019 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products and hay and straw subject to official controls at border control posts and amending Decision 2007/275/EC (OJ L 312, 3.12.2019, p. 1).

⁽¹¹⁾ Commission Delegated Regulation (EU) 2019/2074 of 23 September 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules on specific official controls on consignments of certain animals and goods originating from, and returning to the Union following a refusal of entry by a third country (OJ L 316, 6.12.2019, p. 6).

(2) Article 4 is amended as follows:

(a) the title is replaced by the following:

'Article 4

Research and diagnostic samples, and samples of products of animal origin and of composite products for product analysis and quality testing, including organoleptic analysis';

(b) the following paragraphs 3, 4 and 5 are added:

'3. The competent authority of the Member State of destination may exempt samples of products of animal origin and of composite products for product analysis and quality testing, including organoleptic analysis, from official controls at border control posts provided that:

- (a) the competent authority has issued to the operator responsible for the analysis or testing of the samples in advance of their entry into the Union an authorisation for their introduction into the Union in accordance with paragraph 4 and that authorisation is recorded in an official document delivered by that authority;
- (b) the samples are accompanied by the official document referred to in point (a) or by a copy thereof, the certificate or declaration referred to in paragraph 4(b), or where applicable, any document required under national rules referred to in paragraph 4(c), until the samples reach the operator responsible for the analysis or testing of the samples.

Where samples referred to in the first subparagraph enter the Union via a Member State other than the Member State of destination, the operator shall present such samples at a border control post.

4. The competent authority of the Member State of destination shall specify in the authorisation for the introduction into the Union of samples of products of animal origin and of composite products for product analysis and quality testing, including organoleptic analysis, the following:

- (a) the samples originate from third countries or regions of third countries listed in Commission Implementing Regulation (EU) 2021/404 (*);
- (b) the samples are accompanied by the relevant certificate or declaration drawn up in accordance with the models established in Commission Implementing Regulation (EU) 2020/2235 (**);

I that, depending on the commodity, the samples comply with the following:

- (i) relevant requirements laid down in Commission Delegated Regulation (EU) 2020/692 (***); or
 - (ii) national rules in accordance with Articles 230(2), 234(3) and 238(4) of Regulation (EU) 2016/429, where applicable;
- (d) the public health requirements for:
- entry into the Member State of destination, which may include labelling and packaging requirements for the samples; and
 - the analysis or testing of the samples by the operator;
- (e) the operator responsible for the analysis or testing of the samples, including a reference to the address of the operator's premises for which the samples are destined;
- (f) the competent authority responsible for official controls at the operator's premises for which the samples are destined; and
- (g) the obligations of the operator responsible for the analysis or testing not to mix the samples with food destined for placing on the market, to keep records on the use of the samples and to dispose of the samples after the product analysis or the quality testing in accordance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council (****).

5. The competent authority of the Member State of destination shall specify in the authorisations referred to in paragraphs 1(a) and paragraph 3, first subparagraph, point (a) the maximum amount of samples exempted from official controls at border control posts.

- (*) Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1).
- (**) Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).
- (***) Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).
- (****) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).;

(3) in Article 7, point (a) is replaced by the following:

‘(a) goods listed in Part 1 of Annex I provided that the quantity in each category does not exceed the weight limit of 2 kg;’;

(4) in Article 11, point (a)(ii) is replaced by the following:

‘(ii) meet the conditions laid down in Article 5(1) or Article 5(2) of Regulation (EU) No 576/2013 and are being moved from a territory or a third country other than those listed in Part 1 of Annex II to Implementing Regulation (EU) No 577/2013, provided that they undergo documentary and identity checks in accordance with Article 34 of Regulation (EU) No 576/2013, and where relevant, standard spot checks in accordance with Article 5(3) of that Regulation; or’;

(5) Annexes II and III are amended in accordance with the Annex to this Regulation.

Article 2

Delegated Regulation (EU) 2019/2074 is amended as follows:

(1) in Article 3, paragraph 1 is replaced by the following:

‘1. The competent authority at the border control post of arrival into the Union shall authorise the entry into the Union of the following consignments of products originating from and returning into the Union following a refusal of entry by a third country provided that they comply with the requirements set out in paragraph 2:

(a) products of animal origin listed in the Annex to Commission Implementing Regulation (EU) 2021/632 (*);

- (b) composite products listed in Chapters 15 to 22 of the Annex to Implementing Regulation (EU) 2021/632 that are subject to veterinary checks at border control posts of arrival into the Union in accordance with Article 3 of that Implementing Regulation.

(*) Commission Implementing Regulation (EU) 2021/632 of 13 April 2021 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Implementing Regulation (EU) 2019/2007 and Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 24).;

(2) in Article 3(2), point (a) is replaced by the following:

- (a) the original official certificate issued by the competent authority of the Member State (*) from which the goods originate and were dispatched to a third country ("Member State of origin"), or its electronic equivalent submitted in IMSOC, or an authenticated copy thereof;

(*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation, references to Member States include the United Kingdom in respect of Northern Ireland.'.

Article 3

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

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

Done at Brussels, 21 September 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes II and III to Delegated Regulation (EU) 2019/2122 are amended as follows:

(1) Annex II is replaced by the following:

'ANNEX II

Posters referred to in Article 8(1)

The posters can be found at:

https://ec.europa.eu/food/animals/animalproducts/personal_imports_en



The poster features the European Commission logo at the top center. The main text is split into two sections: a blue section with white text and a red section with white text. To the right of the text are three circular icons with red prohibition signs over them, depicting a sausage, a carton of milk with a wedge of cheese, and a sandwich. The bottom section is dark blue with white text and a QR code.

KEEP ANIMAL DISEASES OUT OF THE EUROPEAN UNION!

TRAVELLERS MUST SURRENDER THESE PRODUCTS FOR OFFICIAL CONTROLS

Products of animal origin may carry pathogens that cause infectious diseases in animals.

There are strict procedures and veterinary controls on the introduction of products of animal origin into the European Union*.

*If you travel between the Member States of the European Union, Andorra, Iceland, Liechtenstein, United Kingdom (Northern Ireland), Norway, San Marino or Switzerland, you may bring products of animal origin in your luggage. Arrivals from the Faroe Islands or from Greenland: not more than 10 kg in your luggage. Arrivals from parts of the United Kingdom other than Northern Ireland (England, Wales, Scotland) are subject to normal procedures and veterinary controls.

Further information: Annex III to Commission Delegated Regulation (EU) 2019/2122

Reg 2019/2122



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Further information: Annex III to Commission Delegated Regulation (EU) 2019/2122

Reg 2019/2122





Keep animal diseases out of the European Union!



**Travellers must surrender
these products for official controls***

**Products of animal origin may
carry pathogens that cause infectious diseases in animals**

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the introduction of products of animal origin into the European Union**

*If you travel between the Member States of the European Union, Andorra, Iceland, Liechtenstein, United Kingdom (Northern Ireland), Norway, San Marino or Switzerland, you may bring products of animal origin in your luggage. Arrivals from the Faroe Islands or from Greenland: not more than 10 kg in your luggage. Arrivals from parts of the United Kingdom other than Northern Ireland (England, Wales, Scotland) are subject to normal procedures and veterinary controls.

Further information: Annex III to Commission Delegated Regulation (EU) 2019/2122

Reg 2019/2122



Health and
Consumers



Diseases don't respect borders



**If you bring in meat or dairy products from outside the EU*,
you risk importing animal diseases.**

**If you do not declare such items, you may be fined or
face criminal prosecution.**

These products will be seized and destroyed on arrival.

*If you travel between the Member States of the European Union, Andorra, Iceland, Liechtenstein, United Kingdom (Northern Ireland), Norway, San Marino or Switzerland, you may bring products of animal origin in your luggage. Arrivals from the Faroe Islands or from Greenland: not more than 10 kg in your luggage. Arrivals from parts of the United Kingdom other than Northern Ireland (England, Wales, Scotland) are subject to normal procedures and veterinary controls.

Further information: Annex III to Commission Delegated Regulation (EU) 2019/2122

Reg 2019/2122



Health and
Consumers

(2) Annex III is amended as follows:

(a) the first paragraph is replaced by the following:

‘Due to the risk of introducing diseases into the European Union (EU) (*), there are strict procedures for the introduction of certain animal products into the EU. These procedures do not apply to the movements of animal products between the Member States of the EU, or for animal products coming in small quantities for personal consumption from Andorra, Iceland, Liechtenstein, Norway, San Marino and Switzerland.’;

(*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this Annex include the United Kingdom in respect of Northern Ireland.’;

(b) the third and fourth paragraphs are replaced by the following:

‘The following goods may be introduced into the EU as long as they comply with the conditions and weight limits indicated in points 1 to 5 below.’;

(c) in point 3, ‘Petfood required for health-related reasons’, the introductory phrase is replaced by the following:

‘You may only bring in or send to the EU personal consignments of petfood required for reasons related to the health of the pet accompanying the passenger provided that:’;

(d) point 7, ‘Exempted products’, is replaced by the following:

‘The following products are exempted from the rules set out in points 1 to 6 provided that they meet the requirements of Article 3(1) of Commission Delegated Regulation (EU) 2021/630 (**):

- confectionery (including sweets), chocolate and other food preparations containing cocoa;
- pasta, noodles and couscous;
- bread, cakes, biscuits, waffles and wafers, rusks, toasted bread and similar toasted products;
- olives stuffed with fish;
- extracts, essences and concentrates, of coffee, tea or maté and preparations with a basis of these products or with a basis of coffee, tea or maté thereof;
- roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof;
- soup stocks and flavourings packaged for the final consumer;
- food supplements packaged for the final consumer, containing processed animal products (including glucosamine, chondroitin or chitosan);
- liqueurs and cordials;

(**) Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 17).’

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2090
of 25 November 2021
concerning the denial of authorisation of titanium dioxide as a feed additive for all animal species
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Titanium dioxide was authorised without a time limit by Directive 70/524/EEC as a colourant additive (colouring agents authorised for colouring foodstuffs by Community rules) for cats and dogs. It was also authorised without a time limit for all animal species, with the exception of cats and dogs, for animal feedingstuffs under certain conditions. That product was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of titanium dioxide as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'sensory additives' and the functional group 'colourants: substances that add or restore colour in feedingstuffs'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') noted in its opinion of 5 May 2021 ⁽³⁾ that it could not conclude on the safety of titanium dioxide for the target species, consumers and environment, given the absence of specific data related to its use as a feed additive and considering that the genotoxicity of particles of titanium dioxide could not be ruled out, raising potential concerns on the safety of the additive for the target species (especially for long-living animals and reproductive animals), consumers and users. In the absence of studies with titanium dioxide, the Authority could not conclude on the assessment of the effects of the additive on eyes and skin. The Authority further noted that titanium dioxide is potentially carcinogenic to workers if inhaled and that, as the genotoxicity of particles of titanium dioxide cannot be ruled out, it should be considered as an additional potential concern to users handling the additive. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The Authority's opinion of 5 May 2021 shows, therefore, that it has not been established that titanium dioxide does not have an adverse effect on animal health, human health or the environment, when used as a feed additive in the functional group 'colourants: substances that add or restore colour in feedingstuffs'.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2021;19(6):6630.

- (6) The assessment of titanium dioxide thus shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied and accordingly, the authorisation of titanium dioxide as a feed additive belonging to the functional group 'colourants: substances that add or restore colour in feedingstuffs' should be denied.
- (7) Therefore, the feed additive titanium dioxide and feed containing it should be withdrawn from the market as soon as possible. However, a limited period should be allowed for the withdrawal from the market of the existing stocks of those products, in order to enable operators to comply properly with the withdrawal obligation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Denial of authorisation

The authorisation of titanium dioxide (E 171) as an additive in animal nutrition, in the additive category 'sensory additives' and in the functional group 'colourants: substances that add or restore colour in feedingstuffs', is denied.

Article 2

Withdrawal from the market

1. Existing stocks of the additive referred to in Article 1 and of premixtures containing it, shall be withdrawn from the market by 20 March 2022.
2. Feed materials and compound feed which have been produced with the additive or the premixtures referred to in paragraph 1 before 20 March 2022 shall be withdrawn from the market by 20 June 2022.

Article 3

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*.

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

Done at Brussels, 25 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2091**of 26 November 2021****on the reimbursement, in accordance with Article 26(5) of Regulation (EU) No 1306/2013 of the European Parliament and of the Council, of the appropriations carried over from financial year 2021**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ⁽¹⁾, and in particular Article 26(6) thereof,

After consulting the Committee on the Agricultural Funds,

Whereas:

- (1) In accordance with Article 12(2), first subparagraph, point (d), of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽²⁾, non-committed appropriations relating to the actions financed by the European Agricultural Guarantee Fund (EAGF) as referred to in Article 4(1) of Regulation (EU) No 1306/2013 may be carried over to the following financial year. Such carryover is limited to 2 % of the initial appropriations voted by the European Parliament and by the Council and to the amount of the adjustment of direct payments as referred to in Article 8 of Regulation (EU) No 1307/2013 of the European Parliament and of the Council ⁽³⁾ which was applied during the preceding financial year.
- (2) In accordance with Article 26(5) of Regulation (EU) No 1306/2013, by way of derogation from Article 12(2), third subparagraph, of Regulation (EU, Euratom) 2018/1046, Member States are to reimburse the carryover referred to in Article 12(2), first subparagraph, point (d), of Regulation (EU, Euratom) 2018/1046 to the final recipients who are subject to the adjustment rate in the financial year to which the appropriations are carried over. That reimbursement only applies to final beneficiaries in those Member States where financial discipline applied ⁽⁴⁾ in the preceding financial year.
- (3) When setting the amount of the carryover to be reimbursed, in accordance with Article 26(7) of Regulation (EU) No 1306/2013 the amounts of the reserve for crises in the agricultural sector referred to in Article 25 of that Regulation, not made available for crisis measures by the end of the financial year, are to be taken into account.
- (4) In accordance with Article 1(1) of Commission Implementing Regulation (EU) 2020/1801 ⁽⁵⁾, financial discipline is applied to direct payments in respect of calendar year 2020 to establish the crisis reserve and to respect the annual ceilings referred to in Article 16 of Regulation (EU) No 1306/2013. The crisis reserve has not been called on in financial year 2021. Moreover, on the basis of the execution of 2021 EAGF appropriations under shared management for the period from 16 October 2020 to 15 October 2021 and an estimated execution under direct management from 1 January 2021 to 31 December 2021, additional non-committed appropriations will remain in the 2021 EAGF budget.

⁽¹⁾ OJ L 347, 20.12.2013, p. 549.

⁽²⁾ 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).

⁽³⁾ Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

⁽⁴⁾ Financial discipline does not apply in financial year 2021 in Croatia in accordance with Article 8(2) of Regulation (EU) No 1307/2013.

⁽⁵⁾ Commission Implementing Regulation (EU) 2020/1801 of 30 November 2020 adapting the adjustment rate for direct payments pursuant to Regulation (EU) No 1306/2013 of the European Parliament and of the Council in respect of the calendar year 2020 (OJ L 402, 1.12.2020, p. 49).

- (5) On the basis of the Member States' declarations of expenditure for the period from 16 October 2020 to 15 October 2021, the financial discipline reduction effectively applied by the Member States in the financial year 2021 amounts to EUR 879,8 million.
- (6) Of this amount of financial discipline applied in financial year 2021, EUR 686,4 million of unused appropriations, which remains within the limit of 2 % of the initial appropriations relating to the actions referred to in Article 4(1) of Regulation (EU) No 1306/2013, can be carried over to financial year 2022 following a decision of the Commission in accordance with Article 12(3) of Regulation (EU, Euratom) 2018/1046.
- (7) In order to ensure that the reimbursement to the final recipients of unused appropriations as a result of the application of financial discipline remains proportionate to the amount of the financial discipline adjustment, it is appropriate that the Commission determines the amounts available to the Member States for the reimbursement.
- (8) To avoid compelling Member States to make an additional payment for that reimbursement, this Regulation needs to apply from 1 December 2021. Consequently, the amounts established by this Regulation are definitive and apply, without prejudice to the application of reductions in accordance with Article 41 of Regulation (EU) No 1306/2013, to any other corrections taken into account in the monthly payment decision concerning the expenditure effected by the paying agencies of the Member States for October 2021, in accordance with Article 18(3) of Regulation (EU) No 1306/2013 and to any deductions and supplementary payments to be made in accordance with Article 18(4) of that Regulation or to any decisions which will be taken within the framework of the clearance of accounts procedure.
- (9) In accordance with the introductory phrase of Article 12(2) of Regulation (EU, Euratom) 2018/1046, the non-committed appropriations may be carried over to the following financial year only. It is therefore appropriate for the Commission to determine eligibility dates for the expenditure of the Member States in relation to the reimbursement in accordance with Article 26(5) of Regulation (EU) No 1306/2013, taking into account the agricultural financial year as defined in Article 39 of that Regulation.
- (10) In order to take into account the short time span between the communication of the execution of 2021 EAGF appropriations under shared management for the period from 16 October 2020 to 15 October 2021 by the Member States and the need to apply this Regulation from 1 December 2021, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The amounts of the appropriations that will be carried over from financial year 2021 in accordance with Article 12(2), first subparagraph, point (d), and Article 12(2), third subparagraph, of Regulation (EU, Euratom) 2018/1046 and that in accordance with Article 26(5) of Regulation (EU) No 1306/2013 are made available to the Member States for the reimbursement to the final recipients who are subject to the adjustment rate in financial year 2022, are laid down in the Annex to this Regulation.

The amounts that will be carried over are subject to the carryover decision of the Commission in accordance with Article 12(3) of Regulation (EU, Euratom) 2018/1046.

Article 2

Member States' expenditure in relation to the reimbursement of the appropriations carried over shall only be eligible for Union financing if the relevant amounts have been paid to the beneficiaries before 16 October 2022.

Article 3

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

It shall apply from 1 December 2021.

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

Done at Brussels, 26 November 2021.

*For the Commission,
On behalf of the President,
Wolfgang BURTSCHER
Director-General
Directorate-General for Agriculture and Rural
Development*

ANNEX

Amounts available for reimbursement of appropriations carried over*(amounts in EUR)*

Belgium	10 148 502
Bulgaria	17 260 226
Czechia	18 592 308
Denmark	16 896 943
Germany	93 879 410
Estonia	3 367 730
Ireland	21 755 772
Greece	27 014 459
Spain	93 988 531
France	140 942 719
Italy	59 291 647
Cyprus	566 767
Latvia	5 308 382
Lithuania	8 354 220
Luxembourg	716 220
Hungary	24 904 327
Malta	60 357
Netherlands	13 043 131
Austria	11 588 177
Poland	43 034 502
Portugal	12 813 987
Romania	29 917 025
Slovenia	1 503 290
Slovakia	8 375 694
Finland	9 928 403
Sweden	13 184 745

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2092**of 29 November 2021****concerning the authorisation of potassium diformate as a feed additive for pigs for fattening and weaned piglets****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of potassium diformate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of potassium diformate as a feed additive for pigs for fattening and weaned piglets, to be classified in the category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 ⁽²⁾ that, under the proposed conditions of use, potassium diformate does not have adverse effects on animal health, consumer safety or the environment. It also concluded that the substance does not raise concerns regarding the effects on the respiratory system and the skin but is an eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the substance has the potential to be efficacious as a technological additive in feedingstuffs. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of potassium diformate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'acidity regulators', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(5):6617.

Article 2

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

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

Done at Brussels, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identifica- tion number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feedingstuff with a moisture content of 12 %			

Category of technological additives**Functional group: acidity regulators**

1j001	Potassium diformate	<i>Additive composition:</i> Potassium diformate ≥ 98 %	Pigs for fattening Weaned piglets	-	-	6 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. The maximum content of potassium diformate shall be 6 000 mg/kg of complete feedingstuff with a moisture content of 12 %, whether used alone as an acidity regulator or used in combination with other sources of potassium diformate. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes protection.	20 December 2031
		<i>Characterisation of the active substance:</i> Potassium diformate CAS No: 20642-05-1 Einecs No: 243-934-6 C ₂ H ₃ O ₄ K						
		<i>Analytical method ⁽¹⁾</i> For the determination of potassium diformate (as total formic acid) in the feed additive, premixture, feedingstuffs: — Ion chromatography with conductivity detection (IC-CD) – EN 17294; For the determination of potassium in the feed additive: — Atomic absorption spectrometry (AAS) – EN ISO 6869; or — Inductively coupled plasma-atomic emission spectrometry (ICP-AES) – EN15510.						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2093
of 29 November 2021
concerning the authorisation of disodium 5'-guanylate as a feed additive for all animal species
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of disodium 5'-guanylate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of disodium 5'-guanylate as a feed additive for all animal species, to be classified in the category 'sensory additives' and in the functional group 'flavouring compounds'.
- (4) The applicant requested disodium 5'-guanylate to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of disodium 5'-guanylate in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 ⁽²⁾ that, under the proposed conditions of use, disodium 5'-guanylate does not have adverse effects on animal health, human health or the environment.
- (6) The Authority further concluded, that disodium 5'-guanylate is efficacious to contribute to the flavour of feed. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of disodium 5'-guanylate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.
- (8) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (9) The fact that disodium 5'-guanylate is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed which is administered via water.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(6):6619.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg active substance/kg of complete feed with a moisture content of 12 %			

Category: Sensory additives**Functional group: Flavouring compounds**

2b627i	-	Disodium 5'-guanylate	<i>Additive composition</i> Disodium 5'-guanylate (GMP). Powder form <i>Characterisation of the active substance</i> Disodium 5'-guanylate (hydrated form) produced with <i>Corynebacterium stationis</i> KCCM 10530 and <i>Escherichia coli</i> K-12 KFCC 11067. Produced by fermentation Purity: min.: 97 % Chemical formula: $C_{10}H_{12}N_5Na_2O_8P$ CAS number: 5550-12-9 Einecs number: 226-914-1 <i>Analytical method</i> ⁽¹⁾ For the identification of disodium 5'-guanylate (GMP) in the feed additive: — FAO JECFA monograph 'disodium 5'-guanylate'	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a pre-mixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance when used alone or in combination with other ribonucleotides up to the same level per kg of complete feedingstuff with a moisture content of 12 %: 50 mg'. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level of active substance in complete feedingstuff referred to in point 3.	20 December 2031
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			For the determination of disodium 5'-guanylate (GMP) in the feed additive, flavouring premixtures and water: — High performance liquid chromatography coupled to UV detection (HPLC-UV)						
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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2094**of 29 November 2021****concerning the authorisation of decoquinate (Deccox and Avi-Deccox 60G) as a feed additive for chickens for fattening (holder of authorisation Zoetis Belgium SA) and repealing Regulation (EC) No 1289/2004****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Articles 9(2) and 13(3) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The use of decoquinate was authorised for 10 years in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 1289/2004 ⁽³⁾. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the substance decoquinate as a feed additive for chickens for fattening. The applicant requested that additive to be classified in the additive category ‘coccidiostats and histomonostats’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted for the modification of the composition of the additive decoquinate (Deccox) as a feed additive for chickens for fattening, in particular replacing vegetable components with minerals. The applicant requested to maintain both compositions of the additive on the market. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 29 November 2018 ⁽⁴⁾, 28 January 2021 ⁽⁵⁾ and 30 October 2014 ⁽⁶⁾ that, under the proposed conditions of use, the substance decoquinate does not have an adverse effect on animal health, human health or the environment and it is efficacious in preventing coccidiosis. It was also concluded that no withdrawal period is required to ensure consumer safety and no Maximum Residue Limits (MRL) are considered necessary. The Authority also concluded that the requested change of carriers and physical form in Avi-Deccox 60G with respect of Deccox do not affect its safety and its capacity to control coccidiosis. Therefore, both forms of the additive are considered equivalent in terms of controlling coccidiosis. The Authority concluded that a post-market monitoring plan to monitor the *Eimeria* spp. resistance should be undertaken. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Commission Regulation (EC) No 1289/2004 of 14 July 2004 concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats other medicinal substances (OJ L 243, 15.7.2004, p. 15).

⁽⁴⁾ EFSA Journal 2019;17(1):5541.

⁽⁵⁾ EFSA Journal 2021;19(3):6453.

⁽⁶⁾ EFSA Journal 2014;12(11):3905.

- (6) The assessment of the substance decoquinate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annexes to this Regulation.
- (7) For reasons of legal certainty, Regulation (EC) No 1289/2004 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance decoquinate specified in the Annexes, belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition, subject to the conditions laid down in those Annexes.

Article 2

Repeal

Regulation (EC) No 1289/2004 is repealed.

Article 3

Transitional measures

The substance specified in Annex I and feed containing that substance, which are produced and labelled before 20 June 2022 in accordance with the rules applicable before 20 December 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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*.

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

Done at Brussels, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Identification number of additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Additive category: coccidiostats and histomonostats									
51756i	Zoetis Belgium SA	Decoquinat (Deccox)	<i>Additive composition:</i> Decoquinat: 60,0 g/kg Soybean oil: 28,5 g/kg Colloidal silica: 0,6 g/kg Wheat middling: q.s. 1 kg <i>Characterisation of the active substance</i> Decoquinat C ₂₄ H ₃₅ NO ₅ Ethyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate CAS number: 18507-89-6 Related impurities: 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0,5 % Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1,0 % Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate (aniline compound) < 0,5 % <i>Analytical method</i> ⁽¹⁾ For the determination of decoquinat in feed additive, premixtures and feedingstuffs:	Chickens for fattening		30	40	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. The additive shall not be mixed with other coccidiostats. 4. Post-market monitoring programmes shall be carried out by the holder of authorisation for: resistance to bacteria and <i>Eimeria</i> spp. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks of their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and	20.12.2031

			Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) – EN 16162					measures, the additive and pre-mixtures shall be used with personal protective equipment.	
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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

ANNEX II

Identification number of additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Additive category: coccidiostats and histomonostats									
51756ii	Zoetis Belgium SA	Decoquinat (Avi-Deccox 60G)	<i>Additive composition</i> Decoquinat: 60,0 g/kg Colloidal silica: 0,6 g/kg Silicon dioxide: 4,0 g/kg Carboximethylcellulose sodium 30,0 g/kg Calcium sulphate dihydrate q.s. ad 1 000,0 g <i>Characterisation of the active substance</i> Decoquinat C ₂₄ H ₃₅ NO ₅ Ethyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate CAS number: 18507-89-6 Related impurities: 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0,5 % Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1,0 % Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate (aniline compound) < 0,5 % <i>Analytical method</i> ⁽¹⁾	Chickens for fattening		30	40	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. The additive shall not be mixed with other coccidiostats. 4. Post-market monitoring programmes shall be carried out by the holder of authorisation for: resistance to bacteria and <i>Eimeria</i> spp. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks of their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and	20.12.2031

			For the determination of decoquinat in feed additive, premixtures and feedingstuffs: — Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) – EN 16162					measures, the additive and pre-mixtures shall be used with personal protective equipment.	
⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports									

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2095**of 29 November 2021****concerning the authorisation of L-lysine base, L-lysine monohydrochloride and L-lysine sulphate as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of L-lysine base, L-lysine monohydrochloride and L-lysine sulphate. The applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The applications concern the authorisation of L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 as feed additives for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 March 2021 ⁽²⁾ ⁽³⁾ and 23 June 2021 ⁽⁴⁾ that, under the proposed conditions of use, L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 do not have an adverse effect on animal health, consumer safety or the environment. For L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227, the Authority concluded that that active substance is not toxic by inhalation, not irritant to skin or eyes, and not a skin sensitiser. With respect to the safety of the user of L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595, the Authority could neither exclude a risk by inhalation, nor that the active substance might be irritant to skin or eyes, or a dermal sensitiser. Further, the Authority stated L-lysine base produced by *Corynebacterium glutamicum* KCCM 80183 to be hazardous by inhalation and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183 to be hazardous by inhalation and mildly irritant to eyes. Therefore, the Commission considers that for the lysine forms produced by *Corynebacterium glutamicum* CCTCC M 2015595 and *Corynebacterium glutamicum* KCCM 80183, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that all additives are efficacious sources of the amino acid L-lysine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the additives should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(4):6520.

⁽³⁾ EFSA Journal 2021;19(4):6537.

⁽⁴⁾ EFSA Journal 2021;19(7):6706.

- (5) The assessments of L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 show that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substances and preparations specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg additive/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c320	-	L-lysine base, liquid	Additive composition: Preparation (aqueous solution) of L-lysine with a minimum of 50 % L-lysine. Characterisation of the active substance: L-lysine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80183 Chemical formula: NH ₂ -(CH ₂) ₄ -CH (NH ₂)-COOH CAS Number: 56-87-1 Analytical methods ⁽¹⁾: For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials:	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive can be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: ‘The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.’ 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	20.12.2031

			— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD), or — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS).						
3c322ii		L-lysine monohydrochloride, technically pure	Additive composition: Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %. Characterisation of the active substance: L-lysine monohydrochloride produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80183 or <i>Corynebacterium glutamicum</i> CCTCC M 2015595 Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 657-27-2	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive can be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced	20.12.2031

			Analytical methods ⁽¹⁾: For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph'. For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD), or — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS).					to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	
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3c325i	-	L-lysine sulphate	Additive composition: Granulated preparation of L-lysine sulphate with a minimum L-lysine content of 52 %, a maximum content of 24 % sulphate and a maximum content of 4 % moisture. Characterisation of the active substance: L-lysine sulphate produced by fermentation with <i>Corynebacterium glutamicum</i> CCTCCM 2015595 Chemical formula: C₁₂ H₂₈ N₄O₄•H₂SO₄/[NH₂-(C H₂)₄-CH (NH₂)-COOH]₂SO₄ CAS number: 60343-69-3 Analytical methods ⁽¹⁾: For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the identification of sulphate in the feed additive: — European Pharmacopoeia Monograph 20301. For the quantification of lysine in premixtures, compound feed and feed materials:	All species	-	-	10 000	1. The L-lysine content shall be indicated on the labelling of the additive. 2. The additive may be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum level by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	20.12.2031
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			— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD).						
3c324i	-	L-lysine sulphate	Additive composition: Granulated preparation of L-lysine sulphate with a minimum L-lysine content of 52 %, a maximum content of 24 % sulphate and a maximum content of 4 % moisture. Characterisation of the active substance: L-lysine sulphate produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80227 Chemical formula: $C_{12}H_{28}N_4O_4 \cdot H_2SO_4 / [NH_2-(CH_2)_4-CH(NH_2)-COOH]_2SO_4$ CAS number: 60343-69-3 Analytical methods ⁽¹⁾: For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine:	All species	-	-	10 000	1. The L-lysine content shall be indicated on the labelling of the additive. 2. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	20.12.2031

			— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the identification of sulphate in the feed additive: — European Pharmacopoeia Monograph 20301. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD).						
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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2096**of 29 November 2021****concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species (holder of the authorisation: Danisco (UK) Ltd, represented in the Union by Genencor International B.V.)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ⁽²⁾ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that that additive should be considered a respiratory sensitiser and a potential eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive has a potential to be efficacious as a zootechnical additive in sows during the lactation period. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(5):6539.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feed with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a11	Danisco (UK) Ltd, represented in the Union by Genencor International B.V.	Endo-1,4-beta-xylanase (EC 3.2.1.8)	Additive composition Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> CBS 143953 with a minimum activity of 40 000 U/g ⁽¹⁾ Characterisation of active substance Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> CBS 143953 Analytical method ⁽²⁾ For quantification of endo-1,4-beta-xylanase activity: colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrates	All poultry species	-	625 U	-	1. In the directions for use of the additive and pre-mixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and pre-mixtures shall be used with personal protective equipment, including eyes and breathing protection.	20.12.2031
			Pigs for fattening Piglets (weaned and suckling) All minor porcine species	2 000 U					

⁽¹⁾ 1 U is the amount of enzyme which releases 0,48 µmol of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH 4,2 and 50 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2097**of 29 November 2021****concerning the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of the authorisation Novus Europe NV)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for turkeys for fattening and turkeys reared for breeding, to be classified in the additive category 'zootechnical additives', functional group 'other zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ⁽²⁾ that, under the proposed conditions of use, the preparation of benzoic acid, calcium formate and fumaric acid does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that the additive presents a low inhalation risk for its users. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive has the potential to improve the performance of turkeys for fattening and this conclusion can be extended to turkeys reared for breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of benzoic acid, calcium formate and fumaric acid shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2021;19(4):6528.

Article 2

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

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

Done at Brussels, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feed with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improving zootechnical performance).									
4d14	Novus Europe NV	Preparation of benzoic acid, calcium formate and fumaric acid	Additive composition: Preparation of benzoic acid, calcium formate and fumaric acid having a minimum content of: benzoic acid: 42,5-50 %, calcium formate: 2,5-3,5 %, fumaric acid: 0,8-1,2 %; Granulated form	Turkeys for fattening Turkeys reared for breeding	-	500	1 000	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall not be used with other sources of benzoic acid or benzoates, calcium formate or formic acid and fumaric acid. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks concern-	20 December 2031
			Characterisation of the active substance: Benzoic acid (purity ≥ 99,0 %); CAS number: 65-85-0; Chemical formula C ₇ H ₆ O ₂ Calcium formate: CAS number 544-17-2; Chemical formula C ₂ H ₂ O ₄ Ca; Fumaric acid (purity ≥ 99,5 %): CAS number 110-17-8; Chemical formula C ₄ H ₄ O ₄ .						
			Analytical method ⁽¹⁾ For the determination of benzoic acid, calcium formate and fumaric acid in the feed additive: — high performance liquid chromatography with UV detection (HPLC-UV);						

			For the determination of total calcium in the feed additive: — atomic absorption spectrometry (AAS) – EN ISO 6869; or — inductively coupled plasma atomic emission spectrometry (ICP-AES) – EN 15510; For the determination of benzoic acid in premixtures and feedingstuffs: — high performance liquid chromatography with UV detection (HPLC-UV); For the determination of calcium formate and fumaric acid in premixtures: — ion-exclusion high performance liquid chromatography with UV or refractive index detection (HPLC-UV/RI).					ing their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	
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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

DECISIONS

COUNCIL DECISION (EU) 2021/2098

of 25 November 2021

further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430, in view of the travel difficulties caused by the COVID-19 pandemic in the Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 240(3) thereof,

Whereas:

- (1) Council Decision (EU) 2020/430 ⁽¹⁾ introduced a 1-month derogation from the first subparagraph of Article 12(1) of the Council's Rules of Procedure ⁽²⁾ as regards decisions to use the ordinary written procedure, where those decisions are taken by the Committee of the Permanent Representatives of the Governments of the Member States (Coreper). That derogation was foreseen to last until 23 April 2020.
- (2) Decision (EU) 2020/430 provides that, if justified by continued exceptional circumstances, the Council may renew that Decision. On 21 April 2020, the Council, by means of Decision (EU) 2020/556 ⁽³⁾, extended the derogation provided for in Article 1 of Decision (EU) 2020/430 for a further period of 1 month from 23 April 2020. That extension of the derogation was foreseen to last until 23 May 2020. On 20 May 2020, the Council, by means of Decision (EU) 2020/702 ⁽⁴⁾, extended the derogation provided for in Article 1 of Decision (EU) 2020/430 until 10 July 2020. On 3 July 2020, the Council, by means of Decision (EU) 2020/970 ⁽⁵⁾, extended that derogation until 10 September 2020. On 4 September 2020, the Council, by means of Decision (EU) 2020/1253 ⁽⁶⁾, extended that derogation until 10 November 2020. On 6 November 2020, the Council, by means of Decision (EU) 2020/1659 ⁽⁷⁾, extended that derogation until 15 January 2021. On 12 January 2021, the Council, by means of Decision (EU) 2021/26 ⁽⁸⁾, extended that derogation until 19 March 2021. On 12 March 2021, the Council, by

⁽¹⁾ Council Decision (EU) 2020/430 of 23 March 2020 on a temporary derogation from the Council's Rules of Procedure in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 88 I, 24.3.2020, p. 1).

⁽²⁾ Council Decision 2009/937/EU of 1 December 2009 adopting the Council's Rules of Procedure (OJ L 325, 11.12.2009, p. 35).

⁽³⁾ Council Decision (EU) 2020/556 of 21 April 2020 extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430 in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 128 I, 23.4.2020, p. 1).

⁽⁴⁾ Council Decision (EU) 2020/702 of 20 May 2020 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430 and extended by Decision (EU) 2020/556 in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 165, 27.5.2020, p. 38).

⁽⁵⁾ Council Decision (EU) 2020/970 of 3 July 2020 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430 and extended by Decisions (EU) 2020/556 and (EU) 2020/702, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 216, 7.7.2020, p. 1).

⁽⁶⁾ Council Decision (EU) 2020/1253 of 4 September 2020 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430 and extended by Decisions (EU) 2020/556, (EU) 2020/702 and (EU) 2020/970, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 294, 8.9.2020, p. 1).

⁽⁷⁾ Council Decision (EU) 2020/1659 of 6 November 2020 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430 and extended by Decisions (EU) 2020/556, (EU) 2020/702, (EU) 2020/970 and (EU) 2020/1253, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 376, 10.11.2020, p. 3).

⁽⁸⁾ Council Decision (EU) 2021/26 of 12 January 2021 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430 and extended by Decisions (EU) 2020/556, (EU) 2020/702, (EU) 2020/970, (EU) 2020/1253 and (EU) 2020/1659, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 11, 14.1.2021, p. 19).

means of Decision (EU) 2021/454 ⁽⁹⁾, extended that derogation until 21 May 2021. On 20 May 2021, the Council, by means of Decision (EU) 2021/825 ⁽¹⁰⁾, extended that derogation until 16 July 2021. On 12 July 2021, the Council, by means of Decision (EU) 2021/1142 ⁽¹¹⁾, extended that derogation until 30 September 2021. On 24 September 2021, the Council, by means of Decision (EU) 2021/1725 ⁽¹²⁾, extended that derogation until 30 November 2021.

- (3) Given that the exceptional circumstances caused by the COVID-19 pandemic continue, with a number of extraordinary preventive and containment measures taken by Member States still in place, it is necessary to extend the derogation provided for in Article 1 of Decision (EU) 2020/430, as extended by Decisions (EU) 2020/556, (EU) 2020/702, (EU) 2020/970, (EU) 2020/1253, (EU) 2020/1659, (EU) 2021/26, (EU) 2021/454, (EU) 2021/825, (EU) 2021/1142 and (EU) 2021/1725, for a further limited period until 28 February 2022,

HAS ADOPTED THIS DECISION:

Article 1

The derogation provided for in Article 1 of Decision (EU) 2020/430 is further extended until 28 February 2022.

Article 2

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

It shall be published in the *Official Journal of the European Union*.

Done at Brussels, 25 November 2021.

For the Council
The President
Z. POČIVALŠEK

⁽⁹⁾ Council Decision (EU) 2021/454 of 12 March 2021 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 89, 16.3.2021, p. 15).

⁽¹⁰⁾ Council Decision (EU) 2021/825 of 20 May 2021 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 183, 25.5.2021, p. 40).

⁽¹¹⁾ Council Decision (EU) 2021/1142 of 12 July 2021 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 247, 13.7.2021, p. 91).

⁽¹²⁾ Council Decision (EU) 2021/1725 of 24 September 2021 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 344, 29.9.2021, p. 5).

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2021/2082 of 26 November 2021 laying down the arrangements for the implementation of Regulation (EU) No 376/2014 of the European Parliament and of the Council as regards the common European risk classification scheme

(Official Journal of the European Union L 426 of 29 November 2021)

On page 37, section 1.2., point e., first indent:

- for:* ‘— Occurrence reports that have a RAT “ATM overall” severity score classification can be mapped directly to the ERCS probability columns as explained in step (g) of Figure 2,’
- read:* ‘— Occurrence reports that have a RAT “ATM overall” severity score classification can be mapped directly to the ERCS probability columns as explained in step (g) of Figure 1.’
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