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## COMMISSION DECISION

of 12.2.2021

**delegating powers to the European Health and Digital Executive Agency with a view to the performance of tasks linked to the implementation of Union programmes in the field of EU4Health, Single Market, Research and Innovation, Digital Europe, Connecting Europe Facility – Digital, comprising, in particular, implementation of appropriations entered in the general budget of the Union**

(Only the English text is authentic)

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**delegating powers to the European Health and Digital Executive Agency with a view to the performance of tasks linked to the implementation of Union programmes in the field of EU4Health, Single Market, Research and Innovation, Digital Europe, Connecting Europe Facility – Digital, comprising, in particular, implementation of appropriations entered in the general budget of the Union**

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THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes<sup>1</sup>, and in particular Article 6(3) thereof,

Having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012<sup>2</sup> and in particular Articles 60, 62(1) (a) and Article 69 thereof,

Whereas:

- (1) Taking account of the cost-benefit analysis for the delegation of the management of the 2021-2027 EU programmes to executive agencies, the European Health and Digital Executive Agency ('the Agency') is established until 31 December 2028 by the Commission Implementing Decision establishing the European Climate, Infrastructure and Environment Executive Agency, the European Health and Digital Executive Agency, the European Research Executive Agency, the European Innovation Council and SMEs Executive Agency, the European Research Council Executive Agency, and the European Education and Culture Executive Agency and repealing Implementing Decisions 2013/801/EU, 2013/771/EU, 2013/778/EU, 2013/779/EU, 2013/776/EU and 2013/770/EU. This Implementing Decision made the Agency responsible for implementing the following Union programmes or parts thereof:
  - (a) Digital Europe: parts of Specific Objective 2 (Artificial Intelligence), Specific Objective 4 (Advanced Digital Skills) and Specific Objective 5 (Deployment, best use of digital capacities and Interoperability);
  - (b) Connecting Europe Facility – the Digital part, with the exception of actions implemented by the Commission or delegated to other funding bodies;

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<sup>1</sup> OJ L 11, 16.1.2003, p. 1.

<sup>2</sup> OJ L 193, 30.7.2018, p. 1–222.

- (c) the legacy activities of Connecting Europe Facility – Telecom strand (2014-2020)<sup>3,4,5</sup>, with the exception of actions implemented directly by the Commission;
- (d) Horizon Europe: Pillar II, cluster 1: Health; cluster 4: Digital, industry and space, with the exception of actions implemented by the Commission or delegated to other funding bodies;
- (e) the legacy activities of the following parts of Horizon 2020 Specific Programme – The Framework Programme for Research and Innovation (2014-2020)<sup>6</sup>:
  - Part II “Industrial leadership”, specific objective “Leadership in enabling and industrial technologies (LEIT)” – ICT, NMBP, space;
  - Part III “Societal challenge” 1: (Health, demographic change and wellbeing) (with the exception of actions implemented by the Commission); “Societal challenge” 5: (Climate action, Environment, resource efficiency and raw materials).
- (f) the legacy activities of the “space” theme of the Cooperation Specific Programme of the Seventh Framework Programme<sup>7</sup>;
- (g) the Food Chain part of the Single Market Programme;
- (h) the legacy activities of the veterinary programmes and plant pest surveys<sup>8</sup>, the food safety training measures, the official controls, EURLs, AMR<sup>9</sup>;

<sup>3</sup> Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010 (OJ L 348, 20.12.2013, p. 129).

<sup>4</sup> Regulation (EU) No 283/2014 of the European Parliament and of the Council of 11 March 2014 on guidelines for trans-European telecommunications networks and repealing Decision No 1336/97/EC (OJ L 086 21.3.2014, p. 14).

<sup>5</sup> Regulation (EU) 1953/2017 of the European Parliament and of the Council of 25 October 2017 amending Regulations (EU) No 1316/2013 and (EU) No 283/2014 as regards the promotion of internet connectivity in local communities (OJ L 286, 1.11.2017, p. 1).

<sup>6</sup> Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104); Council Decision 2013/743/EU of 3 December 2013 establishing the specific programme implementing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC (OJ L 347, 20.12.2013, p. 965).

<sup>7</sup> Council Decision No 2006/971/EC of 19 December 2006 concerning the specific programme ‘Cooperation’ implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) (OJ L 400, 30.12.2006, p. 86).

<sup>8</sup> Regulation (EU) no 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).

<sup>9</sup> 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

- (i) EU4Health Programme;
  - (j) the legacy activities of the third Health programme<sup>10</sup>;
- (2) The Communication to the Commission on the Governance in the European Commission<sup>11</sup> provides further details on the position of the executive agencies in the overall governance of the European Commission and their relationship with it.
  - (3) This Decision should set out the manner in which the executive agencies are to perform the tasks delegated to them by the Commission and the checks to be carried out by the Commission departments responsible for the Union programmes in the management of which an executive agency is involved.
  - (4) Article 62(1)(a) of Regulation (EU, Euratom) 2018/1046 provides that the Commission may implement the general budget of the Union directly through executive agencies.
  - (5) Article 69 of Regulation (EU, Euratom) 2018/1046 provides that the Commission may delegate powers to the executive agencies to implement all or part of a Union programme or project, including pilot projects and preparatory actions and the implementation of administrative expenditure, on its behalf and under its responsibility, in accordance with Regulation (EC) No 58/2003. Pursuant to Article 6 of Regulation (EC) No 58/2003 those powers do not involve a large measure of discretion implying political choices. Those provisions define the executive agencies as legal persons established by a Commission Decision.
  - (6) Pursuant to Article 6(3) of Regulation (EC) No 58/2003, a specific instrument of delegation is to be adopted setting out the terms, criteria, parameters and procedures with which an executive agency must comply when performing the tasks entrusted to it.
  - (7) This Decision should set out in detail all the tasks entrusted to the Agency and the conditions under which the Agency is to exercise the delegated powers.
  - (8) This Decision should set out the Commission departments responsible for the programmes delegated to the Agency and for supervising the Agency, by naming the Directorates-General which are to be considered as parent Directorates-General of the Agency. To ensure coordination and dissemination of information and at the same time to avoid any overlap and to ensure the respect of sound financial management, one of the parent Directorates-General should be designated as a lead parent Directorate-General and assigned specific responsibilities in relation with the monitoring and supervision of horizontal issues in the Agency, such as internal control, human resources, or IT systems.
  - (9) This Decision should set out appropriate provisions for the clear separation of the tasks delegated to the Agency and the tasks under the responsibility of the

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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) (OJ L 95, 7.4.2017, p. 1).

<sup>10</sup> Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1).

<sup>11</sup> C(2020)4240 final.

Commission. It should also set out rules for the supervision of the Agency by the Commission and for the Agency's reporting obligations towards the Commission.

- (10) This Decision should lay down the minimum content requirements for the Memorandum of Understanding setting out the practical modalities of interaction between the Agency and the Commission.
- (11) Adequate planning of the activities and annual reporting should be provided in accordance with the provisions of Regulation (EC) No 58/2003 and Regulation (EU, Euratom) 2018/1046.
- (12) It is appropriate to lay down the administrative rules to be respected by the Agency in the area of security.
- (13) In order to ensure a consistent implementation in time of this Decision and of the programmes concerned, it is necessary to ensure that the Agency shall exercise its tasks linked to the implementation of those programmes subject to and from the date on which those programmes enter into force.
- (14) The conditions for the payment of the Union contribution to the operating budget of the Agency should be specified in this Decision.

HAS ADOPTED THIS DECISION:

## **SECTION 1 GENERAL PROVISIONS**

### *Article 1 Subject matter*

1. This Decision lays down in detail the tasks delegated to the European Health and Digital Executive Agency (the 'Agency') and provides the framework for their implementation and for the relations between the Commission and the Agency.
2. The Commission may at any time suspend or terminate the delegation laid down in this Decision for one or more of the programmes or parts thereof entrusted to the Agency.

### *Article 2 Parent Directorates-General*

1. The following Directorates-General shall be the parent Directorates-General of the Agency:
  - (a) Directorate-General for Communications Networks, Content and Technology;
  - (b) Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs;
  - (c) Directorate-General for Research and Innovation;
  - (d) Directorate-General for Defence Industry and Space;
  - (e) Directorate-General for Health and Food Safety;

In that capacity, they shall handle relations between the Commission and the Agency and shall be responsible for monitoring and supervising the Agency in accordance with Section 5.

2. The Directorate-General for Health and Food Safety shall be the lead parent Directorate-General and shall be assigned specific responsibilities in relation with the

monitoring and supervision of horizontal issues in the Agency, as specified in the Memorandum of Understanding referred to in Article 7.

*Article 3*  
*Reference documents*

1. In performing its tasks the Agency shall apply the provisions of the following acts:
  - Council Regulation (EC) No 58/2003;
  - Rules of Procedure of the Commission<sup>12</sup>;
  - the Implementing Decision establishing the Agency;
  - for implementation of its operating budget, Commission Regulation (EC) No 1653/2004<sup>13</sup>;
  - the annual Commission Decision on the Internal Rules on the implementation of the general budget of the European Union ( ‘the Internal Rules’);
  - Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council<sup>14</sup>;
  - the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-fraud Office (OLAF)<sup>15</sup>;
  - Council Regulation (Euratom, EC) No 2185/96<sup>16</sup>;
  - Directive (EU) 2019/1937 of the European Parliament and of the Council<sup>17</sup>;
  - Council Regulation (EU) 2017/1939<sup>18</sup>;
  - Council Regulation (EEC, Euratom, ECSC) No 259/68 (‘CEOS’)<sup>19</sup>;
  - Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>20</sup>;

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<sup>12</sup> C(2010) 1200, consolidated version of the Commission rules of procedure, amended by C(2011) 9000 and C(2020) 3000.

<sup>13</sup> Commission Regulation (EC) No 1653/2004 of 21 September 2004 on a standard financial regulation for the executive agencies pursuant to Council Regulation (EC) No 58/2003 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes (OJ L 297, 22.9.2004, p. 6).

<sup>14</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

<sup>15</sup> OJ L 136, 31.5.1999, p. 15.

<sup>16</sup> Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

<sup>17</sup> Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).

<sup>18</sup> Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office (‘the EPPO’) (OJ L 283, 31.10.2017, p. 1).

<sup>19</sup> Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1).

- Regulation (EC) No 1049/2001 of the European Parliament and of the Council<sup>21</sup>;
- Council Regulation (EEC, Euratom) No 354/83<sup>22</sup>;
- Regulation (EC) No 1221/2009 of the European Parliament and of the Council<sup>23</sup>.

2. In performing its tasks the Agency shall apply in particular the following acts *mutatis mutandis*:

- the basic acts establishing the programmes referred to in Article 4, the operational appropriations of which are to be managed in whole or in part by the Agency;
- Commission Decision C(2020)3759 amending Commission Decision C(2018) 5120 on the Internal rules on the implementation of the general budget of the European Union (European Commission section) as regards the model grant agreement for use as from 2021;
- the Commission decision on the coordinated implementation of Horizon Europe and on the operating rules for the Common Policy Centre and the Common Implementation Centre for Horizon Europe, the Framework Programme for Research and Innovation (2021-2027);
- Any other relevant rules of Horizon Europe;
- Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 3 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006;
- Commission Decision C(2013)8698 on model grant agreements for Horizon 2020 – the Framework Programme for Research and Innovation of the European Union (2014-2020) and the Research and Training Programme of the European Atomic Energy Community (2014-2018);
- Commission Decision C(2016)5455, of 29 August 2016, on the model contracts for experts for Horizon 2020 – The Framework Programme for Research and Innovation of the European Union (2014-2020), Research and Training Programme of the European Atomic Energy Community (2014-2018) and the Research Fund for Coal and Steel Programme;
- Any other relevant rules of Horizon 2020;

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<sup>20</sup> 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).

<sup>21</sup> 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).

<sup>22</sup> Council Regulation (EEC, Euratom) No 354/83 of 1 February 1983 concerning the opening to the public of the historical archives of the European Economic Community and the European Atomic Energy Community (OJ L 43, 15.2.1983, p. 1).

<sup>23</sup> Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC (OJ L 342, 22.12.2009, p. 1).

- Regulation (EC) No 1906/2006 of the European Parliament and Council of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013);
- Commission Decision C(2007)1509 of 10 April 2007 on the adoption of the model grant agreement in the context of the implementation of the Seventh Framework Programmes of the European Community (2007-2013) and the European Atomic Energy Community (2007-2011) as last amended by Commission Decision C(2012)9381;
- Commission Decision 2012/838/EU, Euratom of 18 December 2012 on the adoption of the rules to ensure consistent verification of the existence and legal status of participants, as well as their operational and financial capacities, in indirect actions supported through the form of a grant under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities and under the Seventh Framework Programme of the European Atomic Energy Community for nuclear research and training activities;
- Any other relevant rules of FP7;
- Commission decisions concerning the adoption of financing decisions within the meaning of Article 110 of Regulation (EU, Euratom) 2018/1046 which are to be managed in whole or in part by the Agency pursuant to the Implementing Decision establishing the Agency;
- Commission Decision (EU, Euratom) 2015/444<sup>24</sup>;
- Commission Decision (EU, Euratom) 2015/443<sup>25</sup>;
- Commission Decision (EU, Euratom) 2017/46<sup>26</sup>;
- Commission Decision (EU, Euratom) 2016/883<sup>27</sup>;
- Commission Decision C/2006/1623 of 26 April 2006 establishing a Harmonised Policy for Health and Safety at Work for all Commission staff;
- Commission Decision 2011/833/ EU<sup>28</sup>;
- the Code of Good Administrative Behaviour for Staff of the Commission in their relations with the public.

3. The Agency shall apply the applicable guidelines and instructions issued by the Commission, and in particular the following documents:

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<sup>24</sup> 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).

<sup>25</sup> Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

<sup>26</sup> Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission (OJ L 6, 11.1.2017, p. 40).

<sup>27</sup> Commission Decision (EU, Euratom) 2016/883 of 31 May 2016 on implementing rules for standard security measures, alert states and management of crisis situations in the Commission pursuant to Article 21 of Decision (EU, Euratom) 2015/443 on security in the Commission (OJ L 146, 3.6.2016, p. 25).

<sup>28</sup> Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents (OJ L 330, 14.12.2011, p. 39).



- Commission Guidelines for the establishment and operation of executive agencies;
- Annual Commission instructions for the Annual Activity Reports and Annual Work Programmes and related guidance material;
- Communication to the Commission on Data, Information and Knowledge Management at the European Commission (C(2016)6626 final);
- Communication to the Commission on the Revision of the Internal Control Framework (C(2017)2373 final);
- Communication to the Commission "Towards an effective and coherent risk management in the commission services" (SEC(2005)1327);
- Commission Communication on Organisation Charts of Commission DGs and Services (SEC(2006)1702/4);
- Communication to the Commission on Framework for business continuity management in the Commission (SEC(2006)898 final);
- Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Strengthening whistleblower protection at EU level (COM(2018)214 final);
- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions and the Court of Auditors on Commission Anti-Fraud Strategy: enhanced action to protect the EU budget (COM(2019)196 final);
- Rules on legal entity validation, the appointment of Legal Entity Authorised Representatives (LEAR) and financial capacity assessment;
- Rules for proposal submission and evaluation and for selection and contracting of independent experts for proposal evaluation and project monitoring;
- Any relevant guidance (including the Vademecum, instructions and manuals) established by the Commission for the implementation of Horizon Europe, Horizon 2020 and FP7.

## **SECTION 2**

### **DELEGATED TASKS**

#### *Article 4*

#### *Tasks delegated to the Agency*

1. The Agency shall implement the following parts of programmes and tasks:
  - for the Digital Europe programme, the parts and tasks set out in Annex I;
  - for the Connecting Europe Facility, the parts and tasks set out in Annex II;
  - for Horizon Europe – the Framework Programme for Research and Innovation (2021-2027), the parts and tasks set out in Annex III;
  - for the programme for single market, competitiveness of enterprises, including small and medium-sized enterprises, and European statistics and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014, (EU)

- No 258/2014, (EU) No 652/2014 and (EU) 2017/826 (SMP programme), the parts and tasks set out in Annex IV;
- for the EU4Health programme, the parts and tasks set out in Annex V;
  - for the legacy of Connecting Europe Facility (2014-2020), the parts and tasks set out in Annex VI;
  - for the legacy of Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020), the parts and tasks set out in Annex VII;
  - for the legacy of the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013), the parts and tasks set out in Annex VIII;
  - for the legacy activities of the food safety training measures covered by Regulation (EU) 2017/625, the veterinary programmes and plant pest surveys covered by the Regulation (EU) No 652/2014, Official controls, EURLs, AMR covered by Regulation (EU) 2017/625, the parts and tasks set out in Annex IX;
  - for the legacy of the third Health programme (2014-2020), the parts and tasks set out in Annex X;

This paragraph shall apply subject to and as from the date of entry into force of each of these programmes.

2. In relation with the tasks set out in Annexes I-X, the Agency may be entrusted with the management of projects funded from other Union programmes or from parts thereof or from funds under shared management, to be implemented together with funding already entrusted to the Agency, where such additional funding is provided for in the respective basic act of the Union programmes, and as set out in the work programme or programmes adopted by the Commission. In the same manner, the Agency may be entrusted with the management of projects funded from other parts of Horizon Europe, the Single Market Programme, the Digital Europe programme, the Connecting Europe Facility, and with the Neighbourhood, Development and International Cooperation Instrument than the ones listed in paragraph 1.

This additional funding is subject to all the following conditions:

- (a) the Agency is not entrusted with tasks that imply political choices;
  - (b) the Agency has been designated as the implementing body within the framework of the relevant work programme;
  - (c) the Director of the Agency agrees with the implementation of additional funding;
  - (d) the Director of the Agency has been granted the necessary powers, as authorising officer by delegation, for the corresponding appropriations.
3. To provide feedback to the Commission to serve as input for monitoring, reviewing and rectifying existing policy measures or shaping new policy initiatives and decisions, the Agency shall identify and report on the relevant knowledge acquired from the management of the programmes and their results. The specific arrangements and content of that feedback to policy activities shall be set out in the Memorandum of Understanding.
  4. The Agency is hereby entrusted with the administrative and logistical support services for Digital Europe programme set out in Annex XII.

5. The Agency may be entrusted with the management of certain tasks related to pilot projects and preparatory actions within the meaning of Article 58(2) of Regulation (EU, Euratom) 2018/1046, as set out in the financing decision adopted by the Commission, subject to all the following conditions:
  - (a) the Agency is entrusted only with those stages of the preparation and implementation of pilot projects and preparatory actions which do not imply political choices;
  - (b) the Agency has been designated as the implementing body within the framework of the relevant financing decision;
  - (c) the Director of the Agency agrees with the additional delegation of tasks without any additional resources;
  - (d) the Director of the Agency has been granted the necessary powers, as authorising officer by delegation, for the corresponding appropriations.
6. The Agency shall act in its own name when implementing the delegated tasks.
7. For the purposes of paragraph 1, 2 and 5, the Agency shall be responsible for implementing the corresponding operational appropriations entered in the general budget of the Union, and appropriations coming from third country contributions to the programme. The budget lines concerned for the year 2021 are provisionally set out in Annex XI and should be confirmed through the Internal Rules of the Commission on the implementation of the general budget of the European Union. For subsequent years they shall be identified annually in the Internal Rules of the Commission on the implementation of the general budget of the European Union.
8. The Director of the Agency shall exercise the delegated tasks by implementing the corresponding operational appropriations under direct management as authorising officer by delegation.
9. Where legacy activities are transferred to the Agency from another executive agency or from the Commission pursuant to Article 7(2) of the Implementing Decision establishing the Agency, all files and legal commitments shall be automatically transferred to the Agency and the latter shall be subrogated ex lege in all the rights and obligations.

#### *Article 5*

##### *Tasks reserved to the Commission*

1. The Agency shall perform only the delegated tasks.
2. The Agency shall not perform any tasks involving a large measure of discretion implying political choices. In particular it shall not:
  - (a) define objectives, strategies and policy priority areas of action;
  - (b) adopt work programmes, including work programmes constituting financing decisions within the meaning of Article 110 of Regulation (EU, Euratom) 2018/1046;
  - (c) represent the Commission in the Committee for Executive Agencies or in any other committee where implementation of a Union programme or action requires, pursuant to its legal basis, the control by Member States of the

Commission's exercise of implementing powers in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>29</sup>;

- (d) adopt award decisions or part thereof submitted to the control by Member States of the Commission's exercise of implementing powers in accordance with Regulation (EU) No 182/2011;
- (e) launch interservice consultations within the Commission;
- (f) take enforceable recovery decisions within the meaning of Article 299 of the Treaty and Article 100(2) of Regulation (EU, Euratom) 2018/1046.

### **SECTION 3**

#### **CONDITIONS FOR THE PERFORMANCE OF TASKS**

#### *Article 6*

##### *General conditions*

1. The Agency shall perform the delegated tasks in accordance with the principle of sound financial management within the meaning of Article 33 of Regulation (EU, Euratom) 2018/1046.
2. In the performance of its tasks, the Agency shall apply the instructions set out in the operational manuals approved by the Commission and shall use the guidance or model documents with any adjustments to its specific needs as agreed by the parent Directorates-General.
3. In the performance of its tasks, the Agency shall follow harmonised interpretations of the rules governing the implementation of the programmes, notably by the parent Directorates-General and notably by the Common Implementation Centre for Horizon Europe and Horizon 2020, and by horizontal services, such as the Secretariat-General, DG Budget and the Legal Service.
4. In case of litigation, the Agency shall, where appropriate, ensure coordination with the parent Directorates-General and the Legal Service.

#### *Article 7*

##### *Memorandum of Understanding*

1. The modalities and procedures of interaction between the Agency and the parent Directorates-General in implementing the delegated tasks shall be set out in a Memorandum of Understanding between the Agency and the parent Directorates-General.
2. The Memorandum of Understanding shall:
  - a) set out the administrative, operational and financial modalities and procedures of cost-effective interaction and cooperation between the Agency, the Commission and other bodies entrusted with programme implementation to ensure that no tasks are duplicated between the Commission services and the Agency;
  - b) set-out appropriate cost-effective supervision mechanisms.

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<sup>29</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

3. The Memorandum of Understanding shall set out in detail the supervision responsibilities and tasks of each parent Directorate-General, including the specific ones assigned to the lead parent Directorate-General referred to in Article 2(2).
4. The interaction and cooperation modalities, procedures and supervision mechanisms set out in the Memorandum of Understanding shall be updated regularly to take into account the new developments, including any extension of the mandate of the Agency. The Memorandum of Understanding may be supplemented, where justified by the specific nature of certain tasks, by individual memoranda signed between the Agency and each parent Directorate-General.

#### *Article 8*

##### *Corporate tools and common services*

1. Where appropriate, the Commission shall make available to the Agency common IT tools, for its operational and administrative management, in order to integrate the Agency as much as possible within the IT environment of the Commission. That may be done on the basis of service level agreements where appropriate.
2. For the performance of the tasks referred to in Article 4, paragraphs 1, 2 and 5, the Agency shall where applicable respect the Commission Decision on the coordinated implementation of Horizon Europe and on the operating rules for the Common Policy Centre and the Common Implementation Centre for Horizon Europe, the Framework Programme for Research and Innovation (2021-2027) and rely on common support services set out in that Decision (such as the Common Policy Centre and the Common Implementation Centre). This is without prejudice to the role of the Legal Service and DG Budget, which are in charge to ensure consistency on legal and financial questions of horizontal nature.
3. For the implementation of the tasks referred to in Article 4(1) and (2) and Annexes I, II and VI, the Agency shall make use of the common support services and tools developed in the context of Connecting Europe Facility programme (2014-2020), notably IT tools to be made available by the Commission and the European Climate, Infrastructure and Environment Executive Agency.

#### *Article 9*

##### *Use of logistical and administrative support services*

For the implementation of the delegated tasks, the Agency shall make use of the following common support services to be provided by the European Research Executive Agency:

- (a) For all programmes, validation of legal entities and preparation of legal entities financial capacity assessment (SEDIA);
- (b) For programmes using eGrants, planning for calls for proposals and contests and support for publication of calls and contests for prizes;
- (c) For Horizon Europe, Horizon 2020 and FP7, the use of the COVE evaluation facility and support services; the legal and financial validation of experts and the contracting and payment of experts involved in the proposal evaluation process.

*Article 10*  
*Annual Work Programme*

1. The Agency shall draw up the Annual Work Programme taking into account the Commission instructions for the Annual Work Programmes referred to in Article 3.
2. The Agency shall submit the Annual Work Programme to the Commission for approval before adoption by the Steering Committee.

*Article 11*  
*Management and internal control systems*

1. The management and internal control systems put in place by the Director of the Agency in accordance with Article 11(7) of Regulation (EC) No 58/2003 shall cover the implementation of both the operational appropriations charged to the general budget of the Union and the operating appropriations in the Agency's budget.
2. The Agency shall set up the internal control systems based on the Communication to the Commission on the Revision of the Internal Control Framework<sup>30</sup>.
3. For the implementation of the operational appropriations, the Charter of tasks and responsibilities of authorising officers by delegation, adopted by the Commission, shall be binding on the Agency. The Charter of tasks and responsibilities of authorising officers by delegation shall be signed by the Director of the Agency, who shall assume responsibility in connection with that function. The authorising officers by sub-delegation shall sign the Charter of tasks and responsibilities of authorising officers by sub-delegation and shall assume responsibility in connection with that function.
4. In accordance with the Framework for Business Continuity Management in the Commission<sup>31</sup>, the Agency shall develop a business continuity plan that addresses the initial reaction to the crisis, the response phase and the recovery process. The Agency shall develop a common business continuity plan with the Directorates-General and services in the same business area.

*Article 12*  
*Early-detection and exclusion system*

The provisions on the early-detection and exclusion system referred to in Title V, Chapter 1, Section 2 of Regulation (EU, Euratom) 2018/1046 shall apply to the Agency. In particular, in connection with public procurement, grants and prizes, and the selection of experts, whether linked to the operational appropriations managed by the Agency or the implementation of its operating budget, the Agency shall have access to the early-detection and exclusion system of the Commission and shall request introduction of the relevant information into that system in accordance with the relevant provisions of Regulation (EU, Euratom) 2018/1046.

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<sup>30</sup> C(2017)2373 final.

<sup>31</sup> SEC(2006)899.

*Article 13*  
*Visibility of Union action*

1. In order to ensure the visibility of Union action in the acts it adopts, the Agency shall always specify in its contracts, grant agreements, prizes, documents and relations with third parties that it is acting under powers delegated to it by the Commission.
2. The Agency shall comply with the guidelines of the Commission concerning the information and visibility of programmes and actions, in particular concerning the use of the graphical images defined by the Commission without prejudice to the use of the logo of the Agency.

*Article 14*  
*Access to documents*

1. The Steering Committee shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001.
2. In accordance with Article 23 of Regulation 58/2003 read in conjunction with Article 8 (1) of Regulation (EC) No 1049/2001, complaints may be made to the European Ombudsman or proceedings may be instituted before the Court of Justice as laid down in Articles 228 and 263 of the Treaty in respect of decisions processing confirmatory applications.

*Article 15*  
*Confidentiality*

1. The Agency shall preserve the confidentiality of information supplied to it by the Commission, in accordance with the Commission's instructions, and it shall not disclose any information which could harm the Commission, other institutions of the Union or third parties.
2. The confidentiality obligation provided for in paragraph 1 of this Article shall be without prejudice to Article 14 of this Decision.
3. The confidentiality obligation provided for in paragraph 1 shall apply to the members and observers of the Steering Committee, all Agency staff, whatever their status, and to any outside service providers used by the Agency, even after the termination of their duties. An appropriate confidentiality clause shall be included in contractual documents governing their relations with the Agency.

*Article 16*  
*Security of information and information systems*

1. The Agency shall apply the relevant Commission legal framework regarding security of persons, assets and information, as laid down in the relevant Commission decisions and their implementing rules.
2. In accordance with Article 15, the Agency shall apply the basic principles, minimum standards and procedures:
  - (a) for protecting European Union classified information ('EUCI') as laid down in the Commission's security rules for protecting EUCI;
  - (b) for protecting sensitive non-classified information as laid down in the Commission's security rules;

- (c) regarding security of information systems, as set out in Commission Decision (EU, Euratom) 2017/46.
3. EUCI may be handled by the Agency only once an assessment visit conducted by the Directorate-General for Human Resources and Security has allowed it to determine that the Agency affords a level of protection for EUCI that is at least equivalent to that in the Commission.
- Thereafter, the Agency may share EUCI with the relevant parent Directorate-General of the Commission once it has concluded an administrative arrangement on sharing and protecting EUCI with that Directorate-General.
- Where the Agency needs to share EUCI with Directorates-General in the Commission other than its parent Directorates-General, an administrative arrangement shall be concluded between the Agency and the Directorate-General for Human Resources and Security acting on behalf of all Commission Directorates-General.
- Without prejudice to the Agency's tasks in industrial security, the Agency may not exchange classified information with any other partner without the prior approval of the Directorate-General for Human Resources and Security.
4. Where appropriate, the Agency shall conclude practical arrangements for the implementation of this Article or service-level agreements for providing services under paragraphs 1, 2 and 3 with the Directorate-General for Human Resources and Security.
5. The parent Directorate-General shall be considered the originator of EUCI created and handled in the context of the implementation of the delegated tasks.
6. EUCI handled by the Research Executive Agency shall be transferred following the determination referred to under the first subparagraph of paragraph 3. Until then, appropriately security-authorized personnel of the Agency shall have access to the EUCI regarding the parts of the programme and tasks delegated to the Agency stored in the Research Executive Agency.

*Article 17*  
*Conflict of interests*

The Agency shall take all appropriate precautions to prevent any risk of conflict of interests within the meaning of Article 61(3) of Regulation (EU, Euratom) 2018/1046. The Agency shall without delay inform the parent Directorates-General of any situation which may constitute a conflict of interest or may give rise to one, including those relating to persons who may be involved in the processing and award of contracts, grants and prizes. The Agency shall adopt measures for the prevention and management of conflicts of interests in respect of its staff.

*Article 18*  
*Duty of information*

1. The Agency shall immediately inform the Directors-General of the parent Directorates-General, providing them with all relevant details, of any event which may:
- (a) harm the Agency, the Commission or the other institutions of the Union;



- (a) delay or jeopardise performance of the delegated tasks.
2. Without prejudice to its obligation to inform the European Anti-Fraud Office (OLAF) and the European Public Prosecutor's Office (EPPO) in accordance with the specific rules applicable, the Agency shall without delay inform the Directors-General of the parent Directorates-General of any fraud or irregularity which comes to its attention and of any situation which may give rise to such cases. However, cases involving members or employees of the EU institutions, offices, agencies and bodies shall be reported only to OLAF<sup>32</sup>, unless the Agency's responsibility to implement the Union's budget may be affected or in cases involving a potentially serious reputational risk for the Union.
  3. The reporting obligations referred to in paragraphs 1 and 2 are without prejudice to the obligations of staff of the Agency deriving from the application of the Staff Regulations and of the Conditions of employment of other servants, including the obligation to inform, without delay, either their immediate superior or their Director-General or, where they consider it useful, the Secretary-General, or the persons in equivalent positions, or OLAF directly, of facts which give rise to a presumption of the existence of possible illegal activity, including fraud or corruption, detrimental to the interests of the Union, or of conduct relating to the discharge of professional duties which may constitute a serious failure to comply with the obligations of staff of the Union.
  4. The Director of the Agency shall designate a contact point which shall have the appropriate powers to cooperate directly with OLAF in order to facilitate the latter's operational activities.

#### **SECTION 4 IMPLEMENTATION REPORTS**

##### *Article 19 Annual Activity Report*

1. The Director of the Agency shall submit to the Steering Committee by no later than 1 March each year a draft Annual Activity Report, prepared in compliance with article 74 of Regulation (EU, Euratom) 2018/1046 and with the related Annual Activity Report instructions referred to in Article 3.
2. No later than 31 March, the Steering Committee shall adopt the final report and submit it to the Commission.
3. The report and the declaration of assurance shall be signed by the Director of the Agency. The Director of the Agency retains the full responsibility of the declaration of assurance.

##### *Article 20 Other reports*

1. The Agency shall report to the Directors-General of the parent Directorates-General and to the Steering Committee on the performance of the tasks assigned to it. The content, the format and the frequency of the reporting shall be set in the

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<sup>32</sup> Those kind of cases need to be reported only to OLAF in order to preserve the confidentiality of information that would justify the opening of such investigation and on which such decision would be based and so as not to jeopardise future investigative activities.

Memorandum of Understanding referred to in Article 7. The reporting shall consist in making available at least the following data and information, where appropriate broken down per delegated tasks as referred to in Article 4:

- (a) performance achieved for each of the programmes' specific indicators set out in the relevant programme;
- (b) calls for tender and calls for proposals, contracts concluded, grants, contests and prizes awarded, compliance with deadlines set by Regulation (EU, Euratom) 2018/1046 and Regulation (EC) No 1653/2004 and in particular time to award, time to grant and time to pay, number and amount of negotiated procedures and grants to identified beneficiaries;
- (c) number of on-going projects, their state of play, monitoring of deadlines and evaluation review results;
- (d) figures, aggregated at least to chapter level, on implementation of the operating budget, as regards both revenue and all expenditure appropriations and including information on the use of human resources, infrastructures and service-level agreements, including the figures relative to the use of appropriations carried over;
- (e) figures on implementation of the operational appropriations;
- (f) figures on outstanding payments and payment delays;
- (g) figures on outstanding commitments (RAL);
- (h) information on the operation of the internal control and financial circuits of the Agency, including an assessment of the entries in the registers for exceptions, non-compliance events and internal control weaknesses reported;
- (i) number and results of ex-post controls carried out, accompanied, where appropriate, by detailed information on the measures taken to remedy any problems detected;
- (j) summary of the number and type of audits conducted by the Internal Audit Service and the European Court of Auditors, the recommendations made and the status of the actions taken for their implementation;
- (k) information meetings and activities carried out;
- (l) list of alleged irregularities or fraud detected by the Agency or brought to its attention, with the exception of cases involving members or employees of the EU institutions, offices, agencies and bodies and cases notified directly to OLAF pursuant to the second subparagraph of Article 18(2);
- (m) OLAF and EPPO investigations relating to the areas of activity of the Agency that have been brought to the Agency's attention;
- (n) cases dealt with by the European Ombudsman in relation with the Agency's activities;
- (o) actions brought against the acts of the Agency, including administrative proceedings referred to the Commission in accordance with Article 22 of Regulation (EC) No 58/2003;
- (p) requests for documents and parliamentary questions about the Agency.

2. The Agency shall establish a reporting system which, through the use of distribution keys, an analytical accounting system or other appropriate method, allows the Directors-General of the parent Directorates-General and other services of the Commission to make the link between the administrative expenditure and the respective parts of the programmes managed by the Agency. That reporting system, as well as any changes to it, shall be approved by the Agency's Steering Committee.
3. In accordance with Article 4(3), the Agency shall gather project-related data and monitor the data quality thereof, and analyse and communicate to the parent Directorates-General all the project-related information needed for the policy developments related to the programmes, the implementation of which is entrusted to the Agency.
4. The Directors-General of the parent Directorates-General may ask the Agency for any other report referred to in Article 11(5) of Regulation (EC) No 58/2003 which they consider necessary to supervise the performance of the Agency in relation to its delegated tasks.

## **SECTION 5**

### **SUPERVISION OF THE AGENCY**

#### *Article 21*

#### *Monitoring and supervision of the Agency's systems and procedures*

1. In accordance with Article 2, the parent Directorates-General shall be responsible for ensuring monitoring and supervision of the work of the Agency at operational level for the programme they are responsible for. The parent Directorates-General should maintain close contacts with their seconded officials to the Agency. The lead parent Directorate-General referred to in Article 2(2) shall have a clearly established leading role to supervise the non-programme specific issues in the Agency.
2. The Directors-General of the parent Directorates-General shall ensure that before the Agency begins implementing the newly delegated tasks, the existing systems and procedures in the Agency are adapted to those tasks. Those systems and procedures shall include an effective and efficient internal control system, where appropriate, local accounting systems and appropriate IT tools.
3. The Directors-General of the parent Directorates-General shall review the situation whenever the Agency makes any substantial change in procedures or systems of the Agency. This does not apply to changes that stem from changes in the Commission's corporate rules and procedures.
4. For the purposes of the review referred to in paragraph 3, the Agency shall supply the necessary information at least 30 days prior to the adoption of any substantial change in its procedures or systems, and shall communicate the reasons for such change.
5. The Directors-General of the parent Directorates-General and other persons authorised by them shall be entitled to carry out documentary and on-the-spot checks at the Agency to ensure:
  - (a) that its management and internal control system is in place and operates properly in such a way as to ensure total compliance with the principle of sound financial management;
  - (b) that the actions performed by the Agency are lawful and comply with the rules.

## Article 22

### *Audits, on-the spot checks by the Commission and the European Court of Auditors and investigations by OLAF*

1. The Agency shall grant the Directors-General of the parent Directorates-General, the Internal Audit Service of the Commission and other persons authorised by them, as well as the European Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, necessary to conduct their audits and supervision tasks.
2. The Directors-General of the parent Directorates-General, the Commission's Internal Audit Service and other persons authorised by them may carry out ex ante and ex post documentary and on-the-spot checks on recipients of Union funds. The contracts, grant agreements and grant decisions signed by the Agency shall state expressly that the recipients of Union funds undertake to accept those checks as well as those of the Court of Auditors.
3. By virtue of Regulation (Euratom, EC) No 2185/96 and Regulation (EU, Euratom) No 883/2013, and the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the European Anti-fraud Office, OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the Union against fraud and other irregularities. References thereto shall also be included in the contracts, grant agreements and grant decisions signed by the Agency.

## SECTION 6

### INTERNAL AUDITOR

## Article 23

### *Appointment, powers and duties of the internal auditor*

1. The Agency shall have an internal auditing function which shall be performed in compliance with the relevant international standards.
2. The internal audit function shall be performed by the Commission's internal auditor in accordance with Articles 117 and 118 of Regulation (EU, Euratom) 2018/1046 and the mission charter of the Internal Audit Service of the Commission. The internal auditor may be neither authorising officer nor accounting officer neither of the Agency nor of the Commission.
3. The internal auditor shall advise the Agency on dealing with risks, by issuing independent opinions on the quality of management and control systems and by issuing recommendations for improving the conditions of implementation of operations and promoting sound financial management.

The internal auditor shall in particular be responsible for:

- (a) assessing the suitability and effectiveness of internal management systems and the performance of departments in implementing programmes and actions by reference to the risks associated with them;
- (b) assessing the efficiency and effectiveness of the internal control and audit systems applicable to each operation for implementation of the budget by the Agency.

4. The internal auditor shall perform his or her duties in relation to all the Agency's activities and departments. The internal auditor shall enjoy full and unlimited access to all information required to perform his or her duties, including where necessary on-the-spot access, in Member States and in third countries.
5. The internal auditor shall take note of the annual report of the authorising officer and any other pieces of information identified.
6. The internal auditor shall report to the Director and to the Steering Committee of the Agency on his or her findings and recommendations. The Director of the Agency shall ensure that action is taken with regard to recommendations resulting from audits, and, together with the Steering Committee, ensure regular monitoring of their implementation.
7. The Agency shall make available the contact details of the Commission's internal auditor to any natural or legal person involved in expenditure operations, for the purposes of confidentially contacting the internal auditor.
8. The reports and findings of the internal auditor shall be accessible to the public only after validation by the internal auditor of the action taken for their implementation.

#### *Article 24*

#### *Independence, liability and action of the internal auditor before the Court of Justice, and set up of the Internal Audit Progress Committee*

1. The independence of the internal auditor, his or her liability for action taken in the performance of his or her duties, the right for the internal auditor to bring action before the Court of Justice of the European Union and the set-up of the Internal Audit Progress Committee shall be determined in accordance with Articles 119 to 123 of Regulation (EU, Euratom) 2018/1046.
2. The committee referred to in Article 123 of Regulation (EU, Euratom) 2018/1046 shall be the Commission's Audit Progress Committee.

### **SECTION 7**

#### **FINANCIAL RESOURCES MADE AVAILABLE TO THE AGENCY FOR THE PERFORMANCE OF ITS TASKS**

#### *Article 25*

#### *Union financial contribution to the operating budget of the Agency*

1. The amount of the Union contribution for the operation of the Agency shall be entered each year in the Commission's section of the general budget of the Union.
2. The authorising officers by delegation for implementation of these appropriations shall inform the Agency of the amount of the contribution as soon as it is adopted by the budgetary authority.

#### *Article 26*

#### *Payment of the Union contribution and recovery of the budget result*

1. The Commission shall pay the Union contribution to the Agency annually taking into account the real cash needs of the Agency.

2. Where the budget result is positive, it shall be the subject of a recovery order issued by the Commission at the annual closure of the Agency's accounts. The amounts recovered shall be considered as general revenue.

*Article 27*  
*Transitional provision*

The delegation laid down in this Decision shall be effective when it has been formally accepted in writing by the Director of the Agency on behalf of the Agency. On a proposal by the Director, the Steering Committee of the Agency, in agreement with the relevant Directors-General of the parent Directorates-General referred to in Article 2, shall fix the dates on which the Director of the Agency starts implementing the operational appropriations as authorising officer by delegation, on the basis of this Decision. These dates may differ for the individual programmes, parts of programmes and support services referred to in Article 4 and Annexes I-X.

*Article 28*  
*Addressee*

This Decision is addressed to the European Health and Digital Executive Agency.

Done at Brussels, 12.2.2021

*For the Commission*  
*Johannes HAHN*  
*Member of the Commission*

