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## NOTE

From:	Presidency
То:	Delegations
No. prev. doc.:	7542/23
No. Cion doc.:	14973/22, ADD1, ADD2, ADD3
Subject:	Proposal for a Regulation of the European Parliament and of the Council laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) - Presidency second compromise text

## I. INTRODUCTION

- The Commission adopted the proposal for a Regulation laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act) on <u>18 November</u> <u>2022</u><sup>1</sup>. The Czech Presidency invited the Commission to give a first, general presentation of its proposal in WP TELECOM on 28 November.
- 2. Under the Swedish Presidency, the WP TELECOM discussed the proposal at several meetings, during which the Commission presented in detail the entire text of the proposal, as well as the accompanying impact assessment. In addition to this, the Swedish Presidency organised one workshop with the participation of the Commission and experts from the capitals, based on the questions and requests for clarifications submitted by the delegations in advance in writing.

<sup>&</sup>lt;sup>1</sup> Doc. 14973/22.

- 3. On 21 February 2023 the Swedish Presidency requested the Member States to provide their initial drafting suggestions and written comments on the entire text and the Presidency's first compromise proposal was discussed at the WP TELECOM on 31 March.
- 4. Based on Member States' comments and on their additional input submitted in writing, the Swedish Presidency has now drafted the second compromise text of the Interoperable Europe Act proposal, contained in the Annex to this document.

# 5. <u>The Swedish Presidency invites the delegations to discuss the changes during the WP</u> <u>TELECOM meeting on 31 May 2023.</u>

6. The changes in the document compared with the first compromise text are <u>underlined</u>, additions are marked with **bold**, deletions with <del>strikethrough</del>.

## II. MAIN CHANGES

## 1. Chapter I

- 1.1 <u>Article 1(3)</u> has been further amended in line with the wording of the NIS2 directive to clarify the general exemption for national security.
- 1.2 In <u>Article 2</u>, the definition of 'cross-border services' (<u>point 2a</u>) has been modified to cater for the inclusion of EU institutions, bodies and agencies. Also, a new definition of 'public services' has been added as <u>new point 2b</u>. The definitions of 'interoperability solution' and 'open source licence' have been updated as well (points 3 and 8b).
- 1.3 In <u>Article 3(1)</u>, <u>point (b)</u> has been deleted from the list of cases in which an interoperability assessment needs to be carried out and the corresponding wording in <u>Recital 8a</u> has been corrected. Text has been added at the end of <u>Article 3(2)</u> to clarify the requirements related to the publication of the outcome of interoperability assessments; <u>Recital 11</u> has been modified accordingly.
- 1.4 **Article 3(5)** has been slightly amended to tackle the possible unclarity of the text related to the recipients' consultation.
- 1.5 <u>New Article 3(7)</u> includes a sentence clarifying that an interoperability assessment should be performed only once with regard to the same (new) requirements. Similar text has therefore been deleted from <u>Recital 8</u>.

## 2. Chapter II

- 2.1 <u>Article 7</u> has been modified and now includes new text to make a clearer distinction between Interoperable Europe solutions (i.e. recommended solutions) and other solutions. In line with this addition, <u>Recital 18</u> now clarifies what is meant by recommended solutions.
- 2.2 Additional wording to help identify the other solutions has been added to <u>Article 8(1)</u>, point (b) and further explanations have been inserted in <u>Recital 21</u>, which also clarifies that only the solutions meeting certain requirements are available on the Interoperable Europe Portal.
- 2.3 With regard to the functions of the Portal, text has been deleted from <u>Article 8(1)(d)</u>, to avoid confusion about the application of GDPR, while relevant explanations have been added in the new <u>Recital 27a</u>. Also, the text concerning the solutions accessible through the Portal has been clarified in <u>new paragraph 2a</u>.

## 3. Chapter III

- 3.1 In <u>Article 11(3)</u>, the reference to paragraph 1 has been deleted, consistently with the previous deletion of that paragraph.
- 3.2 <u>Article 12(10)</u> has been removed, in order to align with the Artificial Intelligence Act.

## 4. Chapter IV

- 4.1 With regard to the tasks of the Interoperable Europe Board in <u>Article 15(4)</u>, the wording of <u>point (a)</u> has been modified to clarify that the Board will provide support to both the national and the EU level. Moreover, the amendment in <u>point (h)</u> clarifies that the Board can withdraw its recommendations of Interoperable Europe solutions. In line with this change, explanatory text has been added at the end of <u>Recital 18</u>.
- 4.2 In <u>Article 17(1)</u>, the references to deadlines for Member States to designate one or more competent authorities as responsible for the application of the Regulation was deleted to make it consist with the amendments to <u>Article 22</u> (see below). In <u>Article 17(2)(a)</u> the task to appoint members to the Interoperable Europe Board has been deleted, in order to allow for a rapid appointment of the members of the Board in line with Commission Decision C(2016) 3301, Article 9.

## 5. Chapter V

- 5.1 <u>Article 20(2)(a)</u> has been modified to soften the wording with regard to the application of the EIF in Member States.
- 5.2 <u>Article 22</u> has been redrafted to allow for a sequential entering into force, by distinguishing between the general date of application and the date of application of specific provisions. This approach would also allow for Article 3 to be applied earlier for Member States' <u>central</u> government public sector bodies and EU institutions, bodies and agencies, compared to <u>other</u> public sector bodies. See also changes in <u>Article 17</u>. These changes are accompanied by the additional explanatory text in <u>Recital 39</u>.

#### 6. Other recitals

- 6.1 In <u>Recital 3</u>, text has been added to emphasise the elements of cross-border interoperability on the one hand, and to address possible confusion about what is meant by 'Interoperable Europe solutions', in line with the modifications in the relevant definition in <u>Article 2(3)</u>.
- 6.2 Examples of interoperability solutions are provided in the new text added in <u>Recital 5.</u>
- 6.3 A <u>new Recital 7a</u> has been drafted to clarify the objectives of the interoperability assessment and additional text in <u>Recital 9</u> makes explicit reference to the principle of proportionality with regard to the scope of such assessment.
- 6.4 <u>New Recital 21a</u> is meant to provide clarifications about the European Union Public Licence (EUPL) and the need for Member States' portals to allow for the use of EUPL, while not excluding the use of other licenses.

# 2022/0379 (COD)

Proposal for a

## **REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

## laying down measures for a high level of public sector interoperability across the Union (Interoperable Europe Act)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 172 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) It is necessary to strengthen the development of cross-border interoperability of network and information systems which are used to provide or manage public services in the Union, to allow public administrations in the Union to cooperate and make public services function across borders. The existing informal cooperation should be replaced with a clear legal framework to enable interoperability across different administrative levels and sectors and to ensure seamless cross-border data flows for truly European digital services. Public sector interoperability has an important impact on the right to free movement of goods and services laid down in the Treaties, as burdensome administrative procedures can create significant obstacles, especially for small and medium-sized enterprises ('SMEs').
- (2) Member States and the Union have been working for more than two decades to support the modernisation of administrations through digital transformation and foster the deep interconnections needed for a truly European digital space. The communication from the Commission '2030 Digital Compass: the European way for the Digital Decade' (COM(2021) 118) underlines the need to speed up the digitalisation of public services by 2030, including by ensuring interoperability across all levels of government and across public services. In addition, the Digital Decade Policy Programme (Decision (EU)

<sup>&</sup>lt;sup>2</sup> OJ C [...], [...], p. [...]

<sup>&</sup>lt;sup>3</sup> OJ C [...], [...], p. [...]

2022/2481) sets clear target of 100 % online accessible provision of key public services by 2030. Such key public services should also cover services that are relevant for major life events for natural persons, such as losing or finding a job, studying, owning or driving a car, or starting up a business, and for legal persons in their professional life-cycle. Furthermore, the COVID-19 pandemic increased the speed of digitalisation, pushing public administrations to adapt to the online paradigm, including for cross-border digital public services, as well as for the smarter and greener use of technologies in accordance with the climate and energy targets set in the European Green Deal and the Regulation (EU) 2021/1119 of the European Parliament and of the Council<sup>4</sup>. This Regulation aims to significantly contribute to these Union goals by creating a structured cooperation framework on cross-border interoperability amongst Member States and the Commission to support the setup of digital public services.

- (3) The new governance structure should have a legal mandate to <u>jointly</u> drive the further development of <u>cross-border interoperability in the Union, including</u> the European Interoperability Framework and other common <u>legal, organisational, semantic and technical</u> interoperability solutions, <u>such as specifications and applications</u>. Furthermore, this Regulation should establish a clear and easily recognisable label for some interoperability solutions <u>('Interoperable Europe solutions')</u>. The creation of a vibrant community around open government technology solutions should be fostered.
- (4) It is in the interest of a coherent approach to public sector interoperability throughout the Union, of supporting the principle of good administration and the free movement of personal and non-personal data within the Union, to align the rules as far as possible for all public sectors that are controllers or providers of network and information systems used to facilitate or manage public services. This objective includes the Commission and other institutions, bodies and agencies of the Union, as well as public sector bodies in the Member States across all levels of administration: national, regional and local. Agencies are playing an important role in collecting regulatory reporting data from Member States. Therefore, the interoperability of this data should also be in scope of this Regulation.
- (5) Cross-border interoperability is not solely enabled via centralised Member State digital infrastructures, but also through a decentralised approach. This entails data exchange between local administrations in different Member States without necessarily going through national nodes. Therefore, it is necessary to develop common interoperability solutions, reusable across all administrative levels<sub>2</sub>. Interoperability solutions encompass different forms ranging from higher-level tools like conceptual frameworks and guidelines to more technical solutions like reference architectures, technical specifications, or standards. Also, concrete services and applications, as well as documented technical components such as source code, including artifacts and AI models can be interoperability solutions, if they address legal, organisational, semantic, or technical aspects of cross-border interoperability particularly for specifications and applications. Needs for cross-border digital interactions are increasing, which requires solutions that can fulfil these needs. With this Regulation, the intention is to facilitate and encourage the exchange between all levels of administration.

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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).

- (6) Interoperability facilitates successful implementation of policies, in particular those with a strong public sector connection, such as justice and home affairs, taxation and customs, transport, health, agriculture, as well as in business and industry regulation. However, a single sector interoperability perspective is associated with the risk that the adoption of different or incompatible solutions at national or sectoral levels will give rise to new electronic barriers that impede the proper functioning of the internal market and the associated freedoms of movement. Furthermore, it risks undermining the openness and competitiveness of markets and the delivery of services of general interest to businesses and citizens. Therefore, this Regulation should also facilitate, encourage and apply to cross-sector interoperability.
- (7) In order to eliminate fragmentation in the interoperability landscape in the Union, a common understanding of interoperability in the Union and a holistic approach to interoperability solutions should be promoted. A structured cooperation should support measures promoting digital-ready and interoperable by default policy set-up. Furthermore, it should promote the efficient management and use of digital service infrastructures and their respective components by public sector bodies and institutions, bodies and agencies of the Union that permit the establishment and operation of sustainable and efficient cross-border public services.
- (7a) Union institutions, bodies and agencies, national and local authorities can introduce requirements for network and information systems used to manage or provide public services. To ensure that such systems can exchange data cross-border when needed, a mechanism should be established to allow for the discovery of legal, organisational, semantic and technical barriers to cross-border interoperability ('interoperability assessment'). The mechanism should ensure adequate consideration of cross-border interoperability aspects in all decisions that can impact on the design of such systems.
- (8) To set up cross-border interoperable public services, it is important to focus on the interoperability aspect as early as possible in the policymaking process. Therefore, the public organisation that intends to set requirements for one or several up a new or to modify an existing network and information system that is likely result in high impacts on the cross-border interoperability, for example in the course of the digitalisation of key public services as referred to in Decision (EU) 2022/2481<sup>5</sup>, should carry out an interoperability assessment. Where an interoperability assessment has already been carried out, for instance in the context of proposing Union or national law, the interoperability assessment does not need to be repeated in relation to those requirements.
- (8a) This assessment is necessary to understand the magnitude of impact of the planned action and to propose measures to reap up the benefits and address potential costs. The interoperability assessment should be mandatory in <u>three two</u> cases, which are in scope for cross-border interoperability. In other situations, the public organisations may decide to carry out the interoperability assessment on a voluntary basis.

<sup>&</sup>lt;sup>5</sup> Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022 establishing the Digital Decade Policy Programme 2030 (Text with EEA relevance) (OJ L 323, 19.12.2022, p. 4–26).

- (9) The approach to conducting interoperability assessments should be proportionate, differentiated in accordance with the level and scope at which they are undertaken. Under some circumstances it may also be reasonable and economical for the subject of an interoperability assessment to be broader than a single project, for example when public sector bodies intend to establish a common application or processing platform. In those other cases, the assessment should be strongly encouraged to go beyond the achievement of the Interoperable Europe objectives towards a full implementation of interoperability. Similarly, the requirements for interoperability assessments conducted at the level of single project implementation, such as in a local authority, should be pragmatic and allow for a narrow focus taking into account the fact that the wider benefits of interoperability assessments are generally harvested at the early stages of policy design and development of reference architecture, specifications and standards.
- (10) The interoperability assessment should evaluate the impacts of the planned action on crossborder interoperability of network and information system, for example, having regard to the origin, nature, particularity and scale of those impacts. The outcome of that assessment should be taken into account when determining the appropriate measures that need to be taken in order to set up or modify the network and information system.
- (11) The organisation should publish the outcome of the interoperability assessment on <u>its</u> website a public location designated by the national competent authorities or the interoperability coordinators for institutions, bodies and agencies of the Union. The publication of the outcome should not compromise intellectual property rights or trade secrets, and should be restricted where justified on the grounds of public order or security. The provisions of Union law governing the protection of personal data should be observed.
- (12) Public sector bodies or institutions, bodies or agencies of the Union that search for interoperability solutions should be able to request from other public sector bodies or institutions, bodies or agencies of the Union the software code the interoperability solutions those organisations use such as good practices, specifications, and software code, together with the related documentation. Sharing should become a default among public sector bodies, and institutions, bodies and agencies of the Union while not sharing would need a legal justification. In addition, public sector bodies or institutions, bodies, or agencies of the Union should seek to develop new interoperability solutions or to further develop existing interoperability solutions.
- (13) When public administrations decide to share their solutions with other public administrations or the public, they are acting in the public interest. This is even more relevant for innovative technologies: for instance, open code makes algorithms transparent and allows for independent audits and reproducible building blocks. The sharing of interoperability solutions among public administration should set the conditions for the achievement of an open ecosystem of digital technologies for the public sector that can produce multiple benefits.
- (14) When monitoring the coherence of the interoperability solutions and proposing measures to ensure their compatibility with existing solutions that share a common purpose, the Interoperable Europe Board should take into account the obsolescence of solutions.
- (15) The European Interoperability Framework (EIF) should ensure coherence and be recognised as the single point of reference for the Union's approach to interoperability in the public service sector. In addition, specialised interoperability frameworks can address the needs of

specific sectors, domains or administrative levels. Those frameworks should further promote the implementation of interoperability solutions.

- (16) The EIF should be developed by the Interoperability Europe Board, composed, among others, by one representative of each Member State. The Member States, with the other members of the Interoperable Europe Board, are thus at the centre of the development and implementation of the EIF. The Interoperable Europe Board should update the EIF when necessary.
- (17) The specialised interoperability frameworks issued to complement the EIF should take into account and not prejudice the existing sector-specific frameworks developed at the Union level (for example in the health sector).
- (18) Interoperability is directly connected with, and dependent on the use of open specifications and standards. Therefore, the Union public sector should be allowed to agree on cross-cutting open specifications and other solutions to promote interoperability. The new framework should provide for a clear process on the establishment and promotion of <u>such agreed</u> recommended interoperability solutions in the future, bearing the label <u>'Interoperable Europe solution'</u>. This way, the public sector will have a more coordinated voice to channel public sector needs and public values into broader discussions. The Interoperable Europe Board should be able to withdraw such recommendations, upon which the 'Interoperable Europe solution' label should be removed from the relevant interoperability solutions and the interoperability solutions should be deleted from the portal, where appropriate.
- (19) Many interoperability specifications used by the public sector could be derived from existing Union legislation. Therefore, it is necessary to establish a link between all specifications for public sector network and information systems that are mandatory to use due to Union legal provisions. It is not always easy for implementing authorities to find the requirements in the most recent and machine-readable format. A single point of entry and clear rules on the metadata of such information should help public sector bodies to have their digital service infrastructures comply with the existing and future rules.
- (20) An Interoperable Europe portal should be established as a point of reference for interoperability solutions, knowledge and community. The portal should be established as a link to official sources but should also be open to input from the Interoperable Europe Community.
- (21) The Interoperable Europe portal should make publicly available <u>and findable</u> interoperability solutions that follow the EIF principles, such as <u>of</u> openness, accessibility, technical neutrality, reusability, <u>and</u> security <u>and privacy</u>. There should be clear <u>distinction between solutions that are recommended by the Board ('Interoperable Europe solutions') and other interoperability solutions, such as those shared proactively for reuse by public administrations, those linked to EU policies and relevant solutions from national portals. Use cases in the portal should be searchable by country or by public service they support.</u>
- (21a) As open source enables users to actively assess and inspect the interoperability and security of the solutions, it is important that open source supports the implementation of interoperability solutions. In this context, the use of open source licences should be promoted to enhance legal clarity and mutual recognition of licences in the Member States.

With the European Union Public Licence (EUPL) the Commission already provides a solution for such licencing. Member States' portals collecting open source solutions that are linked with the Interoperable Europe portal should allow for the use of EUPL, while not excluding that such portals can allow the use of other licences.

- (22) At the moment, the Union's public services delivered or managed electronically depend in many cases on non-Union providers. It is in the Union's strategic interest to ensure that it retains and develops essential technological capacities to secure its Digital Single Market, and in particular to ensure service delivery, protect critical network and information systems, and to provide key services. The Interoperable Europe support measures should help public administrations to evolve and be capable of incorporating new challenges and new areas in cross-border contexts. Interoperability is a condition for avoiding technological lock-in, enabling technical developments, and fostering innovation, which should boost the global competitiveness of the Union.
- (23) It is necessary to establish a governance mechanism to facilitate the implementation of Union policies in a way that ensures interoperability. This mechanism should focus on the interoperable digital implementation of policies once they have been adopted in the form of legal acts and should serve to develop interoperability solutions on a needs-driven basis. The mechanism should support public sector bodies. Projects to support public sector bodies should be proposed by the Interoperable Europe Board to the Commission who should decide whether to set up the projects.
- (24) All levels of government should cooperate with innovative organisations, be it companies or non-profit entities, in design, development and operation of public services. Supporting GovTech cooperation between public sector bodies and start-ups and innovative SMEs, or cooperation mainly involving civil society organisations ('CivicTech'), is an effective means of supporting public sector innovation and promoting use of interoperability tools across private and public sector partners. Supporting an open GovTech ecosystem in the Union that brings together public and private actors across borders and involves different levels of government should allow to develop innovative initiatives aimed at the design and deployment of GovTech interoperability solutions.
- (25) Identifying shared innovation needs and priorities and focusing common GovTech and experimentation efforts across borders would help Union public sector bodies to share risks, lessons learnt, and results of innovation support projects. Those activities will tap in particular into the Union's rich reservoir of technology start-ups and SMEs. Successful GovTech projects and innovation measures piloted by Interoperable Europe innovation measures should help scale up GovTech tools and interoperability solutions for reuse.
- (26)Interoperable Europe support measures could benefit from safe spaces for experimentation, while ensuring responsible innovation and integration of appropriate risk mitigation measures and safeguards. To ensure a legal framework that is innovation-friendly, futureproof and resilient to disruption, it should be made possible to run such projects in regulatory sandboxes. Regulatory sandboxes should consist in controlled test environments that facilitate the development and testing of innovative solutions before such systems are integrated in the network and information systems of the public sector. The objectives of the regulatory sandboxes should be to foster interoperability through solutions by establishing testing innovative а controlled experimentation and environment with a view to ensure alignment of the solutions with this Regulation and other relevant Union law and Member States' legislation, to enhance legal certainty for innovators



and the competent authorities and to increase the understanding of the opportunities, emerging risks and the impacts of the new solutions. To ensure a uniform implementation across the Union and economies of scale, it is appropriate to establish common rules for the regulatory sandboxes' implementation. The European Data Protection Supervisor may impose administrative fine to Union institutions and bodies in the context of regulatory sandboxes, according to Article 58(2)(i) of Regulation (EU) 2018/1725 of the European Parliament and of the Council.

(27) It is necessary to provide a legal basis for the use of personal data collected for other purposes in order to develop certain interoperability solutions in the public interest within the regulatory sandbox, in accordance with Article 6(4) of Regulation (EU) 2016/679 of the European Parliament and of the Council, and Article 6 5 of Regulation (EU) 2018/1725 of the European Parliament and of the Council and without prejudice to Articles 4(2) of Directive (EU) 2016/680. All other obligations of data controllers and rights of data subjects under Regulation (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680 remain applicable. In particular, this Regulation should not provide a legal basis in the meaning of Article 22(2)(b) of Regulation (EU) 2016/679 and Article 24(2)(b) of Regulation (EU) 2018/1725. The Regulation aims only at establishing a legal basis for the processing of personal data in the context of the regulatory sandbox as such. Any other processing of personal data falling within the scope of this Regulation would require a separate legal basis.

#### (27a) In order to increase transparency of processing of personal data by public sector bodies and institutions, bodies and agencies of the Union, the Interoperable Europe portal should give access to information on the processing of personal data in the context of regulatory sandboxes, in accordance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725.

- (28) It is necessary to enhance a good understanding of interoperability issues, especially among public sector employees. Continuous training is key in this respect and cooperation and coordination on the topic should be encouraged. Beyond trainings on Interoperable Europe solutions, all initiatives should, where appropriate, build on, or be accompanied by, the sharing of experience and solutions and the exchange and promotion of best practices.
- (29) To create a mechanism facilitating a mutual learning process among public sector bodies and sharing of best practices in implementing Interoperable Europe solutions across the Member States, it is necessary lay down provisions on the peer review process. Peer reviews ean should lead to valuable insights and recommendations for the public sector body undergoing the review. In particular, they could contribute to facilitating the transfer of technologies, tools, measures and processes among the Member States involved in the peer review. They should create a functional path for the sharing of best practices across Member States with different levels of maturity in interoperability. A peer review is set up upon the request by a public sector body when needed. In order to ensure that the peer review process is cost-effective and produces clear and conclusive results, and also to avoid the placement of unnecessary burden, the Commission may adopt guidelines on the best set-up for such peer reviews, based on the needs that occur and after consulting the Interoperable Europe Board.
- (30) To develop the general direction of the Interoperable Europe structured cooperation in promoting the digital interconnection and interoperability of public services in the Union and to oversee the strategic and implementation activities related to that cooperation, an

Interoperable Europe Board should be established. The Interoperable Europe Board should carry out its tasks taking into consideration cross-border interoperability rules and solutions already implemented for existing network and information systems.

- (31) Certain Union bodies such as the European Data Innovation Board and the European Health Data Space Board have been created and tasked to, among others, enhance interoperability at specific domain or policy level. However, none of the existing bodies is tasked to address cross-border interoperability of network and information systems which are used to provide or manage public services in the Union. The Interoperable Europe Board created by this Regulation should support the Union bodies working on policies, actions and solutions relevant for cross-border interoperability of network and information systems which are used to provide or manage public services in the Union, for example on semantic interoperability for data spaces **as well as data** portability and reusability. The Interoperable Europe Board should interact with all relevant Union bodies in order to ensure alignment and synergies between cross-border interoperability actions and sector specific ones.
- (32) Advancing public sector interoperability needs the active involvement and commitment of experts, practitioners, users and the interested public across Member States, across all levels of government and involving international partners and the private sector. In order to tap into their expertise, skills and creativity, a dedicated open forum (the 'Interoperable Europe Community') should help channel feedback, user and operational needs, identify areas for further development and help scope priorities for EU interoperability cooperation. The establishment of the Interoperable Europe Community should support the coordination and cooperation between the strategic and operational key players for interoperability.
- (33) The Interoperable Europe Community should be open to all interested parties. Access to the Interoperable Europe Community should be made as easy as possible, avoiding unnecessary barriers and burdens. The Interoperable Europe Community should bring together public and private stakeholders, including citizens, with expertise in the field of cross-border interoperability, coming from different backgrounds, such as academia, research and innovation, education, standardisation and specifications, businesses and public administration at all levels.
- (34) To ensure the rules laid down by this Regulation are efficiently implemented, it is necessary to designate national competent authorities responsible for its implementation. In many Member States, some entities have already the role of developing interoperability. Those entities could take over the role of competent authority in accordance with this Regulation.
- (35) An Interoperable Europe Agenda should be established as the Union's main instrument for the coordination of public investments in interoperability solutions. It should deliver a comprehensive overview of funding possibilities and funding commitments in the field, integrating where appropriate the related Union programmes. This should contribute to creating synergies and coordinating financial support related to interoperability development and avoiding duplication.
- (36) Information should be collected in order to guide the effective and efficient implementation of the regulation and the interoperability solutions, and to provide evidence to support the work of the Interoperable Europe Board assess the performance of this Regulation against the objectives it pursues, and to in order give feedback for the an evaluation of this Regulation in accordance with paragraph 22 of the Interinstitutional



Agreement of 13 April 2016 on Better Law-Making<sup>6</sup>. Therefore, the Commission should carry out a monitoring and evaluation of this Regulation. The evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU value added. The evaluation should also be the basis for impact assessments of possible further measures. The monitoring mechanism should be designed to minimise the administrative burden on Member States by reusing integrate existing data sources and creating synergies with existing monitoring processes mechanisms, such as the Digital Economy and Society Index, the eGovernment Benchmark and the trajectories of the Digital Decade Policy Programme.

- (37) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to set out rules and the conditions for the establishment and the operation of the regulatory sandboxes.
- (38) Since the objective of this Regulation, namely interoperability within public administrations on a Union-wide scale, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in the same Article, this Regulation does not go beyond what is necessary in order to achieve the objectives of the Treaties, especially with regards to the strengthening of the Single Market.
- (39)The application of this Regulation should be deferred to three months after the date of its entry into force in order to provide Member States and the institutions, bodies and agencies of the Union with sufficient time to prepare for the application of this Regulation. Such time is necessary to establish the Interoperable Europe Board, and the Interoperable Europe Community and for the designation of designate national competent authorities and interoperability coordinators. In addition, this Regulation should allow time for Member States and the institutions, bodies and agencies of the Union to prepare for the effective implementation of the interoperability assessments and for each Member State to designate one or more national competent authorities. Therefore, the provisions on interoperability assessments and national competent authorities should apply to public sector bodies at State level and to the institutions, bodies and agencies of the Union from [six months following the entry into force of this Regulation]. Moreover, to avoid disproportionate burden on regional and local public sector bodies and to allow for sufficient time to develop the needed capabilities, the provision on interoperability assessments should apply to them from [twelve months following the entry into force of this Regulation].
- (40) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>7</sup> and delivered an opinion on ... 13 January 2023.

<sup>&</sup>lt;sup>6</sup> OJ L 123, 12.5. 2016, p 1.

<sup>&</sup>lt;sup>7</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).

#### Chapter 1 General provisions

#### Article 1

#### Subject matter and scope

- 1. This Regulation lays down measures to promote the cross-border interoperability of network and information systems which are used to provide or manage public services in the Union by establishing common rules and a framework for coordination on public sector interoperability, with the aim of fostering the development of interoperable trans-European digital public services infrastructure.
- 2. This Regulation applies to public sector bodies of Member States and institutions, bodies and agencies of the Union that provide or manage network or information systems that enable public services to be delivered or managed electronically.
- 3. This Regulation is without prejudice to the Member States' responsibility for safeguarding national security <u>and their power to safeguard other essential State</u> <u>functions, including ensuring the territorial integrity of the State and maintaining law</u> <u>and order.</u>

#### Article 2

#### Definitions

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

(1) 'cross-border interoperability' means the ability of network and information systems to be used by public sector bodies in different Member States and institutions, bodies, and agencies of the Union in order to interact with each other by sharing data by means of electronic communication;

(2) 'network and information system' means a network and information system as defined in Article **4-6**, point (1), of the proposal for a Directive (EU) 2022/2555 of the European Parliament and of the Council on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148 [proposal (NIS 2 Directive)<sup>8</sup>];

(2a) 'cross-border services' means data exchange between information systems by dedicated functions and procedures across <u>mational</u> jurisdictions <u>in the Union</u> in support of the provision of public services;

<sup>8</sup> Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive), OJ L 333, 27.12.2022, p. 80.

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(2b) 'public services' means services provided by public sector bodies of Member States or institutions, bodies or agencies of the Union either to one another, or to natural or legal persons in the Union.

(3) 'interoperability solution' means a reusable asset technical specification, including a standard, or another solution, including conceptual frameworks, guidelines and applications, describing concerning legal, organisational, semantic or technical requirements to be fulfilled by a network and information system in order to enhance enable cross-border interoperability, such as conceptual frameworks, guidelines, reference architectures, technical specifications, standards, services and applications, as well as documented technical components, such as source code;

(4) 'public sector body' means a public sector body as defined in Article 2, point (1), of Directive (EU) 2019/1024;

(5) 'data' means data as defined in Article 2, point (1), of Regulation (EU) 2022/868 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act)<sup>9</sup>;

(6) 'machine-readable format' means a machine-readable format as defined in Article 2, point (13), of Directive (EU) 2019/1024;

(7) 'GovTech' means a technology-based cooperation between public and private sector actors supporting public sector digital transformation;

(8) 'standard' means a standard as defined in Article 2, point (1), of Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>10</sup>;

(8a) 'ICT technical specification' means a ICT technical specification as defined in Article 2, point (4), of Regulation (EU) No 1025/2012 of the European Parliament and of the Council;

(8b) 'open source licence' means a licence whereby the reuse, redistribution and modification of the so<u>f</u>tware is permitted for all specified uses in a unilateral declaration by the right holder, and where the source code of the software is made available to users <u>indiscriminately</u>;

(9) 'highest level of management' means a manager, management or coordination and oversight body at the most senior administrative level, taking account of the high-level governance arrangements in each institution, body or agency of the Union.

(10) 'regulatory sandbox' means a controlled environment set up by a public sector body or an institution, body or agency of the Union for the development, training, testing and validation of innovative interoperability solutions, where appropriate in real world conditions, supporting the cross-border interoperability of network and information systems

<sup>&</sup>lt;sup>9</sup> Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (OJ L 152, 03.06.2022, p. 1).

Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

which are used to provide or manage public services to be delivered or managed electronically for a limited period of time under regulatory supervision.

## Article 3

## Interoperability assessment

- 1. Where a public sector body or an institution, an agency or body of the Union intends to set **requirements for one or several** up a new or significantly modify an existing network and information systems that enables public services to be delivered or managed electronically, it shall carry out an assessment of the **expected** impacts of the planned action on cross-border interoperability ('interoperability assessment') in the following cases:(a) where the **requirements** intended set-up or modification affects one or more network and information systems used for the provision of cross-border services across several sectors or administrations; or
- (b) where the **requirements** intended set up or modification will most likely result in procurements for network and information systems used for the provision of crossborder services above the threshold set out in Article 4 of Directive 2014/24/EU; or
- (be) where the requirements intended set-up or modification concerns a network and information system used for the provision of cross-border services and funded through Union programmes.

The public sector body or the institution, body or agency of the Union concerned may also carry out the interoperability assessment in other cases.

2. The interoperability assessment shall be carried out before taking decisions on the legal, organisational, semantic or technical requirements for the new or modified network and information system in a binding manner. A single interoperability assessment may be carried out to address a set of requirements and several network and information systems.

The public sector body or the institution, body or agency of the Union concerned shall publish a report presenting the outcome of the interoperability assessment on <u>its website</u> <u>a</u> <u>public location. The report shall not reveal defence-related or security-related issues</u>.

- 3. The national competent authorities and the interoperability coordinators shall provide the necessary support to carry out the interoperability assessment. The Commission may shall provide technical tools to support the assessment.
- 4. The interoperability assessment shall contain at least:
  - (a) a description of the intended operation and its impacts on the cross-border interoperability of one or several network and information systems concerned, including the estimated costs for the adaptation of the network and information systems concerned;
  - (b) a description of the level of alignment of the network and information systems concerned with the European Interoperability Framework, and with the Interoperable Europe solutions, after the operation and where it has improved compared to the level of alignment before the operation;

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- (c) when applicable, a description of the Application Programming Interfaces that enable machine-to-machine interaction with the data considered relevant for crossborder exchange with other network and information systems.
- 5. The public sector body, or institution, body or agency of the Union concerned shall consult recipients of the services <u>directly</u> affected or their representatives <u>on the intended</u> <u>operation if it directly affects the recipients</u>. This consultation is without prejudice to the protection of commercial or public interests or the security of such systems.
- 6. The Interoperable Europe Board shall adopt guidelines for on the content of the interoperability assessment by ... at the latest [one year after the entry into force of this Regulation], including practical check lists.

#### 7. Where an interoperability assessment has already been carried out in relation to specific requirements, the public sector body, or institution, body or agency of the Union concerned shall not be required to perform a new interoperability assessment in relation to those requirements.

## Article 4

# Share and reuse of interoperability solutions between public sector bodies, institutions, bodies and agencies of the Union

- 1. A public sector body or an institution, body or agency of the Union shall make available to any other such entity that requests it, interoperability solutions that support the public services that it delivers or manages electronically. The shared content shall include the technical documentation and, where applicable, the documented source code. This obligation to share shall not apply to any of the following interoperability solutions:
  - (a) that support processes which fall outside the scope of the public task of the public sector bodies or institutions, bodies, or agencies of the Union concerned as defined by law or by other binding rules, or, in the absence of such rules, as defined in accordance with common administrative practice in the Member State or Union administrations in question, provided that the scope of the public tasks is transparent and subject to review;
  - (b) for which third parties hold intellectual property rights and do not allow sharing;
  - (c) access to which is excluded or restricted on grounds of:
    - (i) sensitive critical infrastructure protection related information as defined in Article 2, point (d) of Council Directive 2008/114/EC<sup>11</sup>;
    - (ii) the protection of defence interests, or public security.
- 2. To enable the reusing entity to manage the interoperability solution autonomously, the sharing entity shall specify **any conditions that may apply to the reuse of the solution**,



<sup>&</sup>lt;sup>11</sup> Council Directive 2008/114/EC of 8 December 2008 on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection (OJ L 345, 23.12.2008, p. 75).

including possible the guarantees that will be provided to the reusing entity in terms of cooperation, support and maintenance. Before adopting the interoperability solution, **upon** request, the reusing entity shall provide to the sharing entity an assessment of the solution covering its ability to manage autonomously the cybersecurity and the evolution of the reused interoperability solution.

- 3. The obligation in paragraph 1 of this Article may be fulfilled by publishing the relevant content on the Interoperable Europe portal or a portal, catalogue or repository connected to the Interoperable Europe portal. In that case, paragraph 2 of this Article shall not apply to the sharing entity. The publication on the Interoperable Europe<u>an</u> portal shall be made by the Commission, at the request of the sharing entity.
- 4. A public sector body, an institution, body or agency of the Union or a third party reusing an interoperability solution may adapt it to its own needs, **unless intellectual property rights held by a third party restricts the adaptation of the solution**. If the interoperability solution was made public as set out in paragraph 3, the adapted interoperability solution shall be made public in the same way.
- 5. The sharing and reusing entities may conclude an agreement on sharing the costs for future developments of the interoperability solution.

#### Chapter 2 Interoperability solutions

## Article 5

## General principles

- 1. The Commission shall publish Interoperable Europe solutions and the European Interoperability Framework on the Interoperable Europe portal-, by electronic means, in formats that are open, machine-readable, accessible<sup>12</sup>, findable and re-usable, if applicable, together with their metadata.
- 2. The Interoperable Europe Board shall monitor the overall coherence of the developed or recommended interoperability solutions, and propose measures to ensure, where appropriate, their compatibility with other interoperability solutions that share a common purpose, while supporting, where relevant, the complementarity with or transition to new technologies.

## Article 6

## European Interoperability Framework and specialised interoperability frameworks

<sup>&</sup>lt;sup>12</sup> Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70–115).

- 1. The Interoperable Europe Board shall develop a European Interoperability Framework (EIF)<sup>13</sup> and propose to the Commission to adopt it. The Commission may adopt the EIF. The Commission shall publish the EIF in the Official Journal of the European Union.
- 2. The EIF shall provide a model and a set of recommendations on legal, organisational, semantic and technical interoperability, addressed to all entities falling within the scope of this Regulation for interacting with each other through their network and information systems. The EIF shall be taken into account in the interoperability assessment in accordance with Article 3(4), point (b) and Article 3(6).
- 3. The Commission, after consulting the Interoperable Europe Board, may adopt other interoperability frameworks ('specialised interoperability frameworks') targeting the needs of specific sectors or administrative levels. The specialised interoperability frameworks shall be based on the EIF. The Interoperable Europe Board shall assess the alignment of the specialised interoperability frameworks with the EIF. The Commission shall publish the specialised interoperability frameworks on the Interoperable Europe portal.
- 4. Where a Member State develops a national interoperability framework and other relevant national policies, strategies or guidelines, it shall take into account the EIF.

## Article 7

## Interoperable Europe solutions

The Interoperable Europe Board shall recommend interoperability solutions for the cross-border interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically in the Union. When an interoperability solution is recommended by the Interoperable Europe Board, it shall carry the label 'Interoperable Europe solution' and shall be published on the Interoperable Europe portal, making a clear distinction between Interoperable Europe solutions and other solutions.

## Article 8

## Interoperable Europe portal

- 1. The Commission shall provide a portal ('the Interoperable Europe portal') as a single point of entry for information related to cross-border interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically in the Union. The portal shall be electronically accessible and free of charge. The portal shall have at least the following functions:
  - (a) access to Interoperable Europe solutions;
  - (b) access to other interoperability solutions not bearing the label 'Interoperable Europe solution', such as solutions: and provided for by other Union policies or fulfilling the requirements set out in Paragraph 2;

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<sup>&</sup>lt;sup>13</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions European Interoperability Framework – Implementation Strategy, COM/2017/0134 final.

## (i) shared according to Article 4(3);

## (ii) provided for by other Union policies;

# (iii) published on other portals or catalogues connected to the Interoperable Europe portal.

- (c) access to ICT technical specifications eligible for referencing in accordance with Article 13 of Regulation (EU) No 1025/2012;
- (d) access to information on processing of personal data in the context of regulatory sandboxes referred to in Articles 11 and 12, if any high risks to the rights and freedoms of the data subjects, as referred to in Article 35(1) of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725, has been identified, as well as access to information on response mechanisms to promptly mitigate those risks. The published information may include a disclosure of the data protection impact assessment;
- (e) fostering knowledge exchange between members of the Interoperable Europe Community, as set out in Article 16, such as providing a feedback system to express their views on measures proposed by the Interoperable Europe Board or express their interest to participate to actions related to the implementation of this Regulation;
- (f) access to interoperability-related monitoring data referred to in Article 20;
- (g) allowing citizens and civil society organisations to provide feedback on the published content.
- 2. The Interoperable Europe Board may propose to the Commission to publish on the portal other interoperability solutions or to have them referred to on the portal.

## **2a.** The solutions accessible through the Interoperable Europe portal <u>Such solutions</u> shall:

- (a) not be subject to third party rights that prevent their distribution and use;
- (aa) not or contain personal data or confidential information;
- (b) have a high-level of alignment with the Interoperable Europe solutions which may be proven by publishing the outcome of the interoperability assessment referred to in Article 3;
- (c) use a licence that allows at least for the reuse by other public sector bodies or institutions, bodies or agencies of the Union or be issued as open source. An open source licence means a licence whereby the reuse of the software is permitted for all specified uses in a unilateral declaration by the right holder, and where the source codes of the software are made available for users;
- (d) be regularly maintained under the responsibility of the owner of the interoperability solution.



- 3. When a public sector body or an institution, body or agency of the Union provides a portal, catalogue or repository with similar functions, it shall take the necessary measures to ensure interoperability with the Interoperable Europe portal. Where such portals collect open source solutions, they shall allow for the use of the European Union Public Licence.
- 4. The Commission may adopt guidelines on interoperability for other portals with similar functions as referred to in paragraph 3.

#### Chapter 3 Interoperable Europe support measures

#### Article 9

#### **Policy implementation support projects**

- 1. The Interoperable Europe Board may propose to the Commission to set up projects to support public sector bodies in the digital implementation of Union policies ensuring the cross-border interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically ('policy implementation support project').
- 2. The policy implementation support project shall set out:
  - (a) the existing Interoperable Europe solutions deemed necessary for the digital implementation of the policy requirements;
  - (b) any missing interoperability solutions to be developed, deemed necessary for the digital implementation of the policy requirements;
  - (c) other recommended support measures, such as trainings or peer-reviews.
- 3. The Commission shall set out, after consulting the Interoperable Europe Board, the scope, the timeline, the needed involvement of sectors and administrative levels and the working methods of the support project. If the Commission has already performed and published an interoperability assessment, in accordance with Article 3, the outcome of that assessment shall be taken into account when setting up the support project.
- 4. In order to reinforce the policy implementation support project, the Interoperable Europe Board may propose to establish a regulatory sandbox as referred to in Article 11.
- 5. The outcome of a policy implementation support project as well as interoperability solutions developed in the project shall be openly available and made public on the Interoperable Europe Portal.

## Article 10

## Innovation measures

- 1. The Interoperable Europe Board may propose to the Commission to set up innovation measures to support the development and uptake of innovative interoperability solutions in the EU ('innovation measures').
- 2. Innovation measures shall:
  - (a) contribute to the development of existing or new Interoperable Europe solutions; and
  - (b) may involve GovTech actors.
- 3. In order to support the development of innovation measures, the Interoperable Europe Board may propose to set up a regulatory sandbox.
- 4. The Commission shall make the results from the innovation measures openly available on the Interoperable Europe portal.

#### Article 11

#### Establishment of regulatory sandboxes

- 1. Regulatory sandboxes shall provide a controlled environment for the development, testing and validation of innovative interoperability solutions supporting the cross-border interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically for a limited period of time before putting them into service.
- 2. Regulatory sandboxes shall be operated under the responsibility of the participating public sector bodies or institutions, bodies, and agencies of the Union., where the Regulatory sandboxes that entails the processing of personal data by public sector bodies, shall be operated under the supervision of other the relevant national supervisory authorities., or where the Regulatory sandboxes that entails the processing of personal data by institutions, bodies, and agencies of the Union, shall be operated under the responsibility of the European Data Protection Supervisor.
- 3. The establishment of a regulatory sandbox <u>as set out in paragraph 1</u> shall aim to contribute to the following objectives:
  - (a) foster innovation and facilitate the development and roll-out of innovative digital interoperability solutions for public services;
  - (b) facilitate cross-border cooperation between national competent authorities and synergies in public service delivery;
  - (c) facilitate the development of an open European GovTech ecosystem, including cooperation with small and medium enterprises and start-ups;
  - (d) enhance authorities' understanding of the opportunities or barriers to cross-border interoperability of innovative interoperability solutions, including legal barriers;
  - (e) contribute to the development or update of Interoperable Europe solutions;-

#### (f) contribute to evidence-based regulatory learning;

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- (g) improve legal certainty and contribute to the sharing of best practices through cooperation with the authorities involved in the regulatory sandbox with a view to ensuring compliance with this Regulation and, where appropriate, with other Union and Member States legislation.
- 4. The establishment of regulatory sandboxes shall contribute to improving legal certainty through cooperation with the authorities involved in the regulatory sandbox with a view to ensuring compliance with this Regulation and, where appropriate, with other Union and Member States legislation.
- 5. The Commission, after consulting the Interoperable Europe Board and, where the regulatory sandbox would include the processing of personal data, the European Data Protection Supervisor, shall upon joint request from at least three participating participants public sector bodies authorise the establishment of a regulatory sandbox. This consultation should not replace the prior consultation referred to in Article 36 of Regulation (EU) 2016/679 and in Article 40 of Regulation (EU) 2018/1725. Where the sandbox is set up for interoperability solutions supporting the cross-border interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically by one or more institutions, bodies or agencies of the Union, eventually including with the participation of public sector bodies, no authorisation is needed.

## Article 12

## Participation in the regulatory sandboxes

- 1. The participating public sector bodies or institutions, bodies, and agencies of the Union shall ensure that, to the extent the innovative interoperability solution operation of the regulatory sandbox requires involves the processing of personal data or otherwise falls under the supervisory remit of other national authorities providing or supporting access to data, that the national data protection supervisory authorities and those other national authorities are associated to the operation of the regulatory sandbox. As appropriate, the participating participants public sector bodies may allow for the involvement in the regulatory sandbox of other actors within the GovTech ecosystem such as national or European standardisation organisations, notified bodies, research and experimentation labs, innovation hubs, and companies wishing to test innovative interoperability solutions. Cooperation may also be envisaged with third countries establishing mechanisms to support innovative interoperability solutions for the public sector.
- 2. Participation in the regulatory sandbox shall be limited to a period that is appropriate to the complexity and scale of the project<del>, and in any case not longer than 2 years from the establishment of the regulatory sandbox</del>. The participation may be extended for up to one more year if necessary to achieve the purpose of the processing.
- 3. Participation in the regulatory sandbox shall be based on a specific plan elaborated by the participants taking into account the advice of other national competent authorities or the European Data Protection Supervisor, as applicable. The plan shall contain as a minimum the following:

- (a) description of the participants involved and their roles, the envisaged innovative interoperability solution and its intended purpose, and relevant development, testing and validation process;
- (b) the specific regulatory issues at stake and the guidance that is expected from the authorities supervising the regulatory sandbox;
- (c) the specific modalities of the collaboration between the participants and the authorities, as well as any other actor involved in the regulatory sandbox;
- (d) a risk management and monitoring mechanism to identify, prevent and mitigate <del>any</del> risks;
- (e) the key milestones to be completed by the participants for the interoperability solution to be considered ready to be put into service;
- (f) evaluation and reporting requirements and possible follow-up;
- (g) where personal data are processed, an indication of the categories of personal data concerned, the purposes of the processing for which the personal data are intended and the actors involved in the processing and their role.
- 4. The participation in the regulatory sandboxes shall not affect the supervisory and corrective powers of any authorities supervising the sandbox.
- 5. Participants in the regulatory sandbox shall remain liable under applicable Union law and Member States legislation on liability for any damage caused in the course of their participation in the regulatory sandbox.
- 6. Personal data **lawfully collected for other purposes** may be processed in the regulatory sandbox subject to the following cumulative conditions:
  - (a) the innovative interoperability solution is developed for safeguarding public interests in the area of a high level of efficiency and quality of public administration and public services;
  - (b) the data processed is limited to what is necessary for the functioning of the interoperability solution to be developed or tested in the sandbox, and the functioning cannot be effectively achieved by processing anonymised, synthetic or other non-personal data;
  - (c) there are effective monitoring mechanisms to identify if any high risks to the rights and freedoms of the data subjects, as referred to in Article 35(1) of Regulation (EU) 2016/679 and in Article 39 of Regulation (EU) 2018/1725, may arise during the operation of the sandbox, as well as a response mechanism to promptly mitigate those risks and, where necessary, stop the processing;
  - (d) any personal data to be processed are in a functionally separate, isolated and protected data processing environment under the control of the participants and only authorised persons have access to that data;

- (e) any personal data processed are not to be transmitted, transferred or otherwise accessed by other parties that are not participants in the sandbox nor transferred to parties other than the participants of the sandbox unless such disclosure occurs in compliance with Regulation (EU) 2016/679 or, where applicable, Regulation 2018/725, and all participants have agreed to it;
- (f) any processing of personal data does shall not affect the application of the rights of the data subjects as provided for under Union law on the protection of personal data, in particular in Article 22 of Regulation (EU) 2016/679 and Article 24 of Regulation (EU) 2018/1725;
- (g) any personal data processed are protected by means of appropriate technical and organisational measures and deleted once the participation in the sandbox has terminated or the personal data has reached the end of its retention period;
- (h) the logs of the processing of personal data are kept for the duration of the participation in the sandbox, and for a limited period after its termination solely for the purpose of and only as long as necessary for fulfilling accountability and documentation obligations under Union or Member States legislation unless provided otherwise by Union or <u>Mn</u>ational law;
- a complete and detailed description of the process and rationale behind the training, testing and validation of the interoperability solution is kept together with the testing results as part of the technical documentation and transmitted to the Interoperable Europe Board;
- (j) a short summary of the interoperability solution developed in the sandbox, its objectives and expected results are made available on the Interoperable Europe portal.
- 6a. Paragraph 1 is without prejudice to Union or Member States laws laying down the basis for the processing of personal data which is necessary for the purpose of developing, testing and training of innovative interoperability solutions or any other legal basis, in compliance with Union law on the protection of personal data.
- 7. The participating participants public sector bodies shall submit periodic reports and a final report to the Interoperable Europe Board and the Commission on the results from the regulatory sandboxes, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the development of this Regulation and other Union legislation supervised within the regulatory sandbox. The Interoperable Europe Board shall issue an opinion to the Commission on the outcome of the regulatory sandbox, specifying, where applicable, the actions needed to implement new interoperability solutions to promote the cross-border interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically.
- 8. The Commission shall ensure that information on the regulatory sandboxes is available on the Interoperable Europe portal.
- 9. The Commission is empowered to adopt implementing acts to set out the detailed rules and the conditions for the establishment and the operation of the regulatory sandboxes, including the eligibility criteria and the procedure for the application for, selection of,

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participation in and exiting from the sandbox, and the rights and obligations of the participants.

10. Where a regulatory sandbox involves the use of artificial intelligence, the rules set out under Article 53 and 54 of the [proposal for a] Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts shall prevail in case of conflict with the rules set out by the Regulation.

## Article 13

#### Training

- 1. The Commission, assisted by the Interoperable Europe Board, shall provide training material on the use of the EIF and on Interoperable Europe solutions. Public sector bodies and institutions, bodies and agencies of the Union shall provide their staff entrusted with strategical or operational tasks having an impact on network and information systems in the Union with appropriate training programmes concerning interoperability issues.
- 2. The Commission shall organise training courses on interoperability issues at Union level to enhance cooperation and the exchange of best practices between the staff of public sector bodies, institutions, bodies and agencies of the Union. The courses shall be announced on the Interoperable Europe portal.

#### Article 14

#### Peer reviews

- 1. A **voluntary** mechanism for cooperation between public sector bodies designed to support them to implement Interoperable Europe solutions in their network and information systems and to help them perform the interoperability assessments referred to in Article 3 ('peer review') shall be established.
- 2. The peer review shall be conducted by interoperability experts drawn from Member States other than the Member State where the public sector body undergoing the review is located. The Commission may, after consulting the Interoperable Europe Board, adopt guidelines on the methodology and content of the peer-review.
- 3. Any information obtained through a peer review shall be used solely for that purpose. The experts participating in the peer review shall not disclose any sensitive or confidential information obtained in the course of that review to third parties. The Member State concerned shall ensure that any risk of conflict of interests concerning the designated experts is communicated to the other Member States and the Commission without undue delay.
- 4. The experts conducting the peer review shall prepare and present within one month after the end of the peer review a report and submit it to the public sector body concerned and to the Interoperable Europe Board. The reports shall be published on the Interoperable Europe portal when authorised by the Member State where the public sector body undergoing the review is located.

#### Chapter 4 Governance of cross-border interoperability

## Article 15

#### **Interoperable Europe Board**

- 1. The Interoperable Europe Board is established. It shall facilitate strategic cooperation and the exchange of information on cross-border interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically in the Union.
- 2. The Interoperable Europe Board shall be composed of:
  - one representative of each Member State; (a)
  - one representative designated by each of the following: (b)
    - (i) the Commission;
    - (ii) the Committee of the Regions;
    - (iii) the European Economic and Social Committee.
- 3. The Board shall be chaired by the Commission. Countries participating in the European Economic Area and candidate countries may be invited as observers. In addition, the Chair may give the status of observer to individuals and organisations after consultation with the Interoperable Europe Board. The Chair may invite to participate, on an ad hoc basis, experts with specific competence in a subject on the agenda. The Commission shall provide the secretariat of the Interoperable Europe Board.

The members of the Interoperable Europe Board shall make every effort to adopt decisions by consensus. In the event of a vote, the outcome of the vote shall be decided by simple majority of the component members. The members who have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the opinions, recommendations or reports.

- 4. The Interoperable Europe Board shall have the following tasks:
  - (a) support the implementation of national interoperability frameworks in Member States and institutions, bodies and agencies of the Union, and other relevant national or Union policies, strategies or guidelines;
  - adopt guidelines on the content of the interoperability assessment referred to in (b) Article 3(6);
  - propose measures to foster the share and reuse of interoperable solutions; (c)

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monitor the overall coherence of the developed or recommended interoperability (d)solutions;

- (e) propose to the Commission measures to ensure, where appropriate, the compatibility of interoperability solutions with other interoperability solutions that share a common purpose, while supporting, where relevant, the complementarity with or transition to new technologies;
- (f) develop the EIF and update it, if necessary, and propose it to the Commission;
- (g) assess the alignment of the specialised interoperability frameworks with the EIF and answer the request of consultation from the Commission on those frameworks;
- (h) recommend Interoperable Europe solutions <u>and withdraw such recommendations;</u>
- (i) propose to the Commission to publish on the Interoperable Europe portal the interoperability solutions referred to in Article 8(2), or to have them referred to on the portal;
- (j) propose to the Commission to set up policy implementation support projects and innovation measures and other measures that the Interoperable Europe Community may propose;
- (k) review reports from innovation measures, on the use of the regulatory sandbox and on the peer reviews and propose follow-up measures, if necessary;
- (l) propose measures to enhance interoperability capabilities of public sector bodies, such as trainings;
- (m) adopt the Interoperable Europe Agenda;
- (n) provide advice to the Commission on the monitoring and reporting on the application of this Regulation;
- (o) propose measures to relevant standardisation organisations and bodies to contribute to European standardisation activities, in particular through the procedures set out in Regulation (EU) No 1025/2012;
- (p) propose measures to collaborate with international bodies that could contribute to the development of the cross-border interoperability, especially international communities on open source solutions, open standards or specifications and other platforms without legal effects;
- (q) coordinate with the European Data Innovation Board, referred to in Regulation (EU) No 2022/686 on interoperability solutions for the common European Data Spaces, as well as with any other Union institution, body, or agency of the Union working on interoperability solutions relevant for the public sector;
- (r) inform regularly and coordinate with the interoperability coordinators and the Interoperable Europe Community on matters concerning cross-border interoperability of network and information systems.
- 5. The Interoperable Europe Board may set up working groups to examine specific points related to the tasks of the Board. Working groups shall involve members of the Interoperable Europe Community.

6. The Interoperable Europe Board shall adopt its own rules of procedure.

# Article 16

## Interoperable Europe Community

- 1. The Interoperable Europe Community is established. It shall contribute to the activities of the Interoperable Europe Board by providing expertise and advice.
- 2. Public and private stakeholders residing or having their registered office in a Member State may register on the Interoperable Europe portal as a member of the Interoperable Europe Community.
- 3. After confirmation of the registration, the membership status shall be made public on the Interoperable Europe portal. Membership shall not be limited in time. It may however be revoked by the Interoperable Europe Board at any time for proportionate and justified reasons, especially if a person is no longer able to contribute to the Interoperable Europe Community or has abused its status as a member of the Community.
- 4. The members of the Interoperable Europe Community may be invited to among other:
  - (a) contribute to the content of the Interoperable Europe portal;
  - (b) participate in the working groups;
  - (c) participate in the peer reviews.
- 5. The Interoperable Europe Board shall organise once a year an online assembly of the Interoperable Europe Community.
- 6. The Interoperable Europe Board shall adopt the code of conduct for the Interoperable Europe Community that shall be published on the Interoperable Europe portal.

## Article 17

## National competent authorities

- 1. <u>By ... at the latest [the date of application of this Regulation]</u>, <u>eE</u>ach Member State shall designate one or more competent authorities as responsible for the application of this Regulation. Member States may designate an existing authority to that effect.
- 2. The competent authority shall have the following tasks:

## (a) appoint a member to the Interoperable Europe Board;

- (ba) coordinate within the Member State all questions related to this Regulation;
- (eb) support public sector bodies within the Member State to set up or adapt their processes to do interoperability assessment referred to in Article 3;

- (dc) foster the share and reuse of interoperability solutions through the Interoperable Europe portal or other relevant portal;
- (ed) contribute with country-specific knowledge to the Interoperable Europe portal;
- $(\underline{fe})$  coordinate and encourage the active involvement of a diverse range of national entities in the Interoperable Europe Community and their participation in policy implementation support projects as referred to in Article 9 and innovation measures referred to in Article 10;
- (<u>ef</u>) support public sector bodies in the Member State to cooperate with the relevant public sector bodies in other Member States on topics covered by this Regulation.
- 3. The Member States shall ensure that the competent authority has adequate competencies and resources to carry out, in an effective and efficient manner, the tasks assigned to it.
- 4. The Member States shall set up the necessary cooperation structures between all national authorities involved in the implementation of this Regulation. Those structures may build on existing mandates and processes in the field.
- 5. Each Member State shall notify to the Commission, without undue delay, the designation of the competent authority, its tasks, and any subsequent change thereto, and inform the Commission of other national authorities involved in the oversight of the interoperability policy. Each Member State shall make public the designation of their competent authority. The Commission shall publish the list of the designated competent authorities.

#### Article 18

## Interoperability coordinators for institutions, bodies and agencies of the Union

- 1. All institutions, bodies and agencies of the Union that provide or manage network and information systems that enable public services to be delivered or managed electronically shall designate an interoperability coordinator under the oversight of its highest level of management to ensure the contribution to the implementation of this Regulation.
- 2. The interoperability coordinator shall support the concerned departments to set up or adapt their processes to implement the interoperability assessment.

#### Chapter 5 Interoperable Europe planning and monitoring

## Article 19

## Interoperable Europe Agenda

1. After organising a public consultation process through the Interoperable Europe portal that involves, among others, the members of the Interoperable Europe Community **and interoperability coordinators**, the Interoperable Europe Board shall adopt each year a strategic agenda to plan and coordinate priorities for the development of cross-border



interoperability of network and information systems which are used to provide or manage public services to be delivered or managed electronically. ('Interoperable Europe Agenda'). The Interoperable Europe Agenda shall take into account the Union's long-term strategies for digitalisation, existing Union funding programmes and ongoing Union policy implementation.

- 2. The Interoperable Europe Agenda shall contain:
  - (a) needs for the development of interoperability solutions;
  - (b) a list of ongoing and planned Interoperable Europe support measures;
  - (c) a list of proposed follow-up actions to innovation measures;
  - (d) identification of synergies with other relevant Union and national programmes and initiatives.
- 3. The Interoperable Europe Agenda shall not constitute financial obligations. After its adoption, the Commission shall publish the Agenda on the Interoperable Europe portal.

## Article 20

## Monitoring and evaluation

- 1. The Commission shall monitor the progress of the development of cross-border interoperable public services to be delivered or managed electronically in the Union. The monitoring shall give priority to the reuse of existing international, Union and national monitoring data and to automated data collection. The Commission shall consult the Interoperable Europe Board on the methodology and process of the monitoring.
- 2. As regards topics of specific interest for the implementation of this Regulation, the Commission shall monitor:
  - (a) the <u>implementation of progress towards applying</u> the EIF <u>by in</u> the Member States;
  - (b) the take-up of the interoperability solutions in different sectors, and across the Member States, and at local level;
  - (c) the development of open source solutions for the public services, public sector innovation and the cooperation with GovTech actors in the field of cross-border interoperable public services to be delivered or managed electronically in the Union.
- 3. Monitoring results shall be published by the Commission on the Interoperable Europe portal. Where feasible, they shall be published in a machine-readable format.
- 4. By ... at the latest [three years after the date of application of this Regulation], and every four years thereafter, the Commission shall present to the European Parliament and to the Council a report on the application of this Regulation, which shall include conclusions of the evaluation. The report shall specifically assess the need for establishing mandatory interoperability solutions.

## Chapter 6 Final provisions

## Article 21

## Costs

- 1. Subject to the availability of funding, the general budget of the Union shall cover the costs of:
  - (a) the development and maintenance of the Interoperable Europe portal;
  - (b) the development, maintenance and promotion of Interoperable Europe solutions;
  - (c) the Interoperable Europe support measures.
- 2. These costs shall be met in compliance with the applicable provisions of the relevant basic act.

## Article 22

## **Entry into force**

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

It shall apply from [3 months after the date of entry into force of this Regulation], except for the following:

- a. <u>Article 3 shall apply to institutions, bodies and agencies of the Union and public sector</u> <u>bodies at State level from [6 months after the date of entry into force of</u> <u>this Regulation].</u>
- b. <u>Article 17(1) shall apply from [6 months after the date of entry into force of this Regulation];</u>
- c. <u>Article 3 shall apply to regional and local public sector bodies [12 months after the date of entry into force of this Regulation].</u>

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

Done at Brussels,

For the European Parliament The President For the Council The President

[...]

TREE.2.B

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