Data Governance Act

Final Compromise Amendments

<u>CA 1: General context and scope (covers Art 1, 2(2), 2(5), 2(6), 2(7), 2(8), 2(12)(a), Rec 1, 2, 3, 4, 5, 44, 45, 46)</u>

All relevant AMs fall, including: AMs 1-3, 20-21, 109-136, 157, 246, 270-275, 278-289, 291, 294-295, 299-301, 304-306, 308-315, 318, 320-321, 328, 332, 338, IMCO 1-6, IMCO 32-36, IMCO 40-45, LIBE 1-6, LIBE 37-43, LIBE 45-46, LIBE 48-51, LIBE 53-54, LIBE 57, JURI 1-8, JURI 39-40, JURI 45-49

Recitals

(1) The Treaty on the functioning of the European Union ('TFEU') provides for the establishment of an internal market and the institution of a system ensuring that competition in the internal market is not distorted. The establishment of common rules and practices in the Member States relating to the development of a framework for data governance should contribute to the achievement of those objectives, *while fully respecting fundamental rights*. *It should also guarantee the strengthening of the open strategic autonomy of the Union while ensuring free flow of data.*

Over the last few years decade, digital technologies have transformed the economy (2)and society, affecting all sectors of activity and daily life. Data is at the centre of this transformation: data-driven innovation will bring enormous benefits both for citizens and the economy, for example through improved personalised medicine, new mobility, and its contribution to the European Green Deal²³. *The data economy has to be built in a way to* enable businesses, especially micro, small and medium sized enterprises (SMEs)^{xx} and start-ups to thrive, ensuring data access neutrality, portability and interoperability, and *avoiding lock-in effects.* In its Data Strategy²⁴, the Commission described the vision of a common European data space, a Single Market for data in which data could be used irrespective of its physical location of storage in the Union in compliance with applicable law, which inter alia can be pivotal for the rapid development of Artificial Intelligence technologies. It also called for the free and safe flow of data with third countries, subject to exceptions and restrictions on the basis of fundamental rights, public security, public order and other legitimate public policy objectives of the European Union, in line with international obligations. In order to turn that vision into reality, it proposes to establish domain-specific common European data spaces, as the concrete arrangements in which data sharing and data pooling can happen. As foreseen in that strategy, such common European data spaces can cover areas such as health, mobility, manufacturing, financial services, energy, or agriculture or thematic areas, such as the European green deal or European data spaces for public administration or skills. In accordance with the FAIR data principles, common European data spaces should make data findable, accessible, interoperable and re-usable, while ensuring a high level of cybersecurity. When there is a level playing field in the data economy, businesses compete on quality of services, and not on the amount of data they control. For the purpose of the design, creation and maintenance of the level playing field in the data economy, a sound governance is needed, in which relevant stakeholders of a common European data space need to be represented and engaged.

xx Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, OJ L 124, 20.5.2003, p. 36–41

2 a (new) The Union's growth potential depends on the skills of its population and workforce. Bearing in mind that 42% of Union citizens lack basic digital skills^{xx}, promoting digital literacy will be a key element in increasing citizens' trust in intensifying data sharing. Improving data literacy should be part of the strategic actions to reduce social inequalities and to promote a just digital environment.

2 b (new) Action at Union and national level is necessary to address the fact that women are under-represented at all levels in the digital sector in Europe.

2 c (new) It is important for the Union to focus on the need to develop the data economy, in particular by building common European data spaces, paying particular attention to software engineering and attracting talent to the ICT sector in order to build European know-how that focuses on next-generation and cutting-edge technologies.

^{xx}<u>Analyse one indicator and compare breakdowns — Digital Scoreboard - Data &</u> <u>Indicators (digital-agenda-data.eu)</u>

It is necessary to improve the conditions for data sharing in the internal market, by (3) creating a harmonised framework for data exchanges, *paying specific attention to facilitating* cooperation. This Regulation should aim to develop further a borderless digital single market and human-centric, trustworthy and secure data society and economy. Sectorspecific legislation can develop, adapt and propose new and complementary elements, depending on the specificities of the sector, such as the envisaged legislation on the European health data space²⁵ and on access to vehicle data. Moreover, certain sectors of the economy are already regulated by sector-specific Union law that include rules relating to cross-border or Union wide sharing or access to data²⁶. This Regulation is therefore without prejudice to Regulation (EU) 2016/679 of the European Parliament and of the Council (27), and in particular the implementation of this Regulation shall not prevent cross border transfers of data in accordance with Chapter V of Regulation (EU) 2016/679 from taking place, Directive (EU) 2016/680 of the European Parliament and of the Council (28), Directive (EU) 2016/943 of the European Parliament and of the Council (29), Regulation (EU) 2018/1807 of the European Parliament and of the Council (³⁰), Regulation (EC) No 223/2009 of the European Parliament and of the Council (³¹), Directive 2000/31/EC of the European Parliament and of the Council (³²), Directive 2001/29/EC of the European Parliament and of the Council (³³), Directive (EU) 2019/790 of the European Parliament and of the Council (³⁴), Directive 2004/48/EC of the European Parliament and of the Council (35), Directive (EU) 2019/1024 of the European Parliament and of the Council (36), as well as Regulation 2018/858/EU of the European Parliament and of the Council (37), Directive 2010/40/EU of the European Parliament and of the Council (³⁸) and Delegated Regulations adopted on its basis, and any other sector-specific Union legislation that organises the access to and re-use of data. This Regulation should be without prejudice to Union or Member State law on the access and use of data for the purpose of international cooperation in the context of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, as well as international cooperation in this context. This Regulation should be without prejudice to the competences of the Member States regarding activities concerning public security, defence and national security. A horizontal regime for the re-use of certain

categories of protected data held by public sector bodies, the provision of data sharing *intermediation* services and of services based on data altruism in the Union should be established. Specific characteristics of different sectors may require the design of sectoral data-based systems, while building on the requirements of this Regulation. Where a sector-specific Union legal act requires public sector bodies, providers of data sharing services providers of data intermediation services or registered entities providing data altruism services to comply with specific additional technical, administrative or organisational requirements, including through an authorisation or certification regime, those provisions of that sector-specific Union legal act should also apply.

(3a) This Regulation is without prejudice to Regulation (EU) 2016/679(1a) of the European Parliament and of the Council and to Directives 2002/58/EC(1b) and (EU) 2016/680(1c) of the European Parliament and of the Council. This Regulation should in particular not be read as creating a new legal basis for the processing of personal data for any of the regulated activities. In the event of conflict between the provisions of this Regulation and Union law on the protection of personal data, the latter should prevail. It should be possible to consider data protection authorities competent authorities for the purpose of this Regulation. Where other entities act as competent authorities under this Regulation, it should be without prejudice to the supervisory powers of data protection authorities under Regulation (EU) 2016/679.

^{1a} Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016, p.1).

^{1b} Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

^{1c} Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA. (OJ L 119, 4.5.2016, p.89).

(3b) In the case of a data set composed of both personal and non-personal data, where these data are inextricably linked, the data set should be considered personal data.

(4) Action at Union level is necessary in order to address the barriers to a wellfunctioning *and competitive* data-driven economy. A Union-wide governance framework *should have the objective of building trust among individuals and businesses* for data access, *control, sharing, use and re-use*, in particular *by establishing proper mechanisms for data subjects to know and meaningfully exercise their rights, as well as* regarding the re-use of certain types of data held by the public sector, the provision of services by *providers of* data *sharing providers intermediation services* to business users and to data subjects, as well as the collection and processing of data made available for altruistic purposes by natural and legal persons. *In particular, more transparency regarding the purpose of data use and* conditions under which data is stored by businesses can help increase trust. This action is without prejudice to obligations and commitments in trade agreements concluded by the Union.

(4a) The Commission's consultation of 9 October 2019 entitled 'SME panel consultation on B2B Data Sharing Principles and Guidance' found that 40% of SMEs struggle to access the data they need to develop data-driven products and services underscoring the need to lower the barriers to a data-driven economy, in particular for SMEs. The Digital Europe Programme, as well as other Union and national programmes, should support cooperation to achieve a European ecosystem for trusted data sharing. European Digital Innovation Hubs and their network should also be able to help businesses, in particular SMEs and start-ups, to benefit from the European data economy.

The idea that data that has been generated at the expense of public budgets should (5) benefit society has been part of Union policy for a long time. Directive (EU) 2019/1024 as well as sector-specific legislation ensure that the public sector makes more of the data it produces easily available for use and re-use. However, certain categories of data (commercially confidential data, data subject to statistical confidentiality, data protected by intellectual property rights of third parties, including trade secrets and personal data not accessible on the basis of specific national or Union legislation, such as Regulation (EU) 2016/679 and Directive (EU) 2016/680) in public databases is often not made available, despite this being possible in accordance with the applicable Union law, notably Regulation (EU) 2016/679, Directive (EU) 2016/680 and Directive (EU) 2002/58, not even for research or innovative activities in the public interest. Due to the sensitivity of this data, certain technical and legal procedural requirements must be met before they are made available, not least in order to ensure the respect of rights others have over such data, or limit negative impact on fundamental rights, the principle of non-discrimination and data protection. Such requirements are usually time- and knowledge-intensive to fulfil. This has led to the underutilisation of such data. While some Member States are setting up structures, processes and sometimes legislate to facilitate this type of re-use, this is not the case across the Union. In order to facilitate the use of data for European research and innovation by private and public entities, clear conditions for access to and use of such data are needed across the Union.

(44) This Regulation should not affect the application of the rules on competition, and in particular Articles 101 and 102 of the Treaty on the Functioning of the European Union. The measures provided for in this Regulation should not be used to restrict competition in a manner contrary to the Treaty on the Functioning of the European Union. This concerns in particular the rules on the exchange of competitively sensitive information between actual or potential competitors through data sharing *intermediation* services.

(45) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the Council (⁴⁷) and delivered an opinion on *10 March 2021*.

(46) This Regulation *uses as its guiding principles the* respect *of* the fundamental rights and observ*ing* the principles recognised in particular by the Charter, including the right to privacy, the protection of personal data, the freedom to conduct a business, the right to property and the integration of persons with disabilities,

Articles

Article 1 – paragraph 1 – point c a (new) (ca) a framework for the establishment of a European data innovation board.

Article 1 – paragraph 2 2. This Regulation is without prejudice to specific provisions in other Union legal acts regarding access to or re-use of certain categories of data, or requirements related to processing of personal *data, including employees' personal data in the employment context,* or non-personal data. Where a sector-specific Union legal act requires public sector bodies, providers of data-sharing-intermediation services or registered entities providing data altruism services to comply with specific additional technical, administrative or organisational requirements, including through an authorisation or certification regime, those provisions of that sector-specific Union legal act shall also apply.

Article 1 - paragraph 2 a (new) (2a) Union and Member State law on the protection of personal data apply to any personal data processed in connection with this Regulation. In particular, this Regulation is without prejudice to Regulations (EU) 2016/679^{1a} and (EU) 2018/1725^{1b} of the European Parliament and of the Council and Directive 2002/58/EC of the European Parliament and of the Council ^{1c}, and the corresponding provisions in Member State law, including the competences and powers of supervisory authorities. In the event of conflict between the provisions of this Regulation and Union law on the protection of personal data, the latter prevails. This Regulation does not create a legal basis for the processing of personal data.

^{1a} Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), (OJ L 119, 4.5.2016, p.1)

^{1b} Regulation (EU) 2016/679 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)

^{1c} Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37)

Article 1 - paragraph 2 b (new) (2b) Where data can be reasonably assumed to lead to the identification or identifiability of natural persons when combined with other datasets, or where personal and non-personal data in a data set are inextricably linked in mixed data sets, the data shall be treated as personal data.

Article 2 – paragraph 1 – point 2 (2) 're-use' means the use by natural or legal persons of data held by public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the data were produced, except for the exchange of data between public sector bodies purely in pursuit of their public tasks;

Article 2 – paragraph 1 – point 2 b (new) (2b) 'data subject' means data subject as defined in Article 4, point (1), of Regulation (EU) 2016/679;

Article 2 – paragraph 1 – point 5 (5) 'data holder' means a *natural or* legal person, or data subject, *public body or international organisation*, who, in accordance with applicable Union or national law, has the right to grant access to or to share certain personal *data*, *subject to consent by data subjects*, or non-personal data under its control;

Article 2 – paragraph 1 – point 6 (6) 'data user' means a natural or legal person who has lawful access to certain personal or non-personal data and is authorised has the right, *including under Regulation (EU) 2016/679 in the case of personal data*, to use that data for commercial or non-commercial purposes;

Article 2 - paragraph 1 - point 6 a (new) (6a) 'consent' means consent as defined in Article 4, point (11), of Regulation (EU) 2016/679 and subject to the conditions set out in Article 7 and Article 8 of that Regulation;

Article 2 - paragraph 1 - point 6 b (new) (6b) 'processing' means processing as defined in Article 4, point (2), of Regulation (EU) 2016/679;

Article 2 paragraph 1 point 7 (7) 'data sharing' means the provision by a data holder of data to a data user for the purpose of joint or individual use of the shared data, based on voluntary agreements, directly or through an intermediary;

Article 2 – paragraph 1 – point 8 (8) 'access' means processing by a data user of data that has been provided by a data holder, in accordance with specific technical, legal, or organisational requirements, without necessarily implying the transmission or downloading of such data;

Article 2 - paragraph 1 - point 12 - point a (a) they are established for the specific purpose of meeting needs in the general interest, and do not have an industrial or commercial character;

CA 2: Privacy, anonymisation, secure processing (covers Art 2 (14), Rec 6)

All relevant AMs fall, including: AMs 4, 137-142, 333-336, IMCO 7, IMCO 48, LIBE 7-8, LIBE 58, JURI 9-10

Recitals

(6) There are techniques enabling privacy friendly analyses on databases that contain personal data, such as anonymisation, pseudonymisation, differential privacy, generalisation, or suppression, and randomisation and other state-of-the-art privacy preserving methods that could contribute to a more privacy-friendly processing of data. Member States should provide support to public sector bodies to make optimal use of such techniques, thus making as much data as possible available for sharing. The Aapplication of these privacyenhancing technologies, together with comprehensive data protection impact assessments and other safeguards approaches can contribute to more safety in the use and re-use of personal data and should ensure the safe re-use of personal data and commercially confidential business data for research, innovation and statistical purposes. In many cases this implies that the data use and re-use in this context can only be done in a secure processing environment set in place and supervised by the public sector. There is experience at Union level with such secure processing environments that are used for research on statistical microdata on the basis of Commission Regulation (EU) 557/2013 (³⁹). In general, insofar as personal data are concerned, the processing of personal data should rely upon one or more of the grounds for processing provided in Article 6 *and 9* of Regulation (EU) 2016/679.

6 a (new) (6a) In accordance with Regulation (EU) 2016/679 the principles of data protection should not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. The European Data Protection Board (EDPB) defines anonymisation in its guidelines as "the use of a set of techniques in order to remove the ability to link the data with an identified or identifiable natural person against any 'reasonable' effort"^{1a}.

^{1a} European Data Protection Board (2020), Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, 21.4.2020 p. 5.

6 aa (new) (6aa) In order to facilitate the protection of personal data or confidential data, and to speed up the process of making such data available for re-use under this Regulation, Member States should encourage public authorities to apply the principle of 'open by design and by default' as referred to in Recital (16) of Directive (EU) 2019/1024 and promote the creation and the procurement of data in formats and structures that allow for swift anonymisation in this regard.

Articles

Article 2 – paragraph 1 – point 14 (14) 'secure processing environment' means the physical or virtual environment and organisational means to re-use data in accordance with applicable law, in particular the preservation of data subject rights under Regulation (EU) 2016/679, and to uphold data confidentiality, integrity and accessibility, and to provide the opportunity that allows for the operator of the secure processing environment to determine and supervise all data processing actions, including to display, storage, download, export of the data and calculation of derivative data through computational algorithms.

CA 3: Definition and categories of data (covers Art 2(1), 3, Rec 7, 8)

All relevant AMs fall, including: AMs 25-26, 143-144, 290, 298, 340-348, IMCO 39, IMCO 49, LIBE 9, LIBE 44, LIBE 60-62, JURI 11, JURI 44, JURI 52-55

Recitals

(7) The categories of data held by public sector bodies which should be subject to re-use under this Regulation fall outside the scope of Directive (EU) 2019/1024 that excludes data which is not accessible due to commercial and statistical confidentiality and data for which third parties have intellectual property rights. *This Regulation should apply to Pp*ersonal data *that* fall outside the scope of Directive (EU) 2019/1024 insofar as the access regime excludes

or restricts access to such data for reasons of data protection, privacy and the integrity of the individual, in particular in accordance with data protection rules. The re-use of data, which may contain trade secrets, should take place without prejudice to Directive (EU) 2016/943⁴⁰, which sets the framework for the lawful acquisition, use or disclosure of trade secrets. This Regulation is without prejudice and complementary to more specific obligations on public sector bodies to allow re-use of data laid down in sector-specific Union or national law. *This Regulation should not create an obligation to allow re-use of personal data held by public sector bodies*.

(8) The re-use regime provided for in this Regulation should apply to data the supply of which forms part of the public tasks of the public sector bodies concerned, as defined by law or by other binding rules in the Member States. In the absence of such rules the public tasks should be defined in accordance with common administrative practice in the Member States, provided that the scope of the public tasks is transparent and subject to review. The public tasks could be defined generally or on a case-by-case basis for individual public sector bodies. As public undertakings are not covered by the definition of public sector body, the data they hold should *be excluded from the scope of* not be subject to this Regulation. Data held by cultural and educational establishments, for which intellectual property rights are not incidental, but which are predominantly contained in works and other documents protected by such intellectual property rights, *and data held by educational establishments,* are not covered by this Regulation.

Articles

Article 2 – paragraph 1 – point 1 (1) 'data' means any digital representation of acts, facts or information and any compilation of such acts, facts or information, including in the form of sound, visual or audiovisual recording;

Article 2 – paragraph 1 – point 2 a (new) (2a) 'personal data' means personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679;

Article 3 – paragraph 2 – point c (c) data held by cultural establishments *and protected by intellectual property rights* and educational establishments;

Article 3 – paragraph 2 – point c a (new) (ca) data held by educational establishments;

Article 3 – paragraph 3 (3) The provisions of this Chapter do not create any obligation on public sector bodies to allow re-use of data nor do they release public sector bodies from their confidentiality obligations *under Union or national law*. This Chapter is without prejudice to Union and national law or international agreements to which the Union or Member States are parties on the protection of categories of data provided in paragraph 1. This Chapter is without prejudice to Union and national law on access to documents and to obligations of public sector bodies under Union and national law to allow the re-use of data.

CA 4: Prohibition of exclusive arrangements (covers Art 4, Rec 9, 10)

All relevant AMs fall, including: AMs 5, 27-28, 145-148, 349-360, IMCO 8-9, IMCO 50-54, LIBE 10, LIBE 63-65, JURI 12, JURI 56-60

Recitals

(9) Public sector bodies should comply with competition law when establishing the principles for re-use of data they hold, avoiding as far as possible the conclusion of agreements, which might have as their objective or effect the creation of exclusive rights for the re-use of certain data. Such agreement should be only possible when justified and necessary for the provision of a service of general interest. This may be the case when exclusive use of the data is the only way to maximise the societal benefits of the data in question, for example where there is only one entity (which has specialised in the processing of a specific dataset) capable of delivering the service or the product which allows the public sector body to provide an advanced digital service in the general interest. Such arrangements should, however, be concluded in compliance with public procurement and concession award rules and be subject to regular review based on a market analysis in order to ascertain whether such exclusivity continues to be necessary. In addition, such arrangements should comply with the relevant State aid rules, as appropriate, and should be concluded for a limited period, which should not exceed 12 month. In order to ensure transparency, such exclusive agreements should be published online, regardless of a possible publication of an award of a public procurement contract.

(10) Prohibited exclusive agreements and other practices or arrangements *pertaining to the re-use of data held by public sector bodies* which do not expressly grant exclusive rights but which can reasonably be expected to *hamper the functioning of the internal market by* restrict*ing* the availability of data for re-use that have been concluded or have been already in place before the entry into force of this Regulation should not be renewed after the expiration of their term. In the case of indefinite or longer-term agreements, they should be terminated within *one* years from the date of entry into force of this Regulation.

Articles

Article 4 - paragraph 1 (1) Agreements or other practices pertaining to the re-use of data held by public sector bodies containing categories of data referred to in Article 3 (1) which grant exclusive rights or which have as their object or effect to grant such exclusive rights or to restrict the availability of data for re-use by entities other than the parties to such agreements or other practices shall be prohibited. *Such agreements or practices and the exclusive rights granted pursuant to them shall be void.*

Article 4 – paragraph 5 5. The period of exclusivity of the right to re-use data shall not exceed *12 months*. Where a contract is concluded, the duration of the contract awarded shall be as aligned with the period of exclusivity.

Article 4 - paragraph 6 (6) The award of an exclusive right pursuant to paragraphs (2) to (5), including the reasons *reasoned justification* why it is necessary to grant such a right, shall be transparent and be made publicly available online, regardless of a possible publication of an award of a public procurement and concessions contract.

Article 4 – paragraph 7 7. Agreements or other practices falling within the scope of the prohibition in paragraph 1, which do not meet the conditions set out in paragraph 2, and which were concluded before the date of entry into force of this Regulation shall be terminated at the end of the contract and in any event at the latest within *one* years after the date of entry into force of this Regulation.

CA 5: Conditions of re-use (covers Art 5, 30, Rec 11, 12, 13, 14, 15, 16, 17, 18, 19, 43)

All relevant AMs fall, including: AMs 6-8, 29-31, 102-106, 149-156, 158-181, 267-269, 361-391, 393-417, 718-730, IMCO 10-15, IMCO 55-67, IMCO 185-188, LIBE 11-16, LIBE 66-82, LIBE 205-212, JURI 13-21, JURI 38, JURI 61-70, JURI 135-139

Recitals

(11)Conditions for re-use of protected data that apply to public sector bodies competent under national law to allow re-use, and which should be without prejudice to rights or obligations concerning access to such data, should be laid down. Those conditions should be non-discriminatory, transparent, proportionate and objectively justified, while enhancing competition, with a specific focus on promoting access to such data by SMEs and start-ups and promoting scientific research. In particular, public sector bodies allowing re-use should have in place the technical means necessary to ensure the protection of rights and interests of third parties and should be empowered to request the necessary information from the reuser. Conditions attached to the re-use of data should be limited to what is necessary to preserve the rights and interests of others in the data and the integrity of the information technology and communication systems of the public sector bodies. Public sector bodies should apply conditions which best serve the interests of the re-user without leading to a disproportionate effort burden for on the public sector. Depending on the case at hand, Conditions should be designed to ensure effective safeguards with regard to the protection of personal data. **b**Before its transmission, personal data should be fully anonymised, so as to definitively not allow the identification of the data subjects, or data containing commercially confidential information modified in such a way that no confidential information is disclosed. Where provision of anonymised or modified data would not respond to the needs of the reuser, and where any requirements of completing a data protection impact assessment and consulting with the supervisory authority pursuant to Articles 35 and 36 of Regulation (EU) 2016/679 have been fulfilled and the risks for the rights and interests of data subjects *are minimal*, on-premise or remote re-use of the data within a secure processing environment could be permitted. Data analyses in such secure processing environments should be supervised by the public sector body, so as to protect the rights and interests of others. In particular, personal data should only be transmitted for re-use to a third party where a legal basis allows such transmission. The public sector body should make the use of such secure processing environment conditional on the signature by the re-user of a confidentiality agreement that prohibits the disclosure of any information that jeopardises the rights and interests of third parties that the re-user may have acquired despite the safeguards put in place. The public sector bodies, where relevant, should facilitate the re-use of data on the basis of consent of data subjects or permissions of legal persons on the re-use of data pertaining to them through adequate technical means. In this respect, the public sector body should support potential re-users in seeking such consent by establishing technical mechanisms that permit transmitting requests for consent from re-users, where practically

feasible. When transmitting the request for consent, the public sector body should inform the data subjects or legal persons of their rights, in particular of the right to refuse such a request and not give their consent. The responsibility for demonstrating that consent has been obtained should lie with the re-users. Public sector bodies should focus in particular on seeking to ensure that SMEs and start-ups are able to compete fairly with other reusers. No contact information should be given that allows re-users to contact data subjects or companies directly. In the event of any re-identification of individuals concerned, the reusers should report the incident to the supervisory authority competent under Regulation (EU) 2016/679 and inform the public sector body.

(11a) The de-anonymisation of datasets should be prohibited unless where data subjects have given their consent or another legal basis permits it. This should be without prejudice to the possibility to conduct research into anonymisation techniques, in particular where finding possible weaknesses in existing anonymisation techniques could lead to the overall strengthening of anonymisation, while duly respecting the fundamental right to the protection of personal data.

(12) The intellectual property rights of third parties should not be affected by this Regulation. This Regulation should neither affect the existence or ownership of intellectual property rights of public sector bodies, nor should it limit the exercise of these rights in any way beyond the boundaries set by this Regulation. The obligations imposed in accordance with this Regulation should apply only insofar as they are compatible with international agreements on the protection of intellectual property rights, in particular the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the WIPO Copyright Treaty (WCT). Public sector bodies should, however, exercise their copyright in a way that facilitates re-use.

(13) Data subject to intellectual property rights as well as trade secrets should only be transmitted to a third party where such transmission is lawful by virtue of Union or national law or with the agreement of the rightholder. Where public sector bodies are holders of the right provided for in Article 7(1) of Directive 96/9/EC of the European Parliament and of the Council (⁴¹) they should not exercise that right in order to prevent the re-use of data or to restrict re-use beyond the limits set by this Regulation.

(14) Companies and data subjects should be able to trust that the re-use of certain categories of protected data, which are held by the public sector, will take place in a manner that respects their rights and interests. Additional safeguards should thus be put in place for situations in which the re-use of such public sector data is taking place on the basis of a processing of the data outside the public sector. Such an additional safeguard could be found in the requirement that public sector bodies should fully *comply with* the rights and interests of natural and legal persons (in particular the protection of personal data, commercially sensitive data and the protection of intellectual property rights) in *all cases including when* such data is transferred to third countries.

(15) Furthermore, *in order to preserve fair competition and an open market economy* it is *of the utmost importance* to protect commercially sensitive data of non-personal nature, notably *in particular* trade secrets, but also non-personal data representing content protected by intellectual property rights from unlawful access that may lead to IP theft or industrial espionage. In order to ensure the protection of fundamental rights or interests of data holders,

non-personal data which is to be protected from unlawful or unauthorised access under Union or national law, and which is held by public sector bodies, should be transferred only to thirdcountries where appropriate safeguards for the use of data are provided. Such appropriate safeguards should be considered to exist when in that third-country there are equivalent measures in place which ensure that non-personal data benefits from a level of protection similar to that applicable by means of Union or national law in particular as regards the protection of trade secrets and the protection of intellectual property rights. To that end, *the* power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission may adopt *delegated* acts that *in respect of* declar*eing* that a third country provides a level of protection that is essentially equivalent to those provided by Union or national law. The assessment of the level of protection afforded in such third-country should, in particular, take into consideration the relevant legislation, both general and sectoral, including concerning public security, defence, national security and criminal law concerning the access to and protection of non-personal data, any access by the public authorities of that third country to the data transferred, the existence and effective functioning of one or more independent supervisory authorities in the third country with responsibility for ensuring and enforcing compliance with the legal regime ensuring access to such data, or the third countries' international commitments regarding the protection of data the third country concerned has entered into, or other obligations arising from legally binding conventions or instruments as well as from its participation in multilateral or regional systems. The existence of effective legal remedies for data holders, public sector bodies or providers of data intermediation services in the third country concerned is of particular importance in the context of the transfer of non-personal data to that third country. Such safeguards should therefore include the availability of enforceable rights and of effective legal remedies.

(16)In cases where there is no *delegated* act adopted by the Commission in relation to a third country declaring that it provides a level of protection, in particular as regards the protection of commercially sensitive data and the protection of intellectual property rights, which is essentially equivalent to that provided by Union or national law, the public sector body should only transmit *non-personal* protected data to a re-user, if the re-user undertakes obligations in the interest of the protection of the data. The re-user that intends to transfer the data to such third country should commit to comply with the obligations laid out in this Regulation even after the data has been transferred to the third country. To ensure the proper enforcement of such obligations, the re-user should also accept the jurisdiction of the Member State of the public sector body that allowed the re-use for the judicial settlement of disputes. In that regard, the public sector bodies should, where relevant and to the extent of their capabilities, provide guidance and legal and administrative support to re-users, in particular small actors, such as SMEs and start-ups, for the purpose of supporting them in complying with those obligations. The Commission should issue guidelines on the obligations as regards the transfer by re-users of non-personal data to a third country. In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to establish standard contractual clauses for the transfer by re-users of non-personal data to a third country.

(17) Some third countries adopt laws, regulations and other legal acts which aim at directly transferring or providing access to non-personal data in the Union under the control of natural and legal persons under the jurisdiction of the Member States. Judgments of courts or tribunals or decisions of administrative authorities in third countries requiring such transfer or access to non-personal data should be enforceable when based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the

Union or a Member State. In some cases, situations may arise where the obligation to transfer or provide access to non-personal data arising from a third country law conflicts with a competing obligation to protect such data under Union or national law, in particular as regards the protection of commercially sensitive data and the protection of intellectual property rights, and including its contractual undertakings regarding confidentiality in accordance with such law. In the absence of international agreements regulating such matters, transfer or access should only be allowed *if* the third-country system requires the reasons and proportionality of the decision to be set out, that the court order or the decision is specific in character, and the reasoned objection of the addressee is subject to a review by a competent court in the third country, which is empowered to take duly into account the relevant legal interests of the provider of such data.

(18) In order to prevent unlawful access to non-personal data, public sector bodies, natural or legal persons to which the right to re-use data was granted, *providers of* data *intermediation services* and entities entered in the register of recognised data altruism organisations should take all reasonable measures to prevent access to the systems where non-personal data is stored, including encryption of data, *cybersecurity measures* or corporate policies.

(19)In order to build trust in re-use mechanisms, it may be necessary to attach stricter conditions for certain types of non-personal data that have been identified as highly sensitive by a specific Union act, as regards the transfer to third countries, if such transfer could jeopardise public policy objectives, in line with international commitments. For example, in the health domain, certain datasets held by actors in the public health system, such as public hospitals, could be identified as highly sensitive health data. In order to ensure harmonised practices across the Union, such types of highly sensitive non-personal public data should be defined by Union law, for example in the context of the European Health Data Space or other sectoral legislation. Insurance companies or any other service provider entitled to access information stored in e-health applications should not be allowed to use those data for the purpose of discriminating in the setting of prices, as this would run counter to the fundamental right of access to health. The conditions attached to the transfer of such data to third countries should be laid down in delegated acts. Conditions should be proportionate, and non-discriminatory, should not restrict competition and should be and necessary to protect legitimate public policy objectives identified, such as the protection of public health, public order, safety, the environment, public morals, consumer protection, privacy and personal data protection. The conditions should correspond to the risks identified in relation to the sensitivity of such data, including in terms of the risk of the re-identification of individuals. These conditions could include terms applicable for the transfer or technical arrangements, such as the requirement of using a secure processing environment, limitations as regards the re-use of data in third-countries or categories of persons which are entitled to transfer such data to third countries or who can access the data in the third country. In exceptional cases they could also include restrictions on transfer of the data to third countries to protect the public interest.

(43) In order to take account of the specific nature of certain categories of data, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to lay down special conditions applicable for transfers to third-countries of certain non-personal data categories deemed to be highly sensitive in specific Union acts adopted though a legislative procedure. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those

consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Articles

Article 5 – paragraph 1 1. Public sector bodies which are competent under national law to grant or refuse access for the re-use of one or more of the categories of data referred to in Article 3(1) shall *be equipped with the necessary human and financial resources and shall* make publicly available the conditions for allowing such re-use *and the procedure to request the re-use via the single information point referred to in Article 8*. In that task, they may be assisted by the competent bodies referred to in Article 7(1).

Article 5 – paragraph 2 (2) Conditions for re-use shall be non-discriminatory, *transparent*, proportionate and objectively justified with regard to categories of data and purposes of re-use and the nature of the data for which re-use is allowed. These conditions shall not be *used to restrict competition, including by being constructed in a way to pose restrictions to participate for SMEs, start-ups or civil society actors*.

Article 5 – paragraph 3 (3) Public sector bodies *shall ensure* may impose an obligation that the protected nature of data is preserved, which may include providing for the following requirements:

(a) to only grant access to re-use only previously processed data where the public sector body or the competent body has ensured that data has been where such pre-processing, performed by the public sector bodies, aims to anonymised or pseudonymised in the case of personal data, or delete and that data has been modified, aggregated or treated by any other method of disclosure control in the case of commercially confidential information, including trade secrets or content protected by intellectual property rights. Where data for re-use has been pseudonymised it may only be accessed within a secure processing environment;

Article 5 paragraph 4 introductory part 4. [*In duly justified circumstances*] public sector bodies may impose obligations:

Article 5 paragraph 4 point a (ab) to access and re-use the data *remotely* within a secure processing environment provided *or* controlled by the public sector *body*;

Article 5 paragraph 4 point b (bc) to access and re-use the data within the physical premises in which the secure processing environment is located *in accordance with high security standards*, if remote access cannot be allowed without jeopardising the rights and interests of third parties.

Article 5 – paragraph 5 (5) The public sector bodies shall impose conditions that preserve the integrity of the functioning of the technical systems of the secure processing environment used, *including high level cybersecurity standards*. The public sector body shall be able reserve the right to verify the process, the means and any results of processing of data undertaken by the re-user and reserve the right, *after giving the re-user the possibility to provide further information*, to prohibit the use of results that contain information jeopardising

the rights and interests of third parties such as intellectual property rights, trade secrets or the rights referred to in Regulation (EU) 2016/679. Re-use of data shall be conditional on the adherence by the re-user to a confidentiality agreement.

Article 5 – paragraph 6 (6) Where the re-use of data cannot be granted in accordance with the obligations laid down in paragraphs 3 to 5 and there is no other legal basis for transmitting the data under Regulation (EU) 2016/679, the public sector body shall support re-users in seeking *valid* consent of the data subjects *insofar as a legal basis exists for the public sector body to collect their consent*, and/or permission from the legal entities whose rights and interests may be affected by such re-use, where it is feasible without disproportionate cost for the public sector, *and where there is no reason to believe that the combination of non-personal data sets would lead to the identification of data subjects*. In that task they may be assisted by the competent bodies referred to in Article 7 (1).

Article 5 – paragraph 6 a (new) (6a) Where public sector bodies make available personal data for re-use pursuant to this Article, the public sector bodies shall support data subjects in exercising their rights, including in relation to any re-users. In that task they may be assisted by the competent bodies referred to in Article 7 (1).

Article 5 – paragraph 7 (7) Re-use of data shall only be allowed in compliance with intellectual property rights. The right of the maker of a database as provided for in Article 7(1) of Directive 96/9/EC shall not be exercised by public sector bodies in order to prevent the re-use of data or to restrict re-use beyond the limits set by this Regulation.

Article 5 – paragraph 8 (8) When data requested is considered confidential, in accordance with Union or national law on commercial confidentiality, the public sector bodies shall ensure that the confidential information is not disclosed as a result of the re-use.

Article 5 – paragraph 9 (9) In consultation with the European Data Innovation Board and where justified by the volume of requests for re-use of non-personal data from specific third countries, the Commission may is empowered to adopt delegated acts in accordance with Article 28, supplementing this Regulation by declaring that the legal, supervisory and enforcement arrangements of a that specific third country:

(a) ensure protection of intellectual property and trade secrets in a way that is essentially equivalent to the protection ensured under Union law;

(b) are being effectively applied and enforced; and

(c) provide effective judicial redress.

Those *delegated* acts shall be *without prejudice to the adequacy decisions set out in Article* 45 of Regulation (EU) 2016/679, including in cases where personal and non-personal data are inextricably linked. adopted in accordance with the procedure referred to in Article.

Article 5 – paragraph 10 (10) Public sector bodies shall only transmit *non-personal* confidential data or data protected by intellectual property rights to a re-user which intends to transfer th*at*e data to a third country other than a country designated in accordance with paragraph 9 *only* if the re-user undertakes *to*:

(a) to comply with the obligations imposed in accordance with paragraphs 7 to 8 even after the data is transferred to the third country; and

(b) to accept the jurisdiction of the courts of the Member State of the *transmitting* public sector body as regards any dispute related to the compliance with *paragraphs 7 and 8* the obligation in point a).

Public sector bodies shall provide guidance and support, where relevant and to the extent of their capabilities, for complying with the obligations referred to in the first subparagraph, in particular to support re-users.

The Commission shall issue guidelines on the obligations referred to in the first subparagraph, in particular to support re-users.

The Commission shall also, by means of implementing acts, establish standard contractual clauses for the transfer by re-users of non-personal data to a third country as referred to in the first subparagraph.

The implementing acts referred to in the fourth subparagraph of this paragraph shall be adopted in accordance with the advisory procedure referred to in Article 29(2).

Article 5 – paragraph 11 (11)Where Specific Union acts adopted in accordance with a legislative procedure *may* establish that certain non-personal data categories held by public sector bodies shall be deemed to be highly sensitive for the purposes of this Article, where their transfer to third countries may put at risk Union policy objectives, such as safety and public health, or may lead to the risk of re-identification of anonymised data. The Commission shall be empowered to adopt delegated acts in accordance with Article 28 supplementing this Regulation by laying down special conditions applicable for transfers to third-countries, based on the recommendations from the European Data Innovation Board. The conditions for the transfer to third-countries shall be based on the nature of data categories identified in the Union act and on the grounds for deeming them highly sensitive, nondiscriminatory and limited to what is necessary to achieve the public policy objectives identified in the Union law act, such as safety and public health, as well as risks of reidentification of anonymized data for data subjects, in accordance with the Union's international obligations. They may include terms applicable for the transfer or technical arrangements in this regard, limitations as regards the re-use of data in third-countries or categories of persons which are entitled to transfer such data to third countries or, in exceptional cases, restrictions as regards transfers to third-countries.

Article 5 – paragraph 12 (12) The natural or legal person to which the right to re-use non-personal data was granted may transfer the data only to those third-countries for which the requirements in paragraphs 9 to 11 are met.

Article 5 – paragraph 13 (13) Where the re-user intends to transfer non-personal data to a third country, the public sector body shall inform the data holder about the *intention to* transfer of data to that third country *and the purpose of such a transfer*.

Article 30 – paragraph 1 1. The public sector body, the natural or legal person to which the right to re-use data was granted under Chapter 2II, the *provider of* data *intermediation services* or the entity entered in the register of recognised data altruism organisations, as the case may be, shall take all reasonable technical, legal and organisational measures in order to prevent transfer or access to non-personal data held in the Union where

such transfer or access would create a conflict with Union law or the law of the relevant Member State, unless the transfer or access are in line with paragraph 2 or 3.

Article 30 – paragraph 2 2. Any judgment of a court or tribunal and any decision of an administrative authority of a third country requiring a public sector body, a natural or legal person to which the right to re-use data was granted under Chapter 2II, a *provider of* data *intermediation services* or entity entered in the register of recognised data altruism organisations to transfer from or give access to non-personal data subject to this Regulation in the Union may only be recognised or enforceable in any manner if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State concluded before [the entry into force of this Regulation].

Article 30 – paragraph 3 – introductory part 3. In the absence of international agreements regulating such matters, where a public sector body, a natural or legal person to which the right to re-use data was granted under Chapter 2II, a provider of data intermediation services or entity entered in the register of recognised data altruism organisations is the addressee of a decision of a court or of an administrative authority of a third country to transfer from or give access to non-personal data held in the Union and compliance with such a decision would risk putting the addressee in conflict with Union law or with the law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only:

Article 30 – paragraph 3 – subparagraph 1 The addressee of the decision shall ask the opinion of the relevant competent bodies or authorities, pursuant to this Regulation, in order to determine if these conditions are met. *The relevant competent bodies may exchange information on international access requests in the framework of the European Data Innovation Board.*

Article 30 – paragraph 3 – subparagraph 2 The addressee of the decision shall ask the opinion of the relevant competent bodies or authorities, pursuant to this Regulation, in order to determine if these conditions are met.

Article 30 – paragraph 4 4. If the conditions in paragraph 2, or 3 are met, the public sector body, the natural or legal person to which the right to re-use data was granted under Chapter 2*II*, the *provider of* data *intermediation services* or the entity entered in the register of recognised data altruism organisations, as the case may be, shall, provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.

Article 30 – paragraph 5 5. The public sector body, the natural or legal person to which the right to re-use data was granted under Chapter 211, the *provider of* data *intermediation services* and the entity providing data altruism shall inform the data holder *or data subject* about the existence of a request of an administrative authority in a third-country to access its data *before complying with the request*, except in cases where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.

CA 6: Fees (covers Art 6, Rec 20)

All relevant AMs fall, including: AMs 32, 182-186, 418-431, IMCO 16, IMCO 68-70, LIBE 17, LIBE 83-85, JURI 22, JURI 71-72

Recitals

(20) Public sector bodies should be able to charge fees for the re-use of data *to cover the costs of providing for such data re-use*, but should also be able to decide to make the data available at lower or no cost, for example for certain categories of re-uses such as non-commercial re-use, or re-use by small and medium-sized enterprises*SMEs and start-ups, civil society and educational establishments*, so as to incentivise such re-use in order to stimulate research and innovation and support companies that are an important source of innovation and typically find it more difficult to collect relevant data themselves, in line with State aid rules. Such fees should be *reasonable proportionate to the costs incurred*, transparent, published online, non-discriminatory *and should not restrict competition*. *A list of categories of re-users to which a discounted fee or no charge applies, together with the criteria used to establish that list, should be made public.*

Articles

Article 6 – paragraph 1 (1) Public sector bodies which allow re-use of the categories of data referred to in Article 3 (1) may charge fees for allowing the re-use of such data.

Article 6 – paragraph 2 (2) Any fees *charged pursuant to paragraph 1* shall be *transparent*, non-discriminatory, proportionate *with the cost of making available data for re-use*, and objectively justified and shall not restrict competition.

Article 6 – paragraph 3 (3) Public sector bodies shall ensure that any fees can *also* be paid online through widely available cross-border payment services, without discrimination based on the place of establishment of the payment service provider, the place of issue of the payment instrument or the location of the payment account within the Union.

Article 6 – paragraph 4 4. Where they apply fees, public sector bodies shall take measures to incentivise the re-use of the categories of data referred to in Article 3(1) for noncommercial purposes and by small and medium sized enterprises SMEs and start-ups in line with State aid rules. In that regard, public sector bodies may also make the data available at a discounted fee or free of charge, in particular to SMEs and start-ups, civil society and educational establishments.

To that end, public sector bodies may establish a list of categories of re-users to which data is made available at a discounted fee or free of charge. That list, together with the criteria used to establish it, shall be made public.

Article 6 – paragraph 5 (5) Fees shall be derived from the costs related to the processing of requests for re-use of the categories of data referred to in Article 3 (1). The methodology for calculating fees shall be published in advance.

CA 7: Competent body and single information point (covers Art 7, 8, Rec 21)

All relevant AMs fall, including: AMs 33-43, 187-190, 432-456, IMCO 71-78, LIBE 18, LIBE 86-93, JURI 23, JURI 73-78

Recitals

In order to incentivise and promote the re-use of these categories of data, Member (21)States should establish a single information point to act as the primary interface for re-users that seek to re-use such data held by the public sector bodies. It should have a cross-sector remit, and should complement, if necessary, arrangements at the sectoral level. In addition, Member States should designate, establish or facilitate the establishment of competent bodies to support the activities of public sector bodies allowing re-use of certain categories of protected data. Their tasks may include granting access to data, where mandated in sectoral Union or Member States legislation and developing a harmonised approach and processes, where applicable, for public sector bodies to make scientific data available for purposes of research. Those competent bodies should provide support to public sector bodies with stateof-the-art techniques, including secure data processing environments, which allow data analysis in a manner that preserves the privacy of the information. Such support structure could support the data holders or data subjects with management of the consent and permission, including consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Without prejudice to the supervisory powers of data protection authorities, Ddata processing should be performed under the responsibility of the public sector body responsible for the register containing the data, who remains a data controller in the sense of Regulation (EU) 2016/679 insofar as personal data are concerned. Member States may have in place one or several competent bodies, which could act in different sectors, while fully respecting the powers of supervisory authorities under Regulation (EU) 2016/679.

Articles

Article 7 – paragraph 1 (1) Member States shall designate one or more competent bodies, which may be sectoral, to support the public sector bodies which grant access to the reuse of the categories of data referred to in Article 3 (1) in the exercise of that task. *In order to fulfil the requirements set out in this Regulation, Member States may delegate the tasks to an existing competent body or bodies, as long as requirements laid down in paragraph 4 are of this Article are met.*

Article 7 – paragraph 2 – point a (a) providing technical support by making available a secure processing environment for providing access for the re-use of data;

Article 7 – paragraph 2 – point a a (new) (aa) providing guidance and technical support on how to best structure and store data to make data easily accessible, in particular through application programming interfaces, interoperable, transferable and searchable, taking into account best practices for data processing, as well as any existing regulatory and technical standards;

Article 7 – paragraph 2 – point b (b) providing technical support in the application of tested techniques for pseudonymisation and ensuring data processing in a manner that effectively preserves the privacy, integrity and accessibility of the information contained in the data for which re-use is allowed, including techniques for the pseudonymisation, anonymisation, generalisation, suppression, randomisation of personal data or other state-of-the-art privacy preserving methods, and the deletion of commercially confidential information, including trade secrets or content protected by intellectual property rights;

Article 7 – paragraph 2 – point c (c) assisting the public sector bodies, where relevant, in obtaining consent or permission by re-users for re-use for altruistic and other purposes in line with specific decisions of data holders, including on the jurisdiction or jurisdictions in which the data processing is intended to take place *and assisting the public sector bodies in establishing technical mechanisms that allow the transmission of requests for consent from re-users, where practically feasible;*

Article 7 - paragraph 2 - point c a (new) (c a) developing a harmonised approach and processes, where applicable, for public sector bodies to make scientific data available for purposes of research;

Article 7 – paragraph 2 – point d (d) providing public sector bodies with assistance on the adequacy *and compliance* of undertakings made by a re-user, pursuant to Article 5 (10).

Article 7 – paragraph 3 3. The competent bodies may also be entrusted, pursuant Union or national law which provides for such access to be given, to grant access for the reuse of the categories of data referred to in Article 3 (1). While performing their function to grant or refuse access for re-use, Articles 4, 5 *and* 6 shall apply in regard to such competent bodies.

Article 7 – paragraph 3 a (new) 3a. Requests for the re-use of the categories of data referred to in Article 3(1) shall be granted or refused by competent public sector bodies or the competent bodies referred to in paragraph 1 of this Article without delay and in any event within two months of the date of the request. In order to contribute to a consistent application of this Regulation, competent public sector bodies shall cooperate with each other, and where relevant with the Commission, when refusing requests for the re-use of the categories of data referred to in Article 3 (1).

Article 7 – paragraph 3 b (new) 3b. Any natural or legal person affected by a decision of a public sector body or of a competent body, as the case may be, shall have the right to an effective judicial remedy against such a decision before the courts of the Member State where the relevant body is located.

Article 7 – paragraph 4 4. The competent body or bodies shall have adequate legal, *financial* and technical capacities and expertise *and shall be sufficiently staffed with skilled personnel* to be able to comply with relevant Union or national law concerning the access regimes for the categories of data referred to in Article 3(1).

Article 7 – paragraph 5 (5) The Member States shall *make public and* communicate to the Commission the identity of the competent bodies designated pursuant to paragraph 1 by ... [date of application of this Regulation]. They shall also *make public and* communicate to the Commission any subsequent modification of the identity of those bodies.

Article 8 – paragraph 1 (1) Member States shall ensure that all relevant information concerning the application of Articles 5 and 6 is available *and easily accessible* through a single information point.

Article 8 – paragraph 2 2. The single information point shall receive requests for the re-use of the categories of data referred to in Article 3(1) and shall transmit them, *where possible and appropriate by automated means*, to the competent public sector bodies, or the competent bodies referred to in Article 7(1), where relevant. The single information point shall make available by electronic means a *searchable* register of available data resources containing relevant information describing the nature of available data, *including at least the data format and size and the conditions for its re-use*.

Article 8 – paragraph 2 a (new) 2a. The single information point shall offer an electronic, public register of single information points of all other Member States and shall be linked to the Single Digital Gateway established by Regulation (EU) 2018/1724 of the European Parliament and of the Council^{xx}.

^{xx} Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1)

Article 8 – paragraph 2 aa (new) (2 aa) The single information point may establish a separate, simplified and well-documented information channel for SMEs and start-ups, addressing their needs and capabilities in requesting the re-use of the categories of data referred to in Article 3 (1).

Article 8 – paragraph 2 b (new) 2b. The Commission shall establish a European single information point offering a searchable electronic register of data available in the national single information points and further information on how to request data via those single information points.

Article 8 – paragraph 3 (3) — Requests for the re use of the categories of data referred to in Article 3 (1) shall be granted or refused by the competent public sector bodies or the competent bodies referred to in Article 7 (1) within a reasonable time, and in any case within two months from the date of the request.

Article 8 – paragraph 4 (4) Any natural or legal person affected by a decision of a public sector body or of a competent body, as the case may be, shall have the right to an effective judicial remedy against such decision before the courts of the Member State where the relevant body is located.

<u>CA 8: Providers of data intermediation services incl. conditions and exception (covers</u> <u>Art 2(4), 2(15), 9, 11, 14, Rec 22, 23, 24, 25, 26, 27, 28, 29)</u>

All relevant AMs fall, including: AMs 9-14, 22-24, 44-48, 66-79, 191-225, 296-297, 302-303, 316-317, 319, 329, 337, 392, 457-473, 500-516, 518-531, 549-554, IMCO 17-22, IMCO 37-38, IMCO 46, IMCO 79-82, IMCO 95-109, IMCO 122, LIBE 19-26, LIBE 47, LIBE 52, LIBE 59, LIBE 94-100, LIBE 118-130, LIBE 138, JURI 24-29, JURI 42-43, JURI 51, JURI 79-82, JURI 95-102, JURI 105-107

Recitals

Providers of *dData* s having services (data intermediaries) *intermediation* services) (22)are expected to play a key role in the data economy, as a tool to facilitate the aggregation and exchange of substantial amounts of relevant data. Providers of data intermediaries intermediation services, which can also include public sector bodies, offering services that connect the different actors have the potential to contribute to the efficient pooling of data as well as to the facilitation of bilateral data sharing. Specialised data intermediaries intermediation services that are independent from both data holders and data users can have a facilitating role in the emergence of new data-driven ecosystems independent from any player with a significant degree of market power, while allowing non-discriminatory access to the data economy for actors of all sizes, in particular SMEs and start-ups with limited *financial, legal or administrative means.* This Regulation should only cover data intermediation services with the main objective of establishing relationships through of a business, a legal, and potentially also technical or other means relation between an undetermined number of data holders or data subjects, including data subjects, and potential data users and which assist both parties in a transaction of data assets between the two to enable or facilitate the sharing, exchange, or pooling of data, under open data or commercial licenses for non-personal data, for a fee or free of cost.

(22a) Where businesses and other actors offer multiple data-related services, including cloud storage, analytics or other value-adding data services, only the activities which directly concern the provision of data intermediation services are covered by this Regulation. It should only cover services aiming at intermediating between an indefinite number of data holders and data users, excluding Data sharing intermediation services that are exclusively used by one data holder in order to enable the use of data they hold, or for the purpose of exchanging data by multiple legal entities in a closed group, including contractually-defined collaborations or supplier or customer relationships, in particular those that have as a main objective the ensuring of functionalities of objects and devices connected to the Internet-of-Things are excluded from the scope of this Regulation. Valueadded data services, which aggregate, transform or combine data with other data, or analyse it for the purpose of adding substantial value to it and make available the use of the resulting data to data users, as well as auxiliary technical, legal, financial or administrative support services, are also excluded from the scope of this Regulation. Providers of cloud infrastructure services should be excluded, as well as service providers that obtain data from data holders, aggregate, enrich or transform the data and licence the use of the resulting data to data users, without establishing a direct relationship between data holders and data users, for example advertisement or data brokers, data consultancies, providers of data products resulting from value added to the data by the service provider. At the same time, providers of data intermediation services should be allowed to make adaptations to the data exchanged, *in order to improve* the usability of the data by the data

user, where the data user so desires this, or improve interoperability such as to convert it into specific formats. In addition, services that focus on the intermediation of content, in particular on copyright-protected content, should not be covered by are excluded from the scope of this Regulation. Data exchange platforms *[Intermediation] Services* that are exclusively used by one data holder in order to enable the use of data they hold as well as platforms developed in the context of objects and devices connected to the Internet of Things with the main objective of ensuring functionalities of the connected object or device and allow value added services, should not be covered by are excluded from the scope of this Regulation. 'Consolidated tape providers' in the sense of Article 4 (1) point 53 of Directive 2014/65/EU of the European Parliament and of the Council⁴² as well as 'account information service providers' in the sense of Article 4 point 19 of Directive (EU) 2015/2366 of the European Parliament and of the Council⁴³ should not be considered as to be providers of data intermediation services for the purposes of this Regulation. Entities which restrict their activities to facilitating use of data made available on the basis of data altruism and that operate on a not-for-profit basis should not be covered by Chapter III of this Regulation, as this activity serves objectives of general interest by increasing the volume of data available for such purposes.

(23)A specific category of *providers of* data intermediation services includes providers of data sharing intermediation services that offer their services to data subjects in the sense of Regulation (EU) 2016/679. Such providers focus exclusively on personal data and seek to enhance individual agency and *in particular* the individuals' control over the data *relating* pertaining to them. They would assist individuals in exercising their rights under Regulation (EU) 2016/679, in particular managing giving and withdrawing their consent to data processing, the right of access to their own data, the right to the rectification of inaccurate personal data, the right of erasure or right 'to be forgotten', the right to restrict processing and the data portability right, which allows data subjects to move their personal data from one controller to the other. In this context, it is important that their business model ensures that there are no misaligned incentives that encourage individuals to make more data available for processing than what is in the individuals' own interest. This could include advising individuals on uses of their data they could allow and making due diligence checks on data users before allowing them to contact data subjects, in order to avoid fraudulent practices. In certain situations, it could be desirable to collate actual data within a personal data storage space, or 'personal data space' so that processing can happen within that space without personal data being transmitted to third parties in order to maximise the protection of personal data and privacy.

(24) Data cooperatives seek to *achieve a number of objectives, in particular to* strengthen the position of individuals in making informed choices before consenting to data use, influencing the terms and conditions of data user organisations attached to data use *in a manner that gives better choices to the individual members of the group* or potentially solving disputes between *finding solutions to conflicting positions of individual* members of a group on how data can be used when such data pertain *relates* to several data subjects within that group. In this context it is important to acknowledge that the rights under Regulation (EU) 2016/679 can only be exercised by each individual and cannot be conferred or delegated to a data cooperative. Data cooperatives could also provide a useful means for one-person companies, micro, small and medium sized enterprises and SMEs that in terms of knowledge of data sharing, are often comparable to individuals. (25) In order to increase trust in such data sharing intermediation services, in particular related to the use of data and the compliance with the conditions imposed by data holders or *data subjects*, it is necessary to create a Union-level regulatory framework, which would set out highly harmonised requirements related to the trustworthy provision of such data sharing intermediation services. This will contribute to ensuring that data holders, data subjects and data users have better control over the access to and use of their data, in accordance with Union law. Both in situations where data sharing occurs in a business-to-business context and where it occurs in a business-to-consumer context, providers of data intermediation services should offer a novel, 'European' way of data governance, by providing a separation in the data economy between data provision, intermediation and use, which is at the core of increasing such trust among data holders, be they individuals or businesses. Providers of data intermediation services may also make available specific technical infrastructure for the interconnection of data holders and data users. In that regard, it is of particular importance to shape that infrastructure in such a way that SMEs and start-ups encounter no technical or other barriers to their participation in the data economy.

(25 a) Providers of data intermediation services which meet the requirements laid down in this Regulation should be able to use the title 'providers of data intermediation services recognised in the Union'. In order to assist data subjects and legal entities to easily identify, and thereby increase their trust in, providers of data intermediation services recognised in the Union, a common logo that is recognisable throughout the Union should be established. In order to ensure uniform conditions for the application of that logo, implementing powers should be conferred on the Commission to establish a design for that common logo.

(26)It is important to enable a competitive environment for data sharing. A key element to bring trust and more control for data holders, data subjects and data users in data sharing intermediation services is the neutrality of providers of data intermediation services as regards the data exchanged between data holders or data subjects and data users. It is therefore necessary that providers of data intermediation services act only as intermediaries in the transactions, and do not use the data exchanged for any other purpose. The pricing and terms of data intermediation services should not be made dependent on whether or to what extent a potential data holder or data user is using other services, including storage, analytics, Artificial Intelligence or other data-based applications, provided by the same provider or a related entity. This will also require structural separation between the data sharing intermediation service and any other services provided, so as to avoid issues of conflict of interest. This means that the data sharing intermediation service should be provided through a legal entity that is separate from the other activities of that *provider of* data intermediation services. Providers of data intermediation services should, however, be able to put at the disposal of data holders, data subjects or data users their own or thirdparty tools for the purpose of facilitating the exchange of data, for example tools for the analysis, conversion or aggregation of data only at the explicit request or approval of the data subject or data holder. The third-party tools offered in that context shall not use data for purposes other than those related to data intermediation services. Providers of data intermediation services that intermediate the exchange of data between individuals as data holders subjects and legal persons as data users should, in addition, bear fiduciary duty towards the individuals, to ensure that they act in the best interest of the data holders subjects.

(26 a) Providers of data intermediation services should take reasonable measures to ensure interoperability with other data intermediation services to ensure the proper

functioning of the market. Reasonable measures could include employing commonly used standards. The European Data Innovation Board should facilitate the emergence of additional standards, where necessary.

In order to ensure the compliance of the providers of data intermediation services (27)with the conditions set out in this Regulation, such providers of such services should have a place of establishment in the Union. Where a provider of data intermediation services not established in the Union offers services within the Union, it should designate a *legal* representative. Designation of a *legal* representative *in such cases* is necessary, given that such *providers of data intermediation services* handle personal data as well as commercially confidential data, which necessitates the close monitoring of the compliance of *providers of* data intermediation services with the conditions laid out in this Regulation. In order to determine whether such a provider of data intermediation services is offering services within the Union, it should be ascertained whether it is apparent that the provider of data intermediation services is planning to offer services to persons in one or more Member States. The mere accessibility in the Union of the website or of an email address and of other contact details of the provider of data intermediation services, or the use of a language generally used in the third country where the *provider of data intermediation services* is established, should be considered insufficient to ascertain such an intention. However, factors such as the use of a language or a currency generally used in one or more Member States with the possibility of ordering services in that other language, or the mentioning of users who are in the Union, may make it apparent that the provider of data intermediation services is planning to offer services within the Union. The *designated legal* representative should act on behalf of the *provider of data intermediation services* and it should be possible for competent authorities to contact the *legal* representative, *including in the case of an infringement, to* initiate enforcement proceeding against a non-compliant provider of data intermediation services not established in the Union. The legal representative should be designated by a written mandate of the provider of data intermediation services to act on the latter's behalf with regard to the latter's obligations under this Regulation. *The designation of such a legal* representative does not affect the responsibility or liability of the provider of data intermediation services under this Regulation. The legal representative should perform its tasks in accordance with the mandate received from the provider of data intermediation services, including cooperating with and comprehensively demonstrating to the competent authorities, upon request, the actions taken and provisions put in place by the provider to ensure compliance with this Regulation. Where a provider of data intermediation services that is not established in the Union fails to designate a legal representative, or such legal representative fails to comply with its obligations under this Regulation, the competent authority should have the power to impose the immediate cessation of the provision of the data intermediation service. In the case of processing of personal data, the previously mentioned providers of data intermediation services not established in the Union should be subject to the rules and principles of the GDPR.

(28) This Regulation should be without prejudice to the obligation of *providers of data intermediation services* to comply with Regulation (EU) 2016/679 and the responsibility of supervisory authorities to ensure compliance with that Regulation. *When providers of data intermediation services process personal data, this Regulation should not affect the protection of personal data.* Where the *providers of* data *intermediation services* are data controllers or processors in the sense of Regulation (EU) 2016/679 they are bound by the rules of that Regulation. This Regulation should be also without prejudice to the application of competition law.

28 a (new) Providers of data intermediation services should have in place procedures and measures to sanction fraudulent or abusive practices in relation to access to data from parties seeking access through their services, including through measures such as the exclusion of data users that breach the terms of service or violate existing legislation.

(29) **Providers of data intermediation services** should also take *effective* measures to ensure compliance with competition law. Data sharing may generate various types of efficiencies but may also lead to restrictions of competition, in particular where it includes the sharing of competitively sensitive information. This applies in particular in situations where data sharing enables businesses to become aware of market strategies of their actual or potential competitors. Competitively sensitive information typically includes information on future prices, production costs, quantities, turnovers, sales or capacities.

29 a (new) Member States should lay down rules on penalties for the infringements of this Regulation, and should ensure that those rules are implemented. Those penalties should be effective, proportionate and dissuasive. Large discrepancies between rules on penalties among Member States should be avoided in order not to distort competition in the Digital Single Market. To facilitate a more consistent application of penalties, nonexhaustive and indicative criteria for the application of penalties should be included in this Regulation.

Articles

Article 2 paragraph 1 point 4 (4) 'metadata' means data collected on any activity of a natural or legal person for the purposes of the provision of a data sharing service, including the date, time and geolocation data, duration of activity, connections to other natural or legal persons established by the person who uses the service;

Article 2 – paragraph 1 – point 15 (15) '*legal* representative' means a natural or legal person established in the Union explicitly designated to act on behalf of a *provider of data intermediation service* or an entity that collects data for objectives of general interest made available by natural or legal persons on the basis of data altruism not established in the Union, which may be addressed by a national competent authority instead of the *provider of data intermediation service* or entity with regard to the obligations of that *provider of data intermediation service* or entity set up *under by* this Regulation, *including to initiate enforcement proceeding against a non-compliant provider of data intermediation services or a data altruism organisation not established in the Union*.

Article 2 – paragraph 1 – point 15 a (new) (15a) 'data intermediation service' means a service, which establishes relationships through technical, legal or other means between an undetermined number of data holders or data subjects and data users to enable or facilitate the sharing, exchange, or pooling of data, under open data or commercial licenses for non-personal data, for a fee or free of cost, not including:

(a) value-added data services, which aggregate data, transform or combine data with other data, or analyse it for the purpose of adding substantial value to it and make available the use of the resulting data to data users, unless they have a direct relationship with data holders for the purpose of data intermediation services; (b) services, exclusively used by one data holder in order to enable the use of data they hold, or used by multiple legal entities in a closed group, including contractually-defined collaborations or supplier or customer relationships, in particular those that have as a main objective the ensuring of functionalities of objects and devices connected to the Internet-of-Things

(c) services that focus on the intermediation of copyright-protected content;

(d) services of consolidated tape providers as defined in point (53) of Article 4(1) of Directive 2014/65/EU and account information service providers as defined in point 19 of Article 4 of Directive(EU) 2015/2366;

Article 2 - paragraph 1 - point 15 b (new) (15b) 'services of data cooperative' means services that support data subjects, one-person companies or SMEs, who are members of the cooperative or who confer power on the cooperative to negotiate terms and conditions for data processing before they consent, in making informed choices before consenting to data processing, and allowing for mechanisms to exchange views on data processing purposes and conditions that would best represent the interests of data subjects or legal persons.

Article 9 – title **Data intermediation services**

Article 9 – paragraph 1 – introductory part 1. *This Chapter applies to the provision of data intermediation services. These* the following data sharing services shall be subject to a notification procedure *include*:

Article 9 – paragraph 1 – point a (a) intermediation services between data holders which are legal persons and potential data users, including making available the technical or other means to enable such services; those services may include bilateral or multilateral exchanges of data or the creation of platforms or databases enabling the exchange or joint exploitation of data, as well as the establishment of a specific infrastructure for the interconnection of data holders and data users;

Article 9 – paragraph 1 – point b (b) intermediation services between data subjects that seek to make their personal data available and potential data users, including making available the technical or other means to enable such services, *and in particular enabling* in the exercise of the *data subjects'* rights provided in Regulation (EU) 2016/679;

Article 9 – paragraph 1 – point c (c) services of data cooperatives, that is to say services supporting data subjects or one-person companies or micro, small and medium-sized enterprises, who are members of the cooperative or who confer the power to the cooperative to negotiate terms and conditions for data processing before they consent, in making informed choices before consenting to data processing, and allowing for mechanisms to exchange views on data processing purposes and conditions that would best represent the interests of data subjects or legal persons.

Article 9 – paragraph 2 2. This Chapter shall be without prejudice to the application of other Union and national law to *data intermediation services*, including powers of supervisory authorities to ensure compliance with applicable law, in particular as regard the protection of personal data and competition law.

Article 9 – paragraph 2 a (new) 2a. The provision of data intermediation services shall be subject to Articles 10 and 11.

Article 9 – paragraph 2 b (new) 2b. The competent authority referred to in Article 12 shall confirm, upon the request of a provider of data intermediation services, that the provider complies with Articles 10 and 11. Upon receipt of such a confirmation, that provider may use the title 'provider of data intermediation services recognised in the Union' in its written and spoken communication, as well as a common logo.

In order to ensure that providers of data intermediation services recognised in the Union are easily identifiable throughout the Union, the Commission shall, by means of implementing acts, establish a design for the common logo. Providers of data intermediation services recognised in the Union shall display the common logo clearly on every online and offline publication that relates to their data intermediation activities.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 29(2).

Article 11 – title Conditions for providing data sharing intermediation services

Article 11 – paragraph 1 – point 1 (1) the provider *of data intermediation services* may not use the data for which it provides services for other purposes than to put them at the disposal of data users; and data sharing *intermediation* services shall be placed in a separate legal entity;

Article 11 – paragraph 1 – point 1 (new) (1a) the commercial terms, including pricing, for the provision of data intermediation services to a data holder or data user may not be made dependent upon whether or to what degree the data holder or data user uses other services from the same provider, or a related entity;

Article 11 – paragraph 1 – point 2 2) the metadata collected with respect to any activity of a natural or legal person for the purposes of from the provision of the data sharing intermediation service, including the date, time and geolocation data, duration of activity and connections to other natural or legal persons established by the person who uses the service, shall be used only for the development of that service, which may entail the use of data for the detection of fraud or cybersecurity, and shall be made available to the data holders upon request;

Article 11 – paragraph 1 – point 3 (3) the *provider of data intermediation services* shall ensure that the procedure for access to its service is fair, transparent and non-discriminatory for both data *subjects and data* holders and *as well as for* data users, including as regards prices *and terms of service*;

Article 11 – paragraph 1 – point 4 (4) the *provider of data intermediation service* shall facilitate the exchange of the data in the format in which it receives it from the data holder *or data subject* and shall convert the data into specific formats only to enhance interoperability within and across sectors or if requested by the data user or where mandated by Union law or to ensure harmonisation with international or European data standards;

Article 11 – paragraph 1 – point 4 a (new) (4a) data intermediation services may include offering additional specific tools and services to data holders or data subjects for

the purpose of facilitating the exchange of data, such as analysis, temporary storage, aggregation, curation, conversion, anonymisation, pseudonymisation; those tools and services shall be used only at the explicit request or approval of the data holder or data subject and third-party tools offered in that context shall not use data for other purposes;

Article 11 – paragraph 1 – point 5 (5) the *provider of data intermediation service* shall have procedures *and measures* in place to prevent *and monitor potential* fraudulent or abusive practices in relation to access to data from parties seeking access through their services;

Article 11 – paragraph 1 – point 6 (6) the *provider of data intermediation service* shall ensure a reasonable continuity of provision of its services and, in the case of services which ensure storage of data, shall have sufficient guarantees in place that allow data holders and data users to obtain access to, *to transfer or to retrieve* their data *or, in the case of providing intermediation services between data subjects and data users, allow data subjects to exercise their rights*, in case of insolvency *of the provider*;

Article 11 – paragraph 1 – point 6 a (new) (6a) the provider of data intermediation services shall avoid lock-in effects and shall ensure interoperability with other data intermediation services to the extent appropriate, in particular as regards data formats and other data standards and by means of commonly used, formal or informal, open standards in the sector in which the data intermediation services operate. To that effect, within 12 months of entry into force of this Regulation, the Commission shall, in consultation with the Data Innovation Board, develop guidance on interoperability standards;

Article 11 – paragraph 1 – point 7 (7) the *provider of data intermediation service* shall put in place adequate technical, legal and organisational measures in order to prevent transfer or access to non-personal data that is unlawful under Union law;

Article 11 – paragraph 1 – point 8 (8) the *provider of data intermediation services* shall take measures to ensure a high level of security, *including state-of-the-art cybersecurity standards*, for the storage, *processing* and transmission of non-personal data, *and the provider shall further ensure the highest level of security, including state-of-the-art cybersecurity, for the storage and transmission of competitively sensitive information and shall inform the competent authority without delay of any security breach that jeopardises the security of such data.*

Article 11 – paragraph 1 – point 9 (9) the *provider of data intermediation service* shall ensure compliance with Union and national *law, in particular* rules on competition *and data protection*; *where such rules impose stricter or more detailed obligations, they shall prevail;*

Article 11 - paragraph 1 - point 10 (10) the *provider of data intermediation service* offering services to data subjects shall act in the data subjects' best interest when facilitating the exercise of their rights, in particular by advising data subjects on potential data uses and standard terms and conditions attached to such uses;

Article 11 – paragraph 1 – point 11 (11) where a *provider of data intermediation services* provides tools for obtaining consent from data subjects or permissions to process data made available by legal persons, it shall specify the jurisdiction or jurisdictions in which the data use is intended to take place and provide to the data subject tools for tracking the use of that data and consent withdrawal and data holders with tools for permission withdrawal.

Article 14 – paragraph 1 This Chapter shall not apply to not for profit entities *recognised data altruism organisations* whose activities consist only in seeking to collect data for objectives of general interest, made available by natural or legal persons on the basis of data altruism.

CA 9: Notification and competent authorities for providers *of* data intermediation services incl. monitoring of compliance (covers Art 10, 12, 13, Rec 30, 31, 32, 33, 34)

All relevant AMs fall, including: AMs 15-16, 49-65, 80-84, 226-229, 474-499, 532-548, IMCO 23-25, IMCO 83-94, IMCO 110-121, LIBE 27-31, LIBE 101-117, LIBE 131-137, JURI 30-33, JURI 83-94, JURI 103-104

Recitals

(31) In order to support effective cross-border provision of services, the *provider of* data *intermediation services* should be requested to send a notification only to the designated competent authority from the Member State where its main establishment is located or where its legal representative is located. Such a notification should not entail more than a mere declaration of the intention to provide such services and should be completed only by *providing* the information set out in this Regulation. *After the relevant notification the provider of data intermediation services should be able to start operating in other Member States without further notification obligations.*

(32) The main establishment of a *provider of data intermediation services* in the Union should be the Member State with the place of its central administration in the Union. The main establishment of a *provider of data intermediation services* in the Union should be determined according to objective criteria and should imply the effective and real exercise of management activities.

(33) The competent authorities designated to monitor compliance of *providers of* data sharing *intermediation* services with the requirements in this Regulation should be chosen on the basis of their capacity and expertise regarding horizontal or sectoral data sharing, and they should be independent as well as transparent and impartial in the exercise of their tasks. Member States should notify the Commission of the identity of the designated competent authorities.

Articles

Article 10 – title Notification of data *intermediation services*

Article 10 – paragraph 1 1. *Providers of data intermediation services providing* the services referred to in Article 9(1) shall submit a notification to the competent authority referred to in Article 12.

Article 10 – paragraph 2 2. For the purposes of this Regulation, a *provider of data intermediation services* with establishments in more than one Member State, shall be deemed to be under the jurisdiction of the Member State in which it has its main establishment, *without prejudice to Union law regulating cross-border actions for damages and related proceedings*.

Article 10 – paragraph 3 3. A *provider of data intermediation services* that is not established in the Union, but offers the services referred to in Article 9(1) within the Union, shall appoint *designate* a legal representative in one of the Member States in which those services are offered. For the purposes of ensuring compliance with this Regulation, the legal representative shall be empowered by the provider of data intermediation services to act on its behalf or together with it, in particular when addressed by competent authorities or data subjects and data holders, with regard to all issues related to the data intermediation services provided. The legal representative shall perform its tasks in accordance with the mandate received from the provider of data intermediation services, including cooperating with and comprehensively demonstrating to the competent authorities, upon request, the actions taken and provisions put in place by the provider to ensure compliance with this Regulation. The provider of data intermediation services shall be deemed to be under the jurisdiction of the Member State in which the legal representative is established.

Article 10 – paragraph 4 4. Upon notification, the *provider of data intermediation services* may start the activity subject to the conditions laid down in this Chapter.

Article 10 – paragraph 5 5. The notification shall entitle the *provider of data intermediation services* to provide data *sharing intermediation* services in all Member States.

Article 10 – paragraph 6 – point a (a) the name of the *provider of data intermediation services*;

Article 10 – paragraph 6 – point b (b) the *provider of data intermediation services*' legal status, form, *ownership structure*, *relevant subsidiaries* and registration number, where the provider is registered in trade or in another similar public register;

Article 10 – paragraph 6 – point c (c) the address of the *provider of data intermediation services'* main establishment in the Union, if any, and, where applicable, any secondary branch in another Member State or that of the legal representative designated pursuant to paragraph 3;

Article 10 – paragraph 6 – point d (d) a website where *complete and up-to-date* information on the *provider of data intermediation services* and the activities can be found, where applicable;

Article 10 – paragraph 6 – point e (e) the *provider of data intermediation services*' contact persons and contact details;

Article 10 – paragraph 6 – point f (f) a description of the service the *provider of data intermediation services* intends to provide;

Article 10 - paragraph 6 - point g (g) the estimated date for starting the activity, or the *date on which the activity started*;

Article 10 – paragraph 6 – point h (h) — the Member States where the provider intends to provide services.

Article 10 – paragraph 6 a (new) (6 a) The competent authority shall ensure that the notification procedure does not impose undue obstacles for SMEs, start-ups and civil society organisations and ensures non-discrimination and competition.

Article 10 – paragraph 7 7. At the request of the *provider of data intermediation services*, the competent authority shall, within one week, issue a standardised declaration, confirming that the *provider of data intermediation services* has submitted the notification referred to in paragraph 4 *and that the notification contains the information referred to in paragraph 6*.

Article 10 – paragraph 8 (8) — The competent authority shall forward each notification to the national competent authorities of the Member States by electronic means, without delay.

Article 10 – paragraph 9 9. The competent authority shall notify *the competent authorities referred to in Article 12 and* the Commission of each new notification *without delay by electronic means*. The Commission shall keep *and regularly update* a *public* register of *all providers of data intermediation services in the Union*.

Article 10 – paragraph 10 (10) The competent authority may charge fees. Such fees shall be proportionate and objective and be based on the administrative costs related to the monitoring of compliance and other market control activities of the competent authorities in relation to notifications of *providers of* data sharing intermediation services. The competent authority may also charge discounted fees or allow free of charge notification for SMEs and start-ups.

Article 10 – paragraph 10 a (new) (10 a) Providers of data intermediation services shall submit any changes of the information provided pursuant to paragraph 6 to the competent authority within 14 calendar days from the day on which the change takes place.

Article 10 – paragraph 11 11. Where a *provider of data intermediation services* ceases its activities, it shall notify the relevant competent authority determined pursuant to paragraphs 1, 2 and 3 within 15 days. The competent authority shall forward without delay each such notification to the national competent authorities in the Member States and to the Commission by electronic means. *The Commission shall update the public register of providers of data intermediation services in the Union accordingly.*

Article 12 – paragraph 1 (1) Each Member State shall designate in its territory one or more authorities competent to carry out the tasks related to the notification framework and shall communicate to the Commission the identity of those designated authorities by [date of application of this Regulation]. It shall also communicate to the Commission any subsequent modification.

Article 12 – paragraph 2(2)The designated competent authorities shall comply withArticle 23.

Article 12 – paragraph 3 3. *The powers of* the designated competent authorities, *are without prejudice to the powers of* the data protection authorities, the national competition

authorities, the authorities in charge of cybersecurity, and other relevant sectorial authorities. In accordance with their respective competences under Union and Member State law, those authorities shall build up a strong cooperation and exchange the information which is necessary for the exercise of their tasks in relation to providers of data intermediation services, and ensure the consistency of the decisions taken in applying this Regulation. On any question regarding compliance with Regulation (EU) 2016/679, the competent supervisory authorities established pursuant to that Regulation are fully competent.

Article 13 – paragraph 2 2. The competent authority shall have the power to request from *providers of data intermediation services or their legal representatives* all the information that is necessary to verify compliance with the requirements laid down in Articles 10 and 11. Any request for information shall be proportionate to the performance of the task and shall be reasoned.

Article 13 – paragraph 3 3. Where the competent authority finds that a *provider of data intermediation services* does not comply with one or more of the requirements laid down in Article 10 or 11, it shall notify that *provider of data intermediation services* of those findings and give it the opportunity to state its views, within *the shortest delay*.

Article 13 – paragraph 4 – introductory part (4) The competent authority shall have the power to require the cessation of the breach *infringement* referred to in paragraph 3 either immediately or within a reasonable time limit *or immediately in the case of a serious infringement* and shall take appropriate and proportionate measures *aiminged* at *to* ensureing compliance. In this regard, the competent authorities shall be able have the power, where appropriate:

Article 13 - paragraph 4 - point a (a) to impose dissuasive financial penalties which may include periodic penalties with retroactive effect.

Article 13 – paragraph 4 – point b (b) to require postponement a temporary cessation of the provision of the data sharing intermediation service, or in the case of a serious infringement that has not been remedied, despite being previously identified and communicated, a permanent cessation.

Article 13 - paragraph 4 a (new) (4a) Where a provider of data intermediation services that is not established in the Union fails to designate a legal representative or the legal representative fails, upon request by the competent authority, to provide the necessary information that comprehensively demonstrates compliance with this Regulation, the competent authority shall have the power to impose the immediate cessation of the provision of the data intermediation service.

The designation of a legal representative by a provider of data intermediation services shall be without prejudice to legal actions that could be initiated against the provider itself.

Article 13 – paragraph 5 (5) The competent authorities shall communicate the measures imposed pursuant to paragraph 4, the reasons on which they are based *as well as the necessary steps to be taken to rectify the relevant shortcomings* to the entity *provider of data intermediation services* concerned without delay and shall stipulate a reasonable period for the entity *provider* to comply with the measures.

Article 13 – paragraph 6 6. If a *provider of data intermediation services* has its main establishment or legal representative in a Member State, but provides services in other Member States, the competent authority of the Member State of the main establishment or where the legal representative is located and the competent authorities of those other Member States shall cooperate and assist each other. Such assistance and cooperation may cover information exchanges between the competent authorities concerned and requests to take the measures referred to in this Article.

<u>CA 10: Data altruism (covers Art 2(10), 15, 16, 17, 18, 19, 20, 21, 22, Rec 35, 36, 37, 38, 39, 42)</u>

All relevant AMs fall, including: AMs 17, 85-89, 230-245, 266, 292, 322-327, 330-331, 555-655, IMCO 26-28, IMCO 47, IMCO 123-157, LIBE 32-35, LIBE 55-56, LIBE 139-192, JURI 34-36, JURI 41, JURI 50, JURI 108-123

Recitals

(35) There is a strong potential in the use of data made available voluntarily by data subjects based on their *informed* consent or, where it concerns non-personal data, made available by legal persons, for purposes of general interest, *in particular scientific research*, Such purposes would include healthcare, combating climate change, improving mobility, facilitating the establishment of official statistics or improving the provision of public services. *Such purposes may also be established by national law*. Support to scientific research, including for example technological development and demonstration, fundamental research, applied research and privately funded research, should *could* be considered as well purposes of general interest. This Regulation aims at contributing to the emergence of pools of data made available on the basis of data altruism that have a sufficient size in order to enable data analytics and machine learning, including across borders in the Union.

(36) Legal entities that seek to support purposes of general interest by making available relevant data based on data altruism at scale and meet certain requirements, should be able to register as 'Data Altruism Organisations recognised in the Union'. This could lead to the establishment of data repositories. As registration in a Member State would be valid across the Union, and this should facilitate cross-border data use within the Union and the emergence of data pools covering several Member States. Data subjects in this respect would consent to specific purposes of data processing, but could also consent to data processing in certain areas of research or parts of research projects as it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Legal persons could give permission to the processing of their non-personal data for a range of purposes not defined at the moment of giving the permission. The voluntary *registration as* 'Data Altruism Organisation Recognised in the Union' and the compliance of such registered entities with a set of requirements should bring trust that the data made available on altruistic purposes is serving a general interest purpose. Such trust should result in particular from a place of establishment within the Union, as well as from the requirement that registered entities have a not-for-profit character, from transparency requirements and from specific safeguards in place to protect rights and interests of data subjects and companies. Further safeguards should include making it possible to process relevant data within a secure processing environment operated by the registered entity, oversight mechanisms such as ethics councils or boards, *including representatives from civil society*, to ensure that the data controller maintains high standards of scientific ethics *and protection of fundamental rights*, effective *and clearly communicated* technical means to withdraw or modify consent at any moment, based on the information obligations of data processors under Regulation (EU) 2016/679 as well as means for data subjects to stay informed about the use of data they made available.

(37) This Regulation is without prejudice to the establishment, organisation and functioning of entities that seek to engage in data altruism pursuant to national law. It builds on national law requirements to operate lawfully in a Member State as a not-for-profit organisation. Entities which meet the requirements *laid down* in this Regulation should be able to use the title of 'Ddata Aaltruism Oorganisations recognised in the Union'. In order to assist data subjects and legal entities to easily identify, and thereby to increase their trust in, data altruism organisations recognised in the Union, a common logo that is recognisable throughout the Union should be established. In order to ensure uniform conditions for the application of that logo, implementing powers should be conferred on the Commission to establish a design for that common logo. The common logo should be accompanied by a QR code with a link to the Union register of data altruism organisations recognised in the Union.

(37 a) This Regulation is without prejudice to the establishment, organisation and functioning of entities other than public sector bodies that engage in the sharing of data and content on the basis of open licenses, thereby contributing to the creation of commons resources available to all. This includes open collaborative knowledge sharing platforms, open access scientific and academic repositories, open source software development platforms and Open Access content aggregation platforms. Organisations building such open Access commons knowledge repositories play an important role in the online infrastructure. Nothing in this Regulation should therefore be interpreted to limit the ability of non-profit organisations to make data and content available to the public under open licenses.

(38) Data Altruism Organisations recognised in the Union should be able to collect relevant data directly from natural and legal persons or to process data collected by others. *Where they are data controllers or processors in the meaning of Regulation (EU) 2016/679, they are bound by the rules of that Regulation.* Typically, data altruism would rely on consent of data subjects in the sense of Article 6(1)(a) and 9(2)(a) and in compliance with requirements for lawful consent in accordance with Article 7 *and 8* of Regulation (EU) 2016/679. In accordance with Regulation (EU) 2016/679, scientific research purposes can be supported by consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research or only to certain areas of research or parts of research projects. Article 5(1)(b) of Regulation (EU) 2016/679 specifies that further processing for scientific or historical research purposes or statistical purposes should, in accordance with Article 89(1) of Regulation (EU) 2016/679, not be considered to be incompatible with the initial purposes.

(39) To *promote trust and* bring additional legal certainty *and user-friendliness* to granting and withdrawing of consent, in particular in the context of scientific research and statistical use of data made available on an altruistic basis, a European data altruism consent form should be developed and used in the context of altruistic data sharing. Such a form should contribute to additional transparency for data subjects that their data will be accessed and used in accordance with their consent and also in full compliance with the data protection rules. It could should also *facilitate the granting and withdrawing of consent and* be used to streamline data altruism performed by companies and provide a mechanism allowing such companies to

withdraw their permission to use the data. In order to take into account the specificities of individual sectors, including from a data protection perspective, there should be a possibility for sectoral adjustments of the European data altruism consent form.

(42) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to develop the European data altruism consent form. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

Articles

Article 2 – paragraph 1 – point 10 (10) 'data altruism' means *voluntary sharing of data based on consent* by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking *or receiving* a reward, for purposes of general interest, such as *healthcare, combating climate change, improving mobility, facilitating the establishment of official statistics, improving public services or scientific research purposes in the general interest. scientific research purposes or improving public services;*

Chapter IV – title IV data altruism

Article 15 - title **Public** registers of recognised data altruism organisations

Article 15 – paragraph 1 1. Each competent authority designated pursuant to Article 20 shall keep *and regularly update* a *public national* register of recognised data altruism organisations.

Article 15 – paragraph 2 2. The Commission shall maintain a *and regularly update a public* Union register of recognised data altruism organisations.

Article 15 – paragraph 3 (3) **Only** an entity registered in the **public national** register of recognised data altruism organisations in accordance with Article 16 may refer to itself as a-use the title 'data altruism organisation recognised in the Union' in its written and spoken communication, as well as a common logo. In order to ensure that data altruism organisations recognised in the Union are easily identifiable throughout the Union, the Commission shall, by means of implementing acts, establish a design for the common logo. Data altruism organisations recognised in the Union shall display the common logo clearly on every online and offline publication that relates to their data altruism activities. The common logo shall be accompanied by a QR code with a link to the Union register of data altruism organisations recognised in the Union.

These implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 29(2).

Article 15 - paragraph 3 a (new) Member States may establish national polices for data altruism and may put in place organisational or technical arrangements to facilitate data altruism.

Article 16 – title General requirements for registration
Article 16 – paragraph 1 – introductory part data altruism organisation shall:

In order to qualify for registration, the

Article 16 – paragraph 1 – point a (a) be a legal entity constituted to meet objectives of general interest;

Article 16 – paragraph 1 – point b (b) operate on a not-for-profit basis and be *legally* independent from any entity that operates on a for-profit basis; *the entity shall not use the data collected based on data altruism for other activities;*

Article 16 – paragraph 1 – point c (c) perform the activities related to data altruism take place through a legally independent structure, separate from other activities it has undertaken, *including for-profit activities*.

Article 16 – paragraph 1 – point c a (new) (ca) have procedures in place to ensure compliance with the Union and national rules on the protection of personal data, including procedures for ensuring the exercise of data subjects' rights;

Article 17 – paragraph 1 (1) Any entity which meets the requirements of Article 16 may request *shall submit an application, to be evaluated by the competent authority,* to be entered in the register of recognised data altruism organisations referred to in Article 15 (1).

Article 17 – paragraph 2 (2) For the purposes of this Regulation, an entity engaged in activities based on data altruism with establishments in more than one Member State, shall register in the Member State in which it has its main establishment.

Article 17 – paragraph 3 (3) An entity that is not established in the Union, but meets the requirements in Article 16, shall *designate* appoint a legal representative in one of the Member States where it intends to collect data based on data altruism. For the purposes of compliance with this Regulation, the legal representative shall be empowered by the entity to act on its behalf or together with it, in particular when addressed by competent authorities or data subjects and data holders, with regard to all issues related to the service or services provided. The legal representative shall perform its tasks in accordance with the mandate received from the entity, including cooperating with and comprehensively demonstrating to the competent authorities, upon request, the actions taken and provisions put in place by the entity to ensure compliance with this Regulation. For the purpose of compliance with this Regulation, that entity shall be deemed to be under the jurisdiction of the Member State where the legal representative is located.

Article 17 - paragraph 3 a (new) (3a) Where an entity that is not established in the Union fails to designate a legal representative or the legal representative fails, upon request by the competent authority, to provide within a reasonable timeframe, the necessary information that comprehensively demonstrates compliance with this Regulation, the competent authority shall have the power to impose the immediate cessation of the provision of the data altruism activity.

Article 17 – paragraph 4 – point c (c) the statutes of the entity, where appropriate;

Article 17 – paragraph 4 – point f (f) a *public* website where *up to date* information on the entity and the activities can be found *including at least the information as referred to in points a, b, d, e and h*;

Article 17 - paragraph 4 - point h (h) the purposes of general interest it intends to promote when collecting data;

Article 17 – paragraph 4 – point h a (new) (ha) the nature of data it intends to control or process, and, in case of personal data, an indication of the categories of personal data.

Article 17 – paragraph 5 (5) Where the entity has submitted all necessary information pursuant to paragraph 4 and *after* the competent authority *has* considers *evaluated the application and has found* that the entity complies with the requirements of Article 16, it shall register the entity in the register of recognised data altruism organisations within twelve weeks from the date of application. The registration shall be valid in all Member States. Any registration shall be communicated to the Commission, for inclusion in the *public* Union register of recognised data altruism organisations.

Article 17 – paragraph 6 (6) The information referred to in paragraph 4, points (a), (b), (f), (g), and (h) shall be published in the national *public* register of recognised data altruism organisations.

Article 17 – paragraph 7 (7) Any entity entered in the *national public* register of recognised data altruism organisations shall submit any changes of the information provided pursuant to paragraph 4 to the competent authority within 14 calendar days from the day on which the change takes place. *The competent authority shall without delay and by electronic means inform the Commission of each such notification.*

Article 18 – paragraph 1 – introductory part (1) Any entity entered in the national *public* register of recognised data altruism organisations shall keep full and accurate records concerning:

Article 18 – paragraph 2 – introductory part (2) Any entity entered in the *national public* register of recognised data altruism organisations shall draw up and transmit to the competent national authority an annual activity report which shall contain at least the following:

Article 18 – paragraph 2 – point b (b) a description of the way in which the general interest purposes for which data was collected have been promoted during the given financial year;

Article 18 – paragraph 2 – point c (c) a list of all natural and legal persons that were allowed to use data it holds, including a summary description of the general interest purposes pursued by such data use and the description of the technical means used for it, including a description of the techniques used to preserve privacy and data protection;

Article 19 – paragraph 1 – introductory part 1. Any entity entered in the *public register* of recognised data altruism organisations shall inform data holders *or data subjects prior to any processing of their data in a clear and easy-to-understand manner*:

Article 19 – paragraph 1 – point a (a) about the purposes of general interest for which it permits the processing of their data by a data user in an easy to understand manner;

Article 19 – paragraph 1 – point aa (new) (aa) in case of personal data, about the legal basis pursuant to Regulation (EU) 2016/679 on which it processes data;

Article 19 – paragraph 1 – point b (b) about *the location of and the purposes of general interest for which it permits* any processing *performed* outside the Union.

Article 19 – paragraph 2 (2) The entity shall also ensure that the data is not be used for other purposes than those of general interest for which it permits the processing. *The entity shall not use misleading marketing practices to solicit donations of data.*

Article 19 – paragraph 2 a (new) 2a. The entity shall also ensure that the consent of data subjects or permission to process data made available by legal persons can be withdrawn easily and in a user-friendly way by the data subject or legal person.

Article 19 - paragraph 2 b (new) (2 b) The entity shall take measures to ensure a high level of security for the storage and processing of data that it has collected.

Article 19 – paragraph 3 (3) Where an entity entered in the *public national* register of recognised data altruism organisations provides tools for obtaining consent from data subjects or permissions to process data made available by legal persons, it shall specify the jurisdiction or jurisdictions in which the data use is intended to take place.

Article 20 – title Competent authorities for registration *of data altruism organisations*

Article 20 – paragraph 1 (1) Each Member State shall designate one or more competent authorities responsible for the *public national* register of recognised data altruism organisations and for the monitoring of compliance with the requirements of this Chapter. The designated competent authorities *for the registration of data altruism organisations* shall meet the requirements of Article 23.

Article 20 – paragraph 2 (2) Each Member State shall inform the Commission of the identity of the designated authorities.

Article 20 – paragraph 3 (3) The competent authority shall undertake its tasks in cooperation with the data protection authority, where such tasks are related to processing of personal data, and with relevant sectoral bodies of the same Member State. For any question requiring an assessment of compliance with Regulation (EU) 2016/679, the competent authority shall first seek an opinion or decision by the competent supervisory authority established pursuant to that Regulation and comply with that opinion or decision *which shall be legally binding for the competent authority*.

Article 21 – paragraph 1 (1) The competent authority shall monitor and supervise compliance of entities entered in the *public national* register of recognised data altruism organisations with the conditions laid down in this Chapter.

Article 21 – paragraph 2 (2) The competent authority shall have the power to request information from entities included in the *public national* register of recognised data altruism

organisations that is necessary to verify compliance with the provisions of this Chapter. Any request for information shall be proportionate to the performance of the task and shall be reasoned.

Article 21 – paragraph 3 (3) Where the competent authority finds that an entity does not comply with one or more of the requirements of this Chapter it shall notify the entity of those findings and give it the opportunity to state its views, within a reasonable time limit.

Article 21 – paragraph 5 – introduction If an entity does not comply with one or more of the requirements of this Chapter even after having been notificationed by the competent authority in accordance with paragraph 3 by the competent authority, the entity shall competent authority shall have the power to require the cessation of the infringement within a reasonable time limit or immediately in the case of a serious infringement and shall take appropriate and proportionate measures aiming to ensure compliance with this Regulation. In this regard, the entity shall, where deemed appropriate by the competent authority:

Article 21 – paragraph 5 – point a (a) lose its rights to collect data made available by natural or legal persons on the basis of data altruism, to perform the activities linked to the realisation of the data altruism purpose and to refer to itself as a 'data altruism organisation recognised in the Union' in any written and spoken communication, use the common logo, as well as be subject to financial penalties.

Article 21 – paragraph 5 – point b (b) be removed from the *public national and Union registers of* recognised data altruism organisations.

Article 21 – paragraph 6 (6) If an entity included in the *public national* register of recognised data altruism organisations has its main establishment or legal representative in a Member State but is active in other Member States, the competent authority of the Member State of the main establishment or where the legal representative is located and the competent authorities of those other Member States shall cooperate and assist each other as necessary. Such assistance and cooperation may *shall* cover *but not be limited to* information exchanges between the competent authorities concerned and *reasoned* requests to take the supervisory measures referred to in this Article.

Article 22 – title European data altruism consent form

Article 22 – paragraph 1 (1) In order to facilitate the collection of data based on data altruism, the Commission may adopt implementing acts developing a European data altruism consent form, *in cooperation with the European Data Innovation Board and the European Data Protection Board*. The form shall allow the collection of consent across Member States in a uniform format. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 29 (2).

Article 22 – paragraph 2 (2) The European data altruism consent form shall use a modular approach allowing customisation for specific sectors and for different purposes.

Article 22 – paragraph 3 (3) Where personal data are provided, the European data altruism consent form shall ensure that data subjects are able to give consent to and withdraw consent from a specific data processing operation in compliance with the requirements of Regulation (EU) 2016/679.

Article 22 – paragraph 4 (4) The form shall be available in *all of the official languages of the Union in* a manner that can be printed on paper and read by humans as well as in an electronic, machine-readable form.

CA 11: European Data Innovation Board (covers Art 26, 27, Rec 40, 41)

All relevant AMs fall, including: AMs 18-19, 93-101, 247-265, 276-277, 293, 307, 339, 517, 667-714, IMCO 29-31, IMCO 167-184, LIBE 36, LIBE 197-204, JURI 37, JURI 126-133

Recitals

(40) In order to successfully implement the data governance framework, a European Data Innovation Board (*the 'Board'*) should be established, in the form of an expert group. The Board should *be gender balanced and* consist of representatives of *the competent authorities of all* the Member States, the Commission, *the European Union Agency for Cybersecurity (ENISA), the EU SME Envoy or a representative appointed by the network of SME envoys* and *other* representatives of relevant data spaces and *competent authorities in* specific sectors (such as health, *energy, industrial manufacturing, environment,* agriculture, *media, cultural and creative sectors,* transport and statistics), *ensuring geographical balance.* The European Data Protection Board *and the European Data Protection Supervisor, as well as the Data Innovation Advisory Council,* should be invited to appoint a representative to the Board.

40 a (new) A data innovation advisory council ('the Advisory Council') should be established as a sub-group of the Board consisting of relevant representatives from industry, research, academia, civil society, standardisation organisations, relevant common European data spaces, and other relevant stakeholders, including social partners, where appropriate depending on the subject matter discussed. The Advisory Council should support the work of the Board by providing advice relating to the tasks of the Board, such as relating to the exchange of data, and in particular on how to best protect commercially sensitive nonpersonal data, in particular trade secrets, but also non-personal data representing content protected by intellectual property rights from unlawful access that may lead to IP theft or industrial espionage. The Advisory Council should nominate a representative to attend meetings of the Board and to participate in its work.

(41) The Board should support the Commission in coordinating national practices and policies on the topics covered by this Regulation, and in supporting cross-sector data use by adhering to the European Interoperability Framework (EIF) principles and through the utilisation of *European and international* standards and specifications (*including through the EU Multi-Stakeholder Platform for ICT Standardisation*, the Core Vocabularies⁴⁴ and the CEF Building Blocks⁴⁵), *and should take into account* standardisation work taking place in specific sectors or domains. Work on technical standardisation may include the identification of priorities for the development of standards and establishing and maintaining a set of technical and legal standards for transmitting data between two processing environments that allows data spaces to be organised, *in particular in clarifying and distinguishing which standards and practices are cross-sectoral and which are sectoral*, without making recourse to an intermediary. The Board should cooperate with *the Advisory Council*, sectoral bodies,

networks or expert groups, or other cross-sectoral organisations dealing with re-use of data. Regarding data altruism, the Board should assist the Commission in the development of the data altruism consent form, in consultation with the European Data Protection Board. By proposing guidelines on common European data spaces, the Board should support the development of a functioning European data economy based on those data spaces, as set out in the European data strategy.

41 a (new) The Commission should ensure systematic cooperation between the Board and other equivalent Union-level bodies established in other legislation on related issues, in particular legislative acts on data and artificial intelligence.

Articles

Article 26 – paragraph 1 1. The Commission shall establish a European Data Innovation Board ("the Board") in the form of an Expert Group, consisting of the representatives of competent authorities of all the Member States, the European Data Protection Board, the European Data Protection Supervisor, the European Union Agency for Cybersecurity (ENISA), the Commission, the EU SME Envoy or a representative appointed by the network of SME envoys, relevant data spaces and other representatives of competent authorities in specific sectors and a representative of the Data Innovation Advisory Council established in paragraph 2. The Board shall be gender balanced.

Article 26 – paragraph 2 2. The Board shall establish a Data Innovation Advisory Council (Advisory Council). The Advisory Council shall be composed of relevant representatives from industry, research, academia, civil society, standardisation organisations, relevant common European data spaces and other relevant stakeholders or third parties appointed by the Board, representing all Member States to maintain geographical balance. The Advisory Council shall support the work of the Board by providing advice relating to the tasks of the Board. The Advisory Council shall nominate a relevant representative, depending on the configuration in which the Board meets, to attend meetings of the Board and to participate in its work. The composition of the Advisory Council and its recommendations to the Board shall be made public.

Article 26 – paragraph 3 (3) The Commission shall chair the meetings of the Board, which may be conducted in different configurations, depending on the subjects to be discussed and in line with the tasks of the Board, including a fixed configuration focused on data interoperability and portability that should meet at regular intervals.

Article 26 – paragraph 4 a (new) 4a. The Board's deliberations and documents shall be made public.

Article 27 – title Tasks of the *European Data Innovation* Board

Article 27 - paragraph 1 - point b (b) to advise and assist the Commission in developing a consistent practice of the competent authorities in the application of requirements applicable to *providers of* data *intermediation services, as well as entities carrying out activities in relation to data altruism*;

Article 27 – paragraph 1 – point b a (new) (ba) to advise and assist the Commission in developing consistent guidelines for the use of technologies to effectively prevent the

identification of data subjects such as anonymisation, pseudonymisation, differential privacy, generalisation, or suppression and randomisation for the re-use of personal and non-personal data;

Article 27 – paragraph 1 – point b aa (new) (bb) to advise and assist the Member States and the Commission on the harmonisation of the legal interpretation of anonymisation of data across the Union;

Article 27 – paragraph 1 – point b aaa (new) (bc) to advise and assist the Commission in developing consistent guidelines on how to best protect, in the context of this Regulation, commercially sensitive non-personal data, in particular trade secrets, but also non-personal data representing content protected by intellectual property rights from unlawful access that risks intellectual property theft or industrial espionage.

Article 27 - paragraph 1 - point b c (new) (bd) to advise and assist the Commission in developing consistent guidelines for cybersecurity requirements for the exchange and storage of data;

Article 27 – paragraph 1 – point c (c) to advise the Commission, *in particular taking into account the input from standardisation organisations*, on the prioritisation of cross-sector standards to be used and developed for data use and cross-sector data sharing *between emerging common European data spaces*, cross-sectoral comparison and exchange of best practices with regards to sectoral requirements for security, access procedures, while taking into account sector-specific standardisations activities, *and in particular in clarifying and distinguishing which standards and practices are cross-sectoral and which are sectoral. For this specific task a fixed configuration of the Board shall meet regularly.*

Article 27 – paragraph 1 – point d (d) to assist the Commission, in particular taking into account the input from standardisation organisations, in addressing fragmentation of the internal market and the data economy in the internal market by enhancing cross-border and cross-sector the interoperability of data as well as data sharing services between different sectors and domains, building on existing European, international or national standards, inter alia with the aim of encouraging the creation of common European data spaces;

Article 27 - paragraph 1 - point d a (new) (da) to propose guidelines for 'common European data spaces', meaning purpose- or sector-specific or cross-sectoral interoperable frameworks of common standards and practices to share or jointly process data for, inter alia, development of new products and services, scientific research or civil society initiatives. Such shared standards and practices shall take into account existing standards, comply with the competition rules and ensure non-discriminatory access for all participants, for the purpose of facilitating data sharing in the Union and reaping the potential of existing and future data spaces.

Those guidelines shall address, inter alia:

(i) cross-sectoral standards to be used and developed for data use and cross-sector data sharing, cross-sectoral comparison and exchange of best practices with regards to sectoral requirements for security, access procedures, while taking into account sector-specific standardisations activities, in particular in clarifying and distinguishing which standards and practices are cross-sectoral and which are sectoral;

(ii) requirements to counter barriers to market entry and to avoid lock-in effects, for the purpose of ensuring fair competition and interoperability;

(iii) adequate protection for legal data transfers outside the Union, including safeguards against any transfers prohibited by Union law;

(iv) adequate and non-discriminatory representation of relevant stakeholders in the governance of a common European data space;

(v) adherence to cybersecurity requirements in line with Union law.

Article 27 – paragraph 1 – point d aa (new) (d aa) to advise the Commission and the Member States on the possibility to set harmonised conditions allowing for re-use of data referred to in Article 3 (1) held by public sector bodies across the single market;

Article 27 – paragraph 1 – point d aaa (new) (d aaa) to assist the Commission in defining policies and strategies with the aim of avoiding any cases of data manipulation and the creation of "falsified data";

Article 27 – paragraph 1 – point e (e) to facilitate the cooperation between national competent authorities, *the Commission and other Union and international bodies* under this Regulation through capacity-building and the exchange of information, in particular by establishing methods for the efficient exchange of information relating to the notification procedure for *providers of* data *intermediation services* and the registration and monitoring of recognised data altruism organisations.

Article 27 – paragraph 1 – point e a (new) (ea) to facilitate cooperation between Member States in relation to the rules on penalties laid down by the Member States pursuant to Article 31 and to issue recommendations as regards the harmonisation of those penalties across the Union, as well as advise the Commission on the need to amend this Regulation with a view to further harmonisation of the rules on penalties referred to in Article 31.

Article 27 - paragraph 1 - point e b (new) (eb) to advise the Commission in the decision to adopt delegated acts referred to in Article 5(9), on the basis of the information on the volume of requests for re-use of data from specific third countries that is regularly provided to the Board by the competent bodies designated in accordance with Article 7 (1);

Article 27 – paragraph 1 – point e c (new) (ec) to assist the Commission in the discussions conducted at bilateral, plurilateral or multilateral level with third countries aimed at improving the regulatory environment for non-personal data, including standardisation, at global level.

CA 12: Competent authorities and procedural provisions (covers Art 23, 24, 25)

All relevant AMs fall, including: AMs 90-92, 656-666, IMCO 158-166, LIBE 193-196, JURI 124-125

Articles

Article 23 – title Requirements relating to competent authorities

Article 23 – paragraph 1 1. The competent authorities designated pursuant to Article 12 and Article 20 shall be legally distinct from, and functionally independent of any *provider* of data intermediation services or entity included in the *public national* register of recognised data altruism organisations. The functions of the competent authorities designated pursuant to Articles 12 and 20 may be carried out by the same entity. Member States may decide to assign the competences under this Regulation to the supervisory authorities designated under Regulation (EU) 2016/679.

Article 23 – paragraph 2 (2) Competent authorities shall exercise their tasks in an impartial, transparent, consistent, reliable and timely manner *and shall safeguard fair competition and non-discriminatory access for natural persons and SMEs and start-ups at all times*.

Article 23 – paragraph 3 (3) The top-management and the personnel responsible for carrying out the relevant tasks of the competent authority provided for in this Regulation cannot be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the services which they evaluate, nor the authorised *legal* representative of any of those parties or represent them. This shall not preclude the use of evaluated services that are necessary for the operations of the competent authority or the use of such services for personal purposes.

Article 23 – paragraph 5 (5) The competent authorities shall have at their disposal the adequate financial and human resources to carry out the tasks assigned to them, including the necessary technical knowledge and resources.

Article 23 – paragraph 6 (6) The competent authorities of a Member State shall provide the Commission and competent authorities from other Member States, on reasoned request, with the information necessary to carry out their tasks under this Regulation. Where a national competent authority considers the information requested to be confidential in accordance with Union and national rules on commercial and professional confidentiality, the Commission and any other competent authorities concerned shall ensure such confidentiality.

Article 24 – paragraph 1 1. Natural and legal persons shall have the right to lodge a complaint, *individually or collectively*, with the relevant national competent authority against a *provider of data intermediation services* or an entity entered in the *public national* register of recognised data altruism organisations.

Article 24 – paragraph 2 (2) The authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken, and

shall inform the complainant of the right to an effective judicial remedy provided for in Article 25.

Article 25 – paragraph 1 – point b (b) decisions of the competent authorities referred to in Articles 13, 17 and 21 taken in the management, control and enforcement of the notification regime for *providers of data intermediation services* and the monitoring of entities entered into the *public national* register of recognised data altruism organisations.

Article 25 – paragraph 2 (2) Proceedings pursuant to this Article shall be brought before the courts of the Member State in which the authority against which the judicial remedy is sought is located *individually or collectively*.

CA 13: Competent authorities and procedural provisions (covers Art 28, 29)

All relevant AMs fall, including: AMs 715-717, JURI 134

Articles

Article 28– title Exercise of the Delegation

Article 28 – paragraph 1 (1) The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

Article 28 - paragraph 2 (2) The power to adopt delegated acts referred to in Article, **5(9)** and 5(11) shall be conferred on the Commission for an indeterminate period of time from [...].

Article 28 - paragraph 3 (3) The delegation of power referred to in Article 5(9) and 5(11) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Article 28 – paragraph 4 (4) Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

Article 28 – paragraph 5 (5) As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Article 28 – paragraph 6 (6) A delegated act adopted pursuant to Article 5 (9) and (11) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 29 – paragraph 2 (2) Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

<u>CA 14: Penalties, evaluation and review, amendment to Regulation (EU) No 2018/1724,</u> <u>transitional arrangements, entry into force / application (covers Art 31, 32, 33, 34, 35)</u>

All relevant AMs fall, including: AMs 107-108, 731-739, IMCO 189, LIBE 213-220

Articles

Article 31 – paragraph 1 Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. *In their rules on penalties, Member States shall take into account the recommendations of the European Data Innovation Board.* Member States shall notify the Commission of those rules and measures by ... [date of application of the Regulation] and shall notify the Commission without delay of any subsequent amendment affecting them.

Article 31 – paragraph 2 (2) Member States shall ensure that the following nonexhaustive and indicative criteria are taken into account for the imposition of penalties on providers of data intermediation services and data altruism organisations for infringements of this Regulation, where appropriate:

- (a) the nature, gravity, scale and duration of the infringement;
- (b) any action taken by the provider of data intermediation services to mitigate or remedy the damage caused by the infringement;
- (c) any previous infringements by the provider of data intermediation services;
- (d) the financial benefits gained or losses avoided by the provider of data intermediation services due to the infringement, insofar as such gains or losses can be reliably established;
- (e) penalties imposed on the provider of data intermediation services for the same infringement in other Member States in cross-border cases where information about such penalties is available;
- (f) any other aggravating or mitigating factors applicable to the circumstances of the case.

Article 32 – paragraph 1 By ... [*two* years after the *date* of application of this Regulation], the Commission shall carry out an evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council as well as to the European Economic and Social Committee. Member States shall provide the Commission with the information necessary for the preparation of that report.

That evaluation shall assess, in particular:

(a) the application and functioning of the rules on penalties laid down by the Member States pursuant to Article 31, in particular focusing on the existence of large discrepancies between the penalties imposed for infringements of this Regulation among Member States that might distort competition across the Union, taking into account the recommendations of the Board and the positions and findings of other relevant bodies and sources;

(b) the level of compliance of the legal representatives of providers of data intermediation services and data altruism organisations not established in the Union with this Regulation and the level of enforceability of penalties on those providers;

(c) the type of data altruism organisations registered under Chapter IV and overview of the purposes of general interests for which data are shared in view of establishing clear criteria in that respect.

Member States shall provide the Commission with the information necessary for the preparation of that report. *The report shall be accompanied, where necessary, by legislative proposals.*

Article 33 – paragraph 1 – table

| Starting, running and closing a business | Notification as a <i>provider of data intermediation services</i> | 1 |
|---|---|----------------------------------|
| | Registration as a European Data Altruism Organisation | Confirmation of the registration |

Article 34 – paragraph 1 Entities providing the data sharing *intermediation* services provided in Article 9(1) on the date of entry into force of this Regulation shall comply with the obligations set out in Chapter III by [date - 2 years after the start date of the application of the Regulation] at the latest.

Article 35 – paragraph 2 It shall apply from [12 months after its entry into force].