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| **HAVE ADOPTED THIS REGULATION:** |
| chapter i general provisions |
| Article 1 Subject matter ***and*** scope |
| (1)This Regulation lays down: |
| (a) conditions for the re-use, within the Union, of certain categories of data held by public sector bodies; |
| (b) a notification ***and*** supervisory framework for the provision of data sharing services; |
| (c) a framework for voluntary registration of entities which collect ***and*** process data made available for altruistic purposes. |
| (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 ***or*** non-personal data. Where a sector-specific Union legal act requires public sector bodies, providers of data sharing 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 2 Definitions |
| For the purpose of this Regulation, the following definitions apply: |
| (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; |
| (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; |
| (3)‘non-personal data’ means data other than personal data as defined in point (1) of Article 4 of Regulation (EU) 2016/679; |
| (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; |
| (5)‘data holder’ means a legal person ***or*** data subject who, in accordance with applicable Union ***or*** national law, has the right to grant access to ***or*** to share certain personal ***or*** non-personal dataunder its control; |
| (6)‘data user’ means a natural ***or*** legal person who has lawful access to certain personal ***or*** non-personal data ***and*** is authorised to use that data for commercial ***or*** non-commercial purposes; |
| (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; |
| (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; |
| (9)‘main establishment’ of a legal entity means the place of its central administration in the Union; |
| (10)‘data altruism’ means the 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 a reward, for purposes of general interest, such as scientific research purposes ***or*** improving public services; |
| (11)‘public sector body’ means the State, regional ***or*** local authorities, bodies governed by public law ***or*** associations formed by one ***or*** more such authorities ***or*** one ***or*** more such bodies governed by public law; |
| (12)‘bodies governed by public law’ means bodies that have the following characteristics: |
| (a)they are established for the specific purpose of meeting needs in the general interest, ***and*** do not have an industrial ***or*** commercial character; |
| (b)they have legal personality; |
| (c)they are financed, for the most part, by the State, regional ***or*** local authorities, ***or*** by other bodies governed by public law; ***or*** are subject to management supervision by those authorities ***or*** bodies; ***or*** have an administrative, managerial ***or*** supervisory board, more than half of whose members are appointed by the State, regional ***or*** local authorities, ***or*** by other bodies governed by public law; |
| (13)‘publicundertaking’ means anyundertaking over which the public sector bodies may exercise directly ***or*** indirectly a dominant influence by virtue of their ownership of it, their financial participation therein, ***or*** the rules which govern it; for the purpose of this definition, a dominant influence on the part of the public sector bodies shall be presumed in any of the following cases in which those bodies, directly ***or*** indirectly: |
| (a)hold the majority of theundertaking's subscribed capital; |
| (b)control the majority of the votes attaching to shares issued by theundertaking; |
| (c)can appoint more than half of theundertaking’s administrative, management ***or*** supervisory body; |
| (14)‘secure processing environment’ means the physical ***or*** virtual environment ***and*** organisational means to provide the opportunity to re-use data in a manner 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. |
| (15)‘representative’ means any natural ***or*** legal person established in the Union explicitly designated to act on behalf of a provider of data sharing services ***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 sharing services ***or*** entity with regard to the obligations of that provider of data sharing services ***or*** entity set up by this Regulation. |
| chapter ii re-use of certain categories of protected data held by public sector bodies |
| Article 3 Categories of data |
| (1)This Chapter applies to data held by public sector bodies which are protected on grounds of: |
| (a)commercial confidentiality ; |
| (b)statistical confidentiality; |
| (c)protection of intellectual property rights of third parties; |
| (d)protection of personal data. |
| (2)This Chapter does not apply to: |
| (a)data held by publicundertakings; |
| (b)data held by public service broadcasters ***and*** their subsidiaries, ***and*** by other bodies ***or*** their subsidiaries for the fulfilment of a public service broadcasting remit; |
| (c)data held by cultural establishments ***and*** educational establishments; |
| (d)data protected for reasons of national security , defence ***or*** public security; |
| (e)data the supply of which is an activity falling outside the scope of the public task of the public sector bodies concerned as defined by law ***or*** by other binding rules in the Member State concerned, ***or***, in the absence of such rules, as defined in accordance with common administrative practice in that Member State, provided that the scope of the public tasks is transparent ***and*** subject to review. |
| (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. 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 bodiesunder Union ***and*** national law to allow the re-use of data. |
| Article 4 Prohibition of exclusive arrangements |
| (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. |
| (2)By way of derogation from paragraph 1, an exclusive right to re-use data referred to in that paragraph may be granted to the extent necessary for the provision of a service ***or*** a product in the general interest. |
| (3)Such exclusive right shall be granted in the context of a relevant service ***or*** concession contract in compliance with applicable Union ***and*** national public procurement ***and*** concession award rules, ***or***, in the case of a contract of a value for which ***neither*** Union ***nor*** national public procurement ***and*** concession award rules are applicable, in compliance with the principles of transparency, equal treatment ***and*** non-discrimination on grounds of nationality. |
| (4)In all cases not covered by paragraph 3 ***and*** where the general interest purpose cannot be fulfilled without granting an exclusive right, the principles of transparency, equal treatment ***and*** non-discrimination on grounds of nationality shall apply. |
| (5)The period of exclusivity of the right to re-use data shall not exceed three years. Where a contract is concluded, the duration of the contract awarded shall be as aligned with the period of exclusivity. |
| (6)The award of an exclusive right pursuant to paragraphs (2) to (5), including the reasons 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. |
| (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 three years after the date of entry into force of this Regulation. |
| Article 5 Conditions for re-use |
| (1)Public sector bodies which are competentunder 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 make publicly available the conditions for allowing such re-use. In that task, they may be assisted by the competent bodies referred to in Article 7 (1). |
| (2)Conditions for re-use shall be non-discriminatory, 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. |
| (3)Public sector bodies may impose an obligation to re-use only pre-processed data where such pre-processing aims to anonymize ***or*** pseudonymise personal data ***or*** delete commercially confidential information, including trade secrets. |
| (4)Public sector bodies may impose obligations |
| (a)to access ***and*** re-use the data within a secure processing environment provided ***and*** controlled by the public sector ; |
| (b)to access ***and*** re-use the data within the physical premises in which the secure processing environment is located, if remote access cannot be allowed without jeopardising the rights ***and*** interests of third parties. |
| (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. The public sector body shall be able to verify any results of processing of dataundertaken by the re-user ***and*** reserve the right to prohibit the use of results that contain information jeopardising the rights ***and*** interests of third parties. |
| (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 dataunder Regulation (EU) 2016/679, the public sector body shall support re-users in seeking consent of the data subjects ***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. In that task they may be assisted by the competent bodies referred to in Article 7 (1). |
| (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. |
| (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. |
| (9)The Commission may adopt implementing acts declaring that the legal, supervisory ***and*** enforcement arrangements of a third country: |
| (a)ensure protection of intellectual property ***and*** trade secrets in a way that is essentially equivalent to the protection ensuredunder Union law; |
| (b)are being effectively applied ***and*** enforced; ***and*** |
| (c)provide effective judicial redress. |
| Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 29 (2). |
| (10)Public sector bodies shall only transmit confidential data ***or*** data protected by intellectual property rights to a re-user which intends to transfer the data to a third country other than a country designated in accordance with paragraph 9 if the re-userundertakes: |
| (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 public sector body as regards any dispute related to the compliance with the obligation in point a). |
| (11)Where specific Union acts adopted in accordance with a legislative procedure 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, 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. 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, non-discriminatory ***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 re-identification 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. |
| (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. |
| (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 transfer of data to that third country. |
| Article 6 Fees |
| (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. |
| (2)Any fees shall be non-discriminatory, proportionate ***and*** objectively justified ***and*** shall not restrict competition. |
| (3)Public sector bodies shall ensure that any fees can 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. |
| (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 non-commercial purposes ***and*** by small ***and*** medium-sized enterprises in line with State aid rules. |
| (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. |
| (6)The public sector body shall publish a description of the main categories of costs ***and*** the rules used for the allocation of costs. |
| Article 7 Competent bodies |
| (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 re-use of the categories of data referred to in Article 3 (1) in the exercise of that task. |
| (2)The support provided for in paragraph 1 shall include, where necessary: |
| (a)providing technical support by making available a secure processing environment for providing access for the re-use of data; |
| (b)providing technical support in the application of tested techniques ensuring data processing in a manner that preserves privacy of the information contained in the data for which re-use is allowed, including techniques for pseudonymisation, anonymisation, generalisation, suppression ***and*** randomisation of personal data; |
| (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; |
| (d)providing public sector bodies with assistance on the adequacy ofundertakings made by a re-user, pursuant to Article 5 (10). |
| (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 re-use 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, 6 ***and*** 8 (3) shall apply in regard to such competent bodies. |
| (4)The competent body ***or*** bodies shall have adequate legal ***and*** technical capacities ***and*** expertise 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). |
| (5)The Member States shall 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 communicate to the Commission any subsequent modification of the identity of those bodies. |
| Article 8 Single information point |
| (1)Member States shall ensure that all relevant information concerning the application of Articles 5 ***and*** 6 is available through a single information point. |
| (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 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 register of available data resources containing relevant information describing the nature of available data. |
| (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. |
| (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. |
| Chapter iii requirements applicable to data sharing services |
| Article 9 Providers of data sharing services |
| (1)The provision of the following data sharing services shall be subject to a notification procedure: |
| (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; |
| (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, in the exercise of the rights provided in Regulation (EU) 2016/679; |
| (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. |
| (2)This Chapter shall be without prejudice to the application of other Union ***and*** national law to providers of data sharing 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 10 Notification of data sharing service providers |
| (1)Any provider of data sharing services who intends to provide the services referred to in Article 9 (1) shall submit a notification to the competent authority referred to in Article 12. |
| (2)For the purposes of this Regulation, a provider of data sharing services with establishments in more than one Member State, shall be deemed to beunder the jurisdiction of the Member State in which it has its main establishment. |
| (3)A provider of data sharing services that is not established in the Union, but offers the services referred to in Article 9 (1) within the Union, shall appoint a legal representative in one of the Member States in which those services are offered. The provider shall be deemed to beunder the jurisdiction of the Member State in which the legal representative is established. |
| (4)Upon notification, the provider of data sharing services may start the activity subject to the conditions laid down in this Chapter. |
| (5)The notification shall entitle the provider to provide data sharing services in all Member States. |
| (6)The notification shall include the following information: |
| (a)the name of the provider of data sharing services; |
| (b)the provider’s legal status, form ***and*** registration number, where the provider is registered in trade ***or*** in another similar public register; |
| (c)the address of the provider’s 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; |
| (d)a website where information on the provider ***and*** the activities can be found, where applicable; |
| (e)the provider’s contact persons ***and*** contact details; |
| (f)a description of the service the provider intends to provide; |
| (g)the estimated date for starting the activity; |
| (h)the Member States where the provider intends to provide services. |
| (7)At the request of the provider, the competent authority shall, within one week, issue a standardised declaration, confirming that the provider has submitted the notification referred to in paragraph 4. |
| (8)The competent authority shall forward each notification to the national competent authorities of the Member States by electronic means, without delay. |
| (9)The competent authority shall notify the Commission of each new notification. The Commission shall keep a register of providers of data sharing services. |
| (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 data sharing services. |
| (11)Where a provider of data sharing 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. |
| Article 11 Conditions for providing data sharing services |
| The provision of data sharing services referred in Article 9 (1) shall be subject to the following conditions: |
| (1)the provider 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 services shall be placed in a separate legal entity; |
| (2)the metadata collected from the provision of the data sharing service may be used only for the development of that service; |
| (3)the provider shall ensure that the procedure for access to its service is fair, transparent ***and*** non-discriminatory for ***both*** data holders ***and*** data users, including as regards prices; |
| (4)the provider shall facilitate the exchange of the data in the format in which it receives it from the data holder ***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; |
| (5)the provider shall have procedures in place to prevent fraudulent ***or*** abusive practices in relation to access to data from parties seeking access through their services; |
| (6)the provider 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 their data in case of insolvency; |
| (7)the provider shall put in place adequate technical, legal ***and*** organisational measures in order to prevent transfer ***or*** access to non-personal data that is unlawfulunder Union law; |
| (8)the provider shall take measures to ensure a high level of security for the storage ***and*** transmission of non-personal data; |
| (9)the provider shall have procedures in place to ensure compliance with the Union ***and*** national rules on competition; |
| (10)the provider 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; |
| (11)where a provider 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 12 Competent authorities |
| (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. |
| (2)The designated competent authorities shall comply with Article 23. |
| (3)The designated competent authorities, the data protection authorities, the national competition authorities, the authorities in charge of cybersecurity, ***and*** other relevant sectorial authorities shall exchange the information which is necessary for the exercise of their tasks in relation to data sharing providers. |
| Article 13 Monitoring of compliance |
| (1)The competent authority shall monitor ***and*** supervise compliance with this Chapter. |
| (2)The competent authority shall have the power to request from providers of data sharing services 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. |
| (3)Where the competent authority finds that a provider of data sharing services does not comply with one ***or*** more of the requirements laid down in Article 10 ***or*** 11, it shall notify that provider of those findings ***and*** give it the opportunity to state its views, within a reasonable time limit. |
| (4)The competent authority shall have the power to require the cessation of the breach referred to in paragraph 3 ***either*** immediately ***or*** within a reasonable time limit ***and*** shall take appropriate ***and*** proportionate measures aimed at ensuring compliance. In this regard, the competent authorities shall be able, where appropriate: |
| (a)to impose dissuasive financial penalties which may include periodic penalties with retroactive effect; |
| (b)to require cessation ***or*** postponement of the provision of the data sharing service. |
| (5)The competent authorities shall communicate the measures imposed pursuant to paragraph 4 ***and*** the reasons on which they are based to the entity concerned without delay ***and*** shall stipulate a reasonable period for the entity to comply with the measures. |
| (6)If a provider of data sharing 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. |
| Article 14 Exceptions |
| This Chapter shall not apply to not-for-profit entities 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. |
| Chapter iv data altruism |
| Article 15 Register of recognised data altruism organisations |
| (1)Each competent authority designated pursuant to Article 20 shall keep a register of recognised data altruism organisations. |
| (2)The Commission shall maintain a Union register of recognised data altruism organisations. |
| (3)An entity registered in the register in accordance with Article 16 may refer to itself as a ‘data altruism organisation recognised in the Union’ in its written ***and*** spoken communication. |
| Article 16  General requirements for registration |
| In order to qualify for registration, the data altruism organisation shall: |
| (a)be a legal entity constituted to meet objectives of general interest; |
| (b)operate on a not-for-profit basis ***and*** be independent from any entity that operates on a for-profit basis; |
| (c)perform the activities related to data altruism take place through a legally independent structure, separate from other activities it hasundertaken. |
| Article 17 Registration |
| (1)Any entity which meets the requirements of Article 16 may request to be entered in the register of recognised data altruism organisations referred to in Article 15 (1). |
| (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. |
| (3)An entity that is not established in the Union, but meets the requirements in Article 16, shall appoint a legal representative in one of the Member States where it intends to collect data based on data altruism. For the purpose of compliance with this Regulation, that entity shall be deemed to beunder the jurisdiction of the Member State where the legal representative is located. |
| (4)Applications for registration shall contain the following information: |
| (a)name of the entity; |
| (b)the entity’s legal status, form ***and*** registration number, where the entity is registered in a public register; |
| (c)the statutes of the entity, where appropriate; |
| (d)the entity’s main sources of income; |
| (e)the address of the entity’s 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); |
| (f)a website where information on the entity ***and*** the activities can be found; |
| (g)the entity’s contact persons ***and*** contact details; |
| (h)the purposes of general interest it intends to promote when collecting data; |
| (i)any other documents which demonstrate that the requirements of Article 16 are met. |
| (5)Where the entity has submitted all necessary information pursuant to paragraph 4 ***and*** the competent authority considers 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 Union register of recognised data altruism organisations. |
| (6)The information referred to in paragraph 4, points (a), (b), (f), (g), ***and*** (h) shall be published in the national register of recognised data altruism organisations. |
| (7)Any entity entered in the 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. |
| Article 18 Transparency requirements |
| (1)Any entity entered in the national register of recognised data altruism organisations shall keep full ***and*** accurate records concerning: |
| (a)all natural ***or*** legal persons that were given the possibility to process data held by that entity; |
| (b)the date ***or*** duration of such processing; |
| (c)the purpose of such processing as declared by the natural ***or*** legal person that was given the possibility of processing; |
| (d)the fees paid by natural ***or*** legal persons processing the data, if any. |
| (2)Any entity entered in the 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: |
| (a)information on the activities of the entity; |
| (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; |
| (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; |
| (d)a summary of the results of the data uses allowed by the entity, where applicable; |
| (e)information on sources of revenue of the entity, in particular all revenue resulted from allowing access to the data, ***and*** on expenditure. |
| Article 19 Specific requirements to safeguard rights ***and*** interests of data subjects ***and*** legal entities as regards their data |
| (1)Any entity entered in the register of recognised data altruism organisations shall inform data holders: |
| (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; |
| (b)about any processing outside the Union. |
| (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. |
| (3)Where an entity entered in the 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 Competent authorities for registration |
| (1)Each Member State shall designate one ***or*** more competent authorities responsible for the register of recognised data altruism organisations ***and*** for the monitoring of compliance with the requirements of this Chapter. The designated competent authorities shall meet the requirements of Article 23. |
| (2)Each Member State shall inform the Commission of the identity of the designated authorities. |
| (3)The competent authority shallundertake 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. |
| Article 21 Monitoring of compliance |
| (1)The competent authority shall monitor ***and*** supervise compliance of entities entered in the register of recognised data altruism organisations with the conditions laid down in this Chapter. |
| (2)The competent authority shall have the power to request information from entities included in the 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. |
| (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. |
| (4)The competent authority shall have the power to require the cessation of the breach referred to in paragraph 3 ***either*** immediately ***or*** within a reasonable time limit ***and*** shall take appropriate ***and*** proportionate measures aimed at ensuring compliance. |
| (5)If an entity does not comply with one ***or*** more of the requirements of this Chapter even after having been notified in accordance with paragraph 3 by the competent authority, the entity shall: |
| (a)lose its right to refer to itself as a ‘data altruism organisation recognised in the Union’ in any written ***and*** spoken communication; |
| (b)be removed from the register of recognised data altruism organisations. |
| (6)If an entity included in the 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 cover information exchanges between the competent authorities concerned ***and*** requests to take the supervisory measures referred to in this Article. |
| Article 22 European data altruism consent form |
| (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. 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). |
| (2)The European data altruism consent form shall use a modular approach allowing customisation for specific sectors ***and*** for different purposes. |
| (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. |
| (4)The form shall be available in a manner that can be printed on paper ***and*** read by humans ***as well as*** in an electronic, machine-readable form. |
| Chapter v competent authorities ***and*** procedural provisions |
| Article 23 Requirements relating to competent authorities |
| (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 sharing services ***or*** entity included in the register of recognised data altruism organisations. |
| (2)Competent authorities shall exercise their tasks in an impartial, transparent, consistent, reliable ***and*** timely manner. |
| (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 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. |
| (4)Top-management ***and*** personnel shall not engage in any activity that may conflict with their independence of judgment ***or*** integrity in relation to evaluation activities entrusted to them. |
| (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. |
| (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 tasksunder 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 Right to lodge a complaint |
| (1)Natural ***and*** legal persons shall have the right to lodge a complaint with the relevant national competent authority against a provider of data sharing services ***or*** an entity entered in the register of recognised data altruism organisations. |
| (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 Right to an effective judicial remedy |
| (1)Notwithstanding any administrative ***or*** other non-judicial remedies, any affected natural ***and*** legal persons shall have the right to an effective judicial remedy with regard to: |
| (a)a failure to act on a complaint lodged with the competent authority referred to in Articles 12 ***and*** 20; |
| (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 sharing services ***and*** the monitoring of entities entered into the register of recognised data altruism organisations. |
| (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. |
| Chapter vi european data innovation board |
| Article 26 European Data Innovation Board |
| (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 Commission, relevant data spaces ***and*** other representatives of competent authorities in specific sectors. |
| (2)Stakeholders ***and*** relevant third parties may be invited to attend meetings of the Board ***and*** to participate in its work. |
| (3)The Commission shall chair the meetings of the Board. |
| (4)The Board shall be assisted by a secretariat provided by the Commission. |
| Article 27 Tasks of the Board |
| The Board shall have the following tasks: |
| (a)to advise ***and*** assist the Commission in developing a consistent practice of public sector bodies ***and*** competent bodies referred to in Article 7 (1) processing requests for the re-use of the categories of data referred to in Article 3 (1); |
| (b)to advise ***and*** assist the Commission in developing a consistent practice of the competent authorities in the application of requirements applicable to data sharing providers; |
| (c)to advise the Commission on the prioritisation of cross-sector 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; |
| (d)to assist the Commission in enhancing the interoperability of data ***as well as*** data sharing services between different sectors ***and*** domains, building on existing European, international ***or*** national standards; |
| (e)to facilitate the cooperation between national competent authoritiesunder 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 data sharing service providers ***and*** the registration ***and*** monitoring of recognised data altruism organisations. |
| Chapter vii committee ***and*** delegation |
| Article 28 Exercise of the Delegation |
| (1)The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. |
| (2)The power to adopt delegated acts referred to in Article 5 (11) shall be conferred on the Commission for an indeterminate period of time from […]. |
| (3)The delegation of power referred to in Article 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. |
| (4)Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. |
| (5)As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament ***and*** to the Council. |
| (6)A delegated act adopted pursuant to Article 5 (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 Committee procedure |
| (1)The Commission shall be assisted by a committee within the meaning of Regulation (EU) No 182/2011. |
| (2)Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply. |
| (3)Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides ***or*** a committee member so requests. In such a case, the chair shall convene a committee meeting within a reasonable time. |
| Chapter viii final provisions |
| Article 30 International access |
| (1)The public sector body, the natural ***or*** legal person to which the right to re-use data was grantedunder Chapter 2, the data sharing provider ***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. |
| (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 grantedunder Chapter 2, a data sharing provider ***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]. |
| (3)Where a public sector body, a natural ***or*** legal person to which the right to re-use data was grantedunder Chapter 2, a data sharing provider ***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: |
| (a)where the third-country system requires the reasons ***and*** proportionality of the decision to be set out, ***and*** it requires the court order ***or*** the decision, as the case may be, to be specific in character, for instance by establishing a sufficient link to certain suspected persons, ***or*** infringements; |
| (b)the reasoned objection of the addressee is subject to a review by a competent court in the third-country; ***and*** |
| (c)in that context, the competent court issuing the order ***or*** reviewing the decision of an administrative authority is empoweredunder the law of that country to take duly into account the relevant legal interests of the provider of the data protected by Union law ***or*** the applicable Member State law. |
| 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. |
| (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 grantedunder Chapter 2, the data sharing provider ***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. |
| (5)The public sector body, the natural ***or*** legal person to which the right to re-use data was grantedunder Chapter 2, the data sharing provider ***and*** the entity providing data altruism shall inform the data holder about the existence of a request of an administrative authority in a third-country to access its data, 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. |
| Article 31 Penalties |
| 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. 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 32 Evaluation ***and*** review |
| By [four years after the data 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. |
| Article 33 Amendment to Regulation (EU) No 2018/1724 |
| In Annex II to Regulation (EU) No 2018/1724, the following line is addedunder “Starting, running ***and*** closing a business”: |
| Starting, running ***and*** closing a business | Notification as a provider of data sharing services | Confirmation of the receipt of notification |
| Registration as a European Data Altruism Organisation | Confirmation of the registration |
| Article 34 Transitional arrangements |
| Entities providing the data sharing 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 Entry into force ***and*** application |
| This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. |
| It shall apply from [12 months after its entry into force]. |
| This Regulation shall be binding in its entirety ***and*** directly applicable in all Member States. |
| Done at Brussels, |
| For the European Parliament    For the Council |
| **The President    The President** |
| (1)    The final form of the legal act will be determined by the content of the instrument. |
| (2)     COM/2020/66 final . |
| (3)    “Data the use of which is dependent on the rights of others” ***or*** “data subject to the rights of others” covers data that might be subject to data protection legislation, intellectual property, ***or*** contain trade secrets ***or*** other commercially sensitive information. |
| (4)     OJ L 119, 4.5.2016 , p. 1-88. |
| (5)     OJ L 201, 31.7.2002 , p. 37-47. |
| (6)     OJ L 172, 26.6.2019, p. 56–83. |
| (7)    See COM/2020/66 final . |
| (8)     https://www.force11.org/group/fairgroup/fairprinciples |
| (9)     OJ L 188 18.7.2009 , p. 1 as amended by OJ L 151, 14.6.2018, p. 1 . |
| (10)     OJ L 337, 23.12.2015 , p. 35-127. |
| (11)     OJ L 158, 14.6.2019 , p. 125-199; OJ L 211, 14.8.2009 , p. 94-136. |
| (12)     OJ L 220, 25.8.2017 , p. 1-120; OJ L 113, 1.5.2015 , p. 13-26. |
| (13)     OJ L 207, 6.8.2010 , p. 1-13. |
| (14)    OJ L 41, 14.2.2003, p. 26-32. |
| (15)    OJ L 108, 25.4.2007, p. 1-14. |
| (16)    A legislative proposal for the European health data space is envisaged for the fourth quarter of 2021. https://eur-lex.europa.eu/resource.html?uri=cellar%3A91ce5c0f-12b6-11eb-9a54-01aa75ed71a1.0001.02/DOC\_2&format=PDF |
| (17)    OJ L 178, 17.7.2000, p. 1-16. |
| (18)     COM(2020) 456 final . |
| (19)     COM/2020/66 final . |
| (20)    European Commission (2020, forthcoming). Support Study to this Impact Assessment, SMART 2019/0024, prepared by Deloitte. |
| (21)    OJ C , , p. . |
| (22)    OJ C , , p. . |
| (23)    Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic ***and*** Social Committee ***and*** the Committee of the Regions on the European Green Deal. Brussels, 11.12.2019. (COM(2019) 640 final) |
| (24)    COM (2020) 66 final. |
| (25)    See: Annexes to the Communication from the Commission to the European Parliament, the Council, the European Economic ***and*** Social Committee ***and*** the Committee of the Regions on Commission Work Programme 2021 (COM(2020) 690 final). |
| (26)    For example, Directive 2011/24/EU in the context of the European Health Data Space, ***and*** relevant transport legislation such as Directive 2010/40/EU, Regulation 2019/1239 ***and*** Regulation (EU) 2020/1056, in the context of the European Mobility Data Space. |
| (27)    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) |
| (28)    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) |
| (29)    Directive (EU) 2016/943 of the European Parliament ***and*** of the Council of 8 June 2016 on the protection of undisclosed know-how ***and*** business information (trade secrets) against their unlawful acquisition, use ***and*** disclosure. (OJ L 157, 15.6.2016, p.1) |
| (30)    Regulation (EU) 2018/1807 of the European Parliament ***and*** of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union. (OJ L 303, 28.11.2018, p. 59) |
| (31)    Regulation (EC) No 223/2009 of the European Parliament ***and*** of the Council of 11 March 2009 on European statistics ***and*** repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament ***and*** of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, ***and*** Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities. (OJ L 87, 31.03.2009, p. 164) |
| (32)    Directive 2000/31/EC of the European Parliament ***and*** of the Council of 8 June 2000, on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce). (OJ L 178, 17.07.2000, p. 1) |
| (33)    Directive 2001/29/EC of the European Parliament ***and*** of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright ***and*** related rights in the information society. (OJ L 167, 22.6.2001, p. 10) |
| (34)    Directive (EU) 2019/790 of the European Parliament ***and*** of the Council of 17 April 2019 on copyright ***and*** related rights in the Digital Single Market ***and*** amending Directives 96/9/EC ***and*** 2001/29/EC. (OJ L 130, 17.5.2019, p. 92) |
| (35)    Directive 2004/48/EC of the European Parliament ***and*** of the Council of 29 April 2004 on the enforcement of intellectual property rights. (OJ L 157, 30.4.2004). |
| (36)    Directive (EU) 2019/1024 of the European Parliament ***and*** of the Council of 20 June 2019 on open data ***and*** the re-use of public sector information. (OJ L 172, 26.6.2019, p. 56). |
| (37)    Regulation (EU) 2018/858 of the European Parliament ***and*** of the Council of 30 May 2018 on the approval ***and*** market surveillance of motor vehicles ***and*** their trailers, ***and*** of systems, components ***and*** separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 ***and*** (EC) No 595/2009 ***and*** repealing Directive 2007/46/EC (OJ L 151, 14.6.2018). |
| (38)    Directive 2010/40/EU of the European Parliament ***and*** of the Council of 7 July 2010 on the framework for the deployment of Intelligent Transport Systems in the field of road transport ***and*** for interfaces with other modes of transport. (OJ L 207, 6.8.2010, p. 1) |
| (39)    Commission Regulation (EU) 557/2013 of 17 June 2013 implementing Regulation (EC) No 223/2009 of the European Parliament ***and*** of the Council on European Statistics as regards access to confidential data for scientific purposes ***and*** repealing Commission Regulation (EC) No 831/2002 (OJ L 164, 18.6.2013, p. 16). |
| (40)    OJ L 157, 15.6.2016, p. 1–18 |
| (41)    Directive 96/9/EC of the European Parliament ***and*** of the Council of 11 March 1996 on the legal protection of databases (OJ L 77, 27.3.1996, p. 20). |
| (42)    Directive 2014/65/EU of the European Parliament ***and*** of the Council of 15 May 2014 on markets in financial instruments ***and*** amending Directive 2002/92/EC ***and*** Directive 2011/61/EU, OJ L 173/349. |
| (43)    Directive (EU) 2015/2366 of the European Parliament ***and*** of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC ***and*** 2013/36/EU ***and*** Regulation (EU) No 1093/2010, ***and*** repealing Directive 2007/64/EC. |
| (44)    https://joinup.ec.europa.eu/collection/semantic-interoperability-community-semic/core-vocabularies |
| (45)    https://joinup.ec.europa.eu/collection/connecting-europe-facility-cef |
| (46)    Regulation (EU) No 182/2011 of the European Parliament ***and*** of the Council of 16 February 2011 laying down the rules ***and*** general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13). |
| (47)    Regulation (EU) 2018/1725 of the European Parliament ***and*** of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices ***and*** agencies ***and*** on the free movement of such data, ***and*** repealing Regulation (EC) No 45/2001 ***and*** Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39). |