

## COCIR feedback on the Data Governance Act proposal <sup>1</sup>

COCIR welcomes the opportunity to provide feedback to the European Commission's proposal for a Data Governance Act. COCIR has in the past presented its views on the European Strategy for Data<sup>2</sup> as well as on the inception impact assessment of a data governance framework for common European data spaces.<sup>3</sup>

COCIR fully endorses the Commission's view that the availability of and access to data holds immense potential for innovation and value creation, and that this will greatly contribute to the recovery and resilience of our society following the COVID-19 pandemic.

Leading the digital health innovation, COCIR and its members strongly believe in the crucial role the use and sharing of data plays in addressing the ongoing COVID-19 pandemic crisis, and the structural role the European Health Data Space will play in the further development of preventive and personalised healthcare, driving research and innovation, leading to better outcomes for patients and the society as a whole.

### **Building Trust**

One of the clear lessons learned from the COVID-19 crisis is that trust is vital to encourage voluntary data sharing for the common good. Highlighting available and trustworthy initiatives will help persons and organisations make determined choices on sharing their data. The Data Governance Act as proposed takes some steps in the right direction. This should be further complemented with sector-specific initiatives and targeted investments in infrastructure, people and skills.

COCIR appreciates the European Commission is taking account of the rapid developments in the area of privacy-enhancing technologies and the opportunities to perform research in secure processing environments. COCIR strongly believes there is an important role to be played by relevant authorities in clarifying the legal and technical options for organisations to act in full compliance with the General Data Protection Regulation.

### **Legal certainty and coherence**

In order to unlock the vast potential of a European digital single market and to adequately address cross-border challenges, COCIR shares the Commission's view that the introduction of a common data governance framework is best addressed through means of a Regulation.

COCIR also agrees that sector-specific legislation should develop, adapt and propose new and complementary elements to this framework and that this should take the form of a *lex specialis*. In this sense, COCIR is very much looking forward to actively and constructively work with the Commission on its proposal for a European Health Data Space,<sup>4</sup>

Considering its broad scope, applicable to all common European data spaces, it is essential that the Data Governance Act provides the highest level of legal certainty. Unfortunately, this Act does not exist in a vacuum and consistency with existing policy frameworks and initiatives is challenging.

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<sup>1</sup> <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12491-Legislative-framework-for-the-governance-of-common-European-data-spaces>

<sup>2</sup> [https://www.cocir.org/fileadmin/Position\\_Papers\\_2020/COCIR\\_input\\_European\\_Strategy\\_for\\_Data.pdf](https://www.cocir.org/fileadmin/Position_Papers_2020/COCIR_input_European_Strategy_for_Data.pdf)

<sup>3</sup> [https://www.cocir.org/fileadmin/Position\\_Papers\\_2020/COCIR\\_response\\_Data\\_governance\\_framework\\_IIA.pdf](https://www.cocir.org/fileadmin/Position_Papers_2020/COCIR_response_Data_governance_framework_IIA.pdf)

<sup>4</sup> [https://www.cocir.org/fileadmin/Position\\_Papers\\_2021/20210203\\_COCIR\\_response\\_European\\_Health\\_Data\\_Space\\_IIA\\_final\\_.pdf](https://www.cocir.org/fileadmin/Position_Papers_2021/20210203_COCIR_response_European_Health_Data_Space_IIA_final_.pdf)

The Data Governance Act concerns both personal and non-personal data. While this Regulation is without prejudice to the General Data Protection Regulation, the introduction of additional provisions regarding the use of and access to non-personal data does raise questions for instance how to handle mixed data sets, which is currently not addressed in the proposal.

The ongoing discussions on the proposal for an e-Privacy Regulation have also underlined the complexity and difficulties in trying to define a coherent framework complementing the General Data Protection Regulation.

Furthermore, the success of the Data Governance Act is for instance dependent on what constitutes personal data as defined under the General Data Protection Regulation, and by consequence non-personal data.

### **Scope and definitions**

Considering the Data Governance Act defines governance rules for the use and access to data, both personal and non-personal data, there is a close reference to the definitions and concepts used in particular under the General Data Protection Regulation.

Clarification is needed how the concepts of data controller and data processor should apply to data sharing services and data altruism mechanisms. Other definitions and terms are being introduced which may create confusion or misunderstanding. Examples include 'access', 'main establishment' and 'pre-processed data'. It is also unclear why a 're-user' (non-defined) should be explicitly distinguished from a data user.

COCIR would also like to remark that data is being defined in the current proposal as digital only, which is not the case in the Open Data Directive. COCIR would recommend defining 'data' more broadly, to include in the scope e.g. paper-based data (such as used at hospitals).

COCIR appreciates that data sharing within the context of the Data Governance Act is explicitly defined as being based on a voluntary agreement between parties.

From a conceptual point it is also not fully clear how data altruism organisations differ from certain data sharing services, other than their non-profit character.

### **Re-use of public sector data**

COCIR would recommend to clarify how and when other data holders would be involved, apart from the public sector bodies holding data.

COCIR welcomes that the proposal supports transparency on the conditions for re-use, which shall be non-discriminatory, proportionate and objectively justified.

In this context, the mechanism of requesting the re-use of public sector data best serves the uptake of innovative data-driven solutions when the processes at national level are simple and time-efficient. Time-consuming investigative work by organisations and administrative burden must be avoided.

COCIR strongly recommends rewriting of Article 5(6). First of all, it is unclear in the fact that there should be clear distinction whether it concerns personal or non-personal data. Next to that, the General Data Protection Regulation defines legal bases for the *processing* of personal data, which is broader than the current reference to transmitting the data. The current wording also seems to imply consent is the main legal basis to use in this case. And finally, there is no indication what should be done in the cases where seeking consent or getting permission is not feasible due to disproportionate costs.

Especially considering the possible mix of personal and non-personal data COCIR is particularly concerned by the introduction of adequacy-like provisions for third countries or undertakings, which may further conflict or complicate transfers to third countries as regulated through the General Data Protection Regulation.

Against this background, more clarity from the European Commission is required on data transfers to third countries under the DGA in case there is no such adequacy decision, and when such adequacy decision is needed, which countries will be assessed in priority and how long the process for adopting adequacy decisions for the types of data covered by the DGA will be. This is of paramount importance as swift adequacy may lead to a competitive advantage.

Moreover, we call on the European Commission to also take into account long-standing international agreements that have brought together a number of like-minded countries on IPR protection and that for these countries, adequate IP protection regimes are already in place. Additional decisions by the European Commission under the DGA on their adequacy may not be required.

### **Requirements applicable to data sharing services**

The scope of data sharing services covered by the Data Governance Act is defined at a very high and abstract level. This may create uncertainty as to which activities are covered – are data sharing services for instance allowed to manage consent or how should the exercise of rights provided in the GDPR be understood?

Considering data sharing services are subject to (mandatory) notification, compared to data altruism organisations, it is unclear why they have no duty to inform updates on their organisation, except in the case of cessation of their activities (cf. Article 17(7) for data altruism organisations).

COCIR appreciates the one-stop shop principle being applied for the notification of data sharing services. To ensure a level playing field this will however require a coordinated and consistent approach among Member States.

### **Data altruism**

As mentioned before, it is not always clear how data altruism organisations are different from some specific data sharing services, especially when it comes to data being voluntarily made available by companies. The current scope as defined for data sharing services does not exclude that data sharing can take place at no cost or without any other reward.

Furthermore, data altruism is being defined from the perspective of the data subject or data holder willing to share data for purposes of general interest. It is therefore strange that data altruism organisations are then being defined on the basis of whether they are not-for-profit or not. The COVID-19 crisis has demonstrated clearly that also for-profit organisations can pursue purposes of general interest. Opening up data altruism organisations for for-profit could help enable further trust.

As with data sharing services, COCIR appreciates the one-stop shop principle being applied for data altruism organisations. COCIR would like to reiterate the need for a coordinated and consistent approach among Member States.

In terms of coordination with other competent authorities, also in the case of data altruism organisations, COCIR would like to recommend coordination with cybersecurity authorities, as is being proposed for data sharing services.

## **Consent**

COCIR fully supports the possibility to have a European consent form, which could include further sector-specific adjustments. This will be a valuable tool to increase trust and legal certainty, both for organisations as well as citizens.

COCIR warmly welcomes the concept of consent that could be provided for data processing in certain areas of research which could not be fully identified at the time of data collection. Such kind of broad consent should be very transparent towards data subjects while ensuring an appropriate level of data protection. It is paramount that this should be developed in full cooperation with data protection authorities and in consultation with sectoral stakeholders, including industry.

Despite this proposal, COCIR would like to stress that the General Data Protection Regulation provides several legal bases for processing, including certain derogations for processing special categories of data. Therefore it is important the Data Governance Act remains aligned with the GDPR in this regard and should not suggest consent as the default legal basis.

## **Competent authorities**

The Data Governance Act calls for the establishment of competent authorities at national level. Preferably and where appropriate, this should not necessarily entail the creation of new authorities but could be integrated within existing structures, be it on the condition that the necessary resources and competences are available to ensure effective monitoring.

Such streamlining of authorities would not only help reduce the costs to the national administrations; considering the various legal dimensions linked to the use of data, it would help reduce the complexity of having meaningful and effective information exchanges between all involved authorities, including those responsible for data protection, cybersecurity and sectoral legislation.

## **European Data Innovation Board**

COCIR appreciates that the governance framework foresees the creation and inclusion of a European Data Innovation Board, to take full account of the various and diverse experiences of all involved stakeholders.

Due stakeholder representation should recognise the crucial role of industry in using and sharing data as well as its strong contributions in the areas of research and standardisation. Representation of industry players through their trade associations should therefore be ensured.

## **International access**

COCIR is concerned about the introduction of provisions that limit data transfers to or data access from third countries, which may further conflict or complicate transfers to third countries as regulated through the General Data Protection Regulation.

## **Evaluation and review**

COCIR recommends to add a more short-term review clause that evaluates the efficiency of the measures related to the re-use of public sector data.

In summary, COCIR considers the Data Governance Act proposal to be an important step in enabling common European data spaces, and in building trust with organisations and citizens. At the same time COCIR would like to caution on provisions that may jeopardise consistency and coherence with existing regulations and initiatives, especially the General Data Protection Regulation.

The success of common European data spaces will further depend on the sector-specific context and frameworks that will need to be created. In this regard, COCIR is warmly welcoming the initiative of the European Commission to establish a legislative framework for a European Health Data Space and will in due time provide its expert feedback, drawing from its vast and long-term experience of improving care provision through innovative and digital health technologies.

COCIR remains fully committed to working with the European Institutions, the Member States and other involved stakeholders in creating a robust data governance framework that will be able to support all common European data spaces, driving new opportunities for research and innovation and building a stronger and more resilient EU economy and society.

### **COCIR References**

[COCIR response on the European Health Data Space \(IIA\)](#) (February 2021)

[COCIR response on Open Data – Availability of Public Datasets](#) (August 2020)

[COCIR response on the data governance framework of common European data spaces](#) (July 2020)

[COCIR input on the European Strategy for Data](#) (May 2020)

[COCIR response on the application of the General Data Protection Regulation](#) (April 2020)

[European Health Data Space – Towards a better patient outcome](#) (November 2019)

### **About COCIR**

*COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.*

*Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. [www.cocir.org](http://www.cocir.org)*