BRIEFING

Initial Appraisal of a European Commission Impact Assessment

European Parliament

Data Governance Act

Impact assessment (SWD(2020) 295, SWD(2020) 296 (summary)) accompanying a Commission proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act) COM(2020) 767

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission impact assessment (IA) accompanying the above-mentioned proposal, submitted on 24 November 2020 and referred to Parliament's Committee on Industry, Research and Energy.

In its communication on a European strategy for data, the Commission observed how data is at the centre of the digital transformation that has brought radical change to the economy and society in recent years, 'affecting all sectors of activity and the daily lives of all Europeans'. The communication anticipates that this transformation will continue and sets out the EU's ambition to 'become a leading role model for a society empowered by data to make better decisions'.[1] To this end, among the key actions envisaged by the communication is the proposal for a legislative framework for the governance of common European data spaces, building on initiatives already taken at Member State level and in some sectors of activity.[2] The aim is 'to enable Europe to become the most attractive, secure and dynamic data-agile economy in the world – empowering Europe with data to improve decisions and better the lives of all its citizens'.[3] The communication highlights the importance of data governance mechanisms if these ambitions are to be achieved: 'for these data spaces to become operational, organisational approaches and structures (both public and private) are needed that enable data-driven innovation on the basis of the existing legal framework.'[4]

The IA also underlines the importance of data for training artificial intelligence (AI) systems, and the Commission, basing itself on the guidelines drafted by the high-level expert group on artificial intelligence,[5] identifies 'privacy and data governance' among the seven requirements that AI applications must meet to be considered trustworthy.[6]

Problem definition

The problem identified by the IA is the limited sharing of data within the EU, despite the potential economic and societal benefits of such sharing. From the IA's investigation of the problem drivers it appears that the problem is caused (i) by a lack of trust in data sharing, (ii) by a lack of culture, structures and processes conducive to the reuse of public sector data and the collection of data for the common good, and (iii) by technical obstacles to the reuse of data.

As laid down in Tool 14 of the Commission's Better Regulation Toolbox, the IA also explores how the problem is likely to evolve without EU intervention, showing a scenario where (i) already dominant big tech platforms continue to consolidate their market power, (ii) the potential economic and societal value of data is still not tapped to the full, (iii) pan-European data-driven innovation remains difficult and cross-border data-driven products and services difficult to develop, and (iv) data research and development of AI systems moves to countries with a more favourable legal environment, leaving the EU dependent on third countries.

The IA refers to a wealth of available literature, stakeholder input and support studies to provide evidence of the nature and scale of the problem.

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Subsidiarity / proportionality

The IA includes a separate section on subsidiarity, in which it explains the necessity and added value of EU action, stating that intervention at EU level would offer a common vision for Member States' endeavours to enhance data sharing, laying down 'the elements that ensure comparable access and use conditions in all data spaces'. This, according to the IA, 'can bring greater value to the European economy and society than action by individual Member States' (IA, p. 18). Some estimates from an OECD report referred to in the IA sum up the potential added value of the initiative:

> 'Data access and sharing can increase the value of data to holders (direct impact), but it can help create 10 to 20 times more value for data users (indirect impact), and 20 to 50 times more value for the wider economy (induced impact) ... Studies suggest that data access and sharing can help generate social and economic benefits worth between 0.1 % and 1.5 % of gross domestic product (GDP) in the case of public-sector data, and between 1 % and 2.5 % of GDP (in few studies up to 4 % of GDP) when also including private-sector data.'[7]

Annex 5 of the IA provides a 'subsidiarity grid' that examines in more detail the competence of the EU to act and the relevant legal basis and investigates adherence with the principles of subsidiarity and proportionality.[8] Proportionality is also one of the criteria used in the comparison of the options for the selection of the preferred policy option in line with the Better Regulation Guidelines and Tool 5 of the Commission's Better Regulation Toolbox.

The deadline for national parliaments to submit reasoned opinions on compliance with the principle of subsidiarity is 23 February 2021. No reasoned opinions had been submitted at the time of writing.

Objectives of the initiative

The IA clearly identifies general and specific objectives. The general objective is to 'leverage the potential of data for the economy and society' (IA, p. 19). As laid down in Tool 16 of the Commission's Better Regulation Toolbox, the specific objectives address the causes of the problem directly, creating a link in the intervention logic between the problem and its drivers and the policy options. Hence, the specific objectives are (i) to reinforce trust in data sharing, (ii) make more public sector data available for reuse and facilitate the collection of data to be used for the common good, and (iii) overcome technical obstacles by improving data fidelity, quality and interoperability across sectors and countries.

As recommended in the Commission's Better Regulation Guidelines and in Tool 16 of the Better Regulation Toolbox, the IA sets operational objectives after having identified the preferred option and within the context of monitoring and evaluation. The IA presents seven operational objectives: three correspond to the three specific objectives and four to the four components of the preferred policy option (see below). The objectives appear to be specific, measurable, achievable and relevant, while the proposal provides an evaluation timeframe for the application of its provisions.

Range of options considered

The IA identifies four intervention areas to cover the specific objectives, and for each of these intervention areas presents four policy options.

- Intervention area 1: mechanisms for enhanced reuse of public sector data
  - Policy option 0: no horizontal action at EU level on data governance and interoperability of common European data spaces, but action may be taken at sectoral or national level.
  - Policy option 1: EU-level coordination and soft regulatory measures, e.g. a recommendation or guidelines with investment actions in support of the deployment of data infrastructures to underpin common European data spaces in specific sectors.
  - **Policy option 2: low intensity regulatory intervention – the reuse of public sector data that is subject to the rights of others would have to comply with basic EU-wide rules (in particular non-exclusivity). Individual public sector bodies allowing this type of reuse would need to be technically equipped to ensure that privacy and**

confidentiality were fully preserved. Member States would have to establish a one-stop shop for persons or organisations seeking to reuse this data, and put in place capacity and services to support public sector bodies for this type of reuse.

- Policy option 3: High-intensity regulatory intervention – the reuse of public sector data that is subject to the rights of others would have to comply with basic EU-wide rules (in particular non-exclusivity). Member States would have to establish a single data authorisation body competent to licence further compatible uses of data contained in any public register subject to the rights of others.

- Intervention area 2: a certification/labelling framework for data intermediaries
  - Policy option 0: no horizontal action at EU level, as in intervention area 1
  - Policy option 1: EU-level coordination and soft regulatory measures, as in intervention area 1
  - **Policy option 2: low intensity regulatory intervention – a voluntary certification/labelling scheme for data intermediaries offering B2B data-sharing services and those offering personal data spaces. A key criterion to obtain the label/certification would be that the data intermediary cannot use the data as part of its business model.**
  - Policy option 3: high-intensity regulatory intervention – compulsory certification scheme for data intermediaries offering B2B data-sharing services and those offering personal data spaces. A key criterion for obtaining the label/certification would be that the data intermediary cannot use the data as part of its business model.
- Intervention area 3: measures facilitating data altruism[9]
  - Policy option 0: no horizontal action at EU level, as in intervention areas 1 and 2.
  - Policy option 1: coordination at EU level and soft regulatory measures as in intervention areas 1 and 2.
  - Policy option 2: low-intensity regulatory intervention – Member States would have to have legal and administrative arrangements in place to enable data altruism, i.e. certification schemes for data altruism mechanisms and/or organisations offering such mechanisms where certification would be voluntary. The certification would be issued by private certification bodies or by a public authority.
  - **Policy option 3: high-intensity regulatory intervention – Member States would have to have legal and administrative arrangements in place to enable data altruism. These would be authorisation schemes for data altruism mechanisms and/or organisations offering such mechanisms where the authorisation would be compulsory. Authorisations would be issued by a public authority.**
- Intervention area 4: a mechanism to coordinate and steer horizontal aspects of governance (European Data Innovation Board)
  - Policy option 0: no horizontal action at EU level, as in intervention areas 1, 2 and 3.
  - Policy option 1: Coordination at EU level and soft regulatory measures, as in intervention areas 1, 2 and 3.
  - **Policy option 2: low-intensity regulatory intervention – a European data innovation board would be created as a light coordination mechanism at EU level in the form of a formal expert group, hosted by the Commission. It would be composed of representatives of the Member States and of representatives for the various sectoral domains (health, statistics, etc.). It would facilitate the exchange of national practices on the items covered by the legal instrument, and would address cross-sector standardisation issues.**
  - Policy option 3: high-intensity regulatory intervention – a European data innovation board would be created as an independent European structure with legal personality and supported by a secretariat (inspired by the structure of European Data Protection Board). In addition to the functions under the lower intensity option, it would be tasked with supervisory functions and keeping registers of awarded labels and authorisations.

The policy options presented in the IA are based on those presented in a support study[10] carried out for the European Commission and appear to offer realistic alternatives. The IA states that no options were discarded from the outset.

Although the outline of the options in the IA might at face value appear to be somewhat generic, this broad description fits the framework nature of the initiative and the options are sufficiently well developed to allow differentiation on the basis of their performance in achieving the identified objectives, as required in Tool 17 of the Commission's Better Regulation Toolbox. The overall preferred option is a mixed package of low and high intensity regulatory intervention. The options in bold in the list above are the preferred options for each intervention area.

Assessment of impacts

For each option in each of the intervention areas, the IA assesses the direct and indirect economic, social and environmental impacts. For this the IA appears to sum up the assessment made in the support study. The support study systematically assesses the impacts of the options on the basis of their effectiveness, efficiency and coherence. This is done through a qualitative assessment in respect of all three criteria, whereas in assessing the efficiency criterion the support study also performs a cost-benefit analysis extracting the benefit-cost ratio of the options for every intervention area. From the results of the qualitative assessment and of the cost-benefit analysis the support study determines that the baseline is not capable of achieving the desired results and resolving the problems identified for any of the intervention areas, and concludes therefore that a policy intervention is necessary. The IA refers to the estimate in the support study that without horizontal action at EU level (the baseline scenario), the data economy and the economic value of data sharing in the EU would be expected to grow to an estimated €533.5 billion (3.87 % of gross domestic product – GDP) by 2028. Under the preferred option this would increase to between €540.7 and €544.4 billion (3.92 % to 3.95 % of GDP). According to the IA, this is a conservative estimate as an increase in trust in data sharing will act as a catalyst for the data economy allowing it to grow beyond the benefits that can be directly attributed to the preferred option (IA, p. 54). The IA concludes that the preferred option would have a range of practical implications to the benefit of public sector bodies, academic and research institutions, consumers, data intermediaries and individuals and society in general.

In order to then determine the type (regulatory or non-regulatory) and the intensity (low of high) of the intervention required, the support study performs a multi-criteria analysis considering the results of the assessment of the impacts and also factoring in legal and political feasibility criteria.

The IA process appears to provide a solid knowledge base capable of underpinning policy decisions to address the identified problem. It is felt, however, that the IA might leave some gaps in the understanding of the analysis of the policy options and in the rationale behind the choice of the preferred option unless the IA is read in conjunction with the support study.

The relevance of the impact of the proposal on fundamental rights is acknowledged in the explanatory memorandum of the proposal, but while the impact on fundamental rights is taken into account to some extent in the support study, it is touched upon only indirectly in the IA.

SMEs / competitiveness

Impacts on SMEs are considered and reported upon in the IA and in the support study. The IA reserves a section of the chapter on the assessment of impacts specifically for SMEs, identifying SMEs as the 'main beneficiaries' of the initiative (IA, p. 45). Among the various stakeholder consultation initiatives feeding into the IA there is also an online consultation conducted between October 2018 and January 2019 targeting SMEs specifically, although the consultation did not refer specifically to this initiative.[11] It thus seems that the first two steps of the SME test as laid down in Tool 22 of the Better Regulation Toolbox are to some extent fulfilled.[12] On the other hand, although there is some differentiation between SMEs and other businesses as to the benefits of the options, it would be a stretch to consider this as a measurement of the impact on SMEs such that would fulfil the third step

of the SME test. The IA cannot really be considered, therefore, to include an SME test, even bearing in mind that Tool 22 subjects the requirement and meticulousness of the assessment of impacts on SMEs to constraints of relevance and proportionality.

Boosting innovation and competitiveness is inherent in the general objective of the initiative. The IA explains in the problem definition that without EU action the economic and societal value derived from data would remain under-exploited, cross-border data-driven innovation, products and services would not develop to their full potential, and eventually the EU would inevitably become dependent on third countries for such innovation, products and services. The IA affirms that action is required to 'meet new market demands and allow the EU to become more competitive in the data-driven world economy'. (IA, p. 11) Competitiveness is also among the categories of benefits that figure in the cost-benefit analysis.

Simplification and other regulatory implications

In setting out the political and legal context of the initiative, the IA describes how the proposal fits into the existing legal framework, in terms of both horizontal and sectoral legislation. It also explains how the proposal fits into the jigsaw of initiatives announced in the communication on a European strategy for data. In particular, it describes how the proposal is the first step in a two-step approach to facilitate the establishment of common European data spaces: the proposal addresses the need 'to facilitate data sharing through an enabling governance framework', while the data act proposal, expected in third quarter of 2021, would then 'address issues about who controls or "owns" the data, i.e. the material rights on who can access and use what data under which circumstances' (IA, p. 6). The IA emphasises that the aim of the horizontal framework is to provide the building blocks to facilitate the establishment of individual data spaces. The latter, however, reflect the needs of the specific sectors, each with their own set-up and standards, and are not prescribed by the horizontal framework.

The IA also acknowledges, before embarking on a description of the policy options, that whatever the preferred policy option, it would be 'combined with investments in common European data spaces envisaged under the Digital Europe programme (DEP) and the Connecting Europe Facility 2 (CEF)' (IA, p. 23).

Monitoring and evaluation

The monitoring plan laid out in the IA is divided into two operational parts: monitoring of the specific objectives of the initiative and monitoring of the four different components (one for each intervention area) of the preferred option. Thus, for every specific objective and for every component of the preferred option the IA presents a corresponding operational objective and corresponding indicators and sources of information.

The proposal states that within four years of its application, the Commission is to carry out an evaluation. The IA specifies that surveys and studies in support of this evaluation will begin within three years of the adoption of the proposal. It also states, although this is not regulated in detail in the proposal, that Member States will 'be asked to report regularly on the efficiency and impact of the different strands of action in their data market' (IA, p. 54).

Stakeholder consultation

Stakeholder views are built in throughout the text of the IA, which, in addition to the mandatory synopsis report of stakeholder consultation activities in Annex 2,[13] also dedicates a section to stakeholders' views in the chapter on the assessment of the impacts. The support study is systematic in reporting on the stakeholders affected for every problem identified and in the assessment of every option.

The stakeholder actions feeding into the IA include actions conducted specifically to inform this initiative (i.e. the open public consultation and several workshops and meetings) and also other recent consultation actions in respect of other related initiatives.

The open public consultation was held between 20 February 2020 and 3 June 2020; that is longer than the mandatory 12-week period stipulated in the Better Regulation Guidelines. According to the IA, 806 contributions were received, including 219 from business enterprises (43 % of which were SMEs), 119 from business associations, 201 from individuals, 98 from academic and research institutions, 57 from public authorities, 7 from consumer associations and 54 from non-governmental organisations. 230 position papers were submitted. Other consultation actions included the feedback received for the inception impact assessment, a series of 10 workshops on common European data spaces held between July and November 2019, and a workshop on labels for or certification of providers of technical solutions for data exchange held online on 12 May 2020.

The IA explains that the consultation process targeted all types of stakeholders, across the EU and across sectors and was 'aimed at understanding how stakeholders consider that data governance mechanisms and structures can best maximise the social and economic benefits of data usage in the EU' (IA, Annex 2, p. 66). From an overview of the stakeholder input available it does appear that stakeholder views 'contributed to the assessment and the choice of the preferred option' (IA, p. 46).

Other stakeholder input was gathered from a special Eurobarometer survey on attitudes towards the impact of digitalisation on daily lives, from an opinion of the European Data Protection Supervisor on the European strategy for data,[14] from the public consultation on building a European data economy held between 10 January and 26 April 2017, from the 2018 public consultation on the revision of the directive on the reuse of public sector information, and (as mentioned under 'SMEs/competitiveness', above) from the 2018 SME panel consultation on the B2B data sharing principles and guidance.

Supporting data and analytical methods used

In many ways the IA reproduces in condensed form the results of the support study's data collection and analysis, which included a cost-benefit analysis and multi-criteria analysis to assess and compare the impacts of the policy options for each of the intervention areas. On the assessment of the environmental and social impacts, the IA acknowledges that it was not possible to quantify the benefits of the different policy options owing to a lack of available data. The result seems to be a reliable assessment underpinned by a mix of qualitative and quantitative data and analysis.

The IA and the support study seem to be transparent about the data sources used, explaining that evidence was gathered from various sources, including support studies conducted by external experts for the Commission, desk research, interviews and focus groups with businesses and other stakeholders, case studies, market analysis and legal analysis. However, although the support study is publicly available on the Commission website, the reference to it given in the IA is not helpful when it comes to locating and accessing it. The assessments and assumptions made appear to be reasonable and to be based on sound research and analysis, while uncertainties are expressly recognised and the unavailability of data is openly recognised. Annex 4 of the IA provides an overview of the overall methodology of the study and the data analysis activities.

Follow-up to the opinion of the Commission's Regulatory Scrutiny Board

The Commission's Regulatory Scrutiny Board (RSB) initially issued a negative opinion on a draft version of the IA on 9 September 2020. Following the submission of a revised version, the RSB issued a positive opinion with reservations on 5 October 2020.[15]

In its second opinion, the RSB acknowledged improvements in the readability and description of objectives, but noted that the IA still contained 'significant shortcomings' that it expected to be rectified. The RSB stated that the IA should (i) further clarify the content of the options, (ii) deepen the analysis of the impacts on SMEs, Member States and the internal market (iii) integrate better the expected effects of the Digital Europe programme (DEP) and the Connecting Europe Facility 2 (CEF) (iv) justify better the preferred option in intervention area 3 concerning measures facilitating data altruism, and (v) examine in more depth how monitoring and evaluation can be better organised on

an ongoing basis. The final IA report seems to reflect to some extent the rectifications expected by the RSB, and in its Annex 1 it describes how these recommendations were addressed.

Coherence between the Commission's legislative proposal and the IA

The proposal appears to correspond essentially to the preferred policy options in respect of mechanisms for enhanced reuse of public sector data (intervention area 1) and in respect of the European data innovation board (intervention area 4).

When it comes to the certification or labelling framework for data intermediaries (intervention area 2) the preferred policy option in the IA is the low-intensity regulatory intervention option, which contemplates a voluntary certification or labelling scheme for data intermediaries. The IA emphasises that 'the provision of data intermediary services remains an unregulated activity' and that 'the label/certificate would not be a requirement for offering data intermediary services in the EU' (IA, p. 26). Article 10 of the proposal, on the other hand, stipulates that providers of data-sharing services who intend to provide data intermediation services must notify the competent authority before they can actually start performing such activity, while Article 11 lays down conditions for providing data intermediation services. Although the provisions of the proposal do not appear to go as far as requiring all intermediation service providers to be certified before they can start operating (as proposed under the high-intensity regulatory intervention option – which is not the preferred option), Articles 10 and 11 of the proposal still seem to depart from the idea of data intermediation as an unregulated activity as espoused in the preferred option.

On measures facilitating data altruism (intervention area 3), the preferred policy option is high-intensity regulatory intervention, which envisages 'a **compulsory** European authorisation scheme as a requirement to offering services facilitating data altruism' (IA, p. 53). However, in the wording of the proposal (Chapter IV) it is not clear that such authorisation is compulsory, and doubt is further fuelled by the statement in the proposal's explanatory memorandum that 'it establishes the **possibility** for organisations engaging in data altruism to register as a "Data Altruism Organisation recognised in the EU" in order to increase trust in their operations' (explanatory memorandum, p. 8).

The IA traces a clear intervention logic, connecting problems and their drivers with specific objectives and policy options. In several sections the IA condenses the data and analysis expounded in a detailed support study under which a cost-benefit analysis and a multi-criteria analysis were performed to assess and compare the impacts of the policy options. The IA process appears to provide a reliable assessment underpinned by a mix of reliable qualitative and quantitative data and analysis. It is felt however that the IA as a self-standing document does not do justice to the considerable data collection and analysis effort that seems to be behind it and a true idea of the substantial process undertaken can only be had if the IA is read in conjunction with the underlying support study. The IA is backed by an extensive stakeholder consultation strategy, also complemented by stakeholder input from other consultation actions conducted in respect of other related initiatives. Finally, with regard to coherence between the IA and the proposal, the proposal does not appear to be fully coherent with the preferred policy option with regard to the certification or labelling framework for data intermediaries or measures facilitating data altruism.

ENDNOTES

1 Communication on a European strategy for data, COM(2020) 66, European Commission, February 2020.

2 The EU has adopted sector-specific legislation on data access to address identified market failures in certain areas, including: the automotive sector (Regulation (EC) No 715/2007 on type approval of motor vehicles); payment services (Directive (EU) 2015/2366 on payment services in the internal market); smart metering (Directive (EU) 2019/944 on common rules for the internal market for electricity and Directive 2009/73/EC concerning common rules for the internal market in natural gas); electricity network data (Commission Regulation (EU) 2017/1485 establishing a guideline on electricity transmission system operation and Commission Regulation (EU) 2015/703 establishing a network code on interoperability and data exchange rules); intelligent transport systems (Directive 2010/40/EU on the framework for the deployment of intelligent transport systems in the field of road transport and for interfaces with other modes of transport).

3 White paper on artificial intelligence – a European approach to excellence and trust, COM(2020) 65, European Commission, February 2020.

4 COM(2020) 66, p. 8.

5 The high-level expert group on AI set up by the Commission was tasked with drafting a set of ethics guidelines for AI and a set of recommendations for a broader AI policy.

6 European Commission, Communication on building trust in human-centric artificial intelligence, COM(2019) 168.

7 OECD, Enhancing access to and sharing of data, 2019, p. 60.

8 The use of a subsidiarity grid that can be used as a foundation for further discussion among the EU institutions and national and regional parliaments is one of the recommendations in the report of the Task Force on Subsidiarity, Proportionality and 'Doing Less More Efficiently'. The task force was formally established by a decision of the President of the Commission on 14 November 2017 under the chairmanship of Commission First Vice-President Frans Timmermans, and comprised three members from the national parliaments of Austria, Bulgaria and Estonia and three members from the European Committee of the Regions.

9 The communication on a European strategy for data (p. 13) describes data altruism as the action of individuals allowing the use of the data they generate for the public good.

10 Impact assessment on enhancing the use of data in Europe, European Commission, November 2020.

11 European Commission, SME panel consultation on B2B data-sharing principles and guidance – Report on the results.

12 The four steps of the SME test according to Tool 22 are to: (1) identify affected businesses; (2) consult SME stakeholders; (3) measure the impact on SMEs; and (4) assess alternative mechanisms and mitigating measures.

13 Required by the Better Regulation Guidelines and by Tool 12 of the Better Regulation Toolbox.

14 Opinion on the European strategy for data, Opinion 3/2020, European Data Protection Supervisor, June 2020.

15 The second RSB opinion made publicly available is not dated and, unusually, does not include the first opinion.

This briefing, prepared for the Committee on Industry, Research and Energy (ITRE), analyses whether the principal criteria laid down in the Commission's own Better Regulation Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal.

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