European Parliament

Artificial intelligence act

Impact assessment (SWD(2021) 84, SWD(2021) 85 (summary)) accompanying a Commission proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021) 206)

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's impact assessment accompanying the above-mentioned proposal, submitted on 21 April 2021 and provisionally referred to the European Parliament's Committee on the Internal Market and Consumer Protection.

In its communication on artificial intelligence for Europe[1] of April 2018, the Commission set out a European initiative on artificial intelligence (AI), aiming at (i) boosting the EU's technological and industrial capacity and AI uptake across the economy, (ii) preparing for the socio-economic changes brought about by AI, by encouraging the modernisation of education and training systems, nurturing talent, anticipating changes in the labour market, supporting labour market transitions and adapting social protection systems, and (iii) ensuring an appropriate ethical and legal framework, based on the Union's values and in line with the EU Charter of Fundamental Rights.

The communication set a process in motion involving Member States and the Commission that led to the adoption of a coordinated plan on artificial intelligence.[2] The plan lays down a set of concrete and complementary actions at EU, national and regional level aiming at maximising the impact of investments at EU and national levels, encouraging synergies and cooperation across the EU, fostering the exchange of best practices and collectively defining the way forward on AI.

In June 2018, the Commission established the High-Level Expert Group on Artificial Intelligence (AI HLEG), an independent group mandated to draft ethics guidelines on AI and policy and investment recommendations in regard to AI. The AI HLEG published its ethics guidelines for trustworthy AI in April 2019, and its policy and investment recommendations for trustworthy AI in June 2019. In its communication on building trust in human-centric artificial intelligence,[3] the Commission welcomed the work of the AI HLEG and launched a targeted piloting phase designed to obtain structured feedback from stakeholders in order to test the practical implementation of ethical guidance for AI development and use.

The Commission *White paper on artificial intelligence*,[4] published in February 2020, outlines a policy framework setting out measures to align efforts at European, national and regional level and identifies the key elements of a future regulatory framework for AI to 'create a unique "ecosystem of trust"'. The proposal is one of the building blocks of the framework envisaged in the white paper (the section 'Simplification and other regulatory implications', below, outlines the package of AI initiatives planned by the Commission).[5]

Since 2017, the European Parliament has adopted a number of resolutions touching upon different aspects relevant to the continuing development and increasing use of AI, laying down its principles on how different aspects of AI should be regulated within the EU, and requesting legislative action according to these principles. Some of the issues raised and recommendations made by the European Parliament in these resolutions are addressed in the proposal.[6]

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In a clear signal of the importance it attached to the subject, the European Parliament decided in June 2020 to set up a special committee on artificial intelligence in a digital age.[7]

Problem definition

The impact assessment identifies six problems that are triggered by the development and use of AI, substantiating its findings with references to the results of stakeholder consultations and other relevant sources:

1 The use of AI poses increased risks to the safety and security of citizens, which are not sufficiently covered by the existing EU safety and security framework;
2 The use of AI poses an increased risk of violations of citizens' fundamental rights and Union values;
3 Authorities do not have the powers, procedural frameworks and resources to ensure and monitor compliance of AI development with applicable rules;
4 Legal uncertainty and complexity on how existing rules apply to AI systems dissuade businesses from developing and using AI systems;
5 Mistrust in AI could slow down AI development in Europe and reduce the global competitiveness of the EU economy;
6 Fragmented measures create obstacles for a cross-border, AI single market and threaten the Union's digital sovereignty.

The impact assessment explains that the drivers behind these problems are the 'specific characteristics of AI systems which make them qualitatively different from previous technological advancements' (impact assessment, p. 28). The impact assessment explores what these specific characteristics are[8] and how they lead to the problems identified.

As to the scale of the problem, the impact assessment quotes a European Added Value Assessment,[9] prepared by the European Parliamentary Research Service, that 'a common EU framework on the ethics of AI has the potential to bring the European Union €294.9 billion in additional GDP and 4.6 million additional jobs by 2030' (impact assessment, p. 25-26).

As laid down in the Commission's Better Regulation Guidelines and in Tool 14 of the Commission's Better Regulation Toolbox, the impact assessment also explores how the problem is likely to evolve without EU intervention. It argues that, given the concerns AI raises regarding safety issues and the potential of violation of human rights, it is likely that there will be a proliferation of ethics principles that cannot be enforced and therefore do not build the necessary trust. The consequences would be a competitive disadvantage for European businesses, and possibly a consumer preference for companies with a proven track record of trustworthy AI, which would favour large companies to the detriment of small and medium-sized enterprises (SMEs).

Subsidiarity / proportionality

The impact assessment includes a distinct section on subsidiarity under 'Chapter 3 – Why should the EU act?' The section explains the necessity and added value of EU action, stating that 'the intrinsic nature of AI which often relies on large and varied datasets and which might be embedded in any product or service circulating freely within the internal market mean that the objectives of the initiative cannot effectively be achieved by Member States alone'. According to the impact assessment, EU action and the consequent boost to the internal market have the potential to improve the competitiveness of European industry and provide it with economies of scale (not quantified) that cannot be achieved by Member States acting individually. It continues that only action at EU level can safeguard the EU's technological sovereignty and 'leverage its tools and regulatory powers to shape global rules and standards' (impact assessment, p. 32).

In line with the Commission's Better Regulation Guidelines, proportionality is also among the criteria used in the comparison of the options for the selection of the preferred policy option.

At the time of writing, no national parliaments had issued a reasoned opinion on non-compliance with the principle of subsidiarity. The deadline for submissions is 2 September 2021.

Objectives of the initiative

The impact assessment clearly identifies general and specific objectives, choosing not to define more detailed operational objectives as laid out in the Commission's Better Regulation Guidelines, and instead linking monitoring and evaluation indicators directly to the specific objectives (see the section on 'Monitoring and evaluation' below. The general objective is to 'ensure the proper functioning of the internal market by creating the conditions for the development and use of trustworthy artificial intelligence in the Union' (impact assessment, p. 32). The specific objectives are: (i) to ensure that AI systems placed on the market and used are safe and respect existing rules on fundamental rights and Union values, (ii) to ensure legal certainty to facilitate investment and innovation in AI, (iii) to enhance governance and effective enforcement of existing rules on fundamental rights and safety requirements applicable to AI systems, and (iv) to facilitate the development of a single market for lawful, safe and trustworthy AI applications and prevent market fragmentation.

As required in the Commission's Better Regulation Guidelines, the objectives set in the impact assessment establish a logical chain between the problems identified and the policy options considered. In this respect, the impact assessment uses an intervention logic tree to good effect, accompanied by explanatory text, to illustrate and summarise the links and correspondence between the specific characteristics of AI systems, the resulting problems and their drivers, and the ensuing objectives.

The objectives appear to be specific, measurable, achievable and relevant, while the proposal provides an evaluation timeframe in regard to the application and possible revision of its provisions.

Range of options considered

The impact assessment identifies four policy options in addition to the baseline. The options, differentiating from each other on the basis of seven dimensions, are summarised in Table 1.

Table 1 – Summary of the analysed policy options

	Option 1 EU voluntary labelling scheme	Option 2 Ad hoc sectoral approach	Option 3 Horizontal risk-based act on AI	Option 3+ Voluntary Codes of conduct for non-high-risk AI (in addition to Option 3)	Option 4 Horizontal act for all AI
Nature of act	An EU act establishing a voluntary labelling scheme	Ad hoc sectoral acts (revision or new)	A single binding horizontal act on AI	Option 3 complemented by codes of conduct for non-high-risk AI	A single binding horizontal act on AI
Scope/ definition of AI	One definition of AI, however applicable on a voluntary basis only	Each sector can adopt a definition of AI and determine the risk level of the AI	One horizontally applicable AI definition and methodology for determination	Option 3 complemented by industry-led codes of conduct for non-high-risk AI	One horizontal AI definition, but no methodology/or gradation (all risks covered)

		systems covered	of high risk (risk-based)		
Requirements	Applicable only for voluntarily labelled AI systems.	Applicable only for sector specific AI systems with possible additional safeguards/ limitations for specific AI use cases per sector	Risk-based horizontal requirements for prohibited and high risk AI systems + minimum information requirements for certain other AI systems	Option 3 complemented by industry-led codes of conduct for non-high-risk AI	For all AI systems irrespective of the level of the risk
Obligations	Only for providers who adopt voluntary scheme and no obligations for users of certified AI systems	Sector specific obligations for providers and users depending on the use case	Horizontal obligations for providers and users of high-risk AI systems	Option 3 complemented by a commitment to comply with codes of conduct for non-high-risk AI	Same as Option 3, but applicable to all AI (irrespective of risk)
Ex-ante enforcement	Self-assessment and an ex ante check by national competent authorities responsible for monitoring compliance with the EU voluntary label	Depends on the enforcement system under the relevant sectoral acts.	Conformity assessment for providers of high-risk systems (third party for AI in a product and other systems based on internal checks) + registration in an EU database	Option 3 complemented by self-assessment for compliance with codes of conduct for non-high-risk AI	Same as Option 3, but applicable to all AI (irrespective of risk)
Ex-post enforcement	Monitoring by authorities responsible for EU voluntary label	Monitoring by competent authorities under the relevant sectoral acts	Monitoring of high-risk systems by market surveillance authorities	False or misleading claims of compliance with a code of conduct are considered unfair commercial practices	Same as Option 3, but applicable to all AI (irrespective of risk)
Governance	National competent authorities designated by Member States responsible for	Depends on the sectoral acts at national and EU level; no platform for	At the national level but reinforced with cooperation between	Complementary to Option 3 – For non-high-risk AI, the EU would have no active role in	Same as Option 3, but applicable to all AI (irrespective of risk)

	the EU label + a light EU cooperation mechanism	cooperation between various competent authorities.	Member States authorities and with the EU level (new AI Board)	the approval or enforcement of voluntary codes of conduct	

Data source: IA, p. 36-37.

It does appear that the impact assessment offers a balanced presentation of a diverse range of realistic alternatives, with the longer presentation of Option 3 (which is also the basis of Option 3+) justifiable by the complexity of that option. The impact assessment systematically explains how the options address (or otherwise) the problems identified, contributing to an easy tracing of the logic linking the problems, the objectives and the policy interventions under consideration. As recommended in the Commission's Better Regulation Guidelines and in Tool 12 of the Better Regulation Toolbox, the impact assessment describes a number of options or sub-options that were considered but discarded at an early stage and explains why these options were not retained for in-depth analysis.

The preferred option is option 3+, marked in the shaded column in Table 1.

Assessment of impacts

The impact assessment looks into the economic impacts, the costs for public authorities, the social impacts, the impacts on safety, the impacts on fundamental rights and the environmental impacts of the options. The analysis of the economic impacts is further subdivided into sections on the impacts on the functioning of the internal market, the impacts on the uptake of AI, the impacts on compliance costs and administrative burdens, the impacts on SMEs, and the impacts on competitiveness and innovation. The analysis is clear and methodical and puts particular focus on economic impacts and the impacts on fundamental rights.

In line with the Commission's Better Regulation Guidelines, the options are compared on the basis of their effectiveness in achieving the four specific objectives, their efficiency, their coherence with other policy objectives and initiatives, and their proportionality. Options 3+ and 4 were the ones that scored highest in the comparison of options. Between them, Option 4 scored higher in its effectiveness in achieving specific objectives (i) and (iii) (see the section on 'Objectives of the initiative' above), whilst Option 3+ scored higher in achieving specific objective (iv). The impact assessment, however, found that Option 4 would not be cost effective and would be disproportionate and this tilted the balance in favour of Option 3+ as the preferred option.

The assessment of impacts and the comparison of the options is in many aspects a qualitative exercise, with a quantitative method used to assess the compliance costs generated by the mandatory regulatory requirements of the horizontal regulatory options.

SMEs / Competitiveness

The impact assessment identifies SMEs as one of the categories of stakeholders affected by the problems and by the policy options put forward, and takes the views of SMEs into consideration as a distinct category of stakeholders in processing input from the stakeholder consultation.

Impacts on SMEs are considered and reported upon in the impact assessment (under the economic impacts) and in an external study supporting the impact assessment (the support study).[10] The impact assessment considers that 'the vast majority of SMEs would not be affected at all' by the obligations introduced under the preferred option, Option 3+, since these obligations would be applicable only for high-risk applications and it is assumed that most AI systems supplied by SMEs do not fall under that category. However, the impact assessment acknowledges that those SMEs that do supply high-risk AI systems (the share of which is not indicated) would 'in principle be more affected than large companies' (impact assessment, p. 70). The support study explains that it used

benchmark comparison and in-depth expert interviews to gain insights into the estimated cost impact of mandatory regulatory requirements on SMEs and concludes that while such requirements 'may bring in additional costs [they] would not make investments substantially unprofitable' (support study, p. 161).

To address the disadvantages for SME providers and users of high-risk AI systems, the preferred option contemplates measures to reduce the regulatory burden on small-scale providers and start-ups and support them within the framework of the initiative. The mitigating measures include the creation of regulatory sandboxes and an obligation to consider SMEs' interests when setting fees related to conformity assessment.

In light of the above, it does appear that the four steps that constitute the SME test as laid down in Tool 22 of the Better Regulation Toolbox have been fulfilled.[11]

The impact assessment dedicates a specific section under the assessment of the economic impacts to analyse the effects of the options on competitiveness and innovation. It explains that the European market for AI is roughly a fifth of the total world market and subject to tough international competition and considers the impact of the options on competitiveness and innovation as 'crucial' in this environment. In this respect, the impact assessment considers it important for any regulatory framework to strike a balance between two contradicting factors. 'On the one hand, the additional compliance costs and administrative burdens ... make AI projects more expensive and hence less attractive for companies and investors. ... On the other hand, the positive impact on uptake ... is likely to increase demand even faster, and hence make projects more attractive for companies and investors' (impact assessment, p. 73).

Simplification and other regulatory implications

Compliance costs and administrative burdens are among the impacts specifically analysed for each of the retained options. The impact assessment estimates that the maximum aggregate compliance costs and administrative burden for high-risk AI applications under options 3 and 3+ would be between €100 million and €500 million by 2025.

In terms of the proposal's coherence with existing and planned EU legislation, the impact assessment explains that the proposal fits into the existing EU legal framework that 'provides non-AI specific principles and rules on the protection of fundamental rights, product safety, services or liability issues' (impact assessment, p. 5). It explains that the proposal is the first of a comprehensive package of three complimentary initiatives to adapt the existing principles and rules to the emergence of AI so that 'the same rights and rules that apply in the analogue world [would] also be respected when AI systems are used' (impact assessment, p. 33):

1 European legal framework for AI to address fundamental rights and safety risks specific to the AI systems;
2 EU rules to address liability issues related to new technologies, including AI systems;
3 Revision of sectoral safety legislation.

Annex 5.3 to the impact assessment outlines the interaction between the proposal and existing sectoral product safety legislation.

Monitoring and evaluation

For the purposes of monitoring and evaluating the operation of the proposal, the impact assessment links a number of provisional and non-exhaustive indicators directly to the specific objectives, also indicating the source of the relevant data to be used for the purposes of monitoring and evaluation.

Stakeholder consultation

The impact assessment and Annex 2 thereto chronicle the various stakeholder consultation activities conducted to feed into the formulation of the proposal, starting with the stakeholder submissions collected by the AI HLEG (see introductory section above).

The online public consultation on the AI White Paper ran from 19 February to 14 June 2020, and received 1 215 contributions from a wide variety of stakeholders (citizens 33 %, business and industry 29 %, civil society 13 %, academia 13 % and public authorities 6 %; 84 % of the contributions came from Member States and the rest from outside the EU). Amongst other things, the consultation sought stakeholders' opinions on the regulatory framework for AI envisaged in chapter 5 of the AI White Paper. In their replies, 42 % of respondents found the introduction of a new regulatory framework on AI, as proposed by the Commission, the best way to address the concerns raised, whilst 33 % thought that it would be more appropriate to adapt existing legislation. According to the impact assessment, 'the vast majority of online respondents seemed to overwhelmingly agree with compulsory requirements' of the type envisaged in the preferred option for high-risk AI applications. The concerns of categories of stakeholders regarding the status quo and their preferences for addressing these concerns is reflected throughout the impact assessment.

Other stakeholder consultation activities included the receipt of feedback on the inception impact assessment, online workshops with experts from different stakeholder groups and input from the European AI Alliance platform.

Supporting data and analytical methods used

The impact assessment banks on a wealth of available research on the topic at hand and uses numerous sources to underpin the discussion. These include specialised literature, reports, studies, case law, surveys, policy documents and position papers from a variety of sources, including in particular the European Parliament and the European Parliamentary Research Service.

These sources are complemented by a support study, which is publicly available and which contributes in particular with a quantitative assessment of the compliance costs generated by the five mandatory legal requirements contemplated in the Commission *White paper on artificial intelligence* (these mandatory legal requirements[12] broadly correspond with the requirements of the policy options envisaging a horizontal legislative act, namely options 3 and 4). The support study explains that the cost estimations therein are based on the Standard Cost Model, which is a common methodology for the assessment of administrative burdens presented in Tool 60 of the Commission's Better Regulation Toolbox.

Annex 4 of the impact assessment provides information about the analytical methods used in the quantitative assessments of the compliance costs and also explains how and why in certain instances the impact assessment and the support study differ in their assumptions and figures.[13] The assessments and assumptions made appear to be reasonable.

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

The Commission's Regulatory Scrutiny Board (RSB) initially issued a negative opinion on a draft version of the impact assessment on 18 December 2020. Following the submission of a revised version, the RSB issued a positive opinion on 22 March 2021.

In its second opinion the RSB acknowledged the significant improvements made on key issues of the impact assessment, but considered that it should be further improved by explaining the methodology and sources for its cost calculations, as well as better discussing the combined effect of the foreseen support measures for SMEs and new market entrants. The final impact assessment seems to reflect recommendations of the RSB, and in its Annex 1 describes how these recommendations were addressed.

Coherence between the Commission's legislative proposal and IA

The proposal appears to essentially correspond to the preferred policy option indicated in the impact assessment. There does seem to be a discrepancy, however, between the impact assessment and the proposal in the timeframe for the publication by the Commission of the report on the evaluation and review of the initiative. While the impact assessment envisages the publication of the report five years after the date of application of the initiative, the proposal lays down a timeframe of three years after the date of application for the first report, with subsequent reports at four-year intervals.

The impact assessment banks on a wealth of available research on the topic at hand and uses numerous sources to underpin the discussion. It traces a clear intervention logic connecting the problems and their drivers with the specific objectives and the policy options. The range of alternative options offered appears to be diverse and realistic and presented in a balanced manner. The analysis of the impacts of the options is clear and methodical and puts particular focus on economic impacts and the impacts on fundamental rights. The assessment of impacts and the comparison of the options is in many aspects a qualitative exercise, with a quantitative method used to assess the compliance costs generated by the mandatory regulatory requirements of the horizontal regulatory options. The views expressed by SMEs in the stakeholder consultation are specifically considered and the impacts on them are assessed and reported upon. The restriction of the scope of the mandatory requirements to high-risk applications means that many SMEs active in the supply of AI systems would not fall within the scope of the obligations. Furthermore, mitigation measures are proposed to reduce to some degree any disproportionate regulatory burdens that an unmitigated application of the options would engender on SMEs and starts-ups that do supply high-risk AI systems.

ENDNOTES

1   Communication on artificial intelligence for Europe, COM/2018/237, European Commission, 2018.

2   Communication on a coordinated plan on artificial intelligence, COM(2018) 795, European Commission, 2018.

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

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

5   For more information and background on EU initiatives on the subject of AI see: T. Madiega, An EU framework for artificial intelligence, EPRS, European Parliament, October 2020.

6   Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics, European Parliament; Resolution of 12 February 2019 on a comprehensive European industrial policy on artificial intelligence and robotics, European Parliament; Resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, European Parliament; Resolution of 20 October 2020 on intellectual property rights for the development of artificial intelligence technologies, European Parliament; Resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence, European Parliament; Resolution of 20 January 2021 on artificial intelligence: questions of interpretation and application of international law in so far as the EU is affected in the areas of civil and military uses and of state authority outside the scope of criminal justice, European Parliament. A resolution on Artificial intelligence in criminal law and its use by the police and judicial authorities in criminal matters is in preparation.

7   Decision of 18 June 2020 on setting up a special committee on artificial intelligence in a digital age, and defining its responsibilities, numerical strength and term of office, European Parliament. The special committee was tasked with analysing the future impact of artificial intelligence on the EU economy, investigating the challenge of deploying artificial intelligence and its contribution to business value and economic growth, analysing the approach of third countries and their contribution to complementing EU actions, and defining common EU objectives in the medium- and long-term.

8   According to the impact assessment the five specific characteristics of AI are (i) opacity (limited ability of the human mind to understand how certain AI systems operate), (ii) complexity, (iii) continuous adaptation and unpredictability, (iv) autonomous behaviour, and (v) data (functional dependence on data and the quality of data).

9   T. Evas, European framework on ethical aspects of artificial intelligence, robotics and related technologies – European added value assessment, EPRS, European Parliament, September 2020.

10   J. Arroyo, G. de Pierrefeu, V. Devenyi, G. Endrodi, R. Fanni, M. Fernandes, S. Georgiev, M. Laurer, G. Maridis, S. Milio, A. Renda, A. Sipiczki, T. Yeung, Study to Support an Impact Assessment of Regulatory Requirements for Artificial Intelligence in Europe, European Commission, April 2021.

11   The four steps of the SME Test, according to Tool 22 are: (1) Identification of affected businesses; (2) Consultation of SME stakeholders; (3) Measurement of the impact on SMEs; (4) Assessment of alternative mechanisms and mitigating measures.

12   The five mandatory requirements envisaged in the Commission *White paper on artificial intelligence* are: training data; data and record-keeping; information to be provided; robustness and accuracy; and, human oversight;

13   One adjustment made was to round figures and where possible express them as ranges of values, because the precise figures in the study are the result of mathematical modelling based on assumptions, 'and indicating amounts to a single euro would signal a precision which is not backed up by the methodology'. Another adjustment involved not taking the compliance costs regarding robustness and accuracy into account, since 'an economic operator trying to sell AI systems would anyway have to ensure that their product actually works, [and] this cost would only arise for companies not following standard business procedures'. Likewise, costs for quality management systems are not taken into account since 'companies supplying high-risk AI systems in general already have a quality management system in place [and] it would be misleading to include these costs for an average company'. Finally, 'compliance costs regarding human oversight have not been added with the other compliance costs into one single amount but kept separate, since it is overwhelmingly a recurring cost for AI users rather than a one-off cost for AI suppliers like the other compliance costs' (IA, Annex 4, p. 32-33).

This briefing, prepared for the Committee on the Internal Market and Consumer Protection (IMCO), 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.