European Commission

INCEPTION IMPACT ASSESSMENT

TITLE OF THE INITIATIVE	Proposal for a legal act of the European Parliament and the Council laying down requirements for Artificial Intelligence
LEAD DG (RESPONSIBLE UNIT)	CNECT.A.2
LIKELY TYPE OF INITIATIVE	legislative
INDICATIVE PLANNING	Q1 2021
ADDITIONAL INFORMATION	

The Inception Impact Assessment is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

Artificial Intelligence[1] (AI) is a fast evolving technology that can contribute to a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation and personalizing service delivery, the use of AI can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education, infrastructure management, energy, transport and logistics, public services, security, and climate change mitigation and adaptation, to name just a few.

In its Communication "Artificial Intelligence for Europe" of April 2018, the Commission put forward a European approach to AI, which includes, among others, the need to ensure an appropriate ethical and legal framework based on the Union's values and in line with the Charter of Fundamental Rights. At the same time, this Communication noted that the Union has a, existing regulatory framework to build on, for example regarding protection of personal data, non-discrimination, product safety and product liability.

The High-Level Expert Group on Artificial Intelligence (HLEG), appointed in June 2018, produced, in April and June 2019 respectively the Ethics guidelines for trustworthy AI, which underwent a piloting process between June and December 2019, and the Policy and investment recommendations for trustworthy AI. With its Communication "Building Trust in Human-Centric Artificial Intelligence" of April 2019, the Commission expressed its support to the seven key requirements for trustworthy AI identified by the HLEG.

As stated in the Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, product safety legislation could be further developed to provide a higher degree of legal certainty. AI poses new challenges for the liability-related rules enshrined in Union and national law. At European level, initiatives are thus being prepared, notably regarding a revision of the General Product Safety Directive, a revision of the Machinery Directive, delegated acts to be adopted under the Radio-Equipment Directive, as well as rules on liability for AI, in order to address, among others things, the challenges linked to new digital technologies.

In December 2018, the Commission presented a Coordinated plan on AI with the Member States to align policies so as to foster the development and use of AI in Europe. The "DEI and AI" group of Member States representatives has been regularly meeting since 2018, discussing among other things the ethical and regulatory aspects of AI. A review of the Coordinated plan is foreseen.

In her Political Guidelines of July 2019, President-elect von der Leyen announced a coordinated European approach to the human and ethical implications of AI. In February 2020, the Commission published a White Paper on AI setting out policy options for a regulatory framework and an approach towards investment.

Problem the initiative aims to tackle

This Inception Impact Assessment concerns a possible initiative aimed at addressing a number of ethical and

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[1] Artificial intelligence refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals: COM(2018) 237 final, p. 1

legal issues raised by AI. The ultimate objective is to foster the development and uptake of safe and lawful AI that respects fundamental rights across the Single Market by both private and public actors while ensuring inclusive societal outcomes.

While the use of AI can do much good, some of its uses and applications may also cause harm, both material (physical) and immaterial. Material harm might relate to the safety and health of individuals and their property (for instance in case of accidents linked to autonomous vehicles or AI-driven robotic applications in general). Immaterial harm can relate to, for instance, loss of privacy or limitations to the right of freedom of expression (possibly caused by intrusive surveillance or monitoring systems) or unlawful discrimination (such as in the case of recruitment tools that display a bias against certain groups of the population) or discrimination in the access to products and services such as lack of accessibility for persons with disabilities, to name but a few.

Harm caused by the use of AI may be the consequence of multiple causes, such as flaws in the overall design of the AI system, the use of poor quality or biased data, or machine learning related characteristics, such as the probabilistic nature of the system or the ability of certain AI systems to continue learning when in use.[2]

While the potential harms above are not *per se* new or otherwise necessarily tied to AI only, the preliminary analysis of the Commission in the White Paper indicates that a number of specific, significant risks are at stake when it comes to AI and are not adequately covered by existing legislation (cybersecurity, protection of employees, anti-discrimination etc.). The main issues identified so far relate to the effective enforcement of EU rules designed to protect fundamental rights, as well as to the application of EU rules on safety and of the rules regarding the attribution of liability.[3]

- Just like for actions and decisions taken by humans, the use of AI to either directly take decisions or to support decision-making may lead to violations of fundamental rights, as guaranteed by and implemented in EU law. In particular, due to AI's technological capabilities, potential breaches of fundamental rights may come from sources of risk that did not exist before (e.g. surveillance by remote biometric identification of individuals in real time) or involve otherwise means and tools assisting or replacing human decision-making. Whilst no new rights are needed, some characteristics of AI, including its opacity ('black box-effect'), the complexity of certain systems and granular applicability of different computed outcomes to individuals, and the scalability of AI systems, may **hamper the effective enforcement of existing EU law meant to protect fundamental rights**. For example, biased and discriminatory outcomes resulting from decisions taken or supported by AI systems might remain completely unperceived (e.g. candidates of a certain sex, disability or ethnicity may not see certain job vacancies in the first place) or difficult to challenge without appropriate documentation about how the system works or about the goals it pursues (e.g. automatic denial or recovery of social security benefits).[4]
- At the same time, **AI may generate new safety risks for users and third parties, which are not yet explicitly tackled clearly by the product safety legislation**. For example, in principle stand-alone software is not explicitly covered by EU product safety legislation[5,] with the consequence that the risks generated by the probabilistic nature of AI are not yet clearly and specifically addressed by existing safety rules[6]. Additionally, such legislation focuses on safety risks present at the time of placing the product on the market and presupposes "static" products, while AI systems can evolve[7]. In addition to generating new safety risks for user and third parties, the lack of clear safety provisions tackling such risks may give rise to:
  - **legal uncertainty for businesses** that are marketing their products involving AI in the Union, as well as for those using such products in their own processes, and
  - **challenges for market surveillance and supervisory authorities** which may find themselves in a situation where they are uncertain whether they can intervene, because they may not be empowered to act and/or may not have the appropriate tools and means to inspect AI-enabled systems.

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[2] In contrast to deterministic models, probabilistic models imply that is not always possible to foresee all the possible types of outcome of the model.
[3] For further details see the White Paper, p. 10.
[4] For a comprehensive analysis on the use of AI in digital welfare state, see Report of the UN Special rapporteur on extreme poverty and human rights, 11 October 2019, A/74/48037. .
[5] With the exception of software intended by the manufacturer to be used for a medical intended purpose, which can be considered a medical device or an in vitro diagnostic medical device failing either under the Medical Device Regulation (Regulation (EU) 2017/745) or In Vitro Diagnostic medical device regulation (IVDR).
[6] In that respect, requirements regarding design principles, training data, robustness and accuracy and human oversight would all contribute to reduce risks for safety due to unintended behaviour.
[7] Even if the AI powering a given product would normally not "learn" or evolve while in operation and instead be "frozen", further machine learning developments "pushed" through software updates may alter the risk profile of the product or its use and require repeated assessments of conformity over the AI life cycle.

Specific challenges on product safety are currently also being addressed by other ongoing initiatives, such as the revisions of the Machinery Directive and of the General Product Safety Directive. The Commission will ensure coherence and complementarity between those initiatives and this initiative.

- Furthermore, if safety risks materialise, the characteristics of AI technologies mentioned above **may make it difficult for persons having suffered harm to obtain compensation under the current EU product liability legislation** because those characteristics make it very difficult to obtain documentation that would allow to identify a person responsible for the damage and to trace back the damaging outcome to a particular human action or omission. Specific challenges on liability are currently being addressed by other ongoing initiatives. The Commission will ensure coherence and complementarity between those initiatives and the present proposal.

As AI tools can be used to perform functions that previously could only be done by humans or not at all, it is necessary to set specific requirements aimed at preventing and/or mitigating intended or unintended negative outcomes. This will (see below policy options) create trust and incentivise the use of such AI systems by citizens and businesses. **Otherwise, besides the fact that the protection of fundamental rights and safety is an end in itself, citizens and businesses would not have the confidence to embrace AI applications affecting them and companies and public organisations would not have the legal certainty to innovate using AI**. Such lack of trust and of legal certainty would **stifle the uptake of AI** and **lead not only to a loss of competiveness**, but also to **foregoing a wide array of possible societal benefits** that AI is poised to bring.

On the other hand, the promotion of AI applications that can be tested and trusted – insofar as their use and functionality are anchored in European values, respects fundamental rights and the rule of law, meets high standards of safety and, in case of harm, ensures that redress is available - should offer a **key competitive advantage to Europe**.

Finally, the risks linked to AI mentioned above have already led a few Member States to adopt or consider adopting separate initiatives and prompted the emergence of a series of uncoordinated private sector efforts such as standards, principles or codes of conduct. Such **increasing fragmentation** can hamper the confidence of European businesses to innovate and the development of beneficial AI solutions, and jeopardise the goals of the digital single market.

Basis for EU intervention (legal basis and subsidiarity check)

This initiative is a key component of the Commission's ambition to make Europe fit for the digital age, notably by exploiting the potential of its internal market and by positioning Europe as a global leader in sustainable technological innovation.

The legal basis of the initiative will be determined by the content and objective of the measures to be proposed, including possibly Article 114 TFEU (Title VII: Common rules on competition, taxation and approximation of laws).

While this policy field is not an area of exclusive competence of the EU, the intrinsic link of the initiative with existing EU law, for example regarding fundamental rights, product safety and product liability, the likely divergent results of national policies and their likely effects on cross-border sales and provision of services, as well as the need to foster trust as a precondition for the uptake and deployment of AI within the EU, imply that **the objectives cannot be reached effectively by Member States alone**. **The objectives of the initiative can be better reached at Union level,** by avoiding a fragmentation of the Digital Single Market into potentially divergent frameworks preventing the free circulation of goods and services containing AI.

B. Objectives and Policy options

<u>**Objective**</u>: the overall policy objective is to ensure the development and uptake of lawful and trustworthy AI across the Single Market through the creation of an ecosystem of trust.

More specifically, the aims are:

(a) to ensure the effective enforcement of rules of existing EU law meant to protect safety and fundamental rights and avoid illegal discrimination by ensuring the relevant documentation for the purposes of private and public enforcement of EU rules;

(b) to provide legal certainty for businesses that are marketing their AI-enabled products or using such solutions in the EU as regards the rules applicable to such products and services;

(c) to prevent where possible or to minimise significant risks for fundamental rights and safety;

(d) to create a harmonised framework in order to reduce burdensome compliance costs derived from legal fragmentation, which could jeopardise the functioning of the Single Market;

(e) to set up a European governance structure on AI in the form of a framework for cooperation of national competent authorities in order to develop needed capacity;

(f) to facilitate the emergence of a market for trustworthy AI, including by ensuring a level playing field.

The White Paper already identified elements of a possible legislative initiative on AI for the purposes of a wide public consultation. In line with the Commission's Better Regulation Guidelines, this Inception Impact Assessment (and the forthcoming impact assessment) complements the White Paper by further analysing relevant policy options and policy instruments.

Baseline (no EU policy change, Option "0"): in the absence of EU action on establishing specific requirements for AI, the risks linked to the latter (see above) would remain unaddressed. While EU legislation on the protection of fundamental rights and consumer protection as well as on product safety and liability remains relevant and applicable to a large number of emerging AI applications, problems with enforcement of existing EU law and national liability rules may emerge. There could also be a lack of clarity regarding possible obligations to address the new risks raised by AI. Given the significant commercial opportunities offered by AI solutions and the pressure to conquer market shares, whether by European or foreign developers interested in the EU market, "untrustworthy" AI solutions could ensue, with a likely backlash against AI technology as a whole by citizens and businesses. Moreover, as indicated, no EU policy change could lead to increased fragmentation due to interventions at Member States level.

Alternative options to the baseline scenario:

The Commission will assess multiple sets of options in order to address the risks linked to the development and use of certain AI applications. These sets of options would follow a gradual intervention logic, ranging from an exclusively "soft law" approach to comprehensive EU-level legislation. Option 3 for a legislative instrument with mandatory requirements could have a narrower or a larger scope of application. It could also be combined with industry-led intervention or not and include ex-ante and/or ex-post enforcement mechanisms.

This approach would also be complemented by other initiatives concerning product safety and civil liability; coherence and coordination between all such initiatives will be ensured.

The preliminary options for the sets of measures that will be explored are the following:

(1) Option 1: EU "soft law" (non-legislative) approach to facilitate and spur industry-led intervention (no EU legislative instrument)

Under this option, EU "soft law" would promote industry initiatives for AI. A large number of AI principles and ethical codes have already been developed by industry actors and other organisations.[8] In the Union, the HLEG developed a set of Ethics guidelines for trustworthy AI with an assessment list aimed at providing practical guidance on how to implement each of the key requirements for AI. The "soft law" approach could build upon existing initiatives and consist of monitoring and reporting on the voluntary compliance with such initiatives based on self-reporting; encouraging industry-led coordination on a single set of AI principles; awareness raising among developers and deployers of AI systems around the existence and utility of existing initiatives; monitoring and encouraging the development of standards.

(2) Option 2: EU legislative instrument setting up a voluntary labelling scheme

Under this option, a EU legislative instrument would establish a voluntary labelling scheme to enable customers to identify AI applications that comply with certain requirements for trustworthy AI. While participation to the labelling scheme would be voluntary, the economic operators who choose to participate would have to comply with certain EU-wide requirements (in addition to existing EU legislation) in order to be able to display a quality AI label. The label would function as an indication to the market that the labelled AI application is trustworthy. The voluntary labelling scheme could follow a model similar to, or be inspired by, the assessment list of the Ethical guidelines piloted by the HLEG. A label could also be used for issues that go beyond regulated aspects and the respect of fundamental rights.

(3) Option 3: EU legislative instrument establishing mandatory requirements for all or certain types of AI

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[8] These documents reflect a growing consensus around the importance of aspects such as privacy, accountability, safety and security, transparency and explainability, fairness and non-discrimination, human control, professional responsibility: Principled Artificial Intelligence: Mapping Consensus in Ethical and Rights-Based Approaches to Principles for AI, Berkman Klein Center Research Publication No. 2020-1.

applications (see sub-options below).

Under this option, the EU legislative instrument would establish certain mandatory requirements on issues such as training data, record-keeping about datasets and algorithms, information to be provided, robustness and accuracy and human oversight. [9]

a. *As a first sub-option*, the EU legislative instrument could be limited to a specific category of AI applications only, notably remote biometric identification systems (e.g. facial recognition). Without prejudice to applicable EU data protection law, the requirements above could be combined with provisions on the specific circumstances and common safeguards around remote biometric identification only.

b. *As a second sub-option*, the EU legislative instrument could be limited to "high-risk" AI applications, which in turn could be identified on the basis of two criteria as set out in the White Paper (sector and specific use/impact on rights or safety) or could be otherwise defined.[10]

c. *In a third sub-option*, the EU legislative act could cover all AI applications.

(4) Option 4: combination of any of the options above taking into account the different levels of risk that could be generated by a particular AI application.

Any of the sub options above can be combined with industry-led intervention or not. In one scenario (industry-led intervention or co-regulation), the legislative instrument would primarily consist in high-level principles and obligations to be complemented by industry-led norms such as in the form of standards or codes of conduct. In another scenario (detailed regulatory framework), the legislative instrument would establish a regulatory framework with a higher degree of detail and specificity, possibly to be achieved also with implementing powers of the Commission.

Furthermore, for any of the sub-options above, the EU legislative instrument should include enforcement mechanisms to ensure effective compliance with any applicable requirements, in particular existing and future requirements under the EU acquis. Such mechanisms could be ex-ante or/and ex-post.[11] Ex-ante mechanisms could consist of conformity/safety assessment procedures that are aligned with the procedures that already exist in the product safety legislation . For AI applications where no mechanisms exist, new ex-ante conformity/safety assessment procedures may need to be established. Moreover, existing ex-ante and ex-post enforcement structures would need to be competent and fully equipped to fulfil their mandate where AI tools are used. Ensuring this competence may include requirements for adequate funding, capacities, competences and mechanisms to work together.

Another core question relates to the scope of the initiative, notably how AI should be defined (narrowly or broadly) (e.g. machine learning, deep neural networks, symbolic reasoning, expert systems, automated decision-making).

The design of the above options can be adjusted and further refined during the Impact Assessment process, and additional or alternative options can also be considered.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

Economic benefits of public intervention stem from an increase in users' trust and a corresponding increase in the demand and use of AI systems by enhancing the compliance with and enforcement of existing Union rules on fundamental rights and product safety. Thus it will also raise the attractiveness for business to invest in and for talents to come to Europe. The public intervention may however impose additional compliance costs, in so far as the development of some AI systems may have to account for new requirements and processes. If compliance costs outweigh the benefits, it may even be the case that some desirable AI systems may not be developed at all.

The compliance costs depend on the one hand on how many companies involved in the design and deployment of AI applications that would be subject to specific requirements: the larger the scope, the higher the costs. Thus, if all AI applications would be covered by the new instrument and the companies concerned would need to implement specific measures, this is more costly than if only certain AI applications are covered, for example those that entail high risks. Costs also depend on the compliance mechanism that is put in place, e.g. on the extent, type, and the clarity of specific requirements and of the procedures relating to ex-ante and ex-post controls. For example, if documentation were to be required, the cost of this documentation requirement would

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[9] For further details see the White Paper, p. 18.
[10] For further details see the White Paper, p. 17.
[11] For further details see the White Paper, p. 23.

depend on how many resources it would take (in terms of money or time) to produce this documentation and store it and to have it verified within procedures based on ex-ante conformity assessments and/or ex-post checks. The assessment will also have to consider which measures a responsible economic operator would take even without explicit public intervention.

The extent of the economic benefits depends, all other things being equal, on the increase in trust. Other things being equal, users will have more trust when they can rely on legal requirements, which they can enforce in courts if need be, than if they have to rely on voluntary commitments (whose benefits depend on the extent that companies have signed up to them); these commitments in turn inspire more trust than simple company policies, which lack credible enforcement mechanisms.

Thus, with increasing levels of obligations on companies both costs and benefits will increase. Soft law would entail very limited additional costs, i.e. the time needed for developing codes of conduct and complying with them, and limited benefits, since trust would depend on the companies' credibility. Voluntary labelling would likely entail limited costs (such as changing business practices so that the conditions of the label are fulfilled and obtaining a label); these costs can be considered to be more than compensated by the benefits (otherwise companies would not voluntarily participate). Mandatory requirements would entail some costs depending on the nature of the requirements, both in terms of changed business practices and in terms of the costs of ex-ante or ex-post control, but also create some significant benefits in terms of improved acceptance by users. Finally, extending legal requirements to AI applications where trust is not relevant (e.g. industrial applications such as optimising factory procedures) may not bring about increases in benefits.

Due to the high scalability of digital technologies, small and medium enterprises can have an enormous reach, potentially impacting millions of citizens despite their small size. Thus it might be argued that SMEs should not be excluded from the application of the regulatory framework. Proportionality will have to be ensured, however, particularly in relation to SMEs. It should also be noted that small and therefore not well-known companies will benefit disproportionately from a higher level of trust in AI than large companies, who can also rely on their brand image.

Likely social impacts

No direct significant negative social impacts are to be expected. Indirectly, by increasing trust the measures will increase uptake and hence development of lawful AI applications, among other things by improving healthcare, education, public services etc. This may also have an impact on the labour market: while AI-enabled automation may replace some jobs, the use of AI will simultaneously lead to the creation of new jobs, although there is no consensus on the characteristics and extent of these effects. As a corollary, it may intensify already existing digital skills shortages.

In terms of other possible social impacts, such as in relation to education, culture or youth, given the ability of AI to generate efficiencies, expand and improve service delivery across sectors (for example by enabling personalised education) and generate new insights, including for creative purposes, positive social impacts can be expected.

Likely environmental impacts

No direct significant environmental impacts are expected from the proposed measures. At most, some limited additional storage and testing may be required, which could increase energy consumption by a small amount (most AI-related energy consumption takes place during the training phase of machine learning models).

Indirectly, by increasing trust the measures will increase uptake and hence development and thus use of resources (machine learning is currently very energy consuming). This may be compensated by the fact that a number of AI applications are beneficial to climate change adaptation and mitigation and to the environment in general (optimising energy systems, controlling the use of pesticides, increasing the efficiency in the use of resources including water, etc.).

AI resource usage and energy consumption can be minimised if properly encouraged to do so. In the context of the coordinated Plan with Member States, the Commission will consider options to encourage and promote AI solutions that have a neutral/positive impact on climate change and environment. This will also reduce potential environmental impacts of the present initiative.

Likely impacts on fundamental rights

Strengthening the respect and effective enforcement of EU fundamental rights is one of the main objectives of the initiative. The positive effect of the policy will increase with regulatory intensity. Where soft law may marginally facilitate implementation of fundamental rights legislation and voluntary labelling can do so to a limited extent, binding requirements will strengthen the respect of existing fundamental rights for all AI systems covered. Possible impacts on the freedom to conduct a business, right to property and freedom of science on concerned entities will be assessed.

Likely impacts on simplification and/or administrative burden

One of the goals of the initiative is to avoid increased regulatory cost that could result from legal fragmentation across the EU. Providing a harmonised framework at the Union level would reduce such a cost driver.
Otherwise, the potentially negative effect on administrative burden will increase with regulatory intensity. Where soft law creates only marginal administrative burden and voluntary labelling an administrative burden only where the benefits compensate the costs, binding requirements could create some administrative burden that is not totally compensated by additional benefits. This applies especially to requirements that could be imposed on AI systems that cannot benefit from increased trust because trust is not relevant. The impact assessment will identify and quantify regulatory costs benefits savings, burden reduction and simplification potential.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment is being prepared to support the preparation of this initiative and to inform the Commission's decision. The completion of the impact assessment is scheduled for December 2020.

Evidence base and data collection

AI is a highly dynamic and rapidly evolving industry so that not a lot of currently valid evidence is available at this stage. However, it is important to steer the development in the right direction from the beginning and not to wait until the technology has developed in a way that is no longer incompatible with European values and legislation.

Furthermore, there is mounting evidence on the lack of trust hindering uptake through surveys at European and national level. In this context, the piloting of the assessment list of the trustworthy AI Ethics guidelines prepared by the High Level Group on AI is an important source of information. The AI Ethics guidelines had already been subject to a public consultation run over the European AI Alliance (a platform counting more than 4,000 members) which lasted 6 weeks and yielded more than 500 submissions.

Other sources of references include consultant reports such as McKinsey (investment levels) and CapGemini, as well as from the EU Fundamental Rights Agency) the Council of Europe, the positions of the EU social partners, and proxies of uptake through the Eurostat ICT surveys of enterprises and of individuals.

Consultation of citizens and stakeholders

A public consultation on the White Paper was launched on 19 February. It was open until 14 June. The objective is to gather views on the issues raised in the White Paper, i.e. on the promotion of European excellence in AI, on the implications for safety and liability regimes of the emergence of AI, and on the the options for the regulatory framework , as well as collecting evidence. The consultation takes place in all languages and can be accessed by the Commission's central public consultation page. The main targeted groups are companies (developers and deployers of AI in the various sectors/ fields of application), citizens and organisations such as consumer associations, certification authorities, research labs, etc. On top of that a consultation strategy envisaged further targeted consultations/workshops with technical experts, conformity assessment bodies, standardisation bodies and experts on biometric data.

The consultation is being promoted through the Alliance platform, which counts more than 4000 stakeholders from academia, civil society, business etc. involved in AI. A summary of the results will be published on the consultation page.

There are also several consultation events scheduled in many Member States and some non-EU countries. However, in view of the corona virus, some of them might be postponed.