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Developers Alliance's response to the Inception Impact Assessment for a legal act of the European Parliament and the Council laying down requirements for Artificial Intelligence

[Developers Alliance](#) welcomes the opportunity to further provide feedback on the European Commission's proposals on requirements for AI.

The Inception Impact Assessment (IIA) presents several regulatory options and the underlying policy objectives, based on the approach initiated by the White Paper on AI. Our response emphasizes the need to avoid excessive regulatory burden and to adopt a fit-for-purpose approach aimed at promoting AI development in the EU.

We commend the EC's engagement to avoid "a fragmentation of the Digital Single Market into potentially divergent frameworks preventing the free circulation of goods and services containing AI".

On the problems the initiative aims to tackle

We suggest extreme caution in extending liability to immaterial harm. This could prove extremely difficult to assess and quantify and therefore pose legal uncertainties. Citizens are interacting with AI embedded in products and services. Applicable legislation, be it general frameworks or sectoral legislation, is already covering risks to fundamental rights and freedoms (e.g. principle of accountability under the GDPR). Appropriate guidance on practical issues and soft law initiatives would ensure better enforcement.

With reference to the potential harms, we disagree with the perspective presented by the IIA. In the case of AI systems used for decision making and the enforcement of EU law meant to protect fundamental rights, the approach should not focus on the characteristics of certain AI systems. Appropriate safeguards in the administrative process itself are more important instead, in order to mitigate biased and discriminatory

outcomes, in the same vein as they should be applied for human only decision-making. It is reasonable to expect that complete explanations on how the outputs of some AI systems are provided might be impossible (e.g. deep learning). This becomes obvious when we consider that human decision-making processes aren't fully known, and that AI targets the same problems. **One should avoid setting a higher standard on AI than human decision-making.**

The alleged new safety risks that AI may generate for users and third parties doesn't need to be "explicitly tackled clearly by the product safety legislation". General requirements, such as not to put users' life and health in danger, provide a sufficient legal base. Stand-alone software is usually put on the market as a specific product and the legal guarantees against harm are already covered by existing relevant specific legislation or civil liability.

We welcome EC's commitment to ensure coherence and complementarity between the legal act setting out requirements for AI and the proposals on the revision of the frameworks for product liability and general product safety.

On the proposed policy options

We agree with the overall objective and the specific aims. European innovators and entrepreneurs should benefit from a coherent, harmonized framework, allowing them to develop and deploy AI products and services across the Single Market and beyond.

It is essential to avoid excessive regulatory burdens. Therefore, a regulatory intervention should only adapt the existing legal requirements and cover the gaps, where necessary. We are looking forward to the impact assessment which "will identify and quantify regulatory costs-benefits savings, burden reduction and simplification potential".

Baseline (no EU policy change, Option "0"):

As indicated in the roadmap, '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'. There are many areas where new legislation is not justified.

Alternative options to the baseline scenario:

Option 1: EU "soft law" (non-legislative)

Industry initiatives for trustworthy AI reflect, as mentioned by the IIA, "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". The Ethics guidelines and the assessment list developed by the AI HLEG could provide a good complementary tool, once agreed. This will ensure a coherent industry-led approach that would meet the proposed objectives

in a more efficient way, avoiding unnecessary burdens. This will allow developers to further innovate while still promoting caution.

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

We reiterate our reservations towards this proposal expressed in the feedback to the White Paper on AI. The proposed labelling system will create pressure on startups and scale-ups. Even if voluntary, the proposed system will add additional costs and administrative burdens that only larger businesses can afford. SME access to the market could be hampered. As mentioned above, developers already benefit from self-regulatory efforts that provide best practices in different software development ecosystems. However, it is still premature to think that AI standardization could offer solutions at scale for the market.

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

The first sub-option (political decision on the use of biometric systems) must be considered in the context of what unique role AI would play versus human surveillance and identification. The regulation of facial recognition is not legally distinct from human surveillance, and regulation in this area needs to be principle-based, and not technology based. Above all, the use of AI in fingerprint or biometric access control (on phones or in secure facilities) should not be impeded through overbroad definitions.

The second sub-option, proposing a scope limited to certain AI applications that might pose “high-risk”, based on the two criteria set out in the White Paper (sector and specific use/impact on rights or safety) could represent a suitable approach in the context of the adaptation of the current applicable legislation. We underline that the “high-risk” formula should be applied case-by-case, according to the proposed cumulative criteria (selected sectors and use cases). Legal clarity is key.

The third sub-option, of a broad scope, covering all AI applications, is disproportionate and unjustified. The only feasible approach is the adaptation of existing legislation. Such a horizontal legal act would be a source of legal uncertainty affecting all industry sectors, with a chilling effect on AI development in the EU.

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.

This option is not feasible. AI systems are embedded in products and services subject already to existing legal requirements, as the IIA also states. Furthermore, AI technologies can have dual-use, or new forms of use can be discovered after they are placed on the market. Other new, innovative solutions can always be discovered. This requires that the applicable legislation be future-proof and technology-neutral.

Regulatory experimentation promoting innovation

We strongly suggest to consider **regulatory sandboxes** as a flexible and agile approach to pursue the policy objectives, a suitable alternative to regulation.

The Coordinated Plan on Artificial Intelligence stated that “bringing state-of-the-art AI applications to the market requires experimenting and testing in real-world environments”¹. The Competitiveness Council called on to “explore the use, where appropriate, of regulatory sandboxes for the regulations that may have impact on the functioning of the Single Market in a digital environment, in particular for the projects related to the use of Artificial Intelligence”². Member States like Finland, Malta or Luxembourg consider this approach in their national AI strategies³. The European Parliament also welcomed “the use of regulatory sandboxes to introduce, in cooperation with regulators, innovative new ideas, allowing safeguards to be built into the technology from the start, thus facilitating and encouraging its market entry” and highlighted “the need to introduce AI-specific regulatory sandboxes to test the safe and effective use of AI technologies in a real-world environment”⁴.

Despite all the political statements mentioned above, the White Paper on AI lacks any reference to regulatory sandboxes.

As a relevant good practice example, the Norwegian Data Protection Authority set out a regulatory sandbox for AI⁵, which “will help to increase knowledge about and provide insight into new innovative solutions, as well as make it easier to identify potential risks at an early stage”.

On the ex-ante conformity assessment

Compulsory ex-ante conformity assessments will only set up a layer of redundant and overlapping obligations. The process of adjusting the current legislation should follow the objective of addressing high risks and identifying where amendments or new specific provisions should be added, as *lex specialis*.

Where justified (e.g. when the use of certain AI applications might pose “high-risks”, clearly defined by the legal act), we recommend an ex-ante risk self-assessment (similar to the data protection impact assessments under GDPR), complemented by ex-post enforcement. We strongly recommend avoiding disproportionate administrative burdens.

We agree that 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.

¹ <https://ec.europa.eu/digital-single-market/en/news/coordinated-plan-artificial-intelligence>

² <https://www.consilium.europa.eu/media/39510/st09743-en19.pdf>

³ [Finland AI Strategy Report | Knowledge for policy](#); [Artificial Intelligence: a strategic vision for Luxembourg](#); [A Strategy and Vision for Artificial Intelligence in Malta 2030 The Ultimate AI Launchpad_vFinal.pdf](#)

⁴ https://www.europarl.europa.eu/doceo/document/TA-8-2019-0081_EN.html

⁵ <https://iapp.org/news/a/norwegian-dpa-creating-regulatory-sandbox-for-ai/>

On a definition of AI

The legal definition should not be over-inclusive but should seek legal clarity, in order to serve regulatory purposes. The definition should describe those elements that are specifically relevant for the scope of the legal act.

EU regulation within the international context

We emphasize the importance of coordination with the current efforts in defining ethical standards for AI at the international level.

The intrinsic nature of software development and the digital economy transcends geographical and political borders. European AI developers should not be forced to work in isolation while advancement continues beyond our borders. Innovative startups should not be limited within the EU borders by obstructive standards and administrative burdens. European consumers should not be deprived of the potential benefits of accessing innovative products.