

## Response to the [European Commission's inception impact assessment on AI ethical and legal requirements](#)

Smart government approaches to regulation will play an important role in boosting public confidence and ensuring that AI is used responsibly, while also encouraging innovation. However, it is important that a proportionate, risk-based approach is taken - balancing potential harms with the social and economic benefits that will be created by AI. In the following points we are providing our feedback to the policy options presented and share our comments on additional points of concern raised by the Commission's initiative.

Policy options:

### No EU policy change

We welcome smart approach on setting up rules for AI. However, it is imperative to maintain clear focus in delivering EU policy change while acknowledging a number of already existing rules, including GDPR, medical devices regulation, and fundamental rights aquis. New prescriptive rules should only be considered in the areas where existing regulation is clearly insufficient.

### Option 1: EU "soft law"

We are certain that the European AI industry would benefit greatly from the European Commission providing us with guiding principles for self-regulation and co-regulation, as they would play an important role helping European businesses to develop advanced technologies responsibly. We would expect this kind of support from the European Commission even if other policy options are pursued by the Union.

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

We are concerned that even a voluntary labelling scheme is likely to create a heavy administrative burden for AI innovators that are often SMEs with limited resources. As a result, the costs of such a scheme could quickly outweigh the benefits of encouraging uptake of AI across Europe. We would especially like to caution basing a labeling scheme on the Assessment List for Trustworthy AI from the EU High-Level Expert Group on AI as its nature inherently limits variation across settings for different cases of application. Just as in Option 1, we would encourage the Commission to work closely with the AI industry to develop a menu of labeling schemes for different AI application settings.

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

We strongly encourage the Commission to factor in the opportunity cost of not using AI when considering any regulatory intervention into AI applications. In deliberating possible options it's vital to reflect not only potential harms but also societal opportunities. The benefits of AI will often outweigh the risks, especially if risks can be mitigated in a thoughtful way with strong safeguards. Regulation must not discourage AI innovation, development, nor limit its use. Proportionality and clear focus of any regulation will help ensure legal certainty for AI innovators and increase trust in AI without unduly hindering AI-driven innovation.

### 3a) EU legislative instrument limited to a specific category of AI applications

We welcome the Commission's approach on singling out clear areas of AI application, like remote biometric identification or facial recognition, when considering future mandatory requirements. In this particular case there appears to be a widespread consensus across the European society that the use of

facial recognition technologies for mass surveillance should be classified as a high-risk application and subjected to straightforward mandatory regulation. We encourage the Commission to approach further high-risk AI regulation discussion in a similarly focused manner.

### 3b) EU legislative instrument limited to “high-risk” AI applications

We support the proposed option to limit future AI regulation to “high-risk” AI applications only. However, we would like to emphasise the need for proportionality when defining “high-risk” applications of AI. In doing so it is important to reflect the probability of harm and not just the possible severity of the harm. It should also take account of the wider operational context when assessing risk, since the same AI application used for the same purpose will pose different risks depending on the way it is integrated into business operations (e.g., extent of human oversight, additional safeguards such as monitoring). We suggest using a combination of sector and use/application as criteria to set up the risk-based approach.

### 3c) EU legislative act covering all AI applications

As mentioned in the previous feedback, we believe that future regulation on AI should be limited to “high-risk” applications only. Otherwise AI applications posing no significant risk or harm would be subjected to disproportionate rules that in no way would advance development, trust and adoption of AI solutions in Europe. Over regulating application of such a promising technology would likely result in severe opportunity costs for the society and quite possibly lower the bar for AI applications with significant risks.

#### On the enforcement mechanisms:

We believe a combination of ex-ante risk self-assessment and ex-post enforcement for high risk AI applications would likely achieve desired results within much faster timeframes and without risking unduly stopping innovation and creating unnecessary burdens. We strongly support building on existing industry practices, including ethical, legal and due diligence practices that guide the responsible and trustworthy development of AI. Furthermore, it would be most practical if regulators were to provide clear “due diligence” guidance for quality self-assessment procedures. We also would discourage relying on third party ex-ante assessments as such approach would subject commercial secrets to external exposure risks and due to lack of familiarity could easily misinterpret aspects of an AI system.

#### On the scope of the initiative:

A clear and widely understood definition of AI is critical to the effectiveness of the future regulatory framework. Just as the Commission’s White Paper on AI described the main elements of AI as data and algorithms so is this Inception Impact Assessment trying to suggest too broad of a scope for future AI regulation. For example if AI were to be defined as “automated decision-making” it would miss out on the desired risk-based focus and would include automated systems that do not pose any risk. Any future AI regulation should avoid disproportional and unjustified regulatory obligations as it would otherwise have adverse effects on the development and deployment of AI-based applications in Europe.

#### On the immaterial harm:

Immaterial harm is not a known legal concept and could mean anything from economic loss to hurt emotions, and could lead to legal uncertainty, discouraging investment and innovation. In order to bring

practical clarity for the AI innovators it would be best to consider an alternative concept - “significantly restricting the exercise of fundamental rights,” which we believe would be easier to interpret and align with the existing legislative framework.