

Request to review the Impact Assessment of the AI Act

A study commissioned by the European Commission¹ that forms the basis of the Impact Assessment (IA) is raising some important questions that are not really taken into account by the AI Act (AIA). Therefore, I would like to request the IMCO/LIBE coordinators to ask the Ex-Ante Impact Assessment Unit of the European Parliament to undertake a substitute impact assessment with a particular focus on the following two points.

(1) Percentage of high-risk AI systems: According to the IA, only 10% of all AI systems will fall under the category of high-risk AI and thus be confronted with high compliance and conformity costs. However, the expansive definition of high-risk AI systems in Art 3(1) AIA combined with Annex I could potentially include basic software tools.

The study mentioned above suspects that the actual number of AI application that fall under high risk is in fact unknown and endogenous.² Tallying up the gross value added of the sectors covered by the “high risk” designation indicates that up to 35% of the European economy could be affected. Therefore, two key questions should be addressed:

- *What is considered/defined as high risk? Does the IA take into account the wide latitude of business sectors considered "high risk" for the purposes of AI?*
- *Does the IA apply the right methodology in order to quantify that 10% of all AI systems are affected? If the actual number of AI systems covered is higher than what the Commission has stated in its IA, should the number of high-risk areas be reduced accordingly?*

(2) High compliance costs: The Regulatory Scrutiny Board initially rejected the AIA as it predicted high compliance costs, in particular for SMEs and start-ups. The calculations of the IA reference an hourly wage rate of €32, which was flagged as too low by the industry during the preparatory workshops in 2020. One could argue that the assumption of a homogeneous 'hourly ICT reference wage' is a radical simplification and does not reflect the reality of finding qualified staff in order to implement the AIA's compliance requirements.

AI developers command massive salary premiums, as do compliance personnel that are necessary to help interpreting complex laws. Even if setting up a Quality Management System (QMS) is a one-off cost, it amounts to at least €400,000. On top, many sectors-specific laws are requiring other types of QSM. The average European SME has a turnover of €10 Million and a profit margin of 10% so this cost would cause their profits to fall by 40%. The study shows that this may hinder the emergence of new technologies for start-ups, SMEs and new players that have to set up a QSM from scratch before entering the market.³

This reminds of the experiences from the GDPR where the IA similarly did not calculate the costs that would arise for businesses to comply with the regulation. However, in the GDPR IA, the Commission did not quantify the compliance costs but only calculated the costs that would be saved as the harmonization arising from the GDPR would lower the costs experienced previously due to

¹ 'Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe' accessible via <https://op.europa.eu/en/publication-detail/-/publication/55538b70-a638-11eb-9585-01aa75ed71a1>

² P. 143: "While these estimates assume that high-risk AI systems only count for 10% of total AI investments, the actual proportion is unknown and will depend on the definition of high-risk AI systems. The private sector will also respond to the new regulation and thus the equilibrium high-risk AI investment will be determined endogenously."

³ P. 149: "The upfront cost of this procedure may be too high for SMEs, however, and could effectively impose an entry barrier to the market."; p. 160 "In the case of full QA, SMEs are less likely to have a QMS in place already and would therefore have to bear high one-off costs to invest in a system to comply with the regulation. [...] That one-off spend may deter new entrants from developing high-risk AI systems, but have less impact on existing companies that have already made their investment decision."

fragmentation of data protection laws, while disregarding the costs that businesses would have to bear in order to comply with the new rules. Nonetheless, in both impact assessments, the Commission does not accurately calculate these costs; either by not exactly quantifying them at all (GDPR) or by underestimating them (AIA), leaving those affected in the dark about the *actual* costs to consider when preparing for the new frameworks.

This brings us to the following questions:

- *Only 14% of European SMEs are in industries with high innovation intensities, which is partly why we have a productivity crisis. Why does the cost estimate not consider the points described above? Why does the IA in particular not consider second-order cost (i.e. SMEs not investing in AI due to the high compliance costs of the AIA)?*
- *What could be a more holistic and realistic assessment from the perspective of a SMEs and start-ups that wants to enter the AI space?*
- *Should the IA not include costs of external legal advice and consultancy fees as well as internal staff costs in terms of resources diverted to ensure compliance?*