Feedback to the European Commission's regulation proposal on the Artificial Intelligence Act

Berlin, August 6, 2021

General

Artificial Intelligence (AI) is a rising digital technology and displays all properties of a general-purpose technology. Therefore, it enables all kinds of innovative applications leading to high expectations for the future. However, concerns about risks are similarly strong but often seem vague and speculative.

Without any doubt, Europe with its diverse and talented AI ecosystem can become a global competitive player in AI. Yet, "AI made in Europe" serving its society and economy in vast ways, needs a flexible, understandable, and future-oriented regulatory framework. Overregulation and too many bureaucratic requirements create an administrative burden and risk of hindering and slowing AI development and innovation. Fulfilling these requirements is burdensome for smaller start-ups and SMEs in particular. It could result in a competitive disadvantage to their global counterparts outside the EU e.g., from China and the US, but also beyond.

Therefore, we welcome the opportunity to provide herewith our feedback and expert opinion related to the European Commission's (Commission) proposal for the regulation of AI in Europe, dated April 2021:

1. Definition

We are aware that one of the main challenges is to horizontally regulate general purpose technologies because of their wide footprint. The proposed AI Regulation demonstrates this challenge: **The AI definition (Article 3.1 and Annex 3) is not distinct enough**. It classifies almost **any existing and future software as "AI"** that would then be covered by the regulatory framework. It remains open about which risks are to be tackled and misses an analysis of why AI adds a layer of risks not present before, in particular in areas which are already regulated.

2. Risk-based approach

We appreciate that the current draft does not directly regulate or ban every AI-system that is theoretically critical without closer examination. In particular, we welcome the fact that the Commission has opted for a risk-based approach. However**, the definition lacks comprehensibility, clear terminology, and delimitations.**

The tendency to place an entire industry under general suspicion and the subsequent approach, that improper usage of AI-system can lead to harm is too generalizing and does not reflect reality. Therefore, we recommend a more detailed consideration of the specific use case category and associated risk-relevant factors (see, for example, risk classes for medical devices). We welcome critical considerations of AI applications but **their generalized classification as a high-risk category requires revaluation.**

3. Risk-assessment

We question the **affordability of self- and 3rd-party assessments**, especially for start-ups and SMEs. In the case of 3rd-party assessments, hiring external experts and specialised audit companies mean costs that can only be paid by large enterprises. **The measures mentioned in the draft to avoid disadvantages for start-ups and SMEs are not sufficient and need to be extended**. For self-assessments, depending on the scope and associated liability risk, the question arises as to **the feasibility of establishing a quality management system by SMEs and other companies without significant inspection and testing infrastructure of their own**. Further specification of the requirements for **the test processes and test infrastructure for risk-assessments** would be desirable, including answers to the following questions:

- Who bears the liability risk for incidents in the testing process?
- How are systematic biases resulting out of systematic testing prevented?
- How are transparency and access to the review process guaranteed, especially for start-ups and SMEs?
- What are the requirements for the qualification of the reviewers?

As already touched upon in Point 2, the risk assessment of critical applications should consider **several criteria that need to be cumulatively examined and fulfilled.**

There is **no (comprehensible) balancing of risk and benefit, in the sense of a risk-benefit ratio, so that a disproportionate risk assessment can quickly occur**. What is the risk assessment when the AI application itself is high risk, but it significantly reduces the risk of existing approaches, as in autonomous driving vs. autonomous vehicle? Article 7, paragraph 2 mentions categories such as severity and reversibility, but further factors of established risk research, such as **probability and controllability of the risk and expected benefit in relation to it are missing**. This should be considered when revising the draft.

We also advocate to **create a harmonised sanctioning infrastructure across Europe**. There must not be any differences in the way the same facts are handled between the individual member states. The regulation proposal is not clear enough about how a harmonised approach to audit processes can be established and ensured within the European framework.

4. Guidelines

In many places, the operationalization of definitions, assessment criteria and requirements in the draft remain unclear. This unclear operationalization creates considerable **uncertainties on the business side and especially among start-ups and SMEs**. We therefore call for the involvement of practical users and relevant institutions in the development and design of national operationalizations of the draft. We strongly suggest that the **current proposal is complemented with application- and industry-specific guidelines. These should be less general than the regulation itself, but refer to concrete sectors, industries and use cases - and are ideally formulated jointly with AI developers.**

5. Existing regulation

We do not see any need for additional regulation concerning product liability for AI based products. As existing product liability regulations are well established t**here is no need to introduce further technology specific regulations**. Most of today's software products are continuously improving with updates and the same shall apply to AI based products. We

strongly support other industry associations' position on that as to the point that we see AI based products bring huge benefits - also in terms of safety - to people, **we therefore strongly position ourselves against additional market barriers and technology specific extra regulations**. The current law sufficiently covers risks that could be justified by AI systems.

Furthermore, also with respect to the existing admission procedure, we strongly recommend taking into consideration **the use of quantitative measures**. The need to understand - as to follow up decision making processes in a simplified way - is to be replaced **by systematically measuring the performance of an algorithm or product.** Otherwise, today's and also future AI developments may not be able to be deployed in society because the admission procedures were created with focus on technologies present at that point in time.

6. **Data**

We welcome the aim of the Commission to create better data sets. **Limited availability of high-quality data can be one of the biggest hurdles in developing AI that accurately represents a population.** However, the question arises for AI software manufacturers on **how to ensure the unrealistic goal of Article 10.3. The most common source of bias is data that does not sufficiently represent the target population**. For example, women and people of color are typically underrepresented in clinical trials. Many diseases present differently in women and men, whether it is cardiovascular disease, diabetes, or mental health disorders such as depression and autism having adverse implications for these underrepresented groups. However, **even a representative sample can be misleading**. What if a sample exactly represents a population distribution considering age, sex, and ethnicity of people living in Germany? The quotes would be representative, but the distribution would be skewed because there are more Germans living in Germany than people from other ethnic backgrounds.

Instead of sanctioning AI developers for the use of historical data, the Commission should promote the development of fair, robust, well-annotated and curated datasets across institutions. They should be aggregated in a way that protects patient privacy and captures diversity between and within demographic groups. This should be clearly more promoted even at an EU level to push innovation.

7. Bias

We raise **concerns in the definition and differentiation between bias and ethics**. Given the line of argumentation in general, one could assume that bias is interchangeably used as a word to describe societal problems. In fact, a bias can exist in society and manifest in data but **not every bias is societal**. For instance, an autonomous car could be biased towards dashed lines (vs. dotted) when changing lines. In fact, this is highly misleading given the alarm system even should be biased to prevent accidents by treating both lines the same way. Because **bias lacks a clear definition, it tends to include all types of AI applications**. For example, even an AI that is intended to realize lower-wear operation of an engine would fall under the EU regulation. Consequently, manufacturers will think twice before making use of AI techniques. This can have a negative impact on innovation.

If we are to understand bias in the form of discrimination, it must be considered **that this is already regulated in laws such as the German AGG** (Allgemeines Gleichstellungsgesetz) independent of the technology employed. It is already clearly defined that consequently no one should be disfavoured according to the standards set in the AGG. Moreover, other rights such as the right to erasure are regulated under the GDPR requirements. Given those regulations, **one could orient on existing legal frameworks**. The Commission needs to demonstrate that through AI these existing frameworks are not sufficient, which it has not done so far.

We instead **understand bias as a method to unveil judgement or decision patterns per se without any connotation or evaluation about whether they are right or wrong**. In fact, reporting a bias and thus decision patterns is recommended. If we follow this approach, it would be easier to have guidelines to compare the output of AI models against clearly defined parameters. Companies could use datasets (e.g., generated from universities) and gauge their output against them.

Bias, fairness, and ethical questions should be regarded on a case-by-case basis.

8. Remote biometrical identification

We **lack the clear prohibition of long-term and large-scale ‘real-time’ remote biometrical identification in public spaces**. The current proposal could be interpreted to allow mass biometric surveillance. Given the underlying aspiration of the regulation, this is not acceptable from our point of view. We urge the Commission to **set clear temporal, geographic and personal limitations** regarding the use of 'real-time’ remote biometrical identification.

9. Responsibilities

Based on the experience of newly introduced regulations, like GDPR, we want to further stress that **clear responsibilities should be defined as early as possible**. This includes but is not limited to the question of who will sit on the planned AI panel, who will clarify existing legal grey areas and cross-jurisdictional harmonization issues, who will be responsible for granting exceptional permission (e.g., for remote biometric identification systems), and who will define currently vague terms (such as the "proportionality" of social scoring systems or representativeness, accuracy, and completeness of data).

10. Recitals

We believe that the **current recitals should be rewritten in a less generalized way** but according to the approach of the overall regulation and **ideally jointly with AI developers**. One proposal for a reformulation, while it is not limited to that, is Recital 70 ("Moreover, natural persons should be notified when they are exposed to an emotion recognition system or a biometric categorisation system."): Apart from the fact that this demand is not actionable, the underlying risk assessment here is based on generalized assumptions. **Suggestion is that natural persons should only be informed of the use of such systems if harm or risk to covered persons results from their use.** However, members of our organisation use biometric categorization of people to create synthetic counterparts that are used for anonymization purposes that simultaneously enable AI-development. As such, the anonymized data needs to be as close as possible to the original to represent reality in a qualified way, a person of colour just cannot be given the synthetic face of an artificially generated *white person*.

Conclusion

Based on beforehand mentioned points, we strongly recommend avoiding indefinite legal terms to the utmost extent possible. In addition, we encourage the Commission to precise any definition used in the regulation as much as possible, for instance, through better drafted recitals This entails explicitly the definition of AI itself, the often-misunderstood term bias and the delimitation of the different risk categories. By using best case examples, the regulation can give a better understanding of their intentions. Moreover, we call for further specification in the risk-assessment and a more realistic aim for data sets. We could not identify any need for technology specific liability regulation. For the industry, and especially start-ups and SMEs, it would be crucial to have clear responsibilities and guidelines.

To allow innovation made in Europe it must be a priority that any approval of a final EU AI regulation must be followed by timely implementation. Not just, but in particular, to enable legal certainty for AI start-ups, SMEs and all developers of cutting-edge technologies and stakeholders involved.

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About the German AI Association

The German AI Association (KI Bundesverband e.V.) is Germany's biggest industry association for Artificial Intelligence (AI) and represents more than 300 innovative SMEs, start-ups and entrepreneurs that focus on the development and application of AI. We support AI entrepreneurs by representing their interests in politics, business, and the media.

Our goal is an active, successful, and sustainable AI ecosystem in Germany and Europe. Because only if the brightest minds and forward thinkers decide to found, research, and teach in the European Union, we can stand up to global competition.

Our members are committed to ensuring that AI-technology is applied in accordance with European and democratic values and that Europe achieves digital sovereignty. To achieve this, the European Union must become an attractive business location for entrepreneurs, where their willingness to take risks is appreciated and innovative spirit meets the best conditions.

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