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Position paper

Bitkom principles for the Artificial Intelligence (AI) Act

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General Remarks

Bitkom welcomes the Commission proposal's risk-based approach of the AI Act presented in April 2021. In order to achieve the intended results it needs to be more precise as outlined below in this paper.

We welcome that the Commissions's proposal is cleary linked to existing horizontal and vertical regulatory dossiers (Such as the NLF at the horizontal level which is well known, established and has a already demonstrated its ability to support future proof legislation. In addition existing sector-specific and application-related regulations at the vertical level). A clear, lean and coherent legal framework should be at best enable and incentivize the integration and application of AI systems in Europe, which is needed to stay competitive on a global level. At the same time, the Proposal should cater for the particularities of AI and, where necessary, make necessary changes. Concretely, while extending the NLF to AI-systems embedded in products makes sense, the limits of adopting a product-safety based approach to stand-alone and foundational AI-systems should be further reflected upon. Policy makers regularly emphasise the overarching strategic goal of their AI policy: The creation of a European ecosystem of excellence in AI that is closely linked to an environment of trust in the use of AI. This should be the benchmark for the further evaluation of the present proposal.

The central question for companies that want to develop and produce AI systems is how the process of market access, ongoing operation and market monitoring for high-risk AI applications will look in the future concretely. The use of artificial intelligence in high-risk application areas in the sense of the AI Act is highly desirable from a social and economic policy perspective and will increase steadily over time. Therefore, the regulatory framework has to be future proof allowing for the seamless integration of AI technology across all industries for companies of all sizes, while being flexible enough to address current and future challenges alike. The goal must therefore be to create a framework in which European excellence in trustworthy AI is encouraged and enabled in high-risk areas, which also means that the requirements and obligations laid out under the proposed framework should be proportionate and should enable both public and private sector in integrating and applying trustworthy high-risk AI applications by taking into account the context how the technology is used. **The main success criterion for the AI Act is therefore to make the ethical and technical requirements underlying**

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trustworthiness in AI practical and operationalizable for economic operators, in particular through harmonized standards.

Central for the success of the proposed European legal framework are: clarity and simple implementation with regard to requirements[1], obligations[2], conformity assessment, placing on the market and continuous monitoring during the life cycle. It is important to note that clarity and ease of implementation include much more than questions of the wording and legal interpretation of the future AI Act. In particular, it is also about which institutional framework the EU and the Member States will design for conformity assessment, market access and market surveillance and the concrete practical operationalisation of the requirements should they remain as layed out by the Commission. The goal and guiding principle of the digital EU'S Digital Single Market (DSM) must be at the centre of this EU-wide design. Lessons and negative experiences from data protection should be analysed carefully and should be taken into account in this context. Overall, we see the risk that the sum and overlap of requirements and obligations, including in parts vaguely defined high risk applications, and the associated legal uncertainty in operationalisation, creates a complexity and compliance burden that inhibits the development of AI systems in the high risk area in the EU. We also see risks of overlap of requirements and obligations with other legislations, i.e. Medical Device Regulation and the newly proposed draft for a Machinery Regulation.

In addition to the general comments outlined above, the following three clusters are central in our view.

I Definition of AI & scope of high-risk.

The definition of AI in the proposal is extremely broad[3] and thus a very large number of software applications would be covered by the regulatory framework. Therefore, we recommend the deletion of the terms: "inference and deductive engines" and "statistical approaches" from Annex I. Moreover, in many cases it is unclear and open to interpretation whether specific applications in certain application scenarios are high-risk systems or not. Also, a systematic risk-assessment and risk differentiation of high-risk AI systems, has to

[1] Articles 8-15 are defining a variety of requirements regarding a.o. risk management, data governance , technical documentation, transparency, robustness, accuracy, human oversight etc.
[2] Articles 16-29 are defining a variety of obligatins such as setting up a quality management system, information duties and the duty to undergo a conformity assessment procedure
[3] Especially the "techniques and approaches": "inference and deductive engines" and "statistical approaches" (Annex I)

be developed in a timely manner, specififcally the possibility for a targeted assessment taking into account the AI's particular context and specific application.[4]

The cumulative approach to classification as a high-risk system from the AI White Paper (both sector and intended use are causing significant risks) should also be an essential part of the AI Act:. The definition & scope of"significant risks" in this context should be clearly and unambiguously defined in Art. 3 in order to ensure legal certainty.

Furthermore, controlled environments and ecosystems[5] should play a central role in allowing AI applications to develop and be tested in a safe environment.

II. Requirements & obligations, harmonized standards.

Harmonised standards as defined in Regulation 1025/2012[6] according to article 40 are key to show compliance with the requirements. Bitkom expressly welcomes this approach. The use of common specifications according to article 41 should only take place in absolute and justified exceptional cases when safety or fundamental rights are not properly addressed in the standards requested by the EC Therefore, one of the two central fields of action for the innovation-friendly implementation of the AI Act is an active-strategic design of the landscape of horizontal and vertical standards that enable proof of compliance with the respective requirements. The regulator must proactively and strategically accompany these standardisation activities, e.g. by timely issuing standardization requests to the European standardization organizations (CEN, CENELEC, ETSI) to specify the technical details of the requirements from Chapter II of the AI Act. One potential problem emerges from the fact that the proposal refers to harmonized standards, which do not yet exist. Relevant standards need to be worked out and specified quickly. Therefore, Bitkom asks the Commission to submit standardisation requests for the AI Act even before the Act is officially published. Furthermore, the Commission needs to be involved in the development of the standards from the very beginning to ensure that the published standards fulfil the requirements for harmonised standards and will be listed in the Official Journal of the European Union.

Industry participation in establishing these standards need to be ensured. Existing and existing standards should be used and further developed where available. In addition, it is important that overlap and redundancies with international standards is avoided. In this

[4] In this context Bitkom recommends to adopt "ISO/IEC 23894 Information Technology — Artificial Intelligence — Risk Management" (ISO/IEC JTC1/SC 42) into the Europeans catalogue with the option to use it as a harmonizend European standard.
[5] AI regulatory sandboxes, article 53
[6] According to Regulation 1025/2012 Article 2 paragraph 1c a „harmonized standard" is a „ a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation".

context Bitkom welcomes the activities from CEN and Cenelec building the European AI standardisation infrastructure, especially the works from CEN/Cenelec JTC21 which ensures the connection to international standardisation (ISO/IEC JTC1/SC42).

III Conformity assessment, Governance design and market access.

The conformity assessment bodies, the notified bodies, the notifying authority, the national competent authority and the market surveillance authority on the member state level as the governance institutions of the AI Act proposal are key for the respective conformity assessment procedure and lifecycle governance of high-risk AI systems have to implement. In this context the interplay and interaction between the AI Act and existing NLF legislation still needs to be clarified. With regards to conformity assessment, it is not clear exactly how bodies (including notified bodies) should be enabled to cover AI Act based requirements & obligations.

A legal framework and governance design based on it, which focuses on clear and easy-to-handle requirements is essential. It is equally important that, sector by sector, the relevant governance institutions have sufficient capacity and resources at their disposal so as not to create additional delays in market access. Therefore, EC standardisation requests, harmonised European standards and a timely listing in the OJEU [7] is absolutely necessary.

This is particularly the case in those areas where AI systems from application scenarios are affected that are not within the scope of the NLF and the resulting conformity assessment procedures. On the EU-level the European AI board is the central governance institution. In our opinion, the focus of the AI board should be on two issues: support for the operationalisation of requirements and the ongoing exchange on governance designs in the member states with the aim of creating a framework that is as uniform as possible across the member states. Ittakes into account future legal uncertainties and inconsistenties which the different economic operators will face in the concrete daily application of the future AI Act. In this context, it should in this context be assisted by a committee of experts made up of representatives from business, science and research to create a framework that takes these perspectives into account. Bitkom stands ready to support the AI board with its expertise in AI and regarding the NLF.

[7] Offiical Journal of the European Union according to arcitle 40.