

GERMAN AI ASSOCIATION

# THE EU AI ACT

Towards the finish line: Key issues and proposals for the trilogue negotiations

*July 2023*





# Executive Summary

We acknowledge the efforts of all three European institutions in proposing legislation to regulate artificial intelligence (AI) in the EU. However, to ensure that the Artificial Intelligence Act (AI Act) does not impose unsustainable regulatory burdens and disproportionate compliance costs on the European AI ecosystem, risking a dangerous competitive disadvantage and loss of innovation, we identify the

following key areas that we and our members argue should be urgently addressed in the upcoming trilogue negotiations:

- Regulation of Generative AI
- Definitions in Article 3
- High-Risk AI Systems
- Standardisation
- Measures in Support of Innovation



Based on expert opinions from the private sector, research, and politics, as well as specific use cases from our members, we formulate five recommendations for EU decision-makers to consider during the trilogue negotiations.

We believe that these issues are critical to ensuring that the AI Act will be a

catalyst for innovation, investment and adoption of AI across Europe, unlocking the economic potential of AI rather than creating obligations that could hamper the development of this game-changing technology in Europe.

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**1 Make regulation of foundation models workable and proportionate**  
Foundation models should be subject to transparency and data governance requirements that are proportionate to the risk level of the specific use case. The compliance requirements currently proposed would be largely unworkable in practice.

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**2 Focus on applications that are indeed high-risk**  
The high-risk classification in ANNEX III should be further narrowed down to critical areas, should more adequately take into account the size and resources of the respective provider/deployer, and should only include use cases that are not already covered by existing regulatory frameworks.

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**3 Define AI precisely and unambiguously**  
The definition of AI in the AI Act should be narrowed to ensure that the focus of the AI Act is strictly on AI systems rather than any advanced software.

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**4 Promote the development of harmonised standards**  
The EU should facilitate the timely development of harmonised standards in line with the rapid technological evolution of AI. Industry experts should be closely involved in the standardisation process in order to provide more clarity and certainty for stakeholders.

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**5 Strengthen support of innovation and SMEs**  
In addition to regulatory sandboxes, the AI Act should include other provisions that have greater potential to stimulate and support private sector initiatives, in particular European AI start-ups and SMEs.



# Foreword

The debates surrounding the AI Act over the past two years have highlighted the complexity of regulating Artificial Intelligence (AI). With the presentation of a first proposal for the AI Act in April 2021, the European Commission laid the foundations for what can be considered a groundbreaking and novel benchmark for AI regulation,

which will undoubtedly set new international standards.

However, in just the two years since the Commission's first proposal, the field of AI has evolved tremendously, making it the game-changing technology of our time. Today, AI underpins the fight against climate change and the success of the



European Green Deal,<sup>1</sup> making important discoveries in medicine,<sup>2</sup> and helping emergency services respond more quickly and efficiently to natural disasters.<sup>3</sup> Generative AI alone has the potential to increase global GDP by seven per cent over the next ten years, unlocking unprecedented economic opportunities, boosting labour productivity and providing a solution to the current skills shortage.<sup>4</sup>

Europe must, therefore, be able to provide its own AI systems that can compete with U.S. or Chinese counterparts. While we do not reject the idea that a regulatory framework coupled with the promotion of investment in AI can be a way to boost innovation, we do, however, disagree with the EU's approach to this objective. We believe that any strategy must include three key components: mitigating potential risks, encouraging domestic development and protecting fundamental rights and European values.

Unfortunately, throughout the legislative process, EU lawmakers have failed to create a regulatory framework that maintains an acceptable level of proportionality and focuses on those AI applications that pose real threats and risks. Unfortunately, by attempting to regulate use cases that are relevant not only to high-risk AI, but to almost any kind of advanced software, the AI

Act runs the risk of becoming an advanced software regulation, rather than the risk-based regulation that the EU was aiming for.

Introducing such far-reaching regulation after US and Chinese big tech companies have been able to consolidate their leading market position will only diminish the chances for European AI companies to strengthen their position. Instead, these big tech companies will cope with any regulation and will even ask for further regulation, as it creates additional barriers to entry and a defensible moat. As a result, they will be able to continuously strengthen their dominance, while the EU will become dangerously dependent on foreign technology.

Therefore, EU regulators must consider the future and avoid unrealistic doom and gloom in the political debate. What is needed now are sensible and practical solutions to mitigate the real risks and threats posed by AI, not ideologically driven political quick fixes.



**Jörg Bienert**  
President  
German AI Association



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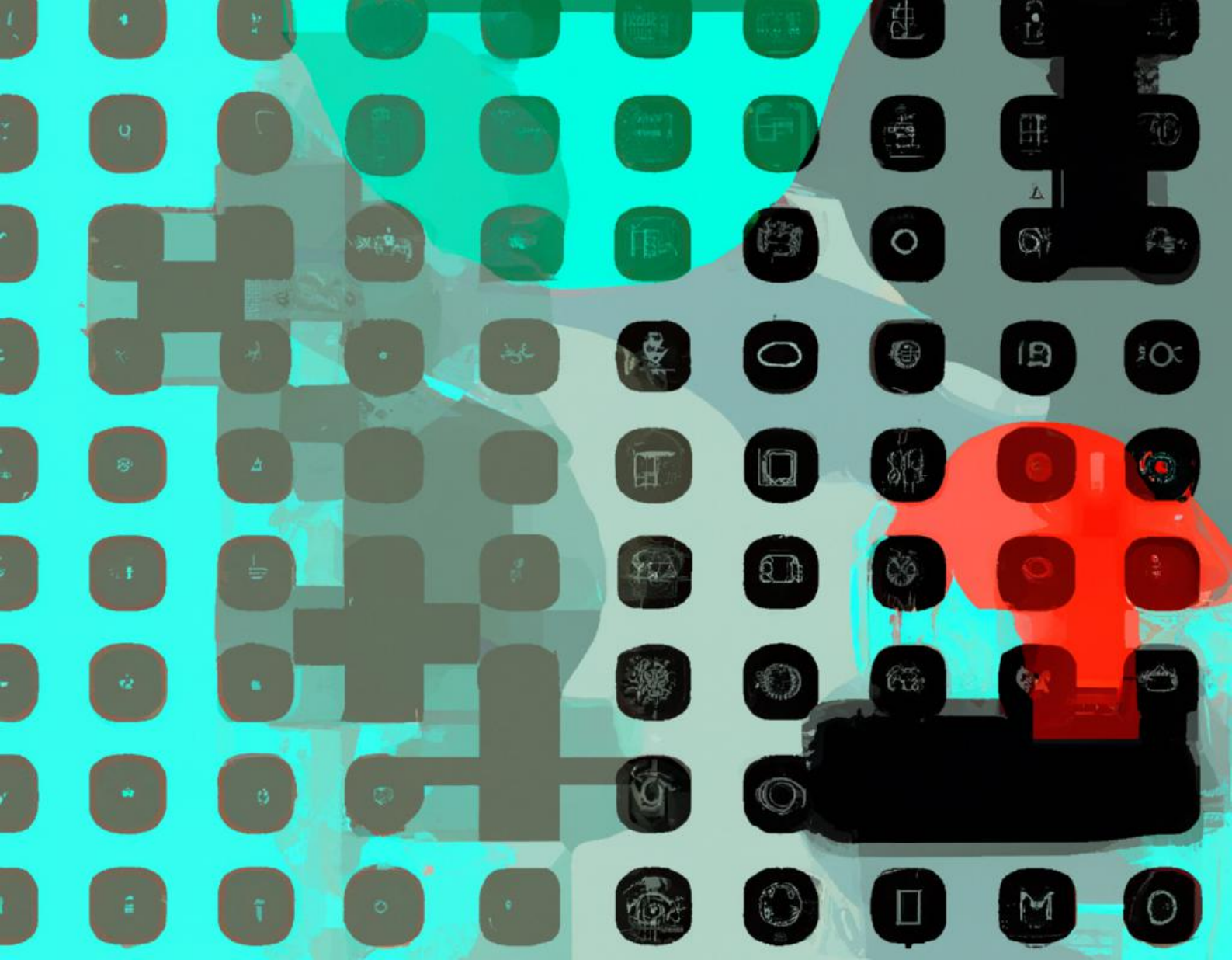
# Introduction

More than two years after it was presented by the European Commission (Commission), the Artificial Intelligence Act (AI Act) is set to enter the final stage of the legislative process: Following the presentation of the Commission's AI Act proposal in April 2021 and the Council of the European Union's (Council) common position ("general approach") on the AI Act in December 2022, the European Parliament (EP) adopted its position in a plenary vote on 14 June 2023, paving the way for trilogue negotiations between the Commission, the Council and the EP. The AI Act is expected to be adopted by the end of 2023.

Over the past years, the German AI Association has worked to ensure that the AI Act provides a regulatory framework that fosters innovation and encourages the adoption of AI across the EU, unlocking unprecedented economic benefits for all Europeans, rather than confronting developers, providers, and deployers of AI systems with complex and impractical regulations, prohibitive costs and legal uncertainties. As Germany's largest AI industry association, representing over 400 SMEs, start-ups and entrepreneurs, we value the fact that our positions reflect the daily

experience of our members in developing and applying AI-driven business models to ensure an active, successful and sustainable AI ecosystem in Europe.

In this position paper, we highlight the key issues that need to be addressed in the upcoming inter-institutional negotiations. The complexity of regulating a dynamic area such as AI is highlighted by the significant differences between the Commission proposal and the positions of the Council and Parliament. Therefore, for each issue area, we first compare and contrast the relevant positions of the Commission, Council and Parliament. As a considerable amount of time has elapsed since the Council's position and, in particular, the Commission's initial proposal, rendering them partly outdated and incomplete, we expect the trilogue negotiations to be centred on the text adopted by the EP and we will, therefore, place particular emphasis on the EP's position. Backed up by concrete use cases of how our members and their business models would be affected by the pending legislation, we then present our assessment. Finally, we propose specific and workable wordings for the forthcoming trilogue negotiations.



# Issue 1: Regulation of Generative AI Systems

## Situation

The treatment of generative AI systems in the AI Act is an excellent example of the issues underlying any AI regulation. While the Commission did not include articles on specific AI models, such as generative AI systems, the EP and

Council felt compelled to do so because of the rapid development of these models over the past two years.

They did, however, choose different focuses in their approaches. The Council focused on a rather new term,



the so-called *General Purpose Artificial Intelligence* (GPAI). By adding Title 1A (*General Purpose Artificial Intelligence*) in the Council's General Approach, all GPAI would, according to Art. 4(b), be classified as high-risk use cases according to Art. 6 and ANNEX III, and must, therefore, meet the requirements set out in said articles.<sup>5</sup>

The regulation would be adopted attending an Implementing Act, which further enhances uncertainty. The EP, on the other hand, focuses on the regulation of foundation models, rather than the entirety of GPAI systems and abstains from an automatic classification of such models as high-risk use cases. Thus, their



**Sina Youn**

IDP Solution Engineer  
super.ai

*“super.AI has developed an AI platform that extracts information from unstructured data in a structured way. We work industry and use case agnostic, for example by helping customers to extract and compare information from images and descriptive text in an online store or after uploading an invoice to a user's system and then telling them who the invoice recipient is and when the amount is owed. super.AI uses a mix of own, open-source, and 3rd party AI models.*

*For example, when we use GPT4.0 for automated identification and extraction of, we place ourselves in a large dependency on OpenAI. We are not ‘providers’, but ‘deployers’. Here we have to hope that OpenAI will perform the required actions in the required timeframe - but we can never be sure that this will happen (and how). Overall, this also raises the question, if a deployer suspects that a provider has not complied with the guidelines correctly/timely/comprehensively/etc. - can we then no longer use their models? And what about liability in such cases?*

*We therefore fear that the AI Act will put the general approach of start-ups, platform solutions, but also the competitive situation of international SMEs at a competitive disadvantage. In the worst case, we would have to move from a broad platform solution using the best models on the market to a use case oriented solution using only our own and potentially less powerful AI models. This would affect all our business and staffing plans for the next few years, as well as the next round of venture capital, and could send us back to square one.”*



**Jonas Andrulis**

CEO and Founder  
Aleph Alpha

*“As a provider of large language and multimodal models, Aleph Alpha expresses serious concerns about Article 28(b) of the EP proposal. Article 28(b) represents an inappropriate upstream shift of responsibility and places an undue and disproportionate burden on providers.*

*Several provisions of the proposed regulation - such as risk mitigation measures, assessment of bias in data sources, or the obligation to prevent unlawful content - are not feasible without a clear understanding of the intended use of AI models by those implementing them.*

*Other obligations relating to performance, security, cybersecurity, environmental efficiency and copyright compliance are sometimes vaguely defined and often irrelevant to the work of foundation model providers. For example, environmental impact is linked to the infrastructure used by those implementing the models, and the complexity of global copyright law makes compliance virtually impossible. Aleph Alpha, therefore, urges EU regulators to adjust the obligations in order to maintain the competitiveness of AI developed in Europe.”*

approach results in the addition of Art. 28(b), including a range of obligations such as data governance measures, performance levels, requirements for energy use, technical documentation, and compliance with certain transparency requirements outlined in Article 52(1) of the EP proposal.<sup>6</sup>

## Opinion

Generative AI (or GPAI / Foundation Models respectively) promises huge

benefits for the European economy and could lead to an increase in labour productivity, increase flexibility in the workplace and become a long-term solution to the current skills shortage.

Given their potentially massive impact on the economy and society, foundation models, therefore, need to be handled carefully. However, the EP's approach puts European foundation



models at risk by imposing an excessive regulatory burden on foundation model developers, ranging from high compliance costs to significant liability risks.

We strongly disagree with the Council and EP approaches to regulating GPAI/ foundation models. Despite the repeated emphasis on the need for the AI Act to be a technology-neutral and proportionate regulation, both the EP and the Council fail to achieve this key objective. Instead, both specifically target one branch of all AI systems and subject it to disproportionate regulatory burdens.

Since the first draft of the AI Act in 2021, the EU has focused on de-risking AI use cases. However, by introducing specific obligations for foundation models, the EP abandons this logic. Moreover, the Council and EP amendments on GPAI and foundation models were not covered by the Commission's initial impact assessment. Therefore, this significant extension of the Regulation has not been adequately evaluated and exposes providers of such AI models to unpredictable compliance costs.

## Proposal

We call lawmakers to focus on specific high-risk applications of foundation

models or GPAIS respectively. Without an intended purpose, a foundation model/GPAIS should not be deemed a high-risk AI system and, therefore, not be treated as such. We criticise the excessive regulatory burden on providers and developers of foundation models by the EP, which in practice will not be implementable.

We, therefore, propose a regulatory framework of foundation models that is based on the following principles outlined on page 11.

We call EU lawmakers to ensure a clear delimitation of liabilities between developers of open-source foundation models and providers who make open-source foundation models commercially available. We recommend that AI components that are available free and open-source must not be held liable for said commercial use.

# Outline for a regulation of Foundation Models

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## 1

### **For developers of foundation models:**

- Reasonable transparency and data governance requirements:
    - Alignment of models requirements to ensure they have appropriate reinforcement on critical issues; this could be performed by "standard or generated bench testing" designed and supervised by a certification authority;
    - Transparency: documentation made available to authorities on-demand (e.g. on the sources of data used for training purposes, specific safety measures, etc.);
    - Disclaimers;
    - Documented cybersecurity testing according to EU standards
- 

## 2

### **For commercial providers who use foundation models:**

- High-risk obligations only for deliberate high-risk use cases of foundation models;
- Lightened impact assessments;
- A coherence of prerequisites between different pieces of legislation applying in parallel (e.g., AI Act and Medical Devices Regulation);
- Information requirements to ensure end users understand the model's power and limitations (e.g. disclaimers on AI-generated images, answers to factual questions, etc.)





## Issue 2: High-Risk AI Systems

### **Situation**

The AI Act as proposed by the Commission in April 2021 is based on a risk-based approach which means that AI systems are confronted with stricter regulations the higher the risk that they pose. The Commission proposed

an automatic categorisation according to ANNEX III, both Council and EP, however, introduced an additional layer which shall ensure that only AI systems are subject to high-risk obligations that are indeed high-risk.

Both Council and EP introduced



## Christoph Hohenberger, PhD

Managing Director / Co-CEO  
retorio

*"retorio is an AI-powered Behavioral Intelligence platform that instantly identifies behavioural challenges and drives winning behaviours at scale through immersive video training.*

*For example, our technology could be used by a company to help employees who need further training on compliance obligations. Despite the objective of educating employees, this and similar use cases could be considered high-risk and result in increased compliance obligations under the proposed AI Act. SMEs will be disproportionately affected by these compliance requirements. The high cost of market entry for start-ups, exacerbated by a lack of access to data, means that it is essential that the AI Act is accompanied by regulatory and support measures to foster an inclusive and competitive AI landscape in Europe."*

significant amendments to the ANNEX III, namely in the field of law enforcement, border control, and, in accordance with the Digital Service Act (DSA), recommender systems by very large online platforms.

## Opinion

We welcome the addition by the Council and the EP of the "significant risk of harm" criterion with the intention to address only those AI systems listed in the areas and use cases of ANNEX III that are truly high-risk. Nevertheless, as elaborated in *Issue 3: Definitions / Significant Risk*, the term currently lacks clarity.

The scope of ANNEX III remains too broad; as currently conceived, the number of AI systems subject to high-risk classification is likely to be significantly higher than intended by the legislator.<sup>7</sup>

A blanket classification of AI systems in certain areas such as education and vocational training or employment, workers management and access to self-employment as 'high-risk' is excessive and misses the point: Rather than discouraging innovative, promising use cases a priori, legislators should focus on promoting accountability and due diligence requirements for providers and deployers of AI systems in these areas.



The significant resources required to comply with the requirements for high-risk AI systems (e.g. extensive documentation and record-keeping requirements in Art. 11 & Art. 12 of the EP proposal<sup>8</sup>) will put European SMEs and start-ups in particular at a competitive disadvantage compared to large non-EU companies.

## Proposal

The high-risk classification should be further narrowed to crucial areas such as critical infrastructure and access to and enjoyment of certain essential private and public services, thus differentiating specific use cases based on their actual risk.



### Alexander Thamm

CEO and Founder

Alexander Thamm GmbH

*"Alexander Thamm GmbH develops numerous AI applications for customers across Germany and Europe. One example is a safe 3D environmental sensor system for robots, to be used in production logistics and in-patient care. The primary aim of this system is to make human-machine interaction more efficient and to identify hazards at an early stage by reliably detecting people, objects and liquids in the immediate environment and taking safety-related actions if necessary.*

*Our use case is affected by ANNEX II and Directive 2006/42/EC, which requires it to be considered as 'protective devices designed to detect the presence of persons'. Our AI system could therefore only be implemented after an extensive risk management process involving the provision of numerous logs of modelling activities and results, technical documentation for third-party audit, conformity assessment, human oversight and the assurance of adequate model accuracy, robustness and cybersecurity as well as a conformity assessment according to the sectoral legislation.*

*The AI Act would therefore significantly increase the cost and complexity of developing a product that supports the occupational safety and workload of hard-working people in hospitals, nursing homes, as well as warehouses. By introducing these compliance requirements, the EU is deliberately taking the risk of stifling new technologies that help improve safety and workload in the workplace. Especially in industries where working conditions are already debatable due to a shortage of skilled workers and cost savings."*



Restrictions and obligations associated with the classification of an AI system as high-risk should be more proportionate to size of the provider or deployer.

Any area of an AI system that is already regulated through another existing regulation (e.g., the Vehicle General Safety Regulation for autonomous

driving or the Medical Devices Regulation for the use of medical AI tools) should not be subject to additional, congruent, or in the worst case contrasting, regulation in the AI Act. We, therefore, call on EU regulators to remove all already regulated use cases from ANNEX III.



**Detlef Eckert**

Founder

Deep Digital Consulting B.V.

*"As generative AI will be the building block for almost all applications, the AI Act de facto regulates all AI, and, therefore, no longer just high risk use cases. This general assumption of AI as a risk significantly departs from the original regulatory approach. Unfortunately, EU regulators seem to be falling into the doomsday scenario trap."*



## Issue 3: Definitions

### “Artificial Intelligence System”

#### Situation

Given the speed at which AI systems are currently being developed and advanced, it is not surprising that all three parties to the legislative process have provided their own definition of

what an AI system is. Both the Council and the EP have removed the definition of an AI system from the ANNEX to the main text, thus ensuring that it cannot be unilaterally changed by the Commission alone. Moreover, the EP proposal introduces a completely new definition of AI systems, using the OECD definition in





order to ensure close alignment with existing definitions:

*'artificial intelligence system' (AI system) means a machine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions that influence physical or virtual environments.<sup>9</sup>*

## Opinion

All three definitions do not focus on the key characteristics of an AI system such as its learning, modelling capabilities, or reasoning. Instead, they all define AI systems too broadly, resulting in an advanced software regulation rather than an AI regulation.

The definition of AI systems will be the foundation of this regulatory framework, so it needs to be as concise and clear as possible and avoid any type of advanced software, such as rule-based spreadsheets.

The definition, such as Art. 3(1) of the EP proposal causes the risk of the AI Act being somewhat of a lump-sum technology/software regulation and by that stifles innovation.

## Proposal

The German AI Association calls for a clearer definition to narrow down the scope of the AI Act and to ensure that the focus of the AI Act is indeed on AI systems. We, therefore, propose the following definition for Artificial Intelligence Systems:

*An 'artificial intelligence system' is a system that uses an algorithmic model, that is developed by a training process using external data from data sources or the environment, to analyse data and provide results that can support decision making.*

Irrespective of whether the EU decides to adapt a new, more concise definition such as the one proposed above, or whether it decides to refine the EP definition, e.g. by adding TRAINED BY DATA to narrow the scope, we further propose an addition to the relevant recital recognising that humans will not be able to understand the exact decision process of any AI system in a reasonable time. A clear distinction is needed to ensure that the scope does not include simply trained systems.

# “Significant Risk”

## Situation

The definition of “significant risk” was introduced by the EP with Art. 3(1b), to further define high-risk use cases according to Art. 6(2). The definition reads as follows:

*‘significant risk’ means a risk that is significant as a result of the combination of its severity, intensity, probability of occurrence, and duration of its effects, and its the ability to affect an individual, a plurality of persons or to affect a particular group of persons.<sup>10</sup>*

## Opinion

The provided definition by the EP is not congruent with the EP’s definition of risk defined in Art. 3(1a) as *“risk’ means the combination of the probability of an occurrence of harm and the severity of that harm”<sup>11</sup>*

The definition is ultimately a tautology and, therefore, inappropriate for such an important and far-reaching regulatory framework.

Thus, the chosen definition is problematic as it is imprecise and will likely introduce legal uncertainty. The definition constitutes a key element of the high-risk use case classification according to Art. 6 and ANNEX III of the

EP version and must, therefore, be as precise as possible.

## Proposal

We welcome the introduction of an additional criterion to better identify use cases that warrant special regulatory attention. However, the term “significant risk” as currently defined is not only too ambiguous, but also ignores the fact that it is not realistic to define a threshold that applies to all AI systems, regardless of their use case and/or industry. No one would, for example, disagree with the argument that the threshold to what constitutes a significant risk in healthcare must be different compared to a use case in the financial sector.

A more practical approach would be to determine the significant risk posed by an AI system in relation to the risk associated with a human performing the same task. If the risk potential of a particular AI system is not higher than the risk inherent in a human performing the same task, then that AI system should not be subject to differential treatment in the form of stricter regulation. This approach would contribute to a clearer understanding of the significant new risks that AI systems actually pose, and would help developers to assess and manage these risks.



# “Foundation Model” / “General Purpose Artificial Intelligence” Situation

The initial proposal by the Commission did not include any provisions, and by that no definitions on specific AI systems such as Foundation Models (FM) or General Purpose AI Systems (GPAIS). Concerning the final proposal by the Council, a chapter on GPAIS was first introduced by the French Presidency and then later adapted by the Czech Presidency. Their definition of all GPAIS reads as follows:

*‘general purpose AI system’ means an AI system that - irrespective of how it is placed on the market or put into service, including as open source software - is intended by the provider to perform generally applicable functions such as image and speech recognition, audio and video generation, pattern detection, question answering, translation and others; a general purpose AI system may be used in a plurality of contexts and be integrated in a plurality of other AI systems.<sup>12</sup>*

While the Council introduced an entirely new chapter on GPAIS, the EP focussed, partly due to the release of new and powerful applications such as OpenAI’s ChatGPT, on foundation

models specifically. It therefore introduced a new definition for foundation models:

*‘foundation model’ means an AI model that is trained on broad data at scale, is designed for generality of output, and can be adapted to a wide range of distinctive tasks.<sup>13</sup>*

Furthermore, the EP also added a new definition for GPAIS:

*‘general purpose AI system’ means an AI system that can be used in and adapted to a wide range of applications for which it was not intentionally and specifically designed.<sup>14</sup>*

## Opinion

The Council and the EP need to agree on an approach, either to regulate all GPAIS or to regulate only foundation models. At present, the EP proposal does not include specific provisions for GPAIS, making a definition redundant.

The added definition for foundation models in the EP proposal does not provide a clear definition of this technology. Instead, it is too broad and lacks perspective, which will be detrimental to the European AI ecosystem.



The general problem with any attempt to define GPAIS is that such a definition will inevitably include almost all AI systems by default, because the ability to generalise is the very nature of machine learning. The question is therefore whether the AI Act needs to define GPAIS at all.

Finally, it is important to note that the authors of foundation models have only limited control over the use cases for which their foundation model is used, and therefore require acknowledgement of such starting position, e.g. in the relevant Recital.

## Proposal

The German AI Association recommends the removal of the definition of GPAIS and a focus on defining foundation models.

Otherwise, the term will needlessly increase the scope and falsely include other AI systems.

However, as mentioned, the current definition by the EP of foundation models lacks clarity and perspective.

We, therefore, propose the following amendment to the existing EP definition in Art. 3(1c) of the EP proposal:

***‘Foundation Model’ means an AI model that is typically trained on a broad data set at scale and is able to generate a variety of output such as texts, images or videos and can be used and adapted for a variety of tasks and applications.***



# Issue 4: Standardisation

## Situation

All three proposals include provisions on conformity assessments, either through a third party or via self-assessment, for high-risk use cases. The EP approach, for example, defines the set-up for these assessments in Art. 40 as follows:

*"1. High-risk AI systems and foundation models which are in conformity with*

*harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation 1025/2012 (AM 2122) shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title or Article 28b, to the extent those standards cover those requirements.*

*1a. The Commission shall issue standardisation requests covering all requirements of this Regulation, in accordance with Article 10 of Regulation 1025/2012 no later than 2 months after the date of entry into force of this Regulation. When preparing standardisation request, the Commission shall consult the AI Office and the Advisory Forum.<sup>15</sup>*

## Opinion

The German AI Association welcomes the obligation to design and apply technical standards, instead of detailed formal legislation, as a more flexible and proven practice for establishing safety requirements in high-tech environments.

Timely development of EU standards for the AI Act is crucial as it ensures alignment with the fast-paced evolution of this technology, and provides clarity and certainty for market participants.

The necessary standards for such conformity assessments must first be established. We question whether it will be possible to establish and execute on said standards uniformly across Europe within the planned transition period of two years.

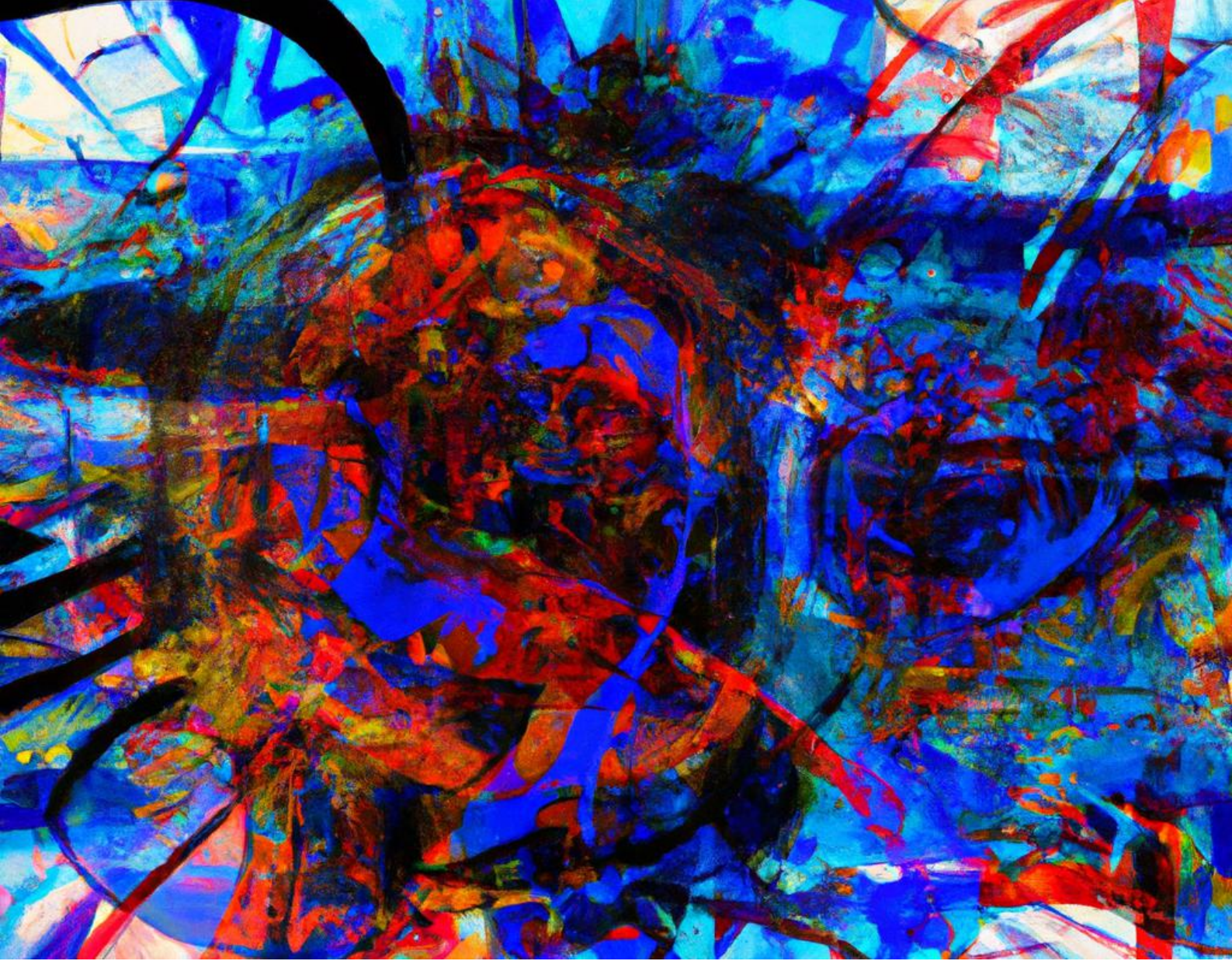
Furthermore, the standards should be clear, transparent and use-case-specific.

## Proposal

The German AI Association, therefore, calls for an immediate execution of the standardisation request by the Commission as noted in Art. 40(1a) of the EP proposal to ensure companies can implement the standard and achieve legal certainty as quickly as possible.

Moreover, we urge EU lawmakers to introduce additional provisions that ensure the inclusion of industry experts in the set up of the needed standardisations.





# Issue 5: Measures in Support of Innovation

## Situation

The Commission, Council and EP all envisage the creation of AI regulatory sandboxes to support innovation, where new AI systems can be developed, tested and validated for a limited period of time under regulatory

supervision before being put into service or on the market. However, while the Commission and Council leave the establishment of sandboxes to the discretion of Member States, the EP introduced an obligation for each Member State to establish at least one

sandbox at national level. The EP text also explicitly provides for the possibility of setting up sandboxes at regional or local level or jointly with other Member States.

In addition, both the Council and the EP added other measures to support innovation, in particular for start-ups and SMEs.

The Council, for example, added Art. 55 on “*Support measures for operators, in particular SMEs, including start-ups*”, which includes support measures such as priority access to regulatory sandboxes or additional awareness training on the effects of the AI Act. Furthermore, the Council proposed in Art. 55(a) that *“the obligations laid*

*down in Article 17 of this Regulation shall not apply to microenterprises as defined in Article 2(3) of the Annex to the Commission Recommendation 2003/361/EC (...), provided those enterprises do not have partner enterprises or linked enterprises as defined in Article 3 of the same Annex”*<sup>16</sup> thus exempting high-risk use cases from such providers from the obligation to establish a quality management system laid out in Art. 17.



**Dr. Tina Klüwer**

Director AI

K.I.E.Z. - Künstliche Intelligenz Entrepreneurship Zentrum

*“The AI Act is a source of uncertainty for our AI startup teams. While our founders care deeply about the responsible use of technology, the bureaucracy associated with additional regulation will make it difficult for small teams with limited resources to enter the market, let alone compete internationally. In a survey conducted with the German AI Association, we found that German AI startups were on average founded three years ago and have three employees. Already burdened with the costs of GDPR compliance, the proposed AI Act means that these teams will have even less time to develop their business model and product. Rather than placing all AI business models under general suspicion, a focused technology-neutral regulation of specific use cases would be a better approach.”*





**Dr. Rasmus Rothe**

Co-Founder

Merantix

*"The AI Act's proposal of regulatory sandboxes is commendable, providing a safer space for AI development. Yet, this isn't sufficient to competitively position European start-ups globally. Uncertainty remains if AI applications from these sandboxes can effectively transition to commercial use, which hinders industry wide innovation. Beyond regulatory measures, we need substantial funding for ethically responsible AI startups and AI investment funds. This will set the right incentives for entrepreneurs and investors alike to support and advocate for ethical AI deployment. I suggest a dedicated committee to evaluate and invest in such ventures and funds, thereby empowering them to thrive within the AI Act's framework to achieve a globally competitive European AI ecosystem."*

## Opinion

We welcome the additional provisions by the Council and EP in favour of start-ups and SMEs. Start-ups and SMEs are the backbone of the European AI ecosystem and, therefore, must receive special protection from potential negative effects of this regulatory framework.

Furthermore, we generally appreciate the existing measures in support of innovation, however, would argue that regulatory sandboxes are not the only approach to foster innovation. In fact, they are more helpful as to compliance. Regulatory Sandboxes can be an innovation-promoting instrument, particularly in research.

For the private sector, however, the proposal is unlikely to compensate for the threat of loss of innovation. When developing their AI systems in Regulatory Sandboxes, a key uncertainty for developers, whether their AI systems can ever be used outside the sandbox, will remain. Thus, we argue that investors will likely refrain from investing in such AI applications.

One particular flaw in these provisions is Art. 55(a) of the Council's General Approach. While the initial objective of this article, to exclude SMEs and start-ups that work with high-risk use cases from particularly burdensome obligations, is indeed positive, it,



unfortunately, cannot find application in practice. In general, it is the goal of start-ups to grow and would, therefore, eventually outgrow the definition applied by the Council. In practice, start-ups and SMEs would, therefore, have to establish a quality management system regardless, in case they exceed the size-threshold set by the Council.

## Proposal

We are convinced that current political decisions will set the course and determine whether Europe will be irrevocably left behind in the development of AI and whether its digital sovereignty will be at risk. We, therefore, urge EU lawmakers to take into account that European investments made in AI must be protected and put at risk with the AI Act. We also propose additional

innovative measures to target and promote “AI made in Europe”.

We recommend that the EU accompanies the AI Act with an investment plan which would include funding and resources for start-ups and SMEs to initially comply with the AI Act. This should be done not only through direct investment, but also through indirect investment, e.g. through funds that are more scalable, with clear requirements that the funding can only be used for European AI companies. Such funding would help mitigate the potential damage to European AI innovation caused by this regulation.

In addition, we suggest that regulators include provisions in the final version of the AI Act to support start-ups and SMEs with training and education, best practices and templates for compliance with the AI Act.



**Sina Youn**

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*“The AI Act in its current form is highly undesirable in terms of promoting start-ups and innovation. As young entrepreneurs and venture capitalists currently face various questions and uncertainties may, therefore, refrain from serving the European marketer from investing in European AI-start-ups that aim to focus on the European market.”*



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# About

The German AI Association (Bundesverband der Unternehmen der Künstlichen Intelligenz in Deutschland e.V.) is Germany's largest industry association for Artificial Intelligence (AI) and represents more than 400 innovative SMEs, start-ups and entrepreneurs focusing 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. After all, we can only compete globally if the brightest minds and visionaries decide to set up businesses, conduct research and teach in the European Union. 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 place for entrepreneurs to do business, where their willingness to take risks is valued and their innovative spirit is met with the best conditions.

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