ZVEI Comments

on the EU Commission's Proposal for a Regulation laying down harmonised Rules on Artificial Intelligence ("AI Act")

August 2021

Introduction

On April 21st the EU-Commission presented its proposal for a Regulation laying down harmonised rules on Artificial Intelligence ("AI Act"). ZVEI welcomes the ambitious goal of the EU-Commission to promote and facilitate the uptake of Trustworthy AI in Europe. Following the discussions around the AI Whitepaper published in February 2020, the EU-Commission puts forward a proposal for a harmonised European approach addressing potential risks and uses of AI applications. It also covers applications that might be opposed to or be incompatible with European values and fundamental rights.

ZVEI pleads to also focus on the immense opportunities related to the uptake of AI. Every market access regulation such as the proposed AI Act, carries the risk of hindering innovation as it sets down requirements for the placing on the market of products including certain technologies. Therefore, each provision in the proposal needs to be carefully examined and justified in particular for its potential impact on innovation and technological development. AI research and development should be strengthened on a European level, experimental space (i.e. regulatory sandboxes) should be provided for, as well as fostering both the continuous evolution of the technology and the understanding of the associated risks. Next to promoting a trustworthy, human-centric approach that aims at tackling risks linked to the usage of AI-technology, a future-proof AI regulation should also facilitate innovation and promote the general goal of boosting AI development and deployment across businesses in Europe.

Industrial artificial intelligence is already a key driver for securing the future of European and German industry in a competitive global environment. AI is used in many applications and domains, as well as in public and private sectors. The deployment of industrial AI can optimise production processes and enable new levels of efficiency. In this way, AI can also make a significant contribution to resource efficiency and sustainability. As an enabling industry at the interface between IT and production world, the electrical industry has a key role to play in facilitating and implementing artificial intelligence in different application contexts. ZVEI represents the interests of a high-tech sector with dynamic industrial applications of AI in the lead markets Industrie 4.0, health, energy, mobility, building and consumer.

General Comments

ZVEI welcomes the **risk-based approach** whereby the applicability of stricter requirements for placing on the market and putting into service of AI-based products is limited only to high-risk AI systems. However, the legislator should carefully assess regulatory gaps, inconsistencies and redundancies when addressing AI as a technology in its entirety. Particularly, in the case of AI embedded in products, potential risks regarding product safety and security are already covered by existing harmonisation legislation, such as the Machinery Directive or the Medical Devices Regulation, or by functional constraints, where products can only act within their intended purpose.

ZVEI in principle supports the **NLF (New Legislative Framework) approach** taken by the EU-Commission referring to established methods of conformity assessment in existing Union harmonisation legislation (Annex II). The electrical industry is highly experienced in using NLF-legislation for placing on the market and putting into service of products in the Union. However, the Commission proposal contains a large number of additional requirements and obligations as compared to the NLF and the EU legislation based on it. Specific justification therefore is necessary for those additional elements, since established Union harmonisation legislation has proved to be effective in addressing public interest protection issues. This horizontal AI regulation should be discussed together with the relevant harmonised and sector-specific legislation and hence, needs to be in line with, and should ideally refer to, the conformity assessment procedures such as defined by the NLF (cf. Decision 768/2008/EC). In this respect the NLF provides the important basis to reach the necessary consistency over the relevant pieces of legislation.

The legislator should carefully review and narrow down the scope of the proposed AI regulation, as the currently proposed **AI definition** is much too broad. It would not only cover AI products, but also applications that use pure statistical and knowledge-based approaches used for conventional data analysis and software that has been well-established for a long time.

Scope (Article 2)

Article 2 defines the scope of the proposal by including all providers "placing on the market" (defined as the first making available of the AI system on the Union market) or "putting into service" (defined as the supply of an AI system for first use) AI systems in the Union as well as the responsible users. Naturally, this applies to every provider of a respective AI system, regardless of whether they are located within the Union or in a third country.

We do not agree with the inclusion of "users" in the scope of the proposal, as the "use" (of an AI system) should not be addressed by legislation setting down the conditions for placing on the market / putting into service of products based on Article 114 TFEU.

Moreover, the current proposal extends the scope in Article 2, paragraph 1 (c) to "providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union". This extension of the provision to include users of AI systems in third countries has no clear justification and seems unrealistic. In most cases providers do not know in advance if the system's output is used in the Union, since this is decided by how the user chooses to operate the system. Hence, providers would need to fulfil obligations based on a choice made by the user (to use system output in the Union, or not) and that providers usually will not be aware of. Therefore, ZVEI calls for a deletion of "users" in Article 2.

It is also not clear how in this context the term "output" is defined and how the inclusion of system output in the scope of the regulation would affect international data transfers. A clarification of what is meant with "output" and how it affects the usage of data or analytical results is necessary. In this respect, it should also be clarified how data sharing, data transfer and data export for usage should be understood.

AI Definition (Article 3 and Annex I)

ZVEI calls for narrowing down the much-too-broad AI definition used in the current proposal. As outlined in the Explanatory Memorandum preceding the legislative proposal, the EU-Commission aims to keep the AI definition "as technology neutral and future proof as possible" (p. 12). While we support this goal in the light of the rapid developments of AI technologies, the current broad definition would lead to significant legal uncertainty for developers, providers and users of AI systems. The definition of "AI system" used in Article 3 (1) refers to a somewhat established description of AI in the recommendations of the OECD Council on artificial intelligence[1]. However, the EU-Commission includes three approaches listed in Annex I. By including logic- and knowledge-based approaches as well as statistical methods to the techniques and approaches defining AI in Annex I, the EU-Commission makes it impossible to differentiate AI software from conventional data analysis tools (e.g. programmable logic controller in applications of safety in machinery, software to optimise appointment scheduling in hospitals, etc.).

Hence, defining AI systems as "software developed with <u>one</u> or more of the approaches listed in Annex I" is far too broad, as it would include "conventional" logic units or software in its definition. Based on the proposed definition, pure statistical applications would be treated in the same way as advanced machine learning applications. The AI definition should be narrowed down, in particular regarding the inclusion of statistical methods and logic-/knowledge-based approaches in Annex I to avoid legal uncertainty and restrict the scope to actual AI software.

Definition of "putting into service" (Article 3 (11))

The definition of "putting into service" as described in Article 3 (11) in the current proposal needs adjustment and alignment with existing NLF-legislation. The definition such as proposed would overlap with the definition of "making available on the market" in Article 3 (10) by including the addition "supply of an AI system". In general, NLF definitions as foreseen in the "Blue Guide" of the EU Commission should be maintained. Also, we object to the inclusion of AI systems for "own use" in the legislative proposal as this definition would include developers of AI systems that develop the AI system for inhouse and experimental space use only.

ZVEI suggests amending the current definition as follows:

- *(11) "'putting into service' means the ~~supply of an AI system for~~ first use ~~directly to the user or for own use~~ by the intended user on the Union market for its intended purpose;"*

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[1] OECD (2019): Recommendations on Artificial Intelligence.
https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449

Definition of "reasonably foreseeable misuse" (Article 3 (13))

ZVEI calls for a review of "reasonably foreseeable misuse" as it remains unclear how this concept should apply in the context of (self-learning) AI. Further considerations are necessary to see if the concept of reasonably foreseeable misuse such as applied under safety related product legislation can be transferred one to one to the supply of AI systems.

Definition Safety Component (Article 3 (14))

The definition of the term "safety component" is too broad in its current wording. Safety components should focus on the health and safety of persons but not of property. The AI regulation should be aligned with the machinery directive in this respect, which does not mention property in its definition. If property would be covered, high-risk AI would also include AI applications for simple quality and predictive maintenance applications of a machine. In addition to that, the current definition seems unclear with respect to the use of the word "or".

Therefore, we propose a rephrasing:

- *"(14) 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system* ~~*or the failure or malfunctioning of which endangers*~~ **so that its malfunctioning endangers** *the health and safety of persons* ~~**or property**~~*;"*

Definition Substantial Modification (Article 3 (23))

ZVEI suggests amending the definition of substantial modification in alignment with the definition in the proposal for the machinery regulation. The words "not foreseen by the provider" should be added:

- *"'substantial modification' means a change to the AI system following its placing on the market or putting into service,* **not foreseen by the provider**, *which affects the compliance of the AI system with the requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed."*

High Risk AI Systems (Title III)

Classification of High-Risk AI Systems (Chapter 1)

Article 6 (1) and Annex II

Article 6 (1) classifies an AI system that is both (a) intended to be used as a safety component of a product, or is itself a product, covered by specific Union harmonization legislation listed in Annex II and (b) that product is required to undergo third-party conformity assessment, as a high-risk AI system.

ZVEI welcomes that the AI Act in Article 6 (1) follows the well-established concept of the New Legislative Framework (NLF) by referring to the Union harmonisation legislation in Annex II. It is positive, with a view to placing on the market and putting into service of high-risk AI systems, that the legislator seeks to establish consistency with existing product safety legislation. However, when addressing risks related to product safety, the EU legislator needs to thoroughly examine the future interlinkage between the AI Act and the respective harmonisation legislation in Annex II in order to avoid any double regulation.

In this respect, the list in Annex II contains an inconsistency regarding the Radio Equipment Directive (2014/53/EU). The legislation listed in Annex II foresees the involvement of a third-party conformity assessment for safety related issues. The Radio Equipment Directive however foresees the involvement of a third party conformity assessment only for Article 3 (2) with respect to the use of radio spectrum or Article 3(3) for further requirements, however not for safety aspects as defined in Article 3 (1) a. The RED (2014/53/EU) should thus be removed from this list.

Article 6 (2)

In Article 6 (2) the EU-Commission extends the high-risk classification to AI systems with fundamental rights implications that are explicitly listed in Annex III. In principle, it is correct to clearly define and restrict the scope of what falls under the high-risk category by providing a list of areas of applications that need further control. ZVEI welcomes that the EU-Commission is largely leaning towards a conformity assessment procedure based on internal control as defined in Annex VI regarding the examples for stand-alone software in Annex III (with the exception of remote biometrical identification systems). The given list of different high-risk application areas in Annex III addressing various aspects and sectors is of high relevance for industry and the society. It needs further in-depth discussion and potentially redefining, especially since the list of AI high-risk systems in Annex III can be expanded with a delegated act by the EU-Commission.

Requirements for High-Risk AI Systems (Chapter 2)

Chapter 2 defines several extensive requirements for high-risk AI systems including risk and quality management, information and transparency obligations, data governance and post-market monitoring. Some of these are still topic of active research and it is yet unclear how the obligations can be fulfilled depending on the specific AI technique. Furthermore, some of the requirements such as risk and quality management, logging obligations, data governance or post-market monitoring go far beyond the NLF and lead to significant financial and administrative burdens, especially for small- and medium sized providers. The EU legislator needs to further investigate to what extent these obligations are proportionate and applicable to providers of high-risk AI systems.

Risk Management System (Article 9)

Article 9 defines an extensive and continuous risk-management system throughout the entire lifecycle, requiring regular systematic updating. The obligation for a "risk management system" goes far beyond what is established under the NLF. Existing harmonisation legislation under the NLF provides for the obligation to carry out an adequate risk analysis and risk assessment, as a fundamental element of each conformity assessment procedure. In our view, this obligation has proved to adequately ensure the achievement of the public protection interest at issue (in particular concerning product safety).

The provider is obligated to identify and analyse all "known and foreseeable" risks arising from the high-risk system (Article 9, 2a), including the detection of possible risks in view of the results from the analysis of post-market monitoring data. Although the risk management system itself is described in detail and the risks are limited to usage "in accordance with its intended purpose and under conditions of reasonably foreseeable misuse" (Art. 9, 2b), the proposal remains inconclusive about the kind of risk that has to be considered. As the type of risks can be manifold (e.g. financial risks, risks in delays of development) and often not relevant

to the objectives of the AI regulation (see p. 3, Explanatory Memorandum), ZVEI suggests a specification of the definition of risks in Article 9:

- *2 (a) "identification and analysis of the known and foreseeable risks __to the health and safety or to the fundamental rights and freedoms of persons__ associated with each high-risk AI system."*

Data and Data Governance (Article 10)

In general, requirements for data governance and management practices for the training, validation and testing of data sets, should not be laid down in the regulation, but instead be left to standardisation. This will also ensure that the relevant requirements keep up with the development of state-of-the-art solutions.

Regarding the extensive obligations on data governance, ZVEI calls at least for a reduction of the unrealistic and impracticable obligations for training, validation and testing data sets in Article 10. While appropriate data governance processes such as labelling, aggregation, cleaning or anonymisation are already well-established practices when analysing data, some of the obligations on high-risk systems in the current proposal are not feasible. Article 10 (3) requires that data sets "shall be relevant, representative, free of errors and complete". These are absolute requirements that cannot be fulfilled depending on the type of data and the respective application context. Data sets are often incomplete, and it does not seem realistic to assume that data can be completely free of any error on an aggregated or individual level. Furthermore, it is not guaranteed that a relevant, representative, and free of errors and complete dataset leads to a free of errors, safe and fair AI system. It is often neither possible nor desired to feed the respective software with error-free data sets, not least because the efforts for minimising errors must be balanced against the actual benefits. In some cases, testing and validation data sets with errors have to be explicitly used. Since it is not clear what type of errors Article 10 is referring to and since it seems unrealistic to comply with this absolute threshold, ZVEI suggests removing the phrasing in Article 10 (3):

"Training, validation and testing data sets should be relevant __and__ representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof."

Accuracy, Robustness and Cybersecurity (Article 15)

The levels of "accuracy, robustness and cybersecurity" as required for high-risk AI systems under Article 15 should be made subject to what "can be reasonably expected" (cf. product safety legislation) as market expectations differ regarding software as opposed to hardware products.

- High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose **and to the extent that can be reasonably expected**, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Obligations of Providers and Users of High-Risk AI Systems (Chapter 3)

Obligations of providers of high-risk AI systems (Article 16)

The fulfilment of the obligations placed on "providers" under Article 16 is not related and limited to the point in time of placing on the market/putting into service, as is the case for the legislation based on the NLF, but appears to extend beyond the placing on the market throughout the entire lifecycle. It must therefore be ensured that the providers are actually able to perform the relevant duties/obligations in relation to products that may no longer be under their control. This also applies to obligations for economic operators along the value chain that take over the obligations of providers according to Article 24. We recommend additional text to clarify that the obligations apply only as far as the providers actually exercise control over the products/AI systems.

The obligation for providers to maintain a Quality Management System (QMS) is neither necessary nor proportionate given the need for conformity assessment, where there already is an explicit or implicit requirement for appropriate quality assurance (cf. Article 16 (b). Rather, it is sufficient to perform the required conformity assessment procedures and draw up the required technical documentation that must be provided to the relevant competent public authorities upon request. We cannot see why this should not be sufficient when an AI system has been integrated into the product/ or is itself a product.

Provider: Quality Management System (Article 17)

The obligation for providers of high-risk AI systems to put in place a quality management system according to Article 17 shall not impose a dedicated AI quality management system but should be covered by existing quality management system such as defined by ISO 9001. A specific, dedicated AI QMS is not necessarily required in case an already existing QMS – established e.g. to fulfill requirements from NLF legislation – can reasonably cover the requirements of the AI Act.

Obligations of Product Manufacturers (Article 24)

For the integration of compliant AI systems into a product, the obligations for product manufacturers should be carefully assessed to avoid double certification of an already CE-marked AI system. Article 24 of the proposal for the AI regulation states that the manufacturer of the product shall take the responsibility of the AI system with this regulation and have, as far as the AI system is concerned, the same obligations imposed by the present regulation on the provider. We call to limit the responsibilities of the product manufacturers, who implements a compliant AI system into his product, to specific aspects of this directive in Article 16, as it is not possible for a product manufacturer to fulfil all requirements set out in Article 16.

Should the obligations for manufacturers remain in the current wording, problems include for example the requirement to draw up a technical documentation (Article 16 (c)) which is not possible without full access to all technical information of the AI system. This includes very specific information such as IPR and would never be shared by the provider along the value chain. Moreover, as the product was already placed on the market under the AI Regulation it bears a CE mark. The product manufacturer will CE-mark the whole product when placing it on the market but not the AI system itself (Article 16 (i)).

We therefore recommend further clarification that the AI system provider remains responsible for the compliance of its AI system (in addition to the responsibility taken by the product manufacturer).

Obligations of Users of High-Risk AI Systems (Article 29)

Article 29 lists user obligations such as relevant input data, monitoring of operation or logging requirements that should either be left to product liability legislation (e.g. use of AI system in accordance with instruction of use) or to contract law. It is questionable what legal basis should justify the definition of obligations for users of products (AI systems) that have already been placed on the market/put into service, and why users as defined in Article 3 (4) should be held responsible to meet those requirements in the context of an legislative act based on Article 114 TFEU (Free movement of goods within the single market).

Standards, Conformity Assessment, Certificates, Registration (Chapter 5)

Harmonised Standards & Common Specifications (Article 40 and Article 41)

The use of voluntary and consensus based harmonized standards is a fundamental principle under the new legislative framework. In order to ensure the timely availability for harmonised standards under the proposed AI-regulation, a standardisation request shall be issued to the European standardisation organisations in a timely manner and standards shall be listed in the official journal for presumption of conformity without any delay.

Common specifications are often no adequate alternative for the use of harmonised standards, as not all relevant stakeholders are involved in their development. It would weaken the inclusion of stakeholders in their development and create a framework parallel to already existing standards on the international, European and national level. Therefore, we suggest deleting article 41.

Presumption of conformity with certain requirements (Article 42)

Article 42 only refers to the Cybersecurity scheme pursuant to regulation 2019/881. It should also consider future horizontal Union harmonised legislation in the area of cybersecurity in order to be future proof.

Conformity Assessment (Article 43 ff.)

ZVEI welcomes that the AI Act makes reference to the conformity assessment concept such as provided for under the New Legislative Framework (NLF) by referring to the Union harmonised framework and seeking to establish consistency with existing product safety legislation. However, when addressing risks related to product safety, the EU legislator should first and foremost thoroughly examine the interlinkages between the AI Act and the respective harmonised product legislation in Annex II in order to avoid any double regulation.

This is especially important, when embedding CE marked AI software to a new component or product. For those cases, a duplication of third-party certification under the AI regulation should be avoided. It must be ensured that existing conformity assessment results under the AI regulation would be passed on along every integration stage in the value chain. This will prevent a repetition of new certifications of conformity by third parties for the same AI system used in the same application context but in different stages of completion.

Article 43 (5) and (6) would grant the European Commission extensive power to change requirements for conformity assessment procedures set out in Annex VI and Annex VII as well as Article 43 (1) and (2). Those paragraphs should be amended in a way that the European Commission cannot change fundamental procedures and requirements without thorough consultation and involvement of affected stakeholders.

Measures in Support of Innovation (Title V)

AI Regulatory Sandboxes (Article 53 and Article 54)

ZVEI supports the introduction of concrete measures aimed at boosting innovation in Europe and facilitate development, testing and validation of innovative AI systems. In addition to addressing risks, it is crucially important to include the immense opportunities of AI technology as one of the key future drivers for Europe's industry into the perspective of the legislative proposal. The establishment of regulatory sandboxes can be a promising instrument to enable data-driven innovations in a controlled environment.

Nevertheless, the EU legislator should clearly specify the legal basis for the establishment of regulatory sandboxes in Article 53 and 54. The measures should be in accordance with the Council's communication (11/2020) and incorporate experimentation clauses, that are already used by many member states. These clauses should be activated on a case-by-case basis in order to guarantee flexibility.

Governance (Title VI)

European Artificial Intelligence Board (Chapter 1, Articles 56 – 58)

The creation of the EU AI Board requires broad representation and participation of all relevant stakeholders, including the relevant experts in the industry, trade associations as well as national and European standardisation organisations. The roles and responsibilities of the AI Board vis-à-vis the national competent authorities should be clearly defined to ensure harmonised processes. Especially in matters related to supervisory activities or recommendations on the implementation of technical specifications and harmonised standards, the involvement of industrial actors and their expertise in the relevant sectors is indispensable. The same applies to a possible European AI Expert Group that was informally announced by the EU-Commission following the release of the AI proposal.

National Competent Authorities (Chapter 2, Article 59)

The interaction between the National Competent Authorities (NCAs) that are designated for the AI Act and those that are designated under existing NLF legislation (listed in Annex II) needs to be clearly and unambiguously defined in a way that avoids redundancy that may be caused by duplicated work and in a way that provides legal certainty for all involved economic operators. In this context, it should be carefully examined if and to what extent horizontal legislation is preferable over sectoral legislation (that may need to be amended) for the topic of Artificial Intelligence.

Post-Market Monitoring, Information Sharing, Market Surveillance (Title VIII)

Post-Market Monitoring (Chapter 1 – Article 61)

The requirements for post-market monitoring as described in Article 61 are not feasible and create an unnecessary burden for the provider of the AI system. The provider can only "actively and systematically collect, document and analyse relevant data" (Article 61, 2) when it has access to such data in the first place and when there are no legal barriers regarding data protection, competition or copyright law. This is especially relevant for companies in the supply chain who under certain circumstances could be deemed as "provider" but have no access to final use cases or to field data of the final product. Furthermore, the extensive post-market monitoring obligations concerning data collection and analysis should not be integrated into existing monitoring systems as stated in Article 61 (4), since existing obligations are only linked to the functioning and safety of the product.

Hence, Article 61 should be significantly reduced, since it implies only additional burden for each provider. Not all systems can be monitored, especially if it is a product with an integrated AI system (e.g. autonomous cars). The provider would have to monitor each of these AI systems, since all AI systems are generating data independently. This is not feasible for the reasons listed above.

General Remarks

<u>Extensive Powers by the Commission to adopt Delegated Acts (Title XI)</u>

The proposed AI Regulation grants the EU-Commission extensive powers to change the definitions, scope, requirements and procedures in different areas through delegated acts. Such substantial modifications of the law should only be possible with consultation of stakeholders and relevant institutions. This refers to the extensive delegation of power in Article 4 (AI Definition in Annex I); Article 7 (High-Risk Areas in Annex III); Article 11 (Technical Documentation); Article 43 (Conformity assessment); Article 48 (Declaration of Conformity).