Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) / Presidency compromise text
– DE remarks –

Germany would like to thank the Presidency for the new compromise text and would like to take the opportunity to present the following comments. In addition, we refer to our previous written statements.

Scope of Application

- We again kindly request the inclusion of an opening clause for more specific national regulations in the employment context under Article 2a. Specific national regulations must be possible to guarantee fundamental rights, health and safety of employees.

- To ensure national response capability, e.g. in the event of severe natural disasters and to save human lives, the immediate deployment of the Bundeswehr in administrative assistance is often required, whereby original military means and resources - which may also include specific AI systems - are regularly deployed. This use of original military means must not depend on the completion of the certification and validation processes to be carried out beforehand. Therefore, we ask for an addition to recital 12a: "Nonetheless, if an AI system ..., such a system would fall within the scope of this Regulation, provided compliance with this Regulation would be feasible within the timeframe of the use of the AI system in question and not contradict national security concerns." As an alternative, the deletion of the two sentences "Nonetheless, ... this Regulation. In that case, ..., unless the system is already compliant with this regulation." could be considered.

- General purpose AI systems have applications in many fields. As it stands now, providers of general purpose AI systems may face a variety of issues that result in investment and innovation attentions. This includes the requirements to be met for providers and their predictability. Therefore, it should become clear that only relevant and proportionate requirements (e.g. Art 4b(2)) should apply. In addition, the chain of responsibility for general purpose AI can be difficult to trace. There may also be different gpAI versions regarding high-risk use which may interplay with an obligation within the AI Act to provide the necessary information to the provider/user. Regarding legal tools, please refer to our written comments. Our review is ongoing.
Extension of the prohibition in Article 5

- **Remote biometric identification** in real time in public spaces must be excluded under European law. However, retrograde biometric identification, e.g. during the evaluation of evidence, must not be excluded under European law. However, discussions are still under way in regard to the prohibition in Article 5(1) letter (d) of remote biometric identification systems. We reserve the right to submit further comments.

- We ask for the inclusion of **further prohibition items** and refer to our written statement. This concerns, "Robo Judges," **assessment of individual's future delinquency, polygraphs, systematic surveillance in the workplace.**

High Risk AI Systems

- We welcome the changes in Article 6(3) in principle, but further request deletion of the **additional layer** in Article 6(3) altogether.

- Essential requirements for high risk AI systems are still inadequate. In particular, it is important to us that the provider does not reduce the risks identified in the **risk management system** under Article 9 by human supervision alone. **Articles 9 and 14 need to be aligned** so that providers reduce risks according to the principle of integrated safety. It seems necessary to describe the envisaged human-machine interface in more detail to enable human supervision and to increase explainability, traceability and trust in an AI system.

- We would like to include “road traffic” and “critical digital infrastructure” in Annex III only if not regulated in sector-specific acts. In addition, we also ask for a recital that clearly states which systems are considered critical (digital) infrastructures and to give concrete examples. Process optimisation methods for complex machines and plants, virtual digital assistants, predictive maintenance and programmable logic controllers (PLCs) should not be considered high-risk.

- We assume that the term **health insurance** in Annex III No 5(e) also includes long-term care insurance. If PRES has a different view, we urge to include long-term care insurance in 5e in order to create a corresponding equivalence with health insurance. Furthermore, we ask to add the word "benefits" to Annex III No 5(e) ("risk assessment, benefits and pricing").

- **Annex III No. 6 (d) and No. 7 (d):** We request further clarification. The description of AI systems covered by respective letters (d) should be clear-cut. It must be ensured that systems without risk to health, safety or fundamental rights are not covered. For Germany, it is very important that letters (d) are defined more narrowly in this respect. At the
same time, systems that pose a risk to the abovementioned protected interests must remain covered.

- We ask for the inclusion of further high-risk AI systems relevant to consumer and environmental protection.

Inconsistencies with other legal acts

- In our view, the numerous special features of existing financial regulation and insurance regulation have not yet been sufficiently taken into account. The same applies to the regulations for medical devices and in vitro diagnostic medical devices. There are inconsistencies. We consider a lex specialis regulation to be necessary.

- It is still not prevented that already notified bodies have to go through a new notification process. For notified bodies notified under the MDR and IVDR, this process takes at least 18 months.

- The definition of "biometric data" in Art. 3 (33) should be aligned to the GDPR and the JI data protection directive.

Separate regulation of AI systems for public administration

- We would like to thank the Presidency for the adjustments already made to the individual articles with regard to the demands outlined in our paper "Regulation of AI – taking greater account of the specific characteristics of the public administration, particularly in the fields of security and migration".

- Nevertheless, we see a need for further adjustments. In particular, we believe that the requirements for secrecy and the guarantee of confidentiality and data security in Art. 70 should be clarified.

- We are also not entirely convinced by the changes in Art 47(1a) within the latest proposal. It is debateable whether the decision of a market surveillance authority should automatically result in a ban on the use of evidence.

Missing Provisions

- We continue to request the introduction of information obligations for providers/users and information rights for natural persons affected by AI as well as the inclusion of the AI Act in Annex I of the directive (EU) 2020/1828.

- DE needs enabling legislation to make selected environmental sustainability aspects of AI systems transparent.
• We further call for the inclusion of a research clause (possibly Art. 62a) to ensure access to data in the AI environment for scientific purposes. We have submitted a proposal for this in our previous comments.

• The standard clause of delegated acts re consultation of MS is not yet included in the text (Art 73).

• The transparency obligations in Art. 52 (1) and recital 70 do not sufficiently reflect the state of the art on inclusion and disregard the demographic change. We do not need specific provisions for “vulnerable groups” as stated in recital 70 but a holistic approach that fulfils the principles of universal design.