TEAM AI REGULATION

SHORT POSITION

General Remarks

The original intention of the AI Act Omnibus was to reduce the bureaucratic burden. With the move of the Machinery Regulation from Annex I Part A of the AI Act into Part B, this could be achieved. During the current legislative revision process, however, this solution has become burdened with complicated new provisions and now seems increasingly out of reach. If the European lawmakers do not find the courage to change course and cannot agree on a substantial and purposeful simplification, VDMA recommends to rather keep the original provisions. A halfway solution might outweigh the potential benefits and create even more confusion.

Position on presidency proposal for the AI Omnibus

We welcome the intention of the Presidency to reach a compromise on the AI Omnibus to facilitate trilogue and reach a position acceptable for the stakeholder involved. However, we firmly stand on our position that at least Regulation 2023/1230 (Machinery Regulation) needs to be moved from Annex I Part A of the AI Act into Part B. If this cannot be agreed on, we would like to make the following comments on the presidency proposal:

1. Addition of a mechanism in Article 2 that allows to resolve situations in which sectoral law has similar AI-specific requirements to the AI Act, by limiting the AI Act's application in those specific cases through implementing acts

We are surprised, that the presidency would suggest an option with implementing acts, as the council would only have very limited stopping power over them. As such, delegated acts would be the better option. Furthermore, propper colision regulations could be introduced in a much simpler way, without adding the burden on the EU regulator of additional legal acts.The AI Act should be improved in a less burocratic manner, by adding a the provisions of Art. 9 of the machinery regulation to Art. 8 (3) of the AI Act:

"For high-risk AI systems referred to in Article 6(1), where the risks addressed by the requirements set out in Articles 9 to 15 are wholly or partly covered by Union harmonisation

legislation listed in Section A of Annex I that is more specific than this Regulation, this Regulation shall not apply to that AI system to the extent that that specific legislation covers such risks."

The most elegant way to resolve this issue remains the merger of Annex I Part A and B, together with the application of the Annex B approach for Annex A. Again we would like to highlight, that the wording regarding essential health and safety requirement changes should not be added. Notably, they do not exist in the AI act. For proper essential health and safety requirements, we would like to point the lawmaker at the machinery regulation (Art. 8 and Annex III).

2. Inclusion of a requirement for the Commission to issue guidelines that explain how procedures under the AI Act and under sectoral law can be combined to avoid duplication (in Article 96). This is already in the Council's mandate but additionally the Presidency is proposing to set a deadline for these guidelines.

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3. A revision of the definition of 'safety component' in Article 3(14), to clearly reduce the number of AI systems that are regulated as high-risk.

A revision of the definition of "safety component" in the AI Act is needed as it would narrow the scope of AI systems that are considered high risk. However, we would propose to add the following sentence to the definition to match the definition of safety component in the Machinery Regulation:

(14) '"safety component" means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons; ~~for the purposes of this definition, a component fulfils a safety function where its intended purpose is to prevent or mitigate risks to health and safety of persons~~, **but which is not necessary in order for that product to function or for which normal components may be substituted in order for that product to function**.

4. A clarification in Article 9 that the risk management does not need to cover risks which are not affected by an AI system.

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5. Removal of a possible duplication of conformity assessment by clarifying in Article 43 that manufacturers of AI-enabled products keep their choice of conformity assessment procedure, in particularly by relying on harmonised standards as a path to conformity.

We support this proposal. Though we suggest a couple of changes to the wording:

In Article 43(3), the third subparagraph is replaced by the following:
“Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option **to rely on a conformity assessment not involving a third-party,** ~~to opt out from a third-party conformity assessment, provided that that manufacturer has applied harmonised standards **to show the compliance** covering all the relevant requirements~~, that manufacturer may use one of the following options to demonstrate compliance: ~~that option only if it has also~~ ~~applied~~ harmonised standards and/or other recognised means under those legal acts, including, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.

The classification of a product as a high-risk AI system under Article 6(1) does not affect the choice of the conformity assessment procedure provided to the manufacturers of products covered by Union harmonisation legislation listed in Section A of Annex I, including, where applicable, an option to rely on harmonised standards. The manufacturers of such products are not obligated to choose a conformity assessment procedure involving third-party conformity assessment only because the product includes a high-risk AI system as a safety component, if this is not required by the Union harmonisation legislation.”;

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