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Comments on AI Act proposal

The European Commission's Proposal for a Regulation laying down harmonised rules on artificial intelligence (the artificial intelligence act) and amending certain Union legislative acts (COM(2021) 206)

Confederation of Swedish Enterprise represents 49 sector-member organisations and 60,000 member companies and would like to state the following in light of the European Commission's consultation on the artificial intelligence act, AIA.

Confederation of Swedish Enterprise

- welcomes the approach to protecting the users of AI systems and **creating trust** in the use of AI
- criticize the proposal as it has extensive negative consequences for competitiveness, innovation, and entrepreneurship; the consequences of the proposal need to be investigated in detail
- emphasize that investments and compliance are ensured by clear, principle-based and technology-neutral rules that last over time
- advocates the use of NLF principles and a legal framework limited to necessary requirements that leave technical implementation to product-specific and updated (state-of-the-art), voluntary standards developed by stakeholders.
- requests compliance with the Better regulation agenda: make simpler and better EU laws with special attention to the implications and costs of applying legislation
- believes that the proposal has a negative impact on the freedom to conduct business and employers relevant AI use
- states that AIA overlaps with other regulations and needs to be harmonised with the Data Protection Regulation, GDPR, regarding data processing and storage
- proposes more extensive initiative for regulatory sandboxes and experimentation to promote test opportunities for innovative solutions in high-risk AI areas
- questions the unjustifiably high levels of sanctions
- would like to point out the considerable need for AI experts and staff with AI skills that must be addressed before the proposal enters into force

The use of AI solutions is important for competitiveness, security, good customer experience and the provision of effective and correct service for citizens. The European Commission's proposal for the AIA, is based on the concept of trust, which is vital to realising the increased use of AI. To strengthen confidence in AI applications and promote rapid technological development, the use of ethical guidelines, certifications, and codes of conduct should be encouraged and used as much as possible.

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There is significant concern amongst our members that the draft AIA is far too comprehensive and vague to boost AI use and EU competitiveness. The proposal is difficult to apply, disproportionate and not technology neutral. The proposal needs stronger innovation and development approaches and an ambition to strengthen the competitiveness of European companies. In addition, the proposal entails increased costs for companies and governments.

Technological neutrality

The pace of technological development is rapid. Extensive regulation of technology use quickly becomes obsolete. If the ambition with the new regulation is to influence all sectors and companies, the regulation should be technology-neutral, principle-based, and clarify what is prohibited.

The regulation should focus on high-risk use, but the definition of high-risk AI used in the proposal is broad and not technology neutral. The Commission's proposal to amend the AIA through delegated acts increases uncertainty. From a business perspective it would be desirable to instead supplement the AIA by clear recommendations and standards as described in the New Legislative Framework, NLF.

The proposal focuses on potential risks and omits rules that could strengthen AI use in a number of areas. Risk-based assessment, of which AI solutions constitute a high degree of risk, is an important starting point and should be defined as specifically as possible, as other comprehensive and sector-specific legislation is already in place. This regulation should only apply to high-risk AI that is not already regulated. To promote the use of AI, the proposal should focus on the actual purpose of processing data with AI solutions and not on potential risks.

Compliance- implications and costs

In order to have a high level of trust in AI, it is important that rules and laws are followed by companies. Compliance is ensured by clear, principle-based and technology-neutral rules that last over time. Overlapping and conflicting rules must be avoided so as to create understanding and establish high levels of compliance which, in addition to trust, establishes a level playing field in the internal market. This proposal contains many vague wordings and unattainable compliance for too many companies. This is unfortunate because it creates legal uncertainty that undermines investment, innovation, and development.

AI is not unregulated, but some aspects of AI solutions challenge existing rules: autonomous systems, self-learning, various actors during the AI life cycle, open and dynamic systems and to some extent the black box problem. These challenges must be addressed in existing regulations to avoid conflict between rules and to promote predictable, applicable, and consistent laws. AIA overlaps and is partly in conflict with current laws on data protection, product security, discrimination, and liability.

The AIA proposal overlaps and conflicts with existing frameworks in a way that few companies are able to address. It imposes unrealistic costs and administrative burdens, not least on start-ups and small and medium-sized enterprises. Therefore, Sweden and other member states will have increased costs for advice and government support for public and private activities. The proposal will also lead to higher costs and bottlenecks due to the fact that the far-reaching and complex requirements require competence in areas where considerable shortages currently exist in terms of employees with relevant knowledge. This situation is a fact both in private and public sector.

Freedom to conduct business and employers AI use

The Confederation of Swedish Enterprise believes that the AIA proposal disproportionately places requirements on companies' organisational structures rather than regulating what is prohibited. In addition, the EU creates a position of power and transparency in corporate research and development as all high-risk AI solutions must be registered in a database provided by the European Commission, Article 60. The database must also be accessible to members of the public, which may conflict with trade secrets and is a disproportionate requirement for information sharing.

The database will be extensive and, together with the establishment of the EU's AI Board, Article 56, will provide intervention opportunities to monitor and control the development and initiatives of the business community. These two articles infringe on the freedom to conduct business.

High-risk classification, and thereby the limitation of employers' accepted use of technical support in HR, appears to be backward-looking and is far-fetched, see Annex III. Using technology as a decision-making tool to, for example, assess job applications and applicants' qualifications is a normal for a HR department. Legislation should not lay down new administrative requirements, but specify what is undesirable, i.e. what is illegal. Creating a large compliance structure for legitimate technical support is unfortunate, complicated, and unjustifiably burdensome. The legislation focuses on risks and not the positive effects of technology use. Technology is used, among other things, as a decision-making tool to get away from human discrimination and bias.

Approval of AI solutions: the administrative burden

How do we ensure that this regulation does not prevent modern and agile working practices?

How can the development and updates of existing AI systems be carried out without having to undergo the entire approval procedure?

The approval process is a challenge for companies as conformity assessments as part of the EU's current market access system focuses on products. Assessment of conformity takes time, requires considerable amounts of administrative work, expertise, and experience in companies. Introducing and extending this to software can create severe bottlenecks, which is highly undesirable in an area where flexibility and speed can be crucial. For example, companies may need to create rapid software updates to correct an error or fix a security issue. In addition, most software companies working with AI are small and medium-sized companies with no experience of conformity assessments.

In addition, there are question marks over the assessment body's capacity to manage and approve all submitted company assessments. It will take time to set up conformity assessment bodies as a high level of technical knowledge is required and conformity structures and procedures need to be built. It will take time and resources to build up and entrench the competence of employees of the assessment body. The assessment body will presumably have to work for a period of before the law can enter into force.

In the automotive industry, there is new legislation that regulates the right to make software updates, UN Regulation No 156, 2021/388. A similar option should be introduced into the AIA to enable continuous improvements in AI systems and to address necessary security updates in particular.

Risk management systems, Article 9

Article 9 needs to be clarified and limited to necessary requirements.

The proposal should be based on the NLF principles, which means that it should be limited to necessary requirements and leave technical implementation to product-specific and updated (state-of-the-art), voluntary standards developed by stakeholders. Requirements for risk management and assessment systems in the proposal need to comply with similar requirements in overlapping legislation, such as the impact assessment in Article 35, GDPR and forthcoming Human Rights Due Diligence Directive, (HRDD). The HRDD requirement that companies perform due diligence on their supply chain is difficult to reconcile with AIA's product liability procedure.

Article 9 contains many vague wordings which create legal uncertainty. What does "foreseeable abuse" mean? Article 9 (2) (b); "Evaluation of other risks that may arise" is unclear, Article 9 (2); and Article 9 (3) is very obscure and unclear, not least because of the combined requirements which must also consider *general acknowledged state-of-the-art* and reflected in *relevant harmonised standards.* Eliminating or reducing risks as much as possible is difficult to define legally and could possibly be moved to Preambles or deleted as it is impossible to know the level of knowledge of users, Article 9.4. In Article 9.5, it is unclear who should conduct testing and how should "most appropriate risk management measures" be defined? Who decides on these measures and what criteria determine what should be included?

GDPR vs AIA, Article 10

Since the European Commission released its proposal for AIA, there has been lively discussion about whether AIA will conflict with or be seen as a *lex specialis* to the GDPR. On June 21, the European Data Protection Board, (EDPB), published a press release announcing a joint comment with the European Data Protection Supervisor, (EDPS), on the AIA. In the statement, the two data protection authorities emphasise the need to explicitly clarify that existing EU data protection legislation (GDPR, EUDPR, and LED) applies to all processing of personal data covered by the draft AI regulation. The authorities' statement underlines the need for a review of the GDPR, otherwise several parts of the AIA proposal will become illegal to implement because they violate the GDPR.

The AIA proposal includes requirements for data used in high-risk AI systems. To meet these requirements, companies will probably be required to collect and process more data than the GDPR allows. Therefore, the GDPR needs to be harmonised with the AI Act to comply and avoid a conflict of rules.

Data quality is decisive for outcomes and results in the AI system, preamble 44 and Article 10. However, the collection and quality of data is currently limited by the GDPR, among other things because the purpose of the collection and legal basis must be stated prior to processing. To enable the highest quality data collection for AI solutions, we assume that the AI Act provides a legal basis, GDPR Article 6, to collect data. However, the GDPR needs to be reviewed and reformulated to clarify the right to more extensively collect and store data before the AI act comes into effect. All principles of Article 5 of the GDPR should be reviewed as well as the right to be forgotten and deleted, Article 17. In addition, the GDPR's rules on the processing of sensitive personal data, Article 9, need to be revised if bias in AI systems can be counteracted and controlled in gradually without the collection being dependent on the individual's consent as consent fatigue is a growing problem and consent is an uncertain legal basis as consent can be revoked.

The requirement in Article 10 (3) that data must be “free of errors and complete” is fundamentally impossible to establish and in conflict with the GDPR and should be deleted. Not all data is available, and this is especially true if data consists of personal data as data may have been deleted, GDPR art. 17, or never processed due to lack of consent, GDPR art. 6 and 9, or lack of other applicable legal basis at the time when the data could have been collected for future possible AI-solutions.

Article 10 (3) and preamble 44 can be reworded to the problematically vague but still realistically possible to achieve available data of high quality and representativeness. The focus should be on ensuring the process of training, validation and testing of the AI application rather than being able to display datasets. Access to data sets does not say much. Article 10 should therefore be reworded as the requirements are inappropriate and the likelihood of guaranteeing them very difficult.

In addition to the rules for permitted personal data processing, the definition of high risk as well as impact assessment requirements need to be harmonised between GDPR and AIA, see GDPR art. 35 when an impact assessment regarding data protection is to be performed compared to AIA art. 9, risk management systems, and Article 17, quality management systems.

Data storage

Logging of data is important but involves extensive data storage requirements. Today, logging is routine for companies that must comply with the Medical Device Regulation MDR, for example.

Introducing logging requirements into the AIA means that many businesses in widely different industries will need to store extensive amounts of data, which requires reliable electricity supply at reasonable prices. Data storage and maintenance costs could be considerable.

Focus should be placed on ensuring processes for training, validation, and testing of the AI application rather than being able to display data sets. Article 10 should therefore be rewritten as the existing requirements are inappropriate and the likelihood of guaranteeing them is very difficult, see above.

Transparency

Transparency is important for all users of AI solutions, not least for business users who need to be able to trust systems and provide information to end users. The aim of the proposal should be to promote the trustworthiness of and use of AI that strengthens the conditions for innovation and investment to shape Europe’s digital future. In its current version, the AI Act is overly bureaucratic and burdensome.

Innovation and sandboxes

The Confederation welcomes the option of sandboxes. Innovation capacity is vital to competitiveness and should therefore be made possible in a clearer and simpler way. The right to experiment under certain conditions should be included directly in the proposal and not left to Member States as this would create differences in the internal market. When it comes to experiments with new AI solutions, current limitations are considerable due to GDPR rules, see above.

Innovation is crucial in high-risk areas, especially in the healthcare sector. Here, the development of industry-driven standards is important. However, work on AI standards is ongoing, and it is not always possible to update them sufficiently quickly to keep pace with technological development. Therefore, companies need the opportunity to experiment and innovate quickly and smoothly, which is why sandboxes are very important. In regulated sandboxes, companies need to be able to test ideas under limited responsibility. Sandboxes should also be an effective way of testing new solutions without being affected by burdensome market access systems that conformity assessments constitute.

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