AI LAW TECH

An Analysis of the Selected Aspects of the Draft Artificial Intelligence Act

13.12.2021

Preface

The digital revolution is not only a process of technological transformation, but also a social and political phenomenon. We understand this much better today than we did only a decade ago, when the Internet seemed to be mainly a source of knowledge and entertainment, rather than a range of new challenges and problems which emerged when the largest technology companies and social networking platforms practically monopolised the range of services offered online. We, as EU legislators, do not want to be surprised once again by the negative effects of innovations, which is why, in the face of the dynamic development of services and products based on artificial intelligence solutions, the European Commission has presented the world's first draft regulation regulating this issue.

However, the discussion about these regulations is only just beginning and we are facing a long battle, also in the European Parliament, to find the best possible form for AI Act. The European Conservatives and Reformists Group sees the need for ambitious but also utilitarian regulation in this area. Carefulness is needed to balance the interests of European consumers, who want to have access to advanced devices and technologies, and businesses, who want to invest and carry out research in a friendly legal environment, with values such as the protection of personal data or human rights in a clash with sophisticated algorithms.

We must also bear in mind that artificial intelligence is an area in which there is a constant technological race and that Europe, despite its potential, is unfortunately not a leader in this competition. We are to large extent consumers of innovation from third countries, and this has a huge impact on our political and economic position in the world. Creating additional obligations and restrictions for European companies to develop their own AI products and services may make it even more difficult for us to catch up with digital powers such as the United States or China.

This study is an attempt at an analytical assessment of the European Commission's project and identifying those of its elements, which may be a real barrier to creating innovations in the field of artificial intelligence in countries such as Poland. I hope that it will be a significant support for MEPs, experts and advisers working on this very important and necessary legislation.

Kosma Złotowski
Member of the European Parliament

I. The Subject Matter and Scope of the Study

The purpose of this study is to present the selected reservations, comments and change recommendations regarding the draft Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (the Artificial Intelligence Act) and amending certain Union legislative acts of 21 April 2021.[1] This study has been developed for the AI LAW TECH Foundation by the following authors:

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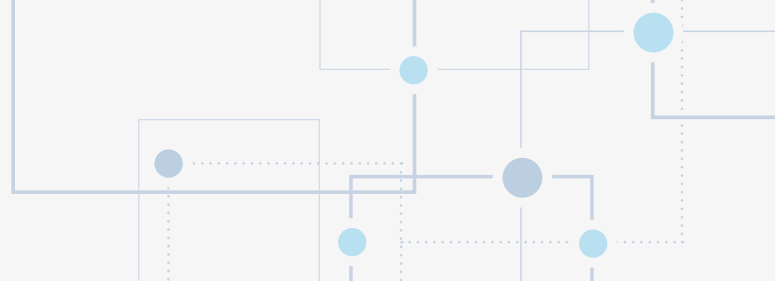
The authors would like to express their gratitude for consultation regarding the technical aspects of artificial intelligence to Messrs. Wojciech Ptak, Tomasz Jaworski and Piotr Mechliński.

This study shall not be considered a comprehensive analysis of the draft Regulation or an exhaustive presentation of all the identified issues, doubts as to the interpretation, potential solutions, etc. All the comments, conclusions and recommendations contained herein stem from the discussion of the aforementioned experts.

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1   https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52021PC0206&from=EN

II. Glossary

Sources of Law	
AIA or draft Regulation	Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (the Artificial Intelligence Act) and amending certain Union legislative acts (COM/2021/206 final)
CFR or Charter of Fundamental Rights	Charter of Fundamental Rights of the European Union (OJEU C 303, 14.12.2007, p. 17)
Decision 768/2008	Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJEU L 218, 13.8.2008, p. 82)
Directive 2009/48	Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJEU L 170, 30.6.2009, p. 1)
Directive 2016/680	Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJEU L 119/89, 4.5.2016)

Sources of Law

draft ePrivacy Regulation	Proposal for a Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications) of 16 February 2017
eIDAS	Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJEU L 257)
GDPR	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJEU L 119, 4.5.2016)
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

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Sources of Law	
New Approach	Approach to technical harmonization based on the principles set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (OJEC C 136, 4.6.1985, p. 1)
NLF	New Legislative Framework established by Decision 768/2008 and Regulation 765/2008 (partially amended by Regulation 2019/1020)
Regulation 765/2008	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJEU L 218, 13.8.2008, p. 30)
Regulation 1025/2012	Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJEU L 316, 14.11.2012, p. 12)
Regulation 2015/1501	Commission Implementing Regulation (EU) 2015/1501 of 8 September 2015 on the interoperability framework pursuant to Article 12(8) of Regulation (EU) No 910/2014 of the European Parliament and of the Council on electronic identification and trust services for electronic transactions in the internal market (OJEU L 235; as amended)

Sources of Law	
Regulation 2016/425	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJEU L 81, 31.3.2016, p. 51)
Regulation 2019/1020	Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJEU L 169, 25.6.2019, p. 1)
Rome I	Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (OJEU L 177)
Rome II	Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (OJEU L 199)
TFUE	Treaty on the Functioning of the European Union (consolidated version; OJEU L 326)

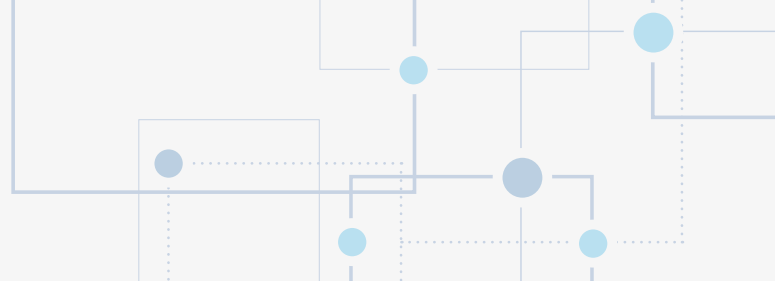| Other abbreviations	
AI system	artificial intelligence system
ECHR	European Court of Human Rights
ECJ/CJEU	Court of Justice / Court of Justice of the European Union (since the entry into force of the Treaty of Lisbon, i.e. 1 December 2009)
OJEU	Official Journal of the European Union
SMEs	small and medium enterprises

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III. Executive Summary

1. It is undoubtedly necessary to adopt a legal framework on the European Union level for the development and use of artificial intelligence. Such a legal framework should be human-oriented, that is it should provide for the effective protection of fundamental rights as well as the development of secure, trustworthy and ethical artificial intelligence systems. At the same time, it is necessary to enable the development of AI solutions, particularly by small and medium enterprises, provide a friendly environment for investments in such solutions, and establish conditions for the broad use of AI systems for the benefit of society. We are fully aware that the development of such a legal framework is an immensely demanding task and may necessitate choices that will probably never satisfy all stakeholders.

2. **Regulation.** We consider it positive that the issues of development and use of artificial intelligence systems will be regulated by means of an EU Regulation, as it is necessary to provide harmonised regulations in this area within the Union. **Importantly, the broad scope of the AIA allows no degree of regulatory discretion for Member States with respect to artificial intelligence systems – and all of them rather than only those of high risk, which are the main focus of the AIA.**

3. **Relation to other legal acts.** The scope of the AIA should be clarified, so as to make the draft Regulation complement rather than duplicate or exclude the existing or intended EU legal acts. It is particularly important to ensure consistency with the NLF system, GDPR, Directive 680/2016 and consumer protection regulations.
Article 1 of the AIA should include clarification that the EU legislation on personal data protection, particularly GDPR and Directive 680/2016, applies to personal data processing covered by the AIA. **The draft Regulation should be added a provision stating that it is without prejudice to the GDPR and EU consumer law and does not prevent amendments thereof, and it is without prejudice to the Member States' right to restrict the use of certain types of artificial intelligence systems regarding the aspects falling outside the scope of the AIA.**

4. **Fundamental rights.** In the legal order of the European Union, fundamental rights have been enshrined in the Charter of Fundamental Rights (CFR), which has been elevated to treaty level[2]. These rights stem also from the European Convention of Human Rights, constitutional traditions common to the Member States and international agreements to which the Union is a party (e.g. United Nations Convention on the Rights of Persons with Disabilities). The detailed principles of protection of fundamental rights are regulated by the EU secondary legislation, which is applicable to both public and private actors using AI technology. Notably, the *Impact*

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2   Cf. Wróblewski M., Karta Praw Podstawowych Unii Europejskiej [in:] System Prawa Unii Europejskiej. Vol. I. Podstawy i źródła prawa Unii Europejskiej [ed.] Biernat S. Warsaw 2020, pp. 725–775.

Assessment developed by the Commission emphasises the Union law on personal data protection, non-discrimination and consumer protection.[3]

Taking into account both benefits and threats related to the use of artificial intelligence, the starting point for the AIA solutions should be the need to ensure respect for human dignity (cf. Article 1 of the CFR) and prevent discrimination[4]. From this perspective, the AIA sets a legal framework to ensure artificial intelligence is developed in ways that respect people's rights and earn their trust[5]. It is worth pointing out here that owing to the nature of the AI technology this trust cannot be built only by ensuring the high quality and protection of data[6].

In line with the *Ethics Guidelines for Trustworthy AI*, trustworthy artificial intelligence should not only be lawful, particularly ensuring compliance with fundamental rights, but also ethical, ensuring adherence to ethical principles and values[7]. It is worth noting that even though the AIA does not have any direct references to ethical principles, the detailed solutions contained therein may imply that such principles have guided its development. Therefore, the AIA should point out more clearly to the relevant documents and standards developed by both the Union and the Council of Europe in this field, and obligate the entities covered by the AIA to comply with them.

5. **Risk-based approach.** We consider it positive that a risk-based regulatory approach has been adopted. Both the decision to prohibit the certain uses of AI systems and the scope of obligations related to the development, distribution and use of AI systems have been rightly correlated with the risk to fundamental rights and the safety of individuals or the society as a whole posed by the use of such systems.

6. **Definitions (Article 3).** We suggest considering a more descriptive definition of AI system, indicating certain attributes of artificial intelligence as well as the ways of operation and purposes of such a system, without reference to specific techniques or approaches. We also recommend clarifying several existing definitions

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3   Cf. Commission Staff Working Document. Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (the Artificial Intelligence Act) and amending certain Union legislative acts. Brussels, 21.4.2021, Swd(2021) 84 Final, Part ½, pp. 5 et seq.

4   Cf. EU Fundamental Rights Agency, #BigData: Discrimination in data-supported decision-making. Vienna 2018.

5   Cf. e.g. section 1.3 of the Explanatory Memorandum of the AIA.

6   For this reason, the AIA should be closely synchronised with the Union regulatory initiatives regarding data, such as data management directive, open data directive or European data strategy, particularly with respect to sensitive data protection (e.g. in the health care sector).

7   Ethics Guidelines for Trustworthy AI, High-Level Expert Group on Artificial Intelligence, European Commission. Brussels, April 2019, pp. 2 et seq.

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and adding a number of new ones (including those of 'risk', 'incident', 'end user', 'critical infrastructure', 'public sector body' or 'public entity').
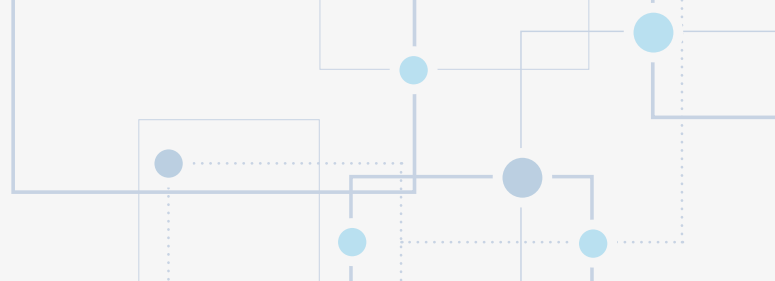
7. **Prohibited systems (Article 5).**

   a) Article 5(1)(a) and (b) of the AIA contains a number of vague and ambiguous notions, such as 'subliminal techniques', 'material distortion of a person's behaviour' or 'psychological harm.' These provisions raise numerous doubts as to the interpretation and result in far-reaching legal uncertainty (i.e. difficulties in assessment whether it is allowed to use a particular AI system or not). Due to the risk of heavy fines, this may have a chilling effect, hampering innovation. On the other hand, ambiguous wording of the provisions may stimulate attempts to circumvent the prohibition. Simultaneously, due to difficulties in demonstrating actual or likely harm, the prohibition may prove difficult to enforce in practice. Therefore, we first of all recommend clarifying the provisions and adding or clarifying the definitions of the vague notions (premises) used therein. We also recommend presuming harmfulness of AI systems in the situations described in these provisions.

   b) In general, the AI systems used by the public sector, or when performing public tasks, for social control of natural persons, involving the assessment of their social behaviour, particularly in social contexts which are unrelated to the contexts in which the data was originally generated or collected, should be prohibited.

8. **Delegated acts (Article 73).** We consider it negative that the draft Regulation delegates power to the Commission to amend the AIA in material issues. An act of such importance and its significant areas should be subject to the 'traditional' legislative process rather than that set out in Article 73 of the AIA. We would recommend introducing an additional fast track option for the AIA amendment should any concrete and justified reasons thereof emerge, e.g. in case of new developments related to high-risk systems. Such reasons, however, should be clearly specified and well defined to avoid arbitrary decisions.

9. **High-risk artificial intelligence systems.** The current classification of AI systems as high-risk is unclear. This may raise legitimate doubts among companies, hindering the proper qualification and generating the risk of non-compliance with the AIA. The recommended solution would be to provide a more descriptive definition of high-risk systems, in line with the principle of technology neutrality and risk-based approach, and leave unchanged the list of currently used solutions set out in Appendices (harmonised framework and Annex III). In addition, exclusion from the requirements for high-risk AI systems could be considered for the purpose of scientific research or R&D.

10. **Data (Article 10).** Article 10 of the AIA, which imposes a number of ambiguous and, in our opinion, excessive obligations related to training of models of high-risk AI systems with data, raises doubts. We recommend replacing the requirement
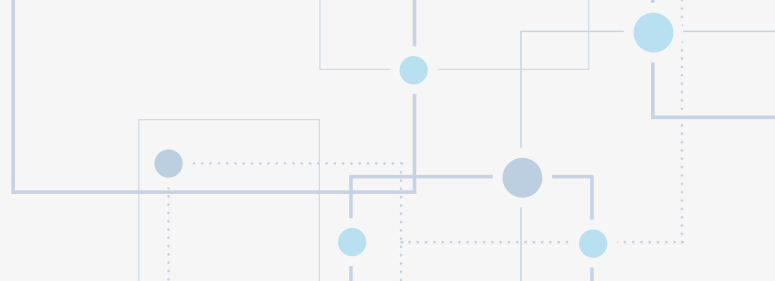
of error-free data with the provider's obligation to exercise due diligence and undertake efforts, adequate to the intended purpose of the AI system, to ensure that data are correct (free of errors). We further recommend clarifying the requirement of data 'completeness' in the preamble of the AIA.

11. **Cybersecurity (Article 15).** We consider it positive that the draft Regulation provides for the need to ensure the cybersecurity of AI systems. However, in our opinion, Article 15 of the AIA should be further clarified. In particular, we recommend adding a reference therein to at least the basic pillars of information security and protection, such as confidentiality, integrity and availability.

12. **Users.** We recommend imposing on users the obligation to perform the risk assessment with respect to the use of AI systems in their own business activity. We further propose imposing the information obligation towards end users (e.g. encompassing information about the risks related to the use of the AI system, and instructions for use).

13. **Vagueness of terms.** Both the Explanatory Memorandum and the preamble indicate that the AIA aims to ensure legal certainty.[8] However, the analysis of the draft Regulation indicates that the legislator has used a considerable number of highly ambiguous terms and notions which are open to different interpretations. For example:
    a) 'material distortion of a person's behaviour' – Article 5(1)(a) and (b) of the AIA;
    b) 'appropriate practices' – Article 10(2) of the AIA;
    c) 'sufficiently transparent' operation of an AI system – Article 13(1) of the AIA.
    The risk of differing interpretations of vague and imprecise terms can undermine the harmonisation effect sought by the AIA. We recommend using more unambiguous terms throughout the AIA, which in particular will make it possible to accurately define the obligations imposed on various entities.

14. **Notification, notified bodies, technical specifications, and conformity assessment.** We consider it positive that the draft Regulation draws solutions related to notification, technical specifications and conformity assessment from the NLF system, but the transposition thereof to the AIA needs to be corrected at some points. In our opinion, the AIA should provide for presumption of conformity with respect to the notified bodies that apply technical specifications ensuring such presumption. In the draft Regulation, it should be specifically left to Member States to choose also other means of assessment of the competence of notified bodies rather than accreditation. We are also of opinion, that the concept of common specifications adopted by the Commission should be renounced, and the AIA should clearly indicate that providers may choose to apply other technical solutions than harmonised

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8   Motives.6, 57 and 71 in the preamble of the AIA.

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standards for demonstrating conformity of AI systems. In addition, we recommend that presumption of conformity be ensured also by certain other specifications than harmonised standards (the references of which have been published in the OJEU).

15. **Regulatory sandboxes.** We consider the idea of establishing regulatory sandboxes as a tool to foster innovation in the AI sector (cf. Articles 53–55 of the AIA) to be positive. However, we recommend indicating the specific facilities for regulatory sandbox users in the AIA itself, e.g.:

   a) issuance of individual interpretations and recommendations by the supervisory authority upon request of a sandbox user;

   b) non-application of administrative fines to a sandbox user acting in line with the individual interpretation or recommendation issued by the supervisory authority;

   c) extending the legal basis for processing of personal data initially collected for other purposes for the purpose of developing and testing AI systems (i.e. extending of the scope of Article 54 of the AIA);

   d) providing concrete mechanisms for reducing conformity assessment fees in case third-party assessment is required;

   e) providing concrete mechanisms for supporting preferential rates for paid access to technical specifications.

16. **Penalties.** In general, we consider the introduction of administrative fines to be positive. In our opinion, however, the relevant provisions need clarification. First of all, the catalogue of circumstances to be taken into account by the supervisory authority when deciding on the amount of the administrative fine, which is set out in Article 71(6) of the AIA, should be expanded. Increasing the number of categories (thresholds) of fines might be considered, so that the amount of the fine could be better adjusted to the gravity of the infringement. We also recommend that the European Artificial Intelligence Board shall issue, within the specified time limit, general guidelines and recommendations on imposing of administrative fines and publish annual reports on the penalties imposed. Finally, we recommend adding a provision on the right to non-administrative remedies (similarly to Articles 79 & 82 of the GDPR).

17. **SMEs.** The obligations related to AI systems set out in the AIA may constitute a significant burden to small and medium enterprises, including start-ups. The draft Regulation acknowledges the importance of innovation and declares support for SMEs and start-ups. However, despite the Member States' support to SMEs claimed in the draft Regulation (including priority access to regulatory sandboxes, reduced costs of conformity assessment and dedicated communication about new regulations), a scenario in which the AIA will hinder business development, especially in case of SMEs, seems possible in practice. Therefore, we recommend introducing additional instruments to support SMEs and start-ups, including the following:

a) providing a scheme for reimbursement of at least a portion of the costs borne by SMEs to meet the requirements under the AIA;

b) providing concrete mechanisms for reducing conformity assessment fees in case third-party assessment is required (a more specific and far-reaching provision compared to current Article 55(2) of the AIA);

c) enabling electronic communication with authorities;

d) obligating the European Artificial Intelligence Board to issue specific recommendations and guidelines addressed to enterprises on the application of the AIA;

e) providing concrete mechanisms for supporting preferential rates for paid access to technical specifications;

f) other regulatory sandbox facilities described above.

IV. Specific Comments

1. Legal basis for the AIA

The EU legislator has chosen a regulation as a form of legislative action for the purpose of the AIA. Pursuant to Article 288 sentence 2 of the TFEU, a regulation shall have general application. It is binding in its entirety and directly applicable in all Member States. Therefore, a regulation does not require transposition into national law.

Importantly, Member States have no regulatory autonomy in the field covered by a regulation (cf. Judgment of the Court of Justice of 18 February 1970, Case 40/69, *Bollmann*, EU:C:1970:12, paragraph 4). The scope of application of the draft Regulation needs to be analysed in this context. It is determined by Articles 1 and 2 of the draft Regulation. Pursuant to Article 1, the subject matter of the AIA encompasses five areas. The letter (a) of this Article is particularly relevant, as it provides that the draft Regulation lays down harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems. **The broad wording of this provision allows no degree of regulatory discretion for Member States with respect to artificial intelligence systems – and all of them rather than only those of high risk, which are the main focus of the AIA.**

The scope of the draft Regulation is specified in Article 2, which provides for few exceptions. In simplified terms, in the matters without any cross-border elements and not resulting from other legal acts of the Union, the regulatory decisions of Member States shall be limited to AI systems developed or used exclusively for military purposes (Article 2(3) of the AIA).

2. Assessment of consistency with the Charter of Fundamental Rights

Section 3.5 of the AIA Explanatory Memorandum clarifies the issue of the protection for fundamental rights. The authors state that AI systems with their specific characteristics can adversely affect a number of fundamental rights enshrined in the CFR. Therefore, they declare that the draft Regulation seeks to ensure a high level of protection for those fundamental rights, particularly the following ones protected by the Charter of Fundamental Rights: respect for private life (Article 7 of the CFR), protection of personal data (Article 8 of the CFR), and non-discrimination (Article 21 of the CFR), especially equality between women and men (Article 23 of the CFR). It also aims to prevent a chilling effect on the rights to freedom of expression (Article 11 of the CFR) and freedom of assembly (Article 12 of the CFR). Furthermore, it mentions the rights to a fair trial (Article 47 of the CFR) and the presumption of innocence (Article 48 of the CFR), which have relevance to criminal law[9], as well as the right to good administration (Article 41 of the CFR).

However, as mentioned above, the key point of reference for the use of artificial intelligence is the right to human dignity (Article 1 of the CFR). The respect for human dignity is to be ensured mainly by the provisions on prohibited artificial intelligence practices, which are set out in Article 5 of the AIA[10].
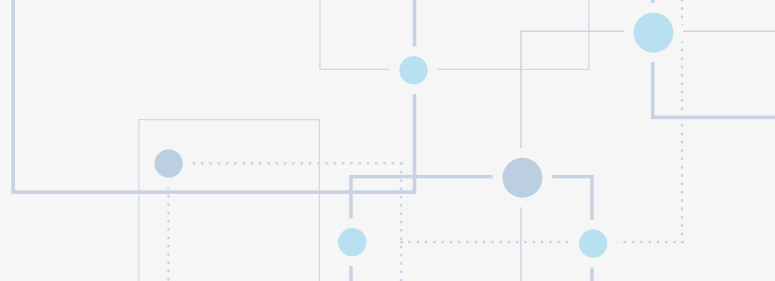
In order to ensure the effective protection of fundamental rights, the AIA authors propose ex ante testing of artificial intelligence solutions, risk management and human oversight over algorithms, particularly in areas such as education and training, employment, law enforcement and the judiciary. They emphasise that ensuring transparency of the applied algorithms should enable potential redress for affected persons. The authors of the draft Regulation foresee some restrictions on the freedom to conduct business and the freedom of art and science in case of high-risk AI technology, proposing the principle of responsible innovation as a concrete expression of the principle of proportionality. Notably, the draft Regulation observes that the AI algorithm transparency obligations shall be imposed with respect for the right to protection of intellectual property in compliance with the relevant legislation in the field.

3. Vagueness of the AIA provisions

The glossary proposed in Article 3 of the AIA is only apparently extensive. Although it comprises as much as 44 definitions of the terms used in the draft Regulation,

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9   Cf. European Parliament Draft Report, Artificial intelligence in criminal law and its use by the police and judicial authorities in criminal matters, 2020/2016 (INI).
10   Cf. the specific comments provided in the section 6 below.

already the analysis of Article 5 indicates that those terms are not precise enough, which will make the application thereof excessively difficult. It is not a theoretical legal problem. **On the contrary, the risk of differing interpretations of vague and imprecise terms that have not been adequately defined in the draft Regulation can undermine the harmonisation effect sought by the AIA**. It is particularly relevant to Article 5 of the AIA, which sets out prohibited artificial intelligence practices. These practises shall be prohibited in each Member State. Differences in the interpretation of terms such as 'distortion of a person's behaviour', 'psychological harm' or 'physical harm' can jeopardise the achievement of that objective and lead to certain business models being allowed in some Member States and prohibited in others. Therefore, we recommend using more unambiguous terms throughout the AIA, which in particular will make it possible to accurately define the obligations imposed on various entities.

4. Scope of application of the AIA

4.1. Treaty basis for the AIA

The European Commission should clarify the legal basis for the draft Regulation. Citing Article 114 of the TFEU (general competence on the internal market regulations) as the primary legal basis in the Explanatory Memorandum carries the risk that this legal basis might be challenged in the future. In line with the case law of CJEU, Article 114 of the TFEU may be used as the legal basis for EU legislation only if there is an actual link between the adopted measure and removal of the existing barriers in the internal market. Consequently, it does not confer on the EU the general competence to regulate any and all aspects of the functioning of the internal market.

For example, the AIA covers also AI systems used in employment, workers management and access to self-employment, notably for the recruitment and selection of persons (Motive 36 and Article 6(2) in conjunction with Annex III), whereas Article 114 of the TFEU shall not be cited with respect to legislation relating to the rights and interests of employed persons. Such legislation shall be adopted pursuant to Article 153 of the TFEU, which differs significantly regarding the EU scope of competence and legislative procedures to be applied.

As for citing Article 114 of the TFEU, the following provisions of the draft Regulation may raise doubts: prohibition on the use of some AI systems by public authorities (Article 5(1)(c) & (d) of the AIA) in the context of removing trade barriers in the internal market; and the aforementioned employment matters (Article 114(2) of the TFEU). The draft Regulation combines provisions reducing trade barriers with those related

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to fundamental rights in the broad sense. Hence, the structure of this legislative act is completely new as far as protection of fundamental rights is concerned, which may have significant consequences for Member States' freedom of action. The draft Regulation imposes some obligations in the areas of national security and law enforcement, which are internal matters of Member States. In fact, the majority of solutions (prohibitions) introduced by the draft Regulation do not contribute to removing trade barriers in the internal market.

Further doubts concern citing Article 16 of the TFEU (personal data protection) as the legal basis for the draft Regulation, especially that the AIA fails to sufficiently clarify its relation to the existing legislation on personal data protection (particularly GDPR).

Furthermore, it seems doubtful whether the AIA can recourse to Article 16(2) of the TFEU with respect to the prohibited practices, as these are not directly aimed at the protection of personal data but rather other fundamental rights and freedoms.

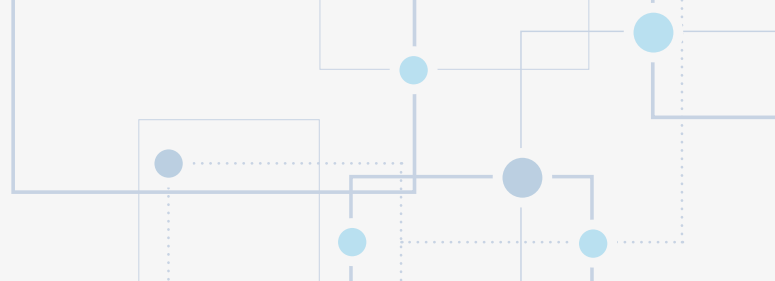4.2. **Relation to the EU and international law**

The introduction of new EU legislation on artificial intelligence poses a significant risk of duplicating the existing regulations, imposing conflicting obligations and over-regulating this area. Therefore, it is critical to introduce a proportionate and technologically neutral regulatory framework.

The scope of the AIA should be clarified, so as to make the draft Regulation complement rather than duplicate or exclude the existing or intended EU legal acts. Notably, it is necessary to coordinate the AIA with the legislative process in the EU regarding digital services, consumer protection, health care, law enforcement, digital markets, data management and industrial machinery.

We recommend abandoning the duplication of requirements and assessments in favour of a more friendly approach towards SMEs.

In the first place, the scope of the AIA should be consistent with the relevant NLF-compliant legal acts, which constitute the basis for the product conformity assessment in the EU.

Also the AIA relation to the existing or intended international legal acts, including those of the Council of Europe, needs to be clarified. Although the intended EU legislation will be probably the world's first legal act to regulate the area of artificial intelligence in such a comprehensive manner, there are legitimate concerns that the

AIA might slow down the AI innovation and reduce the competitiveness of EU companies, especially small and medium enterprises. Despite Member States' support to SMEs claimed in the draft Regulation (including priority access to regulatory sandboxes, reduced costs of conformity assessment and dedicated communication about new regulations), a scenario in which the AIA will hinder their business development seems possible in practice.

4.2.1. **Relation to the NLF**

The scope of the AIA and its relation to the existing NLF legislation should be specified in more detail, particularly differentiating between embedded and stand-alone AI systems.

AI-based medical devices are a good example. The new requirements imposed by the AIA should be incorporated into the existing conformity assessment procedures. The solutions proposed in this respect (Article 43(3) of the AIA) are insufficient. It is evident that the current version of the draft Regulation is inconsistent with or duplicates the provisions of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR).

Significant uncertainty about the legal status of medical devices which involve software might be a consequence of the shortcomings of the definition of AI system. It seems that under the literal wording of the proposed definition a considerable proportion of software may be considered AI systems, while according to the proposed AI system classification any medical device of this type would be considered a high-risk system. The draft Resolution does not account for all the consequences resulting from linking the criteria for high-risk AI systems with the classification of medical devices set out e.g. in the MDR. Therefore, it needs to be supplemented in this respect.

Failure to modify the AIA will create a situation of legal uncertainty for companies (this risk is particularly relevant for SMEs and start-ups) and authorities, increase implementation costs for all health care players (including hospitals, health care professionals and patients), and negatively affect the proper implementation of the MDR and IVDR.

4.2.2. **Relation to other EU legislation**

In the area of artificial intelligence, it is crucial to ensure consistency of the relevant regulations with the General Data Protection Regulation (Regulation (EU) 2016/679) and Directive 2016/680. In fact, the draft Regulation complements these two acts through a set of harmonised provisions on the design, development and use of AI systems.

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The scope of the AIA needs to be modified to ensure consistency with the EU data protection legislation (GDPR).

It should be noted that Motive 41 in the preamble of the AIA, *"This Regulation should not be understood as providing for the legal ground for processing of personal data, including special categories of personal data, where relevant",* is inconsistent with subsequent articles thereof that introduce grounds for personal data processing (Articles 10(5) and 54 of the AIA). The use of the vast majority of AI systems in the public sector will involve personal data processing (e.g. profiling or automated decision-making). Therefore, it is essential to determine the relationship between the EU legal regime and national law provisions, particularly by harmonisation of provisions at the GDPR/AIA meeting points. Lack of proper regulations may lead to major legal doubts whether the public administration is allowed to use AI systems at all.
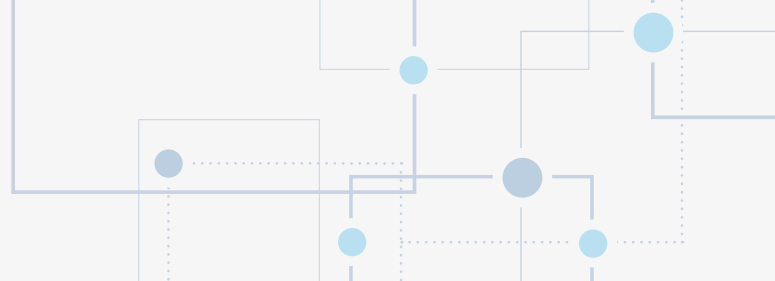
Article 1 of the AIA should include clarification that the EU legislation on personal data protection, particularly GDPR, applies to personal data processing covered by the AIA.

In addition, the relevant motive in the preamble should clarify that the AIA shall not exclude the application of the existing EU data processing regulations, including those setting out the tasks and powers of the relevant supervisory authorities.

Unlike the GDPR, the draft Regulation does not provide for a one-stop-shop (OSS) mechanism. Consequently, each supervisory authority may be competent to carry out supervisory procedures. This may result in the fragmentation of cross-border supervision over AI systems.

Particular consideration should be given to the consequences of the application of the AIA to law enforcement. The scope of the AIA should be limited to creating general legal framework that would enable changes in legislation in response to practical needs. With rapid development of law enforcement technologies, the process of creating regulations to ensure that artificial intelligence is used by judicial authorities in a safe way should remain the Member States' responsibility. This conclusion stems from differences among Member States in both the digitisation of the judiciary and the relevant national legal regulations, as well as the on-going parallel process in the Council of Europe.

The draft Regulation should be added a provision stating that it is without prejudice to the GDPR and EU consumer law and does not prevent amendments thereof, and it is without prejudice to the Member States' right to restrict the use of certain types of AI systems regarding the aspects falling outside the scope of the AIA.

4.2.3. **Relation to the international law**

The AIA should be intended and developed as a global model for legislators and regulatory authorities already involved in the AI system assessment. The act should indicate how the EU intends to cooperate in the field of AI management on the international level. Globally consistent regulations bring a number of benefits, while the existence of fragmentary rules in different regions carries the risk of obstacles, especially to SMEs. A global set of harmonised rules will contribute to consistency, increase confidence, reduce costs and facilitate the development of competition. Without a meticulously coordinated approach, global players may face a complex and potentially conflicting set of rules regarding artificial intelligence.

Furthermore, it is necessary to account for the acquis of the Council of Europe in the field of AI, as this organisation plays a crucial role in providing for the further development of artificial intelligence solutions on the global level, while ensuring their compliance with human rights protection standards.

The exclusion of global law enforcement cooperation from the scope of application of the AIA (Article 2(4)) seems too extensive. Such an exclusion carries the significant risk of circumvention of the AIA provisions (e.g. by third countries or international organisations operating high-risk AI systems on which public authorities within the EU rely).

Notably, the draft Regulation will force all the companies operating in the Union market to adopt risk analysis mechanisms. This may result in certain services either not being offered within the EU or being offered exclusively on the Union market at higher prices. Only large players will be able to overcome such barriers, while the need to meet excessive obligations may hinder the development of SMEs. In particular, the ban on the development of biometric technologies within the EU will not have the effect of preventing their development elsewhere in the world.

4.3. **Geographic scope of the AIA**

The draft Regulation should have a broad geographic scope to reduce the risk of the relocation of AI business (the migration of innovations) to third countries in order to be excluded from the application of its provisions.

The AIA aims at a broad geographic scope, but for the avoidance of doubts as to the interpretation it is necessary to clarify the applied criteria, including the term 'located' (Article 2(1)(b) of the AIA). The English wording of the draft Regulation, 'users of AI systems located within the Union', might suggest the location of AI systems rather than

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the location of users. And as cloud computing technologies are gaining importance, it is becoming increasingly difficult to determine the location of an AI system.

In our opinion, the introduction of the new criterion of 'location' of AI system providers and users will result in interpretation difficulties. Instead, using the established criterion of 'habitual residence / establishment' of AI system providers and users, modelled on the solutions adopted in other legal acts, including GDPR, should be considered. Furthermore, the criterion of being 'established' is used in the relevant motives in the preamble (Motives 10 & 11 of the AIA).

Restricting the geographic scope of the draft Regulation to artificial intelligence systems 'used' in the Union (Article 2(1)(c) of the AIA) excludes the cases when such systems are developed within the EU yet placed on the market in third countries only. It raises legal and ethical concerns regarding users of AI systems located outside the Union.
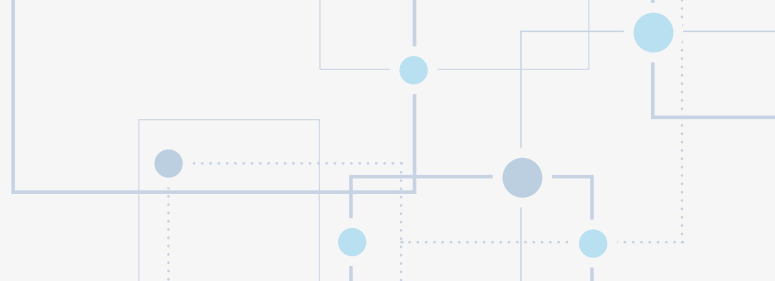
According to the draft Regulation, the AIA shall apply not only to the AI systems placed on the market, put into service or used in the Union, but also, regardless of the location where they are placed on the market or used, if 'the output produced by the system is used in the Union.' It will be difficult to ensure compliance with the latter. AI system providers might not know or not be able to control where their customers will use the output produced by the systems they have developed. For example, providers that do not operate within the EU or attempt to place and sell their AI systems on the single market might still be subject to these provisions if system users decide to use the output in the Union independently of the providers and without their knowledge. This ambiguity could be at least partially eliminated by specifying in more detail the circumstances when the AIA shall apply to providers and users in connection with using 'the output produced by the system' in the EU.

Furthermore, it is essential to clarify the obligations imposed on providers and users of AI systems in case when the output generated by the system (e.g. video content produced with an AI system by a company established outside the EU) is used in the Union, while the system itself is not provided there.

5. Definitions (Article 3 of the AIA)

5.1. Definition of artificial intelligence system

The definition of AI system is crucial for determining the scope of application of the draft Regulation. The scope of this definition determines how many solutions

(systems) will be subject to the prohibitions or extensive obligations under the AIA. The definition of AI system provided in Article 3(1) of the AIA needs to be analysed in conjunction with Annex I, which lists artificial intelligence techniques and approaches. It should be noted that the notion 'artificial intelligence' itself is extremely vague. Even the choice of attributes which characterise AI solutions, technologies or methods is a matter of dispute. It is an umbrella term used to refer to a collection of different, sometimes unrelated technologies and methods. As a consequence, at present it is difficult to definitively determine whether particular data, solution, technology or method should be categorised as artificial intelligence (such categorisation raises doubts and controversies among experts in AI system development themselves). In the light of such an ambiguity of the term 'artificial intelligence', any attempted definition of an AI system might be questioned.

However, the draft Regulation defines an AI system very broadly. Indisputably, the proposed definition encompasses a considerable portion of software which according to the general perception among programmers has not been considered to be 'artificial intelligence' so far. Such a broad scope of the definition of AI system will translate into additional costs for companies. A greater number of systems will be deemed high-risk and, consequently, require additional efforts and expenses to ensure their conformity with the AIA.

At present, the draft Regulation assumes a rather limited catalogue of high-risk AI systems. Therefore, even if according to the AIA certain solutions (systems) using the techniques or methods listed in Annex I are classified as 'artificial intelligence systems', in general they will not be subject to special requirements, which are reserved mainly for high-risk systems. However, the situation might change in the future if the catalogue of high-risk systems is amended by the Commission. If this is the case, due to such a broad definition of AI system, also certain less advanced solutions (e.g. based on simple statistical models) might be in the future classified as high-risk systems by the Commission. As a result, it would even further increase the costs of the development, implementation and use of such AI systems.

One of the potential ways out of this problem is to restrict the scope of the definition of AI system, particularly by limiting the catalogue of techniques and approaches listed in Annex I.

On the other hand, the broad definition of AI system is justified by the objective to protect fundamental rights and safety of people (e.g. it does not matter for people what technical method is used for social scoring). If an AI system were defined exclusively by a reference to specific techniques and approaches listed in Annex I, it might

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allow easy circumvention of the AIA, particularly the prohibition of the practices violating fundamental rights or the public interest.

However, if the EU legislator aims to ensure protection against the use of modern technologies in violation of fundamental rights, it should launch a discussion and wide public consultation on a separate legal act addressing 'prohibited' or 'high-risk' technologies rather than excessively expand the catalogue of techniques and approaches that define AI systems. Otherwise, the adoption of the currently proposed broad list thereof (set out in Annex I) can be misleading to some stakeholders (e.g. entrepreneurs who decide not to take part in the consultation process because they do not expect their solutions to be classified as AI systems) and can increase doubts as to the interpretation whether a particular piece of software is or is not an AI system.

Further to the proposed wording of the definition of AI system, it should be pointed out that the meaning of 'the environments' which can be influenced by such systems (Article 3(1) of the AIA) is unclear.

Irrespective of the ultimate scope of the term 'AI system' to be adopted by the legislator, we suggest considering a more descriptive definition, indicating certain attributes of artificial intelligence as well as the ways of operation and purposes of such a system, without reference to specific techniques or approaches.

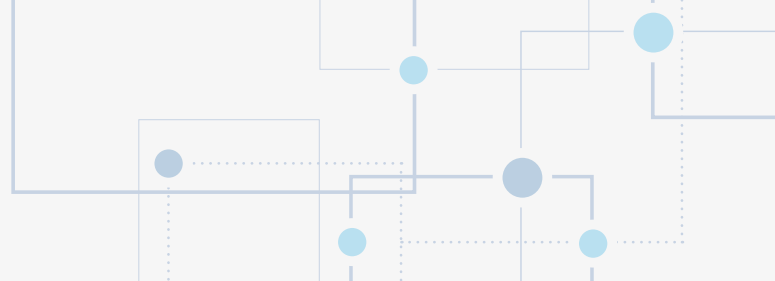### 5.2. **Comments on other selected definitions**

The definitions provided in the draft Regulation require some corrections or additions. Below we present only selected inaccuracies, doubts as to the interpretation and proposed additions. In some cases, we suggest changing definitions which – though modelled on other legal acts – need to be modified due to the doubts encountered in the process of application thereof.

a) **Placing on the market**
Regarding the definition of 'placing on the market' (Article 3(9) of the AIA), adding an exclusion for AI systems used for pilot/test or R&D purposes should be considered.

b) **Serious incident / Incident**
Article 3(44) of the AIA should have the following wording: 'serious incident' means any incident that directly or indirectly leads, might have led or might lead to any of the following: (a) the death of a person or serious damage to a person's health, (b) serious damage to property or the environment, (c) a serious and irreversible disruption of the management and operation of critical infrastructure.

Furthermore, adding the definition of 'incident' to Article 3 of the AIA may be considered; for example, it could mean faulty operation of an artificial intelligence system.

c) User / End user

A fundamental question arises, what is meant by 'authority' over an AI system, which is a criterion for recognising an entity as a user. Undoubtedly, an entity which has implemented an AI system in its enterprise and uses it in the course of its business activity (i.e. decides on the operation of the AI system) will be considered a user.

However, it is uncertain whether, for example, a natural person running a business who has been given access to certain functionalities of an AI system in the course of using services of an entity referred to above should be also considered a user or not.

It is also doubtful whether Motive 36 in the preamble of the AIA allows for excluding employees from the definition of the term 'user.' The explanations provided in the preamble of the AIA, particularly Motives 36 and 59, seem insufficient, and this definition needs to be clarified.

Furthermore, we suggest adding the separate definition of 'end user' as a natural person using an AI system and being the last link in the chain of entities using the system in different ways (e.g. employee, customer, or perhaps also a person using an AI system for personal purposes apart from a professional activity).

d) Lack of definition of risk

If it is added, it should be consistent with the definition of 'risk' in the MDR (and some other acts). Otherwise, medical device manufacturers would have to maintain two parallel systems for risk management.

e) Lack of definition of public sector body or public entity

There are no definitions of 'public sector body' or 'public entity' in the draft Regulation. Instead, the ambiguous terms 'public authority' and 'agency' are used throughout the AIA. The definition of 'public sector body' provided in the eIDAS should be added for disambiguation.

f) Lack of definition of critical infrastructure

Although the draft Regulation refers to 'critical infrastructure'[11], it does not define it. It seems reasonable to add the definition.
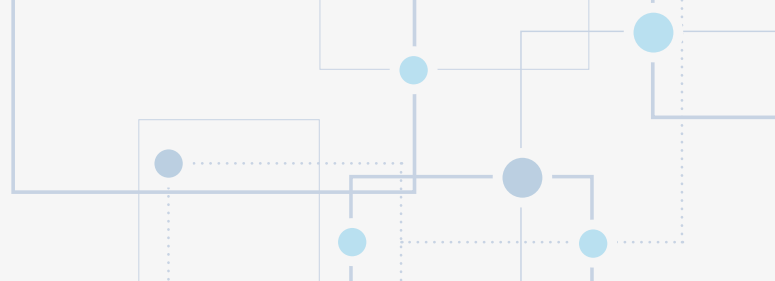
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11   Motive 34 in the preamble and Article 3(44) of the AIA.

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6. **Prohibited artificial intelligence practices (Article 5 of the AIA)**

6.1. **Subliminal techniques and exploiting the vulnerabilities of a group of persons (Article 5(1)(a) & (b) of the AIA)**

Regarding two prohibited practices, i.e. using subliminal techniques and exploiting the vulnerabilities of some groups (Article 5(1)(a) & (b) of the AIA), we would like to express the following reservations and recommendations:

a) In our opinion, the wording of Article 5(1)(a) and (b) of the AIA is highly ambiguous, which will lead to numerous doubts as to the interpretation.

b) At present, due to lack of clarity of the terms used in the catalogue of prohibited practices, a number of companies, fearing potential heavy administrative fines, might avoid economic risk and innovation. The current wording violates the principle of legal certainty, which will generate additional costs for companies (e.g. for analyses and opinions) and, ultimately, may have a chilling effect.

c) Vagueness of the terms used in the analysed section may generate the risk of abuses by circumvention of the AIA provisions. This would pose an enormous challenge for the courts resolving potential disputes related to the use of prohibited practices. First of all, the following terms need to be clarified:

   ▸ Subliminal techniques – In addition to the description thereof, we recommend providing examples of such practices (deploying such techniques). Furthermore, using subliminal techniques as a determinant of the harmfulness of practices is questionable itself. In the literature as well as practice, there is no consensus on whether subliminal techniques actually affect people and, if yes, to what extent. Therefore, introducing restrictions in this area seems not adequately supported by evidence, as it is not clear whether such practices are harmful.

   ▸ Person's consciousness – The meaning of 'consciousness' is not fully clear. As this term has not been clearly defined hitherto, it raises doubts. The effect of various techniques or methods on a person's consciousness is not evident, either. In this case, the recommended solution would be to either provide a clear definition of 'consciousness' (which is the more difficult option) or rephrase the draft Regulation e.g. by pointing to an established causal link between AI system operation and person's behaviour or harm.

   ▸ Material distortion of a person's behaviour – It is unclear what this term means, where the person's autonomy ends, and how the materiality of influence should be determined. As above, this term should be clarified.

   ▸ Psychological harm – It is unclear what 'psychological harm' is or may be, which carries the risk that the subjective assessment of the person 'harmed' will be crucial in this respect. Clarification of this premise is particularly important in the

light of on-going legislative works concerning liability for damage caused by AI systems. This problem could be solved by using the generic term 'harm', which could be subsequently interpreted by courts. Moreover, the current wording seems to imply that potential harm is also an element of the prohibited practice.

▸ Adding damage to property (economic damage) should be considered.

d) It needs to be considered whether the scope of application of the above-mentioned prohibitions should be extended to protect legal persons as well. For example, if using subliminal techniques against a representative of a legal person causes harm to the latter rather than the individual, should such a practice be allowed? It seems that such cases need to be covered by the prohibition as well.

e) To sum up, above all we recommend clarifying Article 5(1)(a) and (b) of the AIA.

f) The prohibition of deploying subliminal techniques (Article 5(1)(a) of the AIA) has been linked to the premise that it *"causes or is likely to cause that person or another person physical or psychological harm."* The requirement to demonstrate the occurrence or likely occurrence of harm is excessive, which may render the prohibition of subliminal systems illusory. Therefore, the presumption of harmfulness of such systems to natural persons might be considered.

g) Similarly to Article 5(1)(a) of the AIA, we also recommend presuming harmfulness of AI systems referred to in Article 5(1)(b) of the AIA.

h) Article 5(1)(b) of the AIA limits the prohibition of the AI systems exploiting people's vulnerabilities to those related to age, physical or mental disability. The legislator has not explained the rationale behind limiting the prohibition to a fixed list of specifically identified premises.

Furthermore, even those premises raise doubts due to their inconsistency with the existing legal definitions that are binding upon the European Union. The term 'mental disability' referred to in the AIA is objectionable, as the Convention on the Rights of Persons with Disabilities[12], to which the EU is a party, provides that *"[p]ersons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments"* (Article 1(2) of the Convention). 'Mental disability' is a medical term, and there has been a shift away from the use thereof within the EU. Therefore, it seems that the prohibition set out in the AIA should rather refer to persons with intellectual disability in this respect.

6.2. **Social scoring (Article 5(1)(c) of the AIA)**

The AIA generally prohibits AI-based social scoring for general purposes done by public authorities. Motive 15 declares that *"[a]side from the many beneficial uses of artifi-*

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12   Convention on the Rights of Persons with Disabilities adopted on 13 December 2006 in New York.

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cial intelligence, that technology can also be misused and provide novel and power-ful tools for manipulative, exploitative and social control practices. Such practices are particularly harmful and should be prohibited because they contradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights, including the right to non-discrimination, data protection and privacy and the rights of the child."
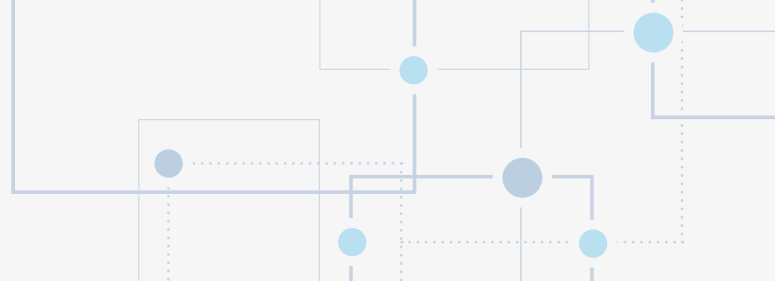
We should agree that *"AI systems providing social scoring of natural persons for general purpose by public authorities or on their behalf may lead to discriminatory outcomes and the exclusion of certain groups. They may violate the right to dignity and non-discrimination and the values of equality and justice. Such AI systems evaluate or classify the trustworthiness of natural persons based on their social behaviour in multiple contexts or known or predicted personal or personality characteristics. The social score obtained from such AI systems may lead to the detrimental or unfavourable treatment of natural persons or whole groups thereof **in social contexts, which are unrelated to the context in which the data was originally generated or collected or to a detrimental treatment that is disproportionate or unjustified to the gravity of their social behaviour."*[13] This motive is summed up by the legislator with a statement that such practices should be prohibited.

Article 5(1)(c) of the AIA in the current wording introduces only a relative ban on social scoring, as it applies exclusively to a situation where the use of such an AI system leads to *"(i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the contexts in which the data was originally generated or collected, or (ii) detrimental or unfavourable treatment of certain natural persons or whole groups thereof that is unjustified or disproportionate to their social behaviour or its gravity."*

The prohibition of social scoring provided by Article 5(1)(c) of the AIA is actualized provided that: an AI system is used with the social score leading to one of the aforementioned outcomes; the system is maintained over a certain period of time; and it is maintained by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons based on their social behaviour or known or predicted personal or personality characteristics. However, such a relative ban on social scoring raises a number of doubts.

Firstly, although motives in the preamble of the AIA plainly declare that social control practices *"are particularly harmful and should be prohibited because they con-*

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13   Motive 17 in the preamble of the AIA.

tradict Union values of respect for human dignity, freedom, equality, democracy and the rule of law and Union fundamental rights"[14] – with which we should agree – the way this idea is implemented in the main body of the AIA, that is through a relative ban only, raises considerable doubts as to both the AIA coherence and respect for fundamental rights in the Union. Secondly, it is not clear who and how is to assess artificial intelligence systems that use social scoring and how this ban is to be implemented in practice. Thirdly, it remains unknown who is to demonstrate the prohibited outcome, so that the ban provided by the AIA can actualize (the issue of the burden of proof). Finally, the scope of the ban set out in Article 5(1)(c) of the AIA makes it difficult to determine to whom the prohibition actually applies; for example, it is not specified what kind of relations between public authorities and other entities, particularly private ones, would actualize the ban.[15]

In view of the above as well as the general experience worldwide,[16] **the AI systems used by the public sector, or when performing public tasks, for social control of natural persons, involving the assessment of their social behaviour, particularly in social contexts which are unrelated to the contexts in which the data was originally generated or collected, should be prohibited.**[17] The exception from the prohibition could include the systems which have been demonstrated by their manufacturers or users to have **exclusively** positive effects, contribute positively to social life, etc., and which are not used for the control of social behaviour.

7. Delegated acts / Amendments to Annexes

As a preliminary remark, it needs to be pointed out that in general the delegation of power to the Commission to amend the AIA in material issues should be viewed negatively (cf. 290 of the TFEU). An act of such importance and its significant areas should be subject to the 'traditional' legislative process rather than that set out in Article 73 of the draft Regulation. We would recommend introducing an additional fast track option for the AIA amendment should any concrete and justified reasons thereof emerge, e.g. in the context of new techniques and methods or new developments related to high-risk systems. Such reasons, however, should be clearly specified and well defined to avoid arbitrary decisions.

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14   Motive 15 in the preamble of the AIA.

15   Cf. Veale M., Borgesius F.Z., Demystifying the Draft EU Artificial Intelligence Act, *Computer Law Review International* 2021:22(4), pp. 97–112.

16   Cf. Lee K.F., AI Superpowers: China, Silicon Valley, and the New World Order. Houghton Mifflin Harcourt, 2018.

17   Seemingly the same opinion: High-Level Expert Group on Artificial Intelligence, *Ethics Guidelines for Trustworthy AI* (April 2019), p. 34; High-Level Expert Group on Artificial Intelligence, *Policy and Investment Recommendations for Trustworthy AI* (26 June 2019), p. 20.

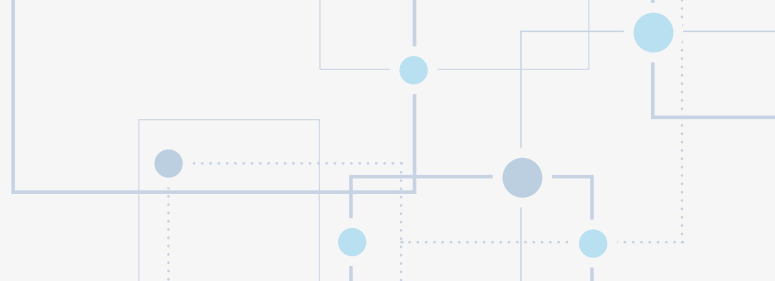FINANCED FROM THE FUNDS OF THE EUROPEAN CONSERVATIVES AND REFORMISTS GROUP.

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Notwithstanding the aforementioned recommendation for the procedure for amending Annexes to the AIA, below we present our comments on the current concept of such amendments by way of delegated acts (Article 73 of the AIA).

Article 73 which clarifies the delegation of power to the Commission to adopt delegated acts should be read in conjunction with specific delegations conferred in Article 4, Article 7, etc. First of all, it should be noted that the reasons specified therein are extremely vague, and thus highly discretionary and arbitrary. This, in combination with a significant impact on the business and innovation area in the broad sense, makes the relevant delegations a dangerous tool, which – in certain conditions – could hamper the development of artificial intelligence or, more broadly, automation. Therefore, first of all, setting a clear framework for the delegation of power should be considered in order to avoid considerable uncertainty among the 'recipients' of the AIA. Only then it will be possible to ensure a high degree of legal and regulatory certainty, which even assuming the technology neutrality and risk-based approach (or, perhaps, all the more) should constitute the basis for any legal act. Notably, the Commission is basically free to define the scope of information to be included in the technical documentation (cf. Article 11(3)), which may generate considerable costs for enterprises, especially in the case of broad adoption of solutions based on high-risk systems.

8. **High-risk artificial intelligence systems**

The current classification of AI systems as high-risk is unclear. This may raise legitimate doubts among companies, hindering the proper qualification and generating the risk of non-compliance with the AIA. The current definition may hamper innovation due to the business community concerns that particular AI systems may be wrongly classified. The recommended solution would be to provide a more descriptive definition of high-risk systems, in line with the principle of technology neutrality and risk-based approach, and leave unchanged the list of currently used solutions set out in Appendices (harmonised framework and Annex III). Introducing a descriptive definition and adopting the aforementioned approach may both stimulate innovation and improve safety.

Notably, the current wording of the provisions related to the requirements for high-risk systems include only references to the legislation applicable to credit institutions. These references enable the latter to fulfil the AIA requirements using the existing solutions, such as risk management or internal control systems they already maintain. Such an approach seems justified and proportional; however, it is not fully clear why

other sectors, in which similar requirements apply, have been excluded from this option. In the current wording, institutions which are subject to similar requirements as banks will have to consider implementing separate processes for high-risk AI systems – which is not justified.

The recommended solution would be to either extend this catalogue (possibly making it a separate annex) or adopt a more general statement, e.g. encompassing any sectors which are subject to regulations that require solutions equivalent to those set out in the AIA.

In addition, exclusion from the requirements for high-risk AI systems could be considered for the purpose of scientific research or R&D. In such case, it would be necessary to introduce certain limitations in order to prevent the violation of fundamental rights, including the right to privacy.

9. **Requirements for high-risk AI systems**

Article 10 of the AIA, which imposes a number of ambiguous and, in our opinion, excessive obligations related to training of models of high-risk AI systems with data, raises particular doubts.
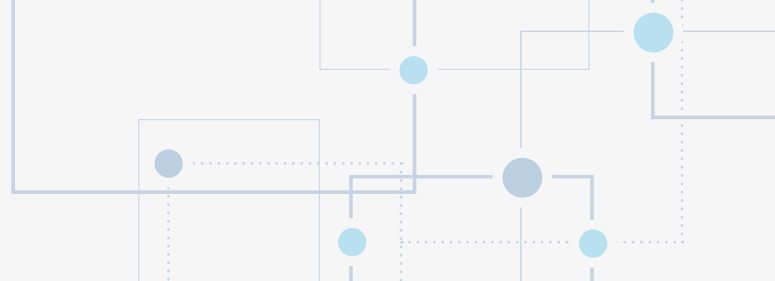
Above all, we would like to point out the following issues:

a) Pursuant to Article 10(2) of the AIA, *"[t]raining, validation and testing data sets shall be subject to appropriate data governance and management practices."* These practices should concern in particular *"the identification of any possible data gaps or shortcomings"* (Article 10(2)(g) of the AIA). In practice, particularly in case of big data sets, the identification of 'any' possible data gaps or shortcomings seems extremely difficult or even impossible. Therefore, we recommend deleting the word 'any.'

b) According to the draft Regulation, the data sets used shall be 'free of errors and complete.' However, in view of the characteristics of machine learning, it may be extremely difficult or even impossible to ensure fully 'error-free' data, especially when using big data sets. Furthermore, sometimes unrealistic ('erroneous') data are used intentionally; for example, AI systems to be used for error identification would be intentionally trained with 'erroneous' data inconsistent with the reality.

c) AI system providers, particularly start-ups, can also use publicly available data sets (e.g. under an open source licence). In such case, the verification whether data are free of errors (which could have originated at the data collection or labelling

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stage) may be very difficult or virtually impossible for companies. This might even hinder the use of such data sets, which would be detrimental to the artificial intelligence development.

d) In our opinion, imposing the obligation to ensure error-free data upon providers is an excessive requirement. This may have a chilling effect, hindering innovation. We recommend assuming that a provider has the obligation to exercise due diligence and undertake efforts, adequate to the intended purpose of the AI system, to ensure that data are correct (free of errors).

e) It also remains unclear what is meant by data 'completeness.' For example, if a provider has machine data from various types of sensors (IoT devices) spanning over a five-year period, yet decides to use only data from the last two years for model training, is it an infringement of the requirement for the data to be 'complete' or not? In practice, providers often have machine data from IoT devices for long periods of time (e.g. temperature data for several years), yet there are gaps in such data sets (e.g. missing readings for two days). According to the industry standards, in such case providers can fill such gaps by artificially generating data for the missing days. A question arises whether the data 'completeness' requirement is met in such case or the artificial generation of the missing data constitutes an infringement thereof. In addition, in some cases using all the available data ('complete' data) could lead to violation of other provisions of the AIA. For example, historical employment data might reflect certain behaviours which are no longer acceptable (e.g. discrimination of women in employment). Then, the training of a model with all the available data might result in an allegation that the data set is not 'relevant' or 'representative' (Article 10(3) of the AIA), or violates Article 10(4) of the AIA. Furthermore, in some cases certain data may be intentionally eliminated during the training of a model (e.g. due to the fact that such data overload the model while adding no value to the machine learning process). Also in such case, providers risk an allegation of data incompleteness, even though such data removal is consistent with the industry standards and aimed at better functioning of AI models.

Another issue related to the preparation of data sets for the training of AI models is different granulation of data, which may sometimes occur as a result of, for example, different sampling frequencies of measuring instruments or feeding of data from external sources in different time intervals. In such cases, artificial data would be generated to fill gaps in sequences of lower sampling time in order to normalise the data density on the time axis. A question arises how such data sets, which are bigger than initial ones owing to artificially added values, should be treated. In other cases, specialists preparing training data sets would adopt an approach of eliminating some data from sets of high density of values, if they

conclude that such elimination could be done to optimise the machine learning process. For example, if one data set (from the source A) is added a new value every 12 hours, while another data set (from the source B) is added a new value every 24 hours, then during preparation of data sets for the training of an artificial intelligence model we can either generate artificial values in the second set to obtain sampling interval of 12 hours or eliminate every second value in the first set to obtain sampling interval of 24 hours. A question arises which of such modified sets will be deemed complete.

The aforementioned examples clearly illustrate that the preparation of training data sets is a complex and multifaceted process, which consumes a considerable portion of time during the AI system development and depends on a number of factors.

Therefore, we recommend clarifying in the preamble of the AIA the context in which the term data 'completeness' should be meant, or, possibly, eliminating this requirement altogether.

f)   Importantly, the infringement of the requirements pursuant to Article 10 of the AIA shall be subject to administrative fines within the highest range of penalties set out in the AIA (i.e. up to 30 million EUR or up to 6% of the company's total worldwide annual turnover for the preceding financial year).[18]

g)   Therefore, the obligations under Article 10 of the AIA should be formulated in a more unambiguous manner to avoid material doubts as to the interpretation.

The AIA provisions concerning capabilities enabling the automatic recording of events should be formulated in compliance with the New Approach and Motive 11 of the Decision 768/2008, that is any technical specifications which are not directly determined by a legislative act should remain voluntary, and any requirements contained therein should be worded precisely. Therefore, we are of opinion that Article 12(1) of the AIA should not impose conformity to 'recognised standards' or 'common specifications.' It seems that it would be sufficient to state that logging capabilities shall enable authorised users to review logs. It should also be pointed out that 'recognised standards' is a vague term, and Article 12(1) of the AIA does not specify what features of logging capabilities should conform to 'recognised standards' or 'common specifications.'

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18   Cf. Article 71(3)(b) of the AIA.

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Further to Article 12, in our opinion, adding an option to delete the recorded events and restore the log to the initial condition (e.g. in case of sale of a high-risk AI system to another party) should be considered. We also recommend clarifying whether the logging function has to record all the events.

We consider it positive that the draft Regulation provides for the need to ensure the cybersecurity of AI systems. However, in view of the broad range of topics related to cybersecurity and information protection, Article 15 of the AIA should be further clarified. We would like to highlight the following issues:
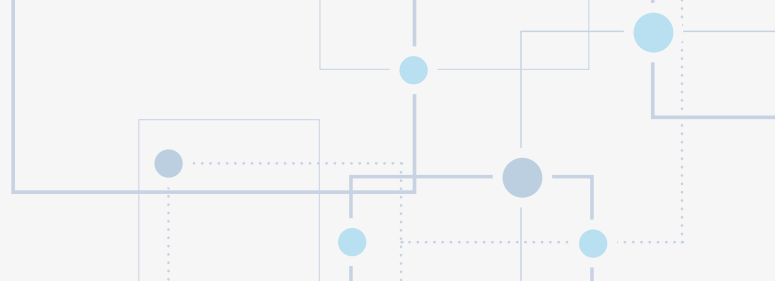
a) Referring security requirements to high-risk AI systems might suggest that other AI systems do not need to ensure cybersecurity. We recommend emphasising in the preamble of the AIA that ensuring cybersecurity is crucial also in case of other AI systems.

b) In the field of cybersecurity it is difficult to formally ensure resilience in the general sense; it is typically assumed that resilience is to be limited to a certain scope, certain risks and/or a certain level of threats, etc. In addition, security is not a state but a process that requires constant activities.

c) It is not quite clear what kind of inconsistencies due to interaction with the environment are meant in Article 15(3) of the AIA.

d) We recommend adding a reference in Article 15 of the AIA to at least the basic pillars of information security and protection, such as confidentiality, integrity and availability.

10. Obligations of users

In general, maintaining a risk management system is a responsibility of the provider. The draft Regulation provides for relatively few obligations on the part of users (cf. Articles 29 & 52 of the AIA). We recommend imposing on users the obligation to perform the risk assessment for the use of high-risk AI systems in their own activity. We further propose imposing the information obligation towards end users (e.g. employees) to whom the AI system is made available by the user; this should include information about the risks related to the use of the AI system, and instructions for use.

11. Notification and notified bodies

In general, we consider it positive that the draft Regulation aims to ensure a uniform pattern of competence for all notified bodies. However, in our opinion, the AIA provisions concerning notification rules should be worded more accurately, so that they

clearly determine the rights and obligations of notified bodies, Member States and the Commission.

Presumption of conformity of notified bodies. In our opinion, a provision equivalent to Article R18 of Annex I to the Decision 768/2008 should be added to the AIA, providing for presumption of conformity of a notified body with the requirements set out in the regulation, if the body conforms with the criteria laid down in the relevant harmonised standards which cover those requirements (provided that the references thereof have been published in the *Official Journal of the European Union*). This solution, similar to the one adopted in the Regulation 2016/425, would mitigate legal uncertainty of notified bodies related to the broad use of general clauses in the notification provisions of the AIA.

Notified body's assessment procedure alternative to accreditation. Without questioning the proper functioning of a system of accreditation based on Regulation 765/2008 and its role as the preferred model of assessment, we suggest that, according with the regulatory model set out in Article R23(4) of Annex I to Decision 768/2008 (implemented e.g. in Regulation 2016/425) as well as in line with Motive 12 and Article 5(2) of Regulation 765/2008, **it should be specifically left to Member States to choose also other means of assessment of the competence of notified bodies rather than accreditation**. The rationale behind using such other means may vary; for example, it may be related to the fact that a Member State is not able to maintain parallel resources for the purpose of assessment within both a national accreditation body and another institution, or to the special character of the bodies being assessed.[19] There is no justification for establishing a compulsory mechanism under which conformity assessment bodies shall apply for accreditation to a national accreditation body in another Member State even though the conformity assessment body's Member State is able to provide proper conformity assessment by other means than accreditation. Leaving an option alternative to accreditation for assessment of conformity assessment bodies may also provide additional protection to the functioning of the process of notification of bodies from a Member State in case the accreditation process therein is disrupted. Consequently, this may provide additional protection to the functioning of the Member State's strategic AI innovation sector. Therefore, we recommend adding a provision modelled on Article R23(4) of Annex I to Decision 768/2008 to Article 32 of the AIA and clearly indicating in Motives in the preamble thereof that in addition to accreditation, notifying authorities may also use alternative means of assessment of the competence of notified bodies.

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19   For example, Poland chose a similar path to notify the Central Office of Measures (GUM) under two NLF-compliant directives.

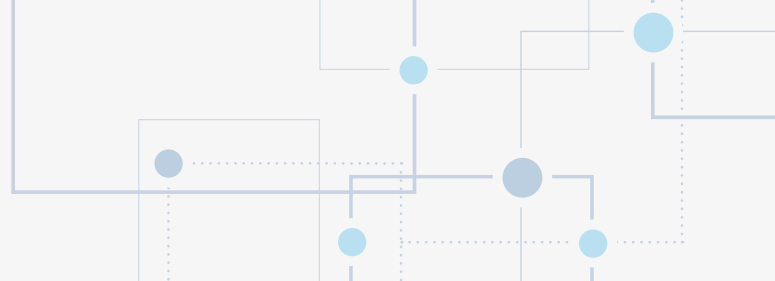FINANCED FROM THE FUNDS OF THE EUROPEAN CONSERVATIVES AND REFORMISTS GROUP.

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Information about the outcome of the notification procedure. Notified bodies shall be entitled to prompt and reliable information that they may perform their activities. Therefore, Article 32(4) of the AIA should be extended to include a provision that the Commission shall promptly (e.g. within 3 days) inform the conformity assessment body concerned (and the notifying authority) that no objections have been raised and it may perform the activities of a notified body.

12. Technical specifications and conformity assessment

Clear indication that the compliance of an AI system with requirements may be demonstrated using other solutions than specifications with a privileged legal status. For obscure reasons, the draft Regulation does not clearly specify that the application of harmonised standards or common specifications prepared by the Commission is only one of the options in demonstrating the compliance of an AI system with legal requirements. Although the AIA does not formally exclude using technical solutions other than harmonised standards and common specifications, the wording of the relevant provisions make it somewhat of a rule that providers should apply harmonised standards (cf. Motive 61, Article 40, Article 43(1), paragraph 2 and Article 43(3), paragraph 3 of the AIA) or common specifications, if adopted by the Commission (Article 41(3) & (4) and Article 43(1), paragraph 2 of the AIA). It should be emphasised that the option to replace harmonised standards with other technical solutions stimulates the emergence of new techniques and technologies without affecting the benefits brought by the voluntary standardisation, such as dissemination of interoperability and new technologies. The voluntary character of harmonised standards is a general rule (with few exceptions) within the EU and it differentiates them from legislative acts. In our opinion, in the spirit of Motive 11 of Decision 768/2008, the AIA should clearly indicate that providers may choose not to apply harmonised standards (or common specifications, if the relevant provisions are left in the draft Regulation).

Clear indication of presumption of conformity. Throughout the draft Regulation, the term 'presumption of conformity' is used in the context of harmonised standards only once, namely in Article 65(6)(b). Notably, Article 40 of the AIA – unlike its equivalent in Decision 768/2008[20]) – does not mention presumption of conformity but only that AI systems are in conformity with the relevant requirements. In our opinion, to add clarity the AIA should specify that the application of technical specifications with a privileged legal status ensures presumption of conformity and is not equivalent to conformity of an AI system with requirements.

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20   Article R8 of Annex I to Decision 768/2008.

Renouncement of an unjustified administrative burden on providers choosing not to apply technical specifications with a privileged legal status. The advantage of applying the technical specifications that ensure presumption of conformity should be the increased legal certainty enjoyed by the providers that want to rely on them rather than an additional burden on their competitors who choose not to apply such specifications (e.g. owing to investments in innovative technical solutions). **In our opinion, the requirement to undergo third-party conformity assessment only because the specifications ensuring presumption of conformity have not been applied is such an unjustified additional burden (Article 43(1), paragraph 2 and Article 43(3), paragraph 3 of the AIA).** We believe that such unjustified differentiation between providers choosing to apply or not to apply technical specifications with a privileged legal status should be renounced. The positive outcome of conformity assessment should always be compliance with legal requirements. The need for the involvement of an independent third party in conformity assessment should result not from the assurance technique declared by the provider but rather the category of risks posed by the AI system. Consequently, the conformity assessment procedures should be the same for providers choosing to apply or not to apply technical specifications with a privileged legal status. Only within the procedure itself, the conformity assessment body (the provider or a notified body) should take into account that technical solutions defined in technical specifications with a privileged legal status ensure presumption of conformity.

Clarification of provisions addressed to providers choosing not to apply technical specifications with a privileged legal status. Furthermore, there should be no differentiation between providers choosing to apply or not to apply technical specifications with a privileged legal status in terms of clarity of provisions addressed to them. However, although Article 41(4) of the draft Regulation allows providers to apply technical solutions alternative to the common specifications adopted by the Commission, Article 43(1), paragraph 2 thereof does not specify which conformity assessment procedure shall be applied by a provider of high-risk AI systems listed in point 1 of Annex III that chooses such an option. In our opinion, this issue should be clarified, while other AIA provisions (particularly concerning conformity assessment) should be worded with equal care for clarity with respect to both groups of providers.

Renouncement of the determination of requirements by common specifications adopted by the Commission. Conformity of AI systems shall be determined on the basis of compliance with the requirements specified directly in the AIA. Particular technical specifications should be only an auxiliary tool in ensuring conformity rather than a source of additional requirements. Therefore, we recommend deleting Article 41(4),
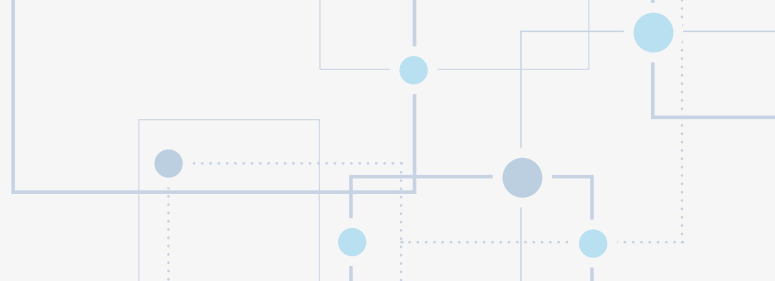
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which obligates providers to adopt technical solutions equivalent to common specifications, from the draft Regulation.

Presumption of conformity for specifications other than harmonised standards the references of which have been published in the *Official Journal of the European Union*. The process of standardisation requests and assessment of harmonised standards prior to their publication in the OJEU pursuant to Regulation 1025/2012 has turned out to be protracted and rather inflexible. As a result, problems persist with the delivery 'on time' (i.e. meeting the deadlines that the market demands) by the EU of references to harmonised standards that ensure presumption of conformity and reflect the current state of technology.[21] The discussion how to make the European standardisation system more sound has already started, but it is impossible to predict when and what potential corrective measures will be implemented and to what effect.[22] In the field of artificial intelligence, the need for quick delivery and update of technical specifications ensuring presumption of conformity seems particularly urgent, as this sector may be expected to undergo rapid evolution in the coming years. As the timely delivery of harmonised standards remains a challenge to the European standardisation system in the traditional sectors of the economy, it should not be expected to be efficient with respect to the AI sector without major transformation. Delays in the delivery of specifications ensuring presumption of conformity to European enterprises result in legal uncertainty and additional risks related to business activity and uptake of innovations. Consequently, the EU may become an unattractive place for investments already at the beginning of the path of development of AI systems. In view of the shortcomings of the current European standardisation system and the specifics of the artificial intelligence sector, we recommend considering a solution where the presumption of conformity would be extended, under certain conditions, also to technical specifications other than harmonised standards (the references of which have been published in the OJEU). An option to use the latest achievements of standardisation organisations (European standardisation organisations and national standardisation bodies within the meaning of Regulation 1025/2012, as well

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21   The need to improve the European standardisation system has been pointed out for a long time. The Commission officially addressed this issue in its Communication of 22 November 2018 [Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market [COM(2018 764 final)].

22   In 2020, 17 Member States sent a non-paper to the Council regarding challenges to the European standardisation system, including delays in the publication of references to harmonised standards (WK 7244/2020 subsequently published as doc. 8600/21). In response to it and other communications, the European Commission released a draft Standardisation strategy in the form of a roadmap for consultation (Ref. Ares(2021)4207776 – 28/06/2021). In addition, a joint task force between the Commission and the European Standardisation Organisations has been set up to develop improved delivery mechanisms.

as international organisations such as ISO, IEC, IEEE or IETF[23]) in a direct and quick process free of an excessive administrative burden and ensuring presumption of conformity may positively influence the development of AI systems within the EU and facilitate the expansion of European enterprises onto third-country markets. Rapidly evolving information and communication technologies call for a flexible approach. For example, presumption of conformity might be enjoyed by the technical specifications notified by Member States, European standardisation organisations or national standardisation bodies within the meaning of Regulation 1025/2012, as well as other standardisation organisations which could be notified by Member States for the purpose of the AIA. Presumption of conformity for the notified specifications would take effect if no objections have been raised by either a Member State or the Commission within the set deadline. References to such notified specifications, similarly to those to harmonised standards, would be subsequently published in the OJEU. Should any shortcomings in the technical specifications notified in such a procedure be later revealed, a publication withdrawal procedure, similar to that for harmonised standards, could be applied.

Renouncement of the Commission's right to adopt common specifications. We believe that authorising the Commission to adopt common specifications, which are in fact a substitute for harmonised standards, is not the right response to the problems with the timely delivery of harmonised standards to European enterprises.

Derogation from conformity assessment procedure. Notably, Article 47(2) of the AIA, which makes the authorisation for 'derogation' dependent on the market surveillance authority's conclusion that the AI system complies with requirements, may result in a situation where the procedure for authorising derogation from the conformity assessment procedure will not be used in practice, as no market surveillance authorities could be reasonably expected to assume responsibility for confirming the compliance of an AI system with requirements if no conformity assessment thereof has been completed.

13. European Artificial Intelligence Board

Pursuant to Article 57(3) of the AIA, the Board shall be chaired by the Commission, yet the latter is omitted in Article 57(1) that sets out the composition of the Board. This should be supplemented. We recommend specifying that the Commission shall provide the Secretariat for the Board (as 'administrative and analytical support' is not

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23   International Organization for Standardization, International Electrotechnical Commission, Institute of Electrical and Electronics Engineers, and Internet Engineering Task Force, respectively.

tantamount to the operation of the Secretariat). Furthermore, Article 59(6) of the AIA shall be amended to make the European Artificial Intelligence Board rather than the Commission responsible for facilitating the exchange of experience between national competent authorities.
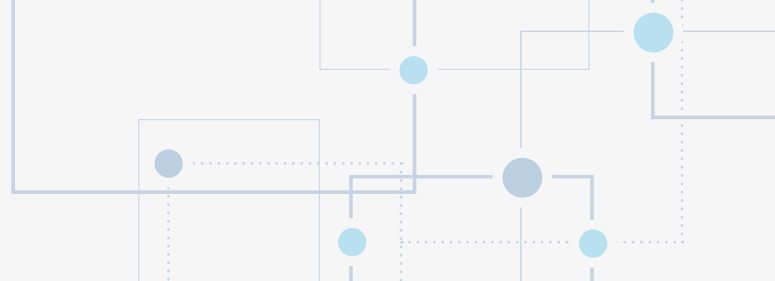
Monitoring of AI systems requires adequate technological instrumentation. In our opinion, the Board should be tasked with recommending RegTech software tools to support the activity of national bodies or even developing uniform tools for that purpose.

Extending the tasks of the Board beyond the current scope of Article 58(b) of the AIA should be considered. This could include consistency mechanisms, cooperation between supervisory authorities and the Board, and assessment of the proposed mechanisms for dispute resolution in cross-border cases e.g. with the participation of the Board, through interpretations or opinions issued by the Board and exchange of information.

In addition, we suggest that the European Artificial Intelligence Board be provided with adequate competence, particularly related to issuance of guidelines and recommendations, as well as identification of best practices. Although certain rudimentary tasks of the Board are set out in Article 58 in conjunction with Article 56 of the AIA, these provisions seem to suggest that the ultimate role of the Board is only to support the Commission and national authorities in issuing such guidelines, and apart from issuance of opinions by the Board no further consistency mechanisms, such as the obligation to consult the Board, are provided.

14. **AI system supervision and monitoring**

The crucial problems in this respect are the conciseness of the proposed provisions and lack of regulatory consistency in specifying the tasks and powers of national competent authorities, defined in Article 3(43) of the AIA as national supervisory authorities, notifying authorities and market surveillance authorities, which are individually defined in points (42), (19) and (26) of Article 43, respectively. The provisions concerning national competent authorities, especially differentiating between national supervisory authorities referred to in Article 59 and market surveillance authorities referred to in Article 63 in conjunction with Regulation 2019/1020, leave open questions, particularly on the division of competence – especially in view of Article 63(2) which seems to suggest that the national supervisory authority is simultaneously the market surveillance authority, which does not follow from the respective definitions

and tasks of these authorities or the aforementioned Article 59 concerning national supervisory authorities.

Consequently, the provisions in this respect need clarification, so that they specify in detail the status of such authorities, particularly in terms of the relation between Article 59 of the AIA and Regulation 2019/1020 if such a relation is intended by the legislator.

However, If such a relation is not intended, which might be implied by Articles 3(26) and (42) in conjunction with Articles 59 and 63(1), then it should be noted that the legislator incorrectly limited Article 59 to indicating certain characteristics, such as objectivity and impartiality, without specifying the tasks and powers of national supervisory authorities, which makes such requirements difficult to concretise.

Naturally, in line with the principle of national procedural autonomy, the provisions concerning national supervisory authorities contained in the draft Regulation should be limited to general requirements (status, tasks and powers) to be met by supervisory authorities in all Member States, while leaving other matters to national regulations. Nevertheless, such requirements could be designed and specified in a coherent manner and gathered in a dedicated chapter. Then, national supervisory authorities, designed in a similar manner and acting with consistency, could become one of the mechanisms improving the uniform application of the AIA.

Furthermore, providing for the independence of the national supervisory authority could be considered in view of the extensive system of penalties at its disposal.

The complexity of the supervisory network might become a challenge. We recommend imposing on the national supervisory authority the obligation to develop a list of other national authorities and public bodies which supervise or enforce the respect of obligations under the AIA and to make it available in electronic form. Currently, it is the obligation of the Member State (Article 64(4) of the AIA).

It seems that the provisions on post-market monitoring and sharing of information on incidents and malfunctioning (Articles 61 & 62 of the AIA) should regulate both monitoring / sharing of information with respect to AI systems placed on the market and monitoring of AI systems put into service.

In our opinion, the wording of Article 61 of the AIA is too general. The monitoring provisions should clearly determine the scope of the AI system data to which the provider should be granted access after providing the system.

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We critically assess the proposal contained in Article 61(3) of the AIA that the Commission shall adopt an implementing act laying down the detailed template for and the mandatory elements of a post-market monitoring plan for high-risk AI systems. The development and implementation of post-marketing monitoring plans will be an obligation imposed on providers, and it seems that this issue should be regulated in the primary legal act. Therefore, the required elements of a post-market monitoring plan should be specified in the AIA provisions, while leaving it to providers to decide on the template and arrangement thereof.

Regarding the reporting of incidents and malfunctioning, due to the potential threats to EU citizens and their fundamental rights resulting therefrom, the proposed time limit of 15 days (Article 62(1) of the AIA) should be shortened to 72 hours, and reporting should be made possible by various means, particularly in electronic form. We also recommend assuming that within the aforementioned time limit the provider shall report all the available information, which it may subsequently supplement (a solution modelled on Article 33(4) of the GDPR).
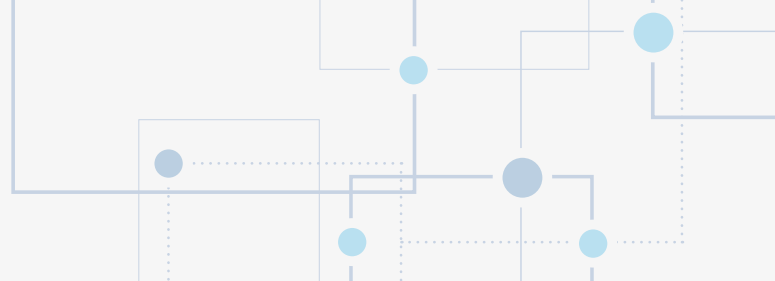
Finally, we recommend clarifying the obligation to monitor high-risk AI systems for threats to fundamental rights pursuant to Article 62(1) and (2) of the AIA by specifying the legal acts that concretise the protection thereof.

15. The term 'written'

Member States differ in the interpretation of the term 'in writing.' The problem is further aggravated by differences in translation; for example, the Polish language version uses the terms 'written form' (e.g. Article 17(1) of the AIA) or 'written' (Articles 48 & 58 of the AIA). Similar interpretation difficulties have occurred regarding the term 'in writing' used in the GDPR. The analysis of the AIA provisions containing the term 'written' and a purposive interpretation imply that the legislator does not mean written form per se or qualified electronic form (based on a qualified electronic signature or a qualified electronic seal), but rather 'textual form', that is documents, statements etc. submitted in readable form. We recommend adding a reference in the definition that 'written' means any form of a document that is composed of linguistic signs and ensures the authenticity and integrity thereof.

16. Regulatory sandboxes

We consider the idea of establishing regulatory sandboxes as a tool to foster innovation in the AI sector to be positive. However, the draft Regulation contains only very general provisions, while the key issues related to the operation of regulatory sand-

boxes shall be set out in implementing acts. We recommend indicating the specific facilities for regulatory sandbox users in the AIA itself (cf. section 15 of the Executive Summary).

17. **Penalties**

a) In general, we consider the introduction of dissuasive administrative fines for infringements of the AIA to be positive.

b) We recommend stating clearly in the draft Regulation that in case of minor infringements, especially if the fine to be imposed would constitute a disproportionate burden to a small provider or start-up, reprimand may be issued by the supervisory authority instead of a fine (a solution modelled on Motive 148 in the preamble of GDPR).

c) Consequently, we recommend specifying in the draft Regulation that fines may be imposed in addition to, or instead of non-cash measures (orders, warnings, etc.).

d) Increasing the number of categories (thresholds) of fines might be considered, so that the amount of the fine could be better adjusted to the gravity of the infringement.

e) The catalogue of circumstances to be taken into account by the supervisory authority when deciding on the amount of the administrative fine, which is set out in Article 71(6) of the AIA, should be expanded. We recommend adding the following circumstances:
   ▸ the intentional or negligent character of the infringement;
   ▸ any actions taken to comply with the regulatory requirements or to prevent or mitigate the consequences of the infringement;
   ▸ the scope of material and non-material damage;
   ▸ the number of persons affected by the infringement, including those who have suffered harm;
   ▸ any previous infringements.

f) Pursuant to Article 71(6)(b) of the AIA, when deciding on the amount of the administrative fine it shall be taken into account whether fines have been already applied by other supervisory authorities to the same operator for the same infringement. However, a question arises whether a previous fine should be considered by the supervisory authority as a mitigating or aggravating circumstance (either option can be reasonably argued for). We recommend clarifying the legislator's intent in the preamble.

g) We recommend that the AIA should obligate the European Artificial Intelligence Board to issue, within the specified time limit, general guidelines and recommendations on imposing of penalties (e.g. the interpretation of the individual

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circumstances listed in Article 71(6) of the AIA) rather than recommendations to the Commission only (which is currently implied by the literal meaning of Article 58 of the AIA), as well as to publish annual reports on the penalties imposed.

h) We recommend adding a provision on the right to non-administrative remedies (similarly to Articles 79 & 82 of the GDPR).

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