Council of the European Union
General Secretariat

**Brussels, 03 November 2021**

**WK 13185/2021 INIT**

**LIMITE**

**TELECOM**

WORKING PAPER

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**CONTRIBUTION**

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| From: | General Secretariat of the Council |
| To: | Working Party on Telecommunications and Information Society |
| Subject: | Artificial Intelligence Act - BE comments Articles 1-29, Annexes I-IV (doc. 8115/21) |

Delegations will find in annex BE comments on Artificial Intelligence Act (Articles 1-29, Annexes I-IV).

Commission proposal (doc. 8115/21 – COM(2021) 206 final) Deadline for comments: **26 *October 2021***

***Artificial Intelligence Act (Articles 1-29, Annexes I-IV)***

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| Commission proposal | Drafting Suggestions | Comments |
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| **2021/0106 (COD)**<br>**Proposal for a**<br>**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS** | | - Belgium acknowledges the fact that the choice for a horizontal approach certainly has its advantages, but nevertheless we must not forget that AI systems can be repurposed for various uses with their own specificities. Hence, a balance between specialization and consistency is needed regarding some specific sectors, e.g. the law enforcement sector.<br><br>- Furthermore, because this Proposal is a first-of-its-kind initiative and will affect companies and users who are already fully engaged with this technology, Belgium wants to emphasize the importance to test this Proposal in practice via policy prototyping. This can be done by the European Commission, the Member States |

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| | | and/or other actors who will ultimately have to enforce this pioneering horizontal legislation when it enters into force. We believe that testing this Proposal engaging (some or all) operators of AI systems identified in the AIA and subsequently taking into account the conclusions of these tests will improve the actual feasibility and enforceability of the AIA.<br><br>- Also, a reference can be made to GDPR compliancy of the AIA. Article 22 of the GDPR is also important (automated individualized decision-making (e.g. profiling)).<br><br>- We understand that the Commission is possibly preparing a complementary EU act to cover specific AI related liability issues. Belgium can definitely support this initiative as we believe it |

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| | | is crucial to have clear and comprehensive rules on liability in the context of AI. However, to prevent fragmentation of AI liability rules in the EU, we would like to stress that as the revision work is still ongoing (public consultation until 10 January 2022), clear delineation of liability rules for harm caused by AI should already be considered in this Proposal. Some questions are raised in this matter: Who is responsible for elimination or lowering the risk (e.g. adaption in AI model – take ownership rights into account – risks of lock-ins), for recovery-actions, actions in case of damage? The user, the developer, the supplier, …? Can this be agreed by contract (with the danger that all responsibilities will then be transferred to the user)? |

***Artificial Intelligence Act (Articles 1-29, Annexes I-IV)***

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| TITLE I | | |
| | | |
| GENERAL PROVISIONS | | |
| | | |
| Article 1<br>Subject matter | | |
| | | |
| This Regulation lays down: | | |
| | | |
| (a) harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems (‘AI systems’) in the Union; | | |
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| (a) prohibitions of certain artificial intelligence practices; | (b) prohibitions of certain artificial intelligence practices; | Practical comment: the numbered list in Article 1 is faulty numbered: see (a) followed by another (a) instead of (b) and so on. |
| | | |
| (b) specific requirements for high-risk AI systems and obligations for operators of such systems; | (c) specific requirements for high-risk AI systems and obligations for operators of such systems; | |
| | | |
| (c) harmonised transparency rules for AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content; | (d) harmonised transparency rules for AI systems intended to interact with natural persons, emotion recognition systems and biometric categorisation systems, and AI systems used to generate or manipulate image, audio or video content; | |
| | | |
| (d) rules on market monitoring and surveillance. | (e) rules on market monitoring and surveillance. | |

***Artificial Intelligence Act (Articles 1-29, Annexes I-IV)***

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| Article 2<br>Scope | | The scope of the AIA is essential as to its applicability and enforcement, requiring clear, easily interpretable and applicable definitions. Belgium therefore suggests refining the scope of the AIA by providing further clarification where needed. |
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| 1. This Regulation applies to: | | |
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| (a) providers placing on the market or putting into service AI systems in the Union, irrespective of whether those providers are established within the Union or in a third country; | | |
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| (b) users of AI systems located within the Union; | | |
| | | |
| (c) providers and users of AI systems that are located in a third country, where the output produced by the system is used in the Union; | | |
| | | |
| 2. For high-risk AI systems that are safety components of products or systems, or which are themselves products or systems, falling within the scope of the following acts, only Article 84 of this Regulation shall apply: | | |
| | | |
| (a) Regulation (EC) 300/2008; | | |
| | | |
| (b) Regulation (EU) No 167/2013; | | |
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| (c) Regulation (EU) No 168/2013; | | |
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| (d) Directive 2014/90/EU; | | |
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| (e) Directive (EU) 2016/797; | | |
| | | |
| (f) Regulation (EU) 2018/858; | | |
| | | |
| (g) Regulation (EU) 2018/1139; | | |
| | | |
| (h) Regulation (EU) 2019/2144. | | |
| | | |
| 3. This Regulation shall not apply to AI systems developed or used exclusively for military purposes. | This Regulation shall not apply to AI systems developed or used exclusively for military or national security purposes | When AI systems are used or developed in order to protect the national security, they should also be excluded from the scope of the Regulation, |

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| | | taking into account the exemption of national security enshrined in Art. 4(2) TEU. |
| | This Regulation shall also not apply to research activites in relation to AI. | Research activities are not in the scope of the regulation. This should be made explicit by introducing wording in the text and by the deleting last sentence of recital 16. |
| 4. This Regulation shall not apply to public authorities in a third country nor to international organisations falling within the scope of this Regulation pursuant to paragraph 1, where those authorities or organisations use AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States. | | We suggest to add a reference to Article 39 and to explain its relation with the Article 2 (4). The applicability of the AI regulation on the third countries has to be clear. |
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| 5. This Regulation shall not affect the application of the provisions on the liability of intermediary service providers set out in Chapter II, Section IV of Directive 2000/31/EC of the European Parliament and of the Council[1] [*as to be replaced by the corresponding provisions of the Digital Services Act*]. | | |
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| Article 3<br>Definitions | | |
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| For the purpose of this Regulation, the following definitions apply: | | |
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[1] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

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| (1) 'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with; | | Belgium believes that the definition of an AI system as provided in Article 3(1), in conjunction with the list of approaches and techniques in Annex I, may be too broad, since it could potentially include more traditional/conventional software systems or analytical processing, that should not fall under the scope of the Proposal. This increases legal uncertainty for users and manufacturers and is harmful for global competition. For example, in law enforcement, some techniques that are already in use are not generally considered strict AI applications, but might fall under the Proposal's broad definition of AI, e.g. certain 'intelligent' search engines regarding personal data or risk assessment techniques; moreover, this is also seen in the medical sector, where randomized control trials |

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| | | fall under 'statistical approaches' as stated in Annex I, but few would see this as AI; furthermore, also in the migration and asylum sector the broad definition can cause uncertainty, e.g. it is not clear if the definition applies to all possible uses by the Immigration Office or only in cases where the use of the technology has a direct impact on the content aspects of an application in one of the procedures included in Annex III. The examples provided by the Commission in its presentations give some additional insight in the intended scope of the definition, but the AIA itself should be sufficiently clear. Therefore, the definition of 'AI system' should be refined and the analysis of the assessment of which approaches and techniques should or should not be covered by Annex I, |

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| | | should be further deepened, as this definition depends on this list. |
| | | |
| (1) ‘provider’ means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge; | | |
| | | |
| (3) ‘small-scale provider’ means a provider that is a micro or small enterprise within the meaning of Commission Recommendation 2003/361/EC[2]; | | |
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[2] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

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| (4) 'user' means any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity; | | |
| | | |
| (5) 'authorised representative' means any natural or legal person established in the Union who has received a written mandate from a provider of an AI system to, respectively, perform and carry out on its behalf the obligations and procedures established by this Regulation; | | |
| | | |
| (6) 'importer' means any natural or legal person established in the Union that places on the market or puts into service an AI system that | | |

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| bears the name or trademark of a natural or legal person established outside the Union; | | |
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| (7) ‘distributor’ means any natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market without affecting its properties; | | In the Dutch version of the text, there is a mistake in the translation. See: *“distributeur”: een andere natuurlijke persoon of rechtspersoon in de toeleveringsketen dan de aanbieder of de importeur, die een AI-systeem in de Unie ~~in de handel brengt~~ op de markt aanbiedt zonder de eigenschappen hiervan te beïnvloeden.* |
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| (8) ‘operator’ means the provider, the user, the authorised representative, the importer and the distributor; | | |
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| (9) ‘placing on the market’ means the first making available of an AI system on the Union market; | | |
| | | |
| (10) ‘making available on the market’ means any supply of an AI system for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge; | | |
| | | |
| (11) ‘putting into service’ means the supply of an AI system for first use directly to the user or for own use on the Union market for its intended purpose; | | |
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| (12) ‘intended purpose’ means the use for which an AI system is intended by the provider, | | |

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| including the specific context and conditions of use, as specified in the information supplied by the provider in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation; | | |
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| (13) ‘reasonably foreseeable misuse’ means the use of an AI system in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems; | | |
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| (14) ‘safety component of a product or system’ means a component of a product or of a system which fulfils a safety function for that product or system or the failure or | | |

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| malfunctioning of which endangers the health and safety of persons or property; | | |
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| (15) 'instructions for use' means the information provided by the provider to inform the user of in particular an AI system's intended purpose and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used; | | |
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| (16) 'recall of an AI system' means any measure aimed at achieving the return to the provider of an AI system made available to users; | | |
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| (17) 'withdrawal of an AI system' means any measure aimed at preventing the distribution, display and offer of an AI system; | | |
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| (18) 'performance of an AI system' means the ability of an AI system to achieve its intended purpose; | | |
| | | |
| (19) 'notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring; | | |
| | | |
| (20) 'conformity assessment' means the process of verifying whether the requirements | | |

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| set out in Title III, Chapter 2 of this Regulation relating to an AI system have been fulfilled; | | |
| | | |
| (21) ‘conformity assessment body’ means a body that performs third-party conformity assessment activities, including testing, certification and inspection; | | |
| | | |
| (22) ‘notified body’ means a conformity assessment body designated in accordance with this Regulation and other relevant Union harmonisation legislation; | | |
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| (23) ‘substantial modification’ means a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the | | |

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| requirements set out in Title III, Chapter 2 of this Regulation or results in a modification to the intended purpose for which the AI system has been assessed; | | |
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| (24) ‘CE marking of conformity’ (CE marking) means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Title III, Chapter 2 of this Regulation and other applicable Union legislation harmonising the conditions for the marketing of products (‘Union harmonisation legislation’) providing for its affixing; | | |
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| (25) ‘post-market monitoring’ means all activities carried out by providers of AI systems to proactively collect and review experience | | |

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| gained from the use of AI systems they place on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions; | | |
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| (26) ‘market surveillance authority’ means the national authority carrying out the activities and taking the measures pursuant to Regulation (EU) 2019/1020; | | |
| | | |
| (27) ‘harmonised standard’ means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012; | | |
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| (28) ‘common specifications’ means a document, other than a standard, containing technical solutions providing a means to, | | |

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| comply with certain requirements and obligations established under this Regulation; | | |
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| (29) ‘training data’ means data used for training an AI system through fitting its learnable parameters, including the weights of a neural network; | | |
| | | |
| (30) ‘validation data’ means data used for providing an evaluation of the trained AI system and for tuning its non-learnable parameters and its learning process, among other things, in order to prevent overfitting; whereas the validation dataset can be a separate dataset or part of the training dataset, either as a fixed or variable split; | | |
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| (31) 'testing data' means data used for providing an independent evaluation of the trained and validated AI system in order to confirm the expected performance of that system before its placing on the market or putting into service; | | |
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| (32) 'input data' means data provided to or directly acquired by an AI system on the basis of which the system produces an output; | | |
| | | |
| (33) 'biometric data' means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification | | |

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| of that natural person, such as facial images or dactyloscopic data; | | |
| | | |
| (34) ‘emotion recognition system’ means an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data; | | |
| | | |
| (35) ‘biometric categorisation system’ means an AI system for the purpose of assigning natural persons to specific categories, such as sex, age, hair colour, eye colour, tattoos, ethnic origin or sexual or political orientation, on the basis of their biometric data; | | |
| | | |
| (36) ‘remote biometric identification system’ means an AI system for the purpose of | | |

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| identifying natural persons at a distance through the comparison of a person's biometric data with the biometric data contained in a reference database, and without prior knowledge of the user of the AI system whether the person will be present and can be identified ; | | |
| | | |
| (37) ''real-time' remote biometric identification system' means a remote biometric identification system whereby the capturing of biometric data, the comparison and the identification all occur without a significant delay. This comprises not only instant identification, but also limited short delays in order to avoid circumvention. | | |
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| (38) ‘‘post’ remote biometric identification system’ means a remote biometric identification system other than a ‘real-time’ remote biometric identification system; | | |
| | | |
| (39) ‘publicly accessible space’ means any physical place accessible to the public, regardless of whether certain conditions for access may apply; | | |
| | | |
| (40) ‘law enforcement authority’ means: | | |
| | | |
| (a) any public authority competent for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the | | |

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| safeguarding against and the prevention of threats to public security; or | | |
| | | |
| (b) any other body or entity entrusted by Member State law to exercise public authority and public powers for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security; | | |
| | | |
| (41) ‘law enforcement’ means activities carried out by law enforcement authorities for the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the | | |

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| safeguarding against and the prevention of threats to public security; | | |
| | | |
| (42) 'national supervisory authority' means the authority to which a Member State assigns the responsibility for the implementation and application of this Regulation, for coordinating the activities entrusted to that Member State, for acting as the single contact point for the Commission, and for representing the Member State at the European Artificial Intelligence Board; | | |
| | | |
| (43) 'national competent authority' means the national supervisory authority, the notifying authority and the market surveillance authority; | | |
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| (44) 'serious incident' means any incident that directly or indirectly leads, might have led or might lead to any of the following: | | Can serious damage also be "a serious damage to a person's identity and rights"? For example, in case of "a new (read: wrong) created identity" by the AI system after two identities of two different persons (for example of twins (same name, same date of birth, similarities in biometrics…) are mixed of combined. If this stays unnoticed for a certain time, it can have long term negative effects for the persons: lost data (and lost rights at level of for example social security rights), long term problems of identification, ….<br>It can be important to introduce specific rules about combining 2 files of what seems to be 2 files of one and the same person, for example "never compile 2 files to 1 file" when there are 2 different unique identification numbers, even |

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| | | when all the other data like last name, date of birth, …. are the same. |
| | | |
| (a) the death of a person or serious damage to a person's health, to property or the environment, | | The word "person" seem to cover only natural persons. What about "serious incidents" seriously damaging the property of legal persons, or threatening its existence, e.g.? |
| | | |
| (b) a serious and irreversible disruption of the management and operation of critical infrastructure. | | A definition of "critical infrastructure" is needed to make sure this area is sufficiently circumscribed, for example by making a reference to the annex of the future CER Directive. |
| | | |
| Article 4<br>Amendments to Annex I | | |
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| The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend the list of techniques and approaches listed in Annex I, in order to update that list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein. | | |
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| TITLE II | | |
| | | |
| PROHIBITED ARTIFICIAL INTELLIGENCE PRACTICES | | |
| | | |
| Article 5 | | |
| | | |
| 1. The following artificial intelligence practices shall be prohibited: | | |

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| (a) the placing on the market, putting into service or use of an AI system that deploys subliminal techniques beyond a person's consciousness in order to materially distort a person's behaviour in a manner that causes or is likely to cause that person or another person physical or psychological harm; | | This Article describes the prohibition of an AI system that deploys subliminal techniques; however, 'subliminal technique' as such is not defined in the Proposal, neither is the cause-and-effect relationship between the applied technique and the harm nor is 'physical or psychological harm'. In this regard, further definition of said terminology is required. |
| | | |
| (b) the placing on the market, putting into service or use of an AI system that exploits any of the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to materially distort the behaviour of a person pertaining to that group in a manner that causes or is likely to cause that | | |

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| person or another person physical or psychological harm; | | |
| | | |
| (c) the placing on the market, putting into service or use of AI systems by public authorities or on their behalf for the evaluation or classification of the trustworthiness of natural persons over a certain period of time based on their social behaviour or known or predicted personal or personality characteristics, with the social score leading to either or both of the following: | | Regarding 'social scoring', further clarification about the practices that fall under the prohibition on general citizen scoring would be welcomed, as the language that is currently used in the AIA and the examples provided by the Commission in its presentations, are not always sufficiently clear. |
| | | |
| (i) detrimental or unfavourable treatment of certain natural persons or whole groups thereof in social contexts which are unrelated to the | | |

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| contexts in which the data was originally generated or collected; | | |
| | | |
| (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; | | |
| | | |
| (d) the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement, unless and in as far as such use is strictly necessary for one of the following objectives: | | Belgium confirms that the use of real-time biometric identification by law enforcement in public spaces is a sensitive matter; however, taking into account the joint-opinion of the EDPB and the EDPS on the AIA of 18 June 20212, we believe that a more general ban on any use of AI for a 'real-time' automated recognition of human features in publicly accessible places should be incorporated in the AIA. In that sense, |

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| | | it should be closely examined if the actual choice to prohibit such a type of identification by law enforcement and provide for a system of exceptions is a workable and effective manner. In any case, we believe that other specific alternatives regarding possible exceptions should be analysed, e.g. providing a list with sufficient and concretely defined exceptions under realistic conditions, in particular for law enforcement objectives. |
| | | |
| (i) the targeted search for specific potential victims of crime, including missing children; | | |
| | | |
| (ii) the prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack; | | |

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| (iii) the detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence referred to in Article 2(2) of Council Framework Decision 2002/584/JHA[3] and punishable in the Member State concerned by a custodial sentence or a detention order for a maximum period of at least three years, as determined by the law of that Member State. | | |
| | | |
| 2. The use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to in paragraph 1 | | |

[3] Council Framework Decision 2002/584/JHA of 13 June 2002 on the European arrest warrant and the surrender procedures between Member States (OJ L 190, 18.7.2002, p. 1).

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| point d) shall take into account the following elements: | | |
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| (a) the nature of the situation giving rise to the possible use, in particular the seriousness, probability and scale of the harm caused in the absence of the use of the system; | | |
| | | |
| (b) the consequences of the use of the system for the rights and freedoms of all persons concerned, in particular the seriousness, probability and scale of those consequences. | | |
| | | |
| In addition, the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement for any of the objectives referred to | | |

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| in paragraph 1 point d) shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations. | | |
| | | |
| 3. As regards paragraphs 1, point (d) and 2, each individual use for the purpose of law enforcement of a 'real-time' remote biometric identification system in publicly accessible spaces shall be subject to a prior authorisation granted by a judicial authority or by an independent administrative authority of the Member State in which the use is to take place, issued upon a reasoned request and in accordance with the detailed rules of national law referred to in paragraph 4. However, in a | | |

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| duly justified situation of urgency, the use of the system may be commenced without an authorisation and the authorisation may be requested only during or after the use. | | |
| | | |
| The competent judicial or administrative authority shall only grant the authorisation where it is satisfied, based on objective evidence or clear indications presented to it, that the use of the 'real-time' remote biometric identification system at issue is necessary for and proportionate to achieving one of the objectives specified in paragraph 1, point (d), as identified in the request. In deciding on the request, the competent judicial or administrative authority shall take into account the elements referred to in paragraph 2. | | |

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| 4. A Member State may decide to provide for the possibility to fully or partially authorise the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement within the limits and under the conditions listed in paragraphs 1, point (d), 2 and 3. That Member State shall lay down in its national law the necessary detailed rules for the request, issuance and exercise of, as well as supervision relating to, the authorisations referred to in paragraph 3. Those rules shall also specify in respect of which of the objectives listed in paragraph 1, point (d), including which of the criminal offences referred to in point (iii) thereof, the competent authorities may be | | |

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| authorised to use those systems for the purpose of law enforcement. | | |
| | | |
| TITLE III | | |
| | | |
| HIGH-RISK AI SYSTEMS | | |
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| Chapter 1 | | |
| | | |
| CLASSIFICATION OF AI SYSTEMS AS HIGH-RISK | | |
| | | |
| Article 6<br>Classification rules for high-risk AI systems | | Belgium considers the classification rules for high-risk AI systems, as set out in Chapter 1 of Title III of the Proposal, in conjunction with Annex III, to be overall vague and in particular challenging to apply in practice. It remains to a |

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| | | large extent unclear which concrete use cases, tools or practices are in scope, especially for in-house development and small scale use. Further clarification on these classification rules and how to apply them correctly to particular cases, e.g. in the security services sector, is therefore welcomed. |
| | | |
| 1. Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled: | | |
| | | |
| (a) the AI system is intended to be used as a safety component of a product, or is itself a | | |

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| product, covered by the Union harmonisation legislation listed in Annex II; | | |
| | | |
| (b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II. | | |
| | | |
| 2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall also be considered high-risk. | | See comment on Article 6. |
| | | |

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| Article 7<br>Amendments to Annex III | | Belgium believes that the Commission's power to adopt delegated acts to update the list of high-risk AI systems in Annex III, in the light of Article 7, goes too far and hence, further clarification as to other possibilities to amend this Annex is needed. In any case, additional clarifications are required and should be duly specified in the AIA, in particular, as to the relevant criteria, consultation procedures and implementation process when making use of this power. It is also very important that a broad set of industry stakeholders is involved in the process, ensuring the consultation of representatives of the civil society, industry, academia and the public sector. We therefore give priority to a more inclusive approach in this |

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| | | matter, in order to provide legal certainty and ensure trust. |
| | | |
| 1. The Commission is empowered to adopt delegated acts in accordance with Article 73 to update the list in Annex III by adding high-risk AI systems where both of the following conditions are fulfilled: | | Article 7 introduces a double conditionality to amend Annex III on high-risk application systems. It does not seem possible to add areas other than those already indicated (as it would probably be considered as a substantial change to the text). This means that an exhaustive list of areas shall be defined with no possibility of revision. Belgium retains a study reservation on this matter. |
| | | |
| (a) the AI systems are intended to be used in any of the areas listed in points 1 to 8 of Annex III; | | |
| | | |

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| (b) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III. | ~~(b)~~ (a) the AI systems pose a risk of harm to the health and safety, or a risk of adverse impact on fundamental rights, that is, in respect of its severity and probability of occurrence, equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III. | |
| | | |
| 2. When assessing for the purposes of paragraph 1 whether an AI system poses a risk of harm to the health and safety or a risk of adverse impact on fundamental rights that is equivalent to or greater than the risk of harm posed by the high-risk AI systems already referred to in Annex III, the Commission shall take into account the following criteria: | | |
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| (a) the intended purpose of the AI system; | | |
| | | |
| (b) the extent to which an AI system has been used or is likely to be used; | | |
| | | |
| (c) the extent to which the use of an AI system has already caused harm to the health and safety or adverse impact on the fundamental rights or has given rise to significant concerns in relation to the materialisation of such harm or adverse impact, as demonstrated by reports or documented allegations submitted to national competent authorities; | | |
| | | |
| (d) the potential extent of such harm or such adverse impact, in particular in terms of its | | |

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| intensity and its ability to affect a plurality of persons; | | |
| | | |
| (e) the extent to which potentially harmed or adversely impacted persons are dependent on the outcome produced with an AI system, in particular because for practical or legal reasons it is not reasonably possible to opt-out from that outcome; | | |
| | | |
| (f) the extent to which potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to an imbalance of power, knowledge, economic or social circumstances, or age; | | |
| | | |

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| (g) the extent to which the outcome produced with an AI system is easily reversible, whereby outcomes having an impact on the health or safety of persons shall not be considered as easily reversible; | | Cf. our remark on the definition of "serious incident" (art. 3, (44)); quid legal persons (e.g. outcome produced with an AI system impacting the existence or viability of a legal person)? |
| | | |
| (h) the extent to which existing Union legislation provides for: | | |
| | | |
| (i) effective measures of redress in relation to the risks posed by an AI system, with the exclusion of claims for damages; | | |
| | | |
| (ii) effective measures to prevent or substantially minimise those risks. | | |
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| Chapter 2 | | |

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| REQUIREMENTS FOR HIGH-RISK AI SYSTEMS | | |
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| Article 8<br>Compliance with the requirements | | |
| | | |
| 1. High-risk AI systems shall comply with the requirements established in this Chapter. | | Belgium believes that the requirements for high-risk AI systems are sometimes slightly vague and may need to be better defined (cf. comment on Article 6), as generally they are perceived as being too strict, especially taking into consideration the broad spectrum of AI systems that would be considered high risk.<br>In addition, several of these requirements are still topics of active research and concrete approaches |

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| | | for achieving these requirements might not be available on time depending on the specific AI technique. |
| | | |
| 2. The intended purpose of the high-risk AI system and the risk management system referred to in Article 9 shall be taken into account when ensuring compliance with those requirements. | | |
| | | |
| Article 9<br>Risk management system | | |
| | | |
| 1. A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems. | | |
| | | |

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| 2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps: | | |
| | | |
| (a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system; | | Will the risks associated with each high-risk AI system be transparent for users and the public? Will the risk analysis report be available for the user before buying and using the AI system? |
| | | |
| (b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse; | | |
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| (c) evaluation of other possibly arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61; | | |
| | | |
| (d) adoption of suitable risk management measures in accordance with the provisions of the following paragraphs. | | |
| | | |
| 3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the generally acknowledged state of the art, | | |

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| including as reflected in relevant harmonised standards or common specifications. | | |
| | | |
| 4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user. | | |
| | | |
| In identifying the most appropriate risk management measures, the following shall be ensured: | | |
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| (a) elimination or reduction of risks as far as possible through adequate design and development; | | |
| | | |
| (b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated; | | |
| | | |
| (c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users. | | |
| | | |
| In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical | | |

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| knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used. | | |
| | | |
| 5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter. | | |
| | | |
| 6. Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose. | | |
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| 7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system. | | |
| | | |
| 8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children. | | |
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| 9. For credit institutions regulated by Directive 2013/36/EU, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by those institutions pursuant to Article 74 of that Directive. | | |
| | | |
| Article 10<br>Data and data governance | | |
| | | |
| 1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5. | | |
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| 2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular, | | |
| | | |
| (a) the relevant design choices; | | |
| | | |
| (b) data collection; | | |
| | | |
| (c) relevant data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation; | | |
| | | |
| (d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent; | | |
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| (e) a prior assessment of the availability, quantity and suitability of the data sets that are needed; | | |
| | | |
| (f) examination in view of possible biases; | | |
| | | |
| (g) the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed. | | |
| | | |
| 3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the | Training, validation and testing data sets shall be relevant, representative~~, free of errors~~ and reliable ~~and complete.~~ | Belgium supports to use "reliable data" sets instead of "free of errors and complete" to make the requirement practically implementable (in relation to the state of the art). |

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| data sets may be met at the level of individual data sets or a combination thereof. | | |
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| 4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used. | | |
| | | |
| 5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) | | |

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| 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued. | | |
| | | |
| 6. Appropriate data governance and management practices shall apply for the development of high-risk AI systems other than those which make use of techniques involving the training of models in order to ensure that | | |

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| those high-risk AI systems comply with paragraph 2. | | |
| | | |
| Article 11<br>Technical documentation | | |
| | | |
| 1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date. | | |
| | | |
| The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the | | |

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| compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. | | |
| | | |
| 2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts. | | |
| | | |
| 3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the | | |

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| necessary information to assess the compliance of the system with the requirements set out in this Chapter. | | |
| | | |
| Article 12<br>Record-keeping | | |
| | | |
| 1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications. | | |
| | | |
| 2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is | | |

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| appropriate to the intended purpose of the system. | | |
| | | |
| 3. In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or lead to a substantial modification, and facilitate the post-market monitoring referred to in Article 61. | | |
| | | |
| 4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum: | | |
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| (a) recording of the period of each use of the system (start date and time and end date and time of each use); | | |
| | | |
| (b) the reference database against which input data has been checked by the system; | | |
| | | |
| (c) the input data for which the search has led to a match; | | |
| | | |
| (d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5). | | |
| | | |
| Article 13<br>Transparency and provision of information to users | | |

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| 1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title. | | |
| | | |
| 2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users. | | |

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| | | |
| 3. The information referred to in paragraph 2 shall specify: | | |
| | | |
| (a) the identity and the contact details of the provider and, where applicable, of its authorised representative; | | |
| | | |
| (b) the characteristics, capabilities and limitations of performance of the high-risk AI system, including: | | |
| | | |
| (i) its intended purpose; | | |
| | | |
| (ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested | | |

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| and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity; | | |
| | | |
| (iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights; | | |
| | | |
| (iv) its performance as regards the persons or groups of persons on which the system is intended to be used; | | |
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| (v) when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system. | | |
| | | |
| (c) the changes to the high-risk AI system and its performance which have been pre-determined by the provider at the moment of the initial conformity assessment, if any; | | |
| | | |
| (d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; | | |
| | | |

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| (e) the expected lifetime of the high-risk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates. | | |
| | | |
| Article 14<br>Human oversight | | |
| | | |
| 1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use. | | |
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| 2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter. | | |
| | | |
| 3. Human oversight shall be ensured through either one or all of the following measures: | | |
| | | |
| (a) identified and built, when technically feasible, into the high-risk AI system by the | | |

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| provider before it is placed on the market or put into service; | | |
| | | |
| (b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the user. | | |
| | | |
| 4. The measures referred to in paragraph 3 shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances: | | |
| | | |
| (a) fully understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected | | |

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| performance can be detected and addressed as soon as possible; | | |
| | | |
| (b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons; | | |
| | | |
| (c) be able to correctly interpret the high-risk AI system's output, taking into account in particular the characteristics of the system and the interpretation tools and methods available; | | |
| | | |

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| (d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system; | | |
| | | |
| (e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a "stop" button or a similar procedure. | | |
| | | |
| 5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons. | | |
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| Article 15<br>Accuracy, robustness and cybersecurity | | |
| | | |
| 1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle. | | |
| | | |
| 2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use. | | |
| | | |
| 3. High-risk AI systems shall be resilient as regards errors, faults or inconsistencies that may | | |

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| occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems. | | |
| | | |
| The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans. | | |
| | | |
| High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs due to outputs used as an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures. | | |

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| 4. High-risk AI systems shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system vulnerabilities. | | |
| | | |
| The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks. | | |
| | | |
| The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset (‘data poisoning’), inputs designed to cause the model | | |

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| to make a mistake (‘adversarial examples’), or model flaws. | | |
| | | |
| Chapter 3 | | |
| | | |
| OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS AND OTHER PARTIES | | |
| | | |
| Article 16<br>Obligations of providers of high-risk AI systems | | |
| | | |
| Providers of high-risk AI systems shall: | | |
| | | |
| (a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title; | | |

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| | | |
| (b) have a quality management system in place which complies with Article 17; | | |
| | | |
| (c) draw-up the technical documentation of the high-risk AI system; | | |
| | | |
| (d) when under their control, keep the logs automatically generated by their high-risk AI systems; | | |
| | | |
| (e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service; | | For the major part of high-risk AI systems, the conformity assessment seems to be a self-assessment (see art. 43). In the field of the administration of Justice, e.g., one can wonder whether this system of self-assessment ex ante by |

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| | | the provider of the high-risk AI system in question<br>- will be sufficient, concerning the potentially large impact of this kind of use?<br>- will be efficient, concerning the apparent undercapacity for control and enforcement ex post, at least in a first stage? (see explanatory memorandum, 5.2.3, last paragraph, that states that "expertise for auditing is only now being accumulated")<br>- will be feasible and not overly burdensome, e.g. for Startups and SME's? |
| | | |
| (f) comply with the registration obligations referred to in Article 51; | | |
| | | |

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| (g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title; | | |
| | | |
| (h) inform the national competent authorities of the Member States in which they made the AI system available or put it into service and, where applicable, the notified body of the non-compliance and of any corrective actions taken; | | |
| | | |
| (i) to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49; | | |
| | | |

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| (j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title. | | |
| | | |
| Article 17<br>Quality management system | | |
| | | |
| 1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects: | | |
| | | |

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| | | |
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| (a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system; | | |
| | | |
| (b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system; | | |
| | | |
| (c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system; | | |
| | | |

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| (d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out; | | |
| | | |
| (e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title; | | |
| | | |
| (f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data | | |

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| retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems; | | |
| | | |
| (g) the risk management system referred to in Article 9; | | |
| | | |
| (h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61; | | |
| | | |
| (i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62; | | |
| | | |

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| (j) the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or supporting the access to data, notified bodies, other operators, customers or other interested parties; | | |
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| (k) systems and procedures for record keeping of all relevant documentation and information; | | |
| | | |
| (l) resource management, including security of supply related measures; | | |
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| (m) an accountability framework setting out the responsibilities of the management and other | | |

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| staff with regard to all aspects listed in this paragraph. | | |
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| 2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation. | | |
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| 3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account. | | |

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| Article 18<br>Obligation to draw up technical documentation | | |
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| 1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV. | | |
| | | |
| 2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive. | | |
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| Article 19<br>Conformity assessment | | |
| | | |
| 1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49. | | |
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| 2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into service by providers that are credit institutions regulated by Directive 2013/36/EU, the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to101 of that Directive. | | |
| | | |
| Article 20<br>Automatically generated logs | | |
| | | |
| 1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is | | |

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| appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law. | | |
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| 2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs automatically generated by their high-risk AI systems as part of the documentation under Articles 74 of that Directive. | | |
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| Article 21<br>Corrective actions | | |
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| Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the | | |

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| market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly. | | |
| | | |
| Article 22<br>Duty of information | | |
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| Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the national competent authorities of the Member States in | | |

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| which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken. | | |
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| Article 23<br>Cooperation with competent authorities | | |
| | | |
| Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned | | |

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| request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. | | |
| | | |
| Article 24<br>Obligations of product manufacturers | Article 24<br>Obligations of ~~product~~ manufacturers of the final product | Cf. recital 55 where this wording is used as well (since there is no definition of 'manufacturer'). |
| | | |
| Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product | | |

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| manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider. | | |
| | | |
| Article 25<br>Authorised representatives | | |
| | | |
| 1. Prior to making their systems available on the Union market, where an importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union. | | |
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| 2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks: | | |
| | | |
| (a) keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7); | | |
| | | |
| (b) provide a national competent authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter | | |

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| 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law; | | |
| | | |
| (c) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system. | | |
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| Article 26<br>Obligations of importers | | |
| | | |
| 1. Before placing a high-risk AI system on the market, importers of such system shall ensure that: | | |

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| (a) the appropriate conformity assessment procedure has been carried out by the provider of that AI system | | |
| | | |
| (b) the provider has drawn up the technical documentation in accordance with Annex IV; | | |
| | | |
| (c) the system bears the required conformity marking and is accompanied by the required documentation and instructions of use. | | |
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| 2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, it shall not place that system on the market until that AI system has been brought into conformity. | | |

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| Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect. | | |
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| 3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable. | | |
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| 4. Importers shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions | | |

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| do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title. | | |
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| 5. Importers shall provide national competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities | | |

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| on any action national competent authority takes in relation to that system. | | |
| | | |
| Article 27<br>Obligations of distributors | | |
| | | |
| 1. Before making a high-risk AI system available on the market, distributors shall verify that the high-risk AI system bears the required CE conformity marking, that it is accompanied by the required documentation and instruction of use, and that the provider and the importer of the system, as applicable, have complied with the obligations set out in this Regulation. | | |
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| 2. Where a distributor considers or has reason to consider that a high-risk AI system is | | |

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| not in conformity with the requirements set out in Chapter 2 of this Title, it shall not make the high-risk AI system available on the market until that system has been brought into conformity with those requirements. Furthermore, where the system presents a risk within the meaning of Article 65(1), the distributor shall inform the provider or the importer of the system, as applicable, to that effect. | | |
| | | |
| 3. Distributors shall ensure that, while a high-risk AI system is under their responsibility, where applicable, storage or transport conditions do not jeopardise the compliance of the system with the requirements set out in Chapter 2 of this Title. | | |

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| 4. A distributor that considers or has reason to consider that a high-risk AI system which it has made available on the market is not in conformity with the requirements set out in Chapter 2 of this Title shall take the corrective actions necessary to bring that system into conformity with those requirements, to withdraw it or recall it or shall ensure that the provider, the importer or any relevant operator, as appropriate, takes those corrective actions. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the distributor shall immediately inform the national competent authorities of the Member States in which it has made the product available to that | | |

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| effect, giving details, in particular, of the non-compliance and of any corrective actions taken. | | |
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| 5. Upon a reasoned request from a national competent authority, distributors of high-risk AI systems shall provide that authority with all the information and documentation necessary to demonstrate the conformity of a high-risk system with the requirements set out in Chapter 2 of this Title. Distributors shall also cooperate with that national competent authority on any action taken by that authority. | | |
| | | |
| Article 28<br>Obligations of distributors, importers, users or any other third-party | | |
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| 1. Any distributor, importer, user or other third-party shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances: | | |
| | | |
| (a) they place on the market or put into service a high-risk AI system under their name or trademark; | | |
| | | |
| (b) they modify the intended purpose of a high-risk AI system already placed on the market or put into service; | | |
| | | |
| (c) they make a substantial modification to the high-risk AI system. | | |
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| 2. Where the circumstances referred to in paragraph 1, point (b) or (c), occur, the provider that initially placed the high-risk AI system on the market or put it into service shall no longer be considered a provider for the purposes of this Regulation. | | |
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| Article 29<br>Obligations of users of high-risk AI systems | | |
| | | |
| 1. Users of high-risk AI systems shall use such systems in accordance with the instructions of use accompanying the systems, pursuant to paragraphs 2 and 5. | | |
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| 2. The obligations in paragraph 1 are without prejudice to other user obligations under | | |

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| Union or national law and to the user's discretion in organising its own resources and activities for the purpose of implementing the human oversight measures indicated by the provider. | | |
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| 3. Without prejudice to paragraph 1, to the extent the user exercises control over the input data, that user shall ensure that input data is relevant in view of the intended purpose of the high-risk AI system. | | |
| | | |
| 4. Users shall monitor the operation of the high-risk AI system on the basis of the instructions of use. When they have reasons to consider that the use in accordance with the instructions of use may result in the AI system | | |

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| presenting a risk within the meaning of Article 65(1) they shall inform the provider or distributor and suspend the use of the system. They shall also inform the provider or distributor when they have identified any serious incident or any malfunctioning within the meaning of Article 62 and interrupt the use of the AI system. In case the user is not able to reach the provider, Article 62 shall apply mutatis mutandis. | | |
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| For users that are credit institutions regulated by Directive 2013/36/EU, the monitoring obligation set out in the first subparagraph shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, | | |

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| processes and mechanisms pursuant to Article 74 of that Directive. | | |
| | | |
| 5. Users of high-risk AI systems shall keep the logs automatically generated by that high-risk AI system, to the extent such logs are under their control. The logs shall be kept for a period that is appropriate in the light of the intended purpose of the high-risk AI system and applicable legal obligations under Union or national law. | | |
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| Users that are credit institutions regulated by Directive 2013/36/EU shall maintain the logs as part of the documentation concerning internal governance arrangements, processes and | | |

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| mechanisms pursuant to Article 74 of that Directive. | | |
| | | |
| 6. Users of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation to carry out a data protection impact assessment under Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, where applicable. | | |
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| **ANNEX I**<br>**ARTIFICIAL INTELLIGENCE TECHNIQUES AND APPROACHES**<br>**referred to in Article 3, point 1** | | This definition can be considered as very broad. It includes a lot of techniques that are not stricto-sensu AI. This large definition of AI can be problematic when combined with Annex III (High Risk systems referred to Art.6 (2) – 6(g) |

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| (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning; | | |
| | | |
| (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems; | | |
| | | |
| (c) Statistical approaches, Bayesian estimation, search and optimization methods. | | |
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| **ANNEX II**<br>**LIST OF UNION HARMONISATION LEGISLATION**<br>**Section A – List of Union harmonisation legislation based on the New Legislative Framework** | | |
| | | |
| 1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation]; | | |
| | | |
| 2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 | | |

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| on the safety of toys (OJ L 170, 30.6.2009, p. 1); | | |
| | | |
| 3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90); | | |
| | | |
| 4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251); | | |
| | | |

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| 5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309); | | |
| | | |
| 6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62); | | |
| | | |

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| 7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164); | | |
| | | |
| 8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1); | | |
| | | |
| 9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment | | |

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| and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51); | | |
| | | |
| 10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99); | | |
| | | |
| 11. 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 (OJ L 117, 5.5.2017, p. 1; | | |

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| 12. 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 (OJ L 117, 5.5.2017, p. 176). | | |
| | | |
| **Section B. List of other Union harmonisation legislation** | | |
| | | |
| 1. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72). | | |

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| 2. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52); | | |
| | | |
| 3. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1); | | |
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| 4. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council | | |

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| Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146); | | |
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| 5. Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44). | | |
| | | |
| 6. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and | | |

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| (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1); 3. Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No | | |

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| 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (OJ L 325, 16.12.2019, p. 1); | | |
| | | |
| 7. Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of | | |

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| the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned. | | |
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| **ANNEX III**<br>**HIGH-RISK AI SYSTEMS REFERRED TO IN ARTICLE 6(2)** | | Cf. comment on requirements for high-risk AI systems. |

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| High-risk AI systems pursuant to Article 6(2) are the AI systems listed in any of the following areas: | | |
| | | |
| 1. Biometric identification and categorisation of natural persons: | | |
| | | |
| (a) AI systems intended to be used for the ‘real-time’ and ‘post’ remote biometric identification of natural persons; | | |
| | | |
| 2. Management and operation of critical infrastructure: | | A definition of “critical infrastructure” is needed to make sure this area is sufficiently circumscribed, for example by making a |

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| | | reference to the annex of the future CER Directive. |
| | | |
| (a) AI systems intended to be used as safety components in the management and operation of road traffic and the supply of water, gas, heating and electricity. | | |
| | | |
| 3. Education and vocational training: | | |
| | | |
| (a) AI systems intended to be used for the purpose of determining access or assigning natural persons to educational and vocational training institutions; | | |
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| (b) AI systems intended to be used for the purpose of assessing students in educational and vocational training institutions and for assessing participants in tests commonly required for admission to educational institutions. | | |
| | | |
| 4. Employment, workers management and access to self-employment: | | |
| | | |
| (a) AI systems intended to be used for recruitment or selection of natural persons, notably for advertising vacancies, screening or filtering applications, evaluating candidates in the course of interviews or tests; | | |
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| (b) AI intended to be used for making decisions on promotion and termination of work-related contractual relationships, for task allocation and for monitoring and evaluating performance and behavior of persons in such relationships. | | |
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| 5. Access to and enjoyment of essential private services and public services and benefits: | | |
| | | |
| (a) AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for public assistance benefits and services, as well | | |

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| as to grant, reduce, revoke, or reclaim such benefits and services; | | |
| | | |
| (b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems put into service by small scale providers for their own use; | | |
| | | |
| (c) AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid. | | |
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| 6. Law enforcement: | | The categorisation as "high risk" of some of those "use cases" can be exaggerated or even inappropriate. As a general comment, the real high risk uses case should be more narrowly defined. When evaluating the risk that those AI use cases represent, one should also compare with the practice in absence of such AI use. In some specific cases, the use of AI, although not perfect, might give similar or even better results than conventional "human" practices. For examples (E.g.), refer to point (a), (c), (e), (g) |
| | | |
| (a) AI systems intended to be used by law enforcement authorities for making individual risk assessments of natural persons in order to assess the risk of a natural person for offending | | E.g. : AI-based risk assessments tools warning police officers of potential risks for specific victims could be complementary to their judgment based on knowledge and experience. |

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| or reoffending or the risk for potential victims of criminal offences; | | |
| | | |
| (b) AI systems intended to be used by law enforcement authorities as polygraphs and similar tools or to detect the emotional state of a natural person; | | |
| | | |
| (c) AI systems intended to be used by law enforcement authorities to detect deep fakes as referred to in article 52(3); | | E.g. : AI systems detecting deep fakes can outperform human experts, so instead of considering this as “high risk”, these AI systems could be considered as extra assistance in addition to human expertise. |
| | | |
| (d) AI systems intended to be used by law enforcement authorities for evaluation of the | | |

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| reliability of evidence in the course of investigation or prosecution of criminal offences; | | |
| | | |
| (e) AI systems intended to be used by law enforcement authorities for predicting the occurrence or reoccurrence of an actual or potential criminal offence based on profiling of natural persons as referred to in Article 3(4) of Directive (EU) 2016/680 or assessing personality traits and characteristics or past criminal behaviour of natural persons or groups; | | E.g. : combined with the broad definition of AI, this could imply that e.g. risk-labelling of known offenders based on their past criminal behaviour (e.g. violent, firearms user, etc.) that are used to warn police officers before interacting with these persons also become “high-risk use”. These risk warnings are already applied nowadays but are mainly based on human judgment (not necessarily in a very consistent way). |
| | | |
| (f) AI systems intended to be used by law enforcement authorities for profiling of natural | | |

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| persons as referred to in Article 3(4) of Directive (EU) 2016/680 in the course of detection, investigation or prosecution of criminal offences; | | |
| | | |
| (g) AI systems intended to be used for crime analytics regarding natural persons, allowing law enforcement authorities to search complex related and unrelated large data sets available in different data sources or in different data formats in order to identify unknown patterns or discover hidden relationships in the data. | | ➔ See comments Annexe I.<br><br>The combination of the broad AI definition and the broad high-risk category (6(d)) implies that a lot of data processing and analytics, with longstanding use, might become high risk (with all the compliance requirements as a consequence)<br><br>For instance:<br><br>• ‘intelligent’ search engine; not only presenting an exact match but also suggesting potentially related information |

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| | | • processing of communications based on specific ontologies or a machine learning model<br>• Geographic profiling techniques<br>• Indicator/rule-based risk scoring (e.g. for potential life-threatening risks in domestic violence situations)<br><br>Users might abandon the use of these techniques to avoid the administrative burden related to the High-Risk AI practical requirements. |
| | | |
| 7. Migration, asylum and border control management: | | See comments Annexe III, point 6. (same reasoning). |
| | | |
| (a) AI systems intended to be used by competent public authorities as polygraphs and similar tools or to detect the emotional state of a natural person; | | |

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| (b) AI systems intended to be used by competent public authorities to assess a risk, including a security risk, a risk of irregular immigration, or a health risk, posed by a natural person who intends to enter or has entered into the territory of a Member State; | | |
| | | |
| (c) AI systems intended to be used by competent public authorities for the verification of the authenticity of travel documents and supporting documentation of natural persons and detect non-authentic documents by checking their security features; | | See comments on Annexe III, point 6, (b).<br>E.g. : AI systems for the verification of the authenticity of travel documents could outperform human experts, so instead of considering this use as “high risk”, these AI systems could be considered as a “welcome extra help” in addition to human expertise. |

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| (d) AI systems intended to assist competent public authorities for the examination of applications for asylum, visa and residence permits and associated complaints with regard to the eligibility of the natural persons applying for a status. | | |
| | | |
| 8. Administration of justice and democratic processes: | | We agree that the sector of the administration of Justice is one where the use of AI systems could generate important risks. |
| | | |
| (a) AI systems intended to assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts. | | We fear however that this definition risks to create a grey zone. For some AI systems, it may not be immediately clear whether they fall under |

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| | | this definition; e.g. a system for the administration of hearings, or a system for case-law enhancement (see https://rm.coe.int/ethical-charter-en-for-publication-4-december-2018/16808f699c, p 64)<br><br>More fundamentally, this presupposes the acceptance of the principle that AI-systems could offer support/assistance with the taking of judicial decisions. This raises important questions, e.g. concerning the avoidance or at the very least limitation of potential biases in the data that are fed to the algorithms concerned, or concerning the desired level of explainability of the decisions reached with the assistance of AI-systems. |

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| | | Furthermore, this proposal does not seem to pay any particular attention to the remedies offered to persons (natural or legal) against decisions (judicial or other) taken with the assistance/support of AI systems, and the particularities that go with it. |
| | | |
| **ANNEX IV**<br>**TECHNICAL DOCUMENTATION referred to in Article 11(1)** | | |
| | | |
| The technical documentation referred to in Article 11(1) shall contain at least the following information, as applicable to the relevant AI system: | | |
| | | |

***Artificial Intelligence Act (Articles 1-29, Annexes I-IV)***

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| 1. A general description of the AI system including: | | |
| | | |
| (a) its intended purpose, the person/s developing the system the date and the version of the system; | | |
| | | |
| (b) how the AI system interacts or can be used to interact with hardware or software that is not part of the AI system itself, where applicable; | | |
| | | |
| (c) the versions of relevant software or firmware and any requirement related to version update; | | |
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| (d) the description of all forms in which the AI system is placed on the market or put into service; | | |
| | | |
| (e) the description of hardware on which the AI system is intended to run; | | |
| | | |
| (f) where the AI system is a component of products, photographs or illustrations showing external features, marking and internal layout of those products; | | |
| | | |
| (g) instructions of use for the user and, where applicable installation instructions; | | |
| | | |

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| 2. A detailed description of the elements of the AI system and of the process for its development, including: | | |
| | | |
| (a) the methods and steps performed for the development of the AI system, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the provider; | | |
| | | |
| (b) the design specifications of the system, namely the general logic of the AI system and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons | | |

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| on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in Title III, Chapter 2; | | |
| | | |
| (c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system; | | |
| | | |

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| (d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection); | | |
| | | |
| (e) assessment of the human oversight measures needed in accordance with Article 14, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of AI systems by the users, in accordance with Articles 13(3)(d); | | |

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| (f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI system with the relevant requirements set out in Title III, Chapter 2; | | |
| | | |
| (g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness, cybersecurity and compliance with other relevant requirements set out in Title III, Chapter 2 as well as potentially | | |

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| discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point (f). | | |
| | | |
| 3. Detailed information about the monitoring, functioning and control of the AI system, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in | | |

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| view of the intended purpose of the AI system; the human oversight measures needed in accordance with Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the users; specifications on input data, as appropriate; | | |
| | | |
| 4. A detailed description of the risk management system in accordance with Article 9; | | |
| | | |
| 5. A description of any change made to the system through its lifecycle; | | |
| | | |

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| 6. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union; where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Title III, Chapter 2, including a list of other relevant standards and technical specifications applied; | | |
| | | |
| 7. A copy of the EU declaration of conformity; | | |
| | | |
| 8. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with | | |

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| Article 61, including the post-market monitoring plan referred to in Article 61(3). | | |
| | | |
| | **End** | **End** |