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LIMITE

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WORKING PAPER

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CONTRIBUTION

| From: To: | General Secretariat of the Council Working Party on Telecommunications and Information Society |
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| Subject: | Artificial Intelligence Act - EE comments, Articles 40-55a (docs. 6239/22 + 6809/1/22 REV 1) |

Delegations will find in annex the EE comments on Artificial Intelligence Act, Articles 40-55a (docs. 6239/22+6809/1/22 REV 1).

Deadline for comments: 11 April 2022

Presidency compromise text for Artificial Intelligence Act (docs. 6239/22 + 6809/1/22 REV 1)

Comments and drafting suggestions requested on Articles 40-55a

Important: In order to guarantee that your comments appear accurately, please do not modify the table format by adding/removing/adjusting/merging/splitting cells and rows. This would hinder the consolidation of your comments. When adding new provisions, please use the free rows provided for this purpose between the provisions. You can add multiple provisions in one row, if necessary, but do not add or remove rows. For drafting suggestions (2nd column), please copy the relevant sentence or sentences from a given paragraph or point into the second column and add or remove text. Please do not use track changes, but highlight your additions in yellow or use strikethrough to indicate deletions. You do not need to copy entire paragraphs or points to indicate your changes, copying and modifying the relevant sentences is sufficient. For comments on specific provisions, please insert your remarks in the 3rd column in the relevant row. If you wish to make general comments on the entire proposal, please do so in the row containing the title of the proposal (in the 3rd column).

| Presidency compromise | Drafting Suggestions | Comments |
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| Proposal for a | | |
| 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 | | |
| | | |
| CHAPTER 5 | | |
| | | |
| STANDARDS, CONFORMITY | | |
| ASSESSMENT, CERTIFICATES, | | |
| REGISTRATION | | |

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| Article 40 Harmonised standards | | |
| 1. High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements. | | |
| 2. When issuing a standardisation request to European standardisation organisations in accordance with Article 10 of Regulation 1025/2012, the Commission shall specify that standards are coherent, easy to implement | | |

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| and drafted in such a way that they aim to | | |
| fulfil in particular the following objectives: | | |
| | | |
| a) ensure that AI systems placed on | | It is unclear to us whether or how the standard |
| the market or put into service in the Union | | would ensure that the AI systems respect human |
| are safe and respect Union values and | | rights/fundamental rights as set out in the |
| strenghten the Union's digital sovereignty; | | Charter of Fundamental Rights of the EU, as |
| | | respect for human rights is a value of the Union |
| | | pursuant to Article 2 TEU. |
| | | Would the standard provide a model for a |
| | | fundamental rights impact assessment (notably, |
| | | as may be required under Article 9)? If not, how |
| | | will a comparable fundamental rights impact |
| | | assessment be ensured throughout the EU (and |
| | | beyond)? Differences in the granularity and |
| | | extent of a fundamental rights impact |
| | | assessment could lead to distortion of the |
| | | internal market. Or would a fundamental rights |

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| | | impact assessment model come in the form of a |
| | | common specification as set out in Article 41? |
| b) | | |
| b) promote investment and | | |
| innovation in AI, as well as competitiveness | | |
| and growth of the Union market; | | |
| | | |
| c) enhance multistakeholder | | |
| governance, representative of all relevant | | |
| European stakeholders (e.g. industry, SMEs, | | |
| civil society, researchers). | | |
| | | |
| d) contribute to strengthening | | |
| global cooperation on standardisation in the | | |
| field of AI that is consistent with Union | | |
| values and interests. | | |
| | | |

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| The Commission shall request the | | |
| European standardisation organisations to | | |
| provide evidence of their best efforts to fulfil | | |
| the above objectives. | | |
| | | |
| Article 41 | | |
| Common specifications | | |
| | | |
| 1. Where harmonised standards referred to in | | |
| Article 40 do not exist or where the Commission | | |
| considers that the relevant harmonised standards | | |
| are insufficient or that there is a need to address | | |
| specific safety or fundamental right concerns, | | |
| the Commission may, after consulting the AI | | |
| Board referred to in Article 56 , by means of | | |
| implementing acts, adopt common | | |
| specifications in respect of the requirements set | | |
| out in Chapter 2 of this Title. Those | | |

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| implementing acts shall be adopted in | | |
| accordance with the examination procedure | | |
| referred to in Article 74(2). | | |
| | | |
| 2. <u>The Commission.</u> <u>Ww</u> hen preparing the | | |
| common specifications referred to in paragraph | | |
| 1, the Commission shall fulfil the objectives | | |
| referred of Article 40(2) and gather the views | | |
| of relevant bodies or expert groups established | | |
| under relevant sectorial Union law. | | |
| | | |
| 3. High-risk AI systems which are in | | |
| conformity with the common specifications | | |
| referred to in paragraph 1 shall be presumed to | | |
| be in conformity with the requirements set out | | |
| in Chapter 2 of this Title, to the extent those | | |
| common specifications cover those | | |
| requirements. | | |

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| 4. Where providers do not comply with the | | |
| common specifications referred to in paragraph | | |
| 1, they shall duly justify <u>in the technical</u> | | |
| documentation referred to in Article 11 that | | |
| they have adopted technical solutions that are at | | |
| least equivalent thereto. | | |
| | | |
| Article 42 | | |
| Presumption of conformity with certain | | |
| requirements | | |
| | | |
| 1. Taking into account their intended | | |
| purpose, hHigh-risk AI systems that have been | | |
| trained and tested on data eoncerning reflecting | | |
| the specific geographical, behavioural and or | | |
| functional setting within which they are | | |
| intended to be used shall be presumed to be in | | |

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| compliance with the <u>respective</u> requirement <u>s</u> set | | |
| out in Article 10(4). | | |
| | | |
| 2. High-risk AI systems that have been | | |
| certified or for which a statement of conformity | | |
| has been issued under a cybersecurity scheme | | |
| pursuant to Regulation (EU) 2019/881 of the | | |
| European Parliament and of the Council ¹ and | | |
| the references of which have been published in | | |
| the Official Journal of the European Union shall | | |
| be presumed to be in compliance with the | | |
| cybersecurity requirements set out in Article 15 | | |
| of this Regulation in so far as the cybersecurity | | |
| certificate or statement of conformity or parts | | |
| thereof cover those requirements. | | |
| | | |

Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 1).

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| Article 43 | | |
| Conformity assessment | | |
| | | |
| 1. For high-risk AI systems listed in point 1 | | |
| of Annex III, where, in demonstrating the | | |
| compliance of a high-risk AI system with the | | |
| requirements set out in Chapter 2 of this Title, | | |
| the provider has applied harmonised standards | | |
| referred to in Article 40, or, where applicable, | | |
| common specifications referred to in Article 41, | | |
| the provider shall <u>follow</u> opt for one of the | | |
| following procedures: | | |
| | | |
| (a) the conformity assessment procedure | | |
| based on internal control referred to in Annex | | |
| VI; <u>or</u> | | |
| | | |

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| (b) the conformity assessment procedure | | |
| based on assessment of the quality management | | |
| system and assessment of the technical | | |
| documentation, with the involvement of a | | |
| notified body, referred to in Annex VII. | | |
| Where, in demonstrating the compliance of a | | |
| high-risk AI system with the requirements set | | |
| out in Chapter 2 of this Title, the provider has | | |
| not applied or has applied only in part | | |
| harmonised standards referred to in Article 40, | | |
| or where such harmonised standards do not exist | | |
| and common specifications referred to in Article | | |
| 41 are not available, the provider shall follow | | |
| the conformity assessment procedure set out in | | |
| Annex VII. | | |
| | | |

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| For the purpose of the conformity assessment | | |
| procedure referred to in Annex VII, the provider | | |
| may choose any of the notified bodies. | | |
| However, when the system is intended to be put | | |
| into service by law enforcement, immigration or | | |
| asylum authorities as well as EU institutions, | | |
| bodies or agencies, the market surveillance | | |
| authority referred to in Article 63(5) or (6), as | | |
| applicable, shall act as a notified body. | | |
| | | |
| 2. For high-risk AI systems referred to in | | |
| points 2 to 8 of Annex III, providers shall follow | | |
| the conformity assessment procedure based on | | |
| internal control as referred to in Annex VI, | | |
| which does not provide for the involvement of a | | |
| notified body. For high-risk AI systems referred | | |
| to in point 5(b) of Annex III, placed on the | | |
| market or put into service by credit institutions | | |

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| 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. | | |
| | | |
| 3. For high-risk AI systems, to which legal | | |
| acts listed in Annex II, section A, apply, the | | |
| provider shall follow the relevant conformity | | |
| assessment as required under those legal acts. | | |
| The requirements set out in Chapter 2 of this | | |
| Title shall apply to those high-risk AI systems | | |
| and shall be part of that assessment. Points 4.3., | | |
| 4.4., 4.5. and the fifth paragraph of point 4.6 of | | |
| Annex VII shall also apply. | | |
| | | |
| For the purpose of that assessment, notified | | |
| bodies which have been notified under those | | |
| legal acts shall be entitled to control the | | |

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| conformity of the high-risk AI systems with the | | |
| requirements set out in Chapter 2 of this Title, | | |
| provided that the compliance of those notified | | |
| bodies with requirements laid down in Article | | |
| 33(4), (9) and (10) has been assessed in the | | |
| context of the notification procedure under those | | |
| legal acts. | | |
| | | |
| Where the legal acts listed in Annex II, section | | |
| A, enable the manufacturer of the product to opt | | |
| out from a third-party conformity assessment, | | |
| provided that that manufacturer has applied all | | |
| harmonised standards covering all the relevant | | |
| requirements, that manufacturer may make use | | |
| of that option only if he has also applied | | |
| harmonised standards or, where applicable, | | |
| common specifications referred to in Article 41, | | |

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| covering the requirements set out in Chapter 2 | | |
| of this Title. | | |
| | | |
| 4. High-risk AI systems shall undergo a new | | |
| conformity assessment procedure whenever they | | |
| are substantially modified, regardless of whether | | |
| the modified system is intended to be further | | |
| distributed or continues to be used by the | | |
| current user. | | |
| | | |
| For high-risk AI systems that continue to learn | | |
| after being placed on the market or put into | | |
| service, changes to the high-risk AI system and | | |
| its performance that have been pre-determined | | |
| by the provider at the moment of the initial | | |
| conformity assessment and are part of the | | |
| information contained in the technical | | |
| documentation referred to in point 2(f) of Annex | | |

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| IV, shall not constitute a substantial | | |
| modification. | | |
| | | |
| 5. The Commission is empowered to adopt | | |
| delegated acts in accordance with Article 73 for | | |
| the purpose of updating Annexes VI and Annex | | |
| VII in order to introduce elements of the | | |
| conformity assessment procedures that become | | |
| necessary in light of technical progress. | | |
| | | |
| 6. The Commission is empowered to adopt | | |
| delegated acts to amend paragraphs 1 and 2 in | | |
| order to subject high-risk AI systems referred to | | |
| in points 2 to 8 of Annex III to the conformity | | |
| assessment procedure referred to in Annex VII | | |
| or parts thereof. The Commission shall adopt | | |
| such delegated acts taking into account the | | |
| effectiveness of the conformity assessment | | |

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| procedure based on internal control referred to | | |
| in Annex VI in preventing or minimizing the | | |
| risks to health and safety and protection of | | |
| fundamental rights posed by such systems as | | |
| well as the availability of adequate capacities | | |
| and resources among notified bodies. | | |
| | | |
| Article 44 | | |
| Certificates | | |
| | | |
| 1. Certificates issued by notified bodies in | | |
| accordance with Annex VII shall be drawn-up | | |
| in an official Union language determined by the | | |
| Member State in which the notified body is | | |
| established or in an official Union language | | |
| otherwise acceptable to the notified body. | | |
| | | |

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| 2. Certificates shall be valid for the period | | |
| they indicate, which shall not exceed five years. | | |
| On application by the provider, the validity of a | | |
| certificate may be extended for further periods, | | |
| each not exceeding five years, based on a re- | | |
| assessment in accordance with the applicable | | |
| conformity assessment procedures. | | |
| | | |
| 3. Where a notified body finds that an AI | | |
| system no longer meets the requirements set out | | |
| in Chapter 2 of this Title, it shall, taking account | | |
| of the principle of proportionality, suspend or | | |
| withdraw the certificate issued or impose any | | |
| restrictions on it, unless compliance with those | | |
| requirements is ensured by appropriate | | |
| corrective action taken by the provider of the | | |
| system within an appropriate deadline set by the | | |

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| notified body. The notified body shall give | | |
| reasons for its decision. | | |
| | | |
| Article 45 | | |
| Appeal against decisions of notified bodies | | |
| | | |
| Member States shall ensure that an appeal | Member States shall ensure that an appeal | If the intention of this amendment is to reflect |
| procedure against decisions of the notified | procedure against decisions of the notified | the fact that such procedural laws are the |
| bodies is available to parties <u>having a legitimate</u> | bodies is available to parties having a legitimate | prerogative of national legislators, there does |
| interest in that decision. | interest in that decision. | not seem to be any reason to keep this clause. |
| A.c. 1. 46 | | |
| Article 46 | | |
| Information obligations of notified bodies | | |
| | | |
| 1. Notified bodies shall inform the notifying | | |
| authority of the following: | | |
| | | |

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| (a) any Union technical documentation | | |
| assessment certificates, any supplements to | | |
| those certificates, quality management system | | |
| approvals issued in accordance with the | | |
| requirements of Annex VII; | | |
| | | |
| (b) any refusal, restriction, suspension or | | |
| withdrawal of a Union technical documentation | | |
| assessment certificate or a quality management | | |
| system approval issued in accordance with the | | |
| requirements of Annex VII; | | |
| | | |
| (c) any circumstances affecting the scope of | | |
| or conditions for notification; | | |
| | | |
| (d) any request for information which they | | |
| have received from market surveillance | | |

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| authorities regarding conformity assessment | | |
| activities; | | |
| | | |
| (e) on request, conformity assessment | | |
| activities performed within the scope of their | | |
| notification and any other activity performed, | | |
| including cross-border activities and | | |
| subcontracting. | | |
| | | |
| 2. Each notified body shall inform the other | | |
| notified bodies of: | | |
| | | |
| (a) quality management system approvals | | |
| which it has refused, suspended or withdrawn, | | |
| and, upon request, of quality system approvals | | |
| which it has issued; | | |
| | | |

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| (b) EU technical documentation assessment | | |
| certificates or any supplements thereto which it | | |
| has refused, withdrawn, suspended or otherwise | | |
| restricted, and, upon request, of the certificates | | |
| and/or supplements thereto which it has issued. | | |
| | | |
| 3. Each notified body shall provide the other | | |
| notified bodies carrying out similar conformity | | |
| assessment activities covering the same artificial | | |
| intelligence technologies with relevant | | |
| information on issues relating to negative and, | | |
| on request, positive conformity assessment | | |
| results. | | |
| | | |
| Article 47 | | |
| Derogation from conformity assessment | | |
| procedure | | |
| | | |

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| 1. By way of derogation from Article 43, any | | |
| market surveillance authority may authorise the | | |
| placing on the market or putting into service of | | |
| specific high-risk AI systems within the territory | | |
| of the Member State concerned, for exceptional | | |
| reasons of public security or the protection of | | |
| life and health of persons, environmental | | |
| protection and the protection of key industrial | | |
| and infrastructural assets. That authorisation | | |
| shall be for a limited period of time while the | | |
| necessary conformity assessment procedures | | |
| are being carried out, taking into account the | | |
| exceptional reasons justifying the | | |
| derogation. while the necessary conformity | | |
| assessment procedures are being carried out, | | |
| and shall terminate once those procedures have | | |
| been completed. The completion of those | | |

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| procedures shall be undertaken without undue | | |
| delay. | | |
| | | |
| 1a. In a duly justified situation of urgency | | |
| for exceptional reasons of public security or | | |
| in case of specific, substantial and imminent | | |
| threat to the life or physical safety of natural | | |
| persons, law enforcement authorities may put | | |
| a specific high-risk AI system into service | | |
| without the authorisation referred to in | | |
| paragraph 1 provided that such | | |
| authorisation is requested during or after the | | |
| use without undue delay, and if such | | |
| authorisation is rejected, its use shall be | | |
| stopped with immediate effect. | | |
| | | |
| 2. The authorisation referred to in paragraph | | |
| 1 shall be issued only if the market surveillance | | |

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| authority concludes that the high-risk AI system | | |
| complies with the requirements of Chapter 2 of | | |
| this Title. The market surveillance authority | | |
| shall inform the Commission and the other | | |
| Member States of any authorisation issued | | |
| pursuant to paragraph 1. | | |
| | | |
| 3. Where, within 15 calendar days of receipt | | |
| of the information referred to in paragraph 2, no | | |
| objection has been raised by either a Member | | |
| State or the Commission in respect of an | | |
| authorisation issued by a market surveillance | | |
| authority of a Member State in accordance with | | |
| paragraph 1, that authorisation shall be deemed | | |
| justified. | | |
| | | |
| 4. Where, within 15 calendar days of receipt | | |
| of the notification referred to in paragraph 2, | | |

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| objections are raised by a Member State against | | |
| an authorisation issued by a market surveillance | | |
| authority of another Member State, or where the | | |
| Commission considers the authorisation to be | | |
| contrary to Union law or the conclusion of the | | |
| Member States regarding the compliance of the | | |
| system as referred to in paragraph 2 to be | | |
| unfounded, the Commission shall without delay | | |
| enter into consultation with the relevant | | |
| Member State; the operator(s) concerned shall | | |
| be consulted and have the possibility to present | | |
| their views. In view thereof, the Commission | | |
| shall decide whether the authorisation is | | |
| justified or not. The Commission shall address | | |
| its decision to the Member State concerned and | | |
| the relevant operator or operators. | | |
| | | |

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| 5. If the authorisation is considered | | |
| unjustified, this shall be withdrawn by the | | |
| market surveillance authority of the Member | | |
| State concerned. | | |
| | | |
| 6. By way of derogation from paragraphs 1 | | |
| to 5, for high-risk AI systems intended to be | | |
| used as safety components of devices, or which | | |
| are themselves devices, covered by Regulation | | |
| (EU) 2017/745 and Regulation (EU) 2017/746, | | |
| Article 59 of Regulation (EU) 2017/745 and | | |
| Article 54 of Regulation (EU) 2017/746 shall | | |
| apply also with regard to the derogation from | | |
| the conformity assessment of the compliance | | |
| with the requirements set out in Chapter 2 of | | |
| this Title. | | |
| | | |

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| Article 48 | | |
| EU declaration of conformity | | |
| | | |
| 1. The provider shall draw up a written <u>or</u> | | |
| electronically signed EU declaration of | | |
| conformity for each AI system and keep it at the | | |
| disposal of the national competent authorities | | |
| for 10 years after the AI system has been placed | | |
| on the market or put into service. The EU | | |
| declaration of conformity shall identify the AI | | |
| system for which it has been drawn up. A copy | | |
| of the EU declaration of conformity shall be | | |
| given submitted to the relevant national | | |
| competent authorities upon request. | | |
| | | |
| 2. The EU declaration of conformity shall | | |
| state that the high-risk AI system in question | | |
| meets the requirements set out in Chapter 2 of | | |

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| this Title. The EU declaration of conformity | | |
| shall contain the information set out in Annex V | | |
| and shall be translated into an official Union | | |
| language or a language that can be easily | | |
| understood by the national competent | | |
| authorities of required by the Member State(s) | | |
| in which the high-risk AI system is made | | |
| available. | | |
| | | |
| 3. Where high-risk AI systems are subject to | | |
| other Union harmonisation legislation which | | |
| also requires an EU declaration of conformity, a | | |
| single EU declaration of conformity shall be | | |
| drawn up in respect of all Union legislations | | |
| applicable to the high-risk AI system. The | | |
| declaration shall contain all the information | | |
| required for identification of the Union | | |

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| harmonisation legislation to which the | | |
| declaration relates. | | |
| | | |
| 4. By drawing up the EU declaration of | | |
| conformity, the provider shall assume | | |
| responsibility for compliance with the | | |
| requirements set out in Chapter 2 of this Title. | | |
| The provider shall keep the EU declaration of | | |
| conformity up-to-date as appropriate. | | |
| | | |
| 5. The Commission shall be empowered to | | |
| adopt delegated acts in accordance with Article | | |
| 73 for the purpose of updating the content of the | | |
| EU declaration of conformity set out in Annex | | |
| V in order to introduce elements that become | | |
| necessary in light of technical progress. | | |
| | | |

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| Article 49 | | |
| CE marking of conformity | | |
| | | |
| 1. The CE marking of conformity referred | | W |
| to in paragraph 1 of this Article shall be | | |
| subject to the general principles set out in | | |
| Article 30 of Regulation (EC) No 765/2008. | | |
| The CE marking shall be affixed visibly, legibly | | |
| and indelibly for high-risk AI systems. Where | | |
| that is not possible or not warranted on account | | |
| of the nature of the high-risk AI system, it shall | | |
| be affixed to the packaging or to the | | |
| accompanying documentation, as appropriate. | | |
| | | |
| 2. The CE marking referred to in paragraph 1 | | |
| of this Article shall be subject to the general | | |
| principles set out in Article 30 of Regulation | | |
| (EC) No 765/2008. The CE marking shall be | | |

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| affixed visibly, legibly and indelibly for high- | | |
| risk AI systems. Where that is not possible or | | |
| not warranted on account of the nature of the | | |
| high-risk AI system, it shall be affixed to the | | |
| packaging or to the accompanying | | |
| documentation, as appropriate. | | |
| | | |
| 3. Where applicable, the CE marking shall | | |
| be followed by the identification number of the | | |
| notified body responsible for the conformity | | |
| assessment procedures set out in Article 43. The | | |
| identification number shall also be indicated in | | |
| any promotional material which mentions that | | |
| the high-risk AI system fulfils the requirements | | |
| for CE marking. | | |
| | | |
| Article 50 | | |
| Document retention | | |
| | | |

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| The provider shall, for a period ending 10 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities: | | |
| (a) the technical documentation referred to in Article 11; | | |
| (b) the documentation concerning the quality management system referred to Article 17; | | |
| (c) the documentation concerning the changes approved by notified bodies where applicable; | | |
| (d) the decisions and other documents issued by the notified bodies where applicable; | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| (e) the EU declaration of conformity referred | | |
| to in Article 48. | | |
| | | |
| Article 51 | | |
| Registration | | |
| | | |
| Before placing on the market or putting into | | |
| service a high-risk AI system listed in Annex | | |
| <u>III</u> referred to in Article 6(23), the provider or, | | |
| where applicable, the authorised representative | | |
| shall register that system in the EU database | | |
| referred to in Article 60. | | |
| | | |
| TITLE IV | | |
| | | |
| TRANSPARENCY OBLIGATIONS | | |
| FOR CERTAIN AI SYSTEMS | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|--|
| | | |
| Article 52 | | In order to protect human dignity, tackle the |
| Transparency obligations for certain AI systems | | spread of AI-generated fake news, reduce |
| | | spamming and harassment by social media bots |
| | | and in general ensure further transparency |
| | | concerning textual content, we propose |
| | | introducing an additional transparency |
| | | obligation in art 52 for users who publish AI- |
| | | generated content, including text content. |
| | | Certain exceptions from the transparency |
| | | obligation may nevertheless be justified. |
| | | |
| 1. Providers shall ensure that AI systems | | We prefer the previous wording as it is more |
| intended to interact with natural persons are | | technology neutral. Being too prescriptive |
| designed and developed in such a way that | | halters innovation. The aim of this provision |
| those systems inform that natural persons are | | should be that the person is informed in a clear |
| informed that they are interacting with an AI | | manner that they are communicating with an AI |
| system, unless this is obvious from the point | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| view of a reasonable person from the | | system and providers should be able to choose |
| circumstances and the context of use. This | | how to achieve that. |
| obligation shall not apply to AI systems | | |
| authorised by law to detect, prevent, investigate | | While we welcome the intent to clarify how to |
| and prosecute criminal offences, unless those | | assess whether it is <i>obvious</i> that a natural person |
| systems are available for the public to report a | | is interacting with an AI system, it remains |
| criminal offence. | | doubtful whether the standard of "reasonable |
| | | person" ensures protection of those who might |
| | | struggle understanding the fact that they are |
| | | interacting with an AI system. We propose |
| | | further clarifying, in the article text or the |
| | | recitals, that this exemption must not be |
| | | interpreted in a manner that would enable to |
| | | systematically undermine the human dignity and |
| | | fundamental rights of people who lack |
| | | knowledge and exposure as regards AI systems. |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|----------|
| 2. Users of an emotion recognition system or | | |
| a biometric categorisation system shall inform | | |
| of the operation of the system the natural | | |
| persons exposed thereto. This obligation shall | | |
| not apply to AI systems used for biometric | | |
| categorisation, which are permitted by law to | | |
| detect, prevent and investigate criminal | | |
| offences, subject to appropriate safeguards | | |
| for the rights and freedoms of third parties. | | |
| | | |
| 2a. Users of an emotion recognition system | | |
| shall inform of the operation of the system | | |
| the natural persons exposed thereto. This | | |
| obligation shall not apply to AI systems used | | |
| for emotion recognition which are permitted | | |
| by law in the context of criminal | | |
| investigations. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|---|---|
| 3. Users of an AI system that generates or | | |
| manipulates image, audio or video content that | | |
| appreciably resembles existing persons, objects, | | |
| places or other entities or events and would | | |
| falsely appear to a person to be authentic or | | |
| truthful ('deep fake'), shall disclose that the | | |
| content has been artificially generated or | | |
| manipulated. | | |
| | | |
| However, the first subparagraph shall not apply | However, the first subparagraph shall not apply | We do not support the deletion of this |
| where the use is authorised by law to detect, | where the use is authorised by law to detect, | exception. Disclaimers are unnecessary when |
| prevent, investigate and prosecute criminal | prevent, investigate and prosecute criminal | people go to concerts or performances to |
| offences or it is necessary for the exercise of the | offences or it is necessary for the exercise of | experience new digital artforms. Does this mean |
| right to freedom of expression and the right to | the right to freedom of expression and the | that CGI in movies would also have to be |
| freedom of the arts and sciences guaranteed in | right to freedom of the arts and sciences | marked? |
| the Charter of Fundamental Rights of the EU, | guaranteed in the Charter of Fundamental | |
| and subject to appropriate safeguards for the | Rights of the EU, and subject to appropriate | |
| rights and freedoms of third parties. | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|---|----------|
| | safeguards for the rights and freedoms of third | |
| | parties. | |
| | | |
| 3a. The information referred to in | | |
| paragraphs 1 to 3 shall be provided to | | |
| natural persons in a clear and visible | | |
| distinguishable manner at the latest at the | | |
| time of the first interaction or exposure. | | |
| | | |
| 4. Paragraphs 1, 2 and 3 shall not affect the | | |
| requirements and obligations set out in Title III | | |
| of this Regulation. | | |
| | | |
| <u>TITLE IVA</u> | | |
| | | |
| GENERAL PURPOSE AI SYSTEMS | | |
| | | |
| Article 52a | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| General purpose AI systems | | |
| 1. The placing on the market, putting into service or use of general purpose AI systems shall not, by themselves only, make those systems subject to the provisions of this | | |
| Regulation. | | |
| 2. Any person who places on the market or puts into service under its own name or trademark or uses a general purpose AI system made available on the market or put | | |
| into service for an intended purpose that makes it subject to the provisions of this Regulation shall be considered the provider | | |
| of the AI system subject to the provisions of this Regulation. | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|----------|
| | | |
| 3. Paragraph 2 shall apply, mutatis | | |
| mutandis, to any person who integrates a | | |
| general purpose AI system made available on | | |
| the market, with or without modifying it, into | | |
| an AI system whose intended purpose makes | | |
| it subject to the provisions of this Regulation. | | |
| | | |
| 4. The provisions of this Article shall | | |
| apply irrespective of whether the general | | |
| purpose AI system is open source software or | | |
| not. | | |
| | | |
| TITLE V | | |
| | | |
| | | |
| MEASURES IN SUPPORT OF | | |
| INNOVATION | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|---|
| | | |
| Article 53 | | We are concerned that the new text is too |
| AI regulatory sandboxes | | prescriptive and not flexible enough to allow |
| | | innovation. We would prefer a more horisontal |
| | | framework, which would be more futureproof. |
| | | We prefer to see a more general description of |
| | | the sandboxes, followed by a guidance |
| | | document, in order to prevent regulatory lock- |
| | | in. |
| | | Additionally, we would like to see an |
| | | experimentation clause in this article, in which |
| | | real world testing and sandboxes can be based |
| | | as we see the two must go hand-in-hand for |
| | | most effective use of sandboxes. |
| | | |
| 1. 1. AI regulatory sandboxes <u>established by</u> | | Testing in real world conditions should be |
| one or more Member States competent | | possible within the sandbox. This is in line with |
| authorities or the European Data Protection | | Council Conclusions on regulatory sandboxes |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|---|
| Supervisor shall provide a controlled | | and experimentation clauses from November |
| environment that facilitates thefor the | | 2020. |
| development, testing and validation of | | |
| innovative AI systems, for a limited time before | | |
| their placement on the market or putting into | | |
| service pursuant to a specific plan. This shall | | |
| take place under the direct supervision and | | |
| guidance by the national competent authorities | | |
| and, where appropriate, in cooperation with | | |
| other relevant national authorities, or by the | | |
| European Data Protection Supervisor in | | |
| relation to AI systems provided by the EU | | |
| institutions, bodies and agencies. with a view | | |
| to ensuring compliance with the requirements of | | |
| this Regulation and, where relevant, other Union | | |
| and Member States legislation supervised within | | |
| the sandbox. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| 1a. The national competent authority or | | |
| the European Data Protection Supervisor, as | | |
| appropriate, may also supervise testing in | | |
| real world conditions upon the request of | | |
| participants in the sandbox. | | |
| | | |
| 1b. The establishment of AI regulatory | | |
| sandboxes as defined in paragraph 1 shall | | |
| aim to contribute to the following objectives: | | |
| | | |
| a) <u>foster innovation and competiveness</u> | | |
| and facilitate the development of an AI | | |
| ecosystem; | | |
| | | |
| b) <u>facilitate and accelerate access to the</u> | | |
| Union market for AI systems, including | | |
| provided by small and medium enterprises | | |
| (SMEs) and start-ups; | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| | | |
| c) <u>improve legal certainty through</u> | | |
| cooperation with the authorities involved in | | |
| the AI regulatory sandbox with a view to | | |
| ensuring compliance with this Regulation | | |
| and, where appropriate, with other Union | | |
| and Member States legislation; | | |
| | | |
| d) enhance authorities' understanding of | | |
| the opportunities and risks of AI systems as | | |
| well as of the suitability and effectiveness of | | |
| the measures for preventing and mitigating | | |
| those risks; | | |
| | | |
| e) <u>contribute to the uniform and effective</u> | | |
| implementation of this Regulation and, where | | |
| appropriate, its swift adaptation, notably as | | |
| regards the techniques in Annex I, the high- | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|---|---------------------------------------|
| risk AI systems in Annex III, the technical | | |
| documentation in Annex IV; | | |
| | | |
| f) contribute to the development or | | |
| update of harmonised standards and | | |
| common specifications referred to in Articles | | |
| 40 and 41 and their uptake by providers. | | |
| | | |
| 2. The AI regulatory sandboxes may be | 2. The AI regulatory sandboxes may be | The deleted sentence does not add any |
| established upon the decision of the national | established upon the decision of the national | considerable value to the AIA. |
| competent authorities, including jointly with | competent authorities, including jointly with | |
| those from other Member States, or by the | those from other Member States, or by the | |
| European Data Protection Supervisor. They | European Data Protection Supervisor. They | |
| may be established upon request of any | may be established upon request of any | |
| provider or prospective provider having an | provider or prospective provider having an | |
| interest in participating in the sandbox, or at | interest in participating in the sandbox, or at | |
| the sole initiative of the national competent | the sole initiative of the national competent | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|---|----------|
| authorities or the European Data Protection | authorities or the European Data Protection | |
| Supervisor. | Supervisor. | |
| | | |
| Member States shall ensure that to the | | |
| extent the innovative AI systems involve the | | |
| processing of personal data or otherwise fall | | |
| under the supervisory remit of other national | | |
| authorities or competent authorities providing or | | |
| supporting access to data, the national data | | |
| protection authorities and those other national | | |
| authorities are associated to the operation of the | | |
| AI regulatory sandbox. | | |
| | | |
| As appropriate, national competent | | |
| authorities may allow for the involvement in | | |
| the AI regulatory sandbox of other actors | | |
| within the AI ecosystem such as national or | | |
| European standardisation organisations, | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|---|---|
| notified bodies, testing and experimentation | | |
| facilities, research and experimentation labs | | |
| and innovation hubs. | | |
| | | |
| 2a. Access to the AI regulatory sandboxes | 2a. Access to the AI regulatory sandboxes | It seems reasonable to clarify in this clause that, |
| and supervision and guidance by the relevant | and supervision and guidance by the relevant | by default, the sandbox should be provided free |
| authorities shall be free of charge, without | authorities shall be free of charge, without | of charge. However, it remains unclear why any |
| prejudice to exceptional costs that national | prejudice to exceptional costs that national | of the other aspects covered in this clause |
| competent authorities may recover in a fair | competent authorities may recover in a fair | require to be regulated in the AIA. Questions |
| and proportionate manner. It shall be open | and proportionate manner. It shall be open | such as maximum participation period or the |
| to any provider or prospective provider of an | to any provider or prospective provider of an | details of the plan agreed between the |
| AI systemwho fulfils the eligibility and | AI systemwho fulfils the eligibility and | participant and sandbox could remain in the |
| selection criteria referred to in paragraph | selection criteria referred to in paragraph | discretion of the competent authority |
| 6(a) and who has been selected by the | 6(a) and who has been selected by the | establishing the sandbox (and steered by the |
| national competent authorities or by the | national competent authorities or by the | good practices and recommendation created |
| European Data Protection Supervisor | European Data Protection Supervisor | within the framework of the European Artificial |
| following the selection procedure referred to | following the selection procedure referred to | Intelligence Board). |
| in paragraph 6(b). Providers or prospective | in paragraph 6(b). Providers or prospective | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|--|--|
| providers may also submit applications in | providers may also submit applications in | |
| partnership with users or any other relevant | partnership with users or any other relevant | |
| third parties. | third parties. | |
| | | |
| Participation in the AI regulatory | Participation in the AI regulatory sandbox | |
| sandbox shall be limited to a period that is | shall be limited to a period that is | |
| appropriate to the complexity and scale of | appropriate to the complexity and scale of | |
| the project in any case not longer than a | the project in any case not longer than a | |
| maximum period of 2 years, starting | maximum period of 2 years, starting | |
| upon the notification of the selection decision. | upon the notification of the selection decision. | |
| The participation may be extended for | The participation may be extended for | |
| up to 1 more year. | up to 1 more year. | |
| | | |
| Participation in the AI regulatory | Participation in the AI regulatory sandbox | We support the requirement to have a plan but it |
| sandbox shall be based on a specific plan | shall be based on a specific plan agreed | should be more dynamic and not prescribe by a |
| agreed between the participant(s) and the | between the participant(s) and the | legal act. In current form, the text is too |
| national competent authoritie(s) or the | national competent authoritie(s) or the | prescriptive and not future proof. |
| European Data Protection Supervisor, | European Data Protection Supervisor, | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|---|----------|
| as applicable. The plan shall contain as a | as applicable. The plan shall contain as a | |
| minimum the following: | minimum the following: | |
| | | |
| a) <u>description of the participant(s)</u> | a) description of the participant(s) | |
| involved and their roles, the envisaged AI | involved and their roles, the envisaged AI | |
| system and its intended purpose, and | system and its intended purpose, and | |
| relevant development, testing and validation | relevant development, testing and validation | |
| process; | process; | |
| | | |
| b) the specific regulatory issues at stake | b) the specific regulatory issues at stake | |
| and the guidance that is expected from the | and the guidance that is expected from the | |
| authorities supervising the AI regulatory | authorities supervising the AI regulatory | |
| sandbox; | sandbox; | |
| | | |
| c) the specific modalities of the | e) the specific modalities of the | |
| collaboration between the participant(s) and | collaboration between the participant(s) and | |
| the authoritie(s), as well as any other actor | the authoritie(s), as well as any other actor | |
| involved in the AI regulatory sandbox; | involved in the AI regulatory sandbox; | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|---|--|
| d) <u>a risk management and monitoring</u> mechanism to identify, prevent and mitigate any risk referred to in Article 9(2)(a); | d) <u>a risk management and monitoring</u> <u>mechanism to identify, prevent and mitigate</u> <u>any risk referred to in Article 9(2)(a);</u> | |
| e) the key milestones to be completed by the participant(s) for the AI system to be considered ready to exit from the regulatory sandbox. | e) the key milestones to be completed by the participant(s) for the AI system to be considered ready to exit from the regulatory sandbox. | |
| 3. The <u>participation in the</u> AI regulatory sandboxes shall not affect the supervisory and corrective powers of the <u>competent</u> authorities <u>supervising the sandbox</u> . Any significant risks to health and safety and fundamental rights identified during the development and testing of such systems shall result in immediate mitigation and, failing that, in the suspension of | | We support this provision and believe it is moving in the right direction in fostering innovation. |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|----------|
| the development and testing process until such | | |
| mitigation takes place. However, provided that | | |
| the participant(s) respect the sandbox plan | | |
| and the terms and conditions for their | | ~ |
| participation as referred to in paragraph 6(c) | | |
| and follow in good faith the guidance given | | |
| by the authorities, no administrative | | |
| enforcement action shall be taken by the | | |
| authorities for infringement of applicable | | |
| Union or Member State legislation. | | |
| | | |
| 4. The pParticipants in the AI regulatory | | |
| sandbox remain liable under applicable Union | | |
| and Member States liability legislation for any | | |
| harm damage caused inflicted on third parties | | |
| in the course of their participation as a result | | |
| from the experimentation taking place in the an | | |
| AI-regulatory sandbox. | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|--|--|
| | | |
| 4a. The AI regulatory sandboxes shall be | 4a. The AI regulatory sandboxes shall be | While EE fully supports effective cross-border |
| designed and implemented in such a way | designed and implemented in such a way | cooperation between AI sandboxes, Article |
| that, where relevant, they facilitate cross- | that, where relevant, they facilitate cross- | 53(5) already regulates coordinating activities |
| border cooperation between national | border cooperation between national | and cooperation within the framework of the |
| competent authorities and synergies with | competent authorities and synergies with | European Artificial Intelligence Board. Creating |
| relevant sectoral regulatory sandboxes. | relevant sectoral regulatory sandboxes. | a requirement to design and implement the |
| Cooperation may also be envisaged with | Cooperation may also be envisaged with | sandbox in such a way that "facilitates cross- |
| third countries outside the Union establishing | third countries outside the Union establishing | border cooperation" seems unnecessary. |
| mechanisms to support AI innovation. | mechanisms to support AI innovation. | |
| | | |
| 5. Member States' National competent | | |
| authorities that have established AI regulatory | | |
| sandboxes and the European Data Protection | | |
| <u>Supervisor</u> shall coordinate their activities and | | |
| cooperate within the framework of the European | | |
| Artificial Intelligence Board. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| They shall publish on their websites | | |
| submit annual reports to the Board and the | | |
| Commission on the results from the | | |
| implementation of those sandboxes, including | | |
| good practices, lessons learnt and | | |
| recommendations on their setup and, where | | |
| relevant, on the application of this Regulation | | |
| and other Union legislation supervised within | | |
| the sandbox. Those annual reports shall be | | |
| submitted to the AI Board which shall | | |
| publish on its website a summary of all good | | |
| practices, lessons learnt and | | |
| recommendations. | | |
| | | |
| 5b. The Commission shall ensure that | | |
| information about AI regulatory sandboxes, | | |
| including about those established under this | | |
| Article, is available through a single | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| information platform as referred to in Article | | |
| <u>55(3)(b).</u> | | |
| | | |
| 6. The detailed modalities and the | | |
| conditions for the establishment and of the | | |
| operation of the AI regulatory_sandboxes <u>under</u> | | |
| this Regulation, including the eligibility criteria | | |
| and the procedure for the application, selection, | | |
| participation and exiting from the sandbox, and | | |
| the rights and obligations of the participants | | |
| shall be set out in implementing acts. Those | | |
| implementing acts shall be adopted through | | |
| implementing acts in accordance with the | | |
| examination procedure referred to in Article | | |
| 74(2). | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|--|
| Those implementing acts shall include | | As a general remark, the eligibility criteria and |
| general common rules on the following | | general common rules of the sandboxes should |
| issues: | | remain flexible. Notably, they should not limit |
| | · · | MSs from providing AI regulatory sandbox also |
| | | to early stage projects nor unnecessarily restrict |
| | | MSs in determining the scope and modalities of |
| | | the collaboration between participant and |
| | | competent authorities. |
| | | |
| a) the eligibility and selection criteria for | | |
| participation in the regulatory sandbox; | | |
| | | |
| b) the procedure for the application, | | |
| selection, participation, monitoring and | | |
| exiting from the sandbox, including | | |
| templates of all relevant documents; | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|----------|
| c) the terms and conditions applicable to | | |
| the participants, including in relation to their | | |
| collaboration with the authorities supervising | | |
| the sandbox, as well as the conditions for | | |
| suspension and termination of the | | |
| participation in the sandbox; | | |
| | | |
| d) the modalities for the involvement in | | |
| the AI regulatory sandbox of other national | | |
| authorities and other actors within the AI | | |
| ecosystem; | | |
| | | |
| e) the modalities and procedures for cross- | | |
| border cooperation, including the | | |
| establishment and operation by two or more | | |
| Member States of cross-border AI regulatory | | |
| sandboxes. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| Article 54 | | |
| Further pProcessing of personal data for | | |
| developing certain AI systems in the public | | |
| interest in the AI regulatory sandbox | | |
| | | |
| 1. In the AI regulatory sandbox personal data | | |
| lawfully collected for other purposes shall may | | |
| be processed for the purposes of developing and | | |
| testing certain innovative AI systems in the | | |
| sandbox under the following cumulative | | |
| conditions: | | |
| | | |
| (a) the innovative AI systems shall be | | |
| developed for safeguarding substantial public | | |
| interest in one or more of the following areas: | | |
| | | |
| (i) the prevention, investigation, detection or | | |
| prosecution of criminal offences or the | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| execution of criminal penalties, including the | | |
| safeguarding against and the prevention of | | |
| threats to public security, under the control and | | |
| responsibility of the competent authorities. The | | |
| processing shall be based on Member State or | | |
| Union law; | | |
| | | |
| (ii) public safety and public health, including | | |
| disease prevention, control and treatment of | | |
| disease and improvement of health care | | |
| systems; | | |
| | | |
| (iii) a high level of protection and | | |
| improvement of the quality of the environment; | | |
| 1, | | |
| (iv) a high level of efficiency and quality of | | |
| public administration and public services. | | |
| public administration and public services. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|----------|
| (b) the data processed are necessary for | | |
| complying with one or more of the requirements | | |
| referred to in Title III, Chapter 2 where those | | |
| requirements cannot be effectively fulfilled by | | |
| processing anonymised, synthetic or other non- | | |
| personal data; | | |
| | | |
| (c) there are effective monitoring mechanisms | | |
| to identify if any high risks to the fundamental | | |
| <u>rights and freedoms</u> of the data subjects, <u>as</u> | | |
| referred to in Article 35 of Regulation (EU) | | |
| 2016/679 and in Article 35 of Regulation (EU) | | |
| 2018/1725, may arise during the sandbox | | |
| experimentation as well as response mechanism | | |
| to promptly mitigate those risks and, where | | |
| necessary, stop the processing; | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|--|--|
| (d) any personal data to be processed in the | | |
| context of the sandbox are in a functionally | | |
| separate, isolated and protected data processing | | |
| environment under the control of the | | |
| participants and only authorised persons have | | |
| access to that data; | | |
| | | |
| (e) any personal data processed are not to be | (e) any personal data processed are not to be | Cross-border cooperation should not be |
| transmitted, transferred or otherwise accessed | transmitted, transferred or otherwise accessed | restricted. We do not see that this paragraph is |
| by other parties that are not participants in | by other parties that are not participants in | in line with the EU's international obligations or |
| the sandbox nor transferred to a third | the sandbox nor transferred to a third | international trade policies. Therefore, we |
| country outside the Union or an international | country outside the Union or an international | suggest deleting this part of the paragraph. |
| organisation; | organisation; | |
| | | |
| (f) any processing of personal data in the | | |
| context of the sandbox-do not lead to measures | | |
| or decisions affecting the data subjects; shall | | |
| not affect the application of the rights of the | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|----------|
| data subjects as provided for under Union | | |
| law on the protection of personal data, in | | |
| particular in Article 22 of Regulation (EU) | | |
| 2016/679 and Article 24 of Regulation (EU) | | |
| <u>2018/1725;</u> | | |
| | | |
| (g) any personal data processed in the context | | |
| of the sandbox are protected by means of | | |
| appropriate technical and organisational | | |
| measures and deleted once the participation in | | |
| the sandbox has terminated or the personal data | | |
| has reached the end of its retention period; | | |
| | | |
| (h) the logs of the processing of personal data | | |
| in the context of the sandbox are kept for the | | |
| duration of the participation in the sandbox and | | |
| 1 year after its termination, solely for the | | |
| purpose of and only as long as necessary for | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| fulfilling accountability and documentation | | |
| obligations under this Article or other | | |
| application Union or Member States legislation; | | |
| | | |
| (i) complete and detailed description of the | | |
| process and rationale behind the training, testing | | |
| and validation of the AI system is kept together | | |
| with the testing results as part of the technical | | |
| documentation in Annex IV; | | |
| | | |
| (j) a short summary of the AI project | | |
| developed in the sandbox, its objectives and | | |
| expected results published on the website of the | | |
| competent authorities. | | |
| | | |
| 1a. For the purpose of prevention, | | |
| investigation, detection or prosecution of | | |
| criminal offences or the execution of criminal | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| penalties, including the safeguarding against | | |
| and the prevention of threats to public | | |
| security, under the control and responsibility | | |
| of law enforcement authorities, the | | |
| processing of personal data in AI regulatory | | |
| sandboxes shall be based on a specific | | |
| Member State or Union law and subject to | | |
| the same cumulative conditions as referred to | | |
| in paragraph 1. | | |
| | | |
| 2. Paragraph 1 is without prejudice to Union | | |
| or Member States legislation excluding | | |
| processing for other purposes than those | | |
| explicitly mentioned in that legislation. | | |
| | | |
| Article 54a | | We strongly support integrating Article 54a into |
| | | Article 53, in order to clearly allow testing in |
| | | real world conditions is possible within the AI |

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| | | regulatory sandboxes. This would streamline the |
| | | Regulation with Council Conclusions on |
| | | regulatory sandboxes and experimentation |
| | · · | clauses from November 2020. Furthermore, we |
| | | believe real time testing to provide actual value |
| | | for using sandboxes and therefore to not support |
| | | keeping the idea of real-life testing separate. |
| | | |
| Testing of high-risk AI systems in real world | | |
| <u>conditions</u> | | |
| | | |
| 1. Testing of AI systems in real world | | |
| conditions may be conducted by providers or | | |
| prospective providers of high-risk AI systems | | |
| listed in Annex III, in accordance with the | | |
| provisions of this Article and the real-world | | |
| testing plan referred to in this Article. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| The detailed elements of the real-world | | |
| testing plan shall be specified in | | |
| implementing acts adopted by the | | |
| Commission in accordance with the | | |
| examination procedure referred to in Article | | |
| <u>74(2).</u> | | |
| | | |
| This provision shall be without | | |
| prejudice to Union or Member State | | |
| legislation for the testing in real world | | |
| conditions of high-risk AI systems related to | | |
| products covered by legislation listed in | | |
| Annex II. | | |
| | | |
| 2. Providers or prospective providers may | | |
| conduct testing of high-risk AI systems | | |
| referred to in Annex III in real world | | |
| conditions at any time before the placing on | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| the market or putting into service of the AI | | |
| system on their own or in partnership with | | |
| one or more prospective users. | | |
| | | |
| The testing in real world conditions | | |
| under this Article may occur in the course of | | |
| the participation in a AI regulatory sandbox | | |
| under the conditions specified in Article | | |
| 53(1a). In such a case, supervision and | | |
| guidance by the national competent | | |
| authorities or, where applicable, the | | |
| European Data Protection Supervisor, may | | |
| be extended to the testing in real world | | |
| conditions. | | |
| | | |
| 3. The testing of high-risk AI systems in | | |
| real world conditions under this Article shall | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| be without prejudice to ethical review that | | |
| may be required by national or Union law. | | |
| | | |
| 4. Providers or prospective providers may | | We are concerned with the high barriers that |
| conduct the testing in real world conditions | | these requirements create for testing AI systems |
| only where all of the following conditions are | | in the real world. The immediate supervision by |
| met: | | a competent authority and other safeguards of |
| | | sandboxes already ensure that any risks to |
| | | fundamental rights in sandboxes remain limited. |
| | | A far greater risk occurs if providers begin to |
| | | avoid sandboxes or real-life testing altogether |
| | | due to overly extensive and time-consuming |
| | | entry procedure. |
| | | |
| (a) the provider or prospective provider | | |
| has drawn up a real-world testing plan and | | |
| submitted it to the market surveillance | | |
| authority in the Member State(s) where the | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| testing in real world conditions is to be | | |
| conducted or the European Data Protection | | |
| Supervisor, as applicable; | | |
| | | |
| (b) the market surveillance authority in | (b) the market surveillance authority in the | |
| the Member State(s) where the testing in real | Member State(s) where the testing in real | |
| world conditions is to be conducted or to the | world conditions is to be conducted or to the | |
| European Data Protection Supervisor, as | European Data Protection Supervisor, as | |
| applicable, have not objected to the testing | applicable, have not objected to the testing | |
| within 30 days after its submission; | within 30 days after its submission; | |
| | | |
| (c) the provider or prospective provider | | |
| or has registered the testing in real world | | |
| conditions in the EU database referred to in | | |
| Article 60(6) with a Union-wide unique single | | |
| identification number and the information | | |
| specified in Annex VIIIa; | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| (d) the provider or prospective provider | | |
| conducting the testing in real world | | |
| conditions is established in the Union or it | | |
| has appointed a legal representative for the | | |
| purpose of the testing in real world | | |
| conditions who is established in the Union; | | |
| | | |
| (e) data collected and processed for the | | |
| purpose of the testing in real world | | |
| conditions shall not be transferred to | | |
| countries outside the Union, unless the | | |
| transfer and the processing provides | | |
| equivalent safeguards to those provided | | |
| under Union law; | | |
| | | |
| (f) the testing in real world conditions | | |
| does not last longer than necessary to achieve | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| its objectives and in any case not longer than | | |
| 12 months; | | |
| | | |
| (g) the testing in real world conditions | | |
| does not involve persons belonging to | | |
| vulnerable groups, unless that testing is | | |
| essential with respect to those vulnerable | | |
| groups insofar as data of comparable validity | | |
| cannot be obtained through testing in real | | |
| conditions on other persons or by other | | |
| methods; | | |
| | | |
| (h) the testing in real world conditions | | |
| is designed to involve as little inconvenience | | |
| as possible for the subjects of that testing; | | |
| such possible inconvenience shall be | | |
| specifically anticipated and defined by the | | |
| provider or prospective provider in the real- | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| world testing plan, monitored and possibly | | |
| mitigated in the course of the testing; | | |
| | | |
| (i) where a provider or prospective | | |
| provider organises the testing in real world | | |
| conditions in cooperation with one or more | | |
| prospective users, the latter have been | | |
| informed of all aspects of the testing that are | | |
| relevant to their decision to participate, | | |
| including the instructions of use of the AI | | |
| system referred to in Article 13; the provider | | |
| or prospective provider and the user(s) shall | | |
| conclude an agreement specifying their roles | | |
| and responsibilities with a view to ensuring | | |
| compliance with the provisions for testing in | | |
| real world conditions under this Regulation | | |
| and other applicable Union and Member | | |
| States legislation; | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| | | |
| (i) the subjects of the testing in real | | |
| world conditions have given informed | | |
| consent in accordance with Article 64b; | | |
| | | |
| (k) the testing in real world conditions | | |
| is effectively overseen by the provider or | | |
| prospective provider and user(s) with | | |
| persons who are suitably qualified in the | | |
| relevant field and have the necessary | | |
| capacity, training and authority to perform | | |
| their tasks; | | |
| | | |
| (l) the predictions, recommendations or | | |
| decisions of the AI system can be effectively | | |
| reversed or disregarded. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| 5. Any subject of the testing in real world | | |
| conditions, or his or her legally designated | | |
| representative, as appropriate, may, without | | |
| any resulting detriment and without having | | ~ |
| to provide any justification, withdraw from | | |
| the testing at any time by revoking his or her | | |
| informed consent. The withdrawal of the | | |
| informed consent shall not affect the | | |
| activities already carried out and the use of | | |
| data obtained based on the informed consent | | |
| before its withdrawal. | | |
| | | |
| 6. Any serious incident or malfunctioning | | |
| identified in the course of the testing in real | | |
| world conditions shall be reported to the | | |
| national market surveillance authority in | | |
| accordance with Article 62 of this Regulation. | | |
| The provider or prospective provider or shall | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| adopt immediate mitigation measures or, | | |
| failing that, suspend the testing in real world | | |
| conditions until such mitigation takes place | | |
| or otherwise terminate it. The provider or | | |
| prospective provider shall establish a | | |
| procedure for the prompt recall of the AI | | |
| system upon such termination of the testing | | |
| in real world conditions. | | |
| | | |
| 7. Providers or prospective providers shall | | |
| notify the national market surveillance | | |
| authority in the Member State(s) where the | | |
| testing in real world conditions is to be | | |
| conducted or to the European Data | | |
| Protection Supervisor, as applicable, of the | | |
| suspension or termination of the testing in | | |
| real world conditions and the final outcomes. | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|--|----------------------|----------|
| 8. The provider and prospective provider | | |
| shall be liable under applicable Union and | | |
| Member States liability legislation for any | | |
| damage caused to the subjects by reason of | | |
| their participation in the testing in real world | | |
| conditions. | | |
| | | |
| Article 54b | | |
| | | |
| Informed consent to participate in testing in | | |
| real world conditions | | |
| | | |
| 1. For the purpose of testing in real world | | |
| conditions under Article 54a, informed | | |
| consent shall be freely given by the subject of | | |
| testing prior to his or her participation in | | |
| such testing and after having been duly | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| informed with concise, clear, relevant, and | | |
| understandable information regarding: | | |
| | | |
| (i) the nature and objectives of the | | |
| testing in real world conditions and the | | |
| possible inconvenience that may be linked to | | |
| his or her participation; | | |
| | | |
| (ii) the conditions under which the | | |
| testing in real world conditions is to be | | |
| conducted, including the expected duration | | |
| of the subject's participation; | | |
| | | |
| (iii) the subject's rights and | | |
| guarantees regarding participation, in | | |
| particular his or her right to refuse to | | |
| participate in and the right to withdraw from | | |
| the field testing at any time without any | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| resulting detriment and without having to | | |
| provide any justification; | | |
| | | |
| (iv) the modalities for requesting the | | |
| reversal or the disregard of the predictions, | | |
| recommendations or decisions of the AI | | |
| system; | | |
| | | |
| (v) the Union-wide unique | | |
| single identification number of the testing in | | |
| real world conditions in accordance with | | |
| Article 54a(c) and the contact details of the | | |
| provider or its legal representative from | | |
| whom further information can be obtained. | | |
| | | |
| 2. The informed consent shall be dated | | |
| and documented and a copy shall be given to | | |
| the subject or his or her legal representative. | | |

| Presidency compromise | Drafting Suggestions | Comments |
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| | | |
| Article 55 | | |
| <u>Support mM</u> easures for operators, in particular | | |
| SMEs, including start-ups small-scale | | |
| providers and users | | |
| | | |
| 1. Member States shall undertake the | | |
| following actions: | | |
| | | |
| (a) provide small-scale SMEs providers, | | |
| including and start-ups, with priority access to | | |
| the AI regulatory sandboxes to the extent that | | |
| they fulfil the eligibility conditions and | | |
| selection criteria; | | |
| | | |
| (b) organise specific awareness raising and | | |
| <u>training</u> activities about the application of this | | |
| Regulation tailored to the needs of the small- | | |

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| Presidency compromise | Drafting Suggestions | Comments |
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| 3. The Commission shall undertake the | | We strongly support the establishment of these |
| following actions: | | measures. |
| | | |
| (a) <u>upon request of the AI Board, provide</u> | | |
| standardised documents for the areas | | |
| covered by this Regulation; | | |
| | | |
| (b) <u>develop and maintain a single</u> | | |
| information platform providing easy to use | | |
| information in relation to this Regulation for | | |
| all operators across the Union; | | |
| | | |
| (c) organise appropriate communication | | |
| campaigns to raise awareness about the | | |
| obligations arising from this Regulation; | | |
| | | |

| Presidency compromise | Drafting Suggestions | Comments |
|---|----------------------|----------|
| (d) evaluate and promote the convergence | | |
| of best practices in public procurement | | |
| procedures in relation to AI systems. | | |
| | | |
| Article 55a | | |
| | | |
| Derogations for specific operators | | |
| | | |
| The obligations laid down in Article 17 of this | | |
| Regulation shall not apply to | | |
| microenterprises as defined in Article 2(3) of | | |
| Commission Recommendation 2003/361/EC | | |
| concerning the definition of micro, small and | | |
| medium-sized enterprises. | | |
| | | |
| | | |
| | End | End |