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
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		

Presidency compromise	Drafting Suggestions	Comments
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	**shall ~~specify~~ ensure that standards are coherent,**	In general we see that a-d are not necessary. There is no need to regulate the standardization process further and this type of requirement can make it even more difficult to develop standards. These types of requirements would

Presidency compromise	Drafting Suggestions	Comments
and drafted in such a way that they aim to fulfil in particular the following objectives:		be more appropriate to impose on COM if they develop common specifications (as proposed in article 41.2). A compromise would be to try to remove the parts that we find most problematic, please compare with the suggestion under 40.2 (a) and comment on 40.2 (c).
a) ensure that AI systems placed on the market or put into service in the Union are safe and respect Union values and strenghten the Union's digital sovereignty;	**a) ensure that AI systems placed on the market or put into service in the Union are safe and respect Union values ~~and strenghten the Union's digital sovereignty;~~**	The reference to "EU digital sovereignty" should be deleted as there is a lack of clarity about what is meant by the term and does not have a legal basis in the constitutive treaties of the Union or any other legal act. We also question if it's standards that ensure digital sovereignty. The ambition behind the AI Act is to ensure citizens' trust and safeguard their health, safety and fundamental rights, why

Presidency compromise	Drafting Suggestions	Comments
		should the standards work for other political aims and would such standards be in line with existing agreements with WTO?
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).		If any of the points a-d should be retained, we would prefer this.
d) contribute to strengthening global cooperation on standardisation in the field of AI that is consistent with Union values and interests.		

Presidency compromise	Drafting Suggestions	Comments
<u>The Commission shall request the European standardisation organisations to provide evidence of their best efforts to fulfil the above objectives.</u>		This wording gives the impression that previous work with harmonised standards has not been in line with article 40.2. Or, international standards, adapted for the EU, do not guarantee EU's digital sovereignty. Is that even possible? The standardisation process is already a balance between different interests to achieve best possible outcome, if the MS are dissatisfied with the operation of the standardisation process this question shold be addressed through a review of 1025/2012 (horisontally).
Article 41 *Common specifications*		We are concerned that the introduction of sector specific processes will lead to fragmentation and therefore advocate for a horizontal approach through regular standardisation procedures.
1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards	~~1. Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards~~	Where the Commission considers relevant harmonised standards insufficient or that there is a need to address specific safety or fundamental

Presidency compromise	Drafting Suggestions	Comments
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 implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).	~~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 implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).~~	right concerns, the commission should work together with relevant standardization organizations so that they may address the problem. Please also note the different paraphrasing compared with the proposal on the machinery regulation.
2. ~~The Commission,~~ **W~~w~~**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.		Representation of "relevant bodies", who are they, how does one apply to be one and is there a process for when one is wrongfully excluded? Common specifications define technical requirements, according to Article 3.28 Common specifications are defined in a different way in Data Act, compared to the AIA.

Presidency compromise	Drafting Suggestions	Comments
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.		
4. Where providers do not comply with the common specifications referred to in paragraph 1, they shall duly justify **in the technical documentation referred to in Article 11** that they have adopted technical solutions that are at least equivalent thereto.		

Presidency compromise	Drafting Suggestions	Comments
Article 42 *Presumption of conformity with certain requirements*		
1. ~~Taking into account their intended purpose,~~ ~~h~~**H**igh-risk AI systems that have been trained and tested on data ~~concerning~~ **reflecting** the specific geographical, behavioural ~~and~~ **or** functional setting within which they are intended to be used shall be presumed to be in compliance with the **respective** requirement**s** set out in Article 10(4).		We support these changes.
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		

Presidency compromise	Drafting Suggestions	Comments
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.		
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		

[1] 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).

Presidency compromise	Drafting Suggestions	Comments
referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall ~~follow~~ **opt for** one of the following procedures:		
(a) the conformity assessment procedure based on internal control referred to in Annex VI; **or**		
(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.		What is meant by "involvement" and is it up to each MS to ensure this?
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		

Presidency compromise	Drafting Suggestions	Comments
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.		
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.		This is not in line with the general practice and would impede free competition and free movement on the single market. Market surveillance authorities cannot act as a notified body and be involved in confomity assesment activites this is against the guidelines in Blue Guide and we are not aware of such solution in other fields. The role of notified bodies should restriced to conformity assesment activies as

Presidency compromise	Drafting Suggestions	Comments
		legally described in other sectorspecific legislation.
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 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		

Presidency compromise	Drafting Suggestions	Comments
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 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.		

Presidency compromise	Drafting Suggestions	Comments
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, 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~~		We support these changes.

Presidency compromise	Drafting Suggestions	Comments
~~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 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~~		This procedure should be regulated through an implementing act. The commission is empowered to change Annex I, III, IV, V, VI and VII – the Commission will

Presidency compromise	Drafting Suggestions	Comments
~~conformity assessment procedures that become necessary~~ in light of technical progress.		have a lot of saying on the proposed AIA on the definitions and how compliance is achieved with that definition. Is that the role of the commission or a democratically chosen body? Or should it be managed by the market?
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 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		This procedure should be regulated through an implementing act.

Presidency compromise	Drafting Suggestions	Comments
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 a~~n~~ ~~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~~.		
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-		

Presidency compromise	Drafting Suggestions	Comments
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 notified body. The notified body shall give reasons for its decision.		
Article 45 *Appeal against decisions of notified bodies*		

Presidency compromise	Drafting Suggestions	Comments
Member States shall ensure that an appeal procedure against decisions of the notified bodies is available to parties ~~having a legitimate interest in that decision~~.	~~Member States shall ensure that a~~An appeal procedure against decisions of the notified bodies shall~~ould~~ be ~~is~~ available. ~~to parties having a legitimate interest in that decision.~~	According to common practice, there are already requirements in accordance with applicable standards for such bodies to have a process for receiving, evaluating and deciding on appeals. Several regulations are under negotiation at the same time as the AIA and there is a horizontal issue of appeals against decisions from the notified bodies. From an internal market perspective and for a more uniform product legislation, "MS" should therefore be deleted and the provision be adjusted in accordance with (EU) Decision 768/2008, which only states that there should be an appeal procedure.
Article 46 *Information obligations of notified bodies*		

Presidency compromise	Drafting Suggestions	Comments
1. Notified bodies shall inform the notifying authority of the following:		
(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;		

Presidency compromise	Drafting Suggestions	Comments
(d) any request for information which they have received from market surveillance 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;		Conformity assessment procedure includes more aspects than quality management systems, it is unclear why specifically quality management system shortcomings should be notified.

Presidency compromise	Drafting Suggestions	Comments
(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*		

Presidency compromise	Drafting Suggestions	Comments
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		

Presidency compromise	Drafting Suggestions	Comments
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.		We support these changes.
2. The authorisation referred to in paragraph 1 shall be issued only if the market surveillance		

Presidency compromise	Drafting Suggestions	Comments
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,	~~4. Where, within 15 calendar days of receipt of the notification referred to in paragraph 2,~~	Article 47.4 transfers to the Commission and the Member States to decide whether a

Presidency compromise	Drafting Suggestions	Comments
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.	~~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.~~	permit/approval is justified. If the regulation does not clearly define the requirements for approval, it can be problematic that different interpretations of both regulation and AI technology can delay the process even in important and exceptional cases. The infringement procedure should be sufficient.

Presidency compromise	Drafting Suggestions	Comments
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.		

Presidency compromise	Drafting Suggestions	Comments
Article 48 *EU declaration of conformity*		
1. The provider shall draw up a written **or 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		It seems to limit the options with regard to choice of language of the companies concerned. We would prefer to not limit the acceptable

Presidency compromise	Drafting Suggestions	Comments
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~~s~~ **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.		languages more than necessary to avoid increasing the administrative burden on companies. May also affect the once-only-principle.
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		See comment above.

Presidency compromise	Drafting Suggestions	Comments
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.		

Presidency compromise	Drafting Suggestions	Comments
Article 49 *CE marking of conformity*		We support these changes.
1. **The CE marking of conformity ~~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 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**		

Presidency compromise	Drafting Suggestions	Comments
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*~~		We support these changes.

Presidency compromise	Drafting Suggestions	Comments
~~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 III** ~~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.	This obligation shall not apply to AI systems in the area of law enforcement **or** This obligation shall not apply to AI systems intended to be used by law enforcement authorities	It is inappropriate for security services/law enforcement agencies to have to expose all their systems and methods in a public EU database. This is not reasonable from a law enforcement perspective as it means that authorities disclose their capabilities by entering this in the database.
TITLE IV		
TRANSPARENCY OBLIGATIONS FOR CERTAIN AI SYSTEMS		

Presidency compromise	Drafting Suggestions	Comments
Article 52 *Transparency obligations for certain AI systems*		We support these changes in most parts (ses comments bellow).
1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way **that those systems inform** ~~*that*~~ natural persons ~~are informed~~ that they are interacting with an AI system, unless this is obvious **from the point view of a reasonable person** from the circumstances and the context of use. This obligation shall not apply to AI systems authorised by law to detect, prevent, investigate and prosecute criminal offences, unless those systems are available for the public to report a criminal offence.	1. Providers shall ensure that AI systems intended to interact with natural persons are designed and developed in such a way **that those systems inform** ~~*that*~~ natural persons ~~are informed~~ that they are interacting with an AI system, unless this is obviously **unnecessary** ~~**from the point view of a reasonable person**~~ from the circumstances and the context of use.	The concept of "reasonable person" is not universal and thus makes the article more unclear.

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.		We support the proposed changes but would also like to see that the requirements for the form of the information should be consistent with the requirements for the form of information for data subjects under GDPR art. 12, either by the text being consistent or by a reference. **Art. 12.1 GDPR:** *The controller shall take appropriate measures to provide any information referred to in Articles 13 and 14 and any communication under Articles 15 to 22 and 34 relating to processing to the data subject in a concise, transparent, intelligible and easily accessible form, using clear and plain language, in particular for any information addressed specifically to a child. The information shall be provided in writing, or by other means, including, where appropriate, by electronic*

Presidency compromise	Drafting Suggestions	Comments
		means. *When requested by the data subject, the information may be provided orally, provided that the identity of the data subject is proven by other means.*
However, the first subparagraph shall not apply where the use is authorised by law to detect, prevent, investigate and prosecute criminal offences ~~or it is necessary for the exercise of the right to freedom of expression and the right to freedom of the arts and sciences guaranteed in the Charter of Fundamental Rights of the EU,~~ ~~and~~ subject to appropriate 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~~		We support the proposed changes but would also like to see that the requirements for the form of the information should be consistent

Presidency compromise	Drafting Suggestions	Comments
distinguishable manner at the latest at the time of the first interaction or exposure.		with the requirements for the form of information for data subjects under GDPR art. 12, either by the text being consistent or by a reference (see comment on 52.3)
4. Paragraphs 1, 2 and 3 shall not affect the requirements and obligations set out in Title III of this Regulation.		
~~**TITLE IVA**~~		
~~**GENERAL PURPOSE AI SYSTEMS**~~		
~~***Article 52a***~~		
~~***General purpose AI systems***~~		

Presidency compromise	Drafting Suggestions	Comments
~~**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.**~~		
~~**3. Paragraph 2 shall apply, mutatis mutandis, to any person who integrates a**~~		

Presidency compromise	Drafting Suggestions	Comments
~~**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		
Article 53 *AI regulatory sandboxes*		

Presidency compromise	Drafting Suggestions	Comments
1. 1. AI regulatory sandboxes ~~established by one or more Member States competent authorities or the European Data Protection Supervisor~~ shall provide a controlled environment ~~that facilitates the~~**for the** 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~~		The term "regulatory sandbox" should be subject to a definition. Furthermore, the provisions include very detailed obligations. Perhaps more suitable for implementing act to ensure swift adoption to keep up with technological developments or a more overall description of the sandboxes, followed by a guidance document.

Presidency compromise	Drafting Suggestions	Comments
~~this Regulation and, where relevant, other Union and Member States legislation supervised within the sandbox.~~		
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) foster innovation and competiveness and facilitate the development of an AI ecosystem;		

Presidency compromise	Drafting Suggestions	Comments
b) <u>facilitate and accelerate access to the Union market for AI systems, including provided by small and medium enterprises (SMEs) and start-ups;</u>		
c) <u>improve legal certainty through 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;</u>		
d) <u>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;</u>		

Presidency compromise	Drafting Suggestions	Comments
e) <u>contribute to the uniform and effective implementation of this Regulation and, where appropriate, its swift adaptation, notably as regards the techniques in Annex I, the high-risk AI systems in Annex III, the technical documentation in Annex IV;</u>		
f) <u>contribute to the development or update of harmonised standards and common specifications referred to in Articles 40 and 41 and their uptake by providers.</u>		
2. **<u>The AI regulatory sandboxes may be established upon the decision of the national competent authorities, including jointly with those from other Member States, or by the European Data Protection Supervisor. They may be established upon request of any</u>**		Not clear if each MS shall or could (according to best effort) establish sandboxes. To avoid competition between MS in EU and promote equal possibilities of innovation with EU, it would be preferable to have establishment of

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provider or prospective provider having an interest in participating in the sandbox, or at the sole initiative of the national competent authorities or the European Data Protection Supervisor.		sandboxes as a "shall" requirement in all MS. Maybe trough the Digital Europe Programme.
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		To avoid risk of leakage of trade secrets it would be recommendable that this is known

Presidency compromise	Drafting Suggestions	Comments
the AI regulatory sandbox of other actors within the AI ecosystem such as national or European standardisation organisations, notified bodies, testing and experimentation facilities, research and experimentation labs and innovation hubs.		when an enterprise joins the sandbox. And possible to, in certain circumstances, make it a more closed sandbox.
2a. Access to the AI regulatory sandboxes and supervision and guidance by the relevant authorities shall be free of charge, without prejudice to exceptional costs that national competent authorities may recover in a fair and proportionate manner. It shall be open to any provider or prospective provider of an AI systemwho fulfils the eligibility and selection criteria referred to in paragraph 6(a) and who has been selected by the national competent authorities or by the		The financing of the sandbox should be decided upon by each MS. By ensuring that each MS establish an effective procedure for sandboxes trough commen EU mesures (see comment under art. 53.2) a proportional entry fee will not become as big of a hindrance for the accesses to sandboxes.

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European Data Protection Supervisor following the selection procedure referred to in paragraph 6(b). Providers or prospective providers may also submit applications in partnership with users or any other relevant third parties.		
Participation in the AI regulatory sandbox shall be limited to a period that is appropriate to the complexity and scale of the project in any case not longer than a maximum period of 2 years, starting upon the notification of the selection decision. The participation may be extended for up to 1 more year.	**The participation may be extended on a yearly basis ~~for up to 1 more year~~.**	There will be cases for studies over longer periods and therefore a restriction to 3 years would exclude such studies.
Participation in the AI regulatory sandbox shall be based on a specific plan	**Participation in the AI regulatory sandbox shall be based on a specific plan agreed**	From a fundamental human rights perspective, it's crucial that the national data protection

Presidency compromise	Drafting Suggestions	Comments
agreed between the participant(s) and the national competent authoritie(s) or the European Data Protection Supervisor, as applicable. The plan shall contain as a minimum the following:	**between the participant(s) and the national competent authoritie(s) or the European Data Protection Supervisor, as applicable. The national data protection authorithy or authorites shall agree to the plan if personal data will be processed in the sandbox.**	authorities agree to the plan if the activities in the sandbox entail processing of personal data, especially given that the national DPA's are being stripped of their enforcement powers in relation to the activities in the sandbox if those activities are carried out in accordance with the plan.
a) description of the participant(s) involved and their roles, the envisaged AI system and its intended purpose, and relevant development, testing and validation process;		
b) the specific regulatory issues at stake and the guidance that is expected from the authorities supervising the AI regulatory sandbox;		

Presidency compromise	Drafting Suggestions	Comments
c) the specific modalities of the collaboration between the participant(s) and the authoritie(s), as well as any other actor involved in the AI regulatory sandbox;		
d) a risk management and monitoring mechanism to identify, prevent and mitigate any risk referred to in Article 9(2)(a);		
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.		
	f) if personal data will be processed in the sandbox, a description of the personal data that will be processed and the technical and organisational measures that will be	A minimum requirement relating to the processing of personal data in the sandbox needs to be introduced in the plan, given that the national data protection authorities are being

Presidency compromise	Drafting Suggestions	Comments
	implemented to protect the personal data that are being processed in the sandbox.	prohibited to resort to administrative enforcement action according to para 3 if the activities in the sandbox are carried out in accordance with the plan. Thus, a minimum requirement relating to processing of personal data needs to be introduced into the plan. This requirement aligns with what is stated in article 54.1(g).
3. The **participation in the** AI regulatory sandboxes shall not affect the supervisory and corrective powers of the ~~competent~~ authorities **supervising the sandbox**. ~~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 the development and testing process until such mitigation takes place.~~ **However, provided that**		

Presidency compromise	Drafting Suggestions	Comments
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 p**~~P~~articipants ~~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 designed and implemented in such a way that, where relevant, they facilitate cross-border cooperation between national competent authorities and synergies with relevant sectoral regulatory sandboxes. Cooperation may also be envisaged with third countries outside the Union establishing mechanisms to support AI innovation.		
5. ~~Member States'~~ **National** competent authorities that have established AI regulatory sandboxes **and the European Data Protection Supervisor** 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 55(3)(b).		
6. The **detailed** modalities and the conditions **for the establishment and** ~~of the~~ operation of the AI regulatory sandboxes **under 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 general common rules on the following issues:		
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;		
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;		

Presidency compromise	Drafting Suggestions	Comments
d) <u>the modalities for the involvement in the AI regulatory sandbox of other national authorities and other actors within the AI ecosystem;</u>	**d) <u>the modalities for the involvement in the AI regulatory sandbox of other national authorities and other actors ~~within the AI ecosystem~~;</u>**	It is unclear what is meant by "the AI ecosystem".
e) <u>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</u>.		
Article 54 *~~Further~~ ~~p~~**P***rocessing of personal data for developing certain AI systems in the public interest in the AI regulatory sandbox*		We support these changes. Will this not requir an added sentence in 2016/679 and 2016/680 that AIA allow for exemptions?

Presidency compromise	Drafting Suggestions	Comments
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 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~~		

Presidency compromise	Drafting Suggestions	Comments
~~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;		
(iv) a high level of efficiency and quality of public administration and public services.		
(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		

Presidency compromise	Drafting Suggestions	Comments
processing anonymised, synthetic or other non-personal data;		
(c) there are effective monitoring mechanisms to identify if any high risks to the ~~fundamental~~ **rights and freedoms** of the data subjects**, as 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;		
(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		

Presidency compromise	Drafting Suggestions	Comments
participants and only authorised persons have access to that data;		
(e) any personal data processed are not **to** be transmitted, transferred or otherwise accessed by other parties **that are not participants in the sandbox nor transferred to a third country outside the Union or an international 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 data subjects as provided for under Union law on the protection of personal data, in particular in Article 22 of Regulation (EU)**		

Presidency compromise	Drafting Suggestions	Comments
2016/679 and Article 24 of Regulation (EU) 2018/1725;		
(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;		
	(biss) other data, especially anonymized data not revealing personal data, including derived data (summative data, higher level representations) and methods (trained AI models, derived systems) may be preserved after being certified by the National competent authorities, or on their behalf.	To ensure that the methods developed, are not lost.
(h) the logs of the processing of personal data in the context of the sandbox are kept for the		

Presidency compromise	Drafting Suggestions	Comments
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 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.		

Presidency compromise	Drafting Suggestions	Comments
1a. For the purpose of 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, 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.~~		

Presidency compromise	Drafting Suggestions	Comments
Article 54a		We support futher innovative measures, but it's difficult to understand the difference between "real world testing" and "regulatory sandboxes". Given the short time frame it has not been possible to analyse the consequences of the proposed article to a full extent and Sweden do not today have sandboxes as decribed in art. 53. We could support an alignment where art. 53 and art. 54a are integrated.
Testing of high-risk AI systems in real world conditions		
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		

Presidency compromise	Drafting Suggestions	Comments
provisions of this Article and the real-world testing plan referred to in this Article.		
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 74(2).		Why implementing acts? Will the implementing acts be sector-specific? Why are they not included in Directive 2001/95/EC?
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.		Both NLF and OAL? If theses rules cover OAL, what will happen with the Swedish ordinance for trialling autonomous vehicles?

Presidency compromise	Drafting Suggestions	Comments
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 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.		

Presidency compromise	Drafting Suggestions	Comments
3. The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to ethical review that may be required by national or Union law.		
4. Providers or prospective providers may conduct the testing in real world conditions only where all of the following conditions are met:		
(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 testing in real world conditions is to be conducted or the European Data Protection Supervisor, as applicable;		

Presidency compromise	Drafting Suggestions	Comments
(b) the 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, have not objected to the testing 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;	This obligation shall not apply to AI systems in the area of law enforcement **or** This obligation shall not apply to AI systems intended to be used by law enforcement authorities	As peviously stated in Art. 43: it is inappropriate for security services/law enforcement agencies to have to expose all their systems and methods in a public EU database. This is not reasonable from a law enforcement perspective as it means that authorities disclose their capabilities by entering this in the database.

Presidency compromise	Drafting Suggestions	Comments
(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;		Is this necessary? This is covered by other EU-legislation?
(f) the testing in real world conditions does not last longer than necessary to achieve		12 months counting from when? From when the tesing plan was submitted to the market surveillance authority in the Member State(s) or

Presidency compromise	Drafting Suggestions	Comments
its objectives and in any case not longer than 12 months;		after the 30 days the surveillance authority had to object tot the plan? Why is the testing period limited to 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;		"does not involve **persons**" – should is state "persons", "natural persons" or even "personal data"? The wording is unclear.
(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		

Presidency compromise	Drafting Suggestions	Comments
provider or prospective provider in the real-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		

Presidency compromise	Drafting Suggestions	Comments
and other applicable Union and Member States legislation;		
(j) 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.		With regard to a (natural) person being able to withdraw his or her consent, but without affecting measures already taken, the legal basis becomes unclear since the relevant data may continue to be processed because the legal basis for consent no longer exists. Or is the data deleted and what is meant is that you can continue to use the model, ie the result of the use of personal data? The later should be a matter of course, otherwise it is impossible to base personal data processing for test activities on consent.
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		

Presidency compromise	Drafting Suggestions	Comments
accordance with Article 62 of this Regulation. The provider or prospective provider or shall 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		

Presidency compromise	Drafting Suggestions	Comments
suspension or termination of the testing in real world conditions and the final outcomes.		
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		The condition that the use of personal data for testing purposes only can be used based on the legal basis of consent is too strict. Without a description of the idea of such a provision makes it difficult to understand the purpose.

Presidency compromise	Drafting Suggestions	Comments
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 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;		

Presidency compromise	Drafting Suggestions	Comments
(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 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		

Presidency compromise	Drafting Suggestions	Comments
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.		
Article 55 ***Support m~~M~~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~~ SME**s** ~~providers~~**,** **including** ~~and~~ start-ups**,** with priority access to the AI regulatory sandboxes to the extent that		

Presidency compromise	Drafting Suggestions	Comments
they fulfil the eligibility ~~conditions~~ **and selection criteria**;		
(b) organise specific awareness raising **and training** activities about the application of this Regulation tailored to the needs of the ~~small-scale~~ **SMEs** ~~providers and users~~**, including start-ups**;		
(c) where appropriate, establish a dedicated channel for communication with ~~small-scale~~ **SMEs** ~~providers and user~~**, including start-ups,** ~~and other innovators~~ to provide ~~guidance~~ **advice** and respond to queries about the implementation of this Regulation.		
2. The specific interests and needs of the ~~small-scale~~ **SME** providers**, including start-**		We believe that there is a conflict between this provision and the requirement for non-

Presidency compromise	Drafting Suggestions	Comments
ups, shall be taken into account when setting the fees for conformity assessment under Article 43, reducing those fees proportionately to their size**,** ~~and~~ market size **and other relevant indicators**.		discrimination in ISO/IEC 17065. Notified bodies will have a hard time fulfilling the requirement for non-discrimination as well as reducing fees based on company size. Also difficult for our national authority to assess compliance for notified bodies with ISO/IEC 17065 in comparison with this provision.
3. The Commission shall undertake the following actions:		
(a) **upon request of the AI Board, provide standardised documents for the areas covered by this Regulation;**		
(b) **develop and maintain a single information platform providing easy to use**		

Presidency compromise	Drafting Suggestions	Comments
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;**		
(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		

Presidency compromise	Drafting Suggestions	Comments
Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises.		
	End	**End**