



EU AI Act 2024 1689

Artikel 60

VI

Article 60

Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes

1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.

The Commission shall, by means of implementing acts, specify the detailed elements of the real-world testing plan. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).

This paragraph shall be without prejudice to Union or national law on the testing in real world conditions of high-risk AI systems related to products covered by Union harmonisation legislation listed in Annex I.

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 the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.

3. The testing of high-risk AI systems in real world conditions under this Article shall be without prejudice to any ethical review that is required by Union or national 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 where the testing in real world conditions is to be conducted;

(b)

the market surveillance authority in the Member State where the testing in real world conditions

is to be conducted has approved the testing in real world conditions and the real-world testing plan; where the market surveillance authority has not provided an answer within 30 days, the testing in real world conditions and the real-world testing plan shall be understood to have been approved; where national law does not provide for a tacit approval, the testing in real world conditions shall remain subject to an authorisation;

(c)

the provider or prospective provider, with the exception of providers or prospective providers of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, and high-risk AI systems referred to in point 2 of Annex III has registered the testing in real world conditions in accordance with Article 71(4) with a Union-wide unique single identification number and with the information specified in Annex IX; the provider or prospective provider of high-risk AI systems referred to in points 1, 6 and 7 of Annex III in the areas of law enforcement, migration, asylum and border control management, has registered the testing in real-world conditions in the secure non-public section of the EU database according to Article 49(4), point (d), with a Union-wide unique single identification number and with the information specified therein; the provider or prospective provider of high-risk AI systems referred to in point 2 of Annex III has registered the testing in real-world conditions in accordance with Article 49(5);

(d)

the provider or prospective provider conducting the testing in real world conditions is established in the Union or has appointed a legal representative who is established in the Union;

(e)

data collected and processed for the purpose of the testing in real world conditions shall be transferred to third countries only provided that appropriate and applicable safeguards under Union law are implemented;

(f)

the testing in real world conditions does not last longer than necessary to achieve its objectives and in any case not longer than six months, which may be extended for an additional period of six months, subject to prior notification by the provider or prospective provider to the market surveillance authority, accompanied by an explanation of the need for such an extension;

(g)

the subjects of the testing in real world conditions who are persons belonging to vulnerable groups due to their age or disability, are appropriately protected;

(h)

where a provider or prospective provider organises the testing in real world conditions in cooperation with one or more deployers or prospective deployers, the latter have been informed of all aspects of the testing that are relevant to their decision to participate, and given the relevant instructions for use of the AI system referred to in Article 13; the provider or prospective provider and the deployer or prospective deployer 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 under other applicable Union and national law;

(i)

the subjects of the testing in real world conditions have given informed consent in accordance with Article 61, or in the case of law enforcement, where the seeking of informed consent would

prevent the AI system from being tested, the testing itself and the outcome of the testing in the real world conditions shall not have any negative effect on the subjects, and their personal data shall be deleted after the test is performed;

(j)

the testing in real world conditions is effectively overseen by the provider or prospective provider, as well as by deployers or prospective deployers through persons who are suitably qualified in the relevant field and have the necessary capacity, training and authority to perform their tasks;

(k)

the predictions, recommendations or decisions of the AI system can be effectively reversed and disregarded.

5. Any subjects of the testing in real world conditions, or their 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 their informed consent and may request the immediate and permanent deletion of their personal data. The withdrawal of the informed consent shall not affect the activities already carried out.

6. In accordance with Article 75, Member States shall confer on their market surveillance authorities the powers of requiring providers and prospective providers to provide information, of carrying out unannounced remote or on-site inspections, and of performing checks on the conduct of the testing in real world conditions and the related high-risk AI systems. Market surveillance authorities shall use those powers to ensure the safe development of testing in real world conditions.

7. Any serious incident identified in the course of the testing in real world conditions shall be reported to the national market surveillance authority in accordance with Article 73. The provider or prospective provider shall adopt immediate mitigation measures or, failing that, shall 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.

8. Providers or prospective providers shall notify the national market surveillance authority in the Member State where the testing in real world conditions is to be conducted of the suspension or termination of the testing in real world conditions and of the final outcomes.

9. The provider or prospective provider shall be liable under applicable Union and national liability law for any damage caused in the course of their testing in real world conditions.





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