



EU AI Act 2024 1689

Artikel 36

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Article 36

Changes to notifications

1. The notifying authority shall notify the Commission and the other Member States of any relevant changes to the notification of a notified body via the electronic notification tool referred to in Article 30(2).
2. The procedures laid down in Articles 29 and 30 shall apply to extensions of the scope of the notification.

For changes to the notification other than extensions of its scope, the procedures laid down in paragraphs (3) to (9) shall apply.

3. Where a notified body decides to cease its conformity assessment activities, it shall inform the notifying authority and the providers concerned as soon as possible and, in the case of a planned cessation, at least one year before ceasing its activities. The certificates of the notified body may remain valid for a period of nine months after cessation of the notified body's activities, on condition that another notified body has confirmed in writing that it will assume responsibilities for the high-risk AI systems covered by those certificates. The latter notified body shall complete a full assessment of the high-risk AI systems affected by the end of that nine-month-period before issuing new certificates for those systems. Where the notified body has ceased its activity, the notifying authority shall withdraw the designation.

4. Where a notifying authority has sufficient reason to consider that a notified body no longer meets the requirements laid down in Article 31, or that it is failing to fulfil its obligations, the notifying authority shall without delay investigate the matter with the utmost diligence. In that context, it shall inform the notified body concerned about the objections raised and give it the possibility to make its views known. If the notifying authority comes to the conclusion that the notified body no longer meets the requirements laid down in Article 31 or that it is failing to fulfil its obligations, it shall restrict, suspend or withdraw the designation as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

5. Where its designation has been suspended, restricted, or fully or partially withdrawn, the

notified body shall inform the providers concerned within 10 days.

6. In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall take appropriate steps to ensure that the files of the notified body concerned are kept, and to make them available to notifying authorities in other Member States and to market surveillance authorities at their request.

7. In the event of the restriction, suspension or withdrawal of a designation, the notifying authority shall:

(a)

assess the impact on the certificates issued by the notified body;

(b)

submit a report on its findings to the Commission and the other Member States within three months of having notified the changes to the designation;

(c)

require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued, in order to ensure the continuing conformity of high-risk AI systems on the market;

(d)

inform the Commission and the Member States about certificates the suspension or withdrawal of which it has required;

(e)

provide the national competent authorities of the Member State in which the provider has its registered place of business with all relevant information about the certificates of which it has required the suspension or withdrawal; that authority shall take the appropriate measures, where necessary, to avoid a potential risk to health, safety or fundamental rights.

8. With the exception of certificates unduly issued, and where a designation has been suspended or restricted, the certificates shall remain valid in one of the following circumstances:

(a)

the notifying authority has confirmed, within one month of the suspension or restriction, that there is no risk to health, safety or fundamental rights in relation to certificates affected by the suspension or restriction, and the notifying authority has outlined a timeline for actions to remedy the suspension or restriction; or

(b)

the notifying authority has confirmed that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension or restriction, and states whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction; in the event that the notifying authority determines that the notified body does not have the capability to support existing certificates issued, the provider of the system covered by the certificate shall confirm in writing to the national competent authorities of the Member State in which it has its registered place of business, within three months of the suspension or restriction, that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.

9. With the exception of certificates unduly issued, and where a designation has been

withdrawn, the certificates shall remain valid for a period of nine months under the following circumstances:

(a)

the national competent authority of the Member State in which the provider of the high-risk AI system covered by the certificate has its registered place of business has confirmed that there is no risk to health, safety or fundamental rights associated with the high-risk AI systems concerned; and

(b)

another notified body has confirmed in writing that it will assume immediate responsibility for those AI systems and completes its assessment within 12 months of the withdrawal of the designation.

In the circumstances referred to in the first subparagraph, the national competent authority of the Member State in which the provider of the system covered by the certificate has its place of business may extend the provisional validity of the certificates for additional periods of three months, which shall not exceed 12 months in total.

The national competent authority or the notified body assuming the functions of the notified body affected by the change of designation shall immediately inform the Commission, the other Member States and the other notified bodies thereof.



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