

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (Text with EEA relevance)

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

Article 21

Notifying authorities

1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 22

Requirements relating to notifying authorities

1 A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2 A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3 A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4 A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5 A notifying authority shall safeguard the confidentiality of the information it obtains.

6 A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 23

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 24

Requirements relating to notified bodies

1 For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2 A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of PPE which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4 A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, purchaser, owner, user or maintainer of the PPE which they assess, nor the representative of any of those parties. This does not preclude the use of assessed PPE that are necessary for the operations of the conformity assessment body or the use of such PPE for personal purposes.

A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes V, VII and VIII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind of PPE for which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- a personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- b descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- c procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7 The personnel responsible for carrying out conformity assessment tasks shall have the following:

- a sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- b satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- c appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards, and of the relevant provisions of Union harmonisation legislation and of national legislation;
- d the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8 The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes V, VII and VIII or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11 Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 36 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 25

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

Article 26

Subsidiaries of and subcontracting by notified bodies

1 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes V, VII and VIII.

Article 27

Application for notification

1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2 The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

Article 28

Notification procedure

1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.

2 They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE concerned and the relevant attestation of competence.

4 Where a notification is not based on an accreditation certificate referred to in Article 27(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.

5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Regulation.

6 The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 29

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2 The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 30

Changes to notifications

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification, 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.

2 In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 31

Challenge of the competence of notified bodies

1 The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

Article 32

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII.

2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the PPE with the requirements of this Regulation.

3 Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.

4 Where, in the course of the monitoring of conformity following the issue of a certificate or approval decision, a notified body finds that a PPE no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision if necessary.

5 Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.

Article 33

Appeal against decisions of notified bodies

Notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

Article 34

Information obligation on notified bodies

1 Notified bodies shall inform the notifying authority of the following:

- a any refusal, restriction, suspension or withdrawal of a certificate or approval decision;
- b any circumstances affecting the scope of or conditions for notification;
- c any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- d on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2 Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

*Article 36***Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Notified bodies shall participate in the work of that group, directly or by means of designated representatives.