

Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (Text with EEA relevance)

CHAPTER VII

NOTIFYING AUTHORITIES AND NOTIFIED BODIES

Article 39

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party tasks in the process of assessment and verification of constancy of performance under this Regulation (hereinafter referred to as ‘notified bodies’).

Article 40

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 the bodies to be authorised to carry out third-party tasks in the process of assessment and verification of constancy of performance for the purposes of this Regulation, and for the monitoring of notified bodies, including their compliance with Article 43.

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by their national accreditation bodies 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 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 41. In addition, it shall have arrangements to cover liabilities arising from its activities.

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

Article 41

Requirements relating to notifying authorities

1 The notifying authority shall be established in such a way that no conflicts of interest with notified bodies occur.

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

3 The notifying authority shall be organised in such a way that each decision relating to notification of a body to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance is taken by competent persons different from those who carried out the assessment.

4 The notifying authority shall not offer or provide activities performed by notified bodies, or consultancy services on a commercial or competitive basis.

5 The notifying authority shall safeguard the confidentiality of the information obtained.

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

Article 42

Information obligation for Member States

Member States shall inform the Commission of their national procedures for the assessment and notification of bodies to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 43

Requirements for notified bodies

1 For the purposes of notification, a notified body shall meet the requirements set out in paragraphs 2 to 11.

2 A notified body shall be established under national law and have legal personality.

3 A notified body shall be a third-party body independent from the organisation or the construction product 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 construction products which it assesses, can on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body.

4 A notified body, its top-level management and the personnel responsible for carrying out the third party tasks in the process of assessment and verification of constancy of performance shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the construction products which it assesses, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the notified body or the use of products for personal purposes.

A notified body, its top-level management and the personnel responsible for carrying out the third party tasks in the process of assessment and verification of constancy of performance shall not become directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of those construction products, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement and integrity related

to the activities for which they have been notified. This shall, in particular, apply to consultancy services.

A notified body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its assessment and/or verification activities.

5 A notified body and its personnel shall carry out the third party tasks in the process of assessment and verification of constancy of performance with the highest degree of professional integrity and requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their assessment and/or verification activities, especially from persons or groups of persons with an interest in the results of those activities.

6 A notified body shall be capable of carrying out all the third party tasks in the process of assessment and verification of constancy of performance assigned to it in accordance with Annex V in relation to which it has been notified, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

At all times and for each system of assessment and verification of constancy of performance and for each kind or category of construction products, essential characteristics and tasks in relation to which it has been notified, the notified body shall have the following at its disposal:

- a the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the third party tasks in the process of assessment and verification of constancy of performance;
- b the necessary description of procedures according to which the assessment of performance is carried out, ensuring the transparency and the ability of reproduction of these procedures; it shall have appropriate policies and procedures in place that distinguish between the tasks it carries out as a notified body and other activities;
- c the necessary procedures to perform its 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 product technology in question and the mass or serial nature of the production process.

A notified body shall have the means necessary to perform the technical and administrative tasks connected with the activities for which it is notified in an appropriate manner and shall have access to all necessary equipment or facilities.

7 The personnel responsible for carrying out the activities in relation to which the body has been notified, shall have the following:

- a sound technical and vocational training covering all the third party tasks in the process of assessment and verification of constancy of performance within the relevant scope for which the body has been notified;
- b satisfactory knowledge of the requirements of the assessments and verifications they carry out and adequate authority to carry out such operations;
- c appropriate knowledge and understanding of the applicable harmonised standards and of the relevant provisions of the Regulation;
- d the ability required to draw up the certificates, records and reports to demonstrate that the assessments and the verifications have been carried out.

8 The impartiality of the notified body, its top-level management and assessment personnel shall be guaranteed.

The remuneration of the notified body's top-level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.

9 A notified body 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 assessment and/or the verification performed.

10 The personnel of the notified body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under Annex V, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11 A notified body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body coordination group established under this Regulation and shall apply as general guidance the administrative decisions and documents produced as a work result of that group.

Article 44

Presumption of conformity

A notified body to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance which 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*, shall be presumed to comply with the requirements set out in Article 43 in so far as the applicable harmonised standards cover those requirements.

Article 45

Subsidiaries and subcontractors of notified bodies

1 Where a notified body subcontracts specific tasks connected with the third party tasks in the process of assessment and verification of constancy of performance or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 43, and shall inform the notifying authority accordingly.

2 The notified body 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 The notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of any subcontractor or the subsidiary and the tasks carried out by such parties under Annex V.

Article 46

Use of facilities outside the testing laboratory of the notified body

1 On request of the manufacturer and where justified by technical, economic or logistic reasons, notified bodies may decide to carry out the tests referred to in Annex V, for the systems of assessment and verification of constancy of performance 1+, 1 and 3 or have such tests carried out under their supervision, either in the manufacturing plants using the test equipments of the internal laboratory of the manufacturer or, with the prior consent of the manufacturer, in an external laboratory, using the test equipments of that laboratory.

Notified bodies carrying out such tests shall be specifically designated as competent to work away from their own accredited test facilities.

2 Before carrying out those tests, the notified body shall verify whether the requirements of the test method are satisfied and shall evaluate whether:

- a test equipment has an appropriate calibration system and the traceability of the measurements is guaranteed;
- b the quality of the test results is ensured.

Article 47

Application for notification

1 A body to be authorised to carry out third party tasks in the process of assessment and verification of constancy of performance shall submit an application for notification to the notifying authority of the Member State in which it is established.

2 The application shall be accompanied by a description of the activities to be performed, the assessment and/or verification procedures for which the body claims to be competent, an accreditation certificate, where one exists, issued by the national accreditation body within the meaning of Regulation (EC) No 765/2008, attesting that the body meets the requirements laid down in Article 43.

3 Where the body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 43.

Article 48

Notification procedure

1 Notifying authorities may notify only bodies which have satisfied the requirements laid down in Article 43.

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

Exceptionally, for cases set out in point 3 of Annex V, for which the appropriate electronic tool is not available, a hard copy of the notification shall be accepted.

3 The notification shall include full details of the functions to be performed, reference to the relevant harmonised technical specification and, for the purposes of the system set out in Annex V, the essential characteristics for which the body is competent.

However, reference to the relevant harmonised technical specification is not required in the cases set out in point 3 of Annex V.

4 Where a notification is not based on an accreditation certificate as referred to in Article 47(2), the notifying authority shall provide the Commission and the other Member States with all documentary evidence which attests to the notified 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 43.

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 2 weeks of notification where an accreditation certificate is used or within 2 months of notification where an accreditation certificate is not used.

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

6 The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 49

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to each 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 bodies notified under this Regulation, including the identification numbers that have been allocated to them and the activities for which they have been notified, notably using the electronic notification tool developed and managed by the Commission.

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

Article 50

Changes to the notification

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 43, 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 to fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly, notably using the electronic notification tool developed and managed by the Commission.

2 In the event of withdrawal, restriction or suspension of notification or where the notified body has ceased its activity, the notifying Member State concerned shall take the 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 51

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 related to the basis for notification or the maintenance of the competence of the 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 inform the notifying Member State accordingly and request it to take the necessary corrective measures, including withdrawal of notification, if necessary.

Article 52

Operational obligations for notified bodies

1 Notified bodies shall carry out third party tasks in accordance with the systems of assessment and verification of constancy of performance provided for in Annex V.

2 Assessments and verifications of constancy of performance shall be carried out with transparency as regards the manufacturer, and in a proportionate manner, avoiding an unnecessary burden for economic operators. The notified bodies shall perform their activities taking due account of the size of the undertaking, the sector in which the undertaking operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing, the notified bodies shall nevertheless respect the degree of rigour required for the product by this Regulation and the part played by the product for the fulfilment of all basic requirements for construction works.

3 Where, in the course of the initial inspection of the manufacturing plant and of factory production control, a notified body finds that the manufacturer has not ensured the constancy of performance of the manufactured product, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate.

4 Where, in the course of the monitoring activity aiming at the verification of the constancy of performance of the manufactured product, a notified body finds that a construction product no longer has the same performance to that of the product-type, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw its certificate 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, as appropriate.

Article 53

Information obligations for notified bodies

- 1 Notified bodies shall inform the notifying authority of the following:
 - a any refusal, restriction, suspension or withdrawal of certificates;
 - b any circumstances affecting the scope of, and conditions for, notification;
 - c any request for information on assessment and/or verification of constancy of performance activities carried out which they have received from market surveillance authorities;
 - d on request, third party tasks in accordance with the systems of assessment and verification of constancy of performance carried out 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 third party tasks in accordance with the systems of assessment and verification of constancy of performance and for construction products covered by the same harmonised technical specification with relevant information on issues relating to negative and, on request, positive results from these assessments and/or verifications.

Article 54

Exchange of experience

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

Article 55

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified pursuant to Article 39 are put into place and properly operated in the form of a group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives, or shall ensure that the representatives of notified bodies are informed thereof.