

Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (Text with EEA relevance)

## CHAPTER 4

### NOTIFYING AUTHORITIES AND NOTIFIED BODIES

#### *Article 17*

##### **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, notification and subsequent monitoring of notified bodies.

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 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 set out in Article 18(1) to (6). In addition the entrusted 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 18*

##### **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 the notified bodies is taken by competent persons different from those who carried out the assessment.

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

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.

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### *Article 19*

#### **Information obligation of notifying authorities**

Member States shall inform the Commission of their national procedures for the assessment, notification and monitoring of notified bodies, and of any changes to that information.

The Commission shall make that information publicly available.

### *Article 20*

#### **Requirements relating to notified bodies**

1 For the purposes of notification, a notified body shall meet the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive.

2 A competent authority, within the meaning of the Annexes to Directive 2008/68/EC may be a notified body provided it meets the requirements set out in the Annexes to Directive 2008/68/EC and in this Directive and that it does not also act as the notifying authority.

3 The notified body shall be established under national law and shall have legal personality.

4 The 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 pursuant to Article 29 and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

### *Article 21*

#### **Application for notification**

1 An inspection body 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:

- a the activities relating to conformity assessment, periodic inspection, intermediate inspection, exceptional checks and reassessment of conformity;
- b the procedures relating to point (a);
- c the transportable pressure equipment for which the body claims to be competent;
- d an accreditation certificate issued by a national accreditation body within the meaning of Regulation (EC) No 765/2008, attesting that the inspection body fulfils the requirements set out in Article 20 of this Directive.

### *Article 22*

#### **Notification procedure**

1 Notifying authorities shall notify only those bodies which have satisfied the requirements set out in Article 20.

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

3 The notification shall include the information required in Article 21(2).

4 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.

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

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

6 In-house inspection services of the applicant as defined in the Annexes to Directive 2008/68/EC shall not be notified.

#### *Article 23*

##### **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 Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

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

#### *Article 24*

##### **Changes to notifications**

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements set out in Article 20, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw 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 withdrawal, restriction or suspension of notification or where the notified body has ceased its activity, the notifying Member State 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 on request.

#### *Article 25*

##### **Challenge to 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.

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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 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 de-notification, if necessary.

#### *Article 26*

### **Operational obligations of notified bodies**

1 Notified bodies shall carry out conformity assessments, periodic inspections, intermediate inspections and exceptional checks in accordance with the terms of their notification and the procedures set out in the Annexes to Directive 2008/68/EC.

2 Notified bodies shall carry out reassessments of conformity in accordance with Annex III.

3 Notified bodies notified by one Member State shall be authorised to work in all Member States. The notifying authority which carried out the initial assessment and notification retains the responsibility for monitoring the ongoing activities of the notified body.

#### *Article 27*

### **Information obligation of notified bodies**

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

- a any refusal, restriction, suspension or withdrawal of a certificate;
- b any circumstances affecting the scope of and conditions for notification;
- c any request for information on activities performed which they have received from market surveillance authorities;
- d on request, 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 Directive carrying out similar conformity assessment, periodic inspection, intermediate inspections and exceptional checks activities covering the same transportable pressure equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### *Article 28*

### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible under this Directive for:

(a) notification policy;

- (b) market surveillance.

#### *Article 29*

#### **Coordination of notified bodies**

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

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