

# **P008**

## **Designation of notified bodies within the framework of the ‘New Approach’ Directives**

Amendments: Full document review

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## 1. Aim

The aim of this procedure is to set the rules for conformity assessment bodies with regard to obtaining, maintaining or amending (restriction, suspension or withdrawal) a notification within the framework of the 'New Approach' Directives and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products. It also sets out the rules to be applied should certain modules be subcontracted.

## 2. Introduction

In order to guarantee a high level of safety for products placed on the market or made available on the market, and to facilitate free movement thereof, the Commission adopted a legislative technique with regard to standardisation in 1985, known as the 'New Approach' (Council Resolution of 7 May 1985 – OJEC No C 136 of 4.6.1985). These directives set out the essential requirements in terms of safety, health, environment protection and consumer protection.

The 'New Approach' Directives define the products, which must comply with these essential requirements to obtain CE marking, a mandatory requirement in order for them to be placed on the European market.

For a certain number of these products, the conformity assessment procedures prescribed by Community legislation require the involvement of conformity assessment bodies (CABs). In order to be authorised to carry out said conformity assessment procedures, these CABs must first be notified to the European Commission and the other Member States.

Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 stipulates, in article R14, that the Member States must designate a notifying authority to assume responsibility for setting up and carrying out the necessary procedures for the assessment and notification of CABs and monitoring of notified bodies. This decision also states that these tasks may be delegated to the national accreditation body.

Article 7 of the modified law of the 4th July 2014 on the reorganisation of ILNAS appoints OLAS as the notifying authority within the framework of the Luxembourgish legislation transposing European Union harmonisation legislation and regulations which include notification.

## 3. Definitions

### **Conformity assessment<sup>1</sup>**

Process demonstrating whether specified requirements relating to a product, process, system, person or body have been fulfilled.

### **Notified body<sup>2</sup>**

Body appointed by a Member State to carry out third-party conformity assessment tasks within the framework of the European Union harmonisation legislation on product marketing.

### **Notifying authority**

OLAS is the notifying authority within the framework of the Luxembourgish legislation transposing European Union harmonisation legislation.

### **Notification of bodies**

Procedure whereby the European Commission and the other Member States of the European Union are informed of the designation by OLAS of a body which fulfils the conditions laid down in the European harmonization legislation for carrying out assessment of conformity with the requirements set out in said directives.

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<sup>1</sup> Paragraph 12, article R1 of annex I of decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

<sup>2</sup> Paragraph 25 of the modified law from the 4 July 2014 on the reorganisation of ILNAS

### **Harmonised standards**

A standard adopted by one of the European standardisation bodies listed in Annex I to regulation (EU) 1025/2012 and based on a proposition by the European Commission for the application of the harmonisation legislation.

### **CE marking**

Marking by which the manufacturer indicates that the product conforms to the applicable requirements set out in Community harmonisation legislation providing for its affixing.

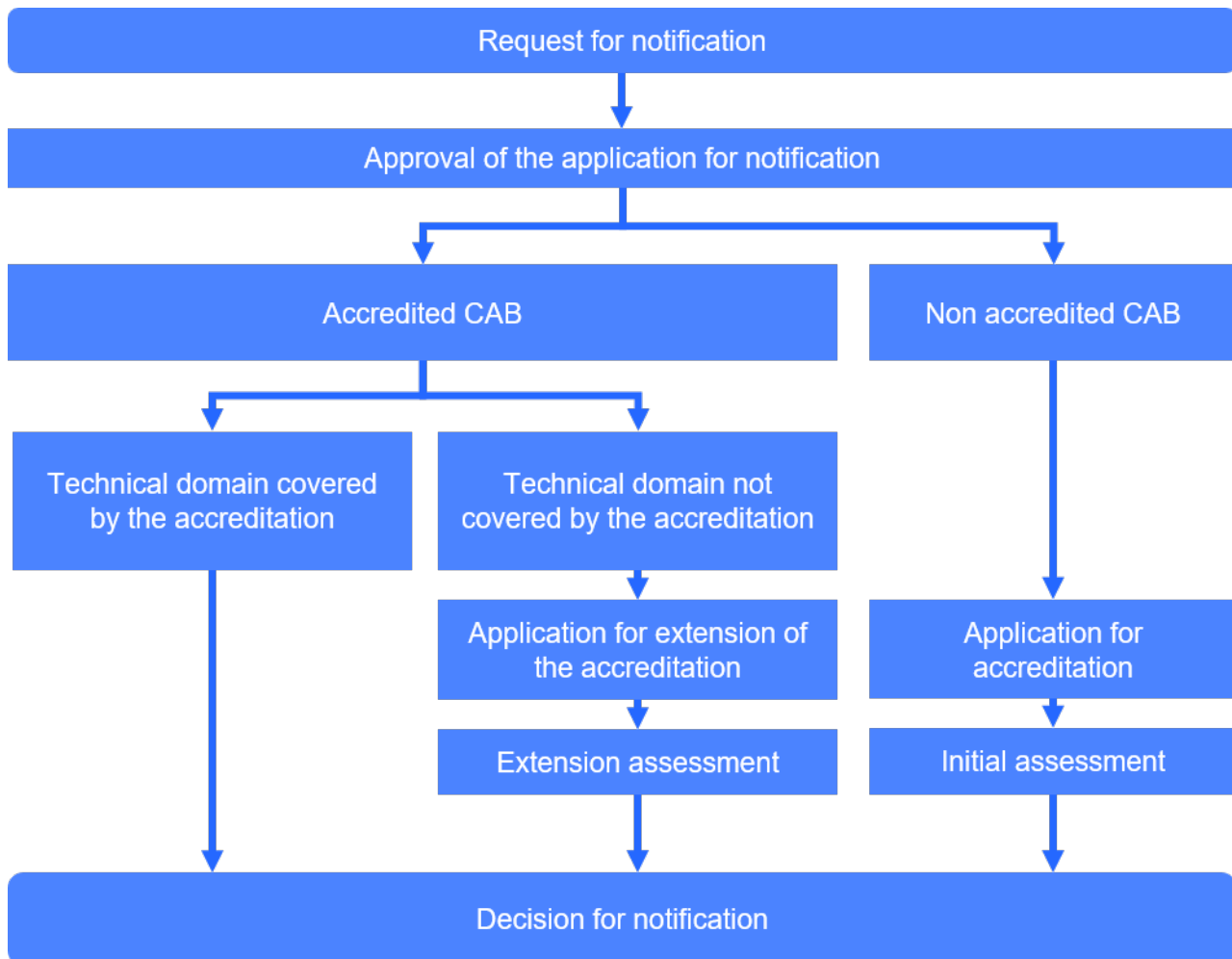
### **Placing on the market**

The first time a product is made available on the Community market.

### **Module**

Procedure for the realisation of conformity assessment as defined in article 4 of decision 768/2008/CE of the European Parliament and the Council of 9 July 2008.

## 4. Notification procedure



\* Accreditation by OLAS or any other accreditation body signatory to the 'European co-operation for Accreditation' mutual recognition agreements if OLAS is not capable of proceeding with the accreditation.

Figure 1 - Flowchart for the notification procedure

### 4.1 General requirements for all notifications

In accordance with article 7 of the law of the 4<sup>th</sup> July 2014, any CAB applying for notification shall be established in Luxembourg, shall have legal personality and shall be accredited in the legal matter for which the notification is requested.

In order to be notified, the CAB shall demonstrate the necessary guarantees of professional qualification, integrity, impartiality, independence and confidentiality which are assessed on the basis of the accreditation issued by OLAS or another recognised body<sup>3</sup> in application of the following documents:

- National, European and international standards and other normative documents applicable as regards accreditation and any other document from European and international departments and bodies active in the accreditation field;
- Minimum requirements set out in the 'New Approach' Directives.

<sup>3</sup> Pursuant to article 5, paragraph 1 point 2° of the amended law on the reorganisation of ILNAS of 4 July 2014

Notification may only be granted for the fields listed in the scope of accreditation of the certificate of accreditation.

OLAS has published the annex A019 to further detail the requirements for accreditation for notification purposes.

**NB:** Before launching the notification procedure, each application has to be approved by the Minister responsible for economy after seeking the opinion of the ministers responsible for the matter within which notification is granted. Accreditation in itself does not therefore guarantee a favourable notification decision.

## 4.2 Application for notification

The application for the notification has to include the following information:

- List of all the conformity assessment activities offered by the CAB;
- Identification of type of the body (inspection body, testing body, body certifying products or systems);
- Identification of the 'New Approach' directives for which the CAB wishes to be notified;
- List of products covered by the notification request;
- Requirements (articles, annexes, modules, systems) set out in the 'New Approach' directives for which the CAB wishes to be notified;
- The CAB's certificate of accreditation and the corresponding scope of accreditation, if existent.

This application has to be send to OLAS.

Please find hereafter some examples from the [NANDO](#) information database, which will give you a better understanding of how to complete your application.

### 88/378/EEC Safety of Toys

Products	Procedures	Articles/annexes
Toys referred to in Article 1	EC-type examination	Art. 10

### 95/16/EC Lifts:

Products	Procedures	Articles/annexes
Lift	Final inspection	Annex VI

### 96/98/EC Marine equipment:

Products	Procedures	Articles/annexes
Fire protection	Production quality assurance	Art. 10.1 (i) (b), Annex B - Module D

### Regulation (UE) 305/2011: Construction project

For Regulation (EU) No 305/2011 – Construction products, the information to be supplied is quite different from that for all other directives. Please consult the NANDO database for a better understanding.

Decision	Product family, product/planned usage	AVCP system	Harmonised technical specification
96/577/EC	Fire alarms/fire detection equipment, fixed firefighting equipment, products for firefighting and smoke control and explosion protection products (1/1): • smoke, heat and flame detectors (fire protection)	Product Certification Body (System 1)	EN 54-10:2002 EN 54-10:2002/A1:2005 EN 54-5:2000/A1:2002 EN 54-7:2000/A1:2002 EN 54-7:2000/A2:2006

## 5. Amendments to an existing notification (Article R25 – Decision 768/2008/EC)

Should it be ascertained (following an assessment, through any information by a third party or through information provided by the body itself) that a notified body no longer meets the requirements or is failing to fulfil the obligations which led to it being notified, the notification may be restricted, suspended or withdrawn, as appropriate.

In the event of restriction, suspension or withdrawal of notification or where the notified body partially or entirely ceases its activities, it must inform its customers thereof so that they may seek another notified body to take over the processing of their file.

The files concerned must be made available to OLAS or to the competent market surveillance authorities on request.

## 6. Rules applying to subcontracting

A notified body may subcontract all or part of a module of a ‘New Approach’ directive to a subcontractor (or subsidiary) on condition that the latter is accredited for the tasks being assigned to it and meets the requirements in Article R17 of Decision 768/2008/EC. Prior to any subcontracting, the notified body shall inform OLAS of its intention and make all relevant documentation proving said compliance available to OLAS. A notified body or candidate shall make available said documentation to OLAS also during accreditation assessments and upon application for notification.

However, in order for subcontracting to be accepted, the notified body (or body applying for notification) must be accredited for the domain in question. The annex A019 contains more information on the standards and technical domains applicable for a certain domain.

Before having any conformity assessment activities carried out by a subcontractor (or a subsidiary), the notified body shall have the agreement of the customer.

The notified body shall be entirely responsible for the tasks carried out by a subcontractor (or a subsidiary). In this regard, it shall have qualified internal staff who are able to interpret the results provided by the subcontractor (or subsidiary).

A body cannot be notified (or remain notified) for a directive for which it has no activity.

## 7. Special provisions

### 7.1 Accreditation for the approval of permanent joining personal according to directive 2014/68/UE – Pressure equipment

A body requesting a notification for the approval of permanent joining personnel under paragraph 3.1.2 of Annex I to the law of 27 June 2016 concerning the placing on the market of pressure equipment (respectively Directive 2014/68/EU), shall be accredited according to the provisions described in Annex A029. Any accreditation assessment report covering this activity shall include form F003T.