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Contents

- Definition of Notifying Authorities
- Notification Process
- Requirements for Notifying Authorities
- Principles of Notification
- Monitoring Notified Bodies

Functioning of the single market

INTERNATIONAL KNOWLEDGE TRANSFER

Accreditation

Member States

Accreditation Bodies

Assess and monitor the competence of laboratories to assess conformity to a specific regulation

Laboratories

Notified (conformity assessment) Bodies

Contribute to the assessment of product conformity

Notification

Member States

Notifying Authorities

[Assess, monitor] and notify laboratories having the competence to assess conformity to a specific regulation

EU

Harmonization Legislation

Defines essential requirements

Manufacturer

Conformity Assessment

Manufacturer assesses conformity to the product

Manufacturer

CE Marking

Manufacturer affixes CE marking and issues declaration of conformity

Products



CEN/CENELEC/ETSI

Harmonized Standards

Define accepted solutions (technical requirements)

Presumption of conformity

Idea: EASA Opinion No 01/2018

Member States

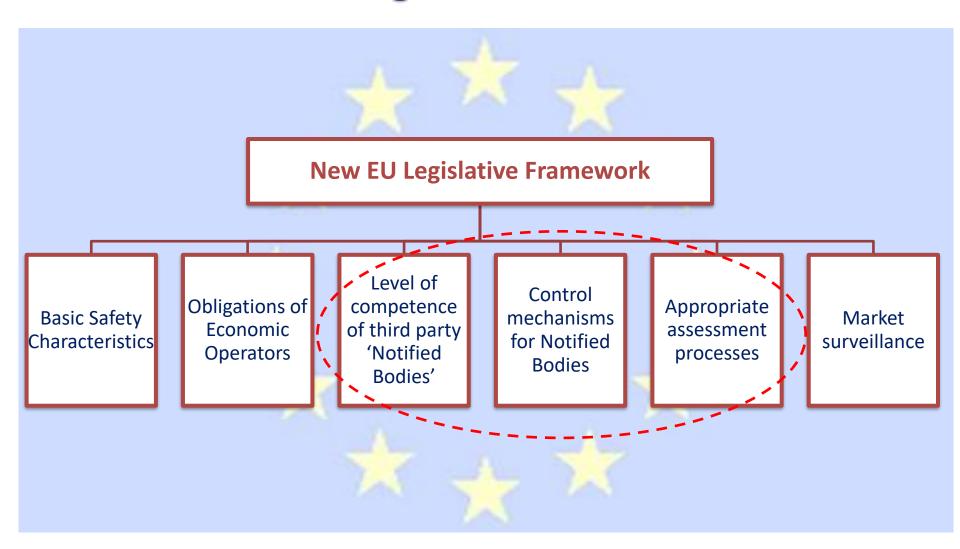
Market Surveillance

MS authorities control compliance

Standardization mandate



New Legal Framework





Notifying Authorities

A notifying authority is the governmental or public body that is tasked with designating and notifying conformity assessment bodies under Union harmonisation legislation.



Notification Process

Notification is the act of the notifying authority informing the Commission and the other Member States that a conformity assessment body:

-has been designated to carry out conformity assessment according to a Union harmonisation act, and

-fulfils the requirements relating to notified bodies set out in that Union harmonisation act.



Requirements for notifying authority

No conflict of interest with CAB. Not offer or provide any activities that CABs perform or consultancy services on a commercial or competitive basis.

Safeguard objectivity and impartiality of its activities.

Decision relating to notification of a CAB is taken by competent persons different from those who carried out the assessment

Safeguard the confidentiality of the information it obtains.

Have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.



Obligations of Member States

Member States **designate a notifying authority** that shall be responsible for setting up and carrying out the necessary procedures for the **assessment and notification of CABs and the monitoring of notified bodies**, including compliance with the provisions of Decision 768/2008/EC.

Member States must **inform the Commission** of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies. The Commission makes that **information publicly available** on its website.



Obligations of Member States

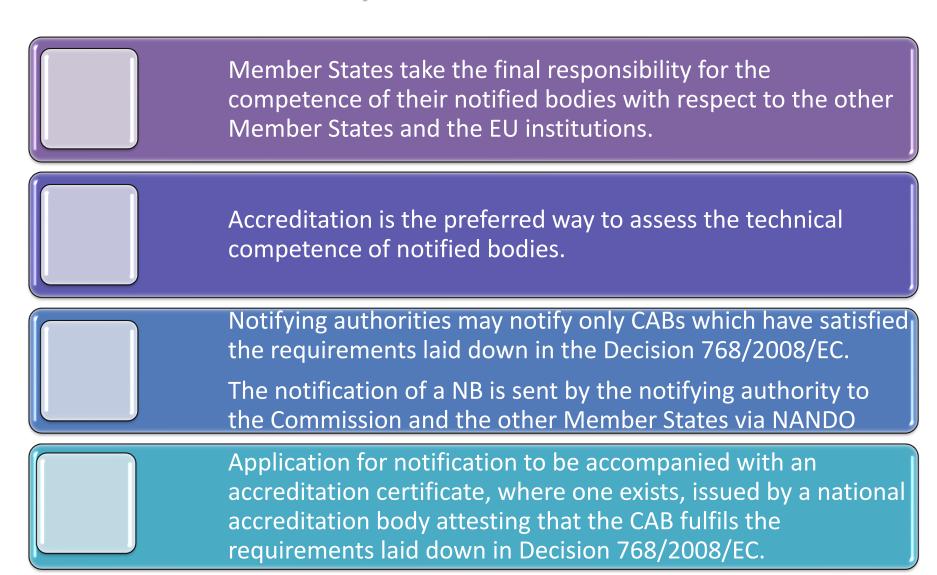
Member States are not obliged to:

Notify all the bodies demonstrating technical competence.

Notify bodies in respect of each procedure to be applied according to a specific Union harmonisation act.



Principles of Notification





Notification

When a Member State does not base its notification on accreditation, "it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Union harmonisation legislation in question".

- a formal application procedure
- assessment against applicable requirements.
- production of an assessment report
- periodic surveillance including on-site visits, in order to verify the continued fulfilment of requirements by the notified body
- demonstration of the national authority's own technical competence to assess conformity assessment bodies
- The assessment itself should consist of: a review of documents and an on-site audit to check technical and procedural aspects
- Reference: Document CERTIF 2010-08 REV1 Notification without accreditation (Art. 5.2 of Regulation 765/2008)



NB 0086

BSI Assurance UK Ltd

Notification

United Kingdom

Bodies			Found : 116
Search criteria	:		
	Legislation :	2014/32/EU Measuring Instruments Directive	
	Procedure /	ALL	~
	Article or annex :		
	Products : Search	ALL	~
Withdrawn/Exp		cations/NBs are not displayed in this list, you can find them in the Bo erlink "Withdrawn/Expired/Suspended Notifications/NBs"	dy module under the
Body type ≜	Name ≜		Country ▲ Bulgaria
▶ NB 1887	"BUSINESS INNOV	"BUSINESS INNOVATION CENTRE - IZOT" Co Directorate "Conformity Assessment"	
▶ NB 1917	"V&V VentMet labo	"V&V VentMet laboratory" Ltd.	
▶ NB 1543	AS METROSERT	AS METROSERT	
▶ NB 0866	ASSOCIAÇÃO POR	ASSOCIAÇÃO PORTUGUESA DE CERTIFICAÇÃO	
NB 2081	AZTENDA SPECIAL	Italy	



https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=direct ive.main

If there is no objection, within 2 weeks with accreditation and 2 months without accreditation, from Commission or other Member States, CAB may perform activities of a notified body.

Notification is electronic (NANDO), providing all details of approved scope



Monitoring of the competence of Notified Bodies

Goal: ensure that notified bodies remain competent over time and that this can be made transparent to the other Member States and the Commission.

National competent authorities shall regularly monitor and assess the continuing competence of the bodies they have notified.

Update of notifications at maximum every 5 years from the date of the initial notification, or the last update, with information on the continuous monitoring of the competence of the NB.

The Commission and the Member States: responsible to act when doubt arises about the competence of a NB, either at the moment of notification or thereafter.



Monitoring of the competence of Notified Bodies

Where a notifying authority has ascertained or has been informed that a NB no longer meets the relevant requirements it shall:

- suspend or withdraw the notification after immediately contacting the body in question.
- immediately inform the Commission and the other Member States accordingly



Thank you for your attention!

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