

A background image showing a hand holding a glowing sphere made of interconnected white lines and small circles, symbolizing a network or data. The hand is positioned at the bottom, with fingers slightly curled around the base of the sphere. The sphere itself is composed of many thin white lines connecting small white circles, some of which are highlighted in a light blue color. The overall effect is a sense of holding a complex, interconnected system.

"EU Requirements for the Notified Bodies"

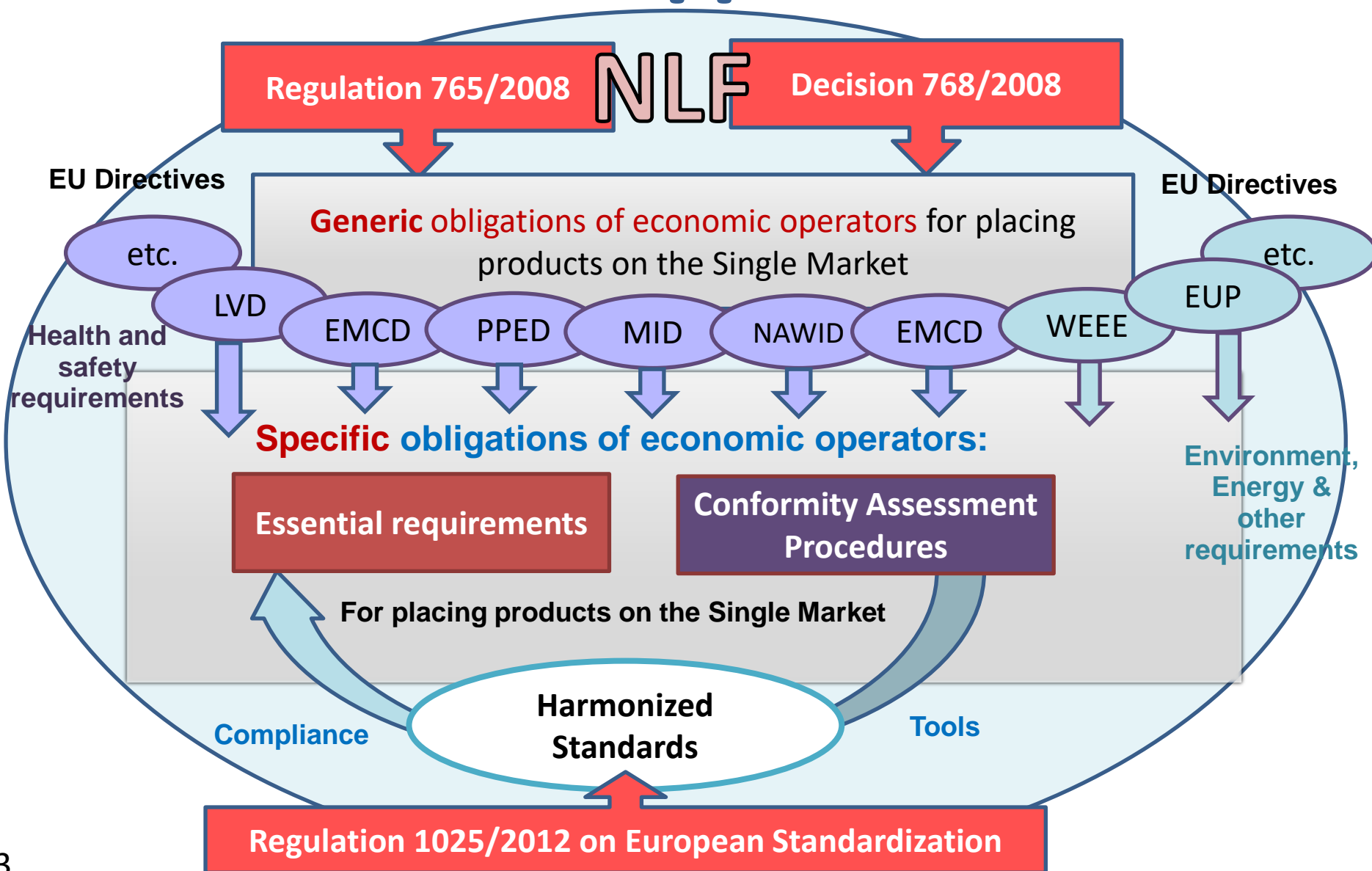
Dr. Irene Flouda

22-23 July 2020

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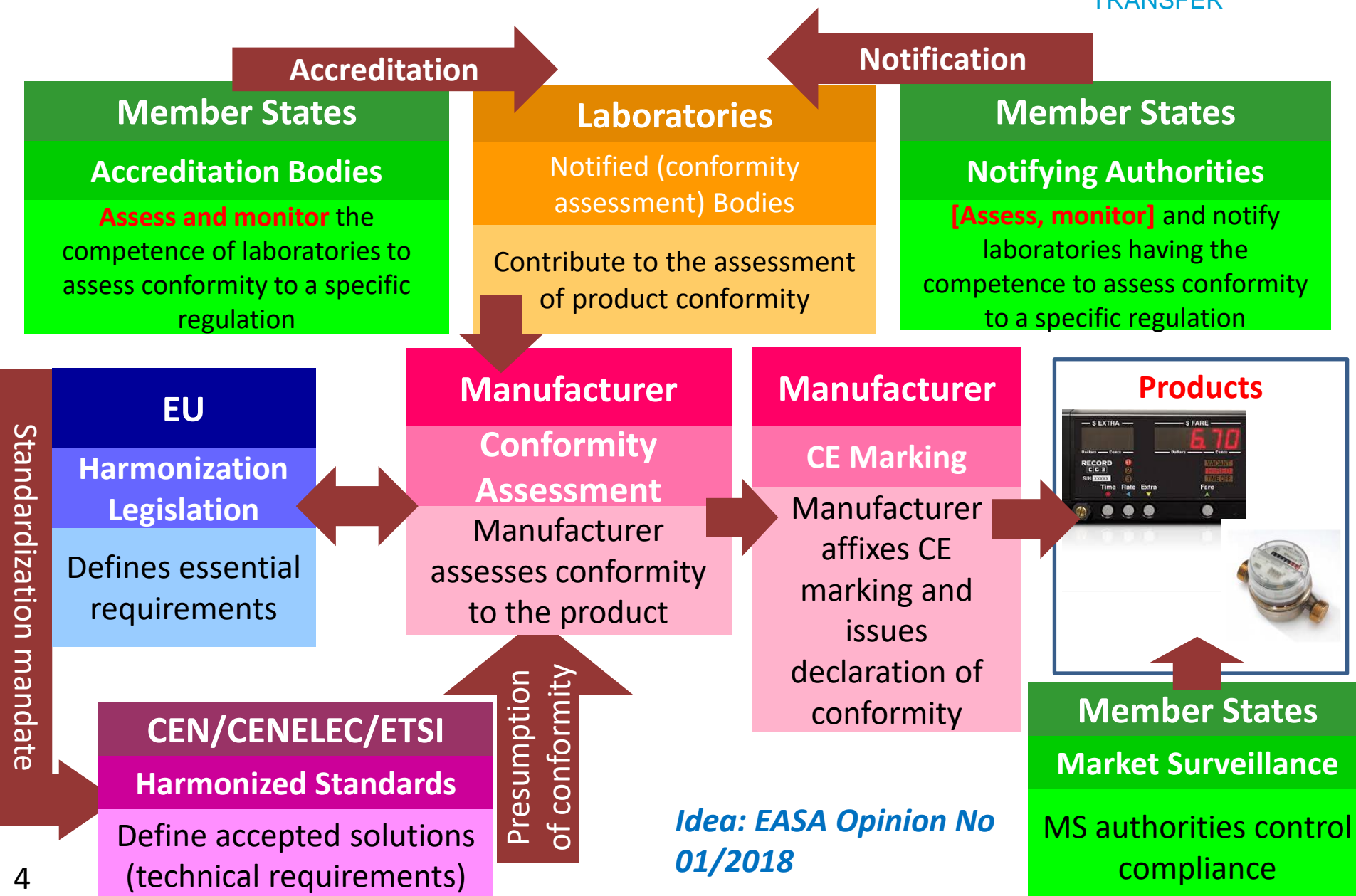
- Tasks of Notified Bodies
- Roles and Responsibilities of Notified Bodies
- Procedure to become Notified Body

New Approach

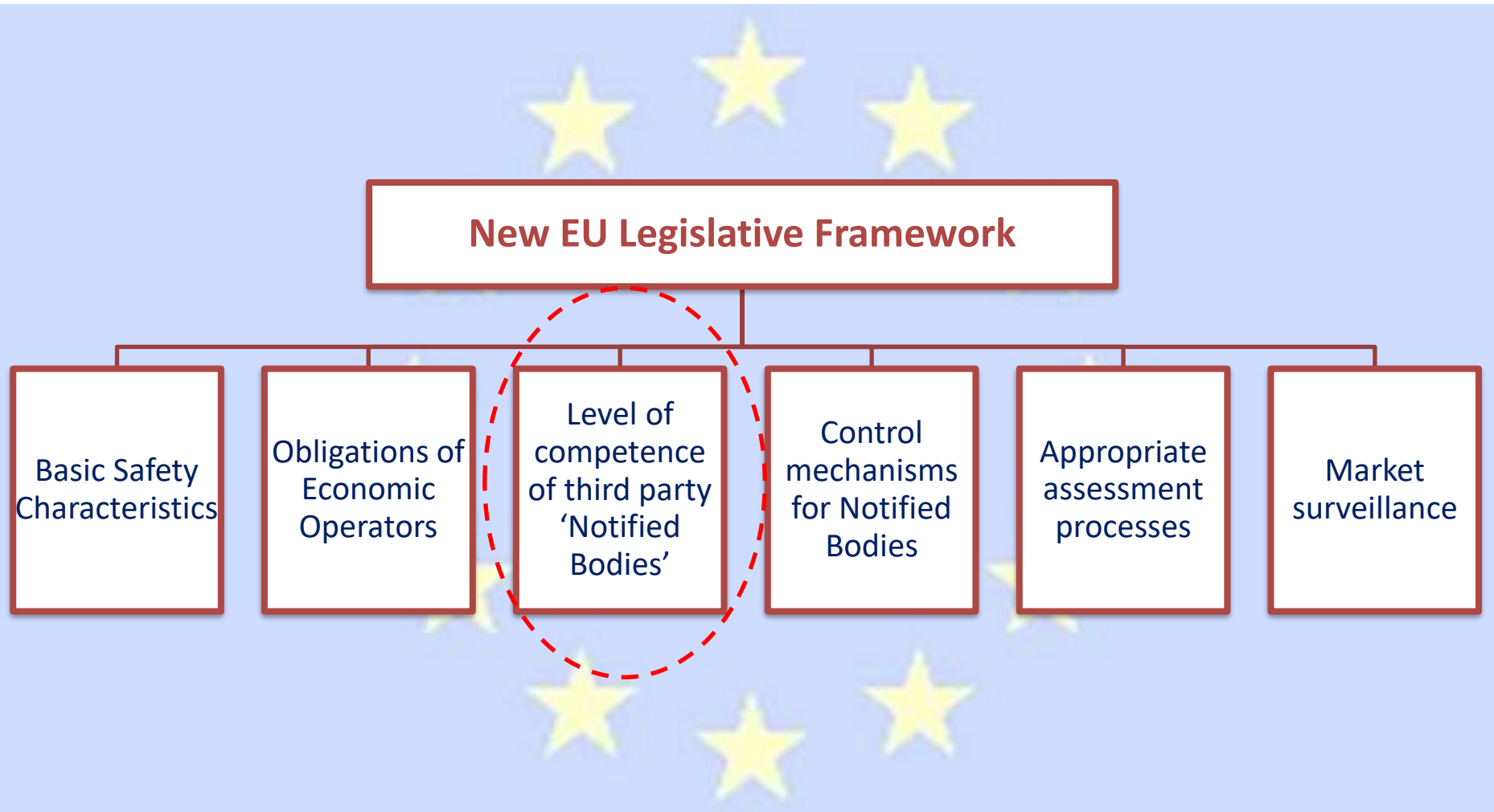


Functioning of the single market

INTERNATIONAL
KNOWLEDGE
TRANSFER



New Legal Framework



Notified bodies

Member States remain free to decide whether or not to notify a body which complies with the requirements laid down in the relevant Union harmonisation legislation.

Notified Bodies provide conformity assessment services on the conditions set out in EU legislation when a third party is required.

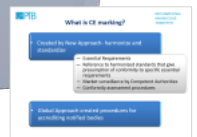
- 1100+
- Independent third parties
- Notified by Member States, who ensure their competence
- Co-operation
-and **competition**

Notified bodies- What are they?

Independent certification organization that is “notified” by a European Member State’s Competent Authority to determine if a product or system meets applicable requirements for CE marking.

“Notification” is when a Competent Authority designates a certification body to perform conformity assessment procedures under a directive.

List of notified bodies and their scope available on the NANDO website: <https://ec.europa.eu/growth/tools-databases/nando/>



What is CE marking?

- Created by New Approach- harmonize and standardize
 - Essential Requirements
 - Reference to harmonized standards that give presumption of conformity to specific essential requirements
 - Market surveillance by Competent Authorities
 - Conformity assessment procedures
- Global Approach created procedures for accrediting notified bodies

What is CE marking?

CE Marking products built an internal market and created a free movement of goods with no technical barriers to trade while keeping a high level of safety and performance and a high level of health care

- A product with CE Marking granted in one of the member states can be launched on the EEA and Turkish market
- CE Marking ≠ “Approval”

Notified bodies- What do they do?

Primary Task: Provide conformity assessment services according to the directives, taking into account all the relevant documents and standards.

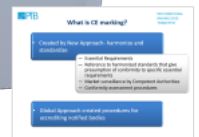
Includes:

Verifying product through sampling, testing, etc.

Certifying and auditing quality management systems

Technical documentation assessments

Auditing critical sub-contractors



Notified bodies- What do they do?

- Notified Bodies are Assessed Assessors- Competent Authorities continually assess Notified Bodies through communications and audits
- Routinely communicate with Competent Authorities regarding:
 - Assessments and their findings
 - Issued, modified, withdrawn or suspended certificates
 - Provide any information about assessments performed supporting a certification decision
- Must inform Competent Authority of any significant change in their organization

Notified bodies- What they can't do?

Activity limits due to duties:

Impartiality:



☐ NB can't be the manufacturer, EU authorized representative, a supplier or a competitor of one of its clients

☐ No consulting on products/quality systems that they audit

Independence



☐ All staff must declare any potential conflict of interest to ensure no economic factors influence the decision to issue a CE certificate

Notified bodies- What they can't do?

Activity limits due to duties:

Confidentiality:



☐ No disclosure of clients or their client's products/technology to anyone but Competent Authority

☐ Required to report to Competent Authority







Competence:



☐ May only carry out conformity assessments for which they are notified

Notified bodies Roles and Responsibilities

Notified bodies **must**:

-  have at their disposal the necessary personnel, who have sufficient and relevant knowledge and experience
-  ensure confidentiality of the information obtained
-  be adequately insured to cover their professional activities (liability)
-  provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies
-  operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner
-  remain accountable to the competent national authorities (as they take responsibilities in areas of public interest)

Notified bodies Roles and Responsibilities

have at their disposal the necessary personnel, who have sufficient and relevant knowledge and experience

- Personnel with sufficient knowledge and experience relating to the products and conformity assessment procedure in question and sound technical training in:
 - ✓ relevant regulatory requirements and enforcement policies,
 - ✓ European and international standardisation activities,
 - ✓ relevant technologies, production methods and verification procedures, and
 - ✓ normal conditions of use of the product in question.
- Be able to **manage, control** and **be responsible** for the performance of all their resources
- **Maintain** comprehensive records concerning the suitability of all the staff they use in particular areas (**employees, employed on contract or provided by external bodies**)
- **Have access** to appropriate facilities and be able to test or re-test in the EU. (To make it possible for the notifying authority to check its competence).

Notified bodies Roles and Responsibilities



ensure confidentiality of the information obtained

- The information to be shared with other notified bodies **cannot concern confidential commercial information on the product.**
- Relevant information to be exchanged on issues relating to negative conformity assessment results **should primarily concern the refusal to issue a conformity assessment attestation identifying the product and manufacturer in question.**

Notified bodies Roles and Responsibilities

be adequately insured to cover their professional activities (liability)

- The scope and overall financial value of liability insurance must correspond to the **level of risk** linked with the activities of the notified body.
- However: the manufacturer **retains the overall responsibility for the conformity of the product** with all the requirements of the applicable legislation, **even if some stages of the conformity assessment are carried out under the responsibility of a notified body.**



Liability

- **Liability** incurs the moment a product is “placed on the market” in the EU.
- A product is placed on the market when it is made available for the first time on the Union market.
- Products made available on the market must comply with the applicable Union harmonization legislation at the moment they are placed on the market.



Clarifications!

"**Making available on the market**" is the overall concept. **Any transfer between economic operators** of a product is considered as making available.

"**Placing on the market**" is a specific case of making available, namely **it is the first time that the product is introduced on the market**. It is important because at that moment the EU legislation applies.

Any subsequent transfer is a "**making available**".

Notified bodies Roles and Responsibilities

provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies

- NBs must **keep their national notifying authorities informed of their activities** (for example concerning the conduct of conformity assessments, availability of resources, subcontracting, situations of conflicts of interest), **either directly or via an authorised body** (for example the national accreditation body).
- They must also be prepared to **provide** either at the request of their notifying authorities or of the Commission, **all information concerning the proper implementation of the conditions under which they were notified.**

Notified bodies Roles and Responsibilities

provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies

- Inform the notifying authority about **all certificates issued or refused, restricted, suspended or withdrawn** due to safety related non-conformities and other conformity assessment activities performed.
- Provide **other bodies notified under the same Union harmonisation legislation**, with relevant information on issues relating to negative and, on request, positive conformity assessment results.
- Provide the **market surveillance authority and the market surveillance authorities of other Member States**, with relevant information for the purpose of market surveillance.

Notified bodies Roles and Responsibilities

operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner

- **Independence** covers **the whole organisation**, including the **board or directors**, and applies also for **bodies belonging to business associations or professional federations**.
- **Impartiality**:
 - the NB and its staff have to be **free from any commercial, financial and other pressure that might influence their judgement**.
 - Implement procedures to ensure that **its work cannot be influenced from outside**.
 - The **structure** must safeguard its impartiality, especially if it has **activities other than those of a NB**.

Notified bodies Roles and Responsibilities



operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner

- A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, **may be a Notified Body** on condition that it demonstrates its independence and absence of any conflict of interest.


Notified bodies Roles and Responsibilities

remain accountable to the competent national authorities (as they take responsibilities in areas of public interest)


- To be **eligible** a body must be **a legal entity established on the territory of a Member State** and, thus, come under its jurisdiction.
- Member States remain **free to decide whether or not to notify a body** which complies with the requirements laid down in the relevant Union harmonisation legislation.

Notified bodies Roles and Responsibilities


Notified bodies:




are free to offer their conformity assessment services to any economic operator established either inside or outside the Union (on the territory of other Member States or of third countries).



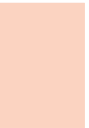
May demonstrate their competence through accreditation (**preferred way**)



Participate in the relevant standardization activities (or be informed of such)



They may subcontract specific tasks connected with CA, but **shall take full responsibility for the tasks performed by subcontractors** and ensure that the subcontractor fulfils the requirements



Subcontracting must be based on a contract, which makes it possible to ensure the transparency of and have confidence in the notified body's operations.

Notified bodies Roles and Responsibilities

Are free to offer their conformity assessment services to any economic operator established either inside or outside the Union (on the territory of other Member States or of third countries).

- Certificates and other conformity assessment attestations are, **always issued by and in the name of the NB.**
- Since the NB always has to carry out its assessment functions within the jurisdiction of the designating Member State, **it has to inform the notifying authority**, which must be capable of ensuring the monitoring of the total body as it has to take the responsibility for its operations.
- If monitoring is not considered possible, the notifying authority **should withdraw or limit the scope** of the notification as deemed necessary.

Notified bodies Roles and Responsibilities

May demonstrate their competence through accreditation (**preferred way**)

- Member States may decide that the **assessment and monitoring** of NBs shall be carried out by a **national accreditation body** within the meaning of and **in accordance with Regulation (EC) No 765/2008**.
- Although **it is not a requirement, accreditation remains an important and favoured instrument** for evaluating the competence and integrity of the bodies to be notified

Notified bodies Roles and Responsibilities

May demonstrate their competence through accreditation (**preferred way**)

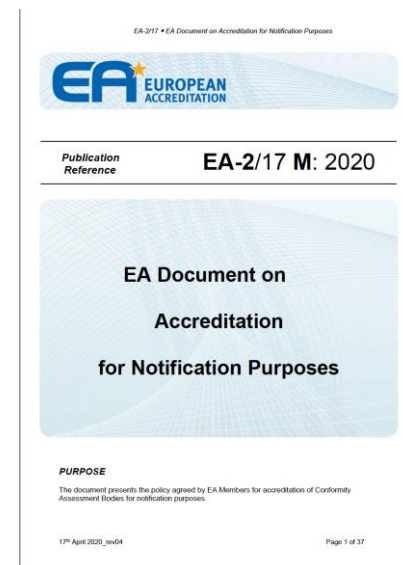
- The preference given to accreditation is because:
 - Accreditation provides an **authoritative statement** of the **competence**, professional **integrity** and **impartiality** of the CABs to be notified
 - The **peer evaluation process** under the European Accreditation (EA) provides **confidence** on the **consistent** operation of ABs across member states
- However, a member state **may decide not to use accreditation** for notification and carry out the evaluation itself. In such cases **detailed evidence must be provided to the Commission and other member states** that the evaluated CAB complies with all the applicable regulatory requirements



Accreditation for Notification purposes

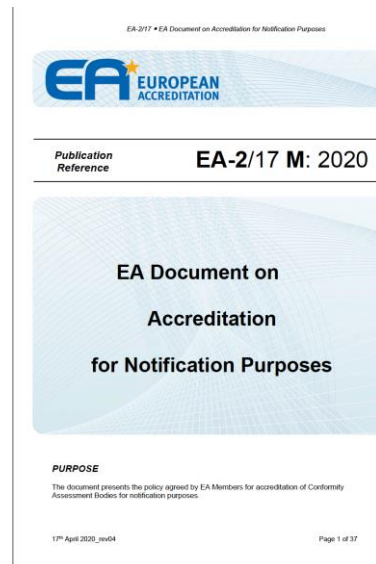
The European Accreditation (EA) has recently published (April 2020):

- A report on Accreditation for Notification (**AfN project**)
- A document **EA-2/17 M:2020** (revision)
- These documents provide analytic guidance / requirements on accreditation for notification purposes:
 - Preferred HS for each Attestation Module / System of 27 pieces product families (Directives/Regulations)
 - Additional requirements ABs have to apply
 - Formulation of accreditation scopes
 - Criteria for selecting witnessing



Accreditation for Notification purposes

- Document **EA-2/17 M:2020** is mandatory
- **ABs** shall start implementing it until **April 2021**
- **CABs accredited for notification** shall comply until **April 2023**



Certificates and other attestations of conformity are always issued in the name and under the responsibility of the notified body

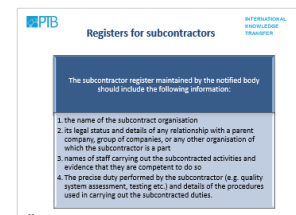
They may subcontract specific tasks connected with CA, but **shall take full responsibility for the tasks performed by subcontractors** and ensure that the subcontractor fulfils the requirements

- A NB can subcontract duties **in relation to the scope for which it is notified** and for which it has the competence itself (not because it does not have the required competence and knowledge).
- A subcontractor can be **located on or outside the Community territory**.
- Subcontracting **does not entail the delegation of powers** or responsibilities.
- The NB shall **ensure** that the subcontractors and their personnel **conform to all the requirements** of the regulations that would apply had the task been performed by its own personnel.
- The body subcontracted by the NB must be **technically competent**, and **display independence and objectivity** according to the same criteria and under the same conditions as the NB.

Notified bodies Roles and Responsibilities

They may subcontract specific tasks connected with CA, but **shall take full responsibility for the tasks performed by subcontractors** and ensure that the subcontractor fulfils the requirements

- The NB shall:
 - ✓ **inform the competent authority** of its **intention** to subcontract duties in relation to the scope for which it was appointed.
 - ✓ **maintain documentary evidence** that the subcontractor has the **necessary technical competence and facilities** to carry out the subcontracted activities.
 - ✓ **keep an up to date register** of all its subcontractors, which **shall be provided to the Commission and the competent authority** without delay and to other member states on request.



Registers for subcontractors

The subcontractor register maintained by the notified body should include the following information:

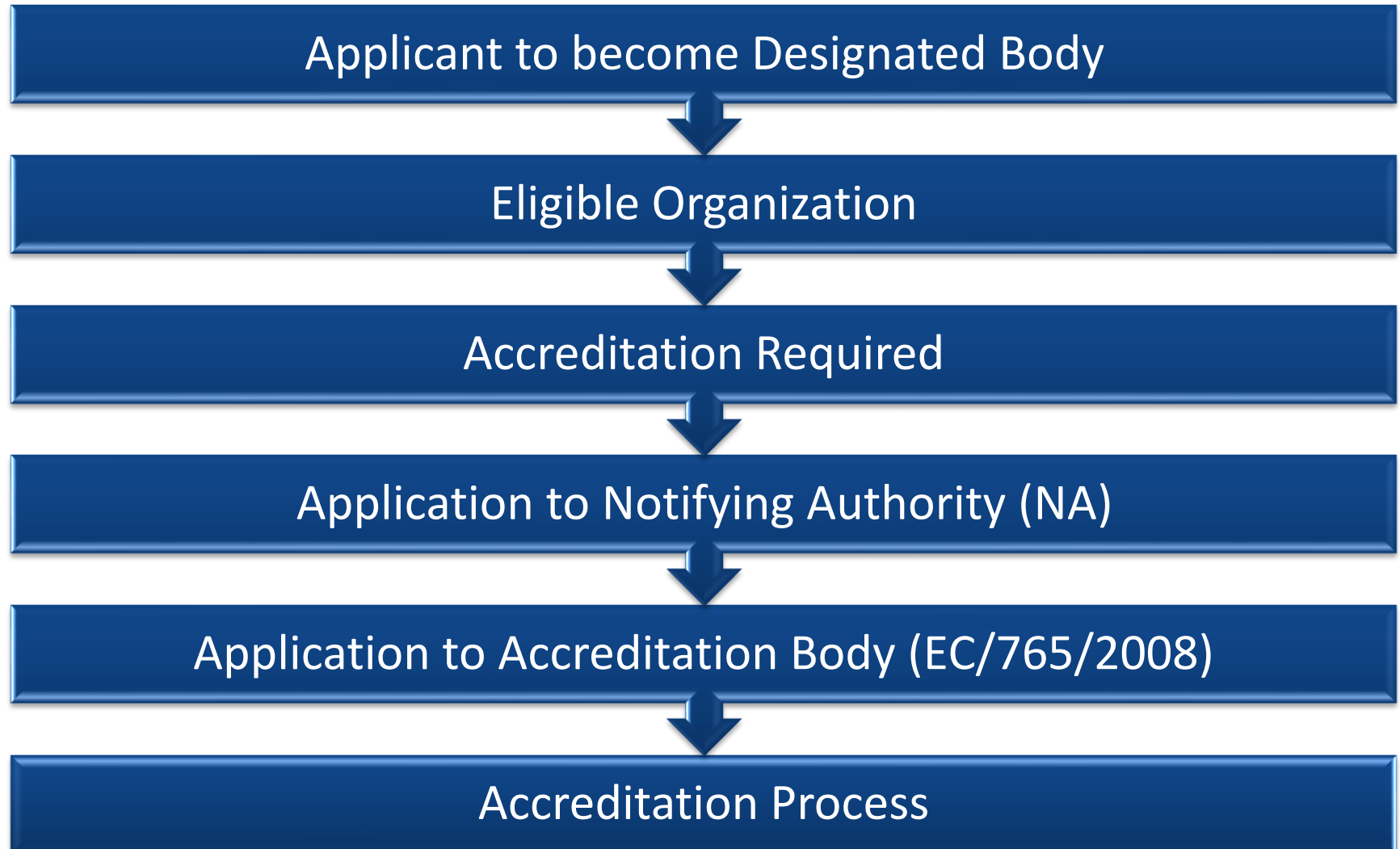
1. the name of the subcontract organisation
2. its legal status and details of any relationship with a parent company, group of companies, or any other organisation of which the subcontractor is a part
3. names of staff carrying out the subcontracted activities and evidence that they are competent to do so
4. The precise duty performed by the subcontractor (e.g. quality system assessment, testing etc.) and details of the procedures used in carrying out the subcontracted duties.

Notified bodies Roles and Responsibilities

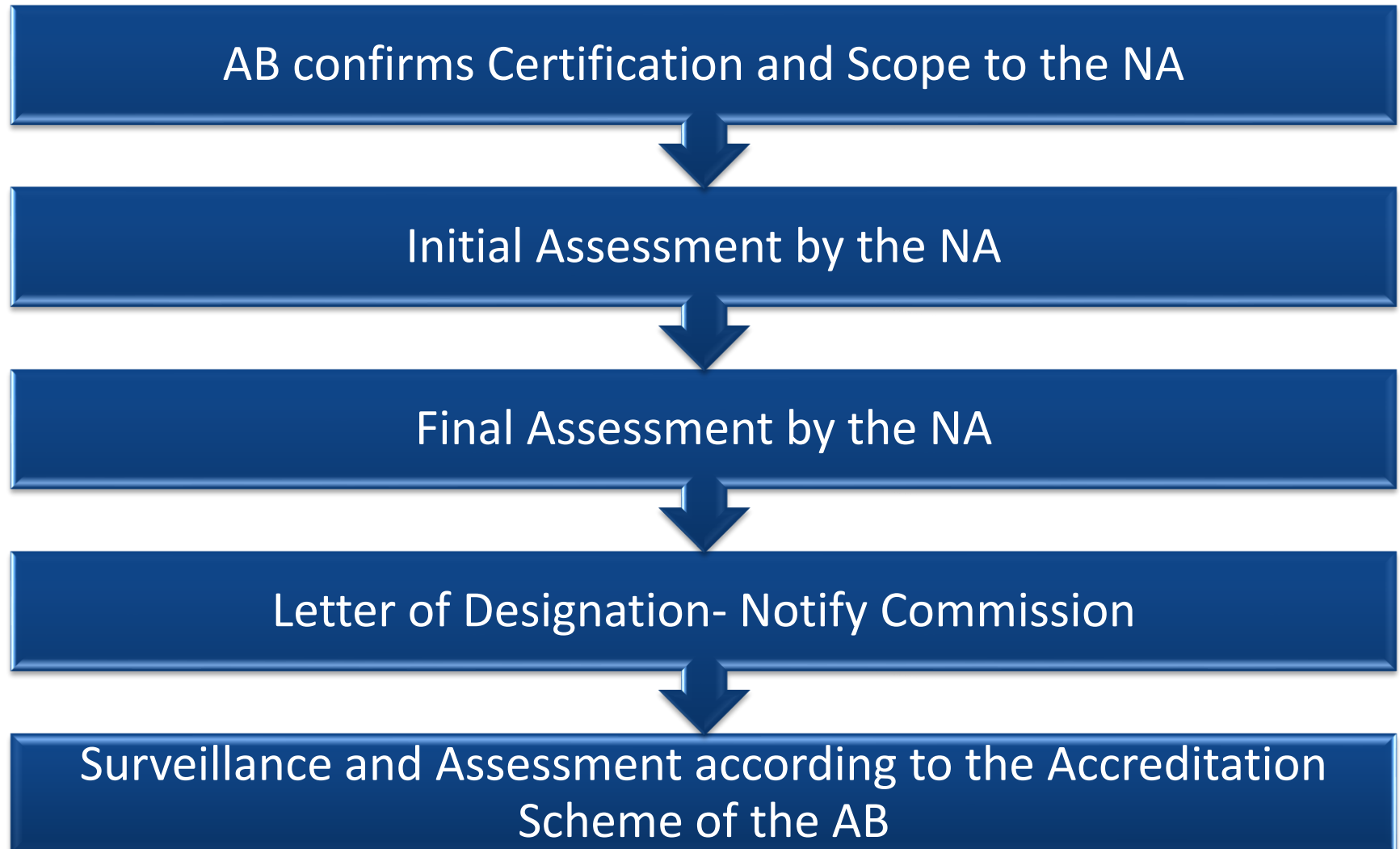
Subcontracting must be based on a contract, which makes it possible to ensure the transparency of and have confidence in the notified body's operations.

- A **documented agreement** shall be drawn up between the notified body and the subcontractor reflecting all aforementioned requirements, including **confidentiality** and the provision of **access for the competent authority**.
- This agreement shall also **prohibit** subcontractors from **further subcontracting** their duties.
- The NB shall ensure that the subcontracted activities are carried out **according to detailed documented procedures** which are the same as, or judged by the NB to be equivalent to, those followed by the NB itself in the context of conformity assessment.

Procedure to become Notified Body



Procedure to become Notified Body



Thank you for your attention!

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