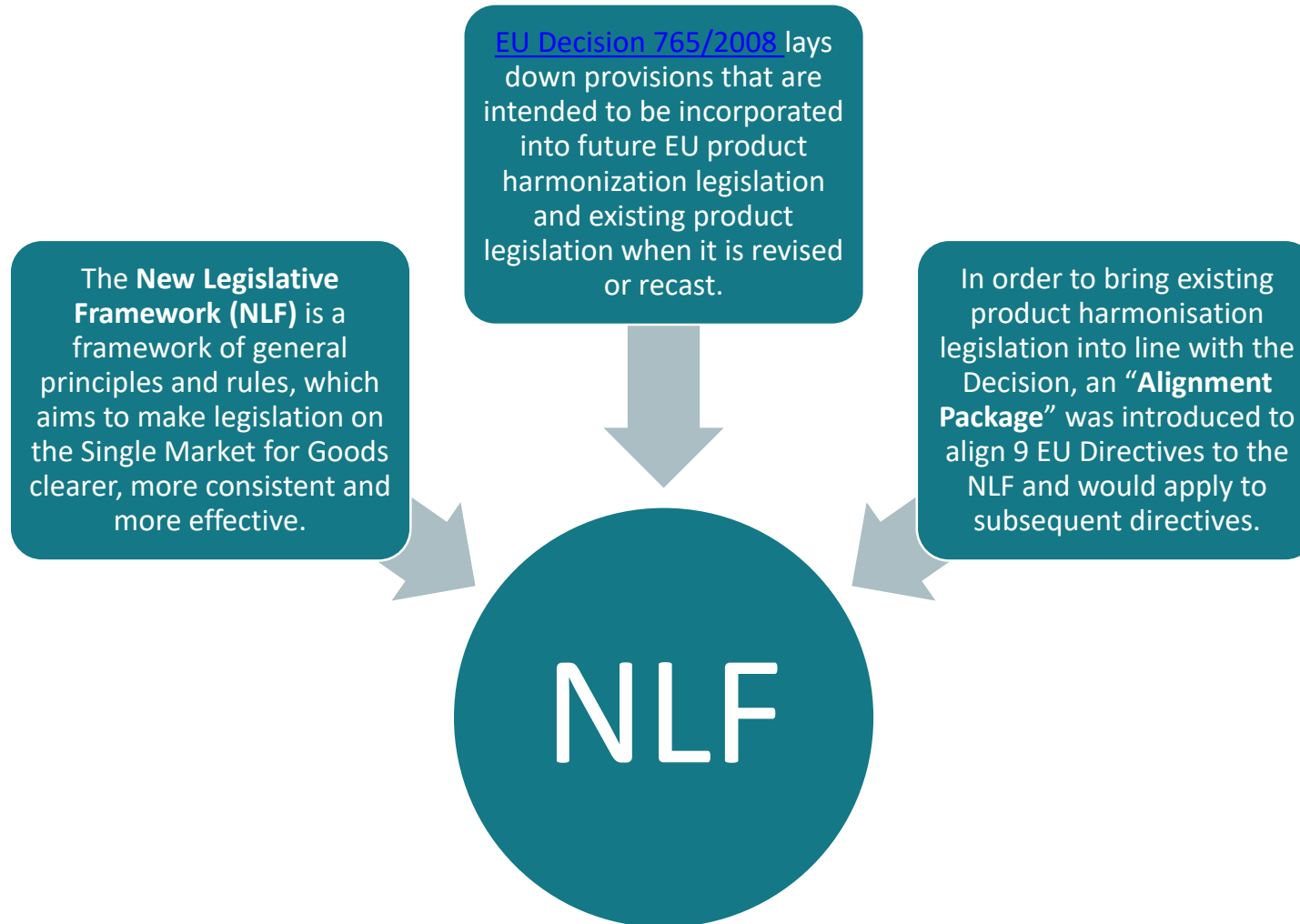




# New Legislative Framework

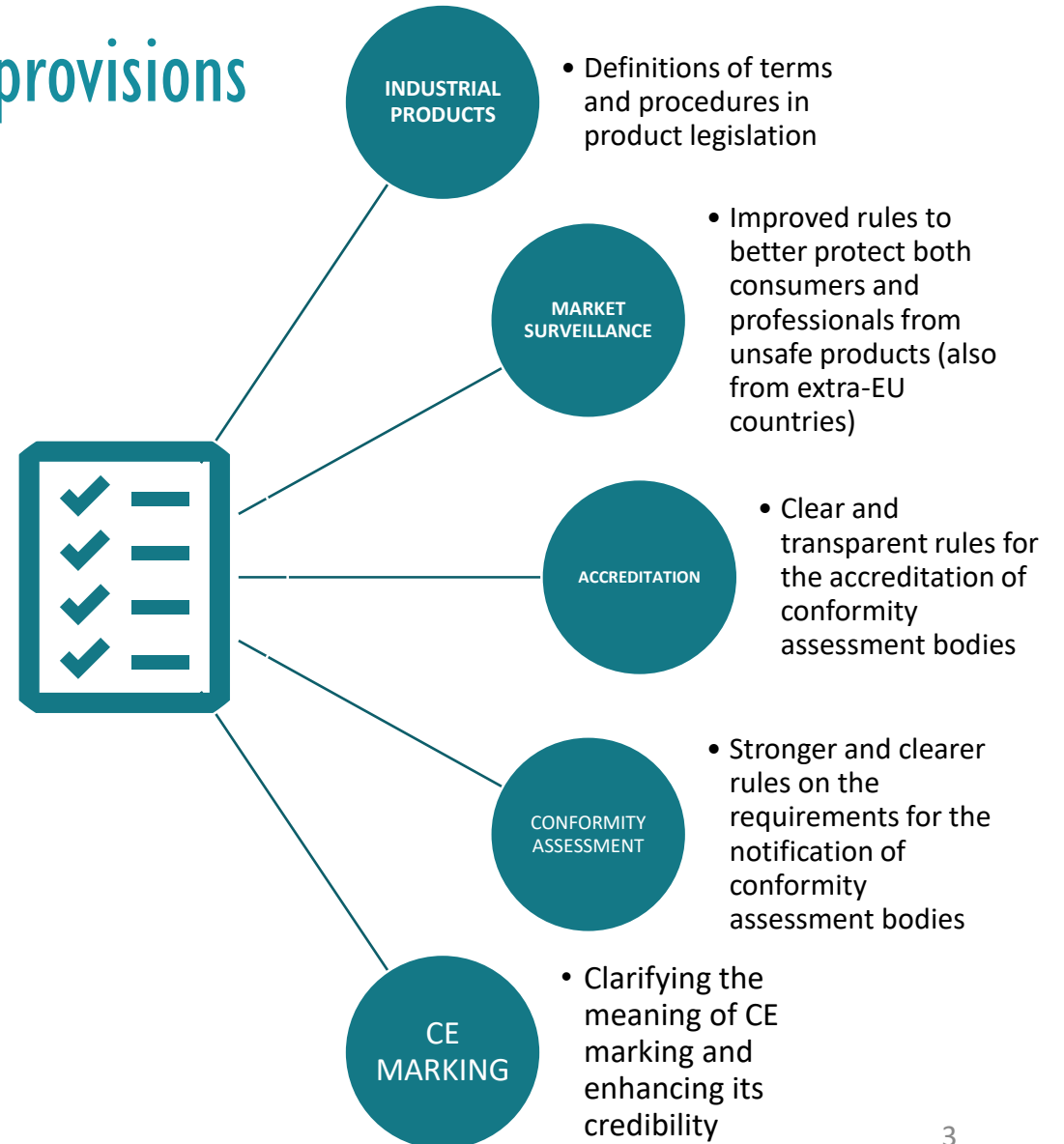
**Disclaimer:** This document is provided for internal information purposes only. It does not reflect any opinion or position of EUROSMART.

## What is it?



## Objectives and provisions

# NEW LEGISLATIVE FRAMEWORK: WHAT DOES IT PROVIDE?



## Three steps

### Two Regulations in 2008

[Regulation \(EC\) 764/2008](#) laying down procedures relating to the application of certain **national technical rules to products** lawfully marketed in another EU country

[Regulation \(EC\) 765/2008](#) setting out the requirements for **accreditation** and the **market surveillance** of products



### One decision in 2008: a first toolbox for the alignment

[Decision 768/2008](#) on a **common framework** for the **marketing of products**, which includes reference provisions to be incorporated whenever product legislation is revised.

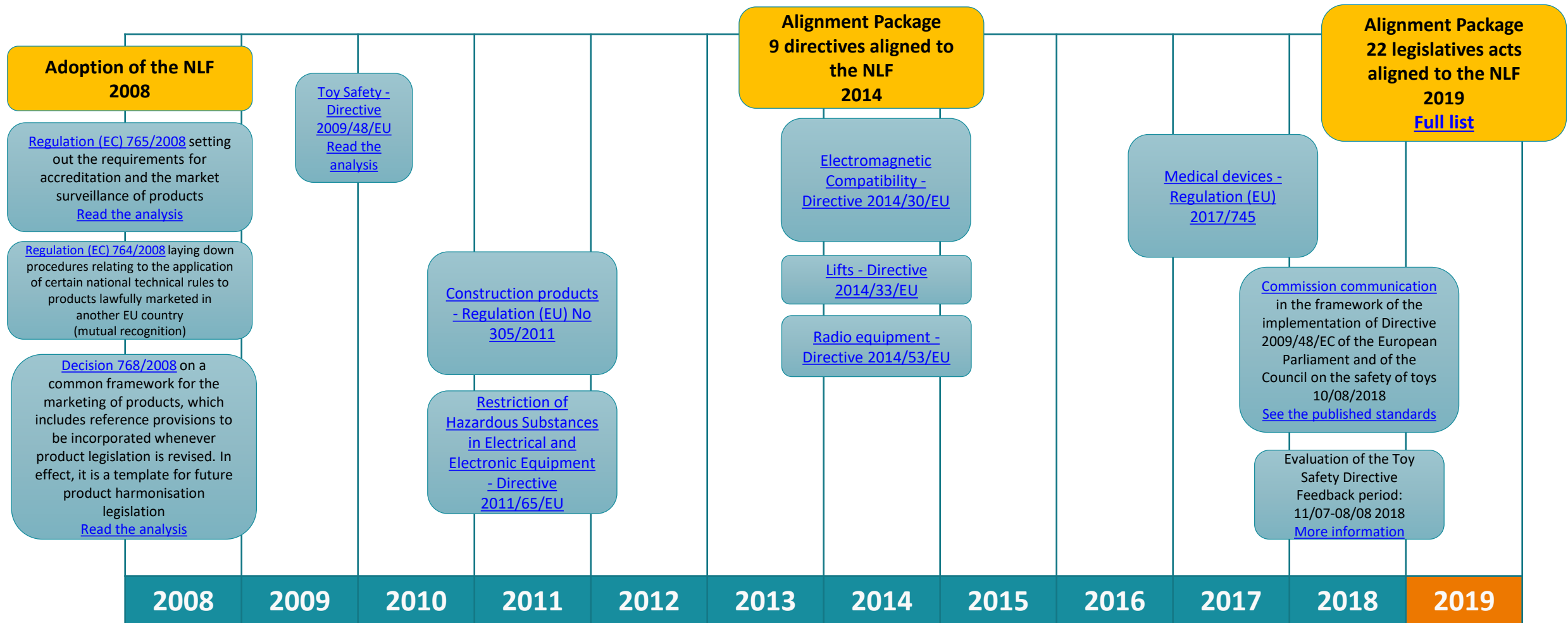


### The alignment package in 2014 to date

It was fully published in March 2014 and it was introduced to align initially **9 Directives (today 21)** to the NLF.

# Aligned directives and regulations concerning EUROSMART industries products

# Timeline from 2008 to 2018



# The Regulation & the Decision

# Vademecum to understand the NLF 1/3

## Regulation

- EU “law” → It becomes law in all Member States at same time;
- Directly Applicable;
- Member States need to apply;
- Immediately enforceable.

## Decision

- Also EU law → *Sui generis* Decision;
- Applies to legislators themselves: European Parliament and Council;
- Model Articles « toolbox »
- To be applied when sectoral legislation is created or revised

# Vademecum to understand the NLF 2/3

## Regulation

- Covers elements not already included in sectoral legislation (in this case: accreditation, market surveillance, etc.)
- Common elements to facilitate the internal market

## Decision

- Covers elements already included in legislation (in this case: notification, safeguard clause mechanisms, etc. )
- BUT sectors can deviate according to specificities of the sector, if required

# Vademecum to understand the NLF 3/3

## Regulation (EC) 765/2008

- Accreditation
- Market
- Surveillance:
  - Internal
  - Imported products
- **CE** marking General principles
- Financing elements
- In force since 2010

## Decision 768/2008

- Definitions / Obligations
- Notification (criteria / process / accreditation)
- Conformity Assessment Procedures
- Safeguard mechanisms & market surveillance
- **CE** marking
- Basis for future legislation

# The Regulation (EC) 765/2008

## Accreditation

- Single accreditation body per Member State;
- Non - competition / public authority;
- Requirements for accreditation bodies;
- Peer evaluation;
- Information obligation / transparency;
- EA (European cooperation for Accreditation);
- No exclusions, regulated or voluntary;

## Market surveillance

- Scope: all products with some exclusions [Article 15 (4)]
- Lex specialis derogat legi generali: Art.15(2) envisages pharmaceuticals, aviation, medical devices and motor vehicles, given as examples in recitals
- Organisation / Surveillance measures
- Restrictive measures
- Communication and coordination
- Control of products entering the EU

## CE marking

- Clarification on use
- Clarification on meaning
- Clarification of role as against other marks

# The Decision 768/2008

## SCOPE:

Recital 6 – « *Whenever legislation is drawn up, the legislator may depart, totally or partially, from the common principles and reference provisions laid down in this Decision on account of the specificities of the sector concerned. Any such departure should be justified* »

## DEFINITIONS & OBLIGATIONS FOR ECONOMIC OPERATORS

Manufacturer / distributor / importer, etc.

## NOTIFICATION

1. Requirements for notifying authorities
2. Requirements for NBs / role of accreditation
3. Subsidiaries and sub-contracting
4. Accredited in-house bodies
5. Electronic notification / de-notification
6. Co-ordination GNBS

## CONFORMITY OF THE PRODUCT

Assessment procedures

## MARKET SURVEILLANCE

Safeguard procedures

## CE Marking

Rules and conditions for affixing - form of the marking

Regulation (EC) 765/2008 setting out  
the requirements for accreditation and  
the market surveillance of products

## The aim

1 It lays down common rules for accrediting bodies that ensure non-food products in the EU conform to certain requirements

2 It establishes a surveillance system to guarantee a high level of safety of those products and in general their compliance with applicable requirements

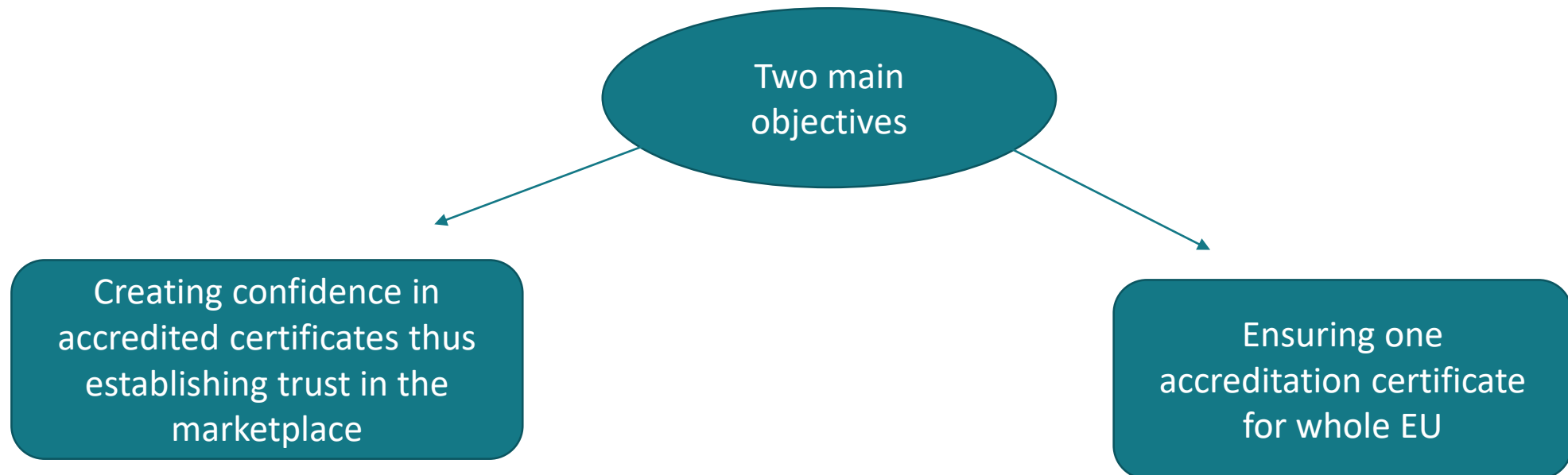
3 It also sets rules in regard to controls on imports from outside the EU and establishes the general principles for CE marking

## Scope and main principles

- Accreditation relating to conformity assessment
- Rules apply both to mandatory and voluntary areas
- Application to product and services
- Not render obligatory
- Last level of control

## The accreditation


- **Article 2** defines the ‘**accreditation**’: an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;



## Public authorities' activity

- **Single national accreditation body:**
  - ✓ Non competition principle
  - ✓ Strict cross border policy
- Separation of responsibilities National Accreditation Bodies from National Authorities
- Information obligations
- **Recognition of EA (European co-operation for accreditation) as official European accreditation infrastructure** dealing with:
  - ✓ management of the peer evaluation
  - ✓ EC can mandate to develop sectoral accreditation schemes

## Requirements for NABs

- Be independent of commercial motivations
- Operate on a not for profit basis
- Be authoritative, objective, impartial
- No competition between NABs and between NABs and accredited CABs
- Not be involved in conformity assessment for which they accredit other bodies
- Balanced involvement of stakeholders
- Member of EA and participation in peer evaluation (presumption of conformity and mutual recognition)
- Monitor CABs they have accredited  suspension/withdrawal of accreditation certificate

## Requirements for Member States

- NAB fulfils requirements → monitoring and corrective actions
- Appropriate resources to NAB;
- NAB is deemed to exercise public authority irrespective of legal status
- NAB undergoes peer evaluation
- Oversee (with EC) peer evaluation
- Procedure for resolution of appeals
- Prove that CAB evaluated not using accreditation complies with requirements

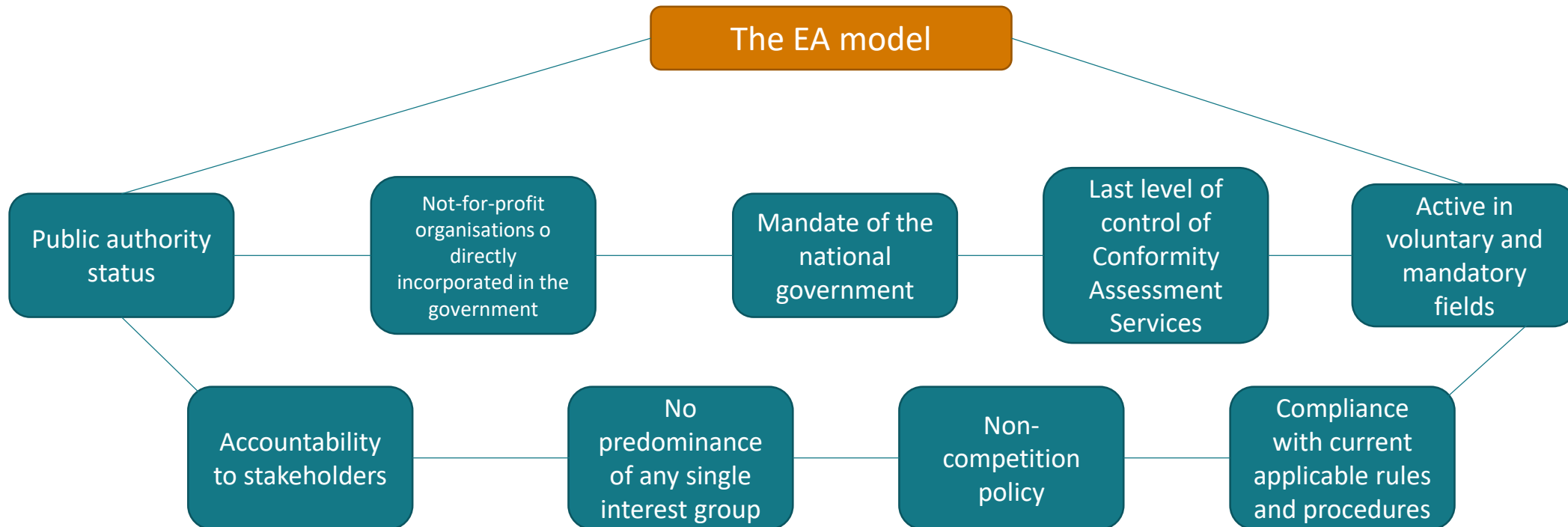
## The European co-operation fo Accreditation

- The European co-operation Accreditation (EA) is the **association of national accreditation bodies** in Europe and is recognized by the European Commission as the **European accreditation infrastructure** (Art. 14 [Reg. \(EC\) No 765/2008](#))
- It provides accreditation for bodies performing different types of **conformity assessment activities** such as:
  - Calibration;
  - Testing;
  - Inspection;
  - Certification of quality, environmental management systems;
  - Certification of products/services;
  - Certification of persons;
  - Verification (EMAS, EU/ETS, ETV).

# Purpose of EA

- Providing Europe with an **effective, reliable accreditation infrastructure**;
- Developing **accreditation criteria and guidelines** supporting harmonisation of practices;
- Operating a sound, robust, reliable **peer evaluation process** to routinely evaluate members;
- Ensuring **equivalence of accreditation** and **equal reliability of accredited results**;
- Cooperating with the **European Commission** and other European and **international stakeholders**

# The EA model



## Main aspects

- **Obligation for a CAB** to ask for accreditation from the NAB of its member state;
- **Obligation for the NAB** not to work in another member state but to subcontract any activities to the local AB;
- **Obligation of all member states** to support its NAB's to be able to carry out the tasks described in regulation 765/2008 EU and all other tasks being delegated to the NAB;
- It shall be ensured that NAB's are not carrying out activities which are not in line with either regulation 765/2008 EU and/or ISO/IEC especially the impartiality and independence of the NAB shall be maintained at all levels

## The Members

- EA currently has **50 Members**
- The EA Members are **National Accreditation Bodies (NAB)** that are officially recognized by their national governments to assess and verify – against international standards – organizations that carry out conformity assessment activities such as certification, verification, inspection, testing and calibration.

## EA Members and MLA signatories

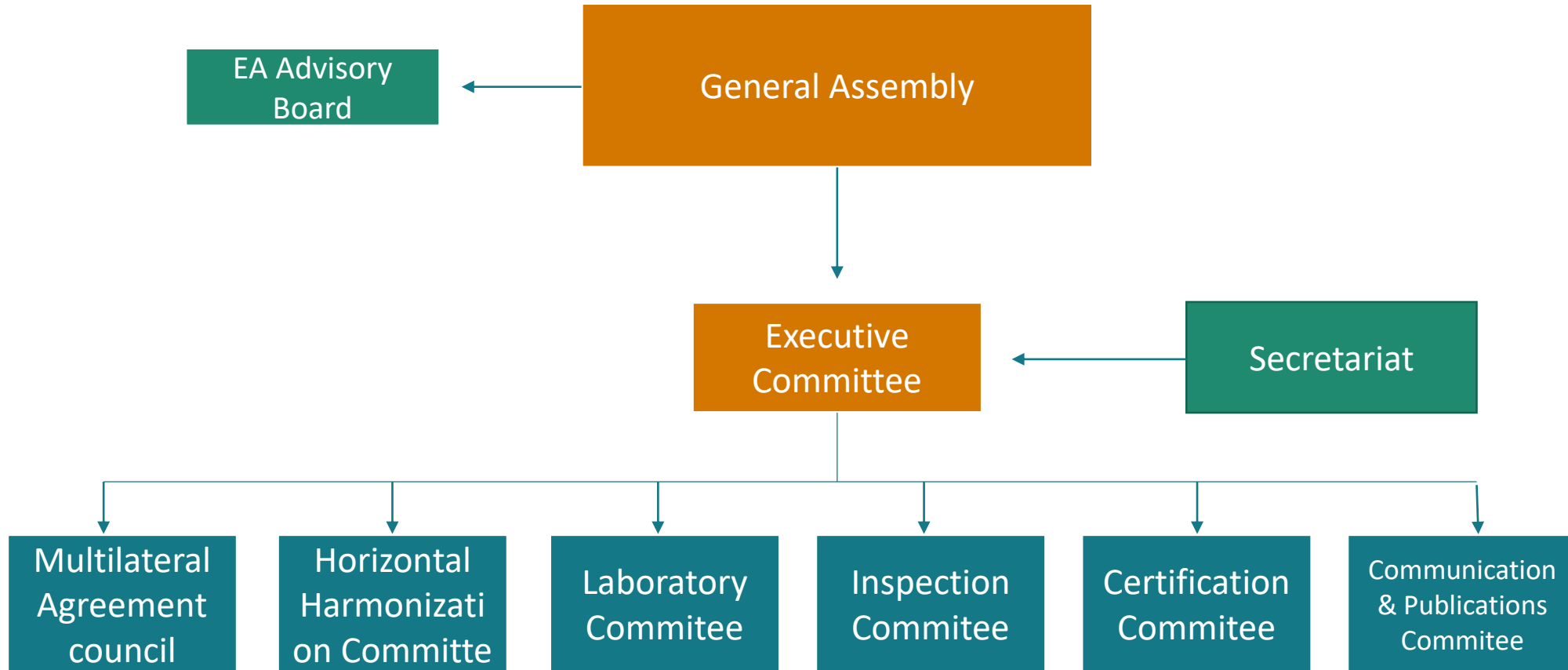
**36 Members** are established in **EU or EFTA countries** or in a country formally identified by the EU or EFTA as a candidate for EU or EFTA membership

**14 Associate Members** are NABs legally appointed as such by countries or economies identified by the EU or EFTA as potential candidate countries or economies for EU or EFTA membership or identified by the EU in the European Commission's European Neighborhood Policy as countries or economies of particular importance.

[FULL LIST OF EU AND NON-EU MEMBERS HERE](#)



## EA Structure

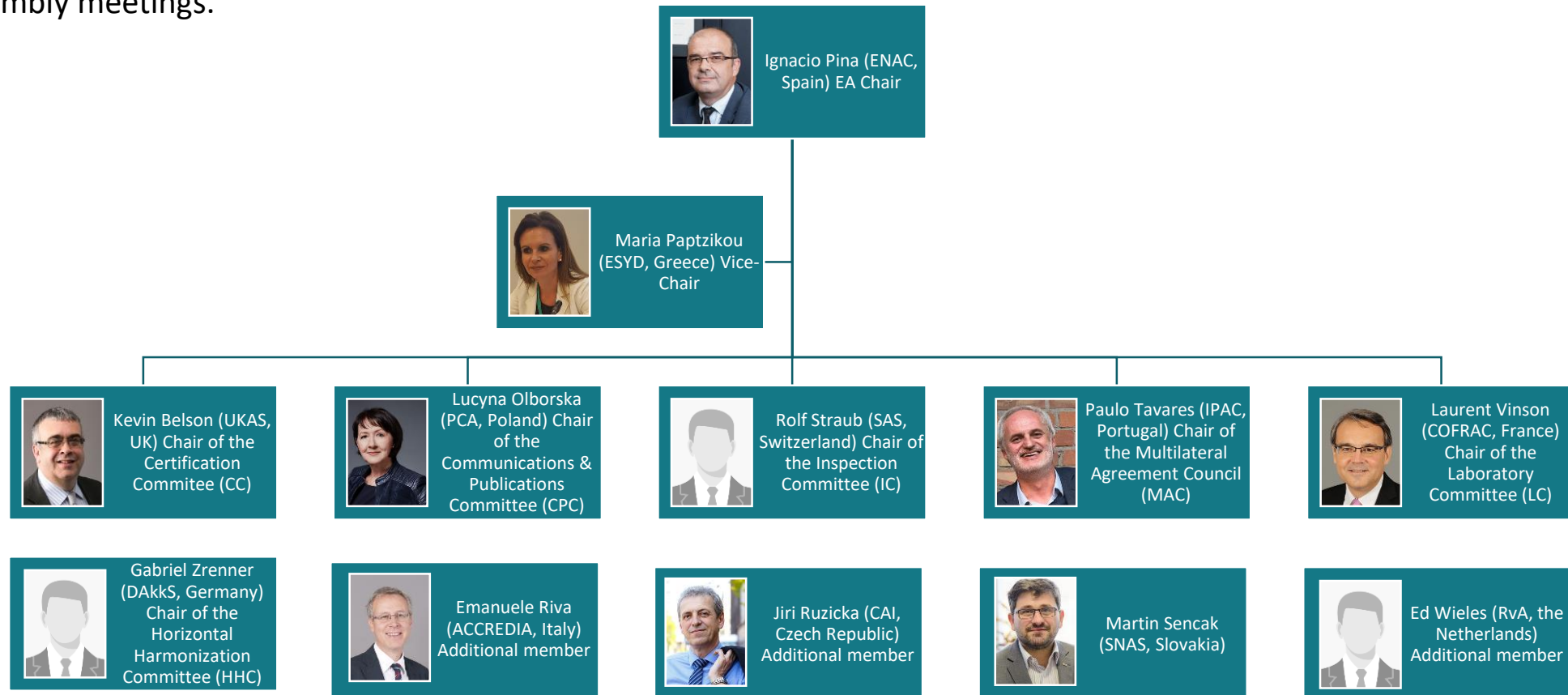


## EA General Assembly (EA GA)

- The General Assembly, the association's **highest decision-making body**;
- It **supervises** EA management and the general course of affairs in the association and takes decisions on strategy and general policies.
- The GA **creates and dissolves EA Committees**.
- It also **elects the Chair and Vice-Chair** of EA as well as the Executive Committee officers.

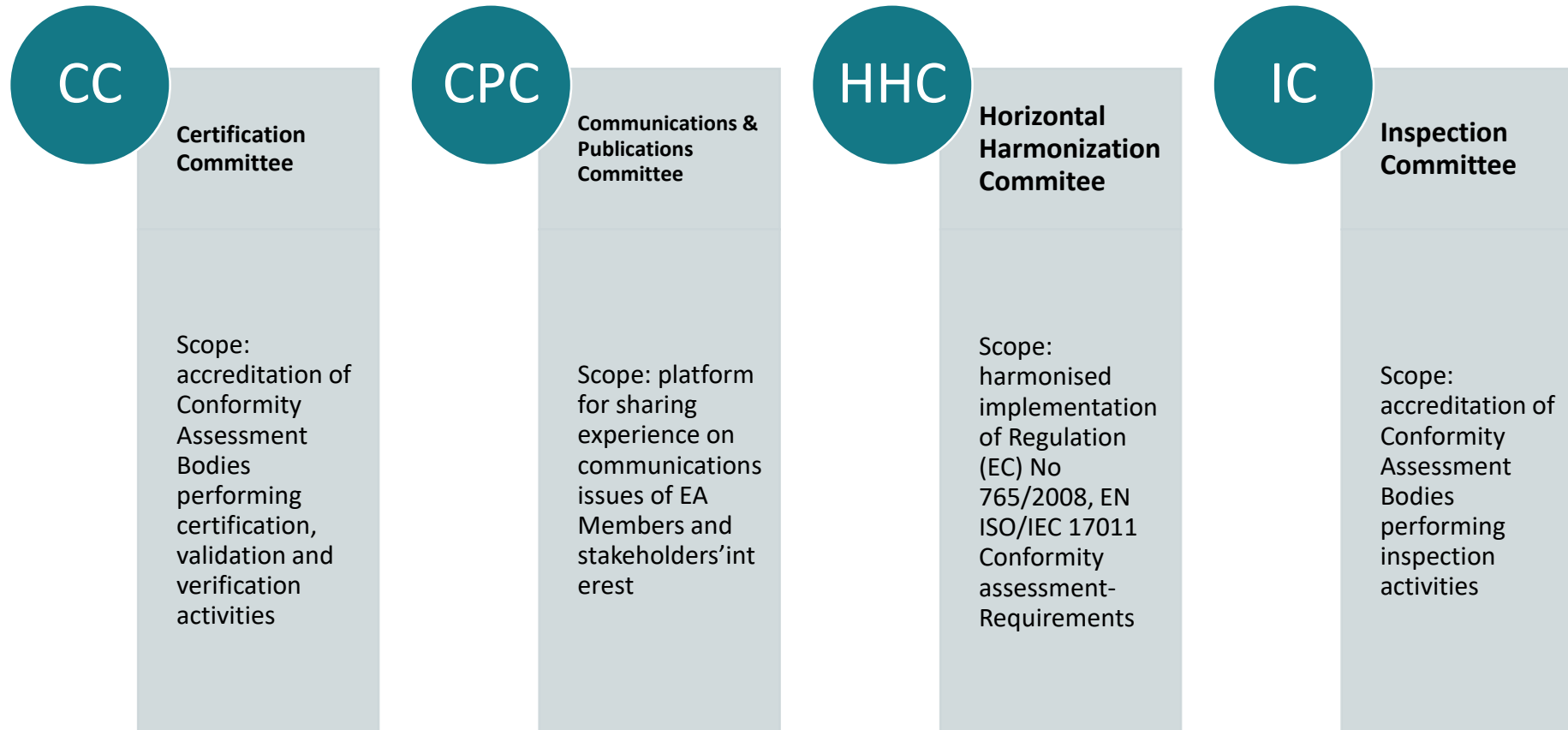
# EA Executive Committee (EA EX)

- The Executive Committee is responsible for implementing EA policies and managing the association between EA General Assembly meetings.

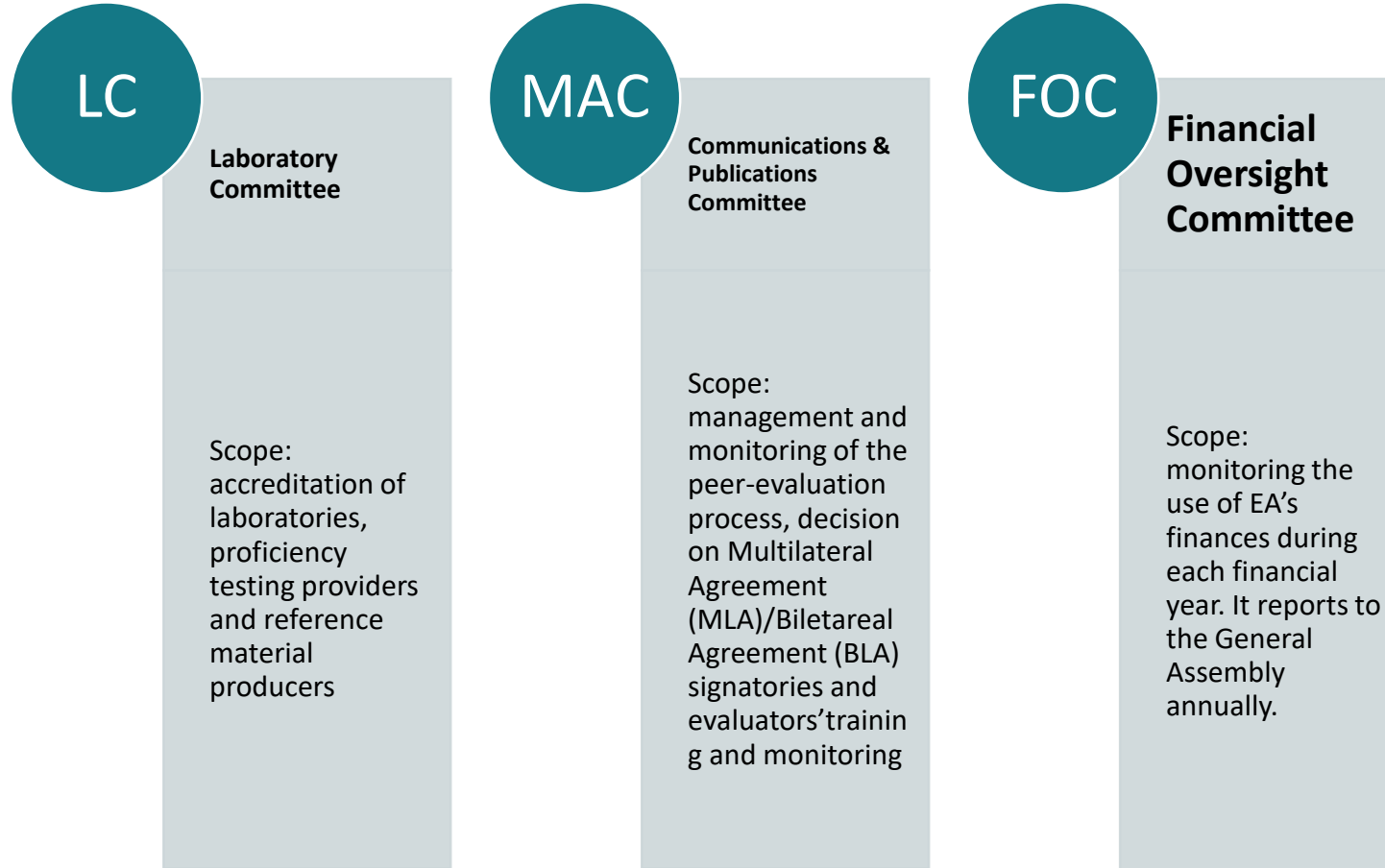


## EA Committees 1/2

- The Committees of the European co-operation for Accreditation ensure that accreditation is managed in Europe in a harmonized, competent and responsible way, taking account of the views and expectations of all EA Members, regulators and stakeholders.



## EA Committees 2/2



## EA Advisory Board (EAAB)

- The EA Advisory Board (EAAB) is the main **forum for relations with stakeholders** and advises EA on a broad range of political and strategic issues.
- The EAAB is **represented in the EA Multilateral Agreement Council**.
- The **Board's composition** constitutes a well-balanced representation of the parties which rely on and contribute to the European accreditation system, **with representatives from:**
  - ❖ Conformity Assessment Bodies;
  - ❖ industry, services and trade;
  - ❖ consumer associations;
  - ❖ metrology institutions;
  - ❖ European standardization organizations
  - ❖ EU Member States' national authorities;
  - ❖ the European Commission and EFTA.

# Alignment Package: 22 legislative acts aligned to the NLF

# The complete framework

## Directives

- [Toy Safety - Directive 2009/48/EU](#)
- [Transportable pressure equipment - Directive 2010/35/EU](#)
- [Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU](#)
- [Pyrotechnic Articles - Directive 2013/29/EU](#)
- [Recreational craft and personal watercraft - Directive 2013/53/EU](#)
- [Civil Explosives - Directive 2014/28/EU](#)
- [Simple Pressure Vessels - Directive 2014/29/EU](#)
- [Electromagnetic Compatibility - Directive 2014/30/EU](#)
- [Non-automatic Weighing Instruments - Directive 2014/31/EU](#)
- [Measuring Instruments - Directive 2014/32/EU](#)
- [Lifts - Directive 2014/33/EU](#)
- [ATEX - Directive 2014/34/EU](#)
- [Radio equipment - Directive 2014/53/EU](#)
- [Low Voltage - Directive 2014/35/EU](#)
- [Pressure equipment - Directive 2014/68/EU](#)
- [Marine Equipment - Directive 2014/90/EU](#)

## Regulations

- [Construction products - Regulation \(EU\) No 305/2011](#)
- [Cableway installations - Regulation \(EU\) 2016/424](#)
- [Personal protective equipment - Regulation \(EU\) 2016/425](#)
- [Gas appliances - Regulation \(EU\) 2016/426](#)
- [Medical devices - Regulation \(EU\) 2017/745](#)

# Toy Safety - Directive 2009/48/EU

## The main provisions

- The [Toy Safety Directive 2009/48/EC](#) replaced the former Directive 88/378/EEC. It adapted the legal framework to technological developments and previously unknown safety issues.
- It lays down the safety criteria that toys must meet before they can be marketed in the EU. The essential safety requirements cover:
  - ❑ **general risks:** the health and safety of children, as well as other people such as parents or caregivers
  - ❑ **particular risks:** physical and mechanical, flammability, chemical, electrical, hygiene and radioactivity risks

## The expert group on Toy Safety

[Expert Group on Toys Safety](#)  
[\(EO1360\)](#)

- **Establishment:** 25 January 2006
- **Lead DG:** GROW - DG Internal Market, Industry, Entrepreneurship and SMEs
- **Associated DG:** TRADE - DG Trade; JUST - DG Justice and Consumers
- **Members:** representatives from stakeholders, Member States authorities and other public entities
- **Mission:** Establish cooperation between Member States, stakeholders and the Commission, in relation to toy safety. Ensure consistent implementation of the legislation within the EU.
- **Task:**
  1. Assist the Commission in the preparation of delegated acts
  2. Coordinate with Member States, exchange of views

## Members from stakeholders world

Name of Organisation	Category	Countries/Areas represented	Membership Status
<a href="#">Bureau Européen des Unions de Consommateurs (BEUC)</a>	NGOs	European	Observer
<a href="#">European Association for the Co-ordination of Consumer Representation in Standardisation (ANEC)</a>	NGOs	European	Observer
<a href="#">European Committee for Electrotechnical Standardization (CENELEC)</a>	Companies/Groups	European	Observer
<a href="#">European Committee for Standardization (CEN)</a>	Companies/Groups	European	Observer
<a href="#">Notified bodies group under the Toy Safety Directive 2009/48/EC (NB-Toys)</a>	Companies/Groups	European	Observer
<a href="#">Toy Industries of Europe (TIE)</a>	Companies/Groups	European	Observer

## Guidance on the application of the Directive

- The Commission and the Expert Group on Toy Safety draw up guidance documents **to assist manufacturers, importers, distributors, and public authorities** in the interpretation and application of the Toy Safety Directive.
- The guidance documents are **not legally binding** but they express the views of the majority of the Expert Group's members.
- The [Guidance No. 16](#) on the application of the Toy Safety Directive (TSD) on the safety of toys intends to provide guidelines to help Member States and stakeholders making the **distinction between toys and electronic equipment**

## The electronic equipment

- **Article 2 (Scope)** provides that the TSD Directive shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age ("toys").
- Some products are not regarded as toys according to Annex I of TSD 2009/48/EC.
- Consequently, some **electronic equipments** are excluded by its application.

## Personal computers, game consoles and their associated peripherals

*“personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are:*

- specifically designed for and targeted at children and*
- have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels”*

## Each product is an individual

1. The fact that a **personal computer/console or a peripheral** device is bundled and sold together with a toy, such as a toy giveaway, does not make the personal computer/console or the peripheral a toy.
2. If a personal computer/console, exempted from the Directive, is bundled together with a toy peripheral, that does not make the personal computer/console a toy.
3. Similarly, if a personal computer, specifically designed for and targeted at children and has a play value on its own, is bundled or sold with a peripheral or another product, it does not automatically mean that the peripheral/other product is to be considered a toy.

## Interactive software

- Interactive software, intended for leisure and entertainment, such as computer games, and their storage media (CDs disk, cartridge, etc) are not to be considered as toys
- This is a **complete exemption for all interactive software** and their storage media, including the case/box in which it is packaged, even if the software has been exclusively designed for and targeted at children or may otherwise be bundled or sold together with a toy product.
- The **software and its storage media is never a toy**

Commission communication in the framework of the implementation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys

(Publication of titles and references of harmonised standards under Union harmonisation legislation)

# Harmonised standards

- The [Commission communication 2018/C 282/02](#) in the framework of the implementation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys contains **titles and references of harmonised standards** under Union harmonisation legislation

ESO	Reference and title of the standard (and reference document)	First publication	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard – Note 1
CEN	EN 71-1:2014+A1:2018 Safety of toys — Part 1: Mechanical and physical properties	This is the first publication	EN 71-1:2014 Note 2.1	28.2.2019
CEN	EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability	13.6.2014	EN 71-2:2011 Note 2.1	30.9.2014
CEN	EN 71-7:2014+A2:2018 Safety of toys — Part 7: Finger paints — Requirements and test methods	This is the first publication	EN 71-7:2014 Note 2.1	28.2.2019
CEN	EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use	This is the first publication	EN 71-8:2011	28.2.2019
CEN	EN 71-12:2013 Safety of toys — Part 12: N- Nitrosamines and N-nitrosatable substances	29.6.2013		

## Harmonised standards


ESO	Reference and title of the standard (and reference document)	First publication	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard – Note 1
CEN	EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets	13.11.2015	EN 71-5:2013 Note 2.1	31.5.2016
CEN	EN 71-7:2014+A2:2018 Safety of toys — Part 7: Finger paints — Requirements and test methods	This is the first publication	EN 71-7:2014 Note 2.1	28.2.2019
CEN	EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use	This is the first publication	EN 71-8:2011	28.2.2019
CEN	EN 71-12:2013 Safety of toys — Part 12: N- Nitrosamines and N-nitrosatable substances	29.6.2013		
CEN	EN 71-13:2014 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games	13.6.2014		
CEN	EN 71-14:2014+A1:2017 Safety of toys — Part 14: Trampolines for domestic use	This is the first publication	EN 71-14:2014 Note 2.1	28.2.2019

## Harmonised standards

ESO	Reference and title of the standard (and reference document)	First publication	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard – Note 1
Cenelec	EN 62115:2005 Electric toys — Safety IEC 62115:2003 (Modified) + A1:2004	11.8.2011		
	EN 62115:2005/A11:2012/AC:2013	29.6.2013		
	EN 62115:2005/A11:2012	15.11.2012	Note 3	15.11.2012
	EN 62115:2005/A12:2015	12.6.2015	Note 3	3.6.2017
	EN 62115:2005/A2:2011/AC:2011	19.10.2011		
	EN 62115:2005/A2:2011 IEC 62115:2003/A2:2010 (Modified)	11.8.2011	Note 3	11.8.2011

# Institutional actors


## DG GROWTH – Directorate B, UNIT B.1

Dir.-Gen.	Department	Name	Picture	Position
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>Mr INGELS Hans</b>		Head of Unit B.1: Single Market Policy, Mutual Recognition and Surveillance
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>Mr BILALIS Z.</b>		Policy Officer - Accreditation, Conformity assessment and ICSMS Unit B.1: Single Market Policy, Mutual Recognition and Surveillance
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>DE LA BARCENA ANGULO P.</b>		Legal Officer - Internal Market Legislation for Products Unit B.1: Single Market Policy, Mutual Recognition and Surveillance
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>PANTAZI F.-A.</b>		Policy Officer - Mutual Recognition Unit B.1: Single Market Policy, Mutual Recognition and Surveillance

## DG GROWTH – Directorate B, UNIT B.1

Dir.-Gen.	Department	Name	Picture	Position
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>DEURWAARDER Ewout</b> 		Policy Officer - Market Surveillance for Products Unit B.1: Single Market Policy, Mutual Recognition and Surveillance
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>MODRIC SKRABALO Katja</b> 		Policy Officer - Internal Market (CE marking) and its International Dimension Unit B.1: Single Market Policy, Mutual Recognition and Surveillance
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>ROELAND C.</b>		Policy Officer - Market surveillance for products Unit B.1: Single Market Policy, Mutual Recognition and Surveillance

## DG GROWTH – Directorate B, UNIT B.3

Dir.-Gen.	Department	Name	Picture	Position
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>MALY Radek</b> 		Head of Unit Unit B.3: Standards for Growth
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>HOSSZU R.</b>		Policy officer – Standardisation Unit B.3: Standards for Growth
European Commission - GROWTH	Directorate B – Single Market Policy, Regulation and Implementation	<b>HENDRIKSEN Martijn</b>		Policy officer – Standardisation Unit B.3: Standards for Growth