



POST-BREXIT

Standards, Certification and the CE Mark

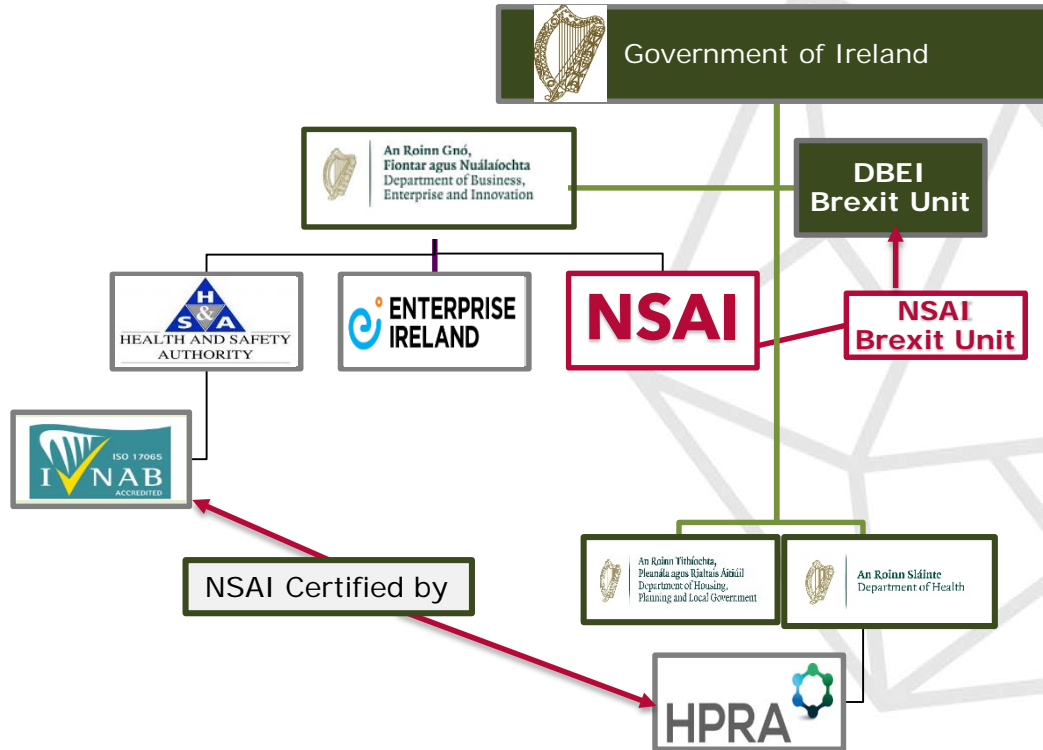
“What Must I Do?”

Mary White
Head of NSAI Brexit Unit

What I will cover

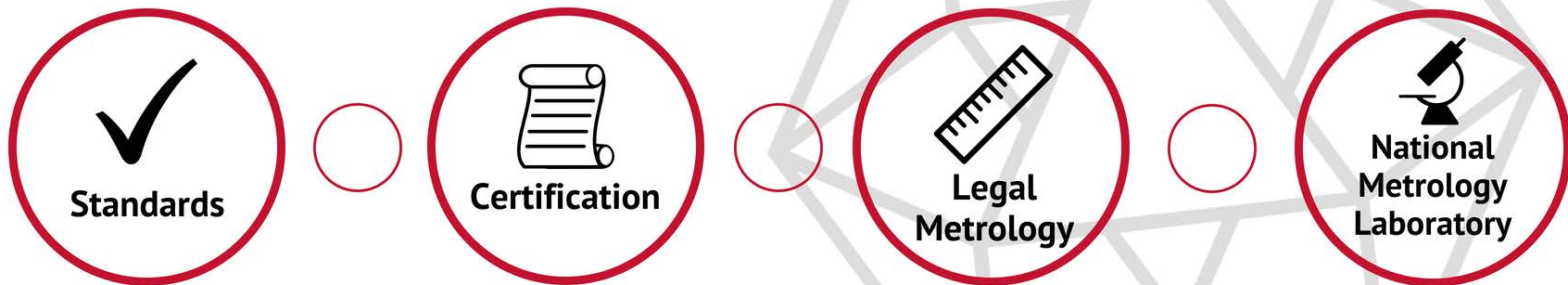
- Introduction to NSAI
- EU Legislation and NANDO
- What CE Does and Notified Bodies (NBs)
- Impact of Brexit for UK Certification
- Responsibility of Manufacturer/Importer
- Transit of Goods (wood packaging material)

NSAI



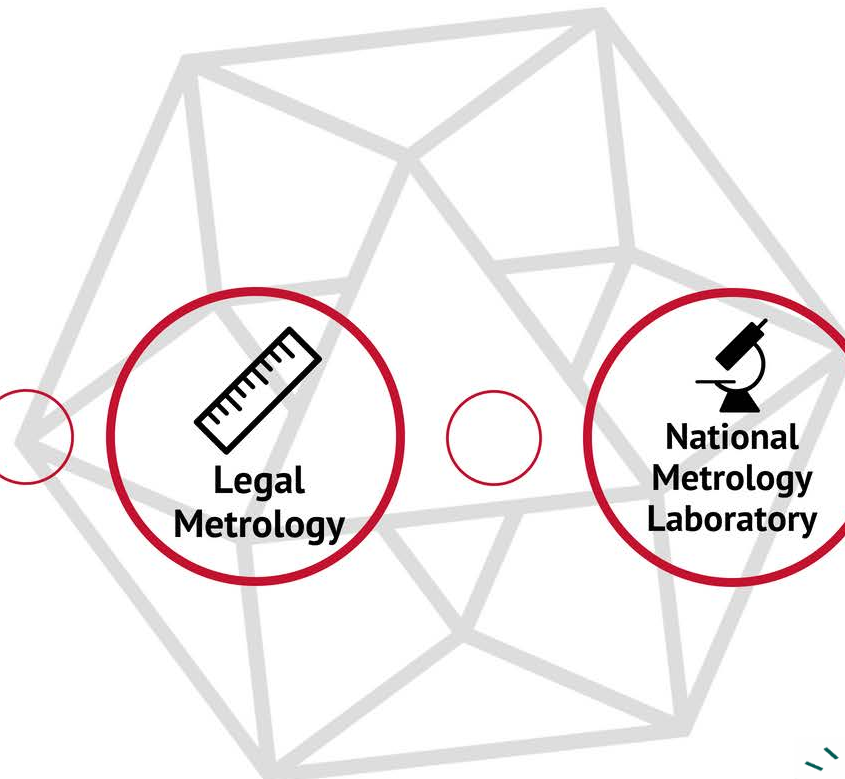
About NSAI

Four main divisions

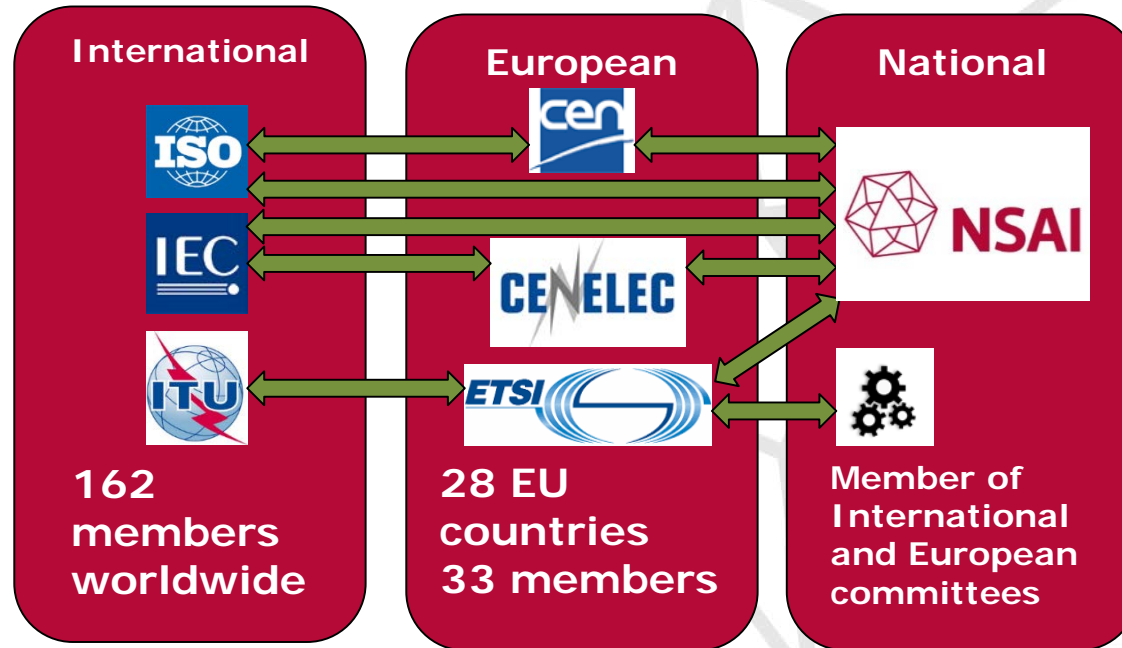


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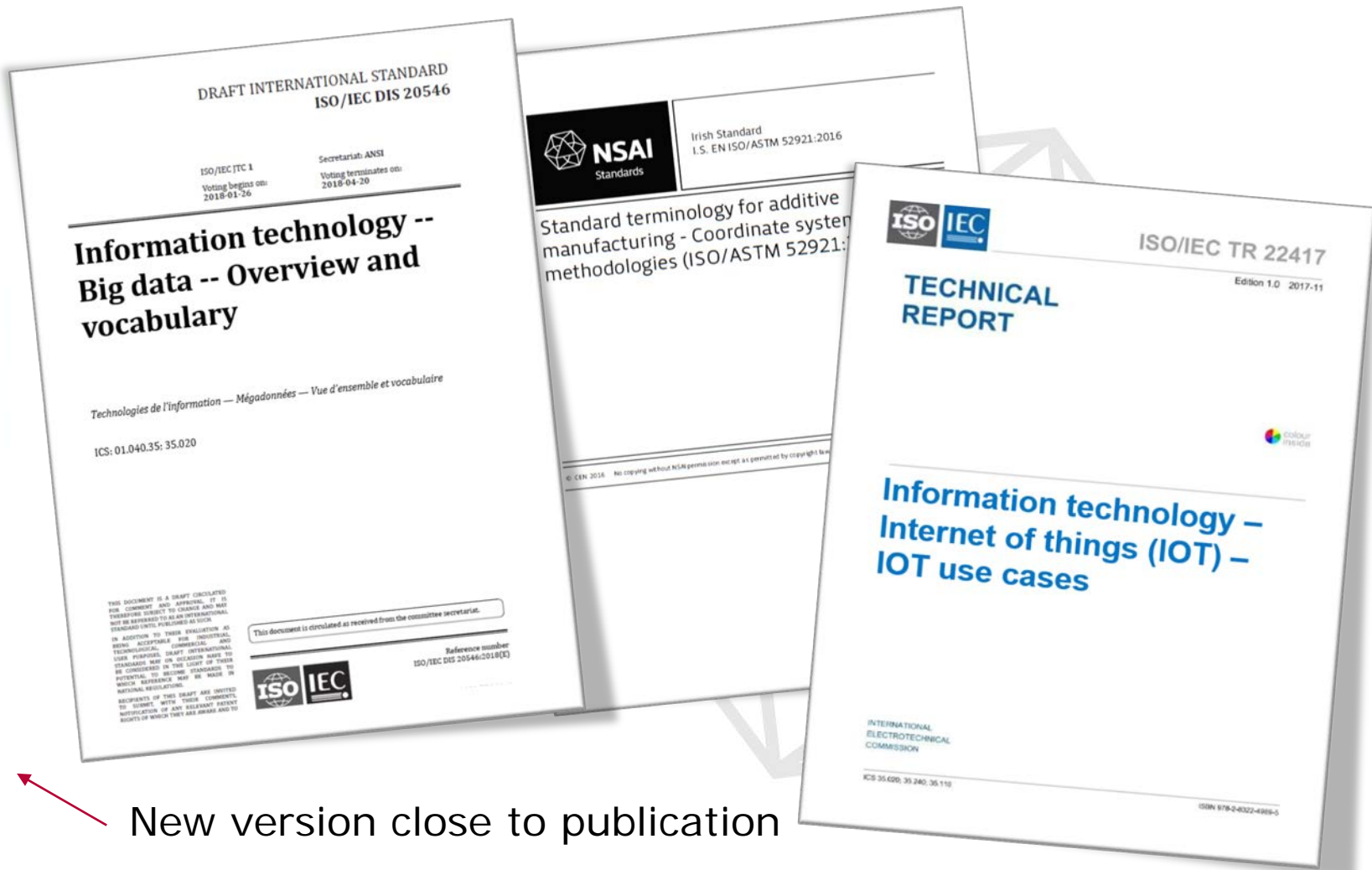
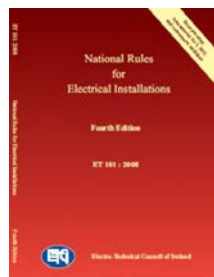
Four main divisions



Where do Standards come from



Process relationships between the Standards Organizations



New version close to publication

Systematic Innovation Management

ISO 56000 Series + 8 Principles



1.
Realization
of value



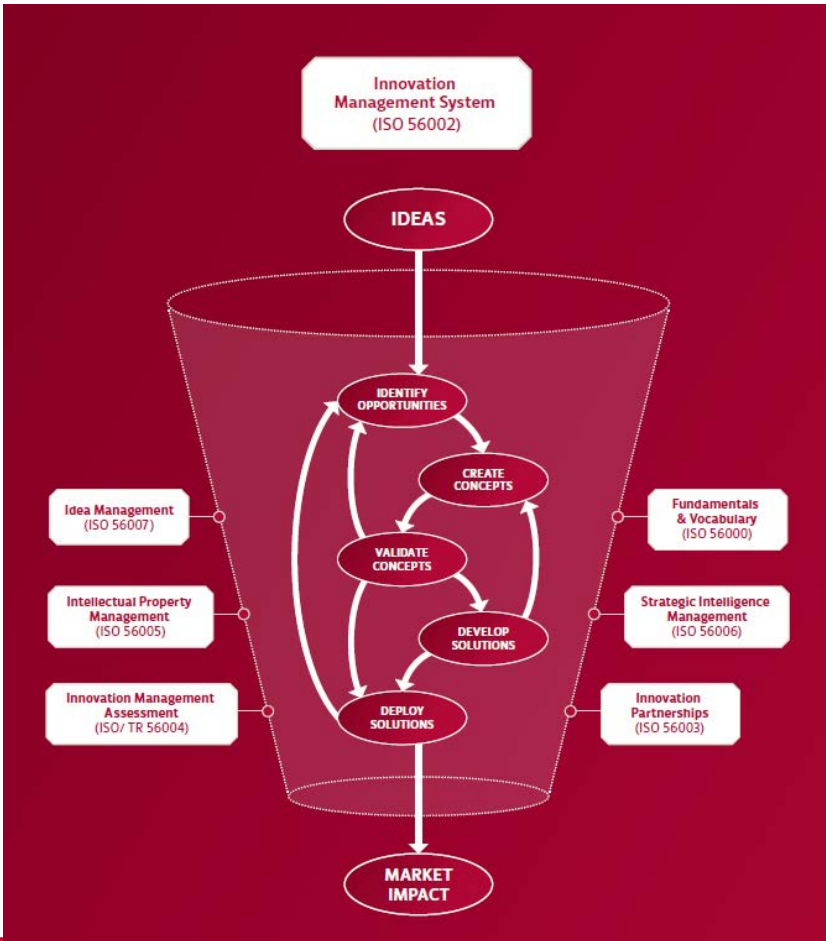
5.
Exploiting
insights



2.
Future-focused
leaders



6.
Managing
uncertainty



3.
Strategic
direction



7.
Adaptability

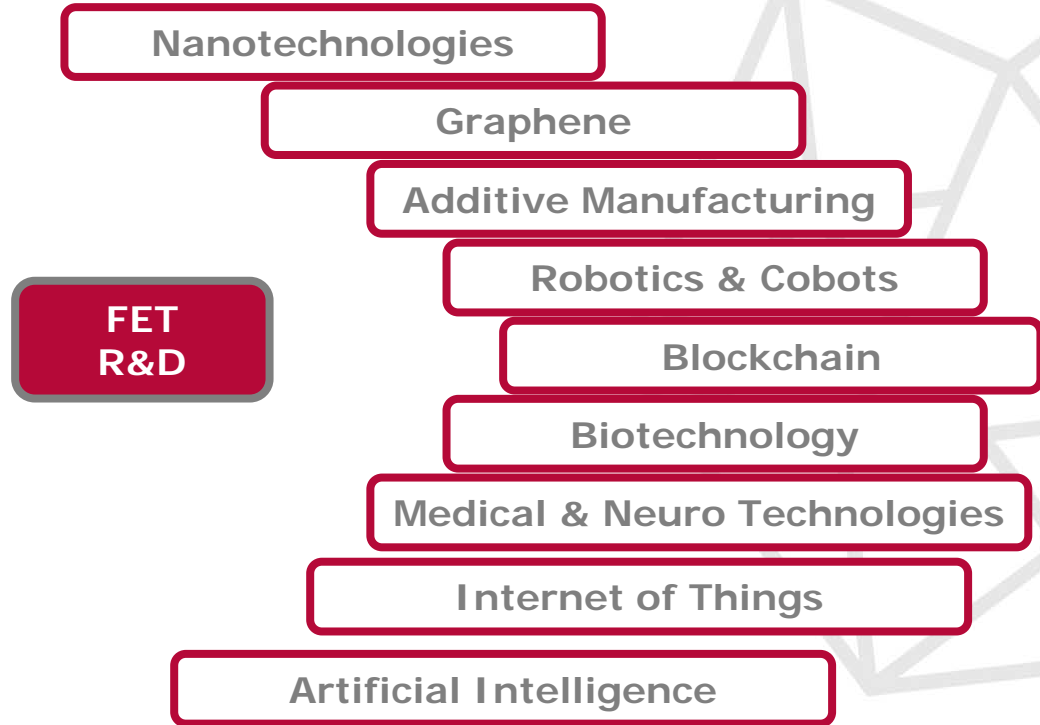


4.
Culture



8. Systems
approach

Future and Emerging Technologies



Emerging Technologies:



**Advanced Manufacturing
& Materials**

Smart Factories

Smart Manufacturing

Key Enablers



5G

Cloud Computing

Internet of Things

Cyber Security

Artificial Intelligence

ICT

ISO/TC 299 - Robotics



Kuka.com

The diagram illustrates the relationship between various international standards for robot safety. At the center is a red box containing **ISO 10218-1** and **ISO 10218-2**. Arrows point from several other standards to this central box:

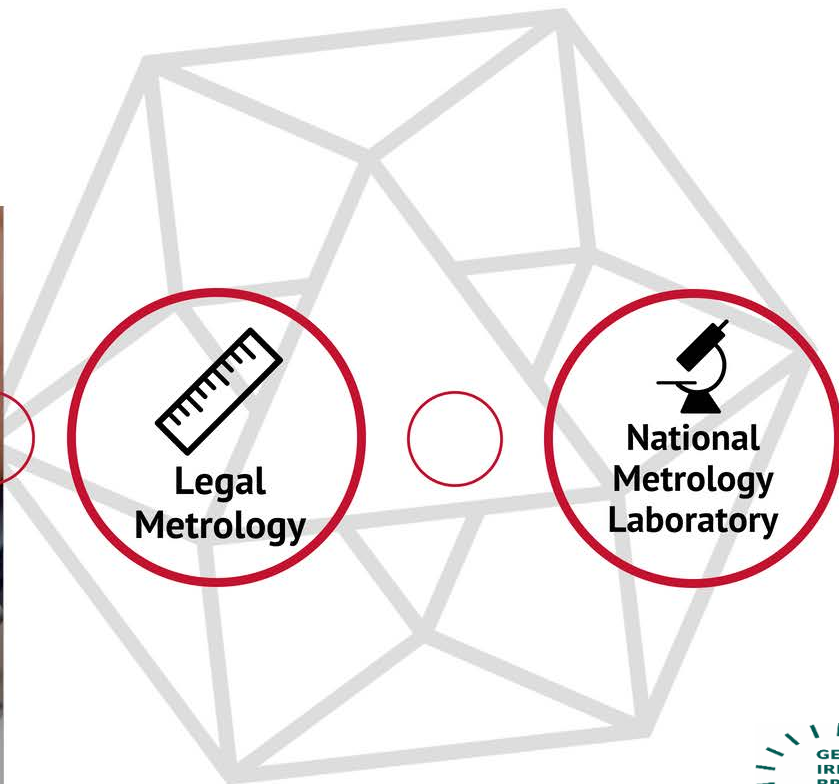
- ISO 62061** (Safety-related SIL)
- ISO 13849** (Safety-related PL)
- IEC 61496 Parts 1,2,3,4** (ESPE in Laser safety, Lights and Vibration)
- ISO 13855**
- RIA TR R15.306**
- ISO 61784-3** (Networking)
- IEC 61508** (Safety-related SIL)
- IEC 62998-7** (Safety-related PL)

Additional standards mentioned in the diagram include **ISO/TS 15066** (Personal guidance for Cobots) and **IEC 61784-3** (Networking).



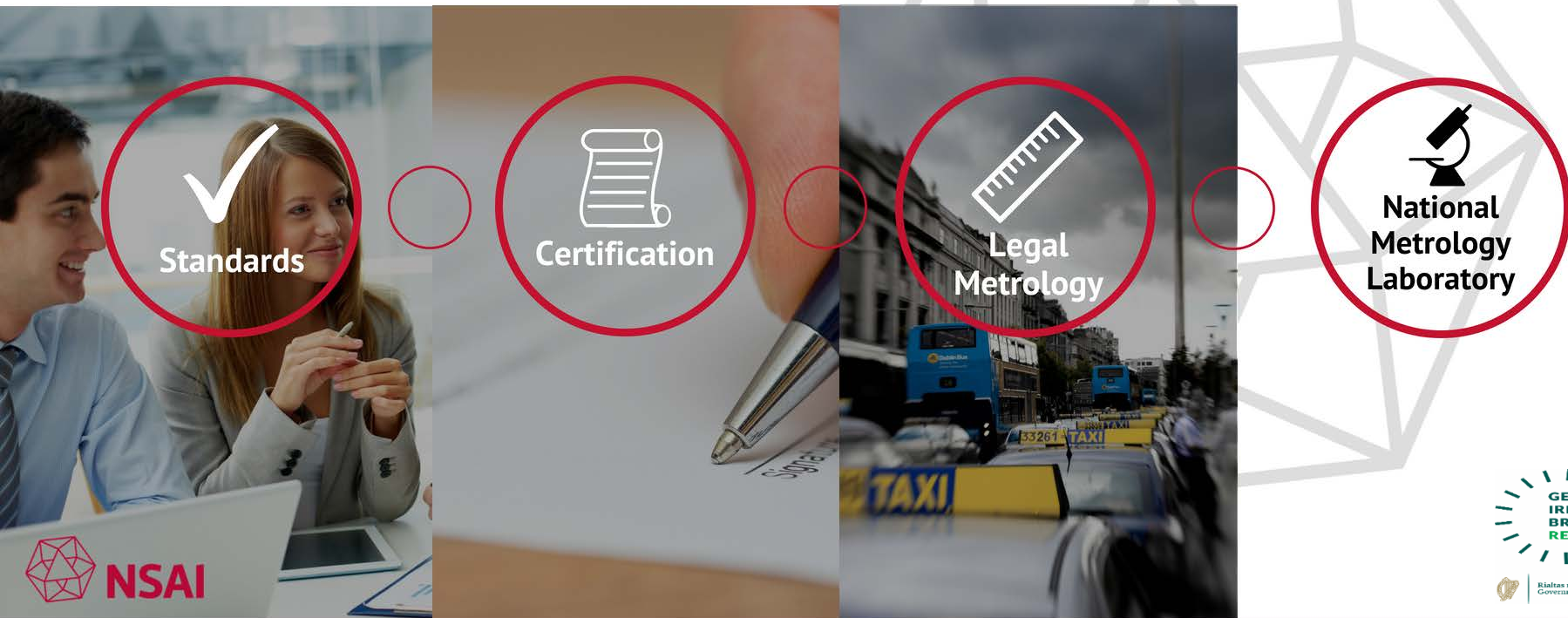
About NSAI

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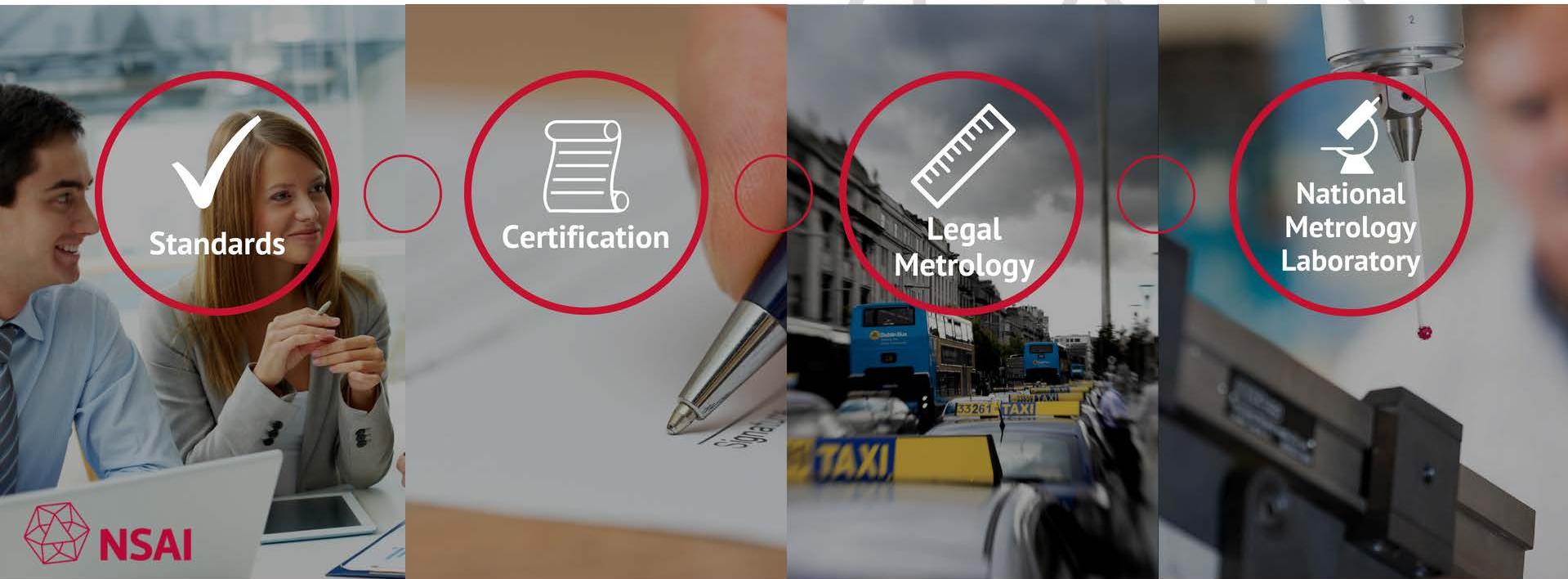
About NSAI

Four main divisions



About NSAI

Four main divisions



Purpose of the European Single Market

- European Standards used to level the playing field

Free trade

- Third Party Certification

Fair trade



Non Harmonised Standards

Reinforcing Steel I.S. EN 10080
Concrete I.S. EN 206



Compression Fittings I.S. EN 1254-2

Product Certification Scheme for ready mixed concrete

- Tightly Regulated
- Industry Led Certification Scheme
- In response to client demand, NSAI has put in place a product certification scheme covering ready-mix concrete.



No CE Marking Required

European standard for Ready Mix Concrete is I.S. EN 206-1:2013, Concrete - Part 1: Specification, performance, production and conformity.



What CE does

- Enables free movement of goods throughout EU member states and beyond. Removes technical barriers to trade.
- Places responsibility with the **manufacturer** or **importer** of goods; whoever places the product on the market.
- Relates to EU Directives/Regulations
Primarily self certification.
- Allows manufacturer to declare performance and place product on market.

EU legislation- 32 Directives

Regulation	Description	EU Notified Bodies
EU 305/2011	Construction Products Regulation	699
2006/42/EC	Machinery	180
2014/33/EU	Lifts and safety components for lifts	230
2014/68/EU	Pressure Equipment	309
2001/95/EC	General product Safety Directive	None
2011/65/EU	Restriction of Hazardous Substance Directive	None
LVD(2014/35/EU)	Low Voltage Directive	None
2014/30/EU	Electromagnetic Capability	116
2014/53/EU	Radio Equipment	78
2016/425	Personal Protective Equipment Regulation	108

Smoke Alarm



6 Steps to CE Marking (hEN Route).

1. Identify Directives and hEN applicable to your product.
2. Verify Essential Characteristics.
3. Determine if a NB is required
4. Test the product
5. Draft Declaration of Performance
6. Affix CE mark.



Notified Bodies

- The primary task of a notified body is to provide conformity assessment services on the conditions set out in the applicable EU harmonisation legislation
- Notified Bodies must be accredited by the National Accreditation Body in the Member State(MS) in which they are established
- Following accreditation they are notified to the EU and are listed on the EU NANDO website
- They may provide conformity assessment to a manufacturer based in any MS or in third countries
- After Brexit all UK Notified Bodies will cease to be recognised as EU NBs and will be removed from the NANDO website

NANDO = New Approach Notified and Designated Organisations

2018 Notified Bodies

- EU 1508
- UK 174
- Construction 78
- Medical Devices 4
- Ireland 8
- Construction 2
- Medical Devices 1

2019 Notified Bodies

- EU 1508
- UK (-2) 172
- Construction (-19) 59
- Medical Devices (-2) 2
- Ireland (+3) 11
- Construction (+3) 5
- Medical Devices 1

EU Notified Bodies based in Ireland

2018	New in 2019
NSAI NSAI Legal Metrology Service	Irish Engineering Services (Vertigo Inspections)
Industrial Pressure Testing	OMNI
Compliance Engineering	BRE
FM Approvals	
Hpi Verification Systems (Ireland)	
Satra Technology Europe	
Safenet	
Total= 8	Total 3

Additional Irish Notified Bodies are currently being accredited or formally notified for Machinery, Personal Protective Equipment, Construction Products, Transportable Pressure Equipment, Pressure Equipment, Radio Equipment, Electromagnetic Capability and Marine Equipment.

CE marking in the EU

CE



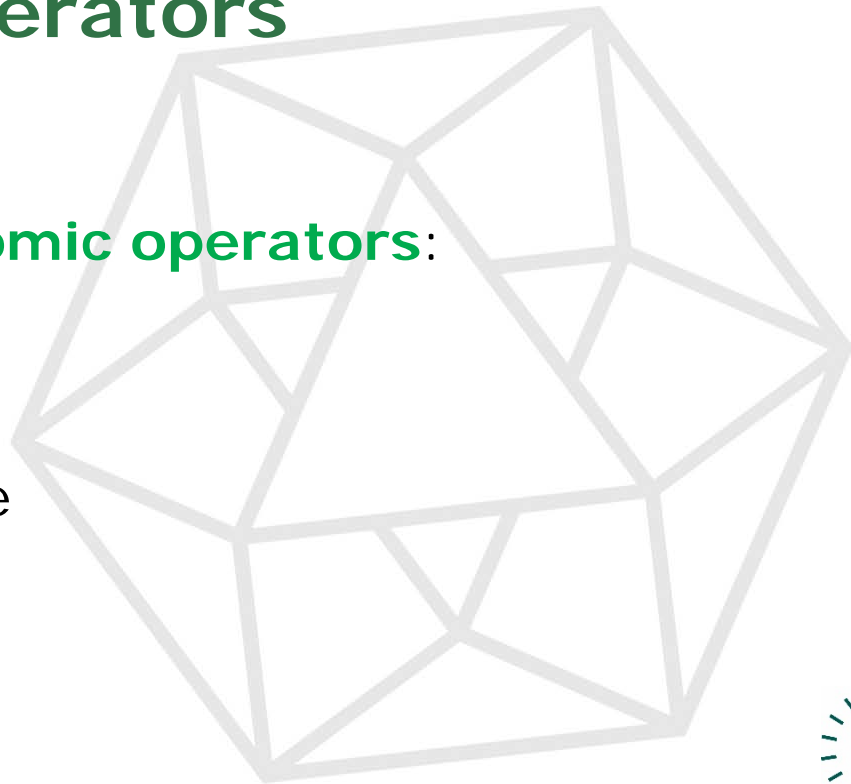
Post-Brexit

UK
CA

Economic Operators

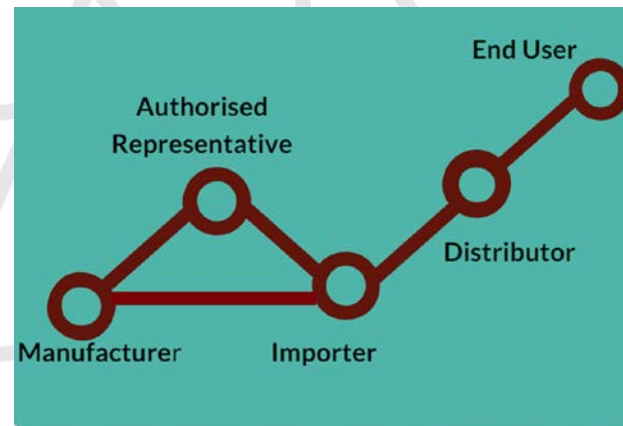
EU legislation defines **economic operators**:

- Manufacturer
- Importer
- Authorised representative
- Distributor



Broad changes for Economic Operators

- **4 Economic Operators:**
Distributor, Importer, Manufacturer & Authorised Representative –
See the **EU Blue Guide** for more info
- *Distributors* become **Importers post-Brexit**, for UK products sold to EU
- Authorised reps **mandatory** for **Marine Medical, Pressure & Cosmetic** products
- UK reps recognition ceases post-Brexit, requires **an EU-based rep** instead
- Irish **exports require UK rep** post-Brexit



Impact of Brexit on 'CE' marking

- If you currently 'CE' mark your product under existing EU rules, you will be required to continue to do so post Brexit
- Post-Brexit, UK Notified Bodies will lose their status as EU Notified Bodies
- If you or one of your product suppliers rely on a UK Notified Body for certification of conformity for 'CE' marking purposes, you will need to obtain alternatives
- While 'CE' marking for products may no longer be a legal requirement in the UK post Brexit, the UK market will still require evidence of conformity of products

Impact of Brexit on Management Systems Certifications

It is expected that Certification to any of the International Standards Organisations Management Systems Standards below will not be directly impacted by Brexit.

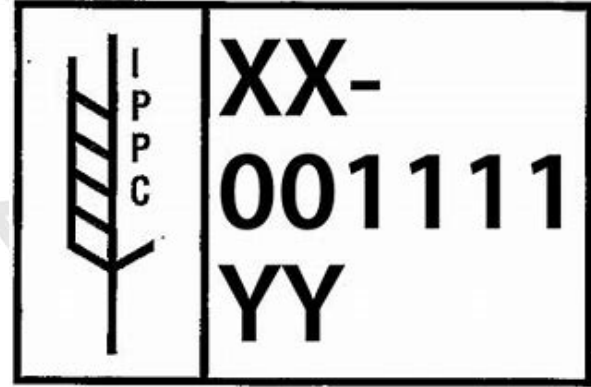
- ISO 9001 Quality
- ISO 14001 Environmental Management System
- ISO 45001 Occupational Health and Safety
- ISO 13485 Medical Devices
- ISO 22000 Food Safety
- ISO 50001 Energy Management

What can I do to minimise disruption?

1. If you import goods from the UK you will:
 - a. be required to hold additional information on your products
 - b. take on additional responsibilities as an importer
2. If you have businesses based in both the UK and EU-27 consider how to reorganise business processes to minimise disruption
3. If you currently use a UK based Notified Body you will have to move to another EU Notified Body based in the EU-27.
4. Check the EU 'NANDO' website and find a NB based in an EU-27 MS
5. Contact the new NB and find out what you need to do to transfer product certification

ISPM 15 Example

- All products either imported from a 3rd country or exported to a 3rd country ([UK Post-Brexit](#)), which are being shipped on a pallet must comply to the following :
- Any Wood Packaging Materials (**WPM**) used has been *debarked*, *heat-treated to 51°C* / *fumigated*
- ***Pallet Stamped*** in accordance with **ISPM 15** standards.



Experience with Turkey

- To imagine a worst case scenario, we could look at Turkey
- Turkey is not in the EU, but is in the customs union.
- Over the past number of years, huge delays have been reported at the main EU/Turkish border post in Bulgaria
- Along with customs documentation it is imperative to have the correct declaration of conformity (DOC) in place
- Experience from one company's challenges
 - *"..... We have until Monday to present an updated CE Declaration of Conformity to the **Turkish** customs authorities. "*
 - *".....We have a shipment that has been sitting at a **Turkish** customs authorities warehouse for three months pending the verification."*
 - *".....We are paying warehouse fees"*



Incorrectly packed crate at the Bulgarian-Turkish border, which is cited as being the busiest road border in Europe

What can I do to minimise disruption

- If you import goods from the UK you will:
 - be required to hold additional information on your products
 - take on additional responsibilities as an importer
 - **engage with your suppliers**
- If you have businesses based in both the UK and EU-27 consider how to reorganise business processes to minimise disruption
- If you currently use a UK based Notified Body you will have to move to another Notified Body based in the EU-27.
- Check the EU 'NANDO' website and find a NB based in an EU-27 MS
- Contact the new NB and find out what you need to do to transfer product certification

NSAI Brexit Unit's Dedicated Website and Email Address

- **Website:** <https://www.nsai.ie/brexit>
- **Email:** brexitunit@nsai.ie
- **NANDO:** <https://ec.europa.eu/growth/tools-databases/nando>



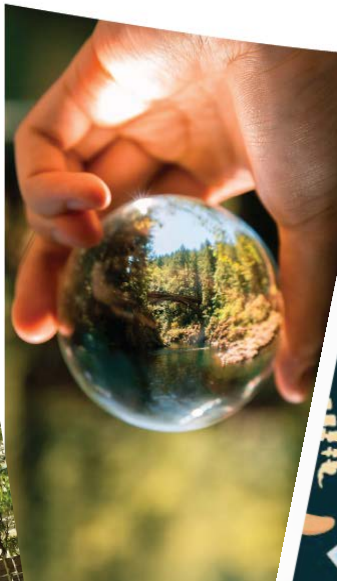
Brexit Series Agri-Food



Brexit Series Construction



Brexit Series Green Procurement



Brexit Series Medical Devices



Brexit Series Product Certification



NSAI

NSAI Brexit Fact Sheets



Thank you.

WWW.NSAI.IE

mary.white@nsai.ie

Head of NSAI Brexit Unit



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