

POST BREXIT

Regulations, Standards, Certification and the CE Mark

“What Must I Do?”

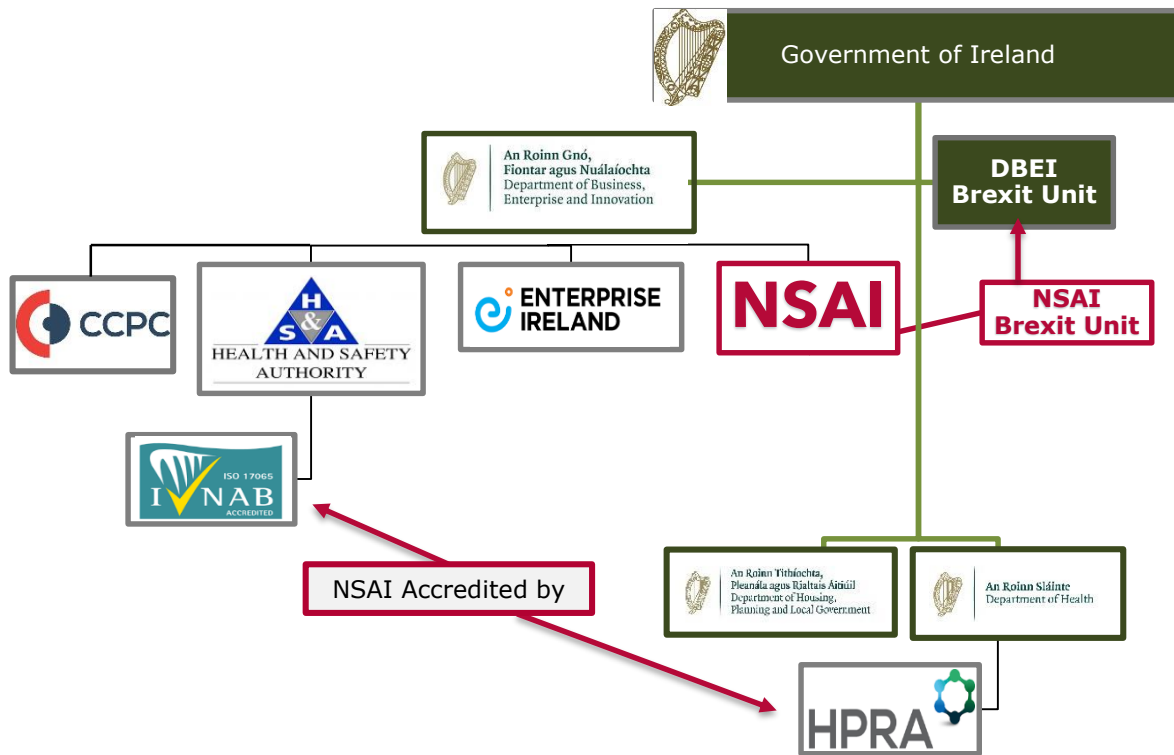
Mary White
Head NSAI Brexit Unit

What we'll cover

- About NSAI
- How does Placing Goods on the Market, EU legislation, NANDO, CE, Notified Bodies (NBs) and Market Surveillance work?
- Economic operators
- The transition period

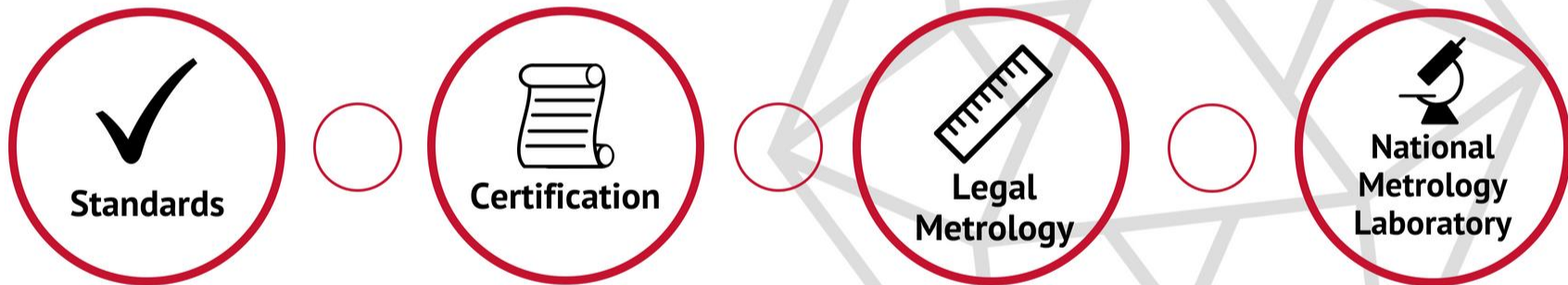


National Standards Authority of Ireland



About NSAI

Four main divisions

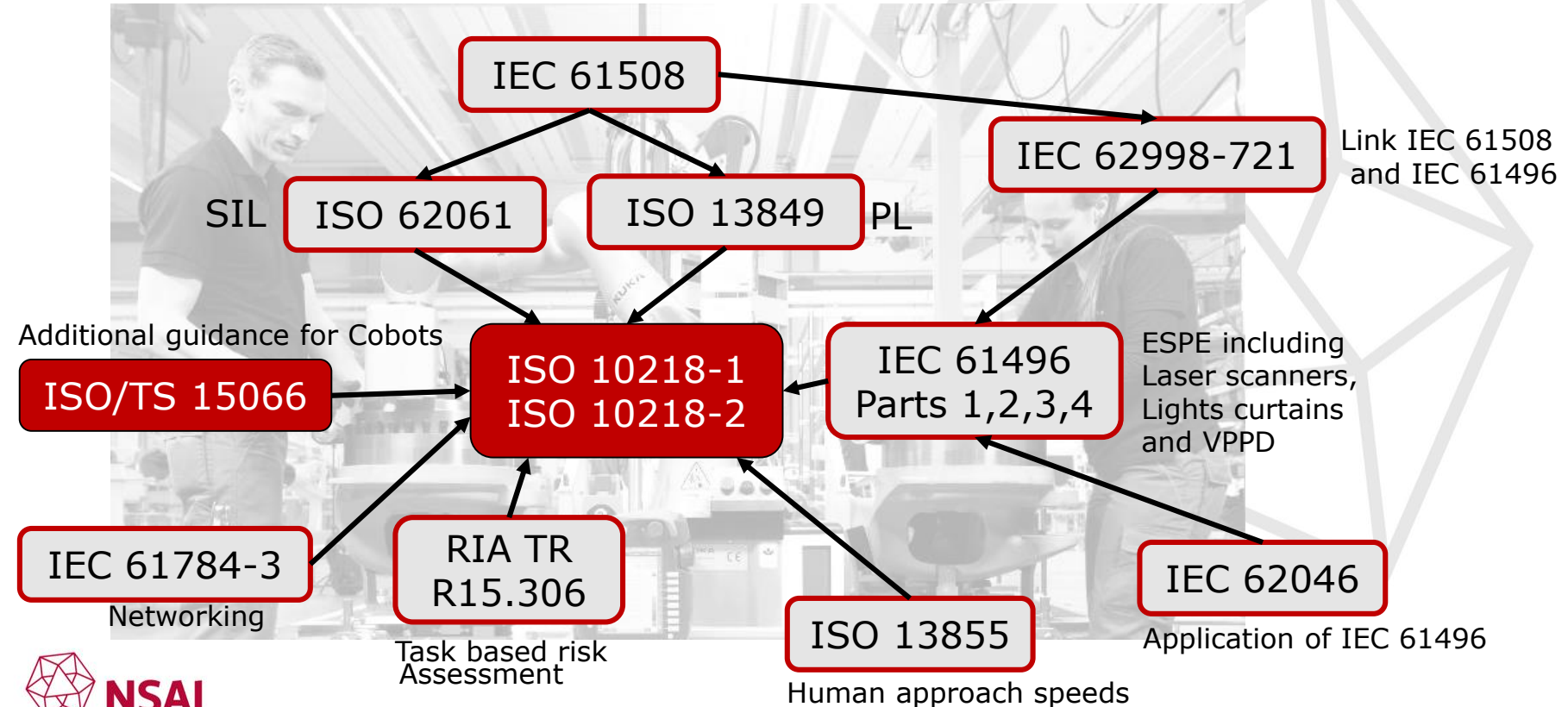


ISO/TC 299 - Robotics



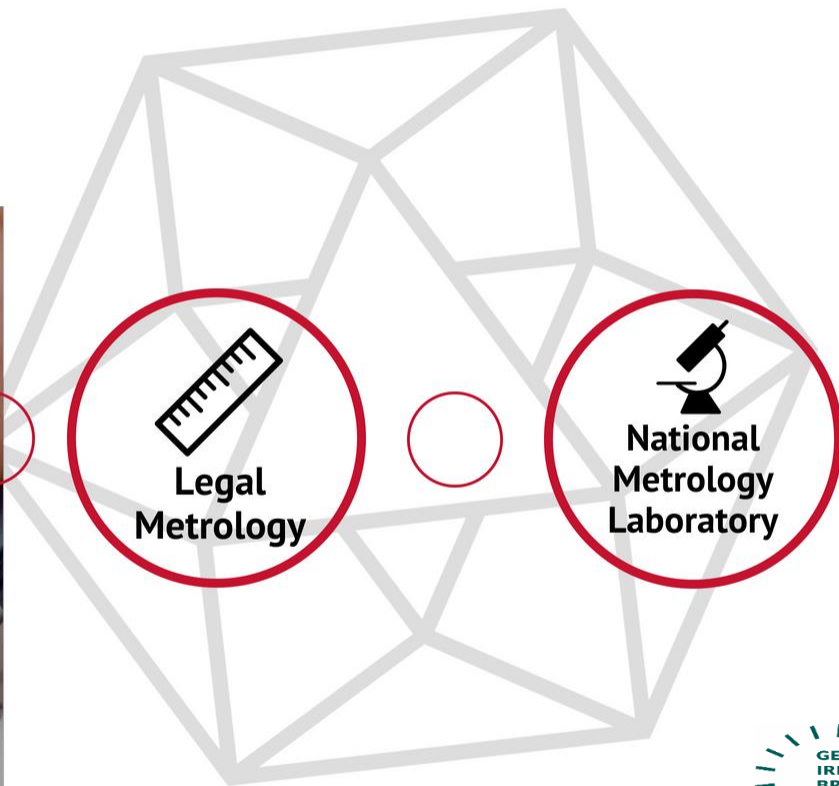
Kuka.com

ISO/TC 299 - Robotics



About NSAI

Four main divisions



Placing Goods on the Market



Regulation

Sets out essential requirements



Standards

Shows how you meet these requirements



**3rd Party
Conformance**

Confirms that you meet the standards via certification



**Market
Surveillance**

Checks products that may/may not meet the regulation



WORLD TRADE
ORGANIZATION

The WTO Agreements Series

Technical Barriers to Trade

GATT

General Agreement for Tariffs and Trade

- Technical Regulations and Standards For Products

TBT

Technical Barriers to Trade

- TBT are regulatory measures that affect trade in Goods
- It strongly encourages the use of international standards and emphasises the need to avoid unnecessary barriers to trade

NTM

Non-Tariff Measures

- Technical Regulations
- Standards
- Conformity Assessment Procedures (3 Categories of TBT Measures)

Standards are used as a basis for both technical regulations and conformity assessment procedures

3rd Party Certification is a form of conformity assessment procedure

Need to improve international cooperation on regulation

A blurred background image on the left side of the slide showing a person's hand pointing at a document on a desk.

Placing Goods on the Market

- EU Single Market
- New Legislative Framework
- CE Marking
- NANDO :
(**N**ew Approach **N**otified **A**nd **D**esignated **O**rganisations)

Purpose of the European Single Market

Free trade

European Standards
level the playing field

Fair trade

Third Party
Certification



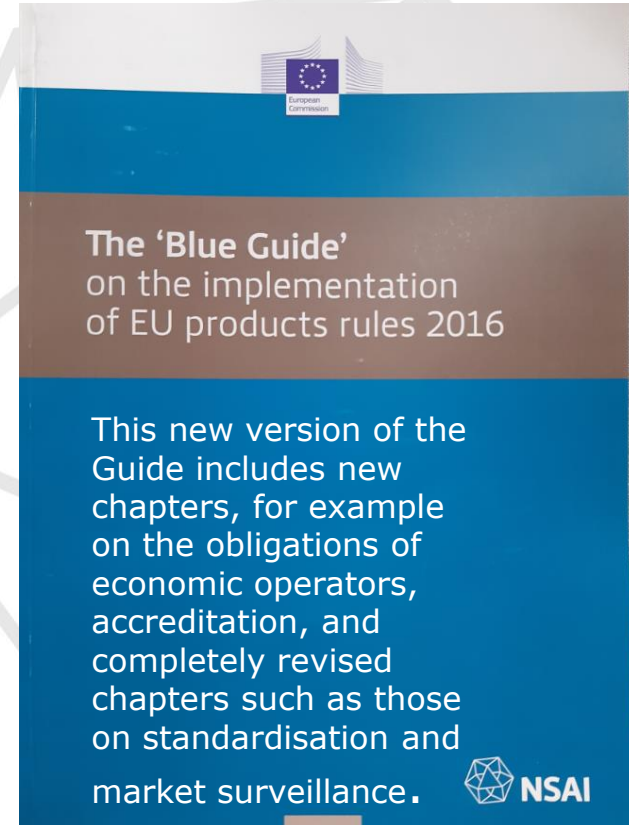
New Legislative Framework

A comprehensive regulatory framework to operate effectively for the safety and compliance of industrial products with the requirements adopted to protect the various public interests and for the proper functioning of the single market

- **Regulation (EC) No 765/2008** established the legal basis for accreditation and market surveillance and consolidated the meaning of the CE marking
- **Decision No 768/2008/EC** updated, harmonised and consolidated the various technical instruments already used in existing Union harmonisation legislation

More information available in the:

The 'Blue Guide' on the implementation of EU product rules 2016 (First version 2000)





The diagram features a central white box with a red border containing the title 'New EU Legislative Framework'. A horizontal red line extends from the bottom of this box, with six vertical red lines connecting it to six white boxes with red borders below. The background is light blue with yellow stars arranged in a circular pattern around the central box.

New EU Legislative Framework

Basic safety characteristics

Obligations of Economic Operators

Level of competence of third party 'Notified Bodies'

Control mechanisms for Notified Bodies

Appropriate assessment processes

Market surveillance

What C € does



- Indicates compliance with relevant EU Directives/Regulations
- Allows manufacturer to place products on the market
- Removes technical barriers to trade throughout the EU
- Places responsibility with the **manufacturer** or **importer** of goods
- **Primarily self certification**

6 Steps to CE Marking

(hEN Route)



Identify Directives and hEN applicable to your product



Verify Essential Characteristics



Determine if a Notified Body is required



Test the product



Draft Declaration of Conformance



Affix CE Mark

EU legislation- 32 Directives/Regulations

Regulation	Description	EU Notified Bodies
EU 305/2011	Construction Products Regulation	696
2006/42/EC	Machinery	181
2014/33/EU	Lifts and safety components for lifts	230
2014/68/EU	Pressure Equipment	314
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	117
2014/53/EU	Radio Equipment	78
2016/425	Personal Protective Equipment Regulation	110

Smoke Alarm



EU legislation- 32 Directives/Regulations

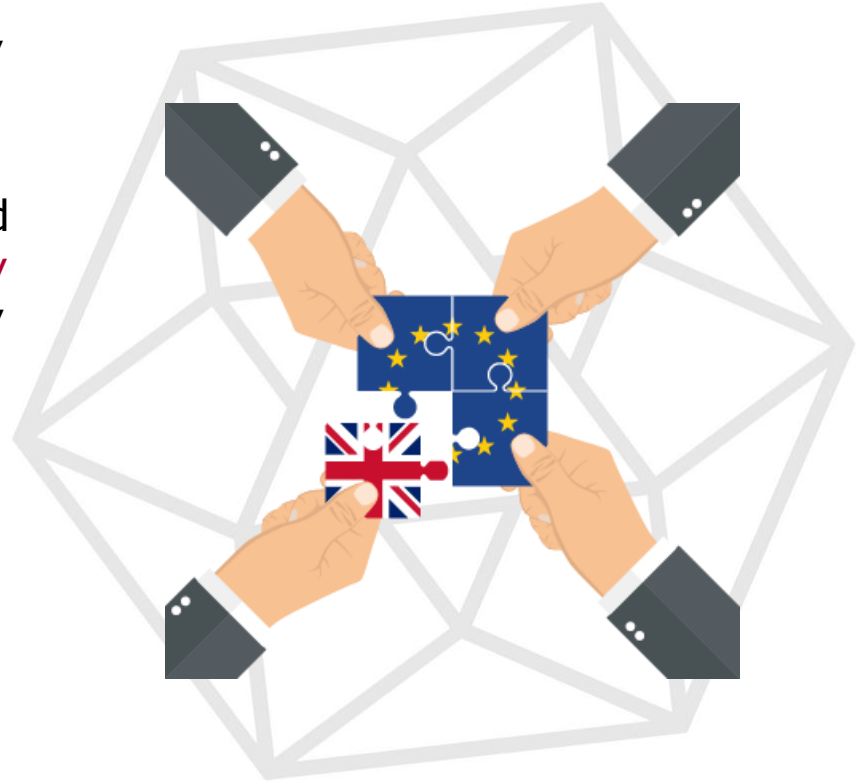
Regulation	Description	EU NBs	UK NBs	Irish NBs
EU 305/2011	Construction Products Regulation	696 (-3)	59 (-19)	8 (+6)
2006/42/EC	Machinery	181 (+1)	20	3(+2)
2014/33/EU	Lifts and safety components for lifts	230	6	0
2014/68/EU	Pressure Equipment	314 (+5)	31	0
2001/95/EC	General Product Safety Directive	None	None	None
2011/65/EU	Restriction of Hazardous Substance Directive	None	None	None
LVD(2014/35/EU)	Low Voltage Directive	None	None	None
2014/30/EU	Electromagnetic Capability	117 (+1)	14	3(+2)
2014/53/EU	Radio Equipment	78 (+1)	10	1
2016/425	Personal Protective Equipment Regulation	110 (+2)	11	2

Smoke Alarm



Notified Bodies

- **Notified Bodies** provide conformity assessment services on the conditions set out in EU legislation
- Notified Bodies must be accredited by the **National Accreditation Body** in the Member State in which they are established (In Ireland, it's INAB)
- Accredited NBs are listed on the EU NANDO website
- **Post 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
Machinery	1
Medical Devices	1
Radio Equipment	1
EMC	1

2020 Notified Bodies

EU	1510
UK (-5)	169
Construction (-19)	59
Medical Devices (-2)	2
Ireland (+7)	15
Construction (+6)	8
Machinery (+2)	3
Medical Devices	1
Radio Equipment	1
EMC (+2)	3

EU Notified Bodies Based in Ireland (2018)



INDUSTRIAL PRESSURE TESTING Limited



EU Notified Bodies Based in Ireland (2020)

CTI
CEM



INDUSTRIAL PRESSURE TESTING Limited



NSAI
Legal Metrology



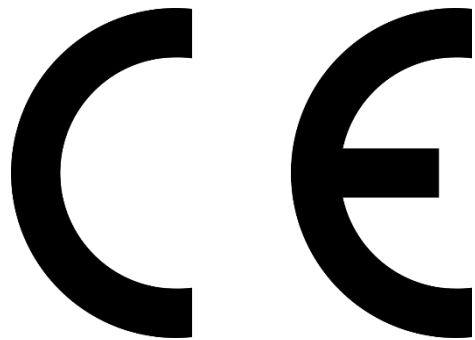
IRISH
ENGINEERING
SERVICES

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CE marking in the EU

Before Brexit



National Accreditation Bodies



Economic Operators



Notified Bodies



Market Surveillance Authorities

Post-Brexit

**UK
CA**

Economic Operators

EU legislation defines **Economic Operators** as:



Manufacturer



Importer



Authorised Representative



Distributor

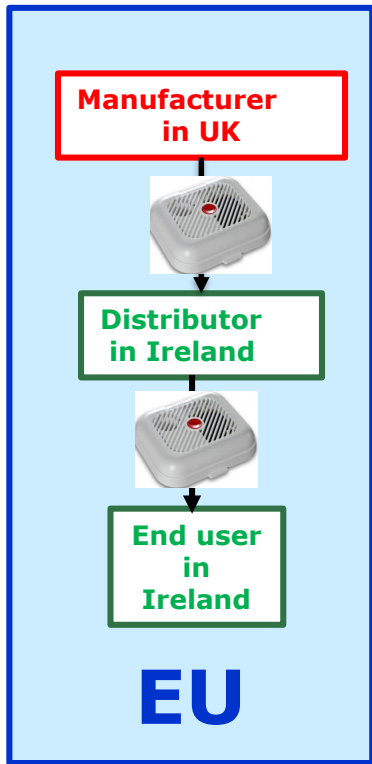
Current Situation

UK member of EU

EU legislation applies in UK & IE

UK NBs same as NBs in other member states

Companies buying products from UK manufacturers are **Distributors**





Importer

- The importer is the economic operator **established in the EU** who places a product from a third country on the EU market.
- Before placing a product on the market the importer must ensure that the manufacturer has:
 - *Carried out the appropriate conformity assessment procedure,*
 - *Drawn up the technical documentation,*
 - *Drawn up the EU Declaration of Conformity,*
 - *Affixed the CE marking,*
 - *Fulfilled their traceability obligations, and*
 - *Accompanied the product required instructions and safety information.*



Authorised Representative

- An Authorised Representative (AR) is **appointed by a Manufacturer** to act on his behalf in carrying out certain tasks
- EU product legislation does not generally oblige the manufacturer to designate an AR
- However, EU legislation for certain products does provide for the obligation for a **non-EU** manufacturer to have an AR
- EU legislation requires the authorised representative to be **established in the EU**
- The AR, if mandated by the manufacturer, may retain copies of the technical file and DoC instead of every importer

Broad changes for Economic Operators

Before Brexit

4 economic operators

(More in the EU Blue Guide)

Authorised reps
mandatory *Marine, Medical, Pressure and Cosmetic* products



Post Brexit

Distributors from the UK become Importers to the EU

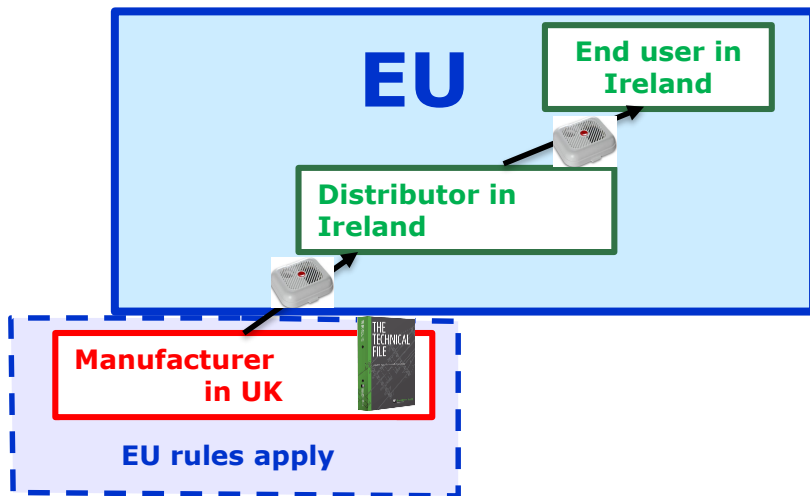
- *UK Exports* require an *EU rep*
- *Irish Exports* require *UK rep*

Main Points of Withdrawal Agreement



- UK will cease to be an EU Member State on 31 January 2020
- There will be a transition period until 31 December 2020
- The future relationship between EU and UK will be subject of negotiations
- If there is no agreement, the future relationship will be based on WTO arrangements
- Protocol on Ireland-Northern Ireland will reduce potential impact of no deal Brexit on island of Ireland

What happens during the Transition Period?



- Comes into effect at 23:00 GMT on 31 January 2020
- UK no longer in EU
- **Relevant EU law shall apply in respect of the goods lawfully placed on the market in the EU or the United Kingdom**
- LVD, EMCD, RED and GPSD will still apply in the UK
- UK business will be treated as if they are part of the EU single market
- Product certification by UK Notified Bodies will be recognised
- Current requirements concerning documentation will still apply
- IE companies buying from UK manufacturers will still be classified as distributors

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



All 169 UK Notified Bodies (NBs) removed from NANDO Database including :

14 EMC NBs, 10 for RED NBs,

20 NBs for Machinery, and 2 for Medical Devices



NSAI



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**

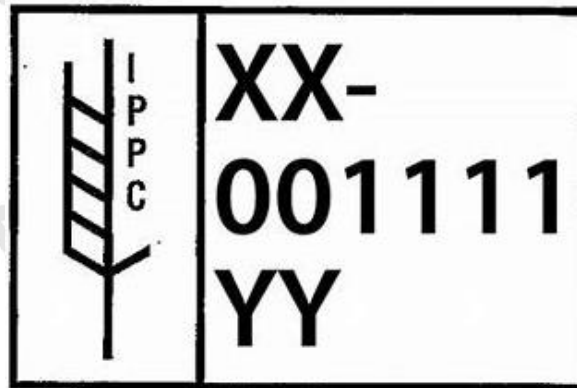
Energy Management

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

- Turkey is not in the EU, but is in the customs union
- Huge delays reported at the main EU/Turkish border post in Bulgaria
- Customs documentation and correct declaration of conformity required
- The experience of one company:

*"..... 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



We've covered..

- NSAI
- Placing goods on the market
- Economic operators
- The transition period



3 Takeaway Messages

- Post Brexit, check status of your Notified Body on **CE Markings**
- As a manufacturer or importer and distributor, **what must I do** to prepare?
- Have I **additional responsibilities**?

Get in Touch

Website

<https://www.nsai.ie/brexit>

Email

brexitunit@nsai.ie

NANDO

<https://ec.europa.eu/growth/tools-databases/nando>



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Brexit Series
Agri-Food



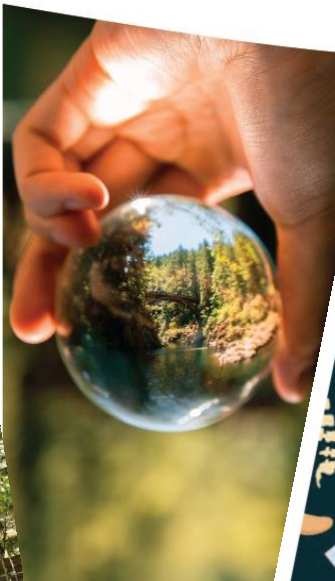
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Construction



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Product Certification



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NSAI Brexit Fact Sheets



Thank you.

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