

Brexit and the Implications on Supply and Use of Chemicals in Irish Businesses

1st November 2018



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Government of Ireland





Brexit and the implications for REACH

Majella Cosgrave, HSA



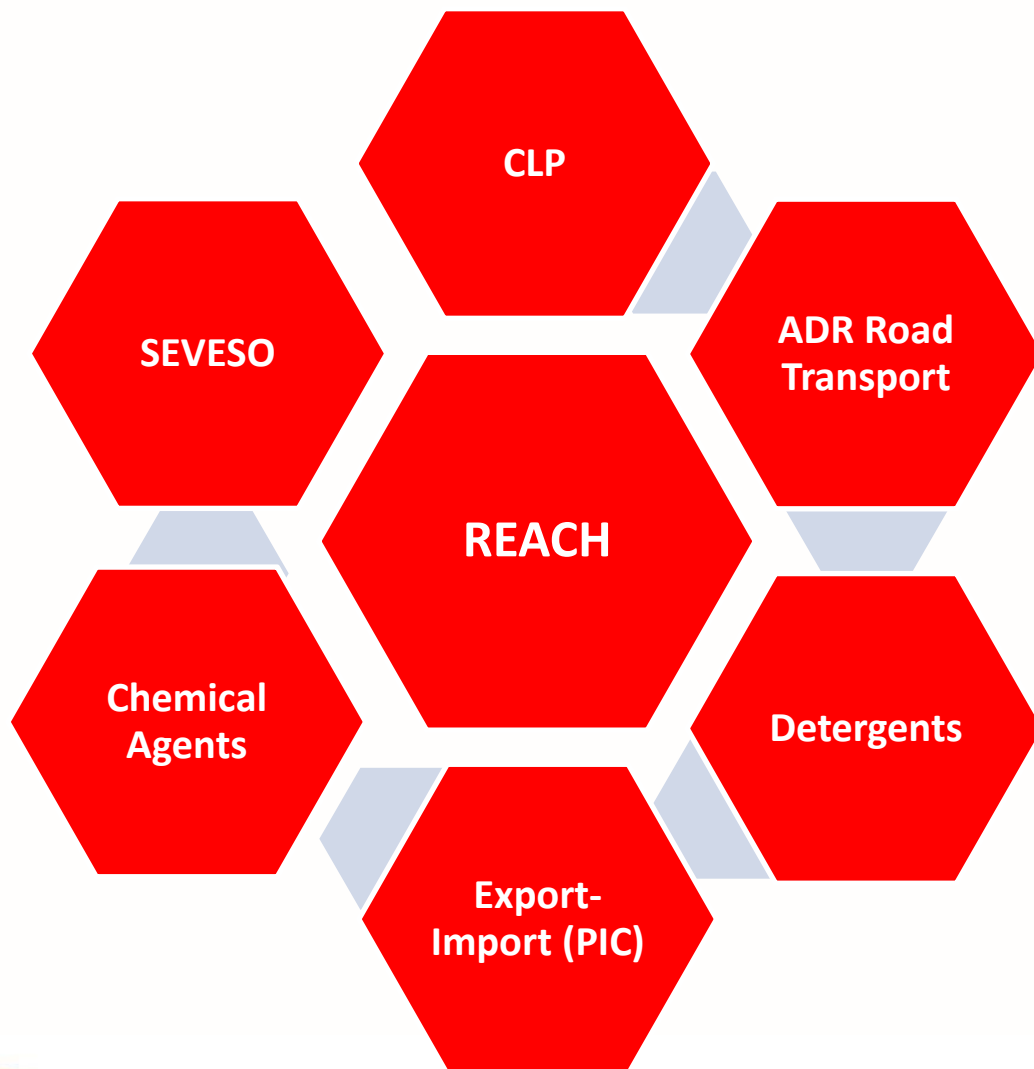
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Health and Safety Authority Mandate

- To regulate and promote the safety, health and welfare of people at work and those affected by work activities
- To promote improvement in the safety, health and welfare of people at work and those affected by work activities
- **To regulate and promote the safe manufacture, use, placing on the market, trade and transport of chemicals**
- To act as surveillance authority in relation to relevant single European market legislation
- To act as the National Accreditation Body for Ireland

HSA Chemicals Mandate



Impacts of Brexit

- There will be impacts across all of our mandates
- Industries we liaise with will be affected
- REACH, CLP, Export/Import, Detergents, Market Surveillance, TPED, Accreditation
- Impacts on trade, supply chains, placing substances on the market
- *Note: Impacts discussed here assume a no-deal Brexit (status as of October 31st)*

REACH

- Most elements of REACH will be impacted by Brexit
- Key areas for Irish companies will be **registration** and **authorisation**
- Non- EU companies and UK-based Only Representatives (ORs) also affected

REACH Registration

- Requirement that substance manufactured in EU, or imported into EU at greater than 1 tonne per annum, must be registered
- UK registration statistics (*as of 25th October 2018*):
 - 12,393 registrations
 - 5,721 substances
 - 1,765 companies

 - 30% importers
 - 15% manufacturers
 - 50% Only Representatives (ORs)
 - 5% manufacturers and importers
- Many Irish companies may be relying on these UK-based registrations for their own supply (or covered by the UK-based OR)

REACH Registrations after Brexit

- UK will be a third country
- UK REACH registrations will become non-existent
- UK authorities will also no longer:
 - Participate in EU regulatory and decision making processes
 - Have access to ECHA databases
 - Be part of, or send experts to, ECHA or Commission committees

Impacts on IE companies - registration

- Currently, if IE company buys chemicals from UK supplier, role under REACH is as a downstream user -> **no registration obligations**
- After Brexit, UK will become a third country
- If IE company continues to buy chemicals from that UK supplier, role under REACH changes to importer -> **registration obligations**
- Consideration also needs to be given to IE distributors that may supply IE companies – their source could be UK-based

Impacts on registration for IE companies (1)

Scenario: IE company purchasing substance from UK registrant

- Currently, IE company is downstream user; no registration obligation
- After Brexit, IE company can't rely on the UK registration

Options:

UK supplier:

- relocate to EU-27/EEA; legal entity change, or
- if manufacturer or formulator, appoint OR and transfer the registration
- if importer, can't appoint OR; UK importer can't transfer registration to OR

IE company:

- sources another EU-27/EEA based supplier, or
- continues to source from UK-based supplier, becomes an importer; registers

If you are in this position, consider your options and talk to your UK supplier now about his intentions post-Brexit

Impacts on registration for IE companies (2)

Scenario: IE company registrant in joint submission with UK lead registrant

- Following Brexit, UK registration will cease to exist

Options to ensure functioning joint submission:

- Lead registrant moves to EU-27/EEA, or
- A new lead registrant is appointed and LR role transferred before Brexit

If you are in such a position, talk to your UK lead registrant now to determine his intentions post-Brexit

Impacts on registration for ORs

Scenario: UK-based Only Representative who has submitted registrations

- After Brexit, such an OR will no longer be 'legally established in the EU'

Options :

- OR moves to EU-27/EEA, or
- Non-EU manufacturer appoints new OR based in EU-27/EEA and OR changed in REACH IT, or
- EU-27/EEA company becomes an importer and registers

If you are dependent on a UK-based OR arrangement, speak to your OR and/or your non-EU supplier to determine their intentions post-Brexit

UK companies moving to EU-27/EEA

- Company cannot be set up 'on paper' only and registrations transferred
- Must be as a result of a legal entity change – e.g. the importing/manufacturing business is transferred to the EU-27/EEA legal entity
- Responsible staff and relevant documentation must be available for inspection by the IE enforcement authority at premises of registrant
- Also applies to ORs; must be in compliance with article 8(2) of REACH
- Changes must be notified in REACH IT ahead of the UK withdrawal
- ECHA expected to provide more details of practical aspects of this

REACH Authorisation

- A manufacturer, importer or downstream user may not place a substance on the market for a use, or use it himself, after a certain date (sunset date) if the substance is included in Annex XIV of REACH
- A company who applies for an authorisation can do so for his own use and the uses of his downstream users
- A M/I/DU can place a substance on the market for a use for which is immediate DU has been granted an authorisation

UK-based companies are authorisation holders and IE companies may be using substances under those UK authorisations

REACH Authorisations after Brexit

- After Brexit, authorisations held by UK-based companies will not be valid

Options:

- UK manufacturer or formulator (but not importer) can transfer its authorisation to EU-27/EEA OR (can only happen after UK withdrawal)
- UK OR can transfer authorisation to EU-27/EEA OR

or

- IE company relying on UK authorisation finds EU-27/EEA supplier with valid authorisation, or
- Apply for an authorisation himself if wishes to continue using the substance

If you are an IE DU covered by an authorisation of your UK supplier, speak to your UK supplier now to determine his intentions post-Brexit

Companies based outside of the EU

Scenario: Non EU manufacturer/formulator has appointed UK OR

Options:

- Can appoint a new OR in an EU-27 MS/EEA
- Requires collaboration between old and new OR to do legal entity change
- Must take place ahead of the UK withdrawal
- Must be notified to ECHA through REACH IT

Companies based outside of the EU

Scenario: Non-EU company exports to a UK based importer who has completed the registrations ; substance further supplied in the EU-27/EEA by UK company

Options:

- Appoint an OR located within the EU-27/EEA, or
- Substance can be registered by the EU-27/EEA importers, or
- (The UK company relocates to an EU-27 Member State/EEA; legal entity change)

Classification, Labelling and Packaging (CLP)

- IE companies currently sourcing substances and mixtures from the UK will become importers under CLP after Brexit
- Will need to comply with duties of importers under CLP
- Will be responsible for classification, packaging and labelling of the product
- May also have notification obligation to the Classification and Labelling Inventory

From a UK perspective....

- If a transitional arrangement is agreed, EU law will continue to apply in the UK during that time (subject to terms set out in Withdrawal Agreement)
- But, HSE/DEFRA will no longer participate in EU committees or act as a 'lead authority'
- Limited/no participation by UK in EU institutions, agencies and bodies

UK: Future Economic Partnership

- White paper published July 2018; sets out UK Government proposal for future economic relationship with EU
- Close alignment on goods, including chemicals (but details to be sorted in negotiations)
- Participation by UK in work of EU agencies ‘that provide authorisations for goods in highly regulated sectors’ – includes ECHA

UK No Deal Contingency Planning

- The EU (Withdrawal) Act became law in June 2018
- Will convert EU chemicals regulations to UK domestic law
- Contingency Statutory Instruments (SIs) will correct deficiencies to ensure regulations are operable outside EU
- SIs ready to come into effect 29 March 2019
- A no deal outcome would mean companies wanting to operate in both UK and EU markets will need to deal with both regulatory systems

Preparing for Brexit - REACH and CLP

- Examine your current supply chain
- Do you source substances from a UK-based supplier?
- Are you a downstream user, relying on a UK-based only Representative?
- Are you reliant on a UK company granted authorisation?
- Can you change your supplier to an EU-27/EEA one?
- Are you in a position to take on the role of importer if you continue to source in the UK post-Brexit?
- Speak to your UK suppliers/ORs to determine their plans post-Brexit

REACH and CLP supports

- HSA chemicals helpdesk: chemicals@hsa.ie
- ECHA webpages on UK withdrawal (Q&As)
<https://www.echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/theukswithdrawalfromtheeu>
- European Commission Notices https://ec.europa.eu/info/brexit_en
- UK Government Brexit Publications – no deal scenarios
<https://www.gov.uk/government/brexit>
- IE Government Departments and Agencies (especially Enterprise Ireland, InterTrade Ireland, Strategic Banking Corporation of Ireland, Revenue)
- Trade organisations

Thank you



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Supply and distribution of chemical products post-Brexit

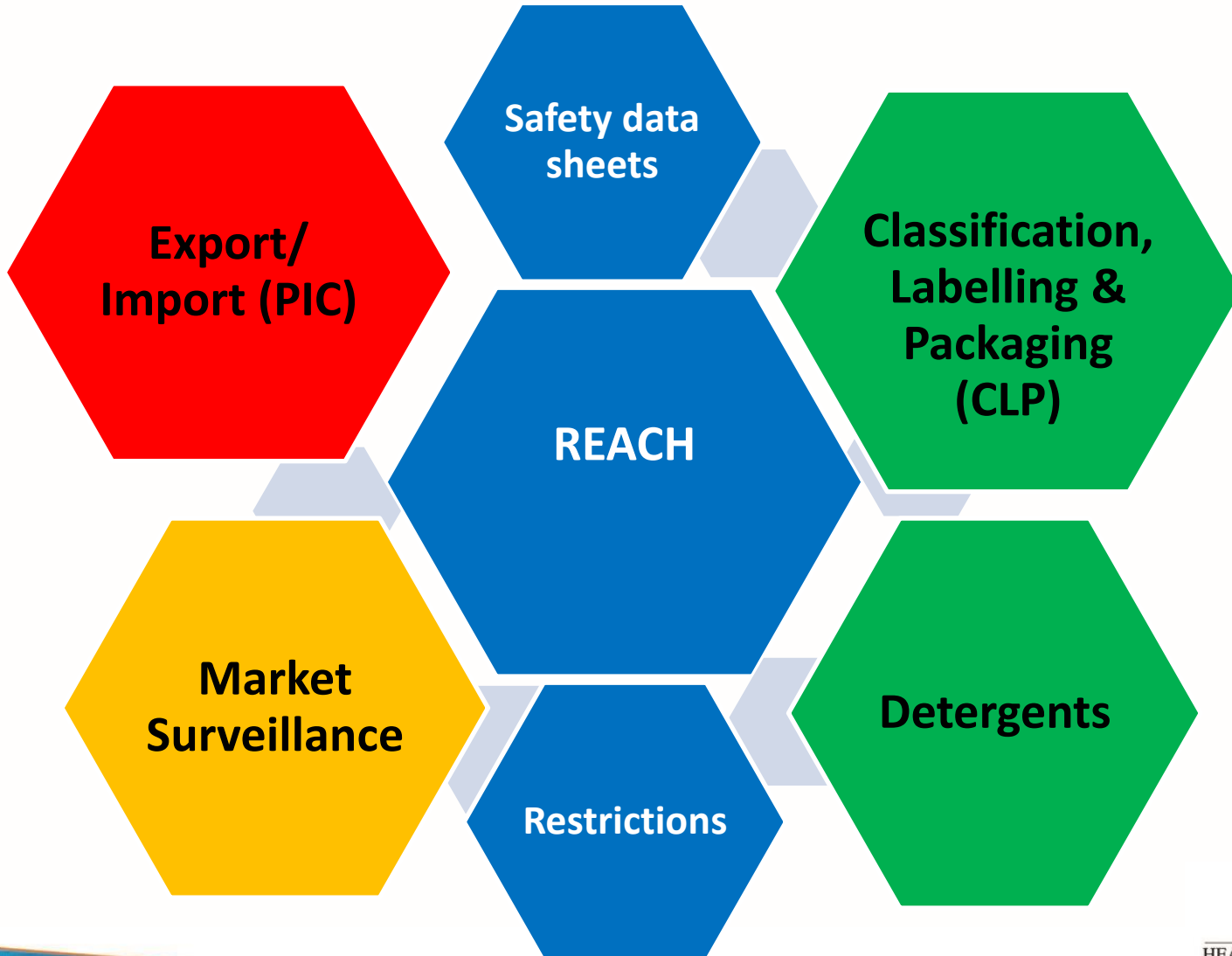
Yvonne Mullooly, HSA



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Supply & Distribution



Trade & Supply between Ireland & UK

- Majority of IE chemical products come from UK suppliers
- Most IE companies are currently “downstream users” under REACH/CLP/Detergents
- When UK leaves, IE companies role may change resulting in higher regulatory obligations and associated costs.
- Chemical Products imported from the UK need to be EU compliant.

Chemical Products

- **Substances**- Alcohols, acids, salts
- **Mixtures**- Paints, Degreasers, Pigments, Detergents, Silicone, Adhesives, Coatings
- **Articles**- Jewellery, Shoes, Furniture, Electronic Equipment, Construction panels

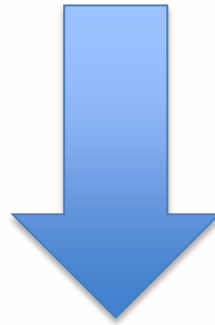
***DO THE CHEMICAL PRODUCTS YOU SUPPLY
or USE COME FROM THE UK ?***

Substances, Mixtures & Articles

- ➔ Substances, mixtures supplied into the EU market must comply with REACH, CLP & Detergents¹ (¹where applicable)
 - ➔ Articles supplied to EU market must comply with REACH
 - ➔ Substances, mixtures & articles supplied to UK market from EU (Ireland) must comply with UK standards
- **Legal responsibility of Distributors and downstream users may change !**

Change in role

Distributor/Downstream users



EU Importer

What does it mean to be an EU Importer of Chemical Products?



MARKET SUPPLY & SAFE USE

- Legal Responsibility for safety of the product lies with the 1st EU Importer from the UK
- Chemical Product: Substance/mixture
 - **Classified, Labelled and Packaged (CLP)**
 - **Notified to the C&L Inventory**
 - **Supplied with an appropriate Safety Data Sheet (SDS)**
- Chemical Product: Substance/Mixture or Article
 - **Doesn't contain prohibited substances (Annex XVII REACH+)**

Detergent Products

- Detergent Regulations: Household & Industrial
- *Personnel hygiene products (shower gels, shampoos) **do not** fall within the scope of Detergents*
- Additional labelling & prohibition of certain substances
- **‘Placing on the market’** means the first making available on the Union market. Import into the Union customs territory shall be deemed to be placing on the market.
- **‘Making available on the market’** means any supply for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

Market Surveillance

- Currently majority of “non compliant” chemical products found on the Irish market are referred to UK Authorities to enforce.
- Product Recall & EU RAPEX Alert
- Major impacts on business resources & reputation
- Major impact on Authority and Customs resources

Options

1. Source another EU supplier willing to supply the Irish market.

Remember labels & SDS's must be in English & SDS must contain relevant Irish standards!

2. Source/employ competent person familiar with REACH, CLP & Irish national standards to ensure you can supply compliant chemical products to the Irish/EU market

Useful information to note

- Existing UK C&L notification information will remain available unless it is removed via REACH IT account
- No “Only Representative” provision in the CLP & Detergent Regulations.
- Irish companies may need to seek new suppliers of their chemicals within EU – may lead to shortages in supply. Look for business opportunities!

Exporting Chemical Products to the UK



Exporting Chemical Products to UK

- Rotterdam Regulation – Prior Informed Consent
- Only applies to banned or severely restricted Pesticides & Industrial Chemicals
- Customs requires a RIN for custom declaration
- Apply via electronic system ePIC- ECHA
- Exports < 10 kg/yr/country for R&D/Testing- Special RIN(SAD Box 44)
- Yearly notification of quantity shipped per country

Exporting to the UK

- Check if any substances listed in *PIC Part 1* are in any of your chemical products
- EU Withdrawal starts earlier than March
- Export notifications must be submitted 35 days before export - **FEBRUARY 2019!**
- UK Export Notifications will cease to exist from March 2019
- As UK still a party to Rotterdam Convention UK companies still have obligations

Export Import

- UK Regulations will also apply to Irish products on the UK market
- If product requirements are different in the UK
 - Divergence may occur on the enforcement side if a non-compliance is observed for a UK product on the IE market.
 - Resolution of non compliant products could fall to the Irish Importer.
- http://www.hsa.ie/eng/Chemicals/Export_Import/

Parting advice

- Your company will experience change if your business supply chain is in any way linked to the UK
 - **Downstream users:** Do you know if your distributor will continue to source your product?
 - Start your market preparations now! Register in ePIC
1. **KNOW YOUR PRODUCT SOURCE**
 2. **TALK TO YOUR SUPPLY CHAIN**
 3. **DIVERSIFY**
- Follow the withdrawal negotiations to determine your future obligations

Information



CHEMICAL IMPORTERS

Information Sheet

October, 2013

Safety Data Sheets for Hazardous Chemicals

Information Sheet

Updated October, 2015

Exporters Duties under the Rotterdam Regulation (EU) No 649/2012 on the Export and Import of hazardous chemicals

Information Sheet

Updated May 2015

REACH - PRODUCTION, IMPORT AND SUPPLY OF ARTICLES

Information Sheet

April 2014



Labelling and Packaging requirements for Detergents & Biocidal Detergent Products

Information Sheet

July, 2014

Chemical Distributor Duties under REACH and CLP

Information Sheet

March 2011

Information for Retailers on Hazard Labelling & Packaging of Chemical Products

July, 2013

Relevant Publications

- Chemical Importers
- Chemical Exporters
- Chemical Distributers
- Retailers- Classification, Labelling and Packaging
- Classification, Labelling and Packaging of substances and mixtures
- Classification, Labelling and Packaging of Detergents
- Safety Data Sheets
- Import and Supply of Articles
- All available at www.hsa.ie/eng/publications/chemicalsandhazardoussubstances

Support

- We are here to help!
- HSA Chemicals helpdesk email chemicals@hsa.ie
- HSA: UK Withdrawal HSA webpage
- ECHA: <https://echa.europa.eu/uk-withdrawal-from-the-eu>
- DBEI: <https://dbei.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit/>
- EU Commission: https://ec.europa.eu/commission/brexit-negotiations_en

Finally!

Chemical Usage Survey

***“Get Brexit Ready &
Know Your Source”***

Thank You



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Brexit and the Transportable Pressure Equipment Directive

Alice Doherty, HSA



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Overview

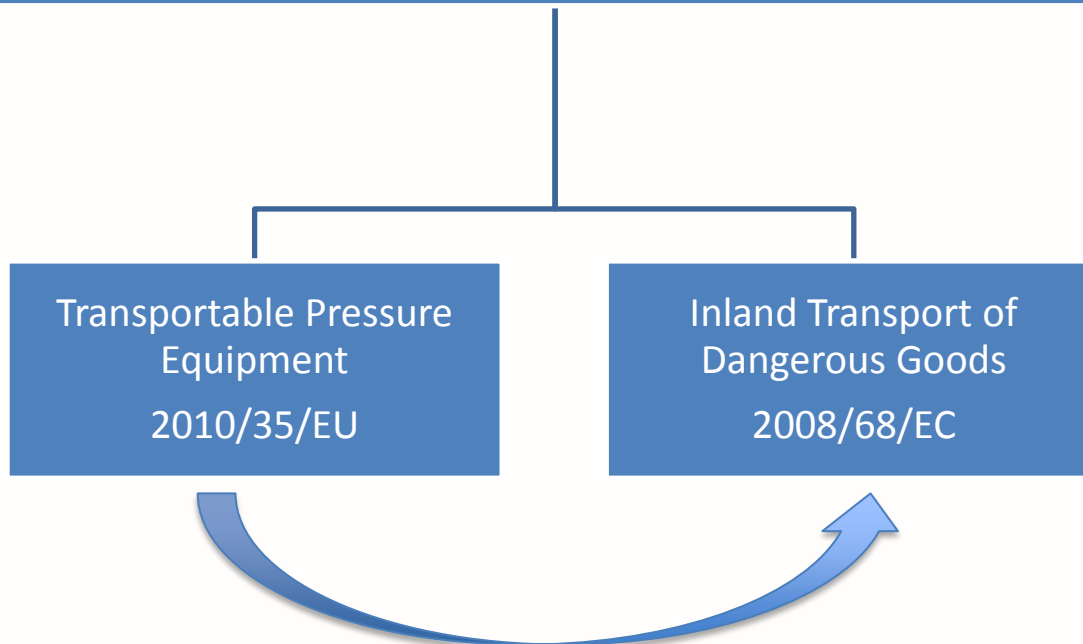
Transportable Pressure Equipment Directive (TPED)

- How is the directive implemented in IE?
- What is transportable pressure equipment?
- What is required under the directive?
- What are the implications of a 'no deal' Brexit?

National Regulations

European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations

2011 to 2018

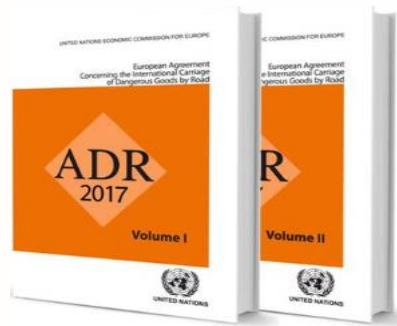


ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road



ADR

European Agreement Concerning the International Carriage of Dangerous Goods by Road



European Agreement

ADR

Geneva, 30 Sept
1957

9 signatories
50 Contracting
Parties
Ireland – 12 Oct
2006

United Nations
Economic
Commission for
Europe



What is transportable pressure equipment?



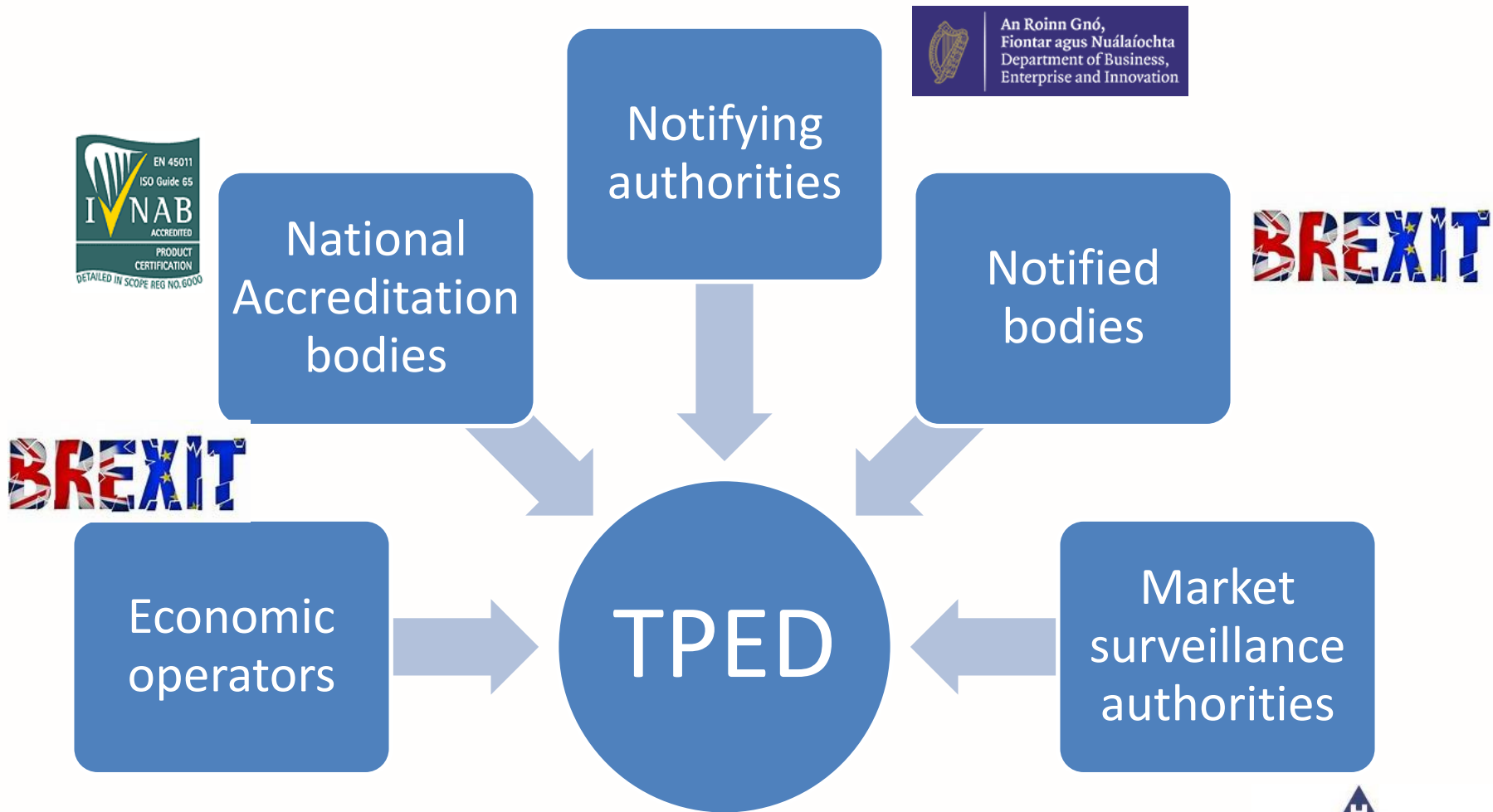
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Transportable Pressure Equipment	Dangerous goods
<p>Pressure receptacles including gas cartridges</p> <p>Chapter 6.2 of ADR</p>	<p>Class 2 gases</p> <p>Annex I of TPED</p> <p>Hydrogen cyanide – Class 6.1</p> <p>Hydrogen fluoride – Class 8</p>
<p>Tanks, battery vehicles/wagons, multiple-element gas containers</p> <p>Chapter 6.8 of ADR</p>	<p>Bromine pentafluoride – Class 5.1</p> <p>Bromine trifluoride – Class 5.1</p> <p>Hydrofluoric acid – Class 8</p> <p>Iodine pentafluoride – Class 5.1</p>

What is not covered by TPED?

- Pressure equipment under the PED
- Aerosols (UN No. 1950)
- Open cryogenic receptacles
- Gas cylinders for breathing apparatus
- Fire extinguishers (UN No. 1044)
- Specific TPE exempted under ADR

Aim of TPED - free movement of TPE within the EU



Withdrawal of the United Kingdom and EU rules in the field of industrial products 22 January 2018

<https://www.hsa.ie/eng/Topics/Brexit/Market>

Surveillance - Industrial and Consumer Products/



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND
SMEs

Brussels, 22 January 2018
Rev1

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL PRODUCTS¹

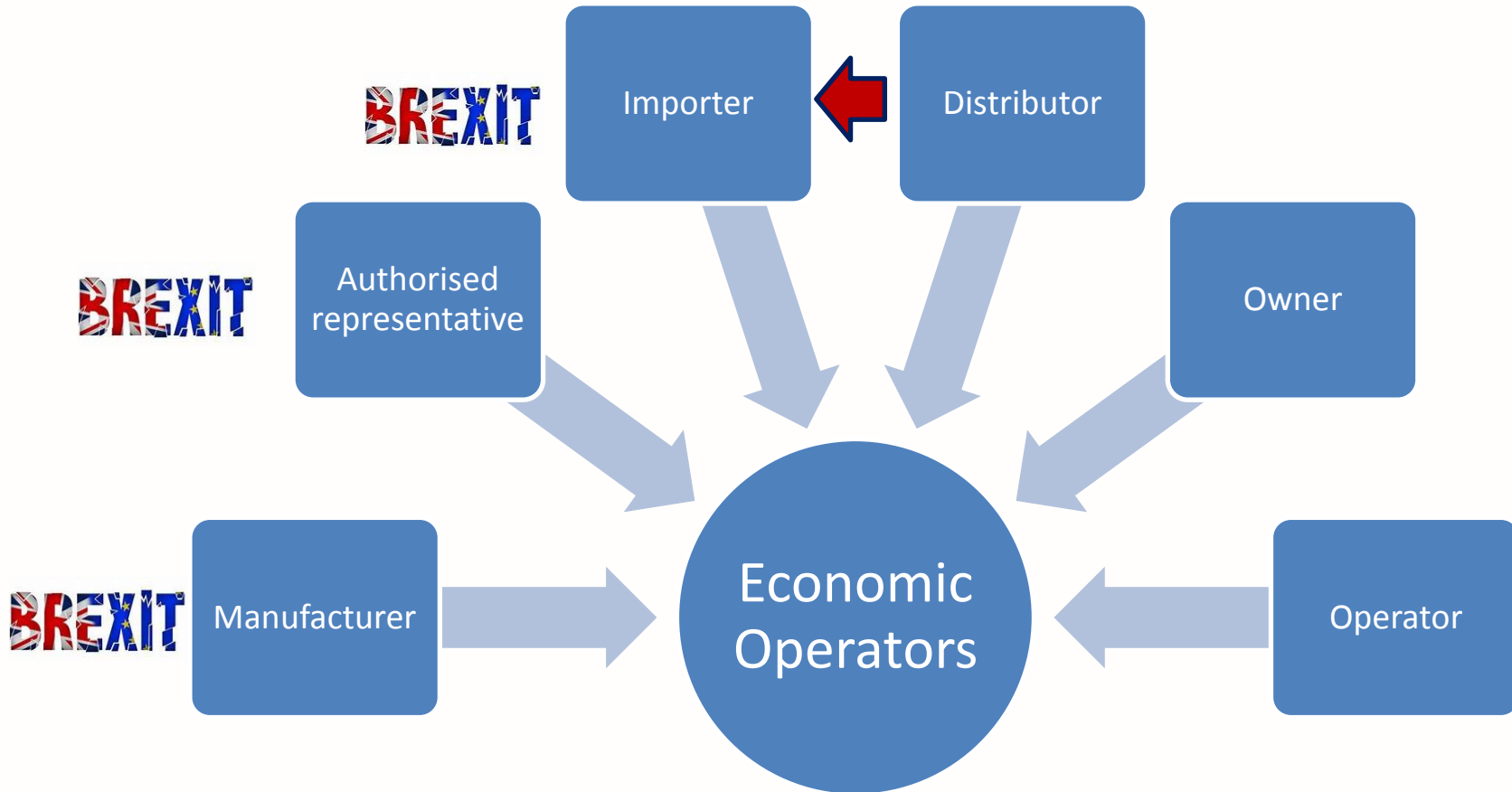
The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that, unless a ratified withdrawal agreement² establishes another date, all Union primary and secondary law will cease to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ('the withdrawal date').³ The United Kingdom will then become a 'third country'.⁴

Consequences

- Identification of economic operators
- Conformity assessment procedures and notified bodies

- Transportable Pressure Equipment
- Pressure Equipment
- Lifts and Safety Components for Lifts
- Equipment for use in Explosive Atmospheres (ATEX)
- Machinery
- Gas Appliance Regulation
- PPE Regulation
- Lifts

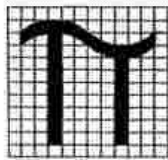
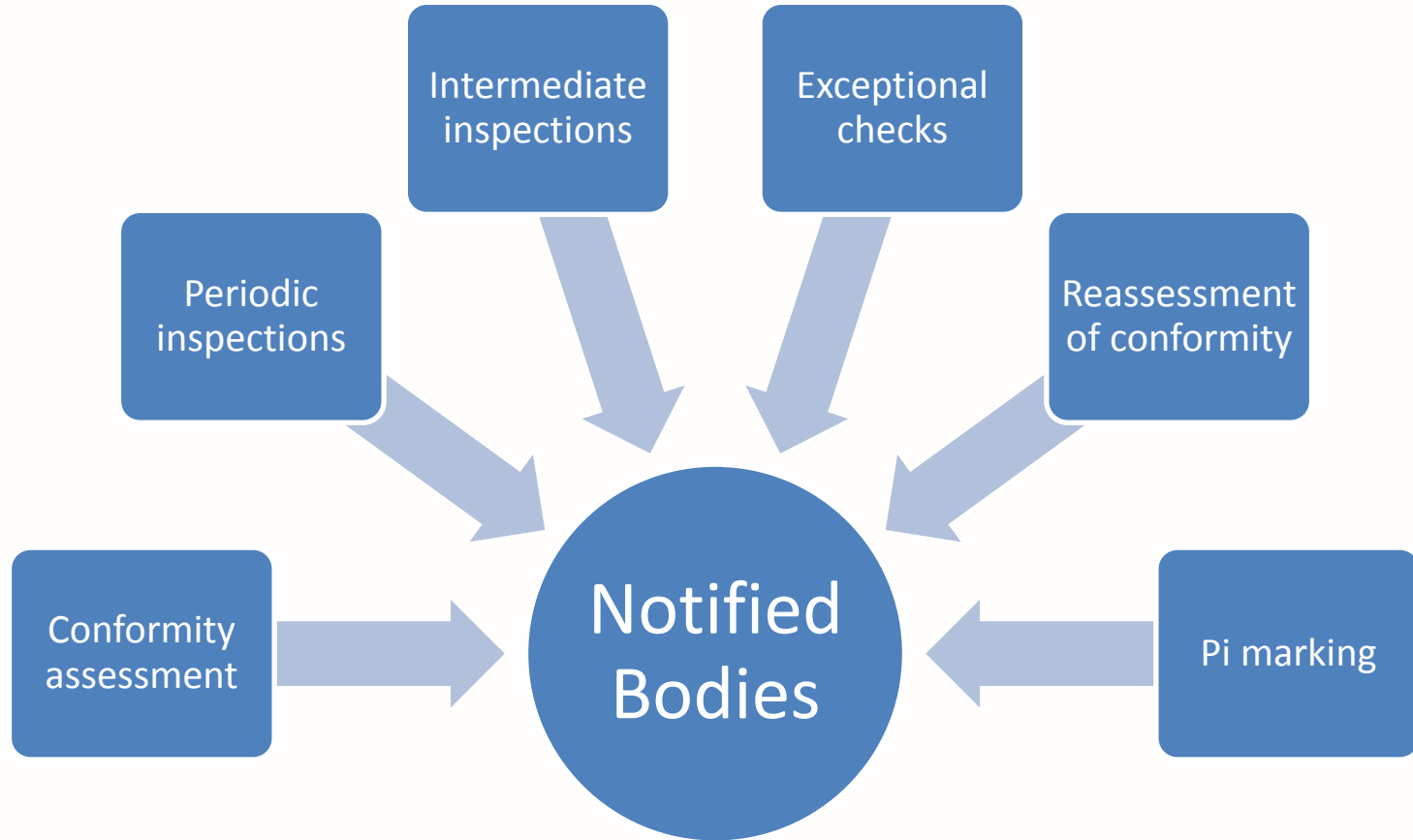
Economic Operators



'placing on the market' – the first making available of TPE on the Union market

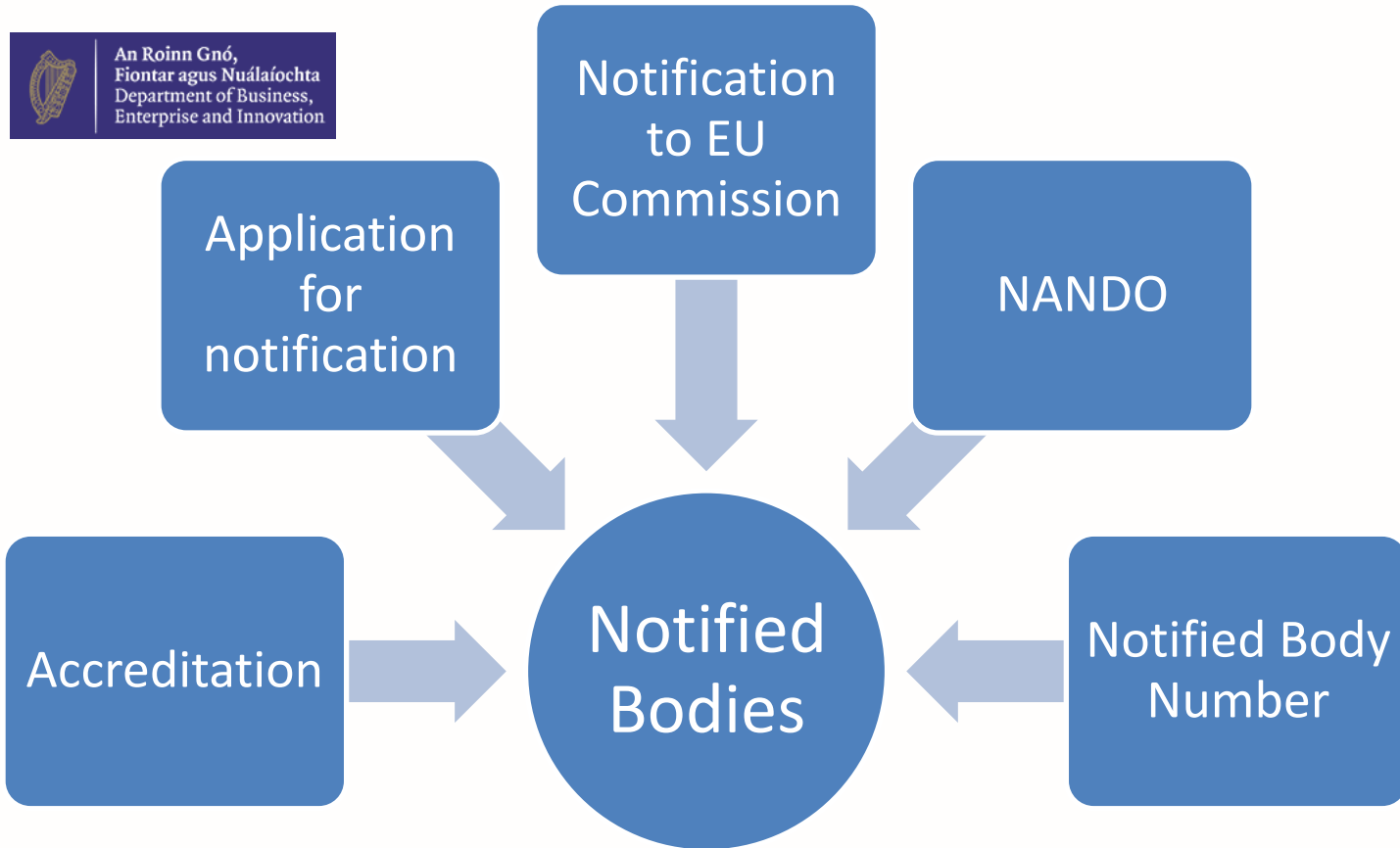
'making available on the market' – any supply of TPE for distribution or use on the Union market in the course of a commercial public service activity, whether in return for payment or free of charge

Notified Bodies



Certificates and reports issued by a notified body are valid in all Member States.

Notification Procedure



- *Established in a Member State*
- *Designated by a Member State notifying authority*
- *Valid in all Member States*

NANDO

- New Approach Notified and Designated Organisations Information Systems
- <http://ec.europa.eu/growth/tools-databases/nando/>



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Notified Body number : 0029

Impact of Brexit on UK Notified Bodies

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL PRODUCTS



- Lose status as EU Notified Bodies (NBs)
- Removed from NANDO
- Unable to do conformity assessment, intermediate inspections, periodic inspections, exceptional checks, reassessment of conformity

Advice re: placing on the market after withdrawal date:

- Certificate issued by an EU-27 NB
- Certificates from UK NB prior to withdrawal
 - Apply for new certificate issued by EU-27 NB
 - Transfer based on contractual arrangement between manufacturer, UK NB and EU-27 NB

UK Notified Bodies (NBs) and TPED



The screenshot shows a web interface for searching notified bodies. On the left is a navigation menu with 'Notified bodies' selected, and sub-items for 'Nando', 'Country', 'Legislation', and 'Body'. The main content area is titled 'Bodies' and shows search criteria: 'Country : United Kingdom' and 'Legislation : 2010/35/EU Transportable pressure equipment'. A dropdown arrow is visible on the right of the legislation field. In the top right corner, it says 'Found : 30'.

- 30 UK NBs under TPED
- 26 UK NBs - pressure receptacles
 - 15 - periodic inspections
 - 9 - conformity assessment, exceptional checks, intermediate inspections, periodic inspections and reassessment of conformity
- 4 UK NBs – tanks
- Irish economic operators currently use UK NBs

What does this mean for you?

- Do you use transportable pressure equipment?
- Does TPED apply? (π mark)
- What is your role as an economic operator?
- Are you currently a distributor for UK transportable pressure equipment?
- Will you become an importer after Brexit?
- If you are an owner or operator under TPED, where is the notified body based? (NANDO)
- If the notified body is UK based, what does that mean for you?
- Mutual agreements??
- Use of UK accredited inspection bodies for national pressure receptacles (not π marked)??

Thank you





Questions and Answers

Session 1



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