

Brexit and the Implications on Supply and Use of Chemicals, Machinery & Products in Irish Businesses

December 5th 2018



Rialtas na hÉireann
Government of Ireland





Brexit and the Transportable Pressure Equipment Directive

Alice Doherty, HSA



Rialtas na hÉireann
Government of Ireland



Overview

Transportable Pressure Equipment Directive (TPED)

What is transportable pressure equipment (TPE)?

How is the TPE directive implemented in IE?

What is required under the TPE directive?

European Commission Notice 22 January 18

What are the implications of a 'no deal' scenario?

What is transportable pressure equipment?



#36046001

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>

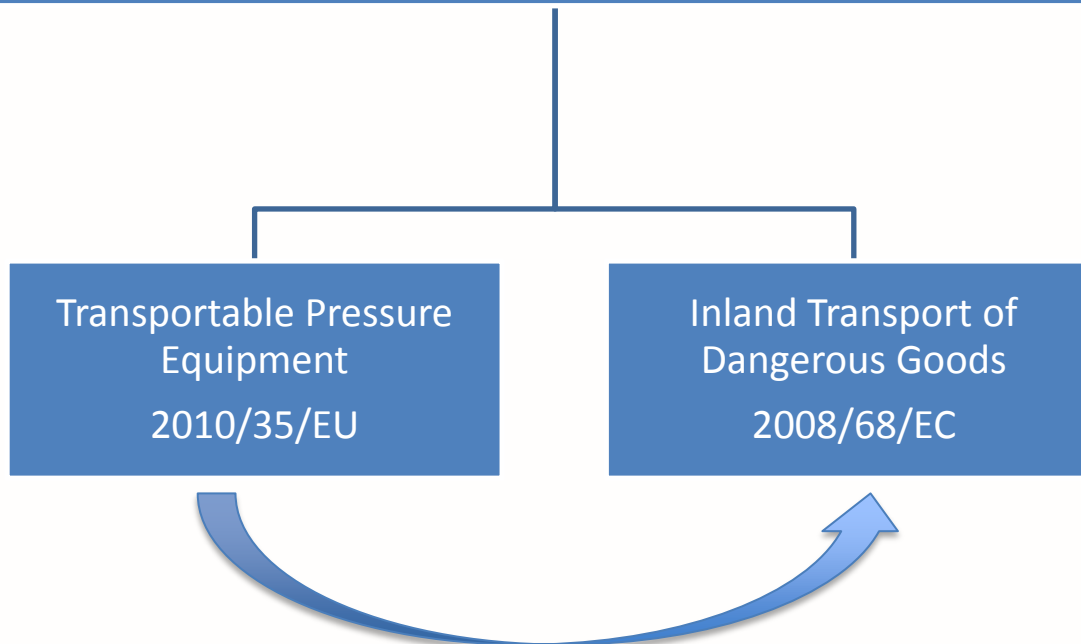
What is not covered by TPED?

- 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

National Regulations

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

2011 to 2018

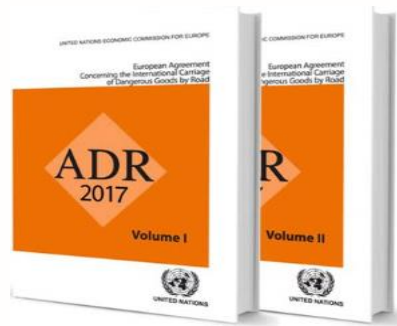


ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road



ADR

European Agreement Concerning the International Carriage of Dangerous Goods by Road



European Agreement

ADR

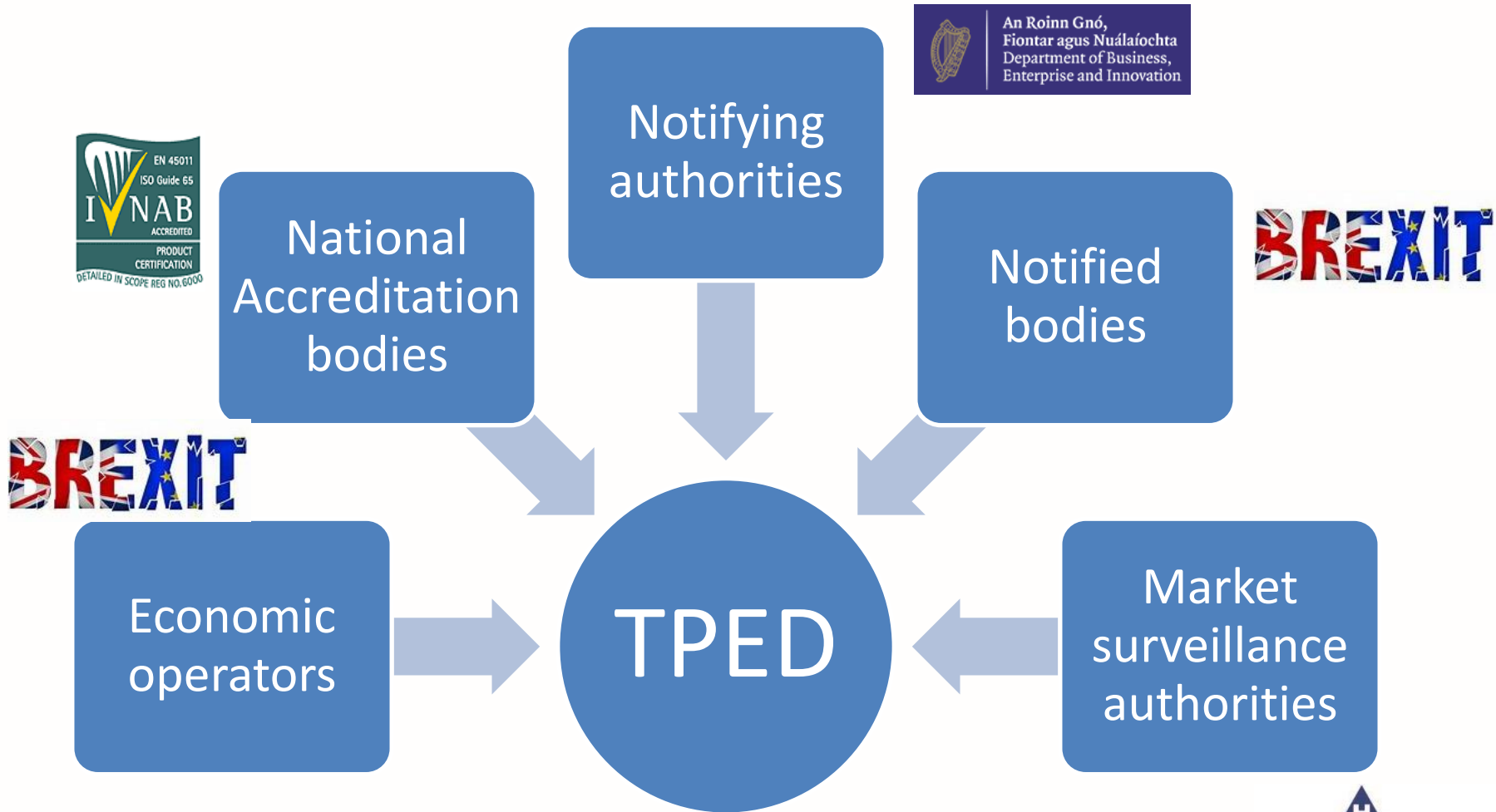
Geneva, 30 Sept
1957

9 signatories
51 Contracting
Parties
Ireland – 12 Oct
2006

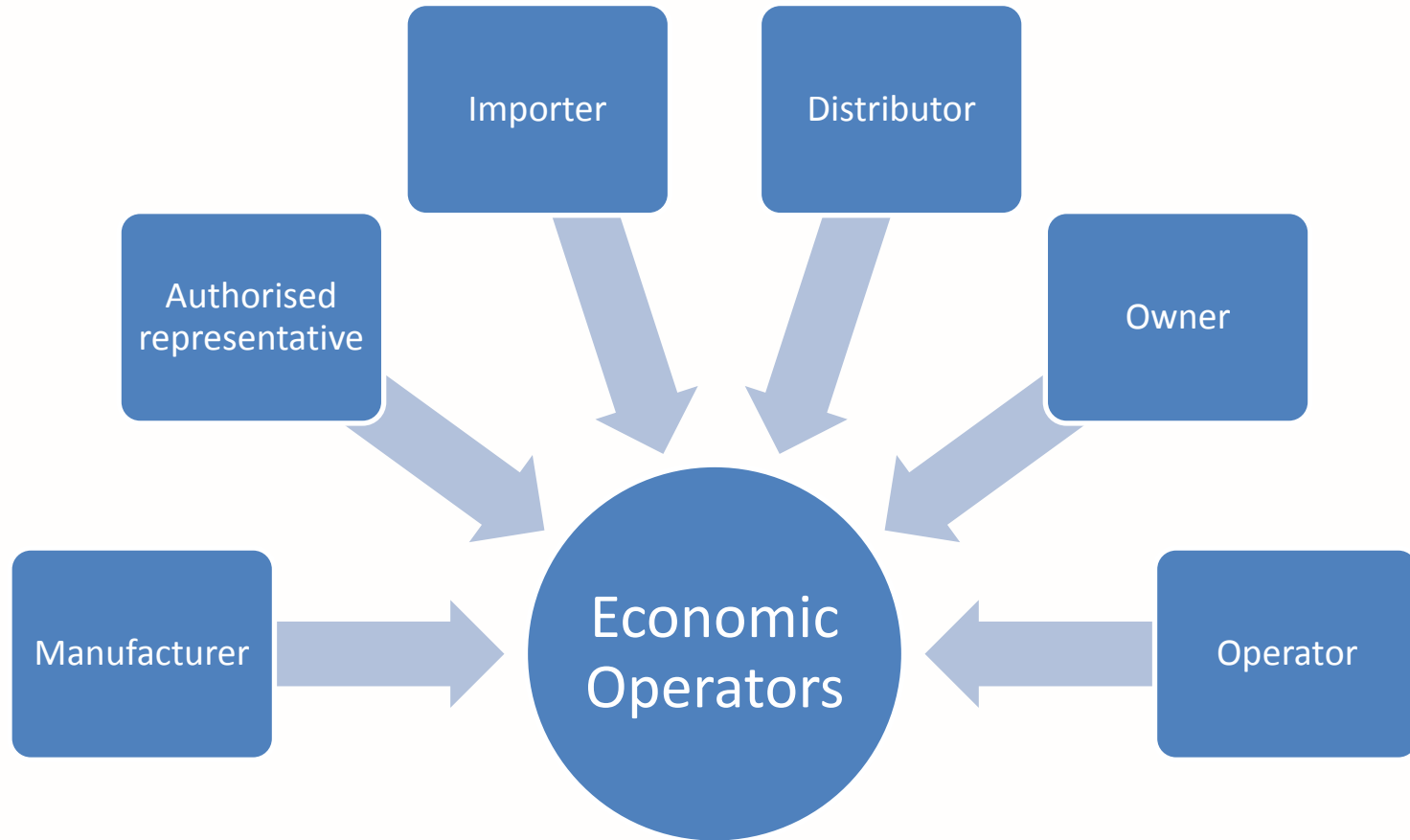
United Nations
Economic
Commission for
Europe



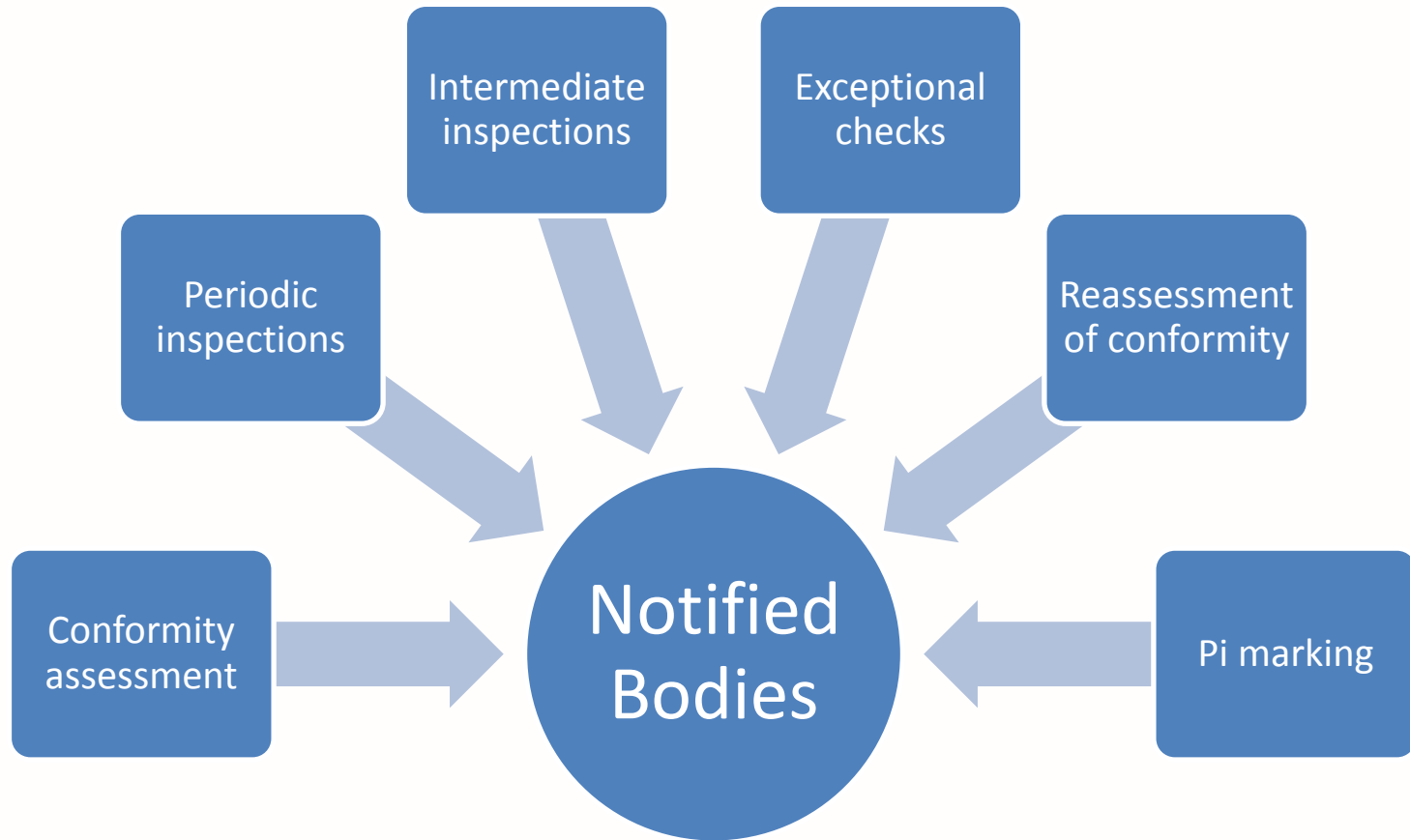
Free movement of TPE within the EU



Economic Operators

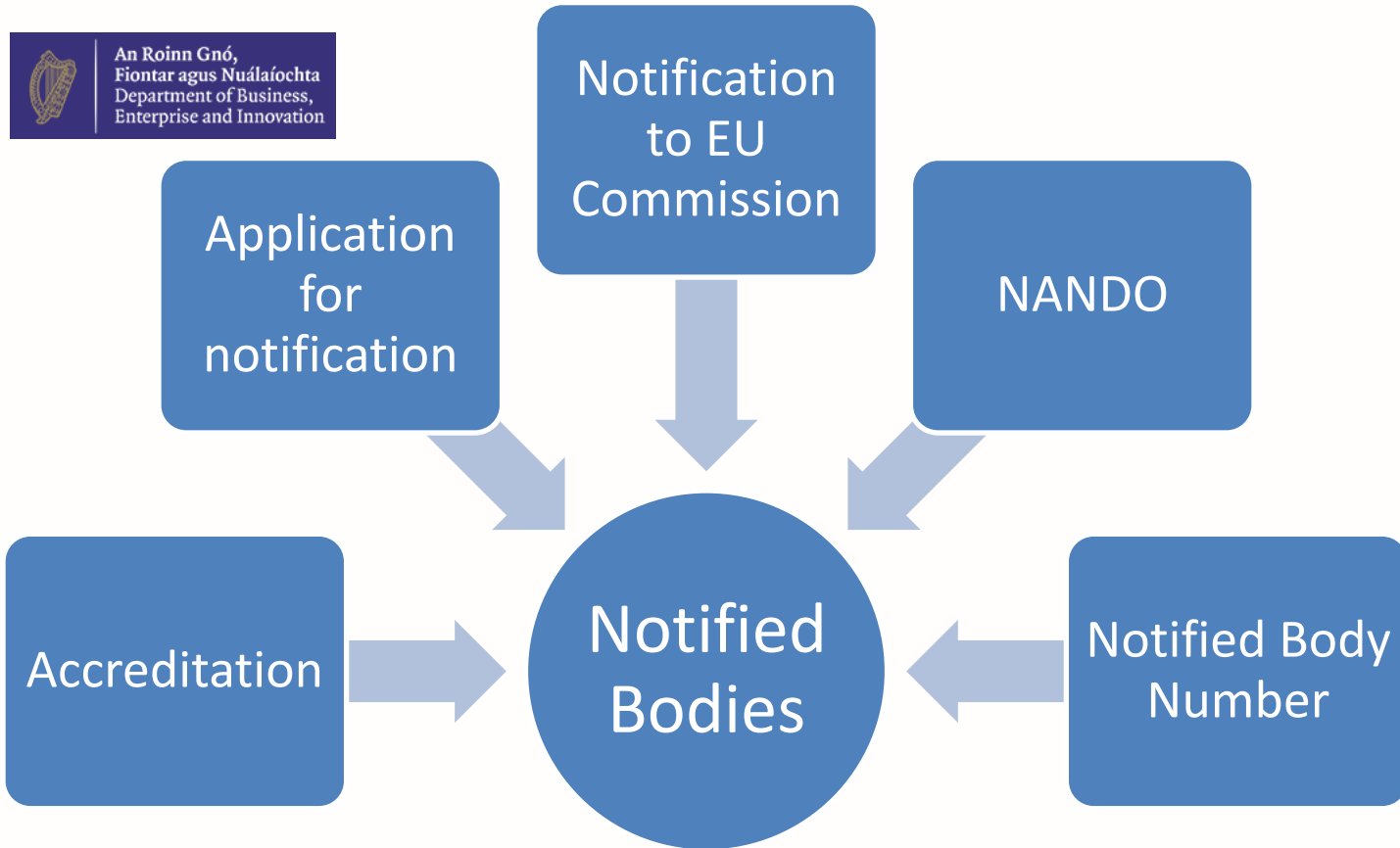


Notified Bodies



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/>



APRAGAZ A.S.B.L.

Chaussée de Vilvorde, 156
1120 BRUXELLES
Country : Belgium

Phone : +32/2 264 03 60
Fax : +32/2 268 89 58

Email : info@apragaz.com
Website : www.apragaz.com

Notified Body number : 0029

What are the implications of Brexit?

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/](https://www.hsa.ie/eng/Topics/Brexit/Market%20Surveillance%20-%20Industrial%20and%20Consumer%20Products/)



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

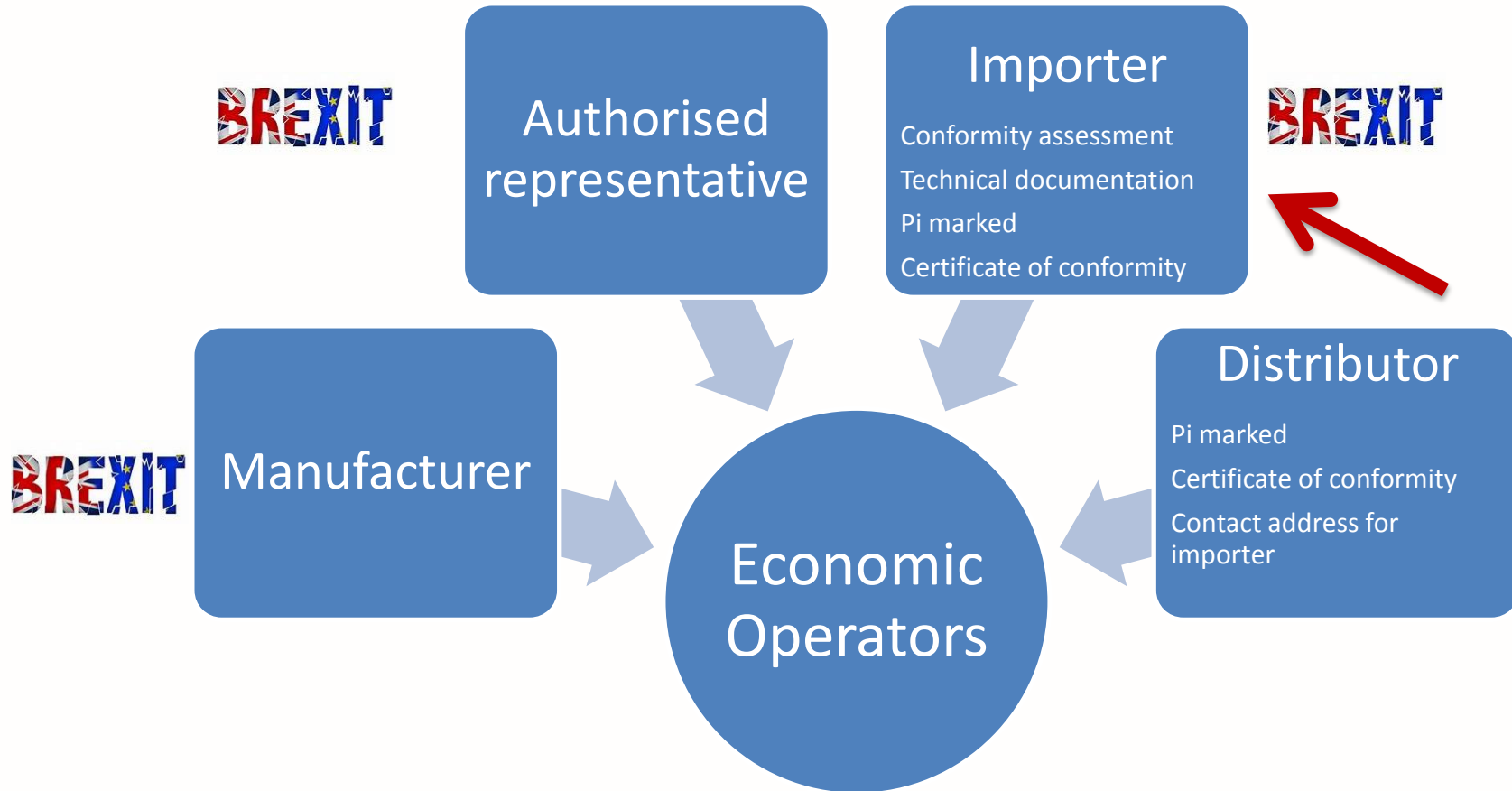
The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that, unless a ratified withdrawal agreement² establishes another date, all Union primary and secondary law will cease to apply 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

- 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

Consequences for goods placed on the market after withdrawal:

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

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

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 search results page for 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 – ‘no deal’ scenario?

- 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?

Thank you



Brexit and the Implications on Supply and Use of Chemicals, Machinery & Products in Irish Businesses

December 5th 2018



Rialtas na hÉireann
Government of Ireland





Brexit and the implications for the supply and use of machinery and products

Alan Costelloe, HSA



Rialtas na hÉireann
Government of Ireland



Ireland UK Trade

- In 2017 UK exports to Ireland worth £ 34 B
- UK Imports from Ireland were £22 B
- Ireland was UK' s 5th largest export market and 9th largest source of imports.
- Over 3 Billion € - Machinery & transport equip imported 2015 to Ireland from UK (CSO)



Imports



Requirements of the EU Market

- Single Market
- Free Movement of Goods
- Safe Products for all users
- Fair Competition
- Ensured by EU Directives and Legislation

HSA – Role as a regulator

- The HSA is currently the competent national body responsible for regulation of machinery and machinery products in Ireland.
- Its role involves ensuring that machinery and certain products coming on the market are to the required safety standards and comply with the relevant EU law and directives.
- The HSA carries out inspections and monitors machinery and products on the market and in the workplace to ensure compliance with the law.

EU Legislation on Machinery and Machinery Products

- Machinery Directive
- Lifts Directive,
- PPE Directive,
- ATEX,
- Low Voltage Directive
- EU Products Directive
- Market Surveillance Guidance – Blue Book (C272)

- Directives are aligned in Irish law by Health and Safety Regulations

Scope of Machinery

'MACHINERY' defined as:

- 'an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application...'
- Machinery Directive includes:
- Interchangeable equipment
- Safety components
- Lifting accessories such as chains, ropes, hooks, slings, and webbing.
- Removable mechanical transmission device [Power Take Off - PTO]
- Partly completed machinery

Examples

- Lathes, Drills,
- Manufacturing machines and equipment,
- Agricultural machinery, Combine harvesters
- Forklift trucks
- Escalators
- Baling machines,
- Meat mincing machines
- Construction machinery, eg Diggers, Bulldozers, Teleporters, Dump Trucks,
- Equipment and parts

- **Exclusions** – Ag and Forestry tractors, Weapons, Fairground equip, items that are covered by other Directives.

Annex IV Machines

- **Annex IV** machines are considered high risk machines. The safety tests and requirements on these machines are particularly stringent and mandatory before these machines can be placed on the EU market. Some examples:-
- Circular saws
- Hand fed planing machinery
- Band saws
- Vehicle Lifts
- Chain saws,
- Press machines
- Roll over protection structures
- Devices for lifting persons involving a hazard of falling more than 3 meters

Harmonised Standards

- When a product is manufactured it must be designed and built to the required standards, which include stringent safety requirements.
- Standards are drafted and approved by the Standards committees, once reviewed and approved by expert groups and ratified by the Directive Working Groups in the EU. They then become harmonised standards.
- Harmonised standards are a result of many months of collaboration and discussion by expert groups.
- If a product is manufactured and built to a harmonised standards there is a presumption of conformity to the Directives.

CE Marking and Compliance



- The “CE” symbol is required on machinery sold in the European Economic Area. The symbol is an indication that the machine is in compliance with the relevant directive.
- The manufacturer, the authorised representative or any natural or legal person who places on the market or puts into service such product is responsible for the compliance and conformity assessment of that product.
- Placing on the market means making a product available for the first time in the Community.

Duty on Manufacturer (Art 5 MD)

Before placing machinery on the market and/or putting it into service, the manufacturer or the authorised representative SHALL

- ensure it satisfies the relevant essential health and safety requirements set out in Annex 1
- Ensure that the technical file referred to in Annex VII, part A is compiled and available,
- Provide, instructions and other information as required,
- Carry out appropriate procedures for assessing conformity in line with Article 12, ie assess whether it is an Annex IV machine
- Draw up the EC Declaration of conformity AS PER Annex II, part 1,
- Affix the EC marking in accordance with Article 16.

ANNEX IV MACHINES

- If an Annex IV machine, the manufacturer must
 - (a) obtain third party verification i.e. a valid type-examination certificate – the test laboratory used must be accredited and affiliated with an EU Notified Body, or,
 - (b) Compile a technical file and submit it to an EU Notified Body for approval or,
 - (c) Carry out an assessment of conformity as set out in Annex VIII, (the product must be manufactured fully in accordance with transposed harmonised standards that cover all relevant essential health and safety requirements (EHSRs) for the product).

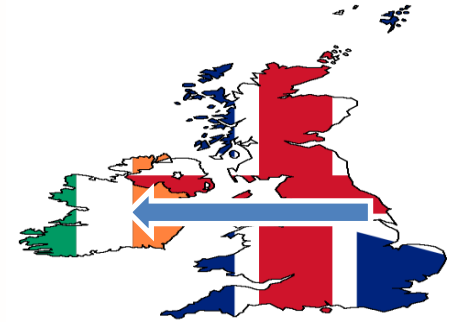
Duties

Importer / Wholesaler importing from UK Now

- Wholesaler is a distributor within the European Economic Area - EEA
- Manufacturer or Importer in UK bears most of the obligations
- Wholesaler may be entitled to rely on the “presumption of conformity” that is afforded by correct CE marking and the provision to the end user of the Declaration of Conformity
- Not necessary to check the whole design of the machine against the essential health and safety requirements of Directive before supplying (once technical file is located with the Community)
- You can pass machinery on in the same package, accompanied by an appropriate DOC and instruction Manual to other distributors.

Duties

Importer / Wholesaler Importing from UK After Brexit

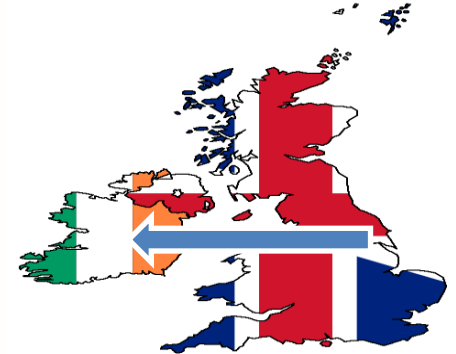


- In the event of a Hard Brexit, the UK will become a 3rd Country (like USA, China). The following will apply:
- Irish Importer / Wholesaler, now has full responsibility for the product as if the manufacturer
- Irish Importer / Wholesaler needs full access to the complete technical file for the product showing how design and construction meets all EHSRs.
- If the file not available, the Importer will need to compile one before making the product available on the market.
- Person responsible for the product must draw up and sign an “EC Declaration of Conformity” stating products are in compliance.

Duties

Importer / Wholesaler Importing from UK After Brexit Annex IV Machinery

- Where product is one of the listed categories in Annex IV of Machinery Directive
- Importer / Wholesaler must:
 - (a) to obtain third party verification i.e. a valid type-examination certificate – the test laboratory used must be accredited and affiliated with an EU Notified Body, or
 - (b) Compile a technical file and submit it to an EU Notified Body for approval, or
 - (c) Carry out an assessment of conformity as set out in Annex VIII,
- The product must meet in full all requirements of the most recent version of the relevant harmonised standard



Notified Bodies

- Notified bodies are conformity assessment bodies which have been officially designated by their national authority to carry out the procedures for conformity.
- Notified bodies carry out inspection, testing, certification referred to in the applicable technical harmonization legislation when an external third party is required.
- Notified Bodies are required for testing and certification under various Directives, particularly, Machinery Directive, Lifts Directive, Pressure Equipment Directive and others.

Notified Bodies after Brexit

- After Brexit **UK Notified Bodies** will NOT be authorised to carry out the function stated.
- Importer must ensure the machine or product when placed on the market after Brexit is certified by an **EU Notified Body**.
- Notified Bodies must have a legal presence in an EU country.
- Notified Bodies must be independent of the Client.
- There are currently 14 NB registered for Machinery Directive in the UK.
- NANDO web site lists all EU approved notified bodies for various Directives,
- Notified Bodies are approved for specific Directives or part of a Directive.
- Following a Hard Brexit UK notified bodies will be removed from NANDO.

Notified Bodies Extract from EU Guidance

- Where economic operators hold certificates issued by a UK Notified Body prior to the withdrawal date and plan to continue placing the product concerned on the EU-27 market as from the withdrawal date, they are advised to consider either applying for a new certificate issued by an EU- Notified Body, or
- arranging for a transfer – of the file and the corresponding certificate from the UK Notified Body to an EU- Notified Body, which would then take over the responsibility for that certificate.
- This responsibility depends on the specific conformity assessment procedure required for the product concerned under the applicable product legislation.

ARE YOU BREXIT READY ?

- **To prepare you should carry out the following steps:**
- Analyse your business and carry out a Brexit Risk Assessment taking the following questions into account:
 - 1) Do you obtain your machinery and equipment from a UK manufacturer,
 - 2) Does your supply chain come from a 3rd country but placed on the market firstly in the UK,
 - 3) Do you need to source a new EU supplier,
 - 4) Do you use a UK Notified Body for compliance,
 - 5) Can you source an EU Notified Body after Brexit
 - 6) Are you aware of your responsibilities as an Importer from a 3rd country,
 - 7) Are you competent to carry out your duties,
 - 8) If exporting to the UK, are you aware of UK requirements after Brexit.

IRISH NATIONAL ACCREDITATION BOARD



Irish National Accreditation Board

- For most product directives, the Irish Authorities have deemed that accreditation by the national accreditation body is mandatory.
- In Ireland, accreditation is provided by the **Irish National Accreditation Board, INAB** – part of the Health and Safety Authority
- INAB carry out the accreditation process for Notified Bodies in Ireland.
- Notified Bodies in UK are relocating to other Member States
- Manufacturers can select the services of any Notified Body based in EU27
- Tradition of relying on Notified Bodies in the UK
- Some re-establishing in Ireland (as new entities), a number of applications have been submitted to INAB in recent months.

Notified Bodies Accreditation

- INAB has accredited or is in the processing of accrediting Irish Notified Bodies for:
 - Machinery (MD)
 - Personal Protective Equipment (PPE)
 - Construction products (CPR)
 - Transportable Pressure Equipment (TPED)
 - Pressure Equipment (PED)
 - Radio equipment (RED)
 - Electromagnetic capability (EMC)
 - Marine Equipment (MED)

FURTHER INFORMATION

- Should you require further information on applicability of the Directives and your responsibility after Brexit please go to our web site at
- www.hsa.ie
- or contact our Workplace Contact Unit at 1890289389, email wcu@hsa.ie
- INAB – further information go to www.inab.ie
- Nando <http://ec.europa.eu/growth/tools-databases/nando/>

Thank you



Brexit and the Implications on Supply and Use of Chemicals, Machinery & Products in Irish Businesses

December 5th 2018



Rialtas na hÉireann
Government of Ireland





Questions and Answers

Session 2



Rialtas na hÉireann
Government of Ireland





Closing remarks



Rialtas na hÉireann
Government of Ireland

