



# Brexit - Implications for Industrial Products.

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Rialtas na hÉireann  
Government of Ireland



# Brexit – Implications for Industrial Products - Overview

- Trade
- EU legislation and the HSA
- Standards and compliance
- Economic Operators before and after 1<sup>st</sup> Jan 2021
- Notified Bodies - requirements
- EU NI Protocol
- Preparation

# Ireland UK Trade Overview

2019 Ireland imported € 18.7Billion goods from UK CSO

Exports € 13.5 Billion goods to the UK 2019

€ 4 Billion - Machinery & Transport imports



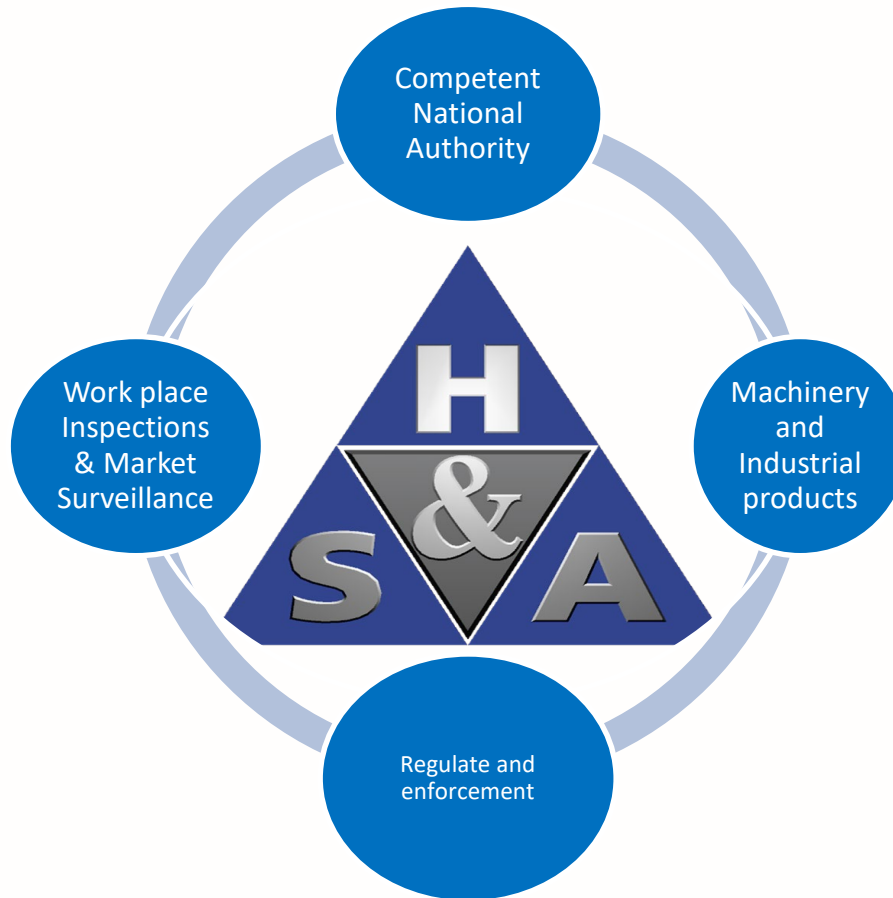
# Requirements of the EU Market

## EU Single Market

- Free Movement of Goods
- Safe Products for all users
- Fair Competition – no unfair advantage
- Ensured by EU Directives and Legislation



# HSA – Role as a Regulator.

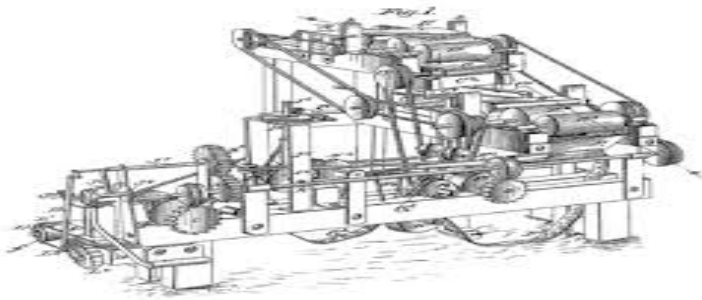


# EU Legislation on Machinery and Machinery Products

- Machinery Directive
- Lifts Directive,
- PPE Directive,
- Pressure Equipment Directive (PED)
- ATEX, (Equip in flammable atmos)
- Gas Appliances Directive (GAD)
- Directives are aligned in Irish law by specific Market Surveillance Regulations
- [Market Surveillance Guidance – Blue Guide \(C272\)](#)



# Scope of Machinery



**MACHINERY**’ defined in the Machinery Directive 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

- Lathes, Drills,
- Manufacturing machines and equipment,
- Agricultural machinery, such as combine harvesters, balers etc.
- Forklift trucks
- Escalators
- Meat processing machines
- Construction machinery:  
such as: diggers, bulldozers, teleporters, dump trucks etc.
- Other equipment and parts
  
- **Exclusions** – Agricultural and Forestry tractors, Weapons, Fairground equip, & items that are covered more specifically by other Directives.



# Annex IV - Machinery Directive

- **Annex IV** machines are considered high risk machines. The safety tests and requirements on these machines are particularly stringent and may require a Notified Body before these products can be placed on the 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



- .
- Standards, once reviewed and approved by expert groups and ratified by the Directive Working Groups in the EU, then become harmonised standards.
- If a product is manufactured and built to harmonised standards there is a presumption of conformity to the Directives.



# EU Requirements.

- The requirements for placing products on the EU market is regulated in EU legislation through Directives and Regulations.
- **This will NOT change after the UK transition period.**
- Products as always will be required to be manufactured to the required standards before they can be placed on the EU market.
- Placing on the market means making a product available for the first time in the European Union.
- Economic Operator 'responsible' established in the EU

# What is an Economic Operator

- An **economic operator** means a manufacturer, authorised representative, importer or distributor.
- A **manufacturer** is the person who manufactures the product *or* has the product designed and manufactured, and markets that product under their trade name.
- An **importer** is a person established within the European Economic Area (EEA) who first places a product from a third country on the market of the EEA.
- A **distributor** (Wholesaler) is any person in the supply chain, other than the manufacturer or importer who makes a product available on the market.
- An **authorised representative** is a person established in the EEA who has received a written mandate from a manufacturer to act on their behalf on specific tasks.

# 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:

- Satisfies the relevant essential health and safety requirements (Annex 1)
- Technical file (Annex VII)
- Instruction manual
- Annex IV machines procedures to ensure conformity, - EU Notified Body or self assessment as required under Article 12 .
- EC Declaration of Conformity (Annex II)
- CE mark Article 16.



# Duty on Importer.



- **Ensure that the manufacturer has carried out the steps above.**
- Name and contact details on the product + manufacturers markings.
- Notify the Authority of any risks or non-compliances.
- Keep copies of Declarations of Conformity (DOC) and technical documentation for 10 years.
- Withdraw or recall unsafe or non-compliant products as appropriate.

# Duty on Distributor.



- Product bears the CE Mark.
- Accompanied by the required documents and instructions.
- Manufacturer and importer markings are on the product.
- Notify the Authority of any risks or non-compliances.
- Keep copies of DOCs and technical documentation for 10 years.
- Must not supply products that they know are not in compliance with the legislation.

# 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, authorised representative who places on the market or puts into service such product is responsible for the compliance and conformity assessment of that product.



# Notified Bodies

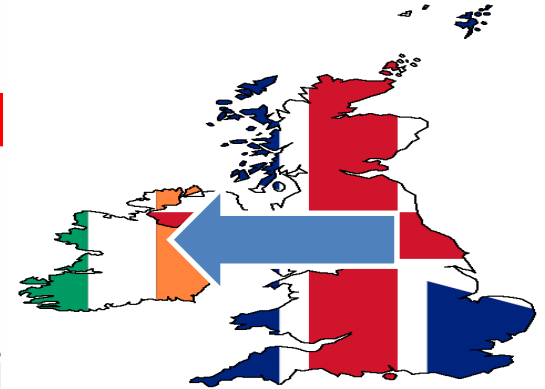
- Notified Bodies are independent conformity assessment bodies accredited to carry out the procedures for conformity.
- Notified Bodies have various requirements for testing and certification under different Directives, particularly, Machinery, Lifts, PED, PPE and others.
- Notified Bodies are approved for specific Directives or part of a Directive.
- Notified Bodies must have a legal presence in an EU member state.
- Nando Website - <https://ec.europa.eu/growth/tools-databases/nando>

# General Duties when importing from UK Now

- Manufacturer or Importer in UK bears most of the obligations
- Wholesaler / Distributor may be entitled to rely on the “presumption of conformity” by correct CE marking and 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 Declaration of Conformity (DOC) and Instruction Manual to other distributors.

# Duties

## Importer **after Transition Period**



- In the event of no deal, on the 1<sup>st</sup> Jan 2021, GB will have the same status as the USA, China, India i.e. a 3<sup>rd</sup> Country.
- The following will apply:
- A distributor of machinery originating from the GB now becomes the Importer.
- Irish Importer, now must ensure that the full conformity assessment has been carried out by the manufacturer.
- Irish Importer needs full access to the complete technical file for the product showing how design and construction meets all EHSRs.
- Person responsible (manufacturer) for the product must draw up and sign an “EC Declaration of Conformity” stating products are in compliance.

# Notified Bodies after Transition Period

- From the 1<sup>st</sup> Jan 2021 **UK Notified Bodies** will be removed from the Nando website.
- Importer must ensure the machine or product when placed on the market (where required) is certified by an **EU Notified Body**.
- Where economic operators hold certificates issued by a UK Notified Body, 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**.

# NI Protocol



- NI will remain aligned to a limited set of EU Rules, notably rules relating to goods. This avoids any customs or regulatory checks or controls on the island of Ireland.
- If NI manufacturers use an EU Notified Body, they can apply the CE mark only – goods valid in the EU and also in the UK.
- A product manufactured in NI and shipped to the EU is not an imported product for the purpose of labelling and identification of economic operators / responsible persons.
- A product shipped from Great Britain to NI is an imported product;

# NI Protocol cont.

- Where a product is certified by a NI or UK Notified Body, the CE + 'UK(NI)' mark must be affixed. - placed on the market in Northern Ireland, but not in the EU.
- Goods from the UK carrying the UKCA mark will not be valid for sale in NI or the EU.
- Basically if it carries a CE mark only it can be placed on the EU market providing a DOC and EU Notified Body is used.

EU NB -> CE Mark      => EU and UK

UK NB -> CE + UK(NI) => NI and UK only

# ARE YOU BREXIT READY ?

To prepare you should carry out a Brexit Risk Assessment taking the following questions into account:

## Distributor => Importer:-

- Do you obtain your machinery and equipment from a GB manufacturer,
- Does your supply chain come from a 3<sup>rd</sup> country but placed on the market firstly in the UK,
- Do you need to source a new EU supplier,
- Are you aware of your responsibilities as an Importer from a 3<sup>rd</sup> country,
- Can you get the technical and safety information required from the GB manufacturer, if continuing to use that supply chain.
- Will your details will be included in packaging and info leaflets.
- Are you competent to carry out your duties,

# ARE YOU BREXIT READY ? Cont.

## Use of Notified Body

- Do you use a UK Notified Body for compliance,
- Engage with your UK notified body to see what you need to do to transfer certification to a new EU-27 notified body.
- Check the EU Nando website to ensure your new Notified Body is accredited as a NB for your products.
- Engage with the new Notified Body to ensure they have taken responsibility for your product certs.
  
- If exporting to the UK, are you aware of UK requirements after Transition period.



# Useful web sites

- [https://www.hsa.ie/eng/news\\_events\\_media/events/hsa\\_webinars/hsa\\_webinars.html](https://www.hsa.ie/eng/news_events_media/events/hsa_webinars/hsa_webinars.html)
- [https://www.hsa.ie/eng/topics/market\\_surveillance/](https://www.hsa.ie/eng/topics/market_surveillance/)
- [https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.notifiedbody&country\\_id=826](https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.notifiedbody&country_id=826)
- [https://ec.europa.eu/ireland/news/key-eu-policy-areas/brexit\\_en](https://ec.europa.eu/ireland/news/key-eu-policy-areas/brexit_en)
- <https://www.gov.ie/en/publication/a7ba02-brexit-info/?referrer=/brexit/>

# Applicable EU and Irish legislation

- Machinery Directive 2006/42/EC - Machinery Regulations SI 407 / 2008
- Pressure Equipment Directive 2014/68/EU - Pressure Equip Regs SI 233/2017
- Lifts Directive 2014/33/EU - Lifts Regs SI 232/2017
- ATEX Directive 2014/34/EU - ATEX Regs SI 230/2017
- EU PPE Regulation (EU) 2016/425 - PPE Regs SI 136/2018
- EU Gas Appliances Regulation (EU) 2016/426 - Gas Appliance Regulations SI 126/2018

**Thank You for your attention**



# QUESTIONS



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