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# Getting Ireland Ready for Brexit Standards & Certification

**FERGAL O'BYRNE**  
**HEAD NSAI BREXIT UNIT**

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[www.nsai.ie](http://www.nsai.ie)



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# Agenda

08:00-08:30: Registration

08:30-08:40: Introduction and Overview

08:40-09:00: Products, Construction and Green Procurement  
Fergal O'Byrne, NSAI

09:00-09:20: Personal Protective Equipment  
Simon Courtney, SATRA

09:20-09:40: Medical Devices  
Colm O'Rourke, NSAI

09:40-10:00: Electromagnetic Compatibility and Radio Equipment  
John McAuley, Compliance Engineering

10:00-10:20: Food Industry  
Anne-Marie Crowley, NSAI

10:20-10:50: Question and Answer Session

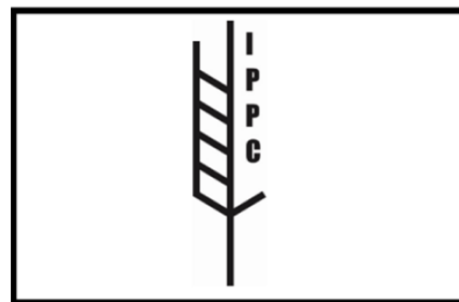
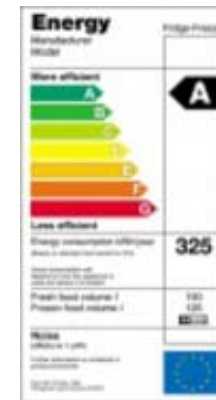
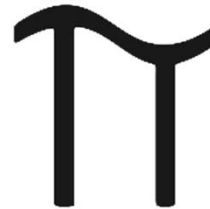
10:50-11:00: Wrap up



# Getting Ireland Ready for Brexit



- International Standards – ISO
- Certification
- 'CE' Mark
- Other marks
- Importers
- Exporters



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# Current Irish Notified Bodies

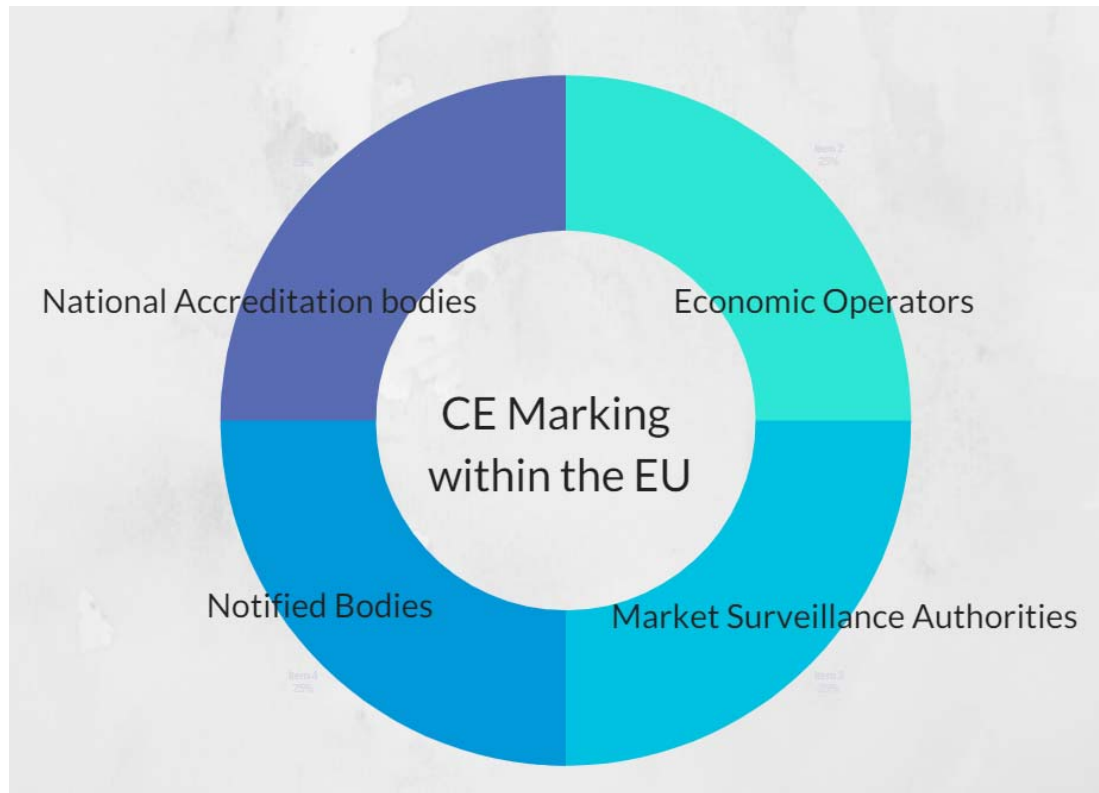


- NSAI
  - Compliance Engineering Ireland
  - SATRA Technology Europe
  - Industrial Pressure Testing Ltd.
  - *Additional Irish Notified Bodies are currently being accredited for Machinery, Personal Protective Equipment, Construction Products, Transportable Pressure Equipment, Pressure Equipment, Radio Equipment, Electromagnetic Capability and Marine Equipment.*
- 



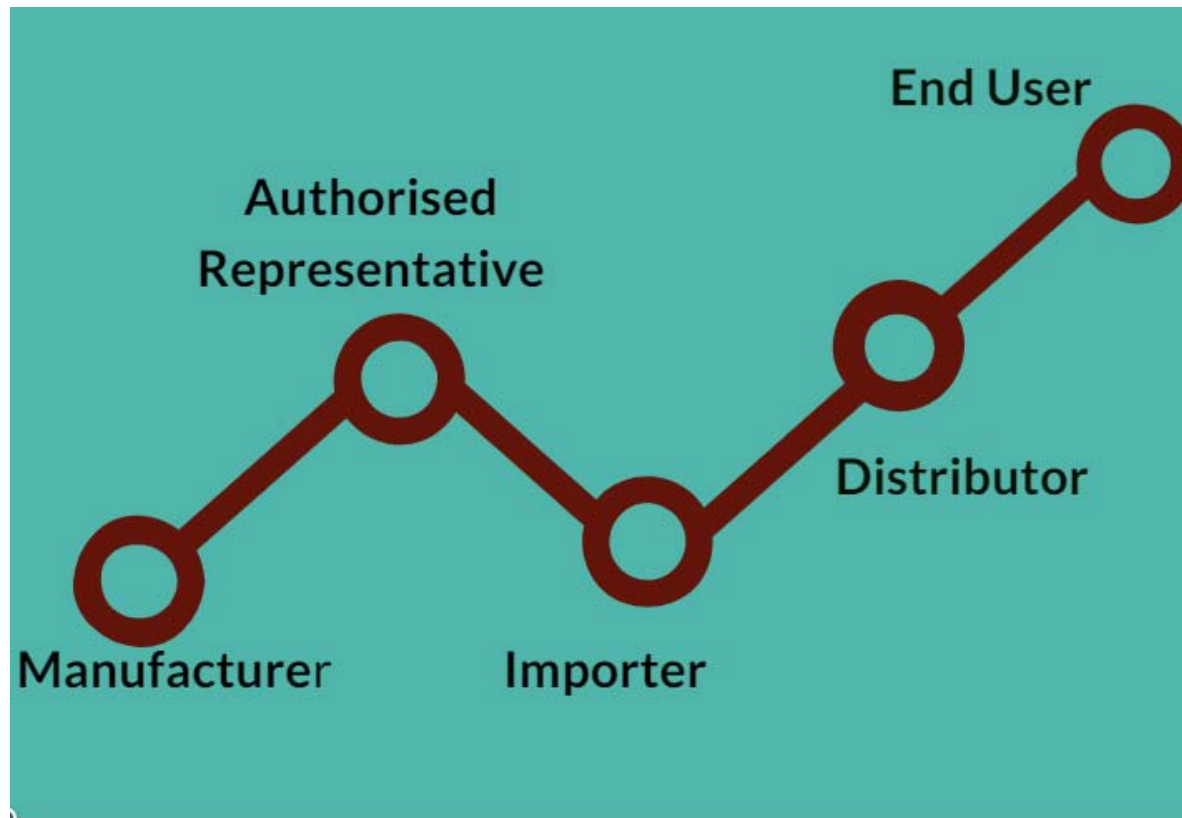
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# 'CE marking' within the EU



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# Economic Operators' Duties



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## ○ European Single Market

Single Market  
Labour  
Capital  
Goods and Services  
  
Customs Union



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## ○ European Single Market

~~Single Market~~

~~Labour~~

~~Capital~~

Goods and Services

~~Customs Union~~



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# Purpose of the European Single Market

European standards used to level the playing field

Free trade

Third party certification

Fair trade



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# Impact of Brexit on Standards



- International Standards – ISO
- *Example: I.S. EN ISO 9001:2015 Quality*
- European Standards - ENs
- *Examples: I.S. EN 3 Fire Extinguishers,*
- *EN 14081-1 Structural Timber*



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# Impact of Brexit on Motor Vehicles

- EU type approval- draft regulations
- UK's automotive industry operates complex supply chains
  - highly integrated with EU MS manufacturers inc. Ireland
- Role of manufacturers' representatives post Brexit
- Supply chain implications



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# 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 British 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, it is likely that the UK market will still require evidence of conformity of products



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# Impact of Brexit on importers

- If the UK is designated a "third country", importers of UK products may be required to fulfil the legal role of "authorised representatives"
- If you're importing products via the UK, the UK supplier can no longer act as an "authorised representative" and you will need to put into place an alternative arrangement
- The 'Blue Guide' on the implementation of EU products rules 2016 provides further information on the implementation of the "New Legislative Framework" for the marketing of products



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# Impact of Brexit on exporters

- If you or one of your product suppliers rely on a British Notified Body for certification of conformity, you will need to obtain alternatives before you can export to any EU Member State.
- For further information, please consult The 'Blue Guide' on the implementation of EU products rules 2016
- Post-Brexit, you may be required to provide evidence of conformity to UK national standards for products exported to the UK market



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# 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 Environment
- ISO 45001 Occupational Health and Safety
- ISO 23485 Medical Devices
- ISO 22000 Food Safety



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# Industrial Pressure Testing Limited

+353 (0)21 4968383 sales@indpt.ie



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- **Industrial Pressure Testing Limited of Cork was established in 1986**
- **Ireland's only accredited inspection body operating a quality system for the inspection and testing of a wide range of pressure receptacles including gas cartridges, their valves and other accessories**
- **Currently certifies for EU Directive 2010/35/EU Transportable pressure equipment**
- **Further information available- [www.indpt.ie](http://www.indpt.ie)**



# Thank you

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# SATRA's Brexit Solution

# Brexit

- UK voted for withdrawal from EU following referendum on 23 June 2016
- UK government evoked Art. 50 of EU treaty on 29 March 2017 to initiate withdrawal
- 29 March 2019 end negotiation period between UK and EU
- Latest news is that EU and UK have agreed a deal
- UK MPs to vote on deal
- EU MPs will then vote on deal

# Current PPE industry situation

- EU published PPE regulation (EU) 2016/425 on 31 March 2016
- Replaced PPE directive 89/686/EEC on 21 April 2018
- 21 April 2019 ends the transition period
- European Notified Bodies accredited against PPE Regulation
- PPE suppliers currently recertifying products



# Potential outcomes of Brexit

- A Hard-Brexit or a No-deal-Brexit
- UK Notified Bodies will lose status and notified body number
- Worst-case-scenario existing UK Notified Body certificates become invalid
- Misunderstanding by border agencies

# SATRA's Brexit solution

- SATRA opened SATRA Technology Europe Ltd in Bracetown, Dublin
- Manager Geoff Graham
- Certification scope all PPE including; footwear, gloves, fall arrest products, acoustic etc.
- On 21st May 2018 appointed by the government of the Republic of Ireland as a Notified Body for Personal Protective Equipment (PPE) Regulation (EU) 2016/425
- Issued Notified Body Number 2777
- Holders of existing certificates can now choose to transfer them to the Irish Notified Body
- New applications are processed through SATRA Technology Europe Limited.

# SATRA's PPE Testing Services

- UK's decision to withdraw from the EU will not affect the validity of existing or future test reports issued from SATRA in the UK
- Test reports will be accepted for certification purposes by SATRA Technology Europe Limited and other PPE Notified Bodies
- Accredited to ISO/IEC 17025:2017 – 'General requirements for the competence of testing and calibration laboratories'
- SATRA's continued involvement with CEN standardization committee

Simon Courtney  
Divisional Manager – Consumer products Division  
SATRA Technology  
[Simon.Courtney@satra.com](mailto:Simon.Courtney@satra.com)

Geoff Graham  
Product Certification Manager  
SATRA Technology Europe Limited  
(Notified body number 2777)  
[Geoff.Graham@satra.com](mailto:Geoff.Graham@satra.com)

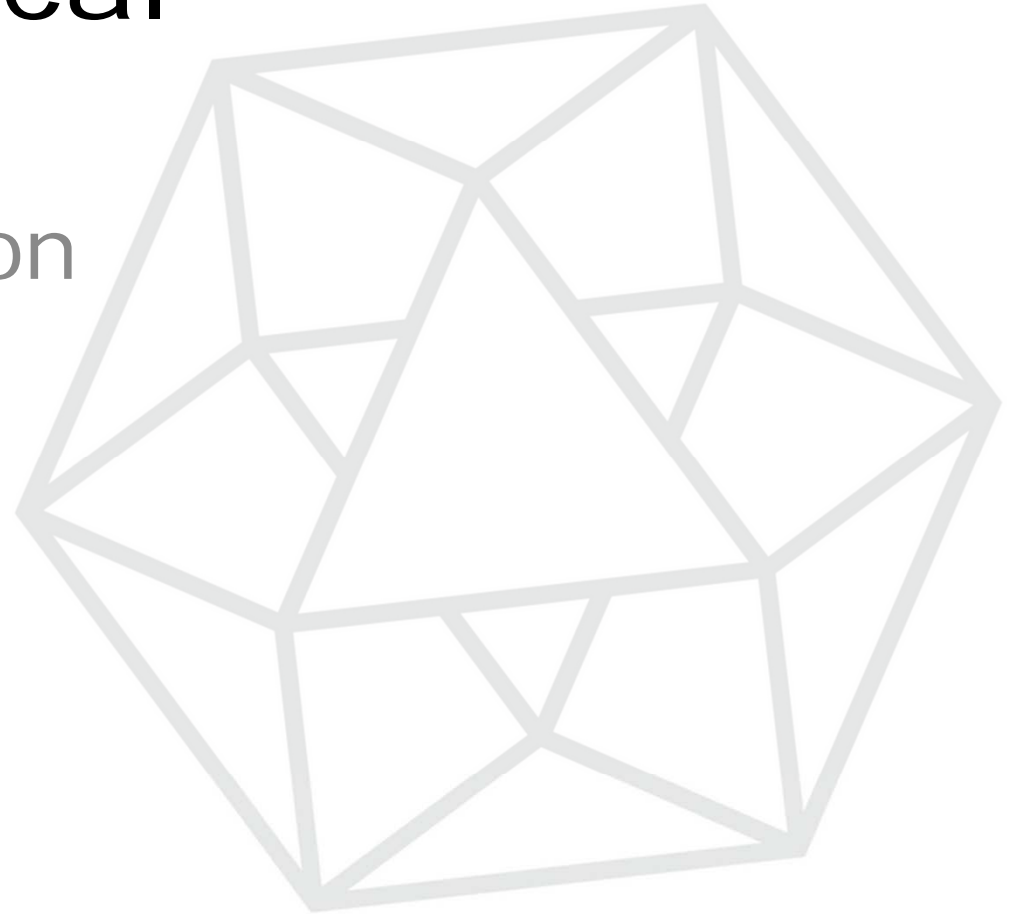


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# Brexit and Medical Devices

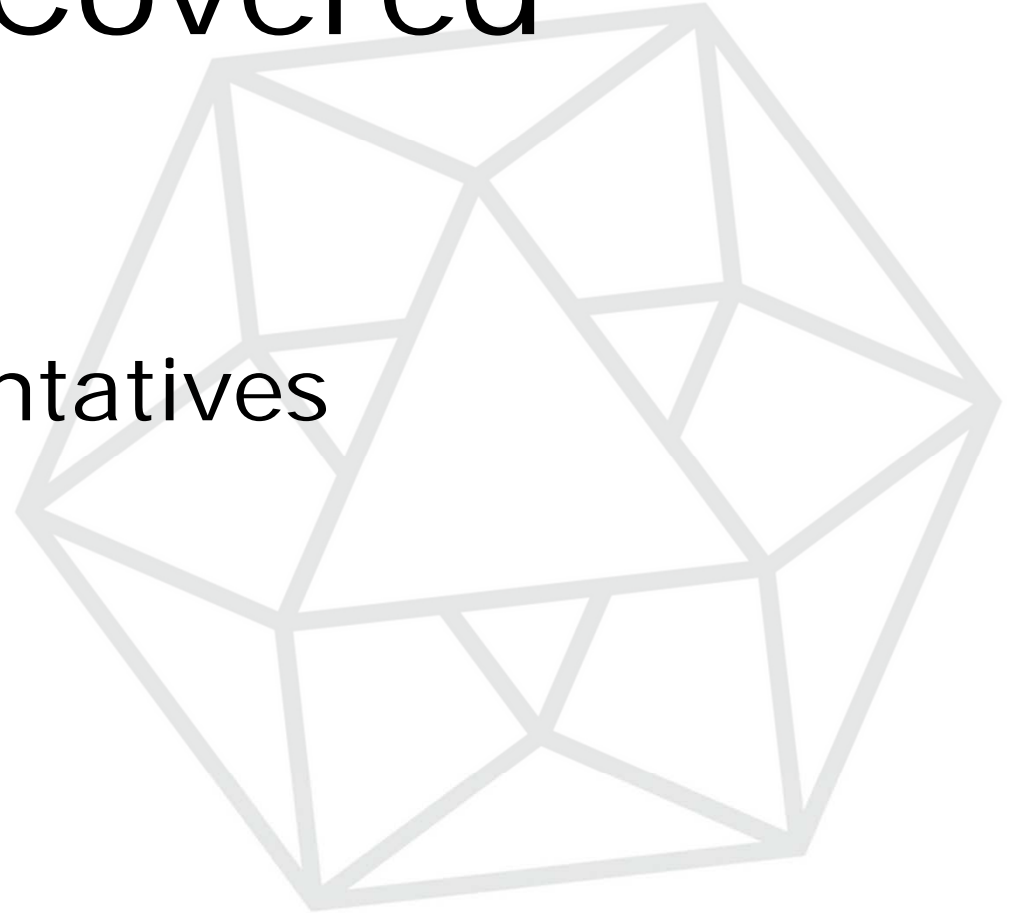
## NSAI Brexit Information Briefing

Colm O'Rourke  
Business Development,  
Medical Devices



# Areas Covered

- Device certification
- Authorised Representatives
- Import/Distribution
- Rules of Origin





# Device Certification

- European system is based on the CE Mark
- Conformity assessment carried out by Notified Bodies – designated by a Member State Competent Authority
- Currently there are 4 UK based Notified Bodies
- Many have made public their process of establishing a “new” NB in a Member State

# Device Certification

- In a no-deal scenario, product certificates issued by UK-based NBs will no longer be valid
- MHRA stated UK will recognise the CE Mark for “time-limited period” post-Brexit
- The UK is planning to comply with MDR & IVDR

# Authorised Representatives (ARs)

- ARs are required for all legal manufacturers who are not located in a Member State
- Irish based manufacturers do not require an AR – however, they may require a UK-based AR to sell into UK post-Brexit
- UK manufacturers will likely need EU based AR
- Non-EU based manufacturers currently using UK-based AR will need to engage an EU-based AR

# Import/Distribution

- Irish entities who bring in devices from UK will assume the role of importer post-Brexit – more information cited in Article 13 of the MDR 2017/745
- If you previously acted as a distributor for a UK-based manufacturer you may now also become the importer of that product

# Rules of Origin

- If exporting to a third country where a FTA is in place – preferential tariff rate may be applicable on products which have enough “EU content”
- Post-Brexit – content from UK sources can not be counted as “EU content”
- Potential supply-chain effects in order to source other “EU content”

# Thank you.

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colm.orourke@nsai.ie



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# Compliance Engineering



Notified Body

EMC

Radio Equipment Directive

John McAuley





# Notified Bodies

- Majority of non medical electrical/electronic goods do not need a Notified Body TEC so those UK manufacturers should experience minimum impact of Brexit (from a regulatory point of view)
- UK Notified Bodies to be withdrawn
- Number of UK NBs applying to INAB
- HPiVS - UK Notified Body for PED and RCD now based at Compliance Engineering Ireland



# Brexit - Irish Manufacturers

- Europe – Business as usual
- Exports to UK –business as usual, for the meantime
- Future UK national mark similar to CE mark?



# EU Declaration of Conformity

***Product model / product:***

Product Radio Product  
Model/type Super 77  
Serial nos. 00120 - 01000

***This declaration is issued under the sole responsibility of the manufacturer.***

***Object of the declaration:***

Product Short Range Radio

***The object of the declaration described above is conformity with the relevant Union harmonisation legislation:***

2014/53/EU	Radio Equipment Directive
2014/30/EU	The Electromagnetic Compatibility Directive
2011/65/EU	The Restriction of Hazardous Substances Directive

***References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:***

- EN 300 220-2 V3.1.1 2017 Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz
- EN 301 489-1 V2.2.0 2017 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- **Signed for and on behalf of:**



# Experience with Turkey

- Turkey is in a customs union with the EU.
- Huge delays at Turkish border over the last few years
- Experience from one of our client companies
  - *“..... 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”*



**The customs union means free movement of our goods. It doesn't mean free movement of our trucks**

- Erman Ereke (*Financial Times*)



Thank you for your attention

John McAuley

Dunshaughlin, Co Meath  
Tel: 01 8017000  
[www.cei-compliance.com](http://www.cei-compliance.com)

# Food Industry and Brexit

Anne Marie Crowley  
SSO Food/Agriculture Sector



# Brexit Proposal Article 185

Contains 30 Pages of Text  
Refers to 50+ EU  
Regs/Directives for food/agri



# Primary Regulations

- All food businesses
  - EU Reg 178/2002 Traceability
  - EU Reg 852/2004 General Hygiene
  - EU Reg 853/2004 Animal origin
  - EU Reg 1169/2011 FIC

# Supply chain

- Assured via EU plant numbers
- Product labelling/information
- Traceability best before/use by
- Product testing – accredited labs

# Certification

- ISO 22000 / FSSC  
suitable for all types  
international recognition  
first published 2005 new 2018  
sector specific documents e.g.  
Transport and storage in 2019

# Thank you.

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# Looking for further information?

Organisation	Website
<b>NSAI</b>	<a href="https://www.nsai.ie/about/news/is-your-business-ready-for-brexit/">https://www.nsai.ie/about/news/is-your-business-ready-for-brexit/</a>
<b>Department of Business, Enterprise and Innovation</b>	<a href="https://dbei.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit/">https://dbei.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit/</a>
<b>Department of Foreign Affairs and Trade</b>	<a href="https://www.dfa.ie/brexit/">https://www.dfa.ie/brexit/</a>
<b>EU Commission NANDO website</b>	<a href="http://ec.europa.eu/growth/tools-databases/nando/">http://ec.europa.eu/growth/tools-databases/nando/</a>
<b>EU Commission Information on Brexit</b>	<a href="https://ec.europa.eu/info/brexit_en">https://ec.europa.eu/info/brexit_en</a>
<b>Selling products in the EU</b>	<a href="https://europa.eu/youreurope/business/selling-in-eu/selling-goods-services/selling-products-eu/index_en.htm">https://europa.eu/youreurope/business/selling-in-eu/selling-goods-services/selling-products-eu/index_en.htm</a>
<b>EU Commission Brexit Preparedness</b>	<a href="https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en">https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en</a>
<b>'Blue Guide' on the implementation of EU product rules</b>	<a href="https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en">https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en</a>



## Looking for further supports?



Organisation	Website
Enterprise Ireland	<a href="https://www.prepareforbrexit.com/">https://www.prepareforbrexit.com/</a>
InterTrade Ireland	<a href="https://intertradeireland.com/brexit/">https://intertradeireland.com/brexit/</a>
IBEC	<a href="http://www.ibec.ie/brexit">http://www.ibec.ie/brexit</a>
Strategic Banking Corporation of Ireland	<a href="https://sbci.gov.ie/">https://sbci.gov.ie/</a>
Bord Bia Brexit Barometer	<a href="https://www.bordbia.ie/brexit">https://www.bordbia.ie/brexit</a>
Local Enterprise Office	<a href="https://www.localenterprise.ie/Discover-Business-Supports/Brexit-Information/">https://www.localenterprise.ie/Discover-Business-Supports/Brexit-Information/</a>



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# Q&As

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