Post Transition – Economic Operators, changed responsibilities & 3rd Party Assessment Bodies

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Compliance & Risks Webinar Series

- 20th January - Post Transition – Economic Operators, changed responsibilities & 3rd Party Assessment Bodies – Liz Kimber, RINA

- 3rd February – UK REACH: The changes in obligations and risks to businesses - Emily Tyrwhitt Jones, RINA

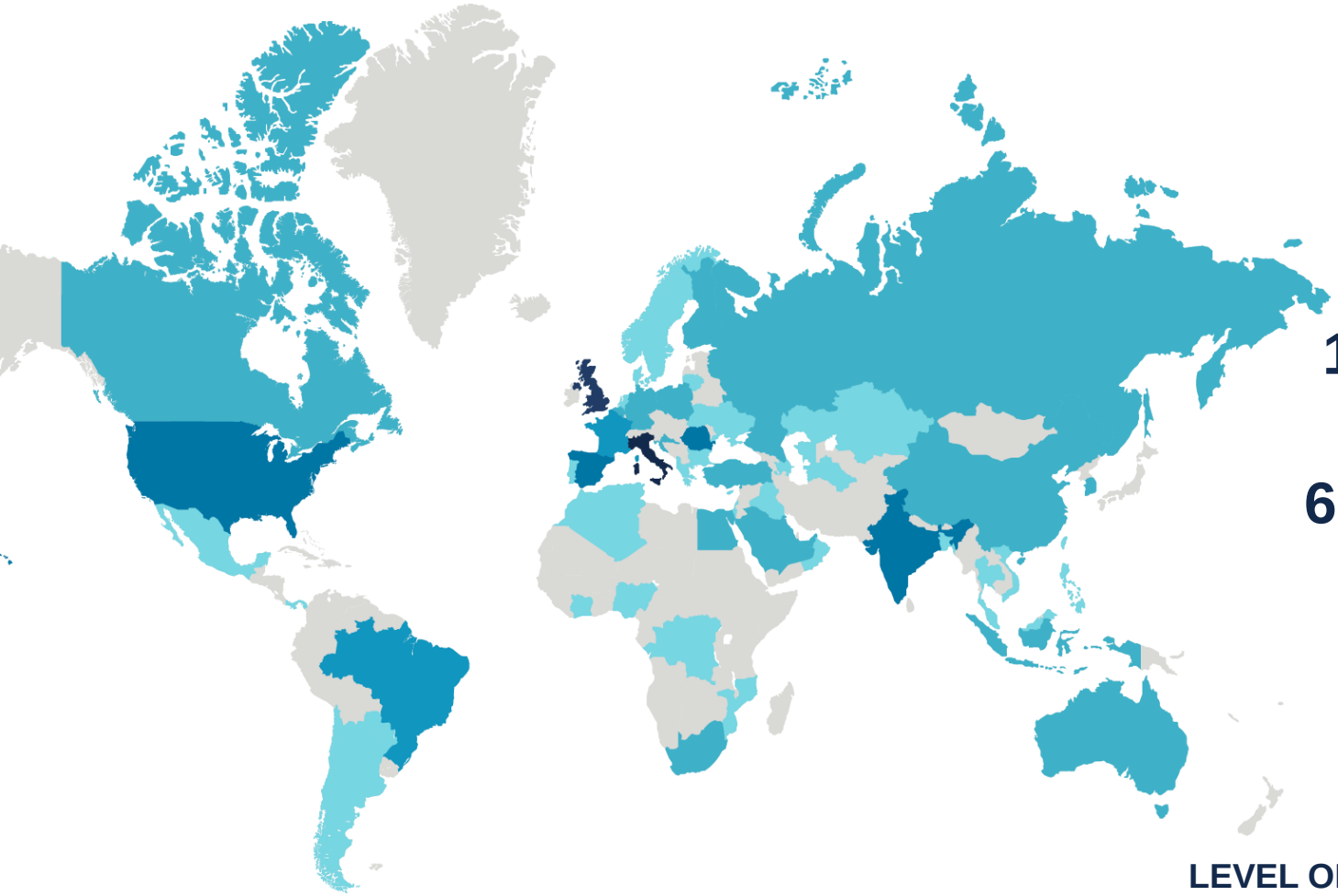
- 17th February – UK Declaration of Conformity & Marking Requirements – Liz Kimber, RINA

Introduction

- Brief RINA overview
- What are the different Economic Operators
- Roles and Obligations of Economic Operators
- Supply chains and Economic Operators
- How has the UKs Departure from the EU impacted this

- 3rd Party Assessment post transition

RINA worldwide



3700+ Staff

170+ Offices

65+ Countries

LEVEL OF RINA PRESENCE:

low → high

RINA capability

SERVICES FOR

Marine

Industry

Energy

Transport & Infrastructure

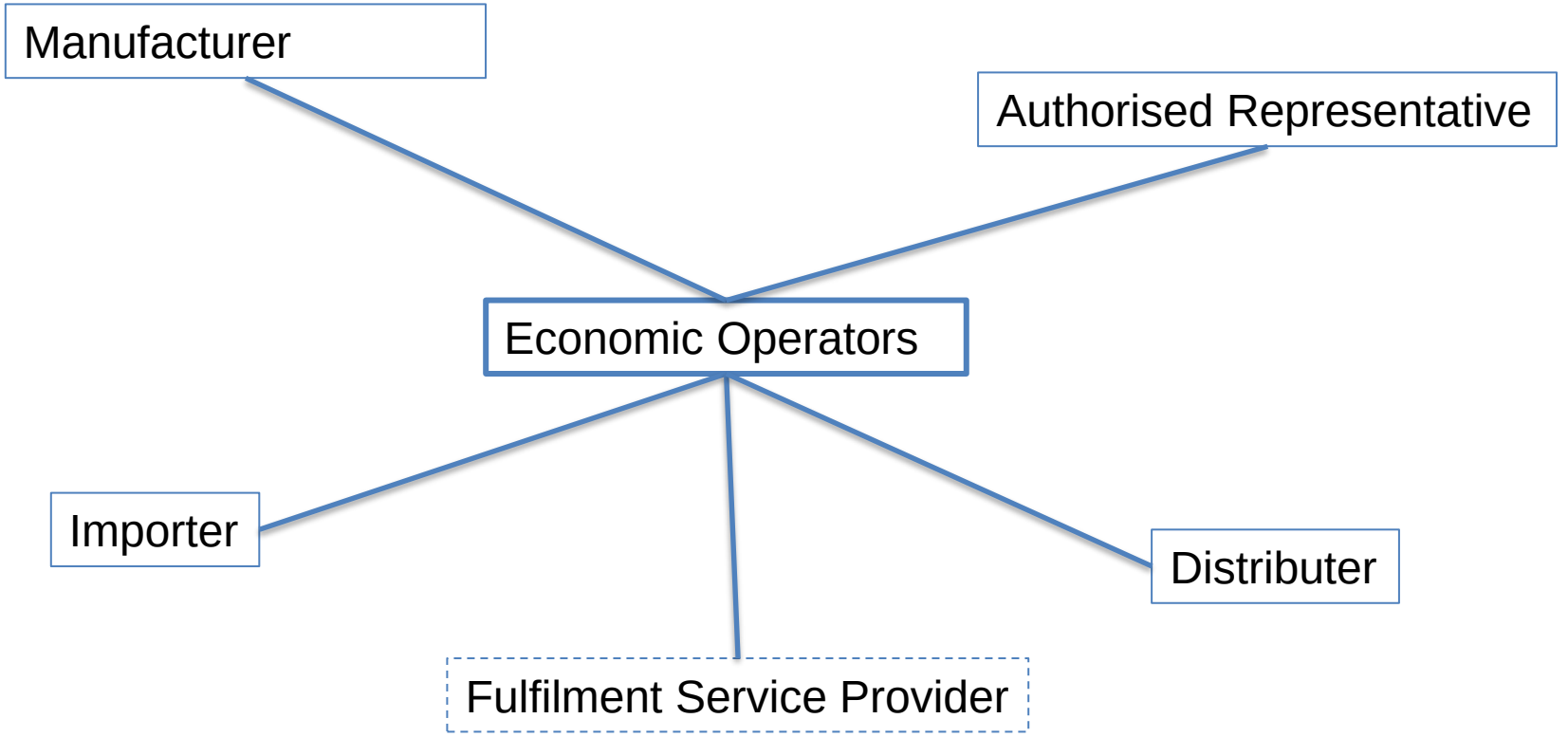
Certification

Product Regulatory Compliance Team

- We support the European Commission, manufacturers, importers and distributors of electrical and engineering products to identify, understand and meet technical and environmental legislation
- Compliance & Risks Knowledge Partner since 2008

What Are the Different Economic Operators

EU Decision no. 768/2008/EC and Regulation 765/2005/EC defines Economic Operators[1] :



[1] EU legislation which applied directly or indirectly to the UK before 11.00 p.m. on 31 December 2020 has been retained in UK law as a form of domestic legislation known as 'retained EU legislation'. This is set out in sections 2 and 3 of the European Union (Withdrawal) Act 2018 (c. 16).

Economic Operators - Definitions

MANUFACTURER

"…any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark."

AUTHORISED REPRESENTATIVE

"…. any natural or legal person established within the *Union* who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant *Union harmonisation* legislation or under the requirements of this Regulation."

IMPORTER

"… any natural or legal person established within the *Union* who places a product from a third country on the *Union market*."

DISTRIBUTER

"….. any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market."

FULFILMENT SERVICE PROVIDER

"…. any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council (31), parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council (32), and any other postal services or freight transport services."

Economic Operators – Roles & Obligations

MANUFACTURER

1. Ensure products meet the requirements of the applicable legislation.
2. Draw up the required technical documentation and carry out the applicable conformity assessment
3. Draw up a Declaration of Conformity and affix marking as applicable
4. Retain the technical documentation and Declaration of Conformity for xx years after the product has been placed on the market
5. Ensure procedures are in place to maintain conformity of series production.
6. When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.
7. Ensure products are labelled correctly with type, batch & serial number or other identifier
8. Indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted
9. Take appropriate action if non-conformity is discovered
10. Support requests for information form competent national authorities.

The obligations of the manufacturer are also placed on the importer or distributer if they place a product on the market under their own name or trademark or modify a product already placed on the market in such a way as to impact its compliance.

Economic Operators – Roles & Obligations

AUTHORISED REPRESENTATIVE

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Economic Operators – Roles & Obligations

IMPORTER

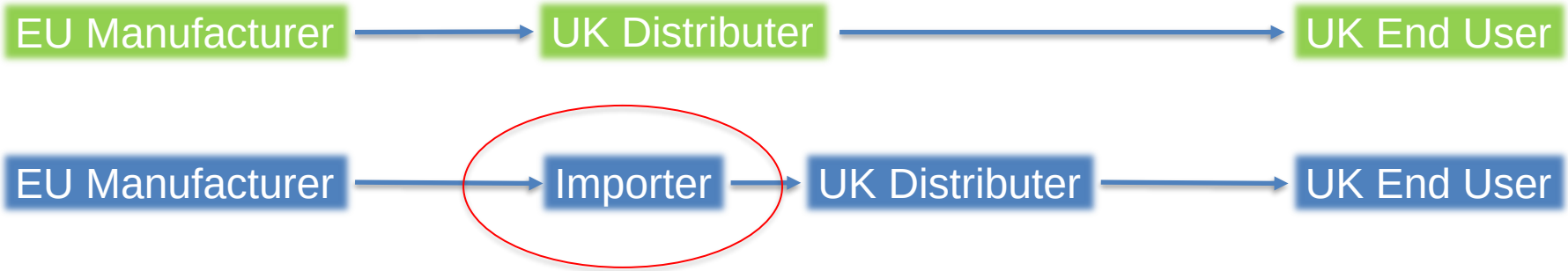
1. Ensure only compliant products are placed on the market.
2. Ensure the manufacturer has:
    1. Carried out the appropriate conformity assessment procedure
    2. Drawn up the technical documentation
    3. Labelled and marked the product as required
    4. Supplied the correct documentation with the product
3. Retain a copy of the Declaration of Conformity for xx years
4. Ensure that while a product is their responsibility it is stored / transported so as to maintain its compliance.
5. When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.
6. Indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.
7. Take appropriate action if non-conformity is discovered
8. Support requests for information form competent national authorities.

Economic Operators – Roles & Obligations

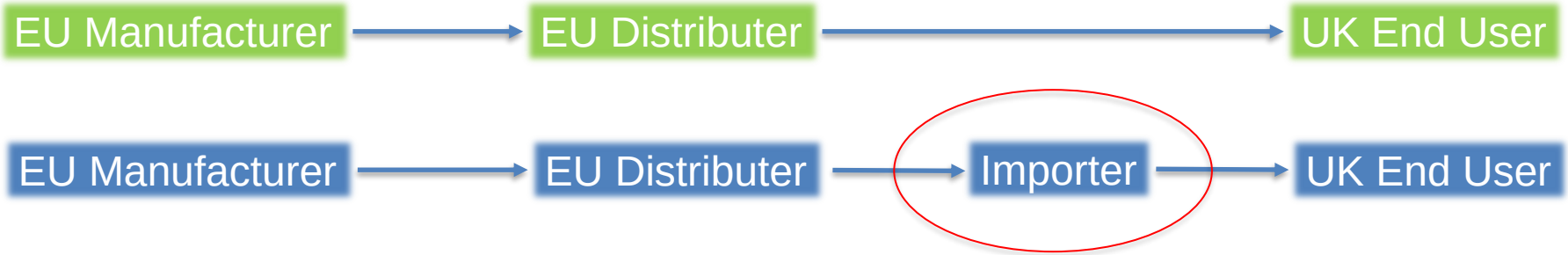
DISTRIBUTER

1. Ensure only compliant products are placed on the market.
2. Ensure the product is :
    1. Labelled and marked as required
    2. Accompanied by the required documents, instructions and safety information
3. Ensure the manufacturer and the importer has:
    1. Indicated their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.
4. Retain a copy of the Declaration of Conformity for xx years
5. Ensure that while a product is their responsibility it is stored / transported so as to maintain its compliance.
6. Take appropriate action if non-conformity is discovered
7. Support requests for information form competent national authorities.

How has the UKs Departure from the EU impacted this



If a separate importer isn't established the Distributer effectively takes on the obligations of 'importer'



Economic Operators - Conclusions

- It is important to establish the roles and obligations of stakeholders in the supply chain so that the respective obligations of each are understood and can be embedded in a company's processes and procedures

- It may be necessary to capture these obligations in contractual documentation especially where the stakeholder is not located in the UK or EU and therefore may not have the same familiarity with UK law and their obligations.

- The capture of these obligations into company processes and procedures is also critical to making sure a company can act on any requests from market enforcement authorities.

- Some of the obligations of stakeholders may have changed with the UKs departure from the EU, it is important these are identified and the affected parties informed, before they result in non compliance issues.

3rd Party Assessment – Post transition

What is affected?:

Product subject to third-party conformity assessment with certification issued by a UK Notified Body.

What has changed?:

As of 01/01/2021 all UK Notified bodies became UK Approved Bodies **AND** the certification of products by UK Notified Bodies ceased to be recognised by the EU (apart from product placed on the market in NI).

What should you do?:

Ensure your product certification is transferred to an EU Notified Body, this will enable you to market your product in both the EU & GB for at least until 31/12/21 after that you will need separate certification for the EU & GB issued by an EU Notified Body & UK Approved Body respectively.

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