

**Your product,
anywhere**



APPROVED

Global Market Access

International network
of accredited laboratories

Keep Calm and CE Mark Your EMC BREXIT Survival Guide (part 2)

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- 
- Where we've come from
 - Where we currently are
 - Where we might be going
 - Preparing for change
 - Market surveillance and compliance issues
 - Ensuring continued market access

CE Marking

- Shows that the manufacturer has checked that these products meet EU safety, health or environmental requirements
- Is an indicator of a product's compliance with EU legislation
- Allows the **free movement** of products within the European market
 - All EU-27 Member States + UK for a time limited period
 - 3 out of 4 EFTA states
 - Norway, Iceland and Liechtenstein
 - Switzerland (non-mandatory)
 - Turkey and 6 Balkan states



CE Marking Directives

1. Cableway installations
2. Construction products
3. Eco-design of energy related products
4. Electromagnetic compatibility
5. Equipment for explosive atmospheres (ATEX)
6. Explosives for civil uses
7. Gas appliances
8. Lifts
9. Low voltage
10. Machinery
11. Measuring instruments
12. Medical devices
13. Medical devices: active implantable
14. Medical devices: in vitro diagnostic
15. Non-automatic weighing instruments
16. Outdoor noise
17. Personal protective equipment
18. Pressure equipment
19. Pyrotechnic articles
20. Radio equipment
21. Recreational craft
22. Restriction of hazardous substances in electrical and electronic equipment
23. Safety of toys
24. Simple pressure vessels

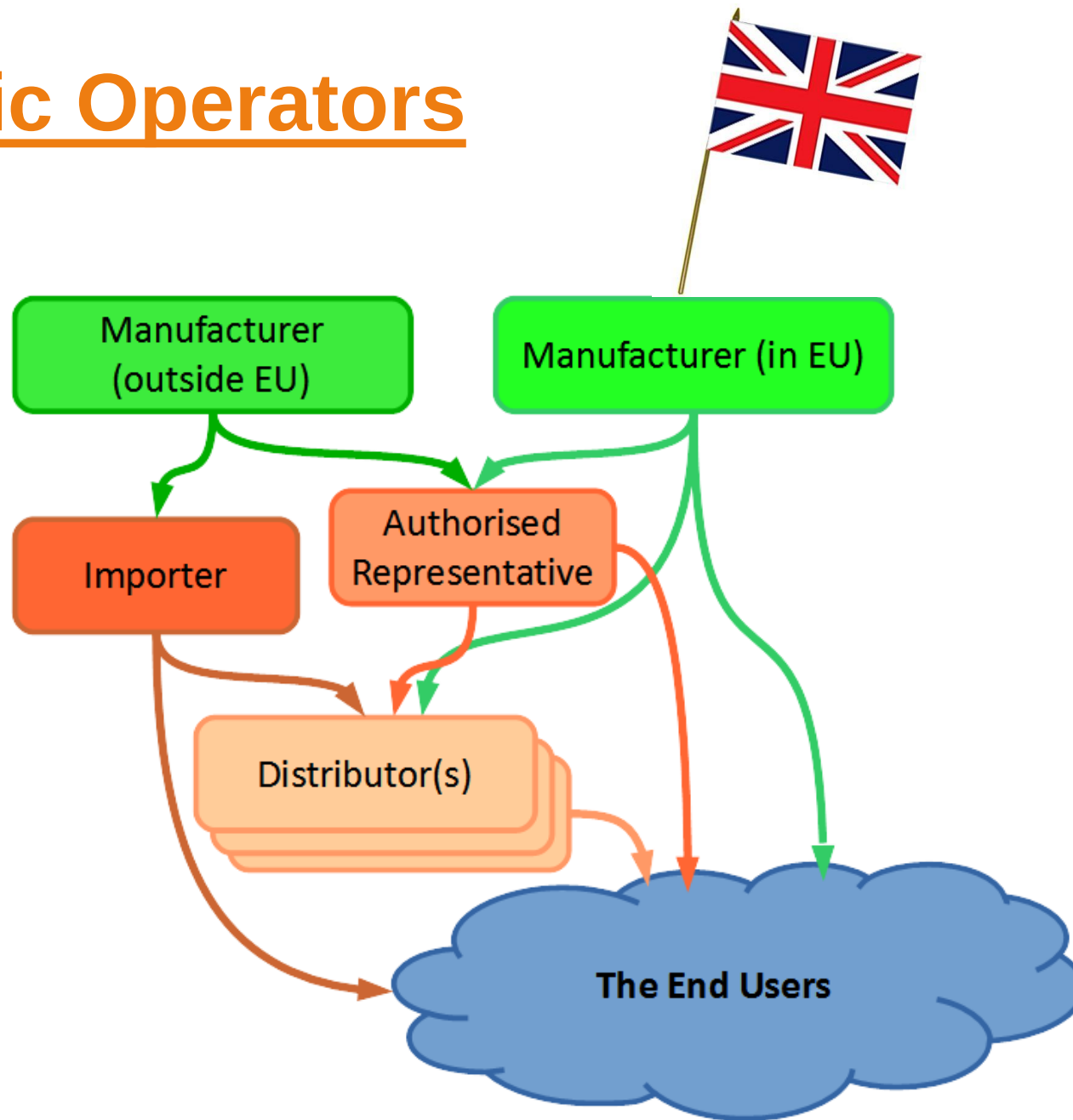


European EMC Directive

- **European** 'New Approach' Directive
 - Directive contains the conformance and marking requirements
 - Technical details specified by **European** harmonised standards
- 2014/30/EU replaced 2004/108/EC in April 2016
- Conformity assessment required
 - Process carried out by the manufacturer to demonstrate that the requirements relating to a product have been fulfilled
 - A product is subjected to conformity assessment **on an on-going basis**



Economic Operators



Distributor

- Someone other than the manufacturer or importer, who makes a product available on the market
- The distributor responsibility is to verify that:
 - CE marking is applied
 - The product is accompanied by required documents for end-users
 - In easily understood language for consumers and end-users
 - Product, manufacturer and importer are identified
- Duty of self-policing
- Duty of careful storage/transport
- Duty to cooperate with National Authorities

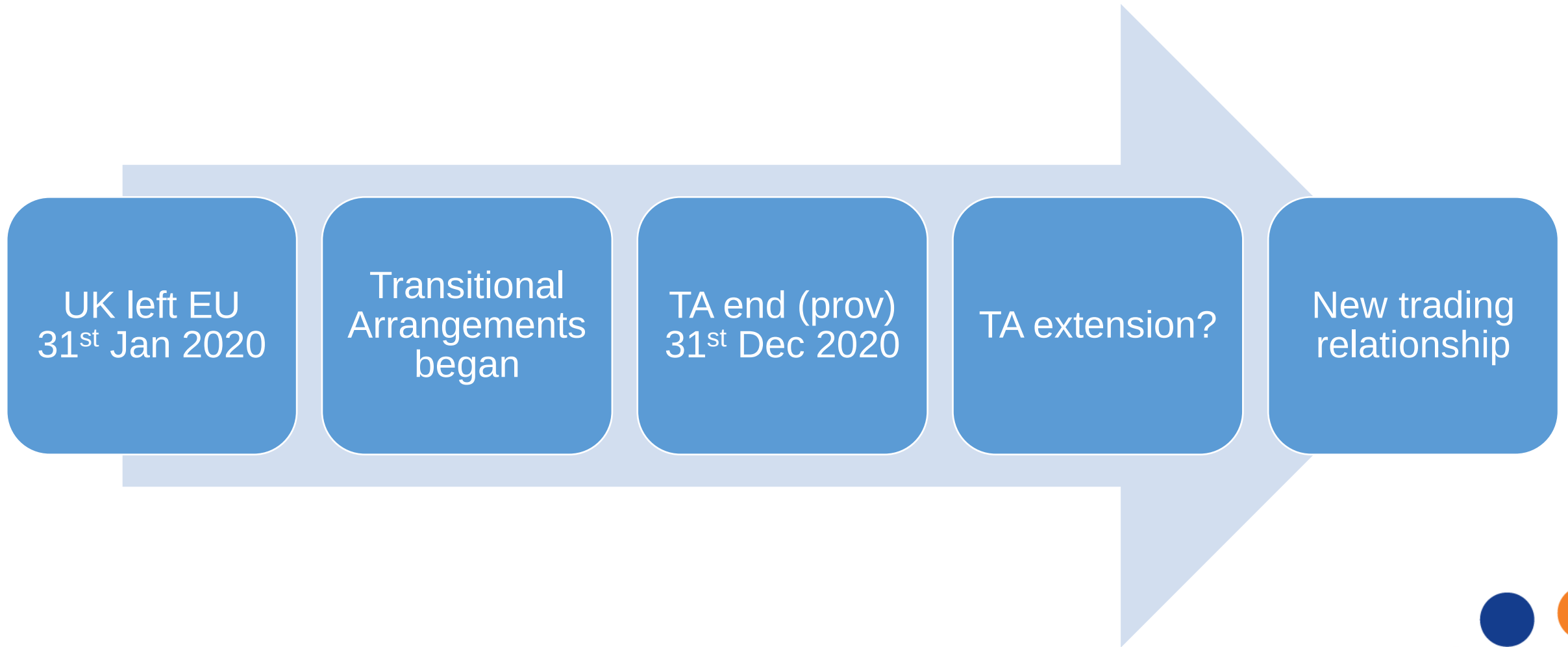


The European Union (Withdrawal) Act 2018

- Repealed the European Communities Act 1972
- Allowed for Parliamentary approval of the Withdrawal Agreement in December 2019
- Enables the transposition of directly-applicable already-existing EU law into UK law
- Creates a new category of domestic law for the United Kingdom known as retained EU law
- Gives the government some restricted power to adapt and remove laws that are no longer relevant
- Cuts off the source of EU law in the UK



BREXIT Timeline



Transitional Arrangements

- ✓ EU Rules continue to apply in the UK
- ✓ CE Marking continues in the UK
- ✓ Economic Operator relationships are unchanged
- ✓ EU appointed Notified Bodies in the UK can continue to operate

✗ UK no longer involved in influencing EU Rules



BREXIT – What's Unchanged?

- ✓ The technical and administrative requirements for placing products onto the EU market
- ✓ The role of UKAS accreditation
- ✓ The status of UKAS accredited laboratories
 - ✓ UKAS accredited test results will have the same validity as before
 - ✓ UKAS accredited testing performed pre-BREXIT will remain valid post-BREXIT
- ✓ UK will remain influential in developing standards
 - ✓ BSI has direct membership of CEN and CENELEC



BREXIT Negotiations...



“We’re not going to be aligning with EU rules, that’s not on the negotiating table, it’s not even an issue of red lines – it is not even in the negotiating room”



Divergence?

- Dominic Raab says so...
- CE Mark is trademarked by the EU
- EU Law is no longer 'connected' to UK Law
- If the EMC Directive was to change today, the UK Regulations would not automatically change





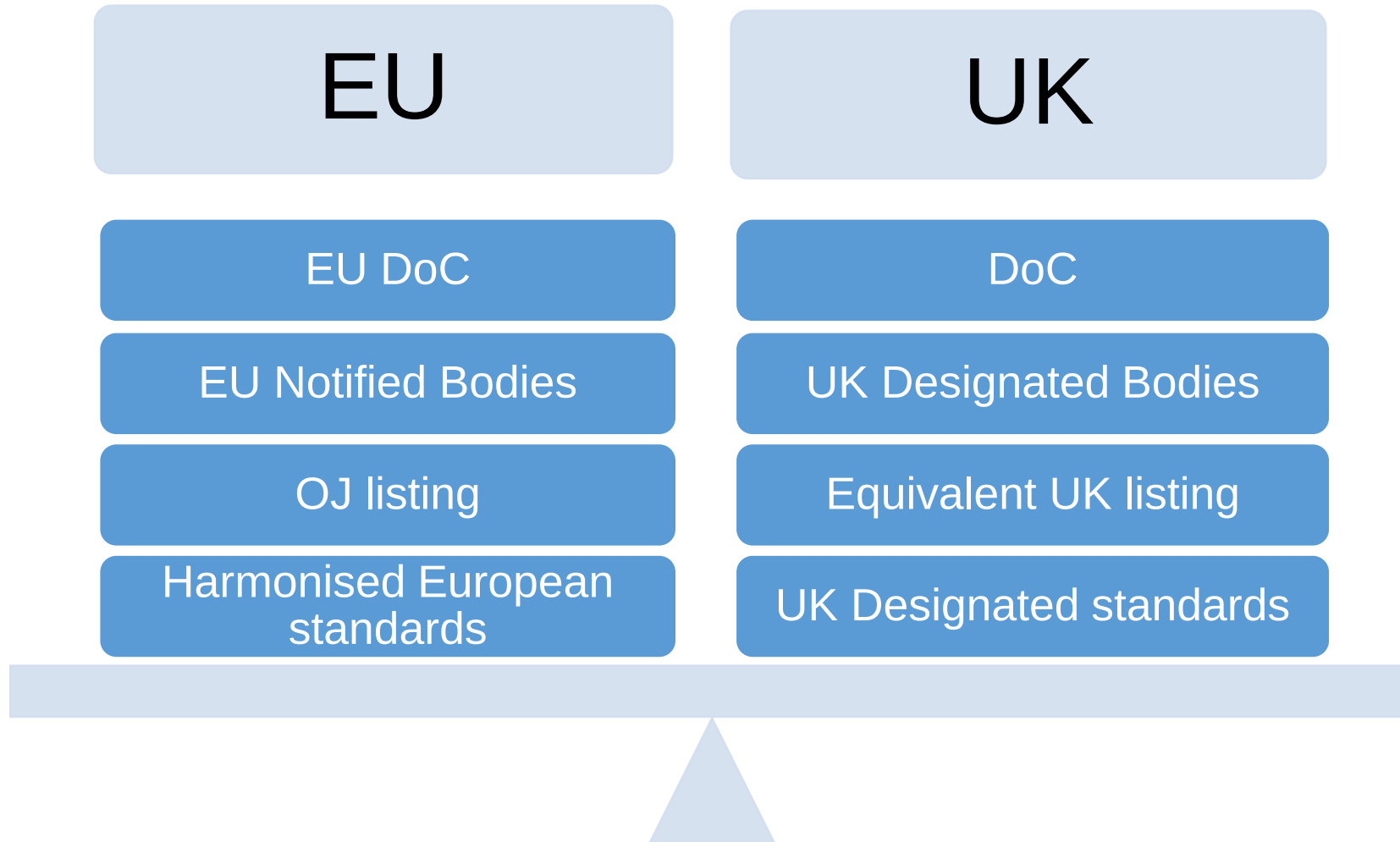
No Deal Preparations = Likely Deal Outcome?

No Deal BREXIT Preparations

- Draft Statutory Instrument
 - Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019
 - Comes into force on exit day assuming No Deal
- SCHEDULE 20 Regulation 23 - Amendment of the Electromagnetic Compatibility Regulations 2016
- Transforms (UK-ises) existing regulations by:
 - Removing references to EU
 - Setting up alternative names for UK processes
- The basic requirements are unchanged



No Deal BREXIT Preparations



Future Arrangements?

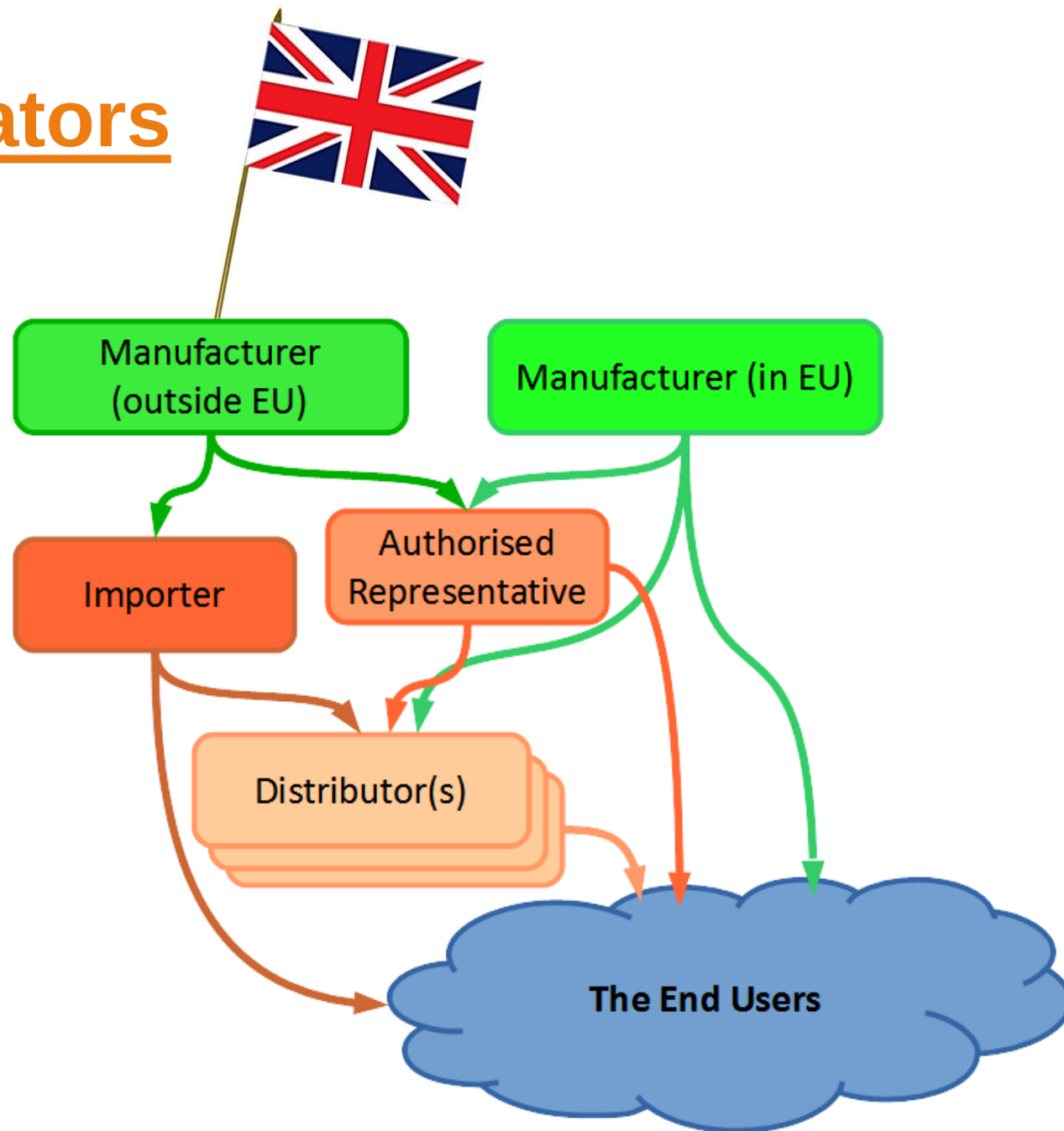
- CE Marking will continue to apply to UK manufacturers placing products on the EU27 market
- CE Marking would cease to apply in the UK
 - For EU manufacturers
 - For UK manufacturers
- Conformity with UK Regulations would be demonstrated by applying the UK Mark
- Likelihood that there will be some form of time limited transition period
- MRA?



UK
CAD



Economic Operators



Importer

- The importer is established in the EU and places a product from a third country onto the EU market
- Responsibilities:
 - Ensure the Manufacturer outside the EU has applied the **correct conformity assessment procedure**
 - To ensure products bear the CE marking and have the required documents
 - To ensure products carry the name of the manufacturer and the importer
 - To keep copies of documents for 10 years after placing on the market and ensure that **Technical Documentation** can be obtained when requested by National Authorities



BREXIT Negotiations...



“All goods coming into the EU will need to comply with its rules on health or other standards and, as a result, goods entering the union *will be subject to regulatory checks.*”

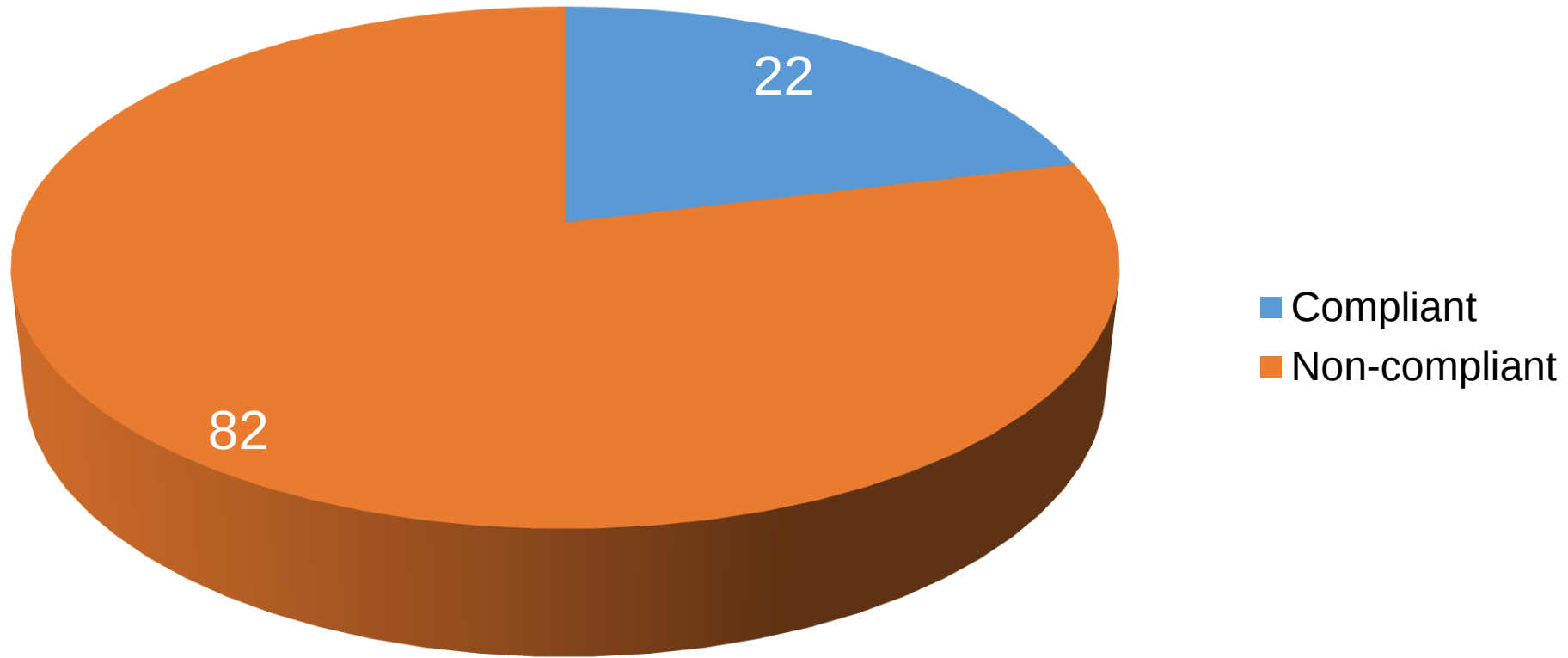






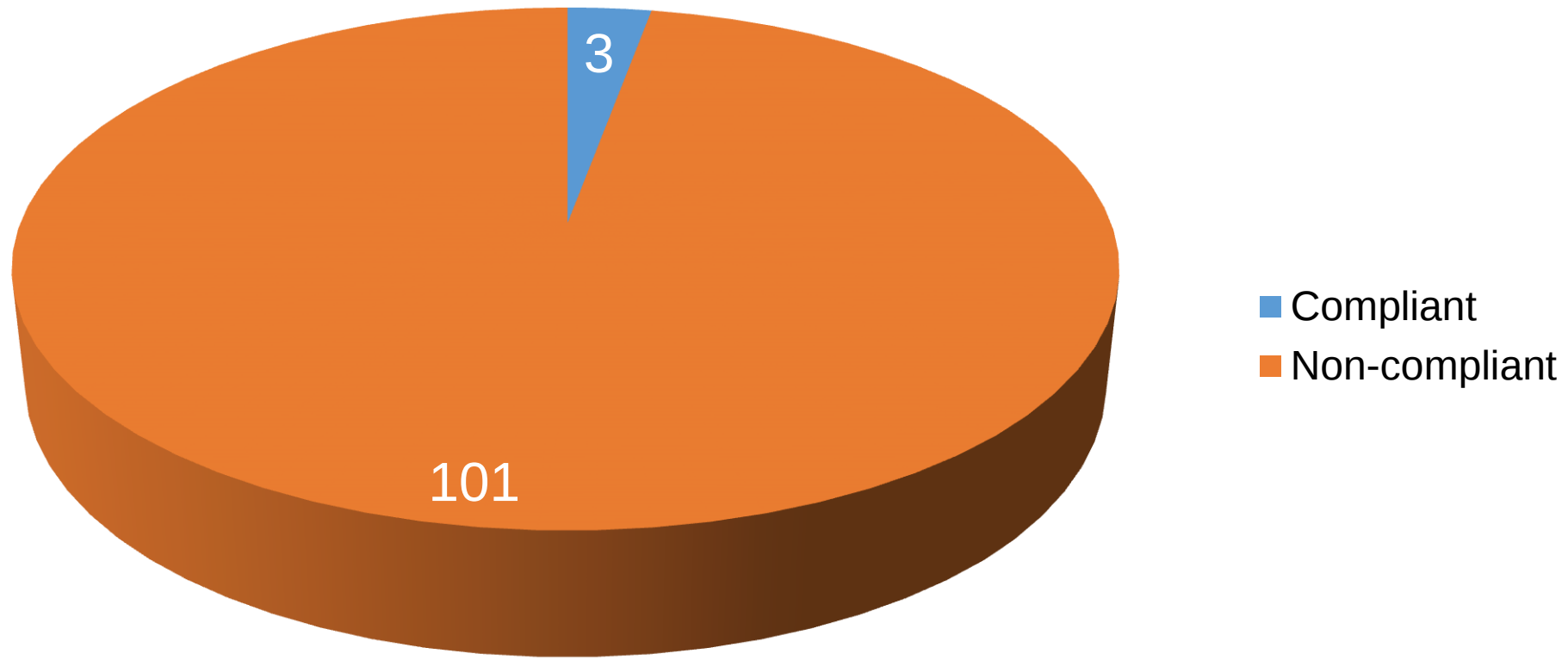
Actual Example – 104 Products

- Technical Compliance

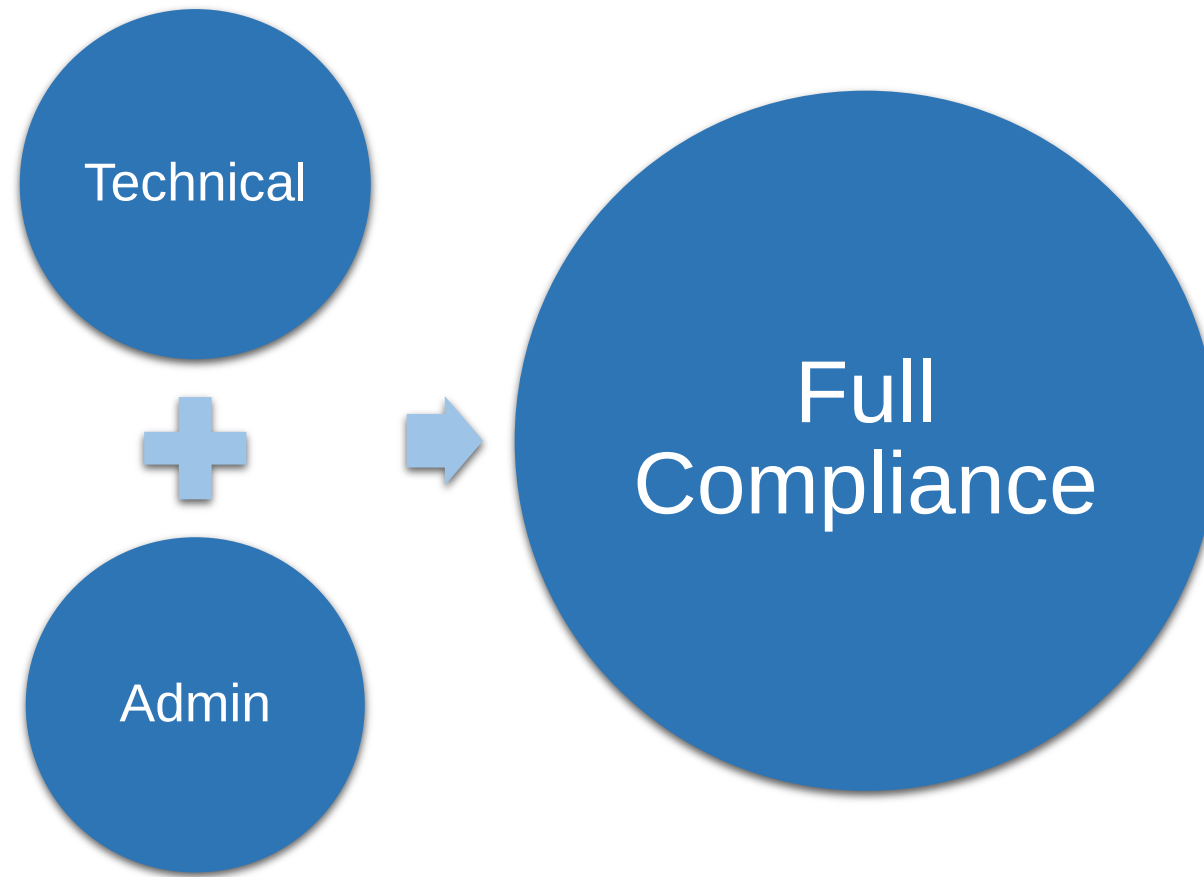


Actual Example – 104 Products

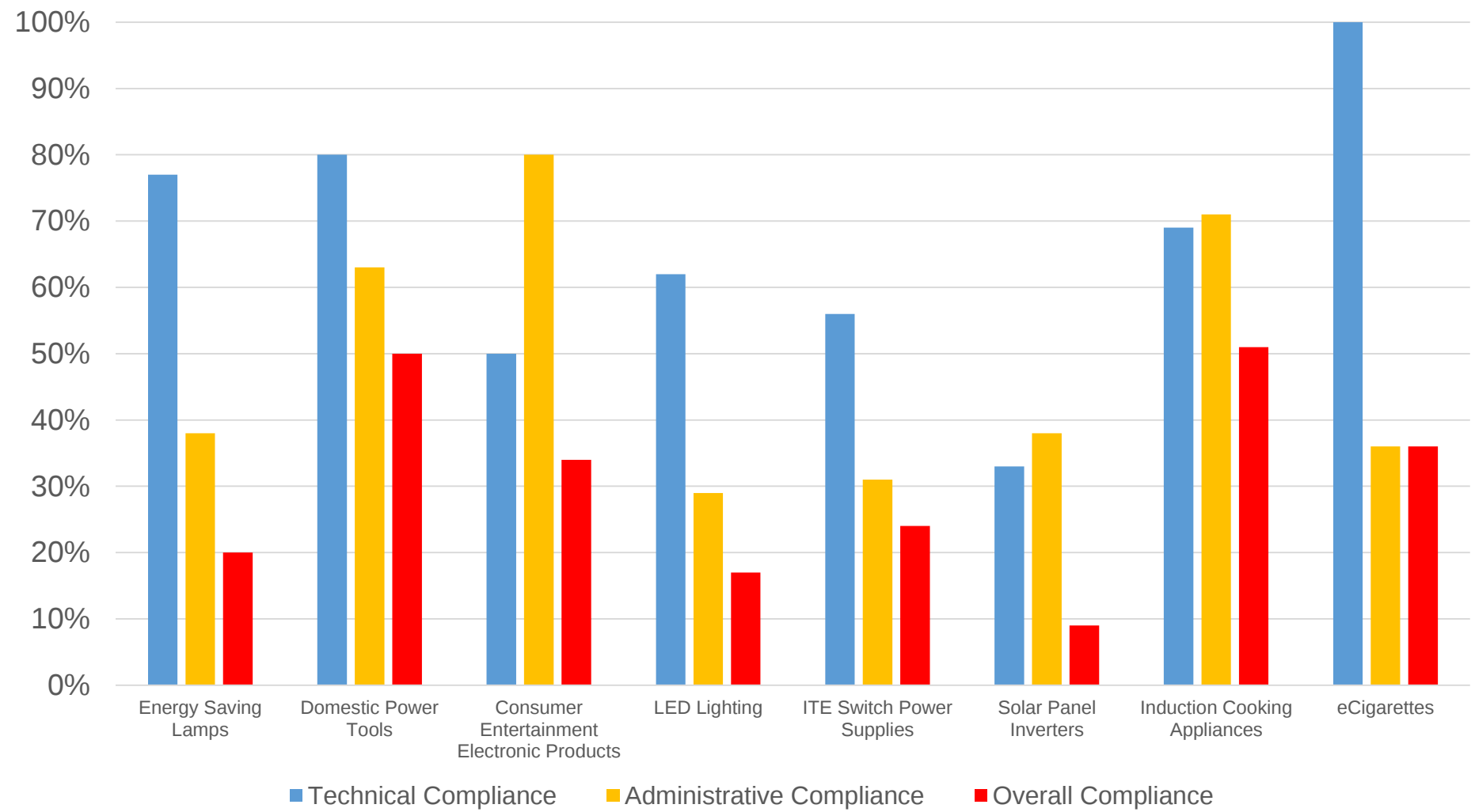
- Administrative Compliance



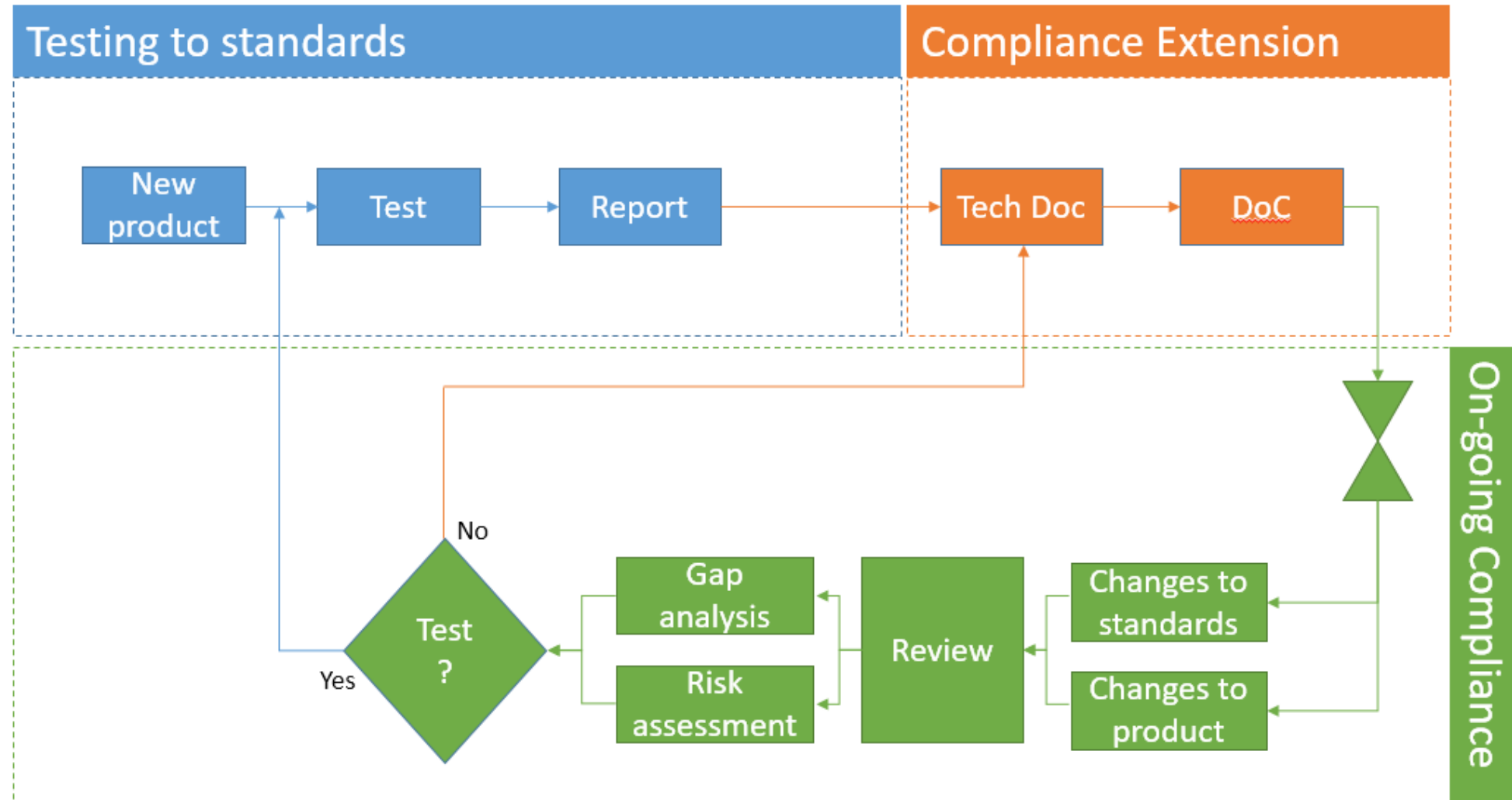
Achieving Conformity



Market Surveillance



The Importance of End-to-End Compliance



BREXIT



