



Department for  
Business, Energy  
& Industrial Strategy

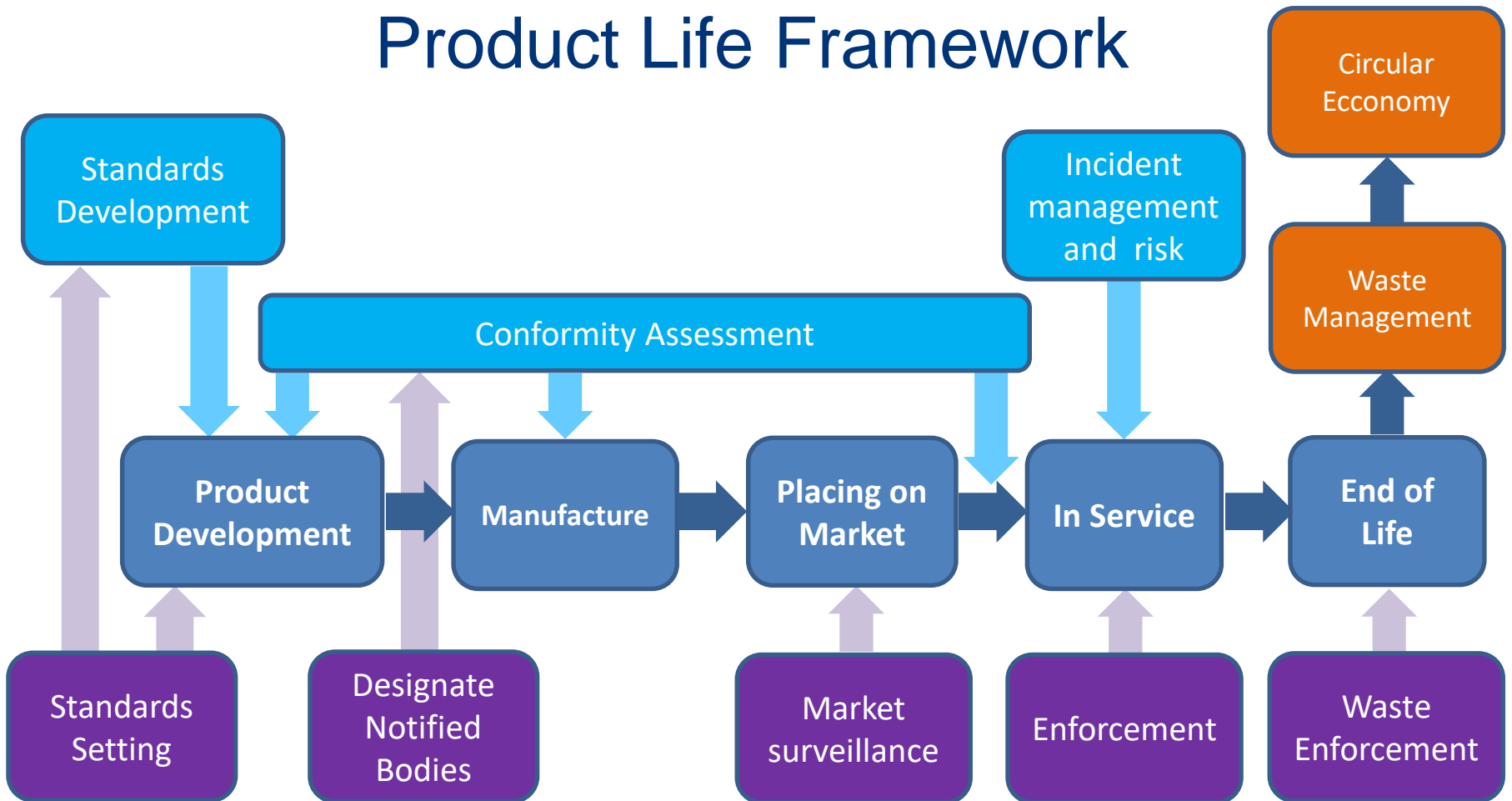
Office for Product  
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# Effective use of Regulatory Framework

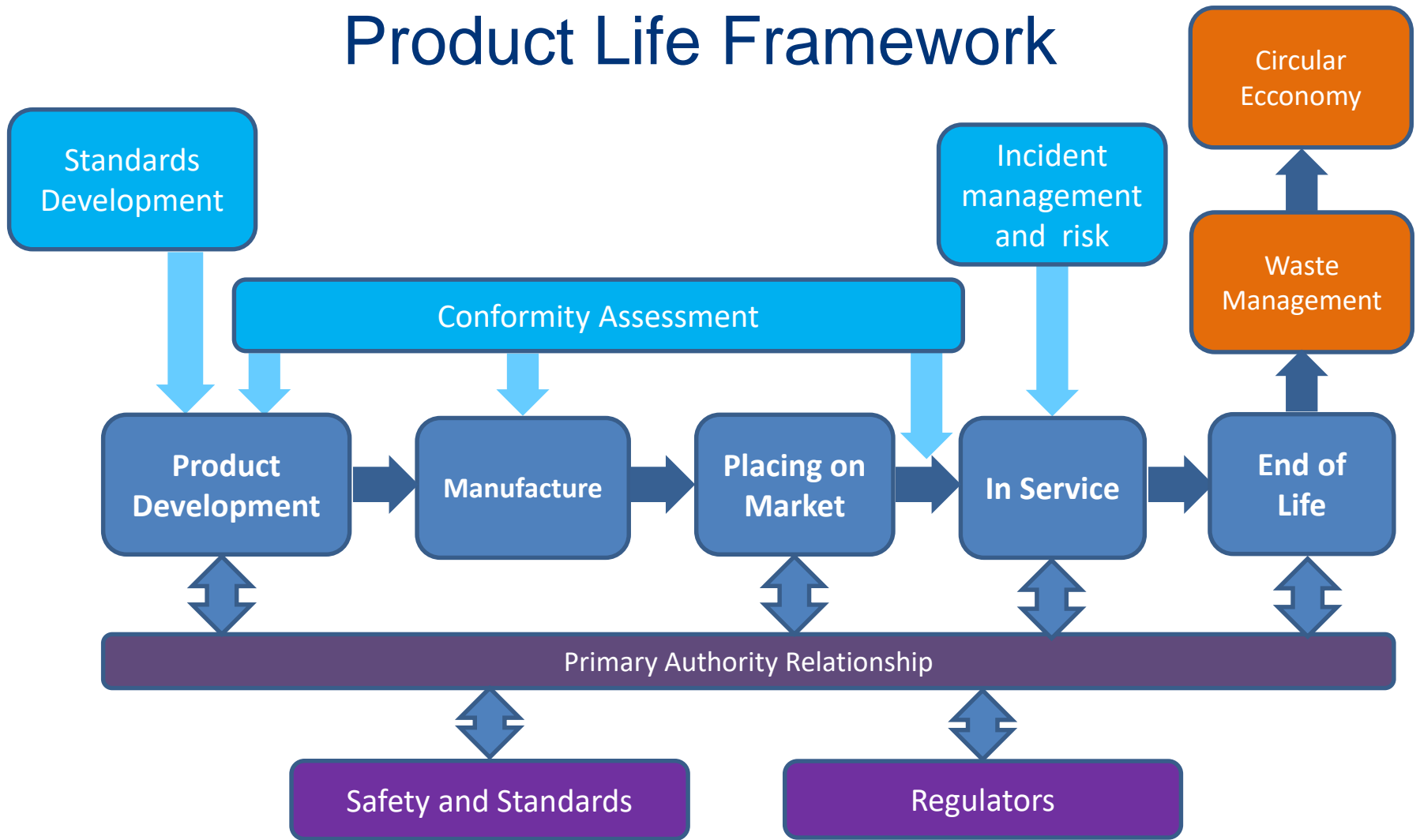
Chris Smith

# Safety and Standards Product Life Cycle Framework

# Product Life Framework



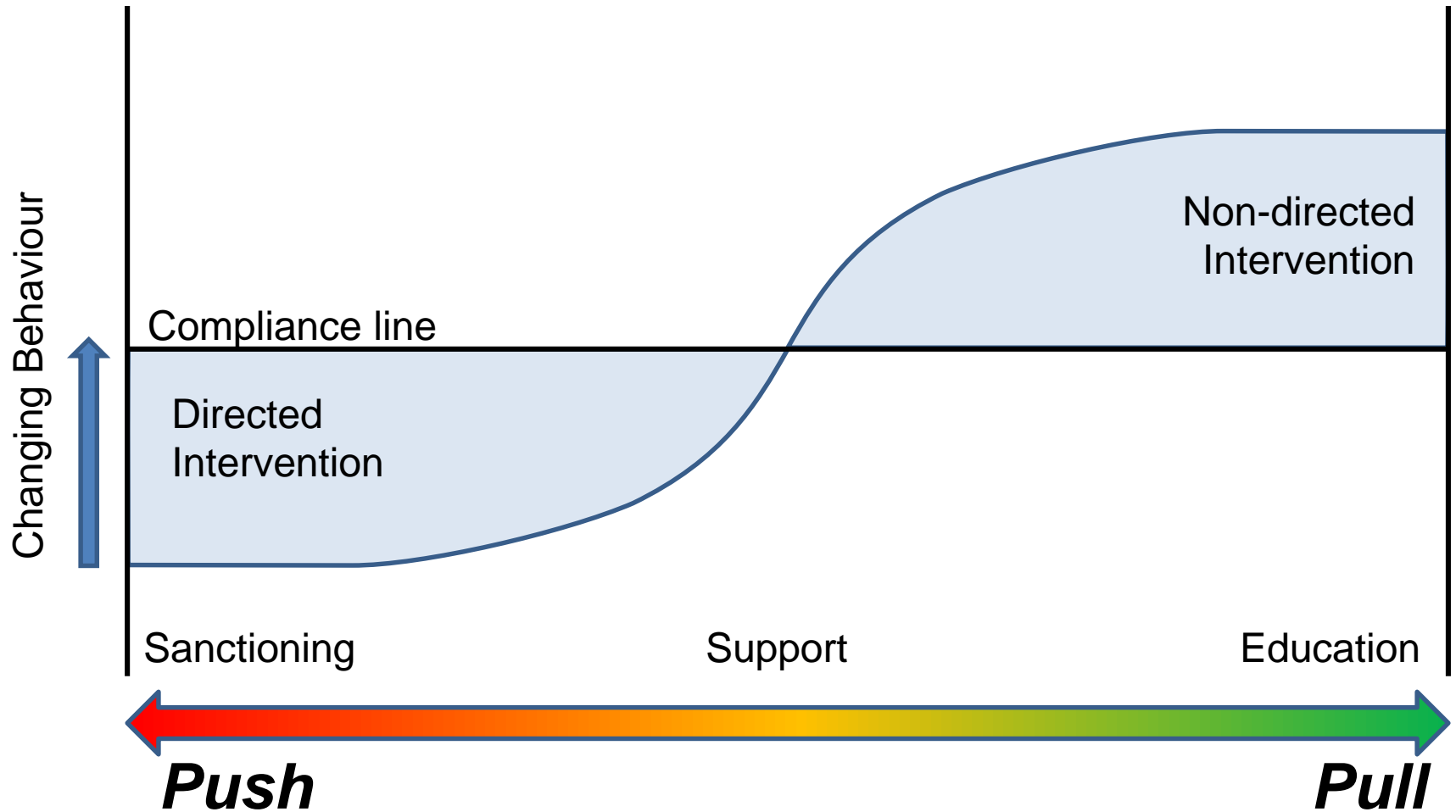
# Product Life Framework



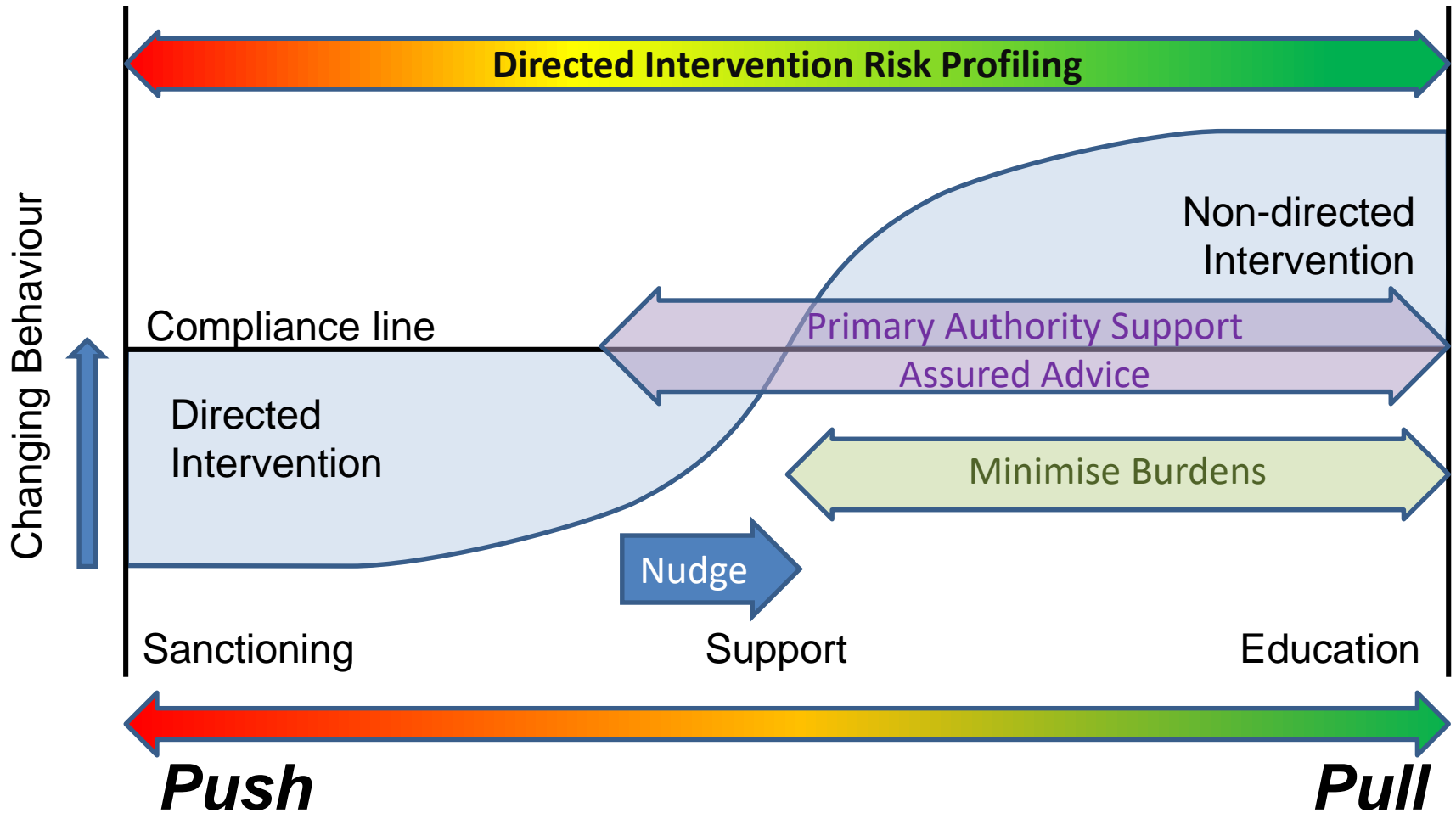


# Interventions

# Balanced Intervention Model



# Balanced Intervention Model









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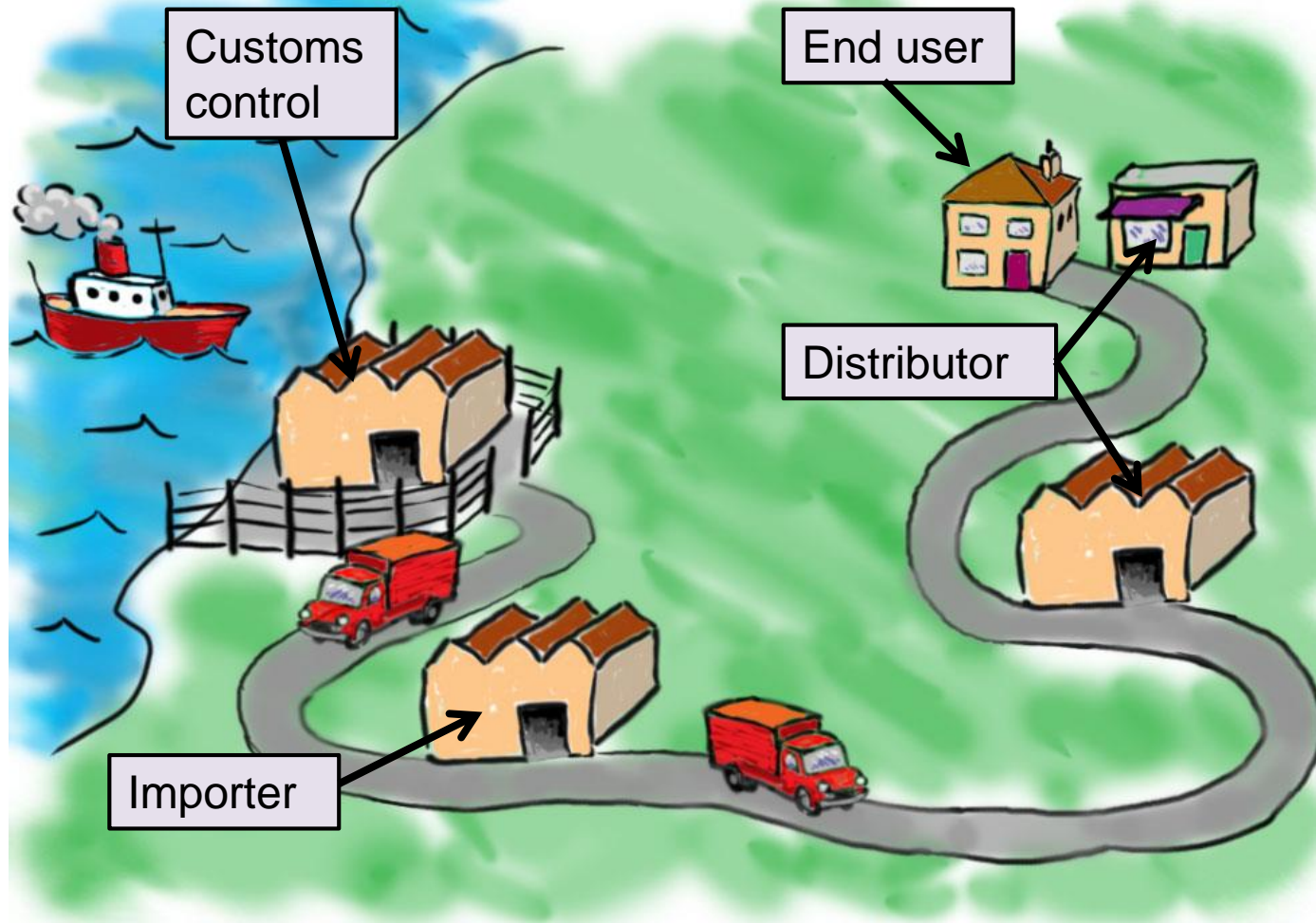
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# Placing on the Market

# Placing on the Market Sets

- Jurisdiction
- Transitional impact
- Level of offence
- Product withdrawal/recall
- Business responsibility to not knowingly place non-compliant product on market

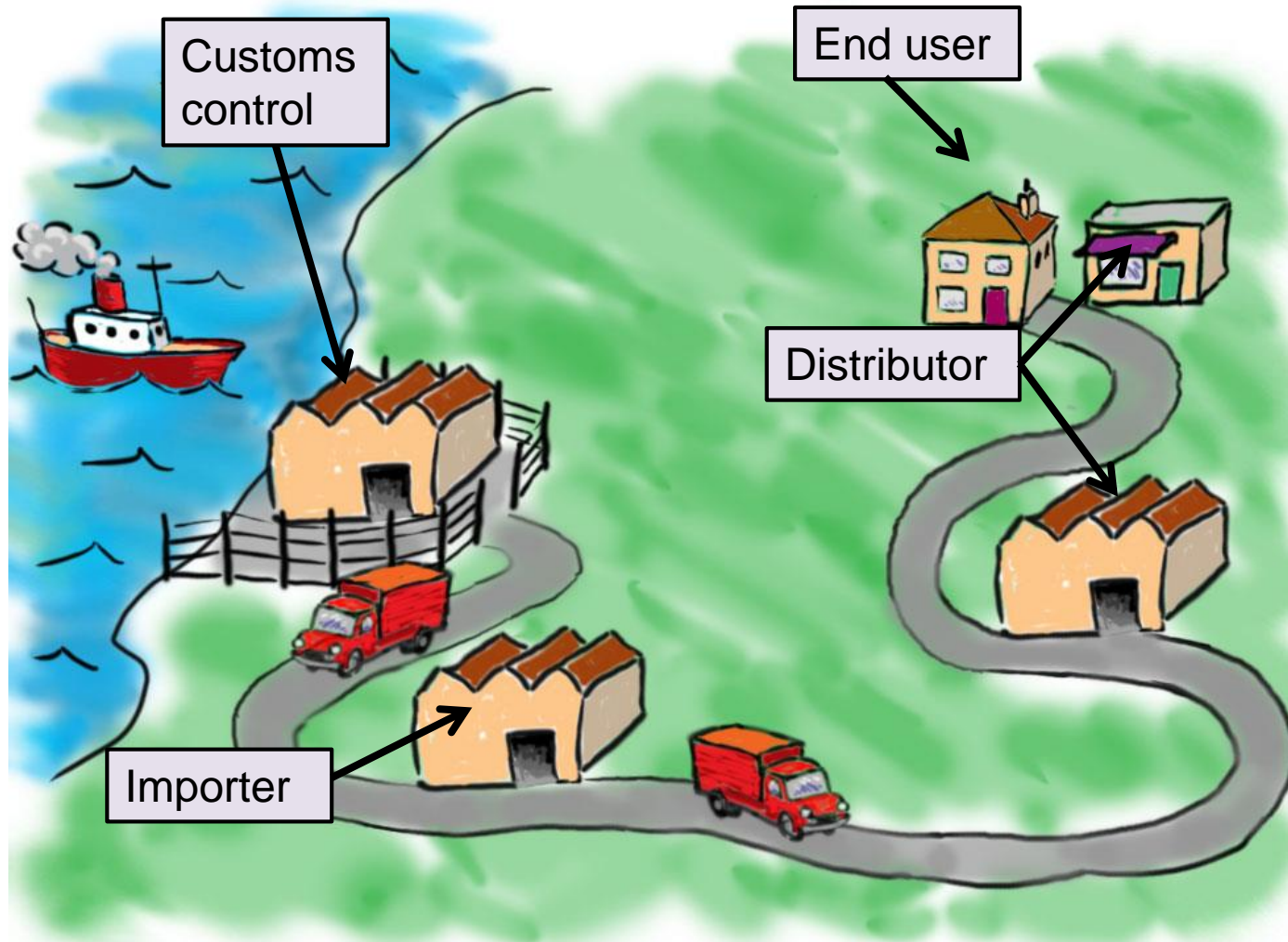
# What do you think?

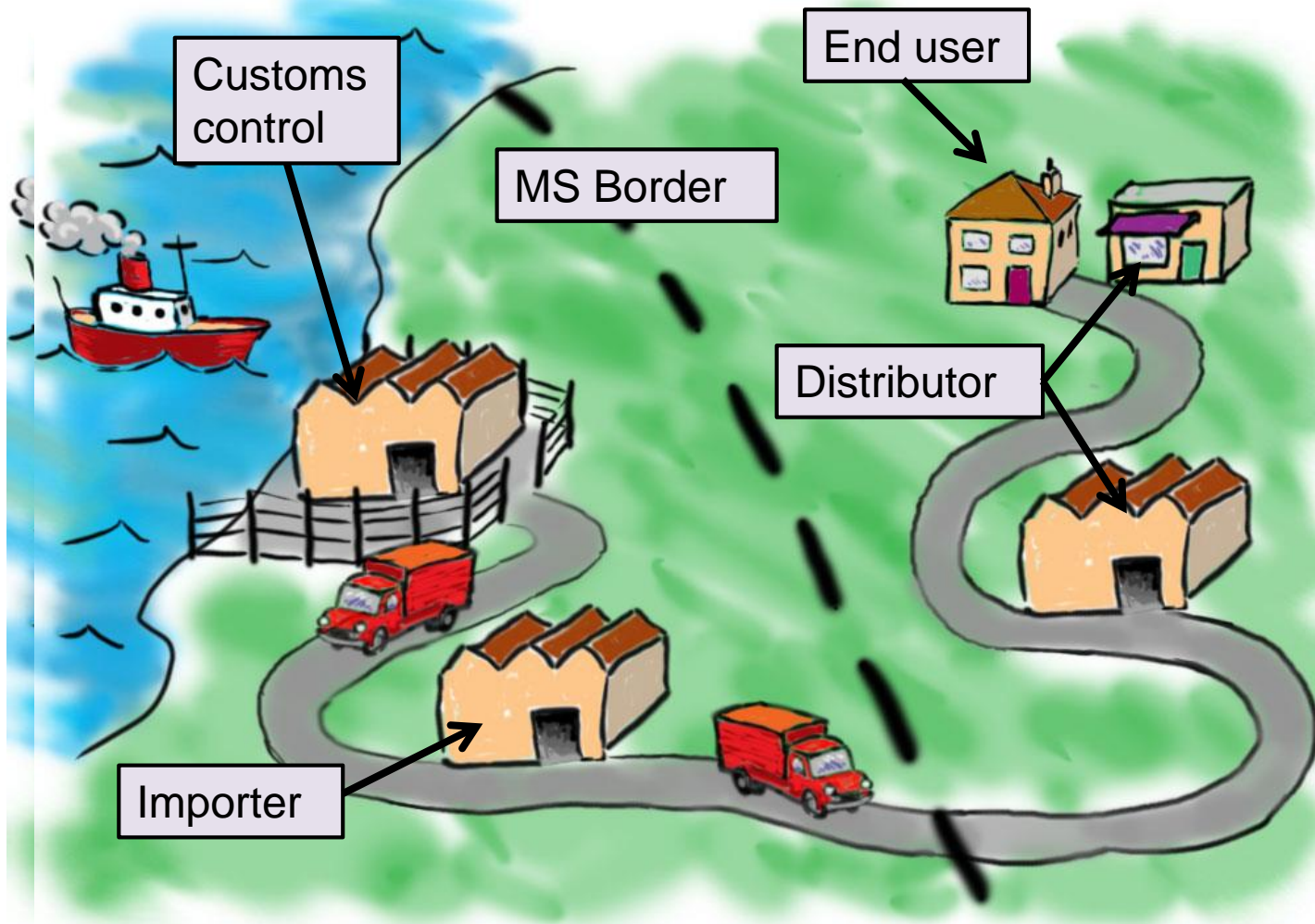


# Probably the most important line in BG

For the purposes of Union harmonisation legislation, a product is placed on the market when it is made available for the first time on the Union market. The operation is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market <sup>(49)</sup>. When a manufacturer or an importer supplies a product to a distributor <sup>(50)</sup> or an end-user for the first time, the operation is always labelled in legal terms as 'placing on the market'. Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.

When a manufacturer or an importer supplies a product to a distributor or an end user for the first time, the operation is always labelled in legal terms as “placing on the market”.





## How Easy is That?

**BUT**

The Blue Guide then goes on to complicate the matter by contracting the basic principle.



## A few Choice Complications

- Different options where the law of tort vary within differing member states (point of offer)
- PoM and internet sales and advertising (L'Oreal V eBay)
- Direct imports
- Fulfilment Houses
- Transfer between parts of same organisation



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# Conformity Assessment and Standards

# Conformity Assessment

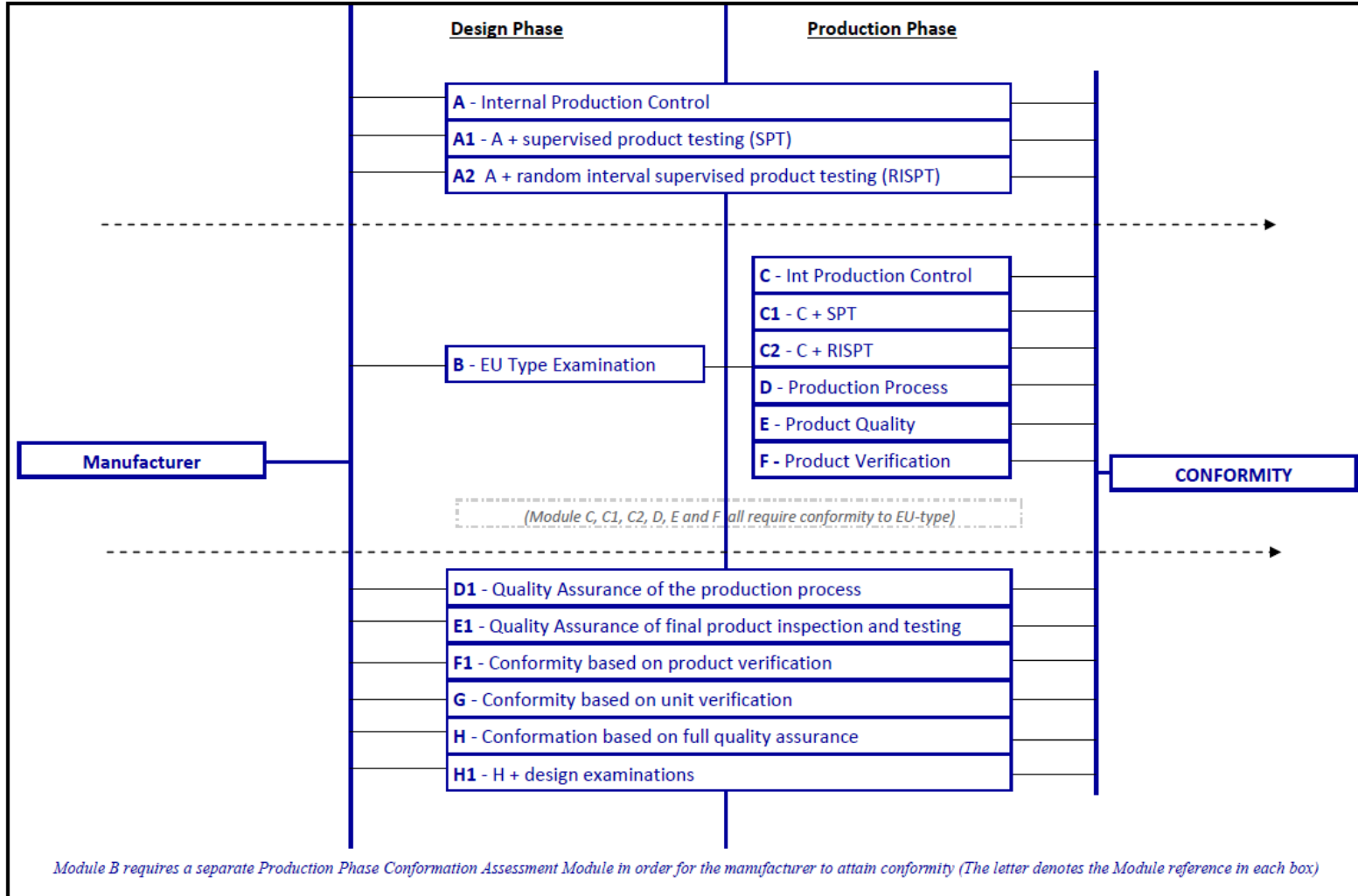
# What is Conformity Assessment?

- Manufacturer process
- Prescribed set of options for assuring repeatable compliance
- May include
  - Design
  - Production control
  - Documentation
  - Testing
  - Verification
  - etc

# Conformity Assessment Modules

- Eight Modules A-H
- Well... more like 16
  - A, A1, A2, B, C, C1, C2, D, D1, E, E1, F, F1, G, H, H1
- One and two module processes prescribed
  - One module processes examples: A or H
  - Two module processes examples: B+E or B+F
- Module selection options set in each individual piece of legislation

# Module Overview and Process



## Module A

- This is the internal control and self declaration module
- Manufacturer is CAB (usually)
- Requires
  - Design assessment
  - Production control
  - Documentation control
  - Records
  - Hold all relevant compliance documentation for 10 years (technical file)

# Conformity Assessment Bodies

- This is the organisation that assesses conformity
- Can be internal to the company (manufacturers design and quality control)
- Can be an externally appointed or approved through a Member State process (Notified Body)
- Different CABs may have different responsibilities under the 2 module approach



## Notified Bodies

- Assessed and appointed by the member state
- Must be within the appointing member state's jurisdiction
- Member state notifies the Commission of the appointment
- Commission issues NB number (RD is 0126)
- Member state responsible for assuring continued competence.



# Standards, Accreditation and Conformity

# Essential Requirements

- EU legislation usually has “essential requirements”
- Written in plain(ish) English
- These are the regulatory technical requirements
- Examples:
  - Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:
    - (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
    - (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.
  - Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.
  - Equipment and protective systems must be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations. Any misuse which can reasonably be anticipated must be taken into account

# Standards

- Standards are produced by standards bodies and Industry
- They are generally very detailed and are intended to generate repeatability
- They may be
  - Specifications
  - Processes
  - Recipes
  - Plans
  - Guides

# Harmonised Standards

- Assessed and recognised by Commission
- Published in OJEC
- Where a harmonised standard is met the essential requirements identified by the Commission are presumed met (presumption of conformity)
- May only partially apply
- Always optional

# Presumption of Conformity

## Presumption of Nonconformity?

## Safe and Unsafe?

# Accreditation

- Accreditation attests the competence of an organisation to carry out specific tasks.
- UKAS is the UK Accreditation body recognised by the legal system
- There is a mutual recognition system (well 2 actually ILAC and IAF) that the UK is a signatory to. Therefore a SWEDAC, CNAS or ANAB accredited report has the same status as a UKAS accredited one.
- Accreditation is the primary approach to demonstrating compliance with a standard
- Accreditation is the primary approach to assessing the competence of bodies to be appointed as Notified Bodies



# Lets Talk Cake!

# Beth's Yellow Cake Regulation

## Essential requirements

- Cake must be yellow
- Cake must not contain dried fruit and definitely not candied peel (yuk)
- Cake must not contain nuts
- Icing and sweet things are optional but encouraged

# The Victoria Sponge Standard

- 4 free-range eggs.
- 225g/8oz caster sugar, plus a little extra for dusting the finished cake.
- 225g/8oz self-raising flour.
- 2 tsp baking powder.
- 225g/8oz baking spread, margarine or soft butter at room temperature, plus a little extra to grease the tins.
- etc...



## VS Standard Harmonised

- Compliance with VS standard is recognised as meeting essential requirements
- Easiest way to ensure compliance is follow standard



- Therefore everybody makes Victoria sponges

## What About Other Cake?

- Madera Cake
- Lemon drizzle cake
- Madeleines
- Pound cake
- Saffron cake
- etc



Are all compliant with the essential requirements (and therefore the regulations) but not the standard

# Essential Requirements Should not Stifle Innovation but Standards often Can



