

# Introduction



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# Introduction - Topics Covered

- **Scope of New Directive – Differences between RoHS I & RoHS II**

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- **Conformity Requirements**

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- **Scope of New Directive – Differences between RoHS I & RoHS II**
- **Conformity Requirements**
- **Economic Operator Obligations**

# Introduction - Topics Covered

- **Scope of New Directive – Differences between RoHS I & RoHS II**
- **Conformity Requirements**
- **Economic Operator Obligations**
- **Some Important Dates**

# Scope Differences- General

## Definition of EEE – RoHS I

*‘ electrical and electronic equipment ‘ or ‘EEE’ means equipment which is dependent on electrical currents or electromagnetic fields in order to work properly and equipment for generation, transfer and measurement of such currents and fields falling under categories set out in Annex IA of Directive 2002/96/EC (WEEE) and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current;*

# Scope Differences- General

## Definition of EEE – RoHS II

*‘electrical and electronic equipment’ or ‘EEE’ means equipment which is dependent on electrical current or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current;*

# Scope Differences- General

## Definition of EEE – RoHS II (Continued)

*‘dependent’ means, with regard to EEE, needing electric currents or electromagnetic fields to fulfil at least one intended function;*



# Scope Differences - Implications

## RoHS II

1. Electricity need **not** be the primary energy source for a product to be within scope.

# Scope Differences- Implications

RoHS I Out of Scope



# Scope Differences- Implications

## RoHS II In Scope



# Scope Differences- Implications

## RoHS II

1. Electricity need **not** be the primary energy source for a product to be within scope.
2. “Primary function” concept is no longer valid.

# Scope Differences- Implications

RoHS I Out of Scope





# Scope Differences Implications

## RoHS II In Scope



# Other Scoping Issues

## RoHS I EEE Category Exclusions

**EEE Category 8: Medical Devices (with the exception of all implanted products)**

**EEE Category 9: Monitoring and Control Instruments**

# Other Scoping Issues

**RoHS II EEE Category 8 & 9 Included**





# Other Scoping Issues

**RoHS II EEE Category 8 & 9 Included**

**EEE Category 8: Medical Devices**

# Other Scoping Issues

## RoHS II EEE Category 8 & 9 Included

### EEE Category 8: Medical Devices

- Medical devices (general) – July 22, 2014

# Other Scoping Issues

## RoHS II EEE Category 8 & 9 Included

### EEE Category 8: Medical Devices

- Medical devices (general) – July 22, 2014
- In vitro diagnostic medical devices – July 22, 2016

# Other Scoping Issues

## RoHS II EEE Category 8 & 9 Included

### EEE Category 9: Monitoring and Control Instruments

# Other Scoping Issues

## RoHS II EEE Category 8 & 9 Included

### EEE Category 9: Monitoring and Control Instruments

- **Non-industrial Monitoring and Control Instruments – July 22, 2014**

# Other Scoping Issues

## RoHS II EEE Category 8 & 9 Included

### EEE Category 9: Monitoring and Control Instruments

- **Non-industrial Monitoring and Control Instruments – July 22, 2014**
- **Industrial Monitoring and Control Instruments – July 22, 2017**

# Other Scoping Issues

## RoHS II Additional EEE Category 11

**EEE Category 11: Other EEE not covered by Categories 1 to 10**

# Other Scoping Issues

## RoHS II Additional EEE Category 11

**EEE Category 11: Other EEE not covered by Categories 1 to 10**

- **Category 11 products placed on the market after July 22, 2019 must be compliant**



# Other Scoping Issues

## RoHS II Additional EEE Category 11

**EEE Category 11: Other EEE not covered by Categories  
1 to 10**

***RoHS II has an Open Scope***

# RoHS II Directive Conformity

## General Requirements:

- EEE placed on the market after certain dates must comply with limits on specified substances or substance groups – Cadmium, Hexavalent Chromium, Lead, Mercury, Polybrominated Biphenyls (PBB) and Polybrominated Diphenyl Ethers (PBDE).

# RoHS II Directive Conformity

## General Requirements (continued):

- RoHS II Directive Conformity – CE Mark aspects

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- RoHS II Directive Conformity – CE Mark aspects
  - Subject to principles set in Regulation 765/2008

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- RoHS II Directive Conformity – CE Mark aspects
  - Subject to principles set in Regulation 765/2008
  - Technical Documentation

# RoHS II Directive Conformity

## General Requirements (continued):

- RoHS II Directive Conformity – CE Mark aspects
  - Subject to principles set in Regulation 765/2008
  - Technical Documentation
    - Internal Production Control/Compliance monitoring

# RoHS II Directive Conformity

## General Requirements (continued):

- RoHS II Directive Conformity – CE Mark aspects
  - Subject to principles set in Regulation 765/2008
  - Technical Documentation
    - Internal Production Control/Compliance monitoring
  - Declaration of Conformity must now include RoHS II Directive

# Economic Operator Responsibilities

**Economic Operators responsibilities are defined**





# Economic Operator Responsibilities

**Economic Operators responsibilities are defined**

- **Manufacturer**



# Economic Operator Responsibilities

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- **Manufacturer**
- **Authorised Representative**

# Economic Operator Responsibilities

**Economic Operators responsibilities are defined**

- **Manufacturer**
- **Authorised Representative**
- **Importer**

# Economic Operator Responsibilities

**Economic Operators responsibilities are defined**

- **Manufacturer**
- **Authorised Representative**
- **Importer**
- **Distributor**

# Economic Operator Responsibilities

**Manufacturer: - any natural or legal person who manufactures an EEE or who has an EEE designed or manufactured and markets it under his name or trademark**

# Economic Operator Responsibilities

## Manufacturer Responsibilities:

**When Manufacturing/Placing EEE on the market**

# Economic Operator Responsibilities

## Manufacturer Responsibilities:

### When Manufacturing/Placing EEE on the market

- Ensure EEE placed on the market is designed and manufactured in accordance with RoHS II requirements

# Economic Operator Responsibilities

## Manufacturer Responsibilities:

### When Manufacturing/Placing EEE on the market

- Ensure EEE placed on the market is designed and manufactured in accordance with RoHS II requirements
- Draw up technical documentation



# Economic Operator Responsibilities

## Manufacturer Responsibilities:

### When Manufacturing/Placing EEE on the market

- Ensure EEE placed on the market is designed and manufactured in accordance with RoHS II requirements
- Draw up technical documentation
- Carry out internal production control

# Economic Operator Responsibilities

## Manufacturer Responsibilities:

### When Manufacturing/Placing EEE on the market

- Ensure EEE placed on the market is designed and manufactured in accordance with RoHS II requirements
- Draw up technical documentation
- Carry out internal production control
- Produce Declaration of Conformity

# Economic Operator Responsibilities

## Manufacturer Responsibilities:

### When Manufacturing/Placing EEE on the market

- Ensure EEE placed on the market is designed and manufactured in accordance with RoHS II requirements
- Draw up technical documentation
- Carry out internal production control
- Produce Declaration of Conformity
- Affix CE marking to EEE

# Economic Operator Responsibilities

## Manufacturer Responsibilities:

### When Manufacturing/Placing EEE on the market

- Ensure EEE placed on the market is designed and manufactured in accordance with RoHS II requirements
- Draw up technical documentation
- Carry out internal production control
- Produce Declaration of Conformity
- Affix CE marking to EEE
- Keep technical documentation and Declaration of Conformity for 10 years after EEE has been placed on the market

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

### When Manufacturing/Placing EEE on the market

- Ensure EEE or packaging (where appropriate) bears product type, batch, serial number or other identification

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

### When Manufacturing/Placing EEE on the market

- Ensure EEE or packaging (where appropriate) bears product type, batch, serial number or other identification
- Ensure EEE or packaging (where appropriate) shows manufacturer's name, registered trade name or trademark and contact address

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

### When Manufacturing/Placing EEE on the market

- Ensure EEE or packaging (where appropriate) bears product type, batch, serial number or other identification
- Ensure EEE or packaging (where appropriate) shows manufacturer's name, registered trade name or trademark and contact address
- Establish/maintain a register of non-conforming EEE and product recalls

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

### When Manufacturing/Placing EEE on the market

- Ensure EEE or packaging (where appropriate) bears product type, batch, serial number or other identification
- Ensure EEE or packaging (where appropriate) shows manufacturer's name, registered trade name or trademark and contact address
- Establish/maintain a register of non-conforming EEE and product recalls
- Inform distributors of non-conforming EEE and product recalls



# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

Where reason to believe he/she **has placed non-complaint EEE**  
**on the market**

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

Where reason to believe he/she **has placed non-complaint EEE on the market**

- Take immediate actions to bring EEE into conformity

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

Where reason to believe he/she **has placed non-complaint EEE on the market**

- Take immediate actions to bring EEE into conformity
- Withdraw, and where appropriate, recall the EEE from the market

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

Where reason to believe he/she **has placed non-complaint EEE on the market**

- Take immediate actions to bring EEE into conformity
- Withdraw, and where appropriate, recall the EEE from the market
- Immediately inform competent authorities in Member States in which EEE concerned was made available providing:

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

Where reason to believe he/she **has placed non-complaint EEE on the market**

- Take immediate actions to bring EEE into conformity
- Withdraw, and where appropriate, recall the EEE from the market
- Immediately inform competent authorities in Member States in which EEE concerned was made available providing:
  - Details of non-conformity
  - Corrective measures taken

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

### Cooperation with National Authority



# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

### Cooperation with National Authority

- Provide all information/documentation demonstrating compliance

# Economic Operator Responsibilities

## Manufacturer Responsibilities (continued):

### Cooperation with National Authority

- Provide all information/documentation demonstrating compliance
- Cooperate in any requested action to ensure compliance



# Economic Operator Responsibilities

**Authorised Representative: - any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks**

# Economic Operator Responsibilities

## Authorised Representative - Minimum:

- Keep technical documentation and Declaration of Conformity at the disposal of the national authorities for a minimum of 10 years after EEE has been placed on the market

# Economic Operator Responsibilities

## Authorised Representative - Minimum:

- Keep technical documentation and Declaration of Conformity at the disposal of the national authorities for a minimum of 10 years after EEE has been placed on the market
- Provide national authorities with information and documentation to demonstrate conformity

# Economic Operator Responsibilities

## Authorised Representative - Minimum:

- Keep technical documentation and Declaration of Conformity at the disposal of the national authorities for a minimum of 10 years after EEE has been placed on the market
- Provide national authorities with information and documentation to demonstrate conformity
- Cooperate with national authorities on any action covered by their mandate to ensure compliance

# Economic Operator Responsibilities

**Importer: - any natural or legal person established within the Union, who places an EEE from a third country on the Union market**

# Economic Operator Responsibilities

## Importer:

- Ensure that only compliant EEE is placed on the market

# Economic Operator Responsibilities

## Importer:

- Ensure that only compliant EEE is placed on the market
- Prior to placing an EEE on the market –



# Economic Operator Responsibilities

## Importer:

- Ensure that only compliant EEE is placed on the market
- Prior to placing an EEE on the market –
  - Ensure conformity assessment procedures have been carried out



# Economic Operator Responsibilities

## Importer:

- Ensure that only compliant EEE is placed on the market
- Prior to placing an EEE on the market –
  - Ensure conformity assessment procedures have been carried out
  - Ensure the manufacturer has produced the technical documentation required

# Economic Operator Responsibilities

## Importer:

- Ensure that only compliant EEE is placed on the market
- Prior to placing an EEE on the market –
  - Ensure conformity assessment procedures have been carried out
  - Ensure the manufacturer has produced the technical documentation required
  - Ensure EEE is CE-marked

# Economic Operator Responsibilities

## Importer:

- Ensure that only compliant EEE is placed on the market
- Prior to placing an EEE on the market –
  - Ensure conformity assessment procedures have been carried out
  - Ensure the manufacturer has produced the technical documentation required
  - Ensure EEE is CE-marked
  - Ensure product is accompanied by relevant documentation

# Economic Operator Responsibilities

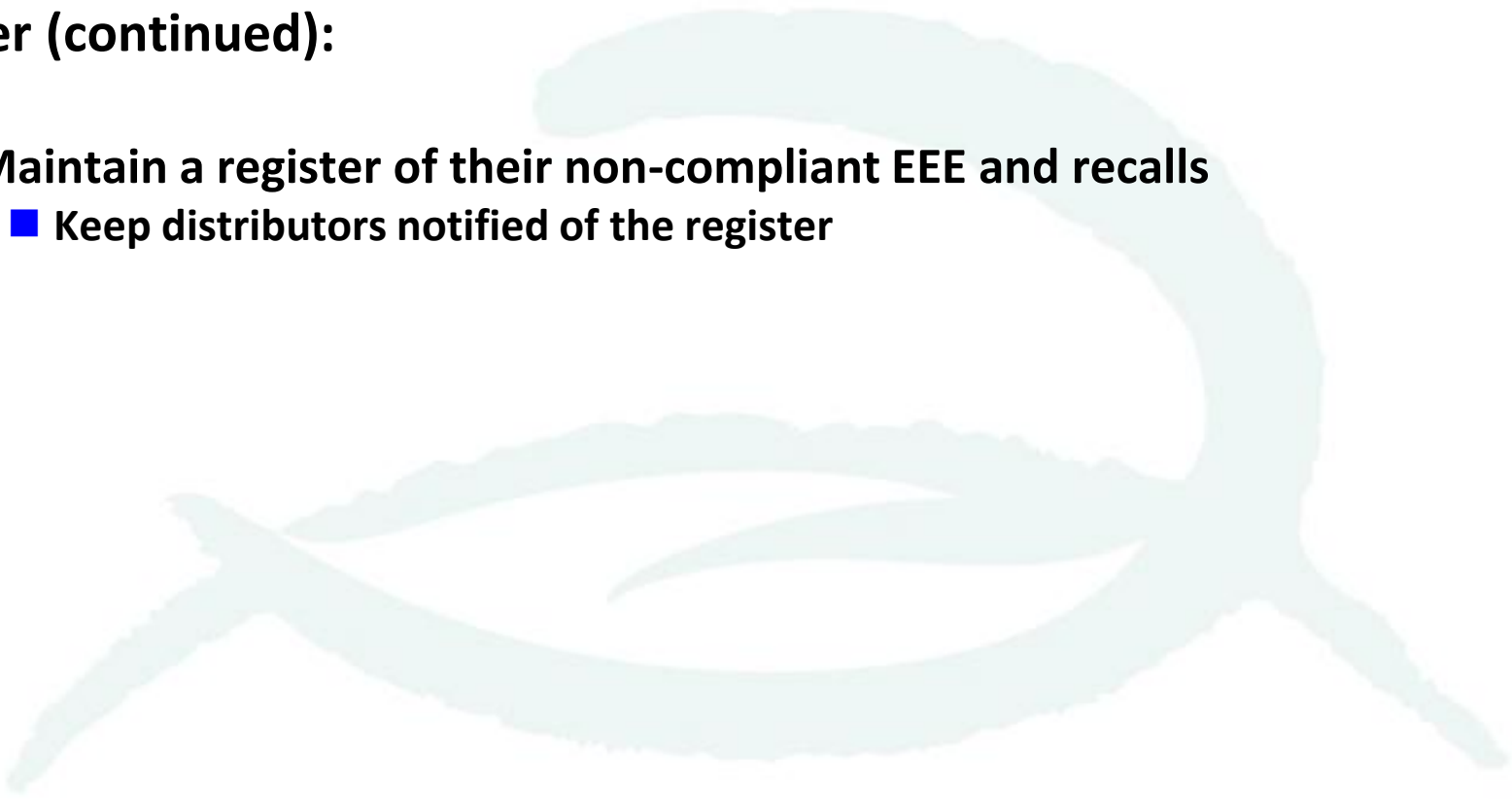
## Importer:

- Ensure that only compliant EEE is placed on the market
- Prior to placing an EEE on the market –
  - Ensure conformity assessment procedures have been carried out
  - Ensure the manufacturer has produced the technical documentation required
  - Ensure EEE is CE-marked
  - Ensure product is accompanied by relevant documentation
- Indicate importer's name, registered trade name or registered trademark on the EEE or as appropriate the packaging

# Economic Operator Responsibilities

## Importer (continued):

- **Maintain a register of their non-compliant EEE and recalls**
  - **Keep distributors notified of the register**



# Economic Operator Responsibilities

## Importer (continued):

- **Maintain a register of their non-compliant EEE and recalls**
  - **Keep distributors notified of the register**
- **Keep product Declaration of Conformity for 10 years after EEE has been placed on the market**

# Economic Operator Responsibilities

## Importer (continued):

- **Maintain a register of their non-compliant EEE and recalls**
  - **Keep distributors notified of the register**
- **Keep product Declaration of Conformity for 10 years after EEE has been placed on the market**
- **Provide documentation demonstrating conformity to national authorities upon request**

# Economic Operator Responsibilities

## Importer (continued):

- **Maintain a register of their non-compliant EEE and recalls**
  - **Keep distributors notified of the register**
- **Keep product Declaration of Conformity for 10 years after EEE has been placed on the market**
- **Provide documentation demonstrating conformity to national authorities upon request**
- **Cooperate in any requested action by national authorities to ensure compliance**



# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe product non-compliant **prior to placement on the market**

# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe product non-compliant **prior to placement on the market**
- Ensure product is not placed on the market

# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe product non-compliant **prior to placement on the market**
  - Ensure product is not placed on the market
  - Ensure product is made complaint before being placed on the market

# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe product non-compliant **prior to placement on the market**
  - Ensure product is not placed on the market
  - Ensure product is made complaint before being placed on the market
  - Inform manufacturer

# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe product non-compliant **prior to placement on the market**
  - Ensure product is not placed on the market
  - Ensure product is made complaint before being placed on the market
  - Inform manufacturer
  - Inform market surveillance authorities

# Economic Operator Responsibilities

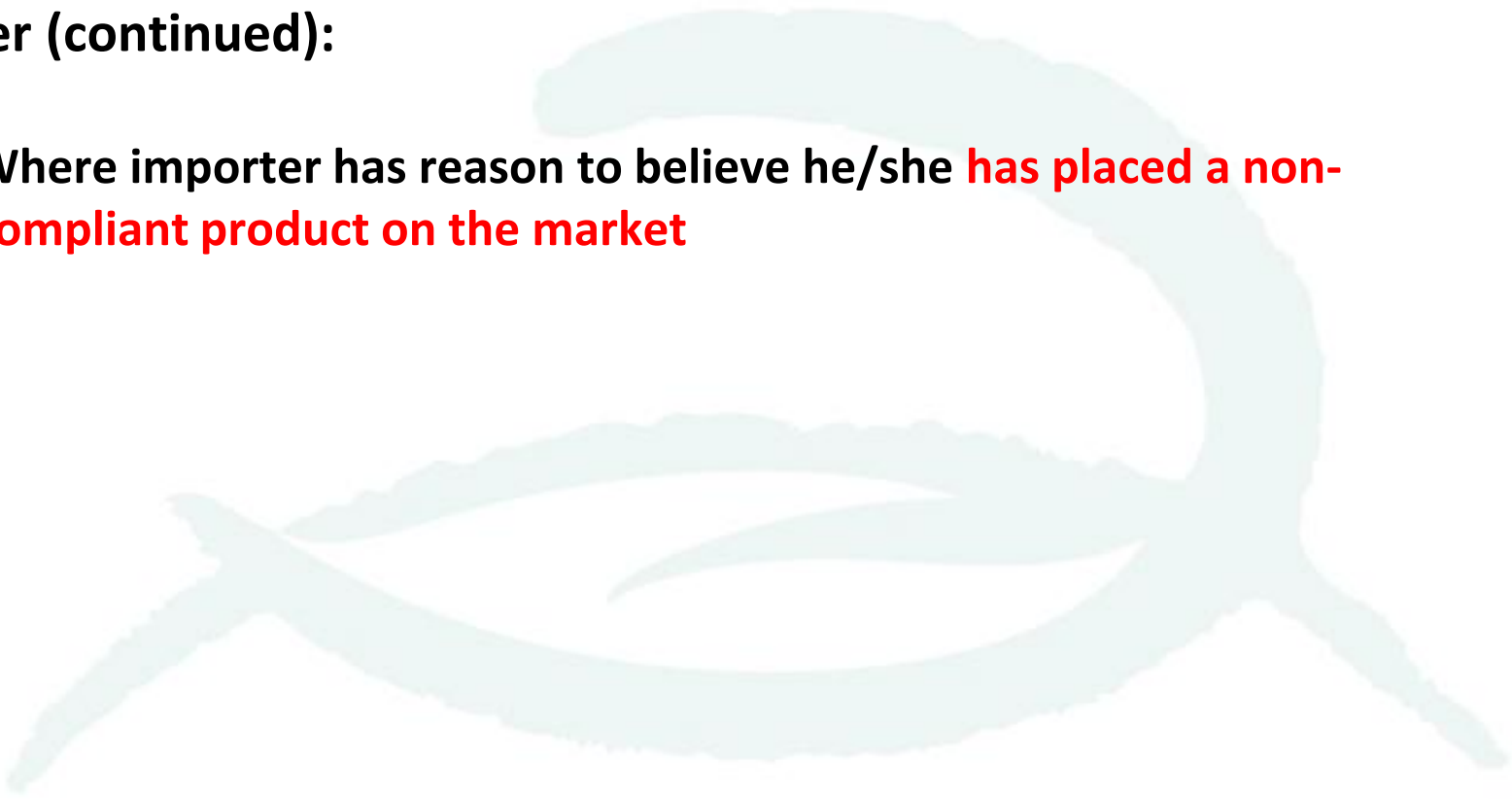
## Importer (continued):

- Where importer has reason to believe product non-compliant **prior to placement on the market**
  - Ensure product is not placed on the market
  - Ensure product is made complaint before being placed on the market
  - Inform manufacturer
  - Inform market surveillance authorities
    - Details of non-conformity
    - Corrective measures taken

# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe he/she **has placed a non-compliant product on the market**



# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe he/she **has placed a non-compliant product on the market**
- Immediately take action to bring product into conformity



# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe he/she **has placed a non-compliant product on the market:**
  - Immediately take action to bring product into conformity
  - Immediately withdraw product from market and/or as appropriate recall the product from the market

# Economic Operator Responsibilities

## Importer (continued):

- Where importer has reason to believe he/she **has placed a non-compliant product on the market:**
  - Immediately take action to bring product into conformity
  - Immediately withdraw product from market and/or as appropriate recall the product from the market
  - Notify national authorities of Member States on whose market non-complaint EEE was made available

# Economic Operator Responsibilities

**Distributor: - any natural or legal person in the supply chain other than the manufacturer or the importer, who makes EEE available**

# Economic Operator Responsibilities

## Distributor:

- Take due care to ensure EEE is compliant when making EEE available on the market

# Economic Operator Responsibilities

## Distributor:

- Take due care to ensure EEE is compliant when making EEE available on the market
- Ensure product is CE-marked

# Economic Operator Responsibilities

## Distributor:

- Take due care to ensure EEE is compliant when making EEE available on the market
  - Ensure product is CE-marked
  - Ensure product is accompanied by required documentation

# Economic Operator Responsibilities

## Distributor:

- Take due care to ensure EEE is compliant when making EEE available on the market
  - Ensure product is CE-marked
  - Ensure product is accompanied by required documentation
  - Ensure manufacturer has identified EEE by type, batch or serial number or other means

# Economic Operator Responsibilities

## Distributor:

- Take due care to ensure EEE is compliant when making EEE available on the market
  - Ensure product is CE-marked
  - Ensure product is accompanied by required documentation
  - Ensure manufacturer has identified EEE by type, batch or serial number or other means
  - Ensure manufacturer's name, registered trade name or registered trade mark and contact address is either on EEE or packaging



# Economic Operator Responsibilities

## Distributor:

- Take due care to ensure EEE is compliant when making EEE available on the market
  - Ensure product is CE-marked
  - Ensure product is accompanied by required documentation
  - Ensure manufacturer has identified EEE by type, batch or serial number or other means
  - Ensure manufacturer's name, registered trade name or registered trade mark and contact address is either on EEE or packaging
  - Ensure importer's name, registered trade name or registered trade mark and contact address is either on EEE or packaging

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe product non-compliant **prior to making available:**

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe product non-compliant **prior to making available** :
  - Ensure product is not made available

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe product non-compliant **prior to making available** :
  - Ensure product is not made available
  - Ensure product is made complaint before being made available

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe product non-compliant **prior to making available** :
  - Ensure product is not made available
  - Ensure product is made complaint before being made available
  - Inform manufacturer

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe product non-compliant **prior to making available** :
  - Ensure product is not made available
  - Ensure product is made complaint before being made available
  - Inform manufacturer
  - Inform market surveillance authorities
    - Details of non-conformity
    - Corrective measures taken

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe he/she **has made available a non-compliant product:**

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe he/she **has made available a non-compliant product**:
  - Immediately take action to bring product into conformity



# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe he/she **has made available a non-compliant product**:
  - Immediately take action to bring product into conformity
  - Immediately withdraw product and/or as appropriate recall the product

# Economic Operator Responsibilities

## Distributor (continued):

- Where Distributor has reason to believe he/she **has made available a non-compliant product**:
  - Immediately take action to bring product into conformity
  - Immediately withdraw product and/or as appropriate recall the product
  - Notify national authorities of Member States non-complaint EEE was made available

# Economic Operator Responsibilities

## Distributor (continued):

### Cooperation with National Authority

- Provide technical documentation to national authorities upon request

# Economic Operator Responsibilities

## Distributor (continued):

### Cooperation with National Authority

- Provide technical documentation to national authorities upon request
- Provide all documentation necessary to demonstrate conformity

# Economic Operator Responsibilities

## Distributor (continued):

### Cooperation with National Authority

- Provide technical documentation to national authorities upon request
- Provide all documentation necessary to demonstrate conformity
- Cooperate in any requested action to ensure compliance

# Some Important Dates

- Products **not** covered by RoHS I Directive and not compliant with RoHS II Directive can be made available until July 22, 2019

# Some Important Dates

- Products **not** covered by RoHS I Directive and not compliant with RoHS II Directive can be made available until July 22, 2019
- Commission review of Scope due before July 22, 2014

## Some Important Dates

- Products **not** covered by RoHS I Directive and not compliant with RoHS II Directive can be made available until July 22, 2019
- Commission review of Scope due before July 22, 2014
- Products covered by RoHS I Directive and placed on the market after January 3, 2013 must be compliant with RoHS II Directive.





*Thank You For Your Attention!*