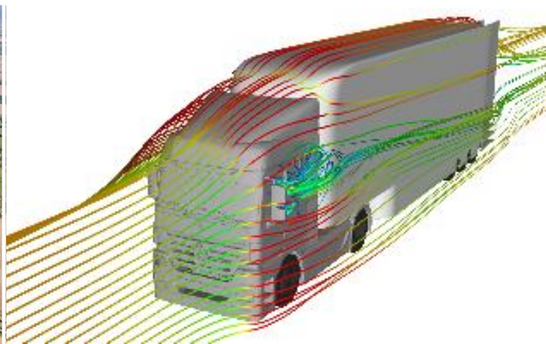
Technical Documentation for CE Marking

De-Mystifying EMC 2018

22 January 2018



Important Note

The information provided in this presentation may be condensed and/or paraphrased for presentation purposes.

Always refer to the actual directive(s), and associated documents where applicable, for the official published text.

Technical Documentation for CE Marking

- The New Legislative Framework (NLF)
- The Blue Guide
- Market Surveillance
- Notified Bodies
- Technical Documentation Elements
- EU Declaration of Conformity
- Further Market Surveillance

The New Legislative Framework (NLF)

The New Legislative Framework (NLF)

- New Legislative Framework
  - Comprised of three key pieces of EU legislation:
    - Regulation 765/2008/EC
    - Decision 768/2008/EC
    - Regulation 764/2008/EC

The New Legislative Framework (NLF)

- Regulation 765/2008/EC
  - Established the legal basis for accreditation and market surveillance
  - Consolidated the meaning of CE marking

The New Legislative Framework (NLF)

- Decision 768/2008/EC
  - Updated, harmonised and consolidated various technical instruments
  - Established a common framework for the marketing of products
    - Definitions
    - Criteria for the designation and notification of conformity assessment bodies
    - Rules for the notification process
    - Conformity assessment procedures (modules)
    - European Union Safeguard Mechanisms
    - Responsibilities of the economic operators
      - Manufacturer, Authorised Representative, Distributor, Importer
    - Traceability requirements

The New Legislative Framework (NLF)

- Regulation 764/2008/EC
  - Laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country
  - Applies to administrative decisions taken by Member States
  - Ensures freedom of movement of goods

New Legislative Framework (NLF) Implementation

EMC	Radio & Telecommunications Terminal Equipment (R&TTE)	Others
2004/108/EC	1999/5/EC	…
⇩	⇩	⇩
2014/30/EU	2014/53/EU	…

The New Legislative Framework (NLF)

- From the ‘Blue Guide’:

> “The most important change brought about by the NLF to the legislative environment of the EU was the introduction of a comprehensive policy on market surveillance. This has considerably changed the balance of EU legislative provisions from being fundamentally oriented at setting product related requirements to be met when products are placed on the market to an equal emphasis on enforcement aspects during the whole life-cycle of products.”

General Product Safety Directive

- The **G**eneral **P**roduct **S**afety **D**irective (GPSD)
  - Directive 2001/95/EC
  - Intended for consumer products not covered by sector-specific EU harmonisation legislation
  - Complements the provisions of sector legislation in some respects
  - Established the Rapid Alert System (see Slide 23)

The Blue Guide

The Blue Guide

- The ‘Blue Guide’ on the implementation of EU product rules 2016
  - Comprehensive document explaining fundamental concepts behind the NLF
    - How it all fits together
    - The actors in the product supply chain and their obligations
      - Manufacturer, Authorised Representative, Importer, Distributor and other intermediaries
    - Traceability requirements
    - The requirement for Technical Documentation (Section 4.3)
    - Conformity Assessment Procedures
    - **EU** Declaration of Conformity
    - CE Marking

The Blue Guide

- Available from:
  - http://ec.europa.eu/DocsRoom/documents/18027/

Official Journal C 272
of the European Union

English edition — Information and Notices — Volume 59, 26 July 2016

Contents

II *Information*

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

European Commission

2016/C 272/01 Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016 (1) 1

EN

(1) Text with EEA relevance

Market Surveillance

Market Surveillance

- EU Member States are responsible for Market Surveillance at National Level
  - The EU Member State must **guarantee** that:
    - Products placed on the market are monitored
    - Marking and **documentation** requirements have been respected
    - Products have been designed and manufactured in accordance with EU harmonisation requirements
    - Market surveillance authorities have the necessary powers, resources and knowledge to perform their functions
    - Procedures are put in place for following up complaints and monitoring accidents
    - Market surveillance programmes are established, implemented and periodically updated
    - The functioning of surveillance activities is reviewed and assessed at least every four years

UK Market Surveillance

- For EMC, there are 2 **M**arket **S**urveillance **A**uthorities (MSAs) in the United Kingdom:
  - **OFCOM**
    Riverside House 2a Southwark Bridge Road London SE1 9HA
    Tel: 0300 123 3000, 020 7981 3000 - Fax: 020 7981 3333
    www.ofcom.org.uk
  - Department for **B**usiness, **E**nergy & **I**ndustrial **S**trategy (BEIS)
    1 Victoria Street London SW1H 0ET
    Tel: 0207 215 5000
    Email: enquiries@beis.gov.uk
    https://www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy

UK Market Surveillance

- Market Surveillance Projects in 2017
  - Laser Pointers
  - Thermos Flasks
  - Horse Riding Helmets
  - Second-Hand Nursery Products
  - Prop Feeding Devices
  - Lithium Batteries
  - Chemicals in Leather Goods / Jewellery
  - Eye Wear for **I**ntense **P**ulsed **L**ight (IPL) Lasers
  - Chinese Steel Products

UK Market Surveillance

- Market Surveillance Projects in 2016
  - LED Floodlights
  - Nightwear
  - Telescopic Leaning Ladders
  - Childcare Articles (Nappy Sacks and Slings)
  - Second-Hand Electrical Goods

EU Market Surveillance

- Every **M**ember **S**tate (MS) has the same obligations
- Each MS has their own individual Market Surveillance programme
  - Some programmes involve the participation of multiple Member States
- In practise there is substantial Market Surveillance happening in line with the NLF

EU MSA Cooperation

- **I**nformation and **C**ommunication **S**ystem for **M**arket **S**urveillance (ICSMS)
  - Comprehensive database of market surveillance
    - Product details: EAN Code, Type Number, Serial No., Country of Origin etc.
    - Accidents
    - Responsible party
    - Proof of conformity
    - Test Results
    - Classification of defects
    - Measures taken
    - https://webgate.ec.europa.eu/icsms/

ICSMS

- There are 2 levels of access to the database
  - Internal - Market Surveillance Bodies, Customs, EU Authorities
    - Facilitates information exchange on market surveillance measures
    - Helps coordinate activities and inspections
    - Enables wide-scale market interventions on dubious products
    - Avoids duplication of effort
    - Feeds into the development of best practises
    - Ensures market surveillance is efficient and uniform across all Member States (and EFTA countries)
  - Public – Consumers, Manufacturers
    - Only references non-conforming products and the reason they have been listed

EU MSA Cooperation

- Rapid Alert System (RAPEX)
  - Information on dangerous products
    - Reports published weekly
    - Subscription service available
    - https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications

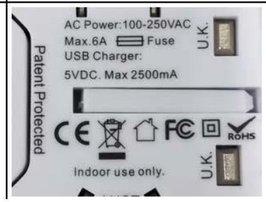
RAPEX Example (1)

- Mocreo Travel Charger

“Live pins are accessible during use. The product does not comply with the requirements of the Low Voltage Directive and the relevant European standard EN 60950.”

European Commission

Rapid Alert System for dangerous non-food products

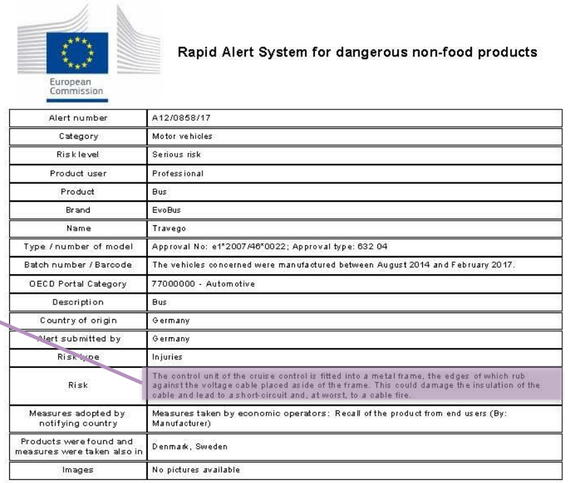
Alert number	A12/1764/17
Category	Electrical appliances and equipment
Risk level	Serious risk
Product user	Consumer
Product	Travel charger
Brand	Mocreo
Name	Unknown
Type / number of model	M1279588, C 161324, ST.033A
Batch number / Barcode	216/T/101600668
OECD Portal Category	78000000 - Electrical Supplies
Description	Travel charger for use in different countries.
Country of origin	Unknown
Alert submitted by	Sweden
Risk type	Electric shock
Risk	Live pins are accessible during use. The product does not comply with the requirements of the Low Voltage Directive and the relevant European standard EN 60950.
Measures adopted by notifying country	Measures taken by economic operators: Recall of the product from end users (By: Importer) Measures ordered by public authorities: Recall of the product from end users
	

Images

RAPEX Example (2)

- EvoBus Travego

"The control unit of the cruise control is fitted into a metal frame, the edges of which rub against the voltage cable placed aside of the frame. This could damage the insulation of the cable and lead to a short-circuit and, at worst, to a cable fire."



European Commission

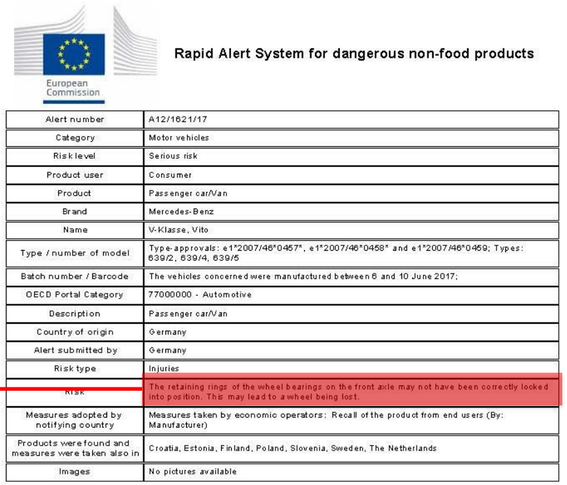
Rapid Alert System for dangerous non-food products

Alert number	A12/0858/17
Category	Motor vehicles
Risk level	Serious risk
Product user	Professional
Product	Bus
Brand	EvoBus
Name	Travego
Type / number of model	Approval No: e1*2007/46*0022; Approval type: 632.04
Batch number / Barcode	The vehicles concerned were manufactured between August 2014 and February 2017.
OECD Portal Category	77000000 - Automotive
Description	Bus
Country of origin	Germany
Alert submitted by	Germany
Risk type	Injuries
Risk	The control unit of the cruise control is fitted into a metal frame, the edges of which rub against the voltage cable placed aside of the frame. This could damage the insulation of the cable and lead to a short-circuit and, at worst, to a cable fire.
Measures adopted by notifying country	Measures taken by economic operators: Recall of the product from end users (By: Manufacturer)
Products were found and measures were taken also in	Denmark, Sweden
Images	No pictures available

RAPEX Example (3) !

- Mercedes-Benz V-Klasse Vito

“The retaining rings of the wheel bearings on the front axle may not have been correctly locked into position. This may lead to a wheel being lost.”



European Commission

Rapid Alert System for dangerous non-food products

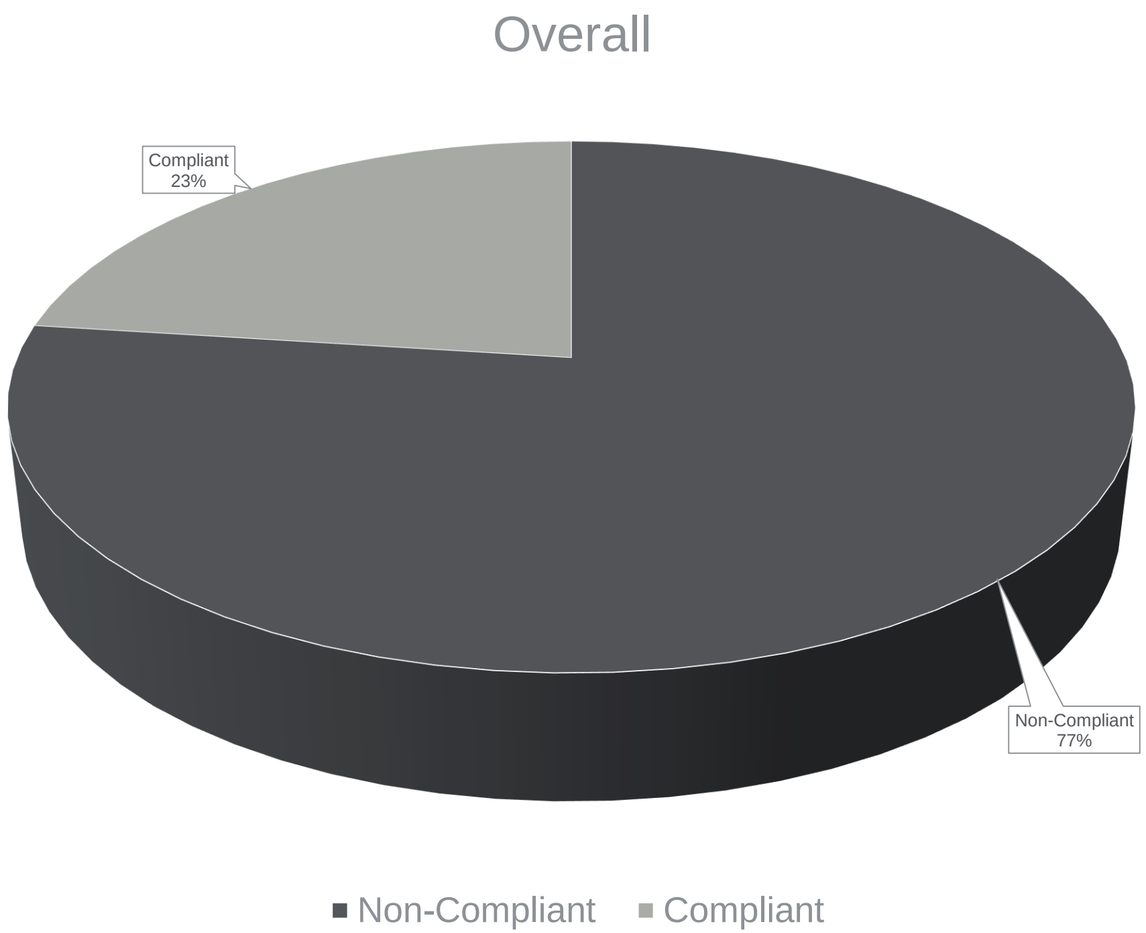
Alert number	A12/1621/17
Category	Motor vehicles
Risk level	Serious risk
Product user	Consumer
Product	Passenger car/Van
Brand	Mercedes-Benz
Name	V-Klasse, Vito
Type / number of model	Type-approvals: e1*2007/46*0457*, e1*2007/46*0458* and e1*2007/46*0459; Types: 639/2, 639/4, 639/5
Batch number / Barcode	The vehicles concerned were manufactured between 6 and 10 June 2017;
OECD Portal Category	77000000 - Automotive
Description	Passenger car/Van
Country of origin	Germany
Alert submitted by	Germany
Risk type	Injuries
Risk	The retaining rings of the wheel bearings on the front axle may not have been correctly locked into position. This may lead to a wheel being lost.
Measures adopted by notifying country	Measures taken by economic operators: Recall of the product from end users (By: Manufacturer)
Products were found and measures were taken also in	Croatia, Estonia, Finland, Poland, Slovenia, Sweden, The Netherlands
Images	No pictures available

EU MSA Cooperation

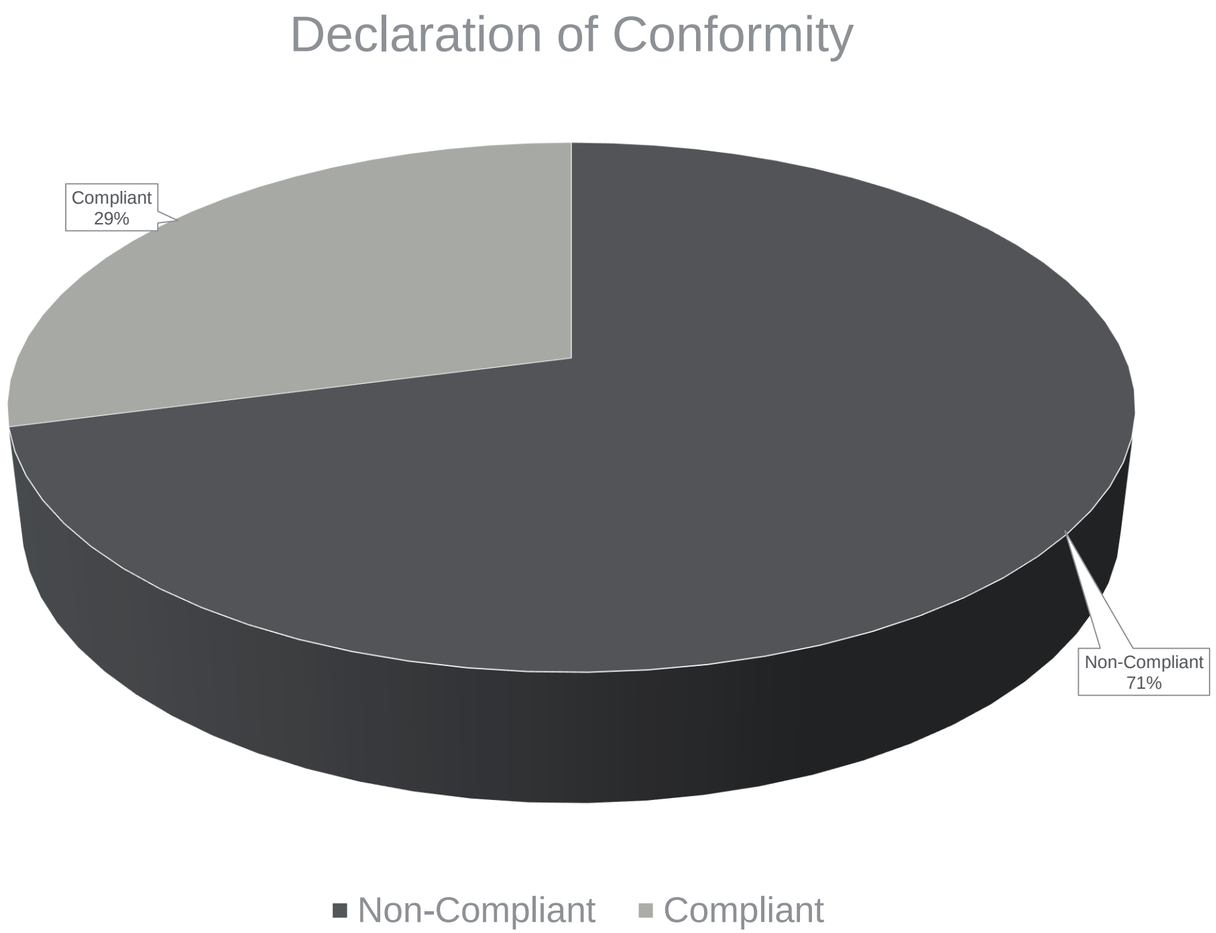
- Informal **Ad**ministration **Co**operation Groups (AdCos) collaborate at EU level
  - Presently there are AdCos covering specific market sectors
    - Electromagnetic Compatibility (AdCo EMC)
    - Radio Equipment (AdCo RED)
    - Medical Devices (AdCo COEN)
    - Low Voltage (AdCo LVD)
    - Energy Labelling (AdCo ENERLAB)
    - and 23 others

AdCo RED 2016 Results
(R&TTE Directive)

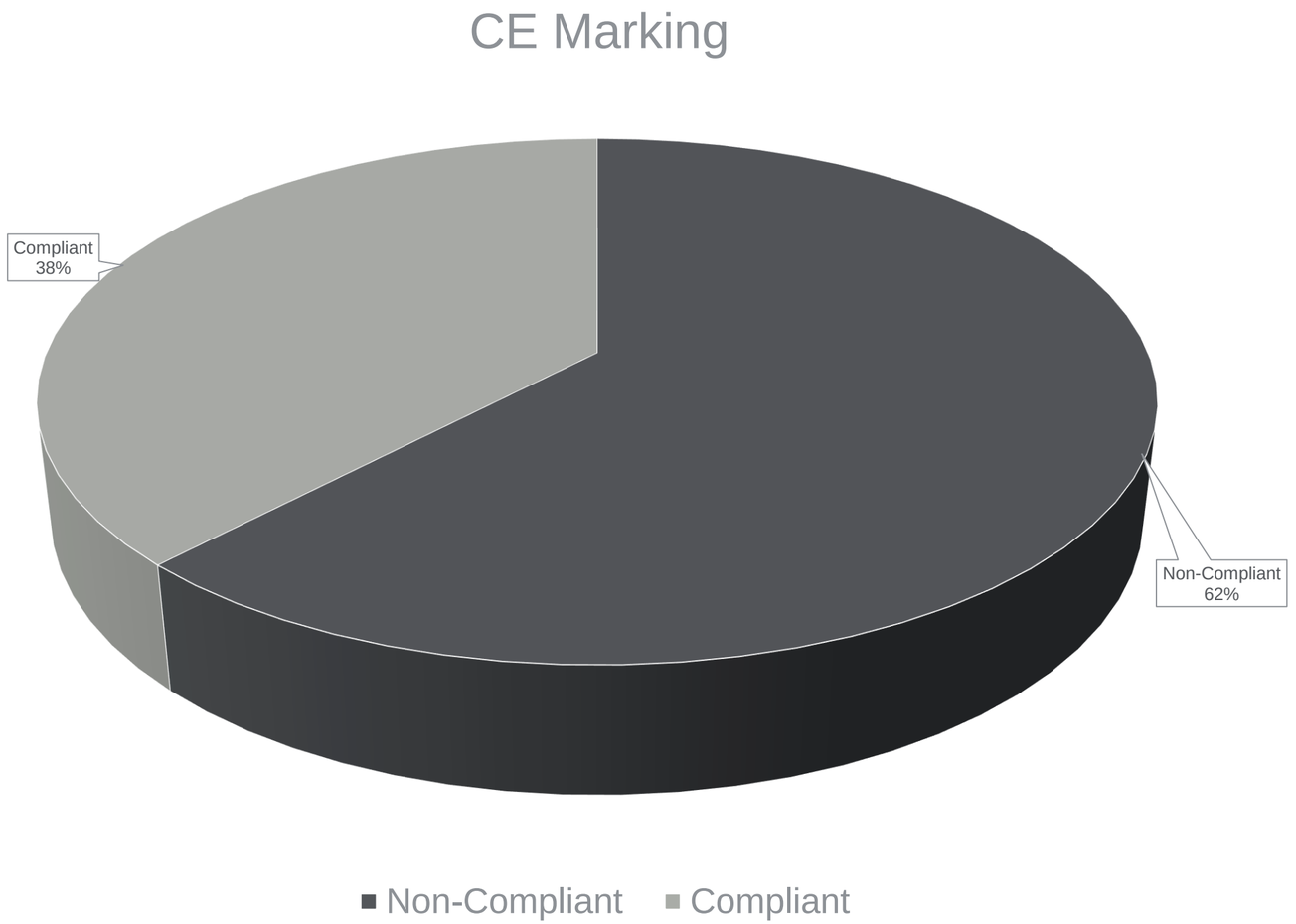
Based on 13,488 Inspections



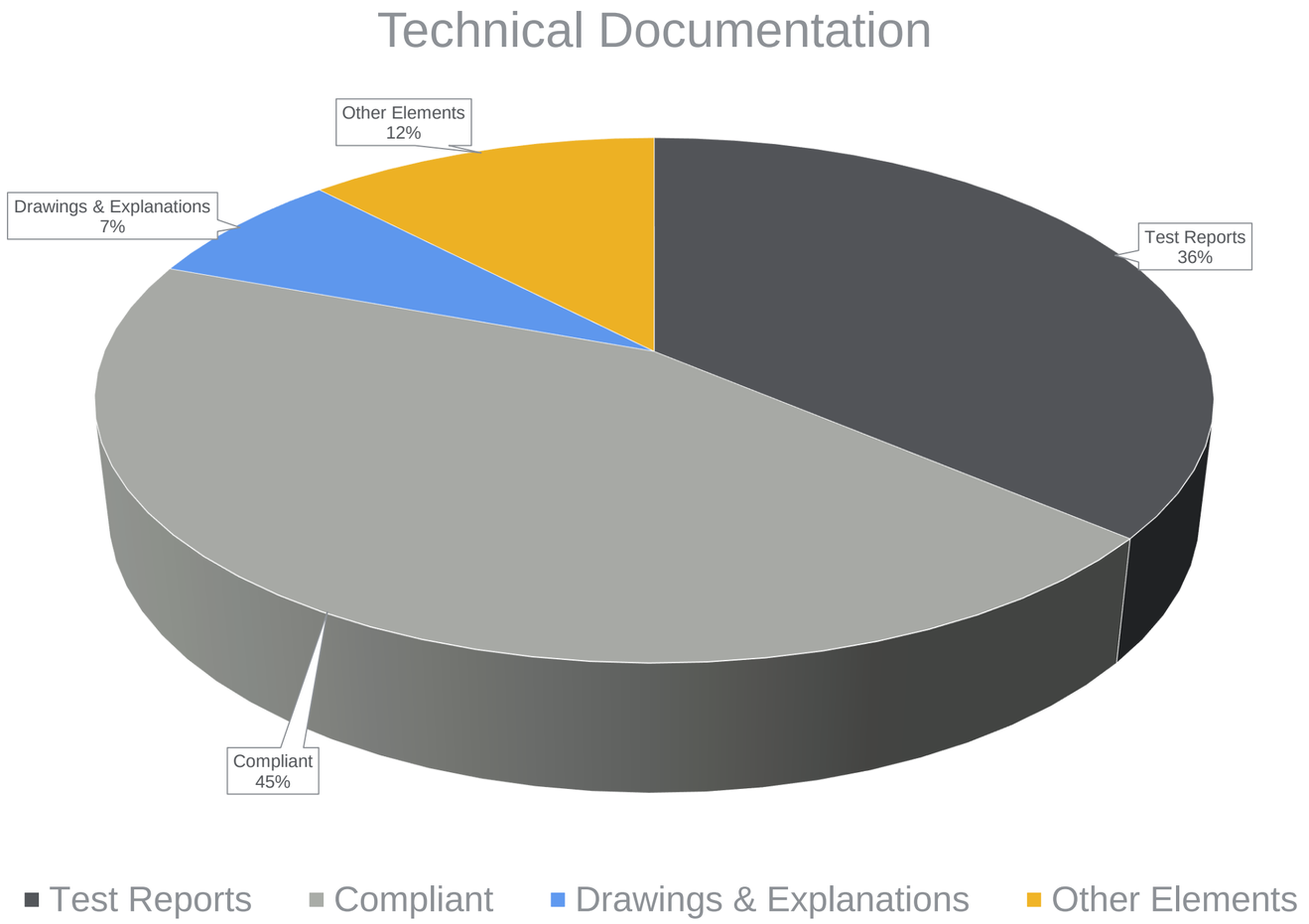
AdCo RED 2016 Results
(R&TTE Directive)



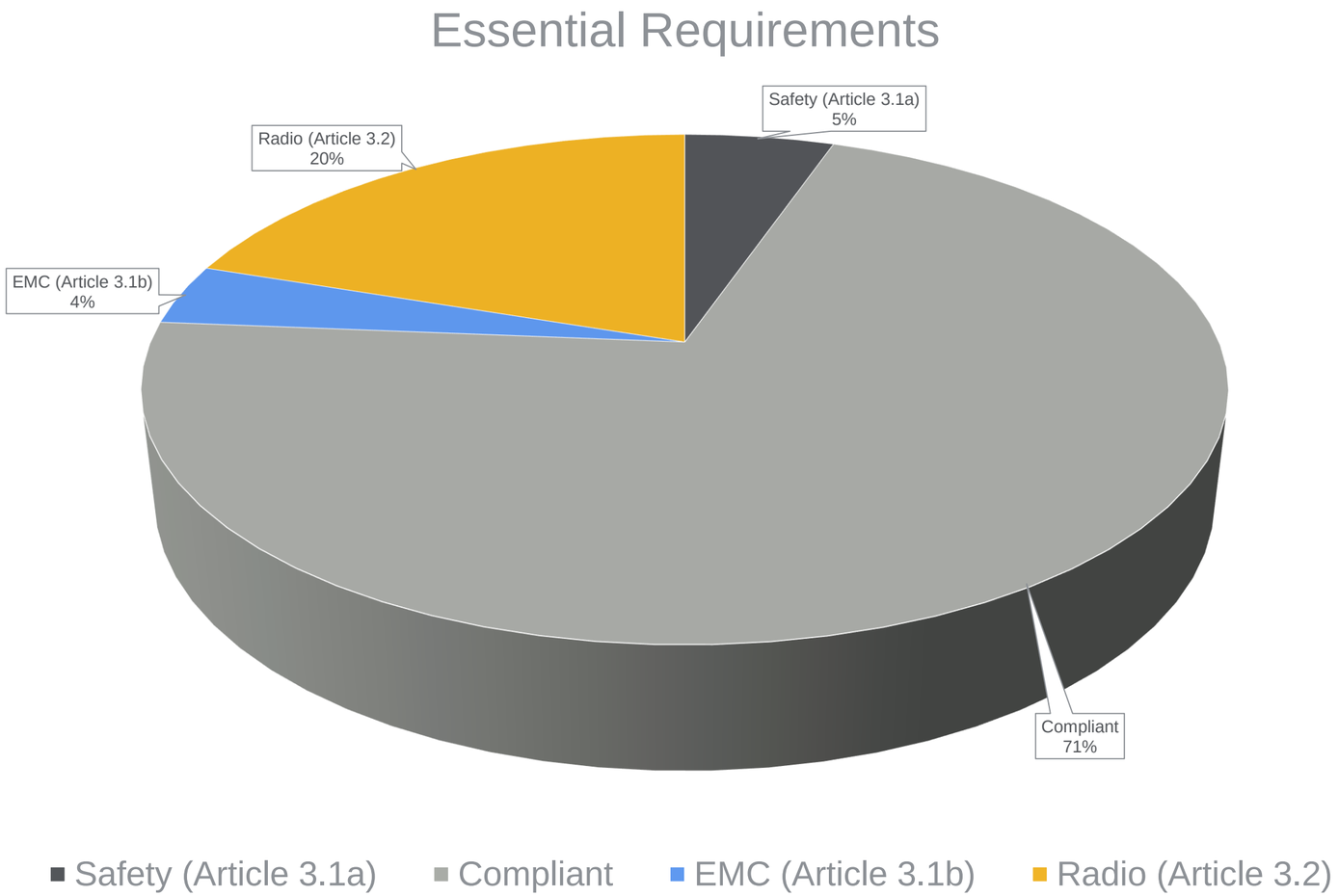
AdCo RED 2016 Results
(R&TTE Directive)



AdCo RED 2016 Results
(R&TTE Directive)



AdCo RED 2016 Results
(R&TTE Directive)



AdCo RED 2016 Results
(R&TTE Directive)

- Data Source:
  - http://ec.europa.eu/docsroom/documents/24223

Notified Bodies

Notified Bodies

- Notified Bodies are officially designated by their National Authority
  - Notified Bodies outside of the EU can be appointed where a **M**utual **R**ecognition **A**greement (MRA) exists between the country concerned and the **EU**
  - A list of Notified Bodies is maintained on the **N**ew **A**pproach **N**otified and **D**esignated **O**rganisations (NANDO) web-site
    - http://ec.europa.eu/growth/tools-databases/nando/

No.

Not that one!

Notified Bodies

- HORIBA MIRA are a Notified Body for:
  - EMC (2014/30/EU)
  - Radio Equipment (2014/53/EU)
  - Machinery (2006/42/EC)
  - Construction Products (2011/305/EU)
  - Outdoor Noise (2000/14/EC)

Notified Bodies

- Notified Bodies are solely responsible for conformity assessment in accordance with the procedure(s) set out in the applicable Union harmonisation legislation
- Notified Bodies do not:
  - ‘CE Mark’ products
  - Certify Products
    - Except EU-Type Examination Certificates [where applicable]
  - Provide legally binding interpretations of EU harmonisation legislation
  - Identify applicable **H**armonised **S**tandards (HS) [Prior to assessment]
  - Provide “Consultancy”
    - “Advice” is allowed

Consultancy vs. Advice

- Consultancy
  - 2014/30/EU Article 24(4)

> "…They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services."

    - Identical text can be found in other EU harmonisation legislation e.g. 2014/53/EU
    - Consultancy can be provided by another organization not involved in the assessment
  - EN ISO/IEC 17065: 2012 Paragraph 4.2.6

> "The certification body and any part of the same legal entity and entities under its organizational control (see 7.6.4) shall not…(d) offer or provide consultancy (see 3.2) to its clients"

Advice

- Advice
  - No restrictions in the NLF relating to “advice”
  - It should not be assumed that “advice” is free-of-charge

Consultancy vs. Advice

- Examples of Consultancy
  - Informing an economic operator specifically of what they have to do to comply
    - Includes identifying applicable **H**armonised **S**tandards (HS)
      - “EN 55032: 2005 is the most appropriate standard to use in this case”
  - Organising and/or carrying out Testing of the product to be assessed
    - Writing Test Plans
  - Assisting with the design of a product
    - Includes specific design recommendations to assist compliance
      - “Add a 10 nF Capacitor from the output of Op-Amp #2 to Ground as close to the IC as possible”
  - Gap Analysis
  - Composition of the Technical Documentation

Consultancy vs. Advice

The fine line between “Consultancy” and “Advice”

Consultancy vs. Advice

- Examples of Advice
  - Making an economic operator aware of where they can obtain information to help them make an appropriate decision
    - “There is a list of HS published in the **O**fficial **J**ournal of the **E**uropean **U**nion (OJEU) that you could review for any that you might consider appropriate to your product”
    - “The minimum requirements for the **T**echnical **D**ocumentation (TD) are set out in Annex V of the Directive”
  - Generic guidance
    - This presentation!
    - Training Courses

Consultancy vs. Advice

- Examples of Advice
  - An EU-Type Examination Assessment Report may contain useful information
    - HORIBA MIRA EU-Type Examination Assessment Reports
      - List non-compliances with reference to the applicable clause of the Directive
      - Provide links to sources of additional information
        - Including paragraph references where appropriate
    - Check with your chosen Notified Body as there is no specific requirement to provide an EU-Type Examination Assessment Report to the applicant

Technical Documentation Elements

Technical Documentation Elements

- **T**echnical **D**ocumentation (TD) must be retained for 10 years from being placed on the market
  - ‘Placed on the market’ refers to each **individual** apparatus
  - Any changes in the product **must** be reflected in the TD
  - Traceability **must** be maintained

Technical Documentation Elements

- The **minimum** requirements for TD are set-out in one or more annexes to the EU harmonisation legislation
  - 2014/30/EU :: Annexes II and III (depending on the chosen conformity assessment procedure)
  - 2014/53/EU :: Annex V
- Annex II to Decision 768/2008/EC
  - Conformity assessment procedures (Modules)

Technical Documentation Elements

"The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the following elements…"

- Risk Assessment is required with respect to the essential requirements
- Applicable Union harmonisation legislation requirements need to be identified
- Design, Manufacture and Operation Elements

Technical Documentation Design Elements

- A general description of the apparatus
- Conceptual design drawings
  - Showing External and Internal features*
- Descriptions and explanations necessary for the understanding of the drawings
- Results of calculations made, examinations carried out etc.
- Test Reports

* Not explicitly stated in all NLF directives

Technical Documentation Manufacture Elements

- Conceptual manufacturing drawings e.g. PCB Layouts, Gerber Files
- Descriptions and explanations necessary for the understanding of the drawings
- Schemes of components
- Sub-Assemblies
- Circuits
- Results of calculations made, examinations carried out etc.

Technical Documentation Operation Elements

- Descriptions and explanations necessary for the understanding of operation of the apparatus
  - This needs to cover all intended use* e.g. Operating Modes, Environments
  - Some NLF Directives require the inclusion of user-information e.g. 2014/53/EU
- Test Reports

* Not explicitly stated in all NLF directives

Technical Documentation Assessment Considerations

"…The documentation shall make it possible to assess the product's conformity with the relevant requirements…"

- Consider who might be making an assessment
  - Economic operators are only obliged to provide the TD to:
    - EU or Member State officials
      - Enforcement officers e.g. Trading Standards, Customs
      - Market Surveillance Authorities
    - A single specified Notified Body
      - If following an EU-Type Examination or Full Quality Assurance conformity assessment procedure
- It is in the authors interest to make the TD as easy to access and understand as possible…

Technical Documentation Assessment Considerations

- TD does not have to be a single document
  - Dedicated documents
    - Easier to maintain
    - Faster to access specific information
    - Easier to digest
- A logical, **organized** structure is a good idea
  - Disorganized documents
    - Take longer to assess = £££ €€€ 🕐🕐🕐
    - Difficult and/or inefficient to maintain
- An Index or Table of Contents is essential to rapidly find information within the TD

Technical Documentation Assessment Considerations

- A document to pull everything together is helpful
  - Some elements do not easily lend themselves to separate documents
    - List of applicable requirements
    - Justification statements e.g. why a particular standard has been partially applied
- The Blue Guide suggests that the TD may be part of the quality system
  - The TD could be a controlled document
    - One or more signatories
    - Modification record
    - Archived document history
  - This is a professional approach and is thoroughly recommended

Technical Documentation Assessment Considerations

- Where performance of the apparatus is dependent on good installation, inclusion of an installation guide is good practise
  - Especially where this has a direct impact on Safety
- Manufacturing elements that could affect compliance with the essential requirements must be adequately documented
  - e.g. Ferrites fitted to cables
    - The position of the Ferrite should be clearly shown on manufacturing drawings, work instructions etc.
  - e.g. Revision level of software controlling duty cycle of RF transmission
    - Assessment of the spectrum density may be necessary to demonstrate applicable limits are not exceeded

EU Declaration of Conformity

EU Declaration of Conformity

- A model of the **D**eclaration **o**f **C**onformity (DoC) is usually provided in an Annex to the applicable directive
  - 2014/30/EU – Annex IV
  - 2014/53/EU – Annex VI
- EN ISO/IEC 17050-1 can alternatively be used
  - Provided all of the requirements of the applicable EU harmonisation legislation are fulfilled

EU Declaration of Conformity

- Common mistakes i.e. Non-Compliances
  - E**C** instead of E**U**
  - Traceability information is not present
    - see Annex I to 768/2008/EC
  - Declaration includes Non-EU harmonisation legislation, e.g. UNECE Regulation 10
  - Declaration is to repealed EU harmonisation legislation, e.g. 89/336/EEC
  - Standard references are incorrect, do not include a Version or Date, or are outdated
  - The signatory is not legally empowered to bind the company
  - No place of issue stated

Further Market Surveillance

Further Market Surveillance

- Notified Bodies are required to inform the Notifying Authority of:
  - Refused, Restricted, Suspended or Withdrawn Certificates
  - Requests from Market Surveillance Authorities for information
- Notified Bodies are required to share information with other Notified Bodies on:
  - Negative assessment results
  - Positive assessment results
- Various databases have been established by the European Commission to facilitate the information sharing obligations of Notified Bodies

In Conclusion

In Conclusion

Thank You for Listening

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