Radio Equipment Directive – RED 2014/53/EU

MRA Workshop March 2016

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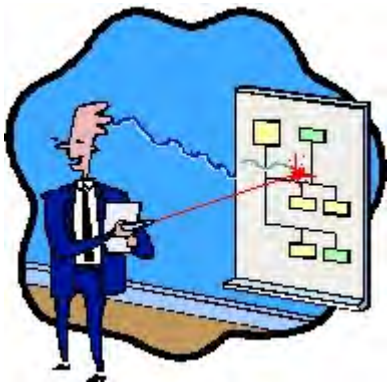


This presentation covers:

REDCA ©

Selection of RED issues with currently most questions asked.

13 June 2016

Are you ready to start the RED?

Putting into service on EU market

Putting into service = the moment of first use by the end user for the purposes for which it was intended. (this definition is not in EMCD & LVD!!)

MS shall allow the putting into service and use of RE:

- ✓ **if it complies with the RED;**
- ✓ **when it is properly installed & maintained; and used for its intended purpose.**

BUT

MS may introduce additional requirements for the putting into service and/or use of RE for reasons related to the:

- ✓**effective & efficient use of the radio spectrum;**
- ✓**avoidance of harmful interference;**
- ✓**avoidance of electromagnetic disturbances;**
- ✓**public health.**

Examples: User licence, MS Law on SAR levels for Mobile phones for children.

MAKE SURE YOU ARE AWARE OF NATIONAL RESTRICTIONS TO MARKET YOUR PRODUCTS OR TO SUPPORT YOUR CLIENTS

EU Legislation applies to Individual products!!

The concept of making available refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.

A very important rule with consequences as we will see later!

The specific product legislation for Radio Equipment

EMC and Low Voltage Directives never apply for Radio Equipment!!

Only the essential requirement

text in the RED is taken from EMCD and LVD!

So do not issue a DOC that references RED + EMCD + LVD! An incorrect DOC is a non-conformity!

Timing and transition periods

For products under R&TTED scope that remain to be in the scope of the RED

Products placed on the market before 13 June 2016

Must use R&TTED

Products placed on the market between 13 June 2016 and 12 June 2017

Can use R&TTED or RED

Products placed on the market after 12 June 2017

Must use RED

Products placed on the market between 13 June 2016 and 12 June 2017

Use R&TTED or RED

Many of you may have been informed that:

- **Products "New on the market" must use the RED, while only**
- **Products of a series or type that were already on the market before June 13, 2016 could still apply the R&TTED during the transition.**

This is absolutely incorrect!!

Any individual product placed on the market between 13 June 2016 and 12 June 2017

Equipment going from EMCD & LVD to RED scope

On June 13, 2016 the following products will move out of the scope of the EMCD and into the RED scope: (with a transition period of 1 year).

- **stand-alone receivers (not under control of a network);**
- **transmitters and transceivers with operating frequencies < 9 kHz;**
- **radio determination equipment operating < 9 kHz.**

Equipment going from EMCD & LVD to RED scope (2)

Examples are:

- **Broadcast receivers & Radio Scanners;**

(maybe DVB-C receivers stay under the EMCD?)

- **Railway applications (500Hz –2kHz),**
- **Robotic lawnmowers (1kHz –9kHz),**
- **Animal fences (1kHz –9kHz),**
- **Metal detectors (3kHz –20kHz),**
- **Stud finder (< 9kHz),**
- **Electronic article surveillance (10Hz –1kHz)**

For products within old EMCD/LVD but then fall within RED scope

Products placed on the market before 20 April 2016

Must use Old EMCD and Old LVD

Products placed on the market between 20 April 2016 and 12 June 2016

MUST use New EMCD and New LVD

Products placed on the market between 13 June 2016 and 12 June 2017

MUST use New EMCD and New LVD or RED

Products placed on the market after 12 June 2017

MUST use RED

Equipment going from R&TTED to EMCD & LVD

On June 13, 2016 the following products will not be covered by the RED or the R&TTED but only by the EMCD (and LVD):

No transition period!!!

All Telecommunication Terminal Equipment (TTE) as far as they have no radio function embedded!

Equipment going from R&TTED to EMCD & LVD (2)

Examples are:

- **Telephones**
- **Routers,**
- **Switches,**
- **Set-top boxes,**
- **Home networking adapters,**
- **LAN internet access gateways,**
- **Pay telephones,**
- **Telephone exchanges,**
- **Fax machines,**
- **Telephone answering machines.**

For products within R&TTED and then outside RED Scope but inside EMCD and LVD

Products placed on the market <u>before 13 June 2016</u>

must use R&TTED

Products placed on the market <u>after 12 June 2016</u>

MUST use New EMCD and New LVD

Note: But if the product is outside LVD voltage range, then LVD is not applicable (but General Product Safety Directive could be applicable

Problem of changing from R&TTED to EMCD and LVD

EU Commission has provided some flexibility applicable to TTE placed on the market before 1 January 2017.

If TTE (placed on the market before 1 January 2017) is covered by R&TTED (until 12 June 2016) and then by LVD/EMCD (from 13 June 2016), the EU DOC could contain the following statement

provided that the TTE is compliant with these Directives!

"The object of the declaration described above is in conformity with the relevant EU legislation: Directive 1999/5/EC (until 12 June 2016), Directive 2014/30/EU (from 13 June 2016) and Directive 2014/35/EU (from 13 June 2016)."

Identifying EO in the chain

All EO shall be able to identify

- **EO who have supplied them with RE, and**
- **EO to whom they have supplied RE**
- **And keep the information for a period of 10 years**

How to comply with this requirement is not prescribed by the RED, but it must be noted that MSA can ask for relevant documents, including invoices, allowing the origin of the product to be traced.

Hence, it could be useful to keep invoices for a longer period than envisaged in accounting legislation to comply with the requirements on traceability.

Tracebility Requirements for EO

Manufacturers & all Importers must indicate the following 3 elements:

(1) name; (2) registered trade name or registered trade mark & (3) postal address at which they can be contacted,

on the product or, where that is not possible, on its packaging or in a document supplied with the product.

A website is additional information, but not enough as an address. Normally an address consists of street & number or post-box & number and postal code and town, but some countries might deviate from this model.

The address is not necessarily the address where the manufacturer is actually established. It can for example be the address of the Authorised Representative or of the "manufacturers customer services" location.

There is no obligation:

- **that addresses have to be preceded by the words "Manufactured by", "Imported by" or "Represented by".**
  - **This information must however not mislead the end-user & the MSA about the place of manufacture and the address of each EO.**
- **to translate into all necessary EU languages the words "manufactured by", "imported by" or "represented by".**
  - **These words are considered to be easily understandable in all official EU languages.**

Tracebility Requirements for Manufacturers

Manufacturers must also ensure that their products bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

Tracebility Requirements: Additional Rules

The identification data on the product has to be the same as the data on DoC and in the Technical Documentation.

The data must, be affixed to the product. However, it may exceptionally be moved from the product, where affixing it to the product was not possible under reasonable technical or economic conditions, excluding however esthetical reasons.

The manufacturer assesses this. This assessment has to be done according to the size or nature of the product. Some products e.g. hearing aids, sensors or the like are simply too small to carry such information.

Order of priority for the alternatives

1. **the information should be on the packaging,**
2. **the information should be on an accompanying document**

Tracebility Requirements: Conclusion (1)

A product normally bears 1 or 2 addresses

A. Manufacturer is within the EU:

Product will bear only 1 (manufacturer's) address as there is no importer involved.

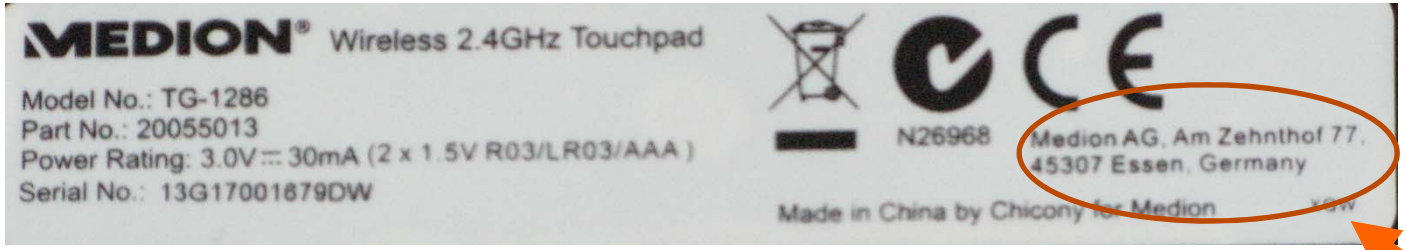
B. Manufacturer is outside the EU and the products are placed on the EU market by an importer:

Product will bear 2 addresses: one of the manufacturer and one of the importer.

Tracebility Requirements: Conclusion (2)

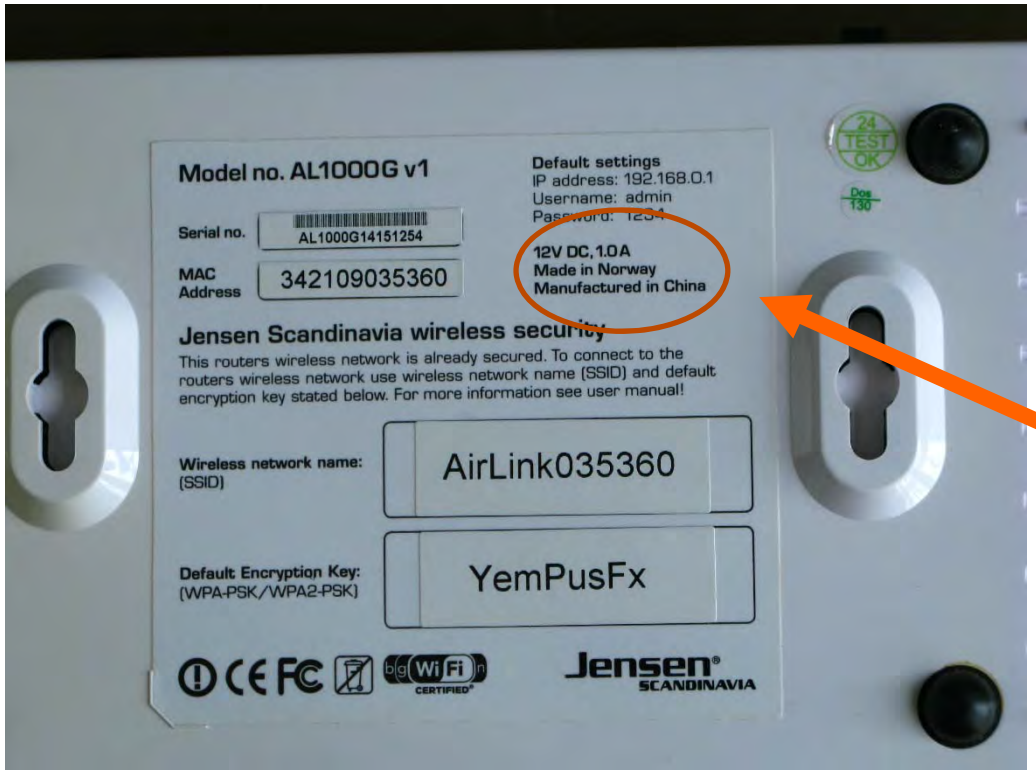
C. Manufacturer is outside EU and importer puts the product under his own name/ trademark on the market, the importer is then considered the manufacturer. The only address in this case is the address of the importer who is considered as the manufacturer.

D. Manufacturer is in EU (a company located in the EU declaring itself to be a manufacturer by putting its name & address on the product) although the products are manufactured outside the EU, that company is considered to be the manufacturer who places the product on the EU market, even if actual importation is done by another company. In this case there is no importer in the meaning of the importer's definition and it is sufficient to put only the manufacturer's address.



OK

Example C or D



NOT OK!

No address at all

Example of confusing CE Marking on wireless waiter call device

NOT OK!

Looks like NB number but it is not!

Risk assessment & Essential Requirements (1)

The Risks are always related to the: Essential requirements.

EMCD: risks are only EMC related (creating interference or due to immunity not allowing a product to perform its function correctly)

LVD: risks are only safety related (electrical hazards to humans, domestic animals and property)

RED: risks are Radio related + Safety related (SAR!) + EMC related + other aspects.

Toys: risks are related to harming children

Administrative non-compliances are not considered to be a risk.

Essential Requirements & Risk Assessment (2)

Essential requirements must be applied as a function of the hazard inherent to the product.
Therefore, manufacturers must:

1. carry out a risk analysis to identify all possible risks that the product may pose, and then
2. determine the essential requirements applicable to the product.

This analysis has to be documented and included in the technical documentation, unless the risk assessment is fully included in the HS applied and cover(s) all applicable essential requirements. (CHECK THAT!!)

Deleted Items in the RED compared to R&TTED

- Notification
- Alert Sign
- CE marking in manual

BUT: CE needs to be on product and packaging! (not for EMCD and LVD)

RE must also be accompanied by a copy of the EU DoC or by a simplified EU DoC TEXT. (not applicable for EMCD or LVD!)

Why is “”Notification”” not necessary anymore??

- **EU Member States have to use the ERO Frequency Information System (EFIS) in order to make information on the use of spectrum in each MS available to the public.**
- **RE Manufacturers can then search in EFIS and evaluate whether and under which conditions RE may be used within each MS.**

Therefore in the RED there is no need to include additional provisions, such as prior notification.

Extra RED requirements (not in EMCD & LVD)

Software requirements
Product registration
Manufacturers Sample testing
Simplified DoC
Information in user instruction
Geographical information

Software Defined Radio

Subgroup on SDR is now active

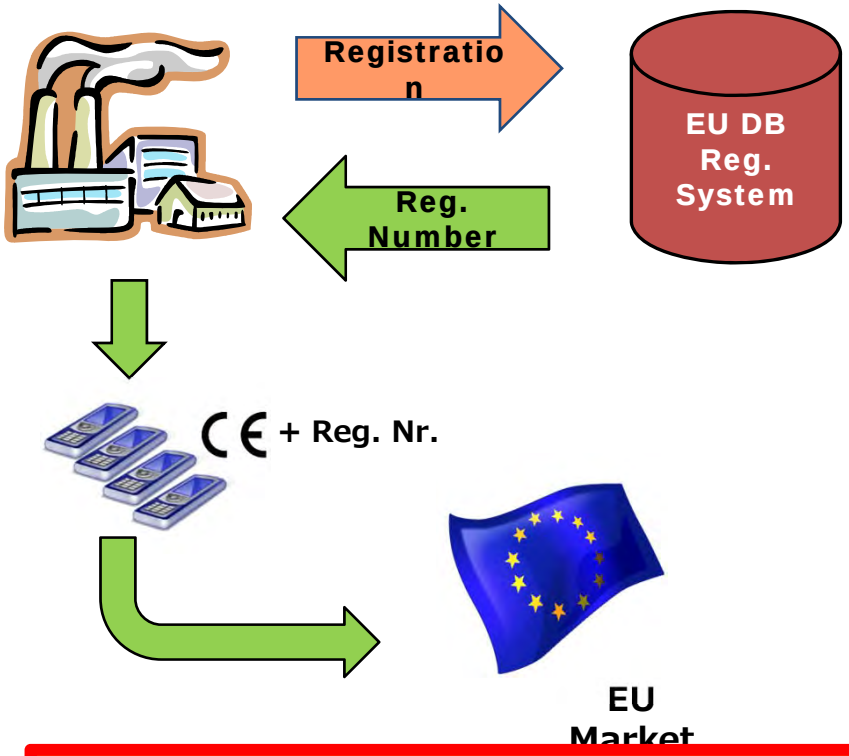
- To provide guidance to the Commission regarding the scope and content of delegated act(s) in accordance with Article 4.1 of the RED.

- Provide guidance to the Commission regarding the scope and content of implementing act(s) in accordance with Article 4.2 of the RED.

- As the state of the art and trends in the industry to cover the essential requirement in Article 3.3(i)

Target date December 2016

Product Registration scheme for Radio Equipment (RED Art. 5)



So the scheme requirements are set but if it ever will be used?

From 12 June 2018, <u>depending on the level of compliance in EU</u>, the Commission **<u>can</u>** set up a registration scheme **for selected radio equipment.**

Criteria to set up registration, types of equipment and information to be registered, operational rules for registration and labelling **<u>will be decided by the Commission</u>**.

After registration, manufacturers are given a **<u>Registration Number</u>**, which shall be **<u>affixed</u>** to the radio equipment.

RED Instruction manual

RE must be accompanied by instructions and safety information in a language which can be easily understood by consumers/end-users.

Instructions shall include:

- ✓**Information on RE intended use.**
- ✓**Where applicable, a description of accessories and components, including software, which allow the RE to operate as intended.**

Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

+ Only for transmitters:

Frequency band(s) in which the RE operates;

Maximum radio-frequency power transmitted in the frequency band(s) in which the RE operates.

Geographical area information

The packaging shall:

- ✓ **allow to identify the MS or the area within a MS where RE cannot be put into service;**
- ✓ **alert the user to potential restrictions or requirements for authorisation of use in certain MS.**

Such information shall be completed in the instructions accompanying RE.

Commission Regulation (Proposal)

The packaging shall indicate a detailed written description or contain a simplified description or contain a pictogram (see next slide), in a language easily understood by end-users.

If a RE is subject to restrictions on putting into service or of requirements for authorisation of use, the instructions accompanying the RE shall indicate, specifically the geographical area within Member States where restrictions on putting into service or requirements for authorisation of use exist, as well as the types of requirements or restrictions applicable in every Member State.

This Regulation shall enter into force on the twentieth day following that of its publication in the *OJEU*, and it shall apply as of …..[6 months after?]

RE, which is placed on the market after [date: one day before the entry into force] and is in conformity with this Regulation, shall be deemed to be in conformity with Article 10 (10) of Directive 2014/53/EU.

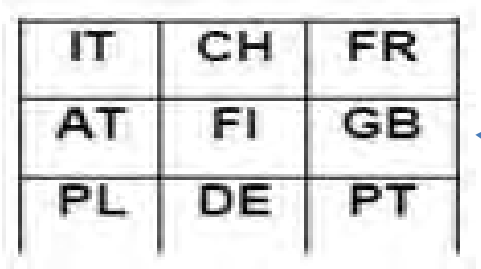
This Regulation shall be binding in its entirety and directly applicable in all Member States.

Text & Pictogram proposal (example of some countries involved)

'Restrictions in IT, CH, FR, AT, FI, GB, PL, DE and PT'

The above simplified description shall only mention the Member States where any restrictions on putting into service or any requirements for authorisation of use exist.

'Restrictions in:



The pictogram shall only mention the abbreviations of the Countries where any restrictions on putting into service or any requirements for authorisation of use exist.

Belgium (BE), Greece (EL), Lithuania (LT), Portugal (PT), Bulgaria (BG), Spain (ES), Luxembourg (LU), Romania (RO), Czech Republic (CZ), France (FR), Hungary (HU), Slovenia (SI), Denmark (DK), Croatia (HR), Malta (MT), Slovakia (SK), Germany (DE), Italy (IT), Netherlands (NL), Finland (FI), Estonia (EE), Cyprus (CY), Austria (AT), Sweden (SE), Ireland (IE), Latvia (LV), Poland (PL) and United Kingdom (UK).

Discussions on other pictograms are ongoing.

Declaration of Conformity – DoC

The DoC shall

- be a complete copy of the original.
- **be packed with each RE. (Not for EMCD / LVD)**
- have the “model structure” and it shall be <u>continuously updated</u>.
- be translated into the language(s) required by the MS in which market the apparatus is placed or made available.

Simplified DoC (not for EMCD or LVD!)

- **Copy of full EU DoC shall accompany each RE.**
- **This may be replaced by a: simplified EU DoC accompanying each RE!**
- **If a simplified EU DoC is provided, it shall be directly followed by the exact internet or e-mail address where the full EU DoC can be obtained.**

Simplified DoC (not for EMCD or LVD) (2)

Simplified EU DoC shall contain the following text:

Hereby, aaaaa declares that the RE type [designation of type of RE] is in compliance with RED 2014/53/EU.

The full text of the EU DoC is available at the following internet address: **********

It shall be translated into the language(s) required by the MS in which market the RE is placed or made available.

(copies of simplified DoC text can be found in each language version of the RED or on EU Commission website)

What is the advantage of using the simplified DoC?

1. **Save paper by providing only the simplified DoC text in the product package. On your website you then store the Full DoC in all the necessary languages.**

2. **when something needs to change in the DoC (*remember the RED says the DoC should be continuously updated*) you can easily do that on the website without having to change the paperwork in the product package. The standard simplified text does not need to change in most cases.**

Manufacturers Sample testing

When deemed appropriate with regard to the risks presented by RE, manufacturers shall, *to protect the health and safety of end-users*,

- **carry out sample testing of RE made available on the market;**
- **Investigate & if necessary, keep a register of complaints of non-conforming RE & RE recalls;**
- **keep distributors informed of any such monitoring.**

When Technical Documentation is not complying and *fails to present sufficient relevant data or means used to ensure compliance of RE with the essential requirements, then:*

MSA may ask the manufacturer or importer to have:

- ***a test performed by a <u>body acceptable to the MSA;</u>***
- ***at the expense of the manufacturer or the importer;***
- within a ***specified period***

in order to verify compliance with the essential requirements. **(not in the EMCD)**

Miscellaneous

Appliances with Radio Modules

Some description in draft ETSI Guide (EG) 203 367 which is now a late stage “draft” (an EG cannot be harmonised!)

None wireless LVD / EMC standards are not referred to by the RED and will not be listed in the RED OJEU when published.
ETSI EN 301 489-x to cover this area (which can then be harmonised).

Next year’s **Market Surveillance Project**: Radio Controlled Toys

Next publication of **list of HS in OJEU for R&TTED** in Q2 of 2016

Formal objection from France to **EN 50566:2013** (Body and Limbs SAR)
Alternative options to wording suggested, EU Commission to review these ideas

MoU on the **Common Charger connection**, this is still a work in progress, if there is no agreement more formal action may be taken by the EU Commission

Is REDCA of interest to you?

Most rapid access to the constantly changing EU legislation / regulation and EU Standards development.

Possibility to get rapid answer from fellow experts on specific RED (technical) questions.

> 165 members (many also from outside EU)

Annual Fee: 500 EURO
Interested? Go for information to:
www.redca.eu
or talk to me!!

RED-CA

Radio Equipment Directive - Compliance Association

Thank you for your attention

Any QUESTIONS ??