MIC MRA International Workshop, March 2019

Questions currently raised in the application of the RED.

Presented by Chairman REDCA: ピーター デ ベアー
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On behalf of:

REDCA
Radio Equipment Directive Compliance Association

Used Abbreviations in RED correspondence

ADCO = Administrative Cooperation group of Member States Authorities
BG = Blue Guide
DoC = EU Declaration of Conformity
EFIS = ECO Frequency Information System
EM = Electromagnetic EMC = Electromagnetic Compatibility
EMCD = EMC Directive2014/30/EU
EO = Economic Operator
EU = European Union (28 countries)
EUANB = EU Association of Notified Bodies (for the EMC-D)
GPSD = General Product Safety Directive2001/95/EC
HS = Harmonised Standard
LVD = Low Voltage Directive 2014/35/EU
MRA = Mutual Recognition Agreement between EU and other countries (Japan/USA/etc)
MS = EU Member States (for applicability of the Directive: covers also EFTA countries)
MSA = Market Surveillance Authority of the MS
NB = Notified Body
OJEU = Official Journal of the EU (where all legislation is published and other material)
RE = Radio Equipment
RED = Radio Equipment Directive 2014/53/EU
REDCA = Radio Equipment Directive Compliance Association
TEC = RED Notified Body EU Type Examination Certificate (also: **EU TEC** or **REDTEC**)
TGN = REDCA Technical Guidance Note
TD = Product Technical Documentation

Radio Equipment Directive 2014/53/EU

Amendments:

- Regulation (EU) 2018/1139 *on common rules in the field of civil aviation of 4 July 2018* and replaces Regulation (EC) No 216/2008 which is repealed with effect from 11 September 2018.
  Therefore modifications made to Annex I of RED, point 3. See also consolidated version of the RED

Other interesting information:

- Proposal 2017/0353 *rules and procedures for compliance with and enforcement of EU harmonization legislation on products and amending Directives ------, 2014/35/EU, 2014/53/EU,* proposed change that could affect the RED, DoC. Manufacturers shall make the DoC publicly available on their website or, by any other means that allows the DoC to be readily accessed by the general public in the EU free of charge. (at EU council, see proposed amendments)

- Communication from the commission related to: *"The Goods Package: Reinforcing trust in the single market" internet-connected radio equipment and wearable radio equipment, (public consultation).* This proposed act aims at strengthening the security of internet-connected devices, most of which are expected to be part of the Internet of Things, and of wearable radio equipment

- *The upload of software on radio equipment (public consultation).* This initiative specifies the categories of radio equipment covered by additional essential requirements relating to reconfigurable radio systems.

- *Publication of the Report on the operation of the Radio Equipment Directive (RED)* prepared for the purposes of both Articles 44 (2) and 47 (2) of the RED.

Delegated & Implementing acts for RED

- The RED Gives the EU Commission power to make additional (detail) legislation without changing the RED text itself. (*this avoids going via the long process of involving the EU Council and EU Parliament*).
- The RED Mentions the elements for delegated acts and/or implementing acts

Status of acts currently under discussion/preparation/or ready

- **Article 3.3a on a common charger,**
- **Article 3.3e and f to cover privacy and prevention of fraud**
- **Article 3.3g Galileo**
- **Article 3.3i and Article 4 relating to the updates of software into RE**
- **Article 5: Registration of RE within some categories**
- **Article 10.10: Restrictions of RE**

Delegated & Implementing acts for RED

Article 3(3)a: Common Chargers *(interworking with accessories)*

Pending: This has been discussed several times in past, and it was noted that there has been unsatisfactory progress, so EU commission is looking for other regulatory options. A delegated act is possible, a study is about to start (7th Jan onwards). The EU commission will publish a roadmap for public consultation. The impact assessment may decide on a delegated act, or not.

Articles 3(3)(e/f) personal data and privacy and prevention of fraud

Pending: EU commission decided to launch a study, similar to common charger, input for study/delegated act. Originally, the commission considered to limit scope of study to higher risk items, toys etc., then later decided to enlarge all connected devices under the scope of the RED. The contract for the study is about to be signed, in January. Then the commission expect a published roadmap and how inputs can be made. EU Commission is trying to ensure that all legislation is consistent, such as working with DG Connect. The commission hopes a roadmap should be available around Feb 2019.

Articles 3(3)g: access to emergency services: Galileo

Pending: An act has been adopted on 12th December 2018 by the EU Commission with a 2 month scrutiny period (if need with 2 more months if parliament need it). The Standards have to be development by ETSI. There are some discussions related to the use of Wi-Fi trade mark and radio access on 5 GHz. In November 2018 there was a consultation, no objection were raised at that time.

Technical solutions for compatibility and interworking with at least the EU Galileo system, for calls made to at least the single European emergency number '112' referred to in Directive 2002/22/EC

Delegated & Implementing acts for RED

Article 3(3)(i) and 4: software into RE related to compliance

Pending: Issues have been discussed e.g. List of classes and categories for further analysis. These were fed into the terms of reference for a study, analysing replies for the study. Once these have been reviewed a contractor will be appointed. Next meeting is planned for 27 Feb 2019. See also the consultation activities.

Software for radio's to be used as intended under conditions allowed.

Additional requirements may be needed.

- EU Subgroup on SDR is now active (TCAM)

- 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)

Some recommendations from the study:

- *Software radio shall be covered by a generic definition.*

- *Only software possibly affecting compliance of the RE in which it is downloaded is to be taken into account.*

- *Article 3.3.i shall be applied where the compliance to the RED essential requirements may be influenced by software.*

- *The Act shall focus on the vertical market model where one single entity is responsible for the conformity of the combination of RE and software,*

- *ETSI to be mandated to develop HS on technical solutions to prevent "non-compliant" software to loaded into RE.*
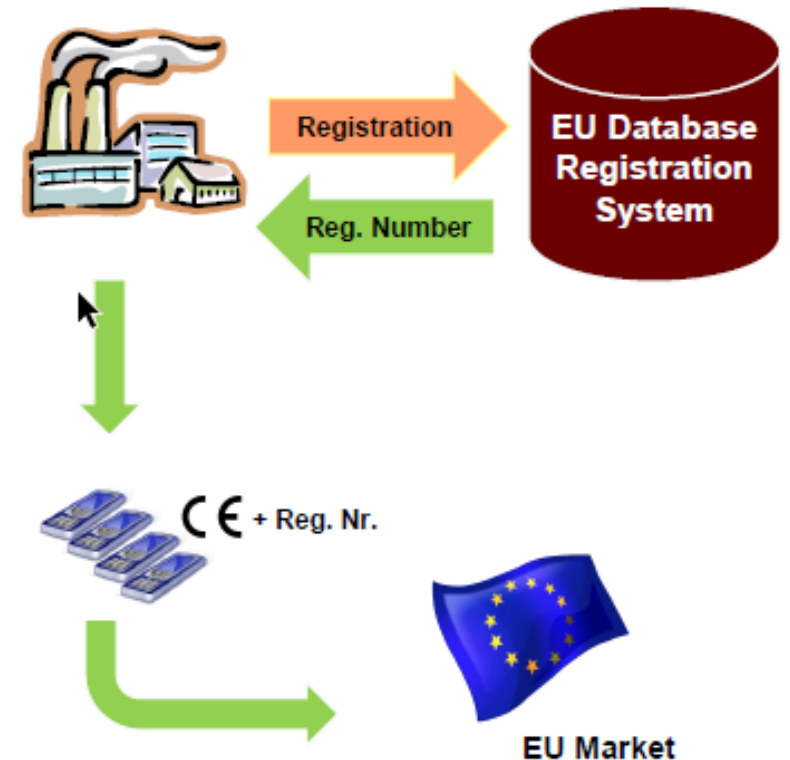
Delegated & Implementing acts for RED

Article 5: Registration of RE within some categories

Ready: to be implemented when needed, however **NO IMPLEMENTATION ACT YET!**

- **From 12 June 2018, <u>depending on the level of compliance in EU</u>**, the Commission **could** 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 labeling **will be decided by the Commission, but not yet ready**

- After registration, manufacturers are given a **Registration Number**, which shall be **affixed** to the radio equipment.

- Definition of *<u>RE with a low level of compliance with essential requirements</u>* will be needed and not yet defined

The scheme requirements are set but will it ever be used?

Registration → EU Database Registration System

Reg. Number

CE + Reg. Nr.

EU Market

Delegated & Implementing acts for RED

Article 10.10: Restrictions of RE

Ready: On 20 July 2017, Regulation(EU) 2017/1354 was adopted and is in force as from August 09, 2018

- In cases restrictions on putting into service or of requirements for authorization of use, **information available on the packaging** shall allow the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorization of use exist. Such information shall be completed in the instructions accompanying the radio equipment.

- If RE is subject to restrictions, the packaging shall indicate visibly and legibly:

a) a pictogram or

b) the words 'Restrictions or Requirements in', in a language easily understood by end users as determined by the MS concerned, followed by the abbreviations of the MS, where such restrictions or requirements exist.

Delegated & Implementing acts for RED

RED art. 10.10 example on package with pictogram

- The pictogram shall be in the form of a table and its contents may take different variations (e.g. color, solid or hollow, line thickness), provided that they remain visible and legible

- Also EFTA countries (e.g. CH, NO, LI, TR) may also be included. These countries are supposed to follow the RED regulations.

AT	BE	BG	CZ	DK
EE	FR	DE	(IS)	IE
IT	EL	ES	CY	LV
(LI)	LT	LU	HU	MT
NL	(NO)	PL	PT	RO
SI	SK	(TR)	FI	SE
(CH)	UK			

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

◯ = EFTA Countries, considered to apply the similar regulation

RED art. 10.10 example on package in text:

- *"Restrictions or Requirements in: BE, BG, CZ, EL, CY, SI"*

Delegated & Implementing acts for RED

Where to find **information related to restrictions and possible use of RE in the EU** (art. 10.10 and art 10.2)

EFIS= ECO Frequency Information System, a database which contains frequency information for CEPT countries. EFIS is also the EU spectrum information portal in accordance with the EU Commission Decision 2007/344/EC on the harmonized availability of information regarding spectrum use in Europe.

- To find out if a so called radio interface exist in the EU (or EU member state), the manufacturer can go to the EFIS database, see: https://www.efis.dk/

- In this database the radio interfaces for each member state can be found (Radio interface => frequency allocation requirements)

- *The manufacturer can also find information in that database (see art RED 10.2):*
  - *Whether the RE can operate legally in at least one MS.!*

- Also other information to find restrictions and radio interfaces for particular categories of Radio Equipment::
  - ERC recommendation 70-03 and 2017/1483
    - Class 1 equipment
    - SRD regulations

- If no solution can be found then go to the relevant country Spectrum Authority, see EU website: http://ec.europa.eu/docsroom/documents/25821

Questions:

1. **After Brexit, can we place CE marking products on the UK market in the same way as in the EU?**
2. **Are RED TEC's issued by a Notified Body in the UK valid after March 29, 2019?**

1. At this moment it will be most likely that there will be no MRA between UK and EU (and also other regions/countries). This means that UK will be considered to have their own rules for market access. There has been a publication how products should be labelled and the process of putting products on the UK market. See info on www.gov.uk

2. A RED TEC can only be issued by an EU Notified Body. Since UK is no longer a EU member state, the Notified Bodies of the UK will no longer be able to submit RED TEC's after March 29th. Also equipment accompanied with a RED TEC issued by a UK Notified Body before March 29th can not be accepted after March 29th. This is based on the fact that each individual product has to comply with EU regulations **valid at the moment it enters the EU market.**

   After March 29, 2019 only RED TEC's issued by valid EU Notified Bodies can be accepted.

   See also information on the EU website…

European safety rules for civil drones

Questions:

1. **What are the current regulations with respect to drones in the EU**
2. **Are drones in the scope of the RED?**

1. National regulations ruling civil operations of drones lighter than 150 kg are replaced by new European legislations.

   Regulation [(EU) 2018/1139](#), applicable as of 11/9/2018, repealed and replaced Regulation 216/2008 as amended.

2. Yes, drones are subject to the RED, see [New RED guide](#) of December 2018, clause 1.6.2.4

   See also [consolidated version](#) of the RED

CIVILIAN DRONES
Rules that apply to all EU countries

"A drone is an aircraft that operates without a crew aboard"

The new EU rules ensure that the following are respected:

safety   privacy   data protection   environment

Possible usage of drones:

Surveillance, inspection, photography

Inspection of pipelines and power cables, spray crops, search and rescue, control borders and monitor forest fires

Geospatial surveying and wide-area surveillance

Source
European Parliamentary Research Service

europarl.europa.eu

Equipment operating below 9 kHz

Question:

Without HS, is it possible to bring equipment operating on frequencies below 9 kHz on the EU market?

- **Yes, but 2 major issues :**
  - 1. Legal certainty: In some MS equipment below 9 kHz, seems to be illegal as there is no legislation permitting their use and in others no legislation is identifying them as either license exempt or requiring a license.
  - 2. Possible RED Compliance standards are not yet acceptable and will not be listed in the OJEU soon:
    - EN 303 348 T-coil devices
    - EN 303 454 metal sensors
    - EN 303 447 robotic mowers
  - *In preparation EN 303 660, RE operating below 9 kHz (generic) however still pending*

- Reasons for this rejection are:
  - No emission limits/measurements for compliance.
  - No other limits are available in CEPT and/or ITU, ETSI

Equipment operating below 9 kHz

- **Current situation:**

- Many millions of hearing aid users are using an illegal device and many millions of shops, theatres etc. are also using illegal transmitting devices with RE operating blow 9 kHz

- Manufacturers of this equipment may (via a NB) place equipment on the market (but do not know how to label it as the spectrum is not harmonized) and the purchaser may not legally use it.

- The absence of regulations and (harmonized) standards affects millions of products and equipment currently on the market.

- You need to use and to consult a Notfied Body for the method chosen to show compliance with the RED art. 3.2 essential requirement for RE equipment operating below 9 kHz

If no solution can be found then go to the relevant country Spectrum Authority, see website:
http://ec.europa.eu/docsroom/documents/25821

Broadcast receivers

Question

> **1. Are broadcast receivers covered by the RED?**
> **2. How can Broadcast receivers comply with the RED?**

1. **Yes**, broadcast receivers are covered by the RED and no longer by the EMC-D and LVD

2. For Broadcast sound receivers (e.g. FM, AM DAB, DVB-T) there are currently no art. 3.2 Harmonized standards available yet.

- Reasons for this rejection are:
  - No acceptable radio receiver parameters and limits/measurements in HS for compliance.

- EN 303 345 standard prepared by ETSI has not been acceptable by the EU com and will not be listed in the OJEU
  - Currently ETSI EN 303 345-1 V1.1.0 (2018-09) out for comments describing only measurement methods, no limits. Other parts will follow for each broadcast application (AM, FM, DAB etc) arte expected
  - Possible option to show compliance is by using EN 303 345 V1.1.7, a version in which receiver parameters have been included, however no consensus about the limits. Limits for e.g. AM are considered to be too severe…

- **You need to use and to consult a Notified Body to show compliance with the RED art. 3.2**

Radio Modules

1. Does a radio modular approvals system exist in the EU?
2. How to show compliance when an approved RE (approved module) is included in the end device

1. RED does not describe or defines "Modules", so RED has no separate regulation for "Modules"

- If a device has a function declared by the manufacturer (Rx, Tx or Rx+Tx) then according the RED **it has to be an end device** and has **to comply with all essential requirements** of the RED:
    - Manufacturer may call a Radio Equipment device a "Module".
    - That Radio Equipment device may consist of components together having Rx/Tx functions
    - Can also be a Soldering device, particular chipset, PCB circuit with, or without, shielding

2. If a Radio Equipment device is incorporated into a non-radio product (such as Toys, Machines, Kitchen Appliances) in a permanent way and cannot be easily accessed and removed by the user, the new end device (the non-radio device + the radio-device) has to comply with the RED.

3. If RE is incorporated into non-electrical equipment, only the RE shall comply with the RED; This means that e.g. the safety of the non-electrical parts is not covered by the RED! But other Directives may apply.

Radio Modules

Other information:

- **Guides & EMC Standards for "Combined Equipment" containing useful guidance.**
  - ETSI Guide EG 203 367 V1.1.0: covering RED articles 3.1b and 3.2
  - EN 303 446-1 V1.1.0 combined equipment in the domestic environment covering essential requirements article 3.1(b)
  - EN 303 446-2 V1.1.0 same as part 1, but for industrial environment
- How conformity can be assessed with an approved non-radio end device and an approved Radio device mounted together is described in **REDCA "Technical Guidance Note 01** on the RED compliance requirements for a Radio Equipment often referred to as Radio Module and the Final Radio Equipment Product that integrates a Radio Module" which is <u>downloadable for free from www.redca.eu</u>

How to let a product comply with the RED

Short summary:

1. **Identify the product**
   - Pictures
   - Product identification
     - type, batch or serial number or other element allowing its identification

2. **Identify the function and environment**
   - Normal operation (to be used for)
   - Indoor/outdoor
   - Usable in at least one EU member state?
     - Air interface available for used frequency?
   - More Directives due to function?

3. **Perform Risk analysis**
   - All related to RED **Essential Requirements**
   - Cover risk by selecting (harmonized) standards
   - Test reports/Test data
     - **Smart testing !!!**
     - CB reports
     - Accredited Lab's

4. **Select conformity assessment procedure**
   - Module A, B/C or H

5. **CE marking and other label requirements**

6. **Make Technical Documentation**
   - Be consistent in identification of product
   - Name, type identifications etc.

7) **Provide Information to the user (art 10!!!)**

8) **Finalize the TD and DoC**

It is the responsibility of the Manufacturer to make a Radio Equipment Compliant with the RED essential requirements and to make the Technical Documentation
A manufacturer cannot delegate this to another Economic Operator e.g. representative, importer, module manufacturer etc.

Risk analysis

Question:

1. How to perform a risk analysis?

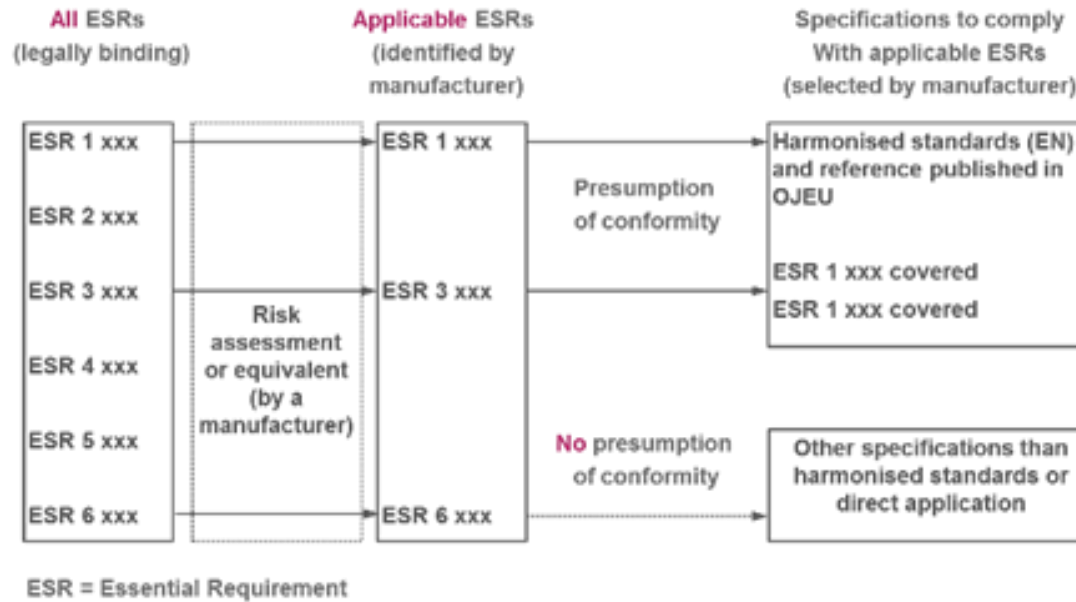The Risks are always related to **all Essential requirements**.

- RED: risks are *Radio related + Safety related (SAR!) + EMC related + other aspects*.
  - *Administrative non-compliances are not considered to be a risk*.
  - 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.
- Risk Assessment also very important when RE will be modified or has been modified
  - *Integrating modules…..*

Risk analysis

Other information:

Risk Assessment and the role of harmonised standards (4.1.2.2 Blue Guide)

All ESRs (legally binding)		Applicable ESRs (identified by manufacturer)		Specifications to comply With applicable ESRs (selected by manufacturer)
ESR 1 xxx		ESR 1 xxx	Presumption of conformity	Harmonised standards (EN) and reference published in OJEU
ESR 2 xxx				
ESR 3 xxx	Risk assessment or equivalent (by a manufacturer)	ESR 3 xxx		ESR 1 xxx covered ESR 1 xxx covered
ESR 4 xxx				
ESR 5 xxx			No presumption of conformity	Other specifications than harmonised standards or direct application
ESR 6 xxx		ESR 6 xxx		

ESR = Essential Requirement

- CENELEC Guide 32: Guidelines for Safety Related Risk Assessment and Risk reduction for Low Voltage Equipment
    - Download free of charge from:
    - https://www.cenelec.eu/membersandexperts/referencematerial/cenelecguides.html
- Blue Guide Section 2.7 and 4.1.1 and 4.3
- **REDCA Technical Guidance Note** for a Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/53/EU (The Radio Equipment Directive) **TGN 30** which is downloadable for free from www.redca.eu

Risk analysis

Summary

1. First identify all possible risks and then determine which RED essential requirements are applicable to the product. This analysis has to be documented and must be included in the TD.

2. Then document the assessment of how the risks identified are going to be addressed (for example, by applying certain HS, or standards or other technical rational).

All risks shall be covered by the technical solutions applied (standard or other technical motivation)!

Notes:

- State the relevant phenomena of the RE and its environment.
- Compare the typical and reasonably foreseeable use of the RE to the parameters in the standards:
    - Do the (*HS)standards used really cover all of the identified risks*?
    - ***Intermodulation, co-location of transmitters, other nearby high RF fields***
- Where the RE can take different configurations, check that the assessment confirms that the RE meets the essential requirements, "in all possible configurations" (see art. 17)
- If only part of the HS is applied or it does not cover all applicable essential requirements, then the way applicable essential requirements not covered by the HS, are dealt with, must also be documented.
    - In case for art 3.2 and 3.3 => NB needed and *also NB must notify member states about this case*

How to be informed about changes?

REDCA

The REDCA provides a forum for people concerned with the compliance of radio equipment with regulations and technical standards in the European Economic Area, as well as in the Countries that have a Mutual Recognition Agreement with the EU, such as the USA, Canada, Japan, New Zealand and Australia.

In particular formed under the requirements of the Radio Equipment Directive 2014/53/EU specifically for Article 26.11 and Article 38 for Notified Bodies (sectorial group of notified bodies)

Members are:
- **Notified Bodies, Manufacturers,**
- **Testing Laboratories & Consulting Companies**
- **Member states and administrations**
- **Authorities from MRA regions, etc.**

and they all need to follow the aims and objectives set out in the Associations Rules and Constitution.
Annual fee for REDCA Membership is €625

REDCA

- REDCA offers the following activities and information (and is not limited to these)
  - Rapid access to the constantly changing EU legislation/regulation and EU Standards development.
  - (Draft) material often available before general public gets it. (e.g. Guides, Implementing Acts, etc.)
  - Liaison with EU Commission, ADCO, ETSI, ECC, TCAM etc.
  - Possibility to get answers from fellow experts on specific RED (technical) questions.
  - Special Workshops
- REDCA publishes Technical Guidance Notes and reference Doc's
  - See website http://www.redca.eu
- The Association meets twice a year in a location within the EEA
  - Members only
  - Representatives of the EU Commission, ECC, ETSI, ADCO RED and authorities from MRA countries.
  - **Next meeting on May 13-14 in Sofia (Bulgaria) with a workshop on May 13th**
- Has a mail server for members where they can ask questions that will trigger answers and comments from the experts within the Association
- Has a specific protected area on the CIRCABC website for all working documents.
- Maintains the Notification data base to other NoBo's as required by Annex III clause 8, on CIRCABC.

Useful links to information related to RED

1. **RED text** and other relevant publications on:
   https://ec.europa.eu/growth/sectors/electrical-engineering/red-directive_en

2. **BG** 2016 on: http://ec.europa.eu/DocsRoom/documents/18027/

3. **RED Guide** (latest version: 19 December 2018) on: https://ec.europa.eu/docsroom/documents/29782

4. **List of RED NB** on NANDO website *(see link item 1)*

5. **List of National Spectrum Authorities** on: http://ec.europa.eu/docsroom/documents/25821

6. **List of HS's** *(see link item 1)*

7. **List of RED Subclasses** *(see link item 1)*

8. **Commission RED delegated acts** *(see Link1)*

9. **List of EU decisions applicable to the RED** *(see link 1)*

10. **E-Commerce Guide Commission** Notice on market surveillance of products sold online on:
    http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=126363

11. **GPSD** on: https://ec.europa.eu/info/business-economy-euro/product-safety-and-requirements/consumer-product-safety/product-safety-rules_en

12. **RED ADCO** on: https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en.

13. **List of MSA** on: http://ec.europa.eu/docsroom/documents/25641.

14. **Class 1 equipment** (harmonized) on: http://ec.europa.eu/docsroom/documents/26843

Useful links to organizations related to RED

1. **REDCA material (e.g. Technical Guidance Notes)** on ***www.redca.eu***.
   Some material is protected and only for members.

2. **ETSI material ((Draft) RE Standards/Guides)** on ***www.etsi.org***.
   All approved EN/HS & Guides are free for downloading

3. **CENELEC material (Standards & Guides) on electrical safety/ SAR/EMC etc**.
   on ***www.cenelec.eu***.

   Mostly only available for a fee. Check EU National Standards Organizations that
   sell, because of substantial different prices**!**

4. **ECO material (EFIS – European Frequency Information System + news
   letters) on https://cept.org/eco**.

REDCA

For more information or to apply for membership of the REDCA please go to:

www.redca.eu

Or contact:

secretariat@redca.EU

THANK YOU
FOR YOUR
ATTENTION