FAQs – Radio Equipment Directive (RE-D)

What is the objective of the RE-D?

The Radio Equipment Directive (2014/53/EU) was adopted in 2014 and Member States had to transpose it into their national law before 13 June 2016. It revises the Directive on Radio and Telecommunication Terminal Equipment (1999/5/EC) and sets down requirements on safety, health protection and electromagnetic compatibility. It also ensures the efficient use of radio spectrum and provides the basis for further regulation governing some additional aspects (e.g. access to emergency services, interoperability, safeguards to ensure the protection of privacy and personal data). The Directive applies to radio equipment, such as domestic television and radio sets, mobile phones as well as Wi-Fi, Bluetooth and GPS or other satellite transceivers. The aim is to provide an open market for telecoms products and allow equipment which has been approved for use in one EEA country to be made available in any other.

Which equipment falls within the scope of RE-D?

- Televisions and radio receivers, which were not covered by the R&TTED, now fall within the scope of the RE-D.
- Equipment operating below 9 kHz also now falls within the scope of the RE-D.
- Radio-determination equipment is now clearly included in the RE-D.
- Any other radio equipment which was under the R&TTED, with the exception of fixed line terminal equipment and custom built evaluation kits, falls under the RE-D.

When does the RE-D start applying?

The Directive is applicable as of 13 June 2016 but provides for a transitional period of one year, during which manufacturers are allowed to place on the market radio equipment compliant with either the new RE-D rules or the old applicable legislation. <u>The transitional period ended on 12 June 2017</u>.

Why did you not postpone the application date?

An additional transitional year was granted to industry to ensure a smooth transition from the old to the new directive. Extending that deadline would have (re)opened the whole Directive and the Commission would have had to propose new legislation to the European Parliament and the Council. In fact, industry and standardisation organisations have had years to prepare for the new rules for radio equipment so there was no reason to postpone the application date even further.

What happens to the equipment which is already on the market but has not been sold to the end user yet?

It depends on the date when the equipment was first placed on the market. As long as equipment conformed to the legislation applicable at that time, it can continue to be sold.

What happens to mobile phones? Will people be able to buy them?

Mobile phones and any other radio equipment that was already placed on the market before 12 June 2017 will continue to be sold, provided they comply with the legislation applicable at that time. The EU is not banning the sale of such products. Manufacturers can also bring new mobile phones and other equipment to the market after 12 June 2017, provided these products comply with the requirements set in the RE-D. Actually, mobile phones are already placed on the market without a full application of harmonised standards. There is a 4-digit number aside the CE marking on your mobile phone: this is the number of the Notified Body that assessed its compliance because some harmonised standards do not exist and/or are not applied. This system is in place since 1999, the date of applicability of the R&TTED. With the RE-D nothing will change.

Will the EU withdraw radio equipment from the market because of the change of legislation from R&TTED to RE-D?

The EU does not withdraw products from the market. The Member States are in charge of market surveillance. In any case, once equipment is placed on the EU market, it can remain on the market even if the legislation changes in the meantime. This is a general rule of the Internal Market and full guidance is given in the 'Blue Guide'. Independently from the availability of or the compliance with standards, the National Market Surveillance Authorities can always withdraw products from the market for justified reasons (e.g. they pose a risk to the safety of the users or the consumers). The rules on withdrawal of equipment in case of risks are specified in the RE-D. National Market Surveillance Authorities, not the Commission, are responsible for enforcing these rules.

What are harmonised standards for?

The application of harmonised standards is voluntary. They are used to demonstrate that products, services, or processes comply with relevant requirements of the EU legislation. However, manufacturers can use any technical specification to demonstrate that the radio equipment complies with all necessary requirements, upon their own responsibility. The essential performance requirements and use of radio spectrum laid down in Articles 3.2 and 3.3 must, however, be certified by a Notified Body, if alternative specifications are applied. The list of notified bodies can be found on the Commission website (NANDO). The manufacturer can give assurance that the equipment meets the safety and health and electromagnetic compatibility requirements laid down in Article 3.1 by showing conformance to harmonised standards, but there is always the option to use alternative technical specifications. In such a case, the manufacturer assumes the risk if a product subsequently presents a risk to anybody.

Notified bodies are overloaded, what can manufacturers do to get their products assessed?

In April 2017, the Commission has made a direct survey of the capabilities of Notified Bodies. Approximately 60% reported low or normal levels of workload.

The NANDO database provides a list of all notified bodies across the EU which can perform conformity assessments. Manufacturers can find a notified body in their own country or elsewhere in the EEA, which has the spare capacity to do the job.

To date, there is no information indicating that all notified bodies are overloaded or are unable to perform their tasks. In fact, Annex III of the RE-D (Modules B and C), which may be applied in situations that harmonised standard do not exist, does not refer to any tests and audits to be performed by the chosen notified body. The responsibility is on the manufacturer to establish and submit the supporting evidence. Hence it is not expected that this procedure would cause any unreasonable delay and burden.

Can manufacturers apply draft standards or other specifications that have not been published as harmonised standards?

Under the RE-D, it is allowed. It is important that the manufacturer demonstrates in the technical documentation that the radio equipment is compliant with EU legislation/the RE-D. In this case, the manufacturer must follow a conformity assessment procedure which involves a notified body as explained above.

Is there any guidance on the application of the RE-D?

The new RE-D Guide, aiming at explaining and clarifying some of the most important issues related to the application of the RE-D, has been published on the Commission website. This is a living document and the intention is to update it soon in order to clarify some remaining issues. The Guide should be read together with the 'Blue Guide' on the implementation of EU product rules. These documents are intended purely as guidance and they are not legally binding.

Who develops harmonised standards?

The European Standardisation Organisations (ESOs) develop harmonised standards on the basis of a request from the Commission. The ESOs are the European Committee for Standardisation (CEN), the European Committee for Electro-technical Standardisation (CENELEC) and European Telecommunications Institute (ETSI). The standardisation organisations are private bodies, composed of industry experts and other stakeholders, and are fully independent from the Commission.

Why are some harmonised standards for the RE-D not available?

Some of the harmonised standards for the RE-D, and requested by the Commission, are currently not available, as they were not delivered on time by the 2 standardisation organisations. According to the Standardisation Regulation 1025/2012, the Commission can only publish the harmonised standards in the official Journal (OJEU) if they have been formally delivered by the standardisation organisations.

The standardisation request was formally adopted in August 2015 and submitted to the European Telecommunications Standards Institute (ETSI) and the European Committee for Electro-technical Standardization (CENELEC). Until now, ETSI has submitted 133 harmonised standards under the RE-D.

Comparing the latest RTTED list and the RED list, there are only 6 harmonised standards on Articles 3(2) or $3(3)^1$ which do not have a correspondence. Some of them have been submitted in May/June 2017, i.e. too late for the latest publication on the OJEU before the end of the transitional period. The problem of missing standards under the RED has hence been reduced to a size that can be managed easily by the Notified Bodies.

The Commission has assessed all of the delivered standards in time, providing feedback to the standardisation organisations. Whenever asked for, the Commission has also given comments on the draft standards in a proactive way to prevent potential problems. Out of the submitted standards, 134 have appeared in the Official Journal by 08 June 2017.

To date, of these 134, 117 provide full presumption of conformity and additional 17 standards from the old R&TTE Directive have been re-published, although they only partially address the modified essential requirements of the RED and therefore can only be used as a reference. Whilst in this case manufacturers are still required to apply for an EU-type examination of a Notified Body, the presence of these harmonised standards on the OJEU may facilitate the demonstration of conformity.

Some standards have shown substantial shortcomings, in particular with regard to their compliance with the essential requirements, and this is why their publication in the Official Journal is delayed. These shortcomings include mainly technical problems, which make the standards difficult to understand and unclear for industry to apply. Requests to improve the standards have been made to ETSI.

Can manufacturers use harmonised standards of the R&TTE to demonstrate compliance with the RED?

Not in all cases. Harmonised standards of the old R&TTE Directive may not fully address the essential requirements of the new RE-D. The references of the old harmonised standards of the R&TTE that fully address the essential requirements of the RE-D have already been published under the RE-D list.

In order to further facilitate the situation for cases where the new harmonised standards under the RED are not are not yet available the Commission has decided to publish also the references of those harmonised standards of the R&TTE Directive which do not fully address the essential requirements of the new RE-D (e.g. receiver performance parameters) However a note has been added specifying that these standards do not confer a presumption of conformity as regards those parameters. Therefore, for the receiver performance parameters, the manufacturer will still need to follow a conformity

¹ i.e. those in which absence the EU-type examination is compulsory

assessment procedure that involves a notified body. The publication of the references of those standards is expected, however, to facilitate the work of the manufacturers and save them time in assessing the conformity of their products since, by applying those standards, would benefit from the presumption of conformity with the corresponding essential requirements i.e. those requirements which are addressed by the standards.

What has the Commission been doing to solve the problem and to avoid such situations in the future?

The Commission has been working in close collaboration with the European standardisation organisations so that the vast number of standards, which are of voluntary nature, are prepared and published.

Notwithstanding the minor changes that were asked by the RED, some harmonised standards were delivered late and last-minute modifications occurred. This is, for instance, the case of EN 301 893 which cover a vast number of Wi-Fi products. We acknowledge that the late availability and changes of this harmonised standard (a few weeks before the end of the transitional period) could make it difficult to industries to adapt to the new requirements. In such cases, a pragmatic approach has been taken to allow sufficient time to adapt to the specifications of new harmonised standards. This is an extraordinary measure which does not constitute a precedent, as we would expect similar issues to be anticipated in the standardization exercise.

In general, the Commission services proposed specific solutions to ETSI to increase the number of published standards and thanks to this approach, the Commission was able to publish additional harmonised standards in the OJEU.

The Commission has also organised a joint workshop with the Standardization Organizations and other stakeholders to describe and explain the most common errors in drafting harmonised standards and avoid them in the future, ensuring a smooth publication in the OJEU.

On a broader field, the Commission is working on the modernisation of the European standardisation system and launched the so-called joint initiative on standardisation. The objective of this initiative is to work in a public and private partnership with standardisation bodies and EU Member States to better respond to European standardisation challenges; to exchange information on new rules and developments; and to improve the understanding on the role of standards.

Why is the EU not helping the industry?

The EU is helping the industry. The transitional period was designed by the co-legislators to help the industry to prepare for the new rules. Moreover, the Commission has, in its standardization request to the European Standardization Organizations, put deadlines to ensure a smooth transition between the old and the new Directive. The preparation of harmonised standardization organizations, which are composed of industry experts and other stakeholders.

The Commission took some steps and made arrangements in order to help the industry and facilitate its work, some examples are enumerated below.

- The Commission published as many harmonised standards as possible in the OJEU after they are delivered by the standardisation organisations.
- On average, the assessment of the received harmonised standards takes less than 30 days from the formal delivery from the ESOs to the Commission. Compared to many other Directives or Regulations under a less critical time pressure, this is a unique result that was accomplished at quite some efforts to all concerned. However, we believe that these extraordinary efforts were necessary and represent time well spent in order to mitigate, once more, for the delays in the delivery.
- Last year, the Commission started publishing the list of harmonised standards in the OJEU every month. This is an unprecedented exercise as harmonised

standards for other Directives or Regulations (including the R&TTED) are usually published quarterly.

- The Commission has also been holding several meetings or initiatives to provide guidance on how to comply with the RE-D without harmonised standards (yes, it is possible!).
- These FAQs are an additional example in that respect.
- As stated above (see ' Can manufacturers use harmonised standards of the R&TTE to demonstrate compliance with the RED?'), where new harmonised standards under the RED are not are not yet available, the Commission publishes the references of those harmonised standards of the R&TTE Directive which do not fully address the essential requirements of the new RE-D (e.g. receiver performance parameters) with a note specifying that these standards do not confer a presumption of conformity as regards those parameters.

Was the standardisation request published too late?

No. The standardisation request was formally adopted in August 2015 and submitted to the European Telecommunications Standards Institute (ETSI) and the European Committee for Electro-technical Standardization (CENELEC). The deadline for delivery – 15 March 2016 - of the standards was laid down in the official standardisation request of the Commission.

Furthermore, discussions on the mandate started between the Commission and ETSI and CENELEC immediately after the adoption of the RE-D in 2014. Both industry and ETSI were clear about the upcoming timelines and the possible necessity to carry out preparatory work ahead of the adoption of the standardisation request mandate.

The changes to the harmonised standards under the old R&TTE Directive to meet the requirements under RE-D are limited and should have been easy to accomplish within the time limit set in the standardisation mandate.