

Introduction and Disclaimer

The purpose of this document is to provide an introduction and certain clarifications on the initiatives in relation to Articles 3 (3) (i) and 4 of the Radio Equipment Directive 2014/53/EU (RED), on combination of radio equipment with software uploaded after the placing of the equipment on the market

This document shall be read together with the RED Guide¹ as well the 'Blue Guide'². These Guides are intended purely as guidance documents and provide clarifications, in particular, on the definitions of 'placing on the market' and 'put into service' as well as on the role and responsibilities of economic actors in the supply chain when they make their products available on the EU market.

It should be noted that this document: shall not be considered as binding, final, conclusive and exhaustive; does not aim at providing a legal analysis on the applicability of the provisions in question; and is without prejudice to any other ongoing or future initiatives under the RED.

What is the “Radio Equipment Directive” 2014/53/EU and what is “radio equipment”?

The RED is a binding EU legal act adopted in 2014 and entered into applicability as of 13 June 2016. Under the RED “radio equipment”³ (wireless electrical/electronic equipment), including its embedded software, cannot be placed on the EU market unless it is compliant with the applicable requirements. Radio equipment which is compliant can move freely within the EU/EEA.

Examples of radio equipment, covered by the RED, are: mobile phones, laptops, radars, broadcasting devices, fitness devices, smartwatches, routers, smart appliances including, in more general terms, combinations of conventional goods with Wi-Fi, Bluetooth, GPS and/or other radio transceivers.

The essential requirements applicable to all types of radio equipment, falling within the scope of the RED, ensure that the compliant radio equipment:

1. is safe: Article 3(1)(a);
2. neither is disturbed by nor disturbs other equipment: Article 3(1)(b);
3. uses effectively and efficiently the radio spectrum where it operates: Article 3(2).

The RED provides also the basis for additional requirements governing some further aspects, set out in Article 3 (3), applying if related delegated acts are adopted⁴.

¹ <https://ec.europa.eu/docsroom/documents/29782>

² <http://ec.europa.eu/DocsRoom/documents/18027>

³ i.e. *an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radio-determination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio-determination, up to 3000 GHz (with few exceptions as in Annex I of the Directive)*

⁴ Apply to those categories or classes of radio equipment specified in the related delegated act (s).

These requirements relate, for example, with interoperability, emergency services, software, fraud, accessibility, privacy, personal data and misuse.

In addition, Article 4 contains requirements on information on the compliance of intended combinations of radio equipment and of the software and Article 5 contains requirements on registration of radio equipment, applying if related delegated and implementing acts are adopted⁵.

Delegated acts for Article 3 (3), with the exception of Article 3 (3) (g), have not been adopted yet. Article 3 (3) (g) of the RED, aiming at ensuring access to emergency services, already applies to specific types of radio equipment⁶.

Also, delegated and implementing acts for Articles 4 and 5 have not been adopted yet.

A product, which has been subjected to significant changes (e.g. following the upload of new/updated software) after it has been placed on the market, may, under certain circumstances (see Chapter 2 of the Blue Guide which provides details), be considered as new product and the RED will re-apply, when that product is made available on the market. The equipment is not considered to be made available when the modifications are done by the user for its own personal use.

Is software covered by the RED? And how?

Software is concerned by the applicability of the RED, as follows:

- the RED is applicable to radio equipment, including any software installed/embedded in the equipment at the time of its placing on the market since in such circumstances, the software is part of the equipment (component) falling within the definition of ‘radio equipment’;

- Article 3 (3) (i) of the RED which requires the manufacturer to incorporate/install certain features in radio equipment (if concerned by a related delegated act), ensuring that the user cannot upload software that can affect the compliance of that equipment with the requirements of the RED applicable at the time of the placing on the market of the radio equipment in question.

- Article 4 of the RED which imposes specific obligations in relation to the combination of radio equipment (if concerned by a related delegated act) and updated/new software, allowing the radio equipment to be used as intended, with the essential requirements set out in Article 3 applicable at the time the radio equipment in question was placed on the market; according to Article 4, information shall be provided to the Commission and Member States; such information shall result from a conformity assessment carried out and provided in the form of a statement of compliance; the obligations in Article 4 are on the manufacturer of radio equipment and of software.

⁵ Apply to those categories or classes of radio equipment specified in the related delegated act (s).

⁶ Five Commission Decisions adopted under the repealed Directive (Directive 1999/5/EC) continue to be valid and apply for the purposes of Article 3 (3) (g) of the RED. In addition, Commission Delegated Regulation (EU) 2019/320 of 12 December 2018 with regard to the application of the essential requirements referred to in Article 3(3)(g) of Directive 2014/53/EU in order to ensure caller location in emergency communications from mobile devices has been adopted; Article 2 provides that it shall apply from 17 March 2022. Recital 14 states that "nothing in this Regulation should be interpreted as preventing economic operators from complying with it from the date of its entry into force".

The purpose of this public consultation is to gather input for the purposes of future initiatives under Articles 3 (3) (i) and/or 4 of the RED

Beyond the provisions of Article 3 (3) (i) and 4 of the RED, which concern software and apply if related delegated acts are adopted, software is concerned by some other provisions of the RED. For instance, Article 10(8) already provides that *manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information [...]. Such information shall include, where applicable, a description of accessories and components, **including software, which allow the radio equipment to operate as intended** [...].*

In addition, Annex VI provides that the EU Declaration of Conformity shall include: where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended [...].

Moreover, Annex V requires manufacturers to produce a technical documentation containing *at least [...] versions of software or firmware affecting compliance with essential requirements [...]*

These provisions of Article 10(8) and Annexes V and VI are further clarified in the RED Guide.

How can software affect the operation and compliance of radio equipment?

Whilst in the past modifying radio equipment required certain expertise or tools, modern conventional radio equipment as mobile phones, routers, remote controllers, base stations, etc., can nowadays be reconfigured by software (including firmware). This is made possible by the software implementation of electronic components that were typically hardware (e.g. diodes, switches, mixers, filters, demodulators). The increased performance of the off-the-shelf electronics may impact on the original compliance which was demonstrated when the radio equipment was placed on the EU/EEA market.

Specifically, software can govern some aspects of the radio equipment or its components so to (i) enable/disable peripherals or components (e.g. fans), (ii) allow an increased power consumption or (iii) alter the transmitting power of radio equipment, having an impact on the safety of the equipment. As chipsets and electronic boards can operate over several frequency bands, the upload of software into radio equipment can allow to operate it in frequencies where transmissions are not permitted or require a license. In some cases, the severity of the problem can be magnified by the very large extent of frequency bands where the equipment can operate. When radio equipment is intended for access to emergency services, the upload of new software may alter the tested protocols and have a major impact on the correct functionality of these devices. In the extreme cases, new software can completely change the intended or reasonably foreseeable use of the equipment. One of the basis for these developments is a flexible hardware that can assume different configurations according to the uploaded software (including firmware).

What are these initiatives relating to the “upload of software into radio equipment” about? Are they going to amend the scope of the RED or any of the provisions of the RED?

Recital 16 of the Directive explicitly clarifies that *the compliance of some categories of radio equipment with the essential requirements set out in this Directive may be affected by the inclusion of software or modification of its existing software. The user, the radio equipment or a third party should only be able to load software into the radio equipment where this does not compromise the subsequent compliance of that radio equipment with the applicable essential requirements.*

This initiative hence focuses on the **radio equipment that has the capability to change its behaviour or be reprogrammed at the upload of new software**, since re-configurability can have an impact on the compliance of radio equipment (e.g. radio spectrum access, safety, disturbance or access to emergency services) with the applicable RED essential requirements.

It aims at assessing whether/how regulatory action under Articles 3(3) (i) and 4 of the RED is needed to **ensure that radio equipment remains compliant**, throughout its entire lifecycle, **with those requirements of the RED, applicable at the time of its placing on the market**, in particular **when certain software is uploaded**.

Under Article 3 (3) (i)

The Commission is empowered to adopt delegated act (s) specifying the classes or categories of radio equipment concerned by these requirements.

These delegated acts cannot go beyond the scope of the RED and cannot amend the provisions of the RED.

Under Article 4

The Commission is empowered to adopt delegated act (s) specifying the classes or categories of radio equipment concerned by these requirements.

In addition, assuming that delegated act (s) is (are) adopted in relation to that provision, the Commission may adopt implementing acts laying down the operational rules for making the information on compliance available for the categories and classes of equipment specified by the delegated acts, in line with the provisions of Article 4(3) of the RED.

These delegated or implementing acts cannot go beyond the scope of the RED and cannot amend the provisions of the RED.

Are there any discussions and analysis ongoing on the scope of this initiative? Will interested citizens and stakeholders be given the opportunity to share their views? How will the principle of proportionality be ensured?

The Commission has worked for 2 years with a dedicated Expert Group on Reconfigurable Radio Systems (RRS)⁷ (E03413) to assess different aspects of the matter.

Discussion with stakeholders are also being held in the Expert Group on Radio Equipment (E03587)⁸. In the discussions of the Expert Groups, a number of controversial topics were brought forward. Representatives of the free software community were also invited to present their views⁹.

The Commission has also launched an Impact Assessment Study, so to have a cost-benefit analysis for possible future legislative initiatives.

Interested citizens and stakeholders have now the opportunity, via this public consultation, to send their view by filling in the relevant questionnaire.

Interested citizens and stakeholders will also be given the opportunity to share their views, via the Better Regulation portal, on any draft delegated acts or implementing acts prepared under the above provisions.¹⁰

Due attention will be paid to ensure a proportionate approach. In particular:

- (i) the choice as to which equipment should be in scope of the delegated acts will have to be based on a careful assessment of relevant risks¹¹. Different policy options may need to be considered for different equipment classes, as a solution that fits all may not be ideal;
- (ii) the impact assessment study, to whose consultations you are replying, will assess the impacts of the different policy options.

What will be the role of harmonised standards?

With respect to the essential requirements set out in Article 3, the RED already allows the manufacturers to demonstrate conformity through:

⁷ All documents are publicly available in <https://circabc.europa.eu/ui/group/814ed9cd-0ef5-46e7-b9a4-3bac8123583a/library/a4e17874-f093-4138-986d-760196911db8>

⁸ <https://circabc.europa.eu/ui/group/43315f45-aaa7-44dc-9405-a86f639003fe/library/024d00b8-f744-48d4-bc8d-fd22edf2e83e>

¹⁰ https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how_en#preparation

¹¹ Annex I to these [minutes](#)

- harmonised standards, if they exist and their references are published in the Official Journal of the EU, which provide presumption of conformity with the corresponding essential requirements; or
- other technical specifications (the manufacturer carries the burden of demonstrating that these technical specifications answer the needs of the essential requirements);, in this case - and if for the purposes of conformity with the requirements of Article 3 (2) or (3)¹² - they will have to follow a conformity assessment procedure (example an EU-type examination) involving a Notified Body¹³.

Assuming that delegated act (s) is (are) adopted in relation to Article 3 (3) (i), the Commission will ask the European Standardization Organizations (ESOs) to prepare harmonised standards in support of the essential requirements of Article 3 (3) (i). This will allow laying down technical specifications to help manufacturers (including software developers) to demonstrate compliance with the RED. Harmonised Standards are typically the preferred option for manufacturers as they represent a simplified way for demonstrating compliance at reduced costs.

In order to understand the current technologies and what can be technologically feasible, the Commission services have already asked the ESOs to provide preliminary information. Some documents have already been produced and have been circulated to the Expert Group¹⁴. Also in this case, different harmonised standards can set out different technical solutions tailored on the equipment and the risk. This is not a new approach for radio equipment: for instance, there are more than 140 harmonised standards in support of the efficient use of the radio spectrum, ensuring a proportionate approach for demonstrating compliance of different technologies.

Is there any other link where I can find information on this initiative or other general information on the RED?

- The general page of the RED on the Commission website: https://ec.europa.eu/growth/sectors/electrical-engineering/red-directive_en
- The RED Guide, which also explains how software is already considered in the conformity assessment procedures (in particular sections 2.6.d, 2.6.e and 2.6.k): <https://ec.europa.eu/docsroom/documents/33162>
- Commission Inception Impact Assessment on the “upload of software on radio equipment”: https://ec.europa.eu/info/law/better-regulation/initiative/2042/publication/380919/attachment/090166e5c0fe9ef0_en

¹² For example for the requirements in point (i) of the first subparagraph of Article 3 (3), if point (i) is applicable, and harmonised standards are partially applied or not applied or do not exist for point (i).

¹³ https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en

¹⁴ <https://circabc.europa.eu/ui/group/43315f45-aaa7-44dc-9405-a86f639003fe/library/3c8c4e81-8191-4393-aa05-4386a6373efd/details> and <https://circabc.europa.eu/ui/group/43315f45-aaa7-44dc-9405-a86f639003fe/library/ab392108-3ac6-4635-8af1-fc4f1b44532f/details>

- A Q&A paper on the delegated acts under the RED, developed with the Expert Group on Radio Equipment (working document): <https://circabc.europa.eu/ui/group/43315f45-aaa7-44dc-9405-a86f639003fe/library/51bcb709-c794-4653-ba15-a872cb99fa4f/details>