

Orgalim comments on the draft delegated act for internet-connected radio equipment and wearables

Executive summary

Orgalim, Europe's Technology Industries, welcomes the open and constructive discussions during the Expert Group Radio Equipment (EG-RE) meeting on February 24-25. We also welcome the opportunity provided by the European Commission to give comments and suggestions on document EG RE (09)05r01 in view of the activation of a delegated act pursuant to article 3(3) of the Radio Equipment Directive (RED) (sub-articles d,e,f).

Orgalim follows these developments very closely and believes that cybersecurity protection in the EU market will benefit all stakeholders. While we believe that our views and those of the Commission are not far apart, we consider that the proposed text does not seem to fully capture our common goals. For this reason, we would like to take the opportunity to comment on the Delegated Act's scope as well as on the proposed transitional period.

Orgalim comments and proposals

1. Scope: definition of "internet-connected device"

Communication over the internet

Orgalim appreciates the consideration given by the Commission to our previous comments and representative examples. We welcome and support the inclusion of the concept "communicate over the internet" in document EG RE (09)05r01.

Capability and intended use

The RED is based on the key principle of "intended use given by the manufacturer", as defined in Article 7, Article 10 and especially in Article 17. Rightly so, even the definition of "wearable device" in the draft DA refers to "designed or intended". For this reason, we believe the term "capable" goes beyond the spirit of the RED. It is the manufacturer's obligation to define the conditions for the use of a product, e.g. consumers versus professional users or environmental conditions. The definition of internet-connected device should refer to the "intended use" of that device.

Manufacturers cannot be held responsible for any (mis)use of any given radio equipment if a user/installer deviates from its intended use. The RED is specific in this regard: the assessment against Articles 3.1b and 3.2 needs to be done according to the equipment's intended use; the assessment against Article 3.1a should take into account reasonably foreseeable conditions. Essential requirements under Articles 3.3d/e/f should follow the same approach, since a more stringent application of these articles goes against the RED principles and has not been justified. Furthermore, the RED offers provisions to the Market Surveillance Authorities to act against radio equipment which is not employed according to its intended use and goes against the RED essential requirements.

➤ Example:

Manufacturers should have the opportunity to ensure security by design. An isolated network (i.e. no connection to the internet at any time), particularly in industrial environments, is a way to ensure cybersecurity. Devices in that isolated network may eventually be "capable" of connecting to the internet. However, that was definitely not the intention of the manufacturer when the product was designed and placed on the market. Introducing additional requirements for that type of equipment, which will never be connected to the internet, is not proportionate.

Communication with the internet via radio

Orgalim understands the intention of the Commission and the Member States to take this opportunity to cover as many risky products as possible. However, we understand that this DA aims to protect radio devices against cybersecurity risks from the internet and to protect the network from those radio devices. Any cybersecurity risk related to a wired connection to the internet should not be covered by this DA. For this reason, we believe that the definition of "internet-connected device" should read "...communicate over the internet via radio...".

➤ Example:

An industrial machine with no wireless functionality is not covered by the RED, even if it is connected to the internet via cable. However, a manufacturer may decide to add an RFID tag for maintenance purposes which is used once every three months. The device clearly falls under the RED and must meet the essential requirements under Article 3.1 and 3.2. However, the radio capability and intention have nothing to do with the internet. This represents a real problem when it comes to the eventual application of Article 3.3d to this type of equipment which does not communicate with the internet via radio. Which radio network is this equipment supposed to protect? For this reason, we believe the term "via radio" needs to be included in the definition.

Orgalim proposal

For the reasons above, Orgalim finds it necessary to modify the proposed definition of "internet-connected device" as follows:

'internet-connected device' means any product or component, falling within the scope of Directive 2014/53/EU, which is **intended** ~~capable itself~~ to communicate **by itself** over the internet **via radio**, regardless ~~if~~ **of whether** it communicates directly or via any other equipment.

2. Transitional period

While we understand the urgency of this matter, Orgalim would like to reiterate that precipitating this DA will inevitably produce a significant market disruption in the EU.

The essential requirements of Article 3.3 are new requirements for radio equipment which need to be considered and implemented in the product planning, design and production. This process usually takes between 10 and 12 months for

manufacturers. The proposed 24-month transitional period would leave an unrealistic 12-month period for the development of appropriate standards.

This situation becomes even more worrying when we hear from ETSI that 24 months would not be enough time to develop new standards due to the wide scope of the DA. Furthermore, European Notified Bodies report that they do not have the expertise or the capacity to perform a cybersecurity assessment, especially without any standard as a reference.

Therefore, to avoid a bottleneck or even an obstruction of the EU market, Orgalim asks for a longer transitional period. If the Commission is certain that the standardisation process can be concluded within 18-24 months, then an absolute minimum transitional period of 36 months should be considered. However, to anticipate foreseeable additional delays in the standardisation and citation processes, a longer time would be required.

Conclusion

To sum up, Orgalim has put forward the following concrete suggestions:

- Redefining the scope through an amended definition of internet-connected devices putting emphasis on the 'intended use' and 'communication via radio' as the key criteria to define the scope of this delegated act.
- Proposing a longer transitional period. In the event that the Commission is certain that the standardisation process can be completed in 18-24 months, then an absolute minimum of 36 months for the transition period is required. A longer time is suggested in order to anticipate delays in the standardisation process.

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of €2,298 billion, manufacturing one-third of all European exports and providing 11.55 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.