

Brussels, XXX
[...] (2026) XXX draft

COMMISSION DELEGATED REGULATION (EU) .../...

of XXX

on supplementing Regulation (EU) 2023/1542 of the European Parliament and of the Council as regards derogations for the removability and replaceability of portable batteries

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Batteries are a crucial technology for sustainable development, green mobility, clean energy, and climate neutrality. Portable batteries are used to power an increasing number of products, from wearable devices to toys, textiles or medical devices.

The Regulation on Batteries and Waste Batteries (the Regulation) introduces in its Article 11 general requirements for the removability and replaceability of portable batteries incorporated in products being placed on the market. As a general rule, portable batteries need to be removable and replaceable by end-users at any time during the lifetime of the products in which they are incorporated. This is meant to prevent premature obsolescence and increase the collection of waste portable batteries at the end-of-life

However, in specific justified cases, as set out in Article 11(2) of the Regulation, portable batteries may be removable and replaceable by independent professionals, instead of by end-users. The Commission is empowered by Article 11(4) of the Regulation to adopt delegated acts adding further products to the list of products for which batteries only need to be removable and replaceable by independent professionals. This delegated act is the first such act stemming from that empowerment.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

As this is a technical act, an impact assessment or an open public consultation were not required.

The delegated act draws on the evidence collected through a call for applications published on the EU Survey website, which was open for three months between February and April 2025. The purpose of the call was to identify candidate products for which additional derogations, pursuant to Article 11(4) of the Regulation, could be justified. The Commission carried out a technical assessment of the merits of the applications received.

The expert group on waste, consisting of experts designated by each Member State and other selected experts representing business organizations and civil society, was consulted on the draft delegated act on 11 December 2025 and on 5 February 2026.

The draft delegated act was published for public feedback on the Better Regulation Portal from [XX.XX.2026] to [XX.XX.2026]. The draft delegated act was submitted to World Trade Organisation's Committee on Technical Barriers to Trade for feedback from [XX.XX.2026] to [XX.XX.2026].

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act is adopted pursuant to Article 11(4) of the Regulation, which empowers the Commission to adopt a delegated acts to add further products to be exempted from the removability and replaceability requirements laid down in paragraph 1 of that Article.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2023/1542 of the European Parliament and of the Council of 10 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC , and in particular Article 11(4) thereof,

Whereas:

- (1) Article 11 of Regulation (EU) 2023/1542 sets out generic requirements for end-user removability and replaceability of portable batteries incorporated into products which are placed on the market but also includes a list of derogations for certain products for which portable batteries only need to be made removable and replaceable by independent professionals, instead of by end-users.
- (2) It is necessary to include certain wearable devices into the scope of derogation already given to wet appliances to provide legal certainty. Wearables are portable electronic devices that are worn on the body and often have sensors and connectivity to collect and transmit data. Their use has increased significantly since Regulation (EU) 2023/1542 was adopted. Examples of wearables include smartwatches, fitness trackers, smart glasses or other electronic devices integrated into clothing and other accessories. The guidelines in Commission's Notice C/2025/214 provide guidance on what constitutes a wet appliance.
- (3) The miniaturization of wearable devices and the portable batteries powering them may result in situations where the battery is so tightly encapsulated in its receptacle that its removal may create a non-negligible risk of damage or piercing of the battery. Where the nature of the product hinders its redesign (anatomic or ergonomic considerations), it is justified that such small batteries be removable and replaceable only by independent professionals.
- (4) Regulation (EU) 2025/2509 of the European Parliament and of the Council establishes that, as of 1 August 2030, electric toys with batteries that constitutes small parts are to be designed in a way as to ensure that the battery cannot be accessed without the use of a tool, and that where the size or nature of the toy so requires, a rechargeable battery may instead be made inaccessible, and removable or replaceable only by independent professionals. Until such date, it is appropriate to ensure that a temporary derogation is provided in accordance with Article 11(4) of Regulation (EU) 2023/1542.

- (5) In the case of wireless thermometer probes specifically designed for food contact, it is considered that the end-user removability of portable batteries would present a considerable safety risk for end-users during normal operation in case the probe's sealing would be damaged and leaked chemicals from the battery would contaminate food.
- (6) Products falling in the scope of Article 1 of Directive 2014/34/EU are specifically designed to operate in potentially explosive environments. End-user removability of any portable battery contained in such products could result in a violation of the safety requirements for the users provided for in that Directive.
- (7) On-body delivery systems incorporate small portable batteries to administer medication subcutaneously. End-user removability of such batteries could result in improper functioning of the device and in a false administration of medication, which could be a safety risk for the user.
- (8) Telematics devices intended for roof mounted installation in agricultural and construction machinery and designed to be exposed to harsh vibrations, dust and wet conditions during their normal use are usually maintained by certified personnel having access to the necessary training and tools. Therefore, end-user removability of portable batteries incorporated in such devices could result in safety risks for end users.
- (9) Regulation (EU) 2023/1542 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Article 11(2) of Regulation (EU) 2023/1542 is replaced by the following:

‘2. By way of derogation from paragraph 1, the following products incorporating portable batteries may be designed in such a way as to make the battery removable and replaceable only by independent professionals:

- (a) appliances, **including wearable devices**, specifically designed to operate primarily in an environment that is regularly subject to splashing water, water streams or water immersion, and that are intended to be washable or rinseable;
- (b) professional medical imaging and radiotherapy devices, as defined in Article 2, point (1), of Regulation (EU) 2017/745, and *in vitro* diagnostic medical devices, as defined in Article 2, point (2), of Regulation (EU) 2017/746;
- (c) **wearable devices for which the safety, durability, or water resistance may be compromised by user access to the battery and which:**
 - (1) **due to their nature, size or form, are considered to be too small to allow the end-user to properly and safely handle a battery replacement; or**
 - (2) **rely on a compact, sealed enclosure to maintain functional integrity, including protection against dust, and shock;**
- (d) **until 31 of July 2030, electric toys that incorporate rechargeable batteries. when, due to the nature or size of the toy, the derogation is necessary to ensure**

the safety of the toy when used in accordance with Article 10(2) of Directive 2009/48/EC of the European Parliament and of the Council¹,

- (e) wireless thermometer probes specifically designed for food contact during food preparation processes;
- (f) products falling within the scope of Article 1 of Directive 2014/34/EU of the European Parliament and of the Council²;
- (g) on-body delivery systems specifically designed for the subcutaneous administration of medicinal products;
- (h) telematics devices intended for roof mounted installation in agricultural and construction machinery and designed to be exposed to harsh vibrations, dust and wet conditions during their intended use.

The derogations set out in points (a), (c), (d), (e), (f), (g) and (h) of this paragraph shall only be applicable where such derogation is required to ensure the safety of the user and the appliance.”

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels,

For the Commission
The President
[...]

¹ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1, ELI: <http://data.europa.eu/eli/dir/2009/48/oj>).

² Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309, ELI: <http://data.europa.eu/eli/dir/2014/34/oj>).