Technical support to the adoption of delegated acts and Commission reports related to the new Batteries Regulation between 2024 and 2027 – Task 1 Report

Task 1: Support to the adoption of a delegated act pursuant to Article 11

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Technical support to the adoption of delegated acts and Commission reports related to the new Batteries Regulation between 2024 and 2027 – Task 1 Report

Task 1: Support to the adoption of a delegated act pursuant to Article 11

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Abbreviations

Header cell	Header cell
BattReg	Batteries Regulation (Regulation (EU) 2023/1542, 2024)
BIOS	Basic Input/Output System
BWC	Body worn cameras
CMOS	Complementary Metal-Oxide-Semiconductor
DCU	Direct control unit
EC	European Commission
ECC	Error-Correcting Code
ECU	Electronic control unit
EDR	Event data recorder
LAN	Local area network
Li-Ion	Lithium ion (battery chemistry)
LMT	Light means of transport
NiMH	Nickel metal hydride (battery chemistry)
PCB	Printed circuit board
OBCU	On-board computer unit
OBDS	On-body Delivery System
QKD	Quantum Key Distribution
RAM	Random-Access Memory
RF	Radio frequencies
RTC	Real-time clock
SLI battery	Starting, lighting and ignition battery
TWS	True Wireless Stereo
WLAN	Wireless local-area network

1. Introduction

Article 11(1) of the Batteries Regulation (EU) 2023/1542 ('BattReg') requires that, for products incorporating 'portable batteries', it shall be ensured that the batteries are readily removable and replaceable by the end-user at any time during the lifetime of the product. (Regulation (EU) 2023/1542, 2024)

Article 11(2) of the Batteries Regulation specifies a few cases of derogations from Article 11(1) where products incorporating portable batteries still have to be designed in a way that the batteries are removable and replaceable, however, only 'by independent professionals'. Article 11(4) empowers the European Commission to add additional derogations through the amendment of Article 11(2). (Regulation (EU) 2023/1542, 2024)

To this end, the European Commission published a call for applications for derogations at the beginning of 2025, allowing stakeholders to request derogations for specific products. Requests had to be submitted by the end of April 2025. In total, 81 applications were submitted, some addressing multiple applications.

Against this background the European Commission has requested Oeko-Institut and Ramboll Germany to support in assessing the applications.

1.1. Background to the BattReg Article 11

In the evaluation of the Batteries Directive (Directive 2006/66/EC, 2006), it was identified that, despite the requirement for portable batteries to be removable from the appliances in which they are incorporated, many of these batteries are not removed and thus do not undergo separate waste management. This was related in some cases to users disposing of appliances with batteries improperly; however, a market trend was also identified of appliance design that hindered the user to remove the battery from the product and dispose of it separately. This aspect was then investigated in the impact assessment of the Batteries Regulation, suggesting that battery removability and replaceability could support higher collection and treatment rates of portable batteries, while also contributing to appliance repairability and prolongation of appliance service life.

The Batteries Regulation was published in 2023 and included new provisions under Article 11 with this in mind, addressing portable batteries as well as batteries of light means of transport (LMT) (Regulation (EU) 2023/1542, 2024).

Article 11(1) lays down the obligation for economic operators placing products that incorporate portable batteries on the market to ensure both the removability

and the replaceability of these batteries, applying to the battery in its entirety and not to individual battery cells. (Regulation (EU) 2023/1542, 2024)

Removability is explained to mean that the battery 'can be removed' by the end-user 'from a product with the use of commercially available tools, without requiring the use of specialised tools, unless provided free of charge with the product, proprietary tools, thermal energy, or solvents to disassemble the product'. Products must be accompanied in such cases with instructions and safety information on the removability and replaceability of the batteries. In cases where other legislation is stricter than these requirements, it prevails over the BattReg. (Regulation (EU) 2023/1542, 2024)

Replaceability is explained later on in article 11(6), which specifies a battery to be 'readily replaceable where, after its removal from an appliance […], it can be substituted by another compatible battery without affecting the functioning, the performance or the safety of that appliance […]'.

Article 11(2) of the BattReg specifies a few derogations from the requirement specified in Article 11(1) and requires that a product incorporating a portable battery may be designed to limit battery removability and replaceability to independent professionals. These derogations apply only when this ensures the safety of the user and of the appliance:

> (a) appliances 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.
>
> (Regulation (EU) 2023/1542, 2024)

Article 11(3) specifies that Article 11(1) shall not apply 'where continuity of power supply is necessary and a permanent connection between the product and the respective portable battery is required to ensure the safety of the user and the appliance or, for products that collect and supply data as their main function, for data integrity reasons'. In other words, in this case the battery does not need to be removable and replaceable by the end-user nor by independent professionals.

Article 11(4) empowers the Commission to amend Article 11(2) by adding additional derogations. From the formulation of this article, it is not clear whether derogations already listed therein could be amended or removed. Nonetheless, the article also specifies a few criteria to be fulfilled by new

derogations as a condition to their addition to Article 11(2), requiring that the EC take 'account of market developments and technical and scientific progress'. Derogations can only be added:

> provided that there are scientifically grounded concerns over the safety of end-users removing or replacing the portable battery, or
>
> in cases where there is a risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law.
>
> (Regulation (EU) 2023/1542, 2024)

Finally, Article 11(9) requires the Commission to publish guidelines to facilitate the harmonised application of this Article. Against this background, a study was undertaken by the Joint research Centre (Spiliotopoulos & Magrini, 2024) investigating the aspects of removability and replaceability, and exploring technical elements of the concepts of 'independent professionals' and 'compatible battery'. The study also looked into the derogations initially included in Article 11 to provide guidance on their interpretation. This study was later used as a basis by the Commission in the drafting of the Commission guidelines to facilitate the harmonised application of provisions on the removability and replaceability of portable batteries and LMT batteries in Regulation (EU) 2023/1542 (Commission Notice C/2025/214, 2025). Both documents provide guidance on how to interpret the various provisions listed under Article 11 and have been consulted in the development of this study's methodology for assessing applications for derogations to be added to Article 11(2).

1.2. Summary of applications

As a result of the call for applications for derogations to the removability and replaceability requirements for portable batteries incorporated into products, 81 applications were submitted by stakeholders and made available by DG ENV for assessment in this study. Some applications covered more than one product so that all in all, a total of 101 products are documented. Some applications were judged as inadmissible due to an insufficient level of detail and in addition, it was not clear that all requests covered portable batteries or rather referred to other types of batteries not covered by the legal obligations specified in Article 11(1) to 11(4) (i.e., LMT batteries or SLI batteries). 94 entries were found to concern portable batteries. However, in several cases, requests for derogations for similar products were made or the main argumentation brought forward in the requests was similar; these were clustered together to facilitate the assessment.

The following table shows this clustering and the respective number of applications in each cluster.

Table 1-1 – Initial clustering of the applications following the product description or the main argumentation

Cluster	Number of applications	Comments on the assessment
NOT IN SCOPE	5	No assessment
E-CIGARETTES	2	No assessment
INDIVIDUEL CASES	10	Assessment of the individual products
ATEX	11	Assessment of the cluster
TOYS	4	Assessment of the cluster
MEDICAL DEVICES	4	Assessment of the individual products
ARTICLE 11(2)(a)	4	Assessment of the individual products
WEARABLE DEVICES	10 (+1 as one application covered two products from different clusters)	Assessment of the cluster
WATCHES	7	Assessment of the cluster
EARBUDS	10	Assessment of the cluster
AUTOMOTIVE APPLICATIONS	4	Assessment of individual products
SENSORS	1	Assessment of the individual products
SHOKZ - CHARGING CASE,	1	Assessment of the individual products
XIAOMI - POWER BANK	1	
VEHICLE BATTERY JUMP STARTER	2	SLI batteries, no further assessment necessary
PORTABLE RESP: WIRELESS DEVICES	5	Assessment of the cluster

Source: Own compilation

Table 1-2 summarises all cases in which an additional derogation from Article 11(1) has been found to be justified in compliance with the criteria specified in Article 11(4), taking into consideration the clustering of the various requests.

Table 1-2 – Summary of applications for derogations for portable batteries found to be justified

Product	Proposal for formulation of the derogation
ATEX products	Products falling under the Directive 2014/34/EU
Toys (applicable only to some applications)	Electric toys that constitute small parts when due to the nature, size or form of the toy, the removability and replaceability of the battery is required by independent professionals to ensure the safety of the toy, as set out in Article 10(2) of Directive 2009/48/EC
On-Body Delivery System controllers	Multiple use controllers of On-Body Delivery Systems for the subcutaneous administration of medicinal products

Product	Proposal for formulation of the derogation
Wireless meat thermometer	Wireless thermometer probe designed for food contact during food preparation processes
Wearable products (applicable only to some applications)	Wearable appliances that meet the criteria ([1]) for 'small form factor' and/or that rely on compact, sealed construction to maintain functional integrity, including protection against water, dust, and shock, and where user access to the battery may compromise the safety, durability, or water resistance of the device
Earbuds (applicable in some cases)	Wireless earphones (earbuds) that meet the criteria ([2]) for 'small form factor'. The derogation could also be merged (and covered) by the derogation for wearables should one be granted
Telematics unit	DCU unit of a telematics module intended for installation on the exterior of agricultural and construction machinery
Wireless earphone (earbud) cases	Casings, comprising battery, circuitry, and housing, which functions as a dedicated energy unit for wireless earbuds, are exempt from the obligations described in Art. 11 (1) provided the maximum battery capacity does not exceed 600 mAh
Power banks (and Jump starters)	If the product is not considered a battery in itself, one of the following derogations could be granted: Power banks that meet the definition of a portable battery under Article 3(9), specifically those not exceeding 5 kg in weight or Appliances, with batteries not exceeding 5 kg in weight, specifically designed with an internal storage, consisting of one or more non-rechargeable or rechargeable battery cells, modules or of packs, and with the primary function of delivering electrical energy to another product or products

Source: Own compilation

Table 1-3 specifies all cases which have been found to be covered by derogations already listed in the BattReg. Aside from the applicant and product, the table also specifies in each case the derogation under which the product is considered to fall. Where relevant, it is specified if an amendment of the existing derogations under Article 11(2) could be considered.

Table 1-3 – Summary of applications for derogations considered to fall under existing derogations

Product	Existing derogation considered to apply and possible needs for amendments of the derogation
Pleasure gadgets	Article 11(2)(a)
Water flossers	Article 11(2)(a)

[1] Criteria that should be defined and listed in the delegated act.

[2] Criteria that should be defined and listed in the delegated act.

Product	Existing derogation considered to apply and possible needs for amendments of the derogation
Wearable products (applicable only to some applications)	Article 11(2)(a) under certain conditions. The article could be amended as follows (addition in italics): 'appliances 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,' *provided that the indicators (i-v) specified under Commission Notice C/2025/214, for appliances specifically designed to operate in a wet environment are fulfilled*
Heart rate monitor strap	Article 11(2)(a). The article could be amended as follows (addition in italics): 'appliances 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,' *provided that the indicators (i-v) specified under Commission Notice C/2025/214, for appliances specifically designed to operate in a wet environment are fulfilled.*
Other watches (non-digital, non-smart)	Article 11(2)(a) under certain conditions. The article could be amended as follows (addition in italics): 'appliances 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,' *provided that the indicators (i-v) specified under Commission Notice C/2025/214, for appliances specifically designed to operate in a wet environment are fulfilled*
Earbuds	Article 11(2)(a) under certain conditions. The article could be amended as follows (addition in italics): 'appliances 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,' *provided that the indicators (i-v) specified under Commission Notice C/2025/214, for appliances specifically designed to operate in a wet environment are fulfilled*
Floor washing appliances	Article 11(2)(a)
Wireless devices (applicable only to some applications)	Article 11(2)(a)
Surgical utensils and endoscope washer disinfectors	Article 11(3)
Blood glucose biosensor system	Article 11(3)
eCall system	Article 11(3)
Tyre pressure monitoring system (TPMS)	Article 11(3)
Anti-theft alarm systems	Article 11(3)
Battery temperature warning systems	Article 11(3)
Intelligent Speed Assistance (ISA) system	Article 11(3)
Tachographs	Article 11(3)
Event data recorder (EDR)	Article 11(3)

Product	Existing derogation considered to apply and possible needs for amendments of the derogation
Quantum key distribution systems	Article 11(3)
AiroSensor temperature sensor	Article 11(3)
Veterinary in vitro diagnostic medical devices	Article 11(3)

Source: Own compilation

1.3. Cases not assessed

The following section summarises the applications submitted but not subject to an assessment.

1.3.1. LMT applications

A number of applications were made for batteries used in light means of transport (LMT; see Table 1-4 below). As Article 11(1) is only applicable to portable batteries, these requests do not fall under the mandate of the consultant and have not been assessed.

Table 1-4 – Summary of applications for derogations for LMT batteries submitted during the call

Applicant	Product
LMT manufacturer	Ebike batteries
LMT manufacturer	LMT batteries for shared micromobility devices (e-scooters, e-bikes)
emTransit BV	Battery packs for light electric vehicles (e-scooters as regulated under EN17128 and e-bikes as regulated under EN15194)
Neutron Holdings, Inc. DBA Lime	Shared electric scooters (e-scooters) and electric bicycles (e-bikes)

Sources: (emTransit BV, 2025; Neutron Holdings, Inc. DBA Lime, 2025)

1.3.2. E-cigarettes

Two applications were submitted to the call for ‘vapes’ or single use e-cigarettes (see Table 1-5 below). The EC instructed the consultants that no in-depth assessment was necessary for these applications.

Table 1-5 – Summary of applications for derogations for E-cigarettes submitted during the call

Applicant	Product
E-cigarettes manufacturer	Electronic cigarette 'ELFA', a closed-system device designed exclusively to power an interchangeable atomiser unit (single use cartridges)
Shenzhen Geekvape Technology Co.,Ltd	Electronic cigarette, E-vape device

Source: (Shenzhen Geekvape Technology Co., 2025)

1.3.3. Incomplete applications

In one case, the submitted application lacked sufficient data to clarify whether the grounds for a derogation complied with the Article 11(4) criteria. As the application did not include contact data, it was declared to be inadmissible.

Table 1-6 – Summary of applications for derogations considered incomplete

Applicant	Product
Battery manufacturer	Lithium batteries

Source: Anonymised.

1.4. Methodology

To assess the requests for derogation, a methodology was developed by the consultants, taking into consideration Article 11 of the BattReg and its various provisions related to portable batteries. (Regulation (EU) 2023/1542, 2024)

For each request or cluster of requests, a **summary** was developed addressing the main argumentation put forward by the applicant or applicants.

The **assessment** was then carried out in consideration of existing derogations already specified in the BattReg (also looking at the criteria for derogation applied in these cases) or by considering the criteria specified in article 11(4). In this respect, the following considerations were made.

Article 11(2) derogations: As the BattReg initially included two derogations in this Article, both of these were considered to see if requests referring to new products could be covered.

- Article 11(2)(a) 'appliances 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'. In this case, the indicators specified in Commission Notice C/2025/214 under 'Appliances specifically designed to operate in a wet

environment' were taken into consideration. As described in this guidance, it was assumed that all five indicators need to be fulfilled, namely:

  - (i) '**specifically'**: the appliance is designed with the main purpose to operate in the environment described;
  - (ii) '**primarily'**: the environment described is the primary environment of the appliance, as Recital 39 explicitly specifies, 'for the majority of the active service of the appliance'. In other words, not just an environment in which the device may only coincidentally or accidentally operate;
  - (iii) '**washable or rinseable'**: the appliance is intended to be washable or rinseable;
  - (iv) '**compromising safety'**: there is evidence in the product documentation when placing the product on the market that battery replaceability and removability by end-users would compromise the safety of the user or the appliance;
  - (v) '**no way to redesign'**: there is evidence in the product documentation when placing the product on the market that there is no way to redesign the appliance with the current state of the art technology, without severely affecting the health and safety of the end-user or the performance and functionality of the product.

- **Article 11(2)(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'. Derogation requests were checked to consider whether they would fall into the scope of the medical devices benefiting from the existing derogation.

The Article 11(3) derogation applies to products that require a continuous power supply. The Commission Notice provides clarification on the interpretation and application of Article 11(3) and identifies and lists certain devices to which these criteria apply. Within the framework of the BattReg, the introduction of any application-specific derogations to this article is not envisaged. However, in this study it was also considered whether the derogation in Article 11(3) could be relevant for products for which a derogation request was submitted, in cases where:

> a continuity of power supply is necessary and a permanent connection between the product and the respective portable battery is required to ensure the safety of the user and the appliance,
>
> or

> for products that collect and supply data as their main function, for data integrity reasons.
>
> (Regulation (EU) 2023/1542, 2024)

Article 11(4) specifies criteria for adding derogations to Article 11(2). These criteria were interpreted to break down into two cases:

- Cases where there are 'scientifically grounded concerns over the safety of end-users removing or replacing the portable battery': In such cases the arguments of applicants were considered to see if a safety risk for end-users exists in the course of replacing a battery or as a result of a replacement. Though some applicants raised the risk of an end-user performing the replacement in a false manner, it was considered that where the end-user followed the instructions made available by the producer of the product, that this should be avoidable. Or,
- Cases 'where there is a risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law': In such cases, applicants were required to specify the standard or legislation that removability would be in violation of. The documents were then checked to ensure that it was indeed required that the battery not be removable by the end-user to comply with safety requirements.

It should be noted that the assessment did not include a market analysis or stakeholder survey to check whether products similar to those for which derogations were requested used removable and replaceable batteries or not. This approach was agreed with the EC and has already been reflected in Commission Notice C/2025/214 in relation to the Article 11(2)(a) derogation, for which examples of products benefiting from the derogation are specified as 'oral hygiene appliances (e.g. toothbrushes as in IEC 60335-2-52), and shavers, hair clippers and epilators', while also explaining that:

> At the same time, […] there may still be appliances used in wet environment that incorporate batteries that are removable and replaceable by end-users, as long as this does not compromise safety. Examples of such appliances include toothbrushes and shavers powered by portable batteries of general use.
>
> (Commission Notice C/2025/214, 2025) p. 5

Where a derogation was found to be justified, a **formulation** was proposed for its wording.

1.5. General aspects

This section addresses general aspects that arose during the assessments that may be of relevance to more than one application.

1.5.1. Miniaturisation: Products that are too small for redesigning the battery integration and interface

In some of the applications submitted for derogation, the existing design is presented and argued to result in safety risks to end-users should they attempt to replace the battery. Though this logic can be followed in some cases, this would not generally exclude that applications can be redesigned in a way that would eliminate such safety risks as a result of battery replacement. However, when the application is very small, applicants may argue that the size or dimensions of the product or relevant component would hinder a design that would enable a practical and safe replacement of the battery. This can be relevant in some products due to the trend towards miniaturisation.

To ensure a harmonised approach in the assessment of such arguments on miniaturization, the consultant suggests following an approach found in a standard developed for toy safety.

Directive 2009/48/EC on the Safety of Toys is currently undergoing revision and proposed to be turned into a regulation. Recital 20 of the amended proposal for a Regulation specifies that

> toys that include batteries should be designed in such a way that the batteries are difficult for children to access. In situations where, due to the nature, size or form factor of the toy, or of the small electronics contained within, it would not be possible to design the toy in a way that the internal battery would be removable and replaceable by the end-user while also ensuring the safety of the child and the safe continued use of the toy, the toy could be designed in such a way as to make the battery removable and replaceable by independent operators.
>
> (PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS Subject: Proposal for a Regulation of the European Parliament and of the Council on the Safety of Toys and Repealing Directive 2009/48/EC (COM(2023)0462 – C9-0317/2023 – 2023/0290(COD)), 2025)

This intention is then stipulated in Annex II (Particular Safety Requirements), Part IV (Electrical properties), Point 10 of the proposal as follows:

> Electric toys with batteries that constitute small parts shall be designed and manufactured in such a way as to ensure that access to the battery is prevented by requiring the use of a tool. 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.
>
> (PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS Subject: Proposal for a Regulation of the European Parliament and of the Council on the Safety of Toys and Repealing Directive 2009/48/EC (COM(2023)0462 – C9-0317/2023 – 2023/0290(COD)), 2025)

Where the battery is considered a small part, the product is to be designed so that it is only accessible by using tools. The above proposal does not clarify what type of tools are meant, however as these would need to be in possession of the end-user (or rather the parents of the child), the consultant assumes that standard tools or as referred in Article 11 of the BatReg commercially available tools are meant ([3]). Where, however, this is not possible due to the size or nature of the toy and where a rechargeable battery is used, instead of ensuring replacement through the application of tools, the battery could be made replaceable only by independent professionals. The consultants consider this requirement to be equivalent to the replaceability requirement addressed in Article 11 of the Batteries Regulation and to the possibility of derogation specified in Article 11(4). The reference to size or nature of the toys is understood to give two alternatives that do not necessarily need to coincide for the 'replacement only by an independent professional' to be considered justified. In the case of size, this is assumed to mean a small product or one where the form would not allow redesigning access to the battery through the use of standard tools. For example, a product may be long and narrow, in which case it may not be considered small, but the form would still hinder replacement with standard tools. In the case of the nature of the product, this is understood to mean that the way the product is used dictates a form that would prevent a redesign. For example, in the case of the application for derogation for earbuds (see section 3.6), the necessity of the product to fit in the outer ear limits the size of the product.

[3] See also guidance in Commission Notice C/2025/241 section 2.1 (Tool types). (Commission Notice C/2025/214, 2025)

As part of the toy legislation and its associated standards, EN IEC 62115 (Electric toys – Safety) explains that

> The requirement of 13.4.1 is designed to minimise the risk of swallowing by requiring that access to small part batteries is reduced. The risk is minimised by requiring that small part components containing batteries are not able to be removed without the aid of a tool, unless the same part prevents access to the batteries under the test conditions of this clause. Also, for batteries that are small parts, the battery cover should only be able to be removed with the aid of a tool.
>
> (*EN IEC 62115:2020*, 2020)

To clarify whether a product or part can be considered as a small part, Standard EN 71-1:2014+A1:2018 (CEN, 2014), which was developed in conjunction with the Directive 2009/48/EC on the Safety of Toys can be applied (Directive 2009/48/EC, 2009). Under Article 8.2 of Standard EN 71-1, what can be considered as a cylinder test, is described as a method for determining whether a product or one of its parts is small. For a toy or part thereof to be considered small, it needs to fit in its entirety and without compression in a diagonally cut cylinder with a 31.7-millimetre diameter and a length of between 25.4 and 57.1 millimetres. In contrast, if the application or part does not fit within this cylinder, it would not be considered small and a redesign that enables battery replaceability with the aid of a tool (in the case of toys) would be concluded as possible. Where the article is not a toy, the consultants further interpret that replaceability through redesign would not necessarily need to be possible through the use of a tool. For example, a screwing mechanism could be applied to allow opening and accessing the battery compartment without the use of a tool, possibly requiring less space and thus enabling smaller dimensions.

The cylinder test is relevant for products in which the battery should be built-in in such a way that they cannot be removed or replaced by the user but only by a professional, to ensure that the battery is not accessible for swallowing. This case is different from some cases at hand, where redesign is not related to risks to small children. Nonetheless, the reference to small size and nature would also be relevant for these cases and thus the cylinder test and the dimensions referred therein are considered to give indication to what form factors should be considered as too small to allow a redesign of the product.

The parameters of the cylinder test could be applied as a possible specification in the following assessments in cases where applicants claim a redesign to be hindered due to size. However, in the consultant's view, in the case that the battery is located in a long and narrow product (or long and narrow part thereof), redesign may also be impractical.

Nonetheless, in cases where the product is found to be too large it would still need to be determined if the product integrity could be affected through battery replacement.

1.5.2. Products in which battery replaceability would pose a risk of swallowing and choking for children

In some of the applications for derogations, applicants argue that hindering battery replacement is necessary to prevent the risk of swallowing the battery in the case that a child opens the battery compartment. The Directive on Toys Safety was consulted in this respect following a discussion with the relevant policy officers. The current Directive includes 'Particular Safety Requirements' in its Annex II, referring in Part I to physical and mechanical properties. Item 4(d) in this part reads as follows:

> Toys, which are clearly intended for use by children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.
>
> (Directive 2009/48/EC, 2009)

This makes clear that the risk of swallowing and inhalation associated with small parts is referred to in toys that are intended for use by children below the age of 36 months as also toys intended for older children but where the toy or the part is intended to be put in the mouth in the course of its normal use.

The validity of arguments made based on a risk of swallowing and choking of the battery in the case of replaceability is thus assessed in relation to the application at hand and its intended purpose. For the argument to be valid, the application would need to:

- Be designed for use by children below the age of 36 months, and/or
- Be a toy designed with the intention of the toy, or its part in which the battery is incorporated, to be placed in the mouth of the user during normal use.

In this respect it is also useful to consider the scope of the Directive on Toys Safety or in other words the products for which its stipulations apply. Article 1 of the Directive states that it 'shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age (hereinafter referred to as toys)' (Directive 2009/48/EC, 2009). The consultants interpret this to mean that the safety argument on the risk of swallowing related to children

would only be relevant in applications designed for use in play by children below the age of 36 months (general risk of swallowing or inhalation) or for children below the age of 14 years when the toy or its part in which the battery is incorporated it intended to be placed in the mouth. It is proposed that only in such cases and for such users would the risk of swallowing, choking and/or inhalation be considered to be valid.

1.5.3. Products with a relatively short lifetime or single use products

In a few of the applications, a derogation is requested for products that have a relatively short lifetime. Though some products can be considered as consumables or single use products, in other cases, it could be that the product is usually only used by the initial consumer for a short period (e.g. due to change in age and interests). This time is then considered as the product lifetime.

In the case of a medical product, there may be important health and hygiene reasons for making a product a single use one. For sex toys (pleasure gadgets), there are also hygienic as well privacy reasons why a product would only be used by the end user.

In other cases, like for the music card application submitted by (Depesche Vertrieb GmbH & Co. KG, 2025b), a greetings card is assumed to have a relatively short lifespan, mainly attributed to the time at which the card is opened by the recipient. As most cards will have a personal inscription, they are not suitable for reuse through secondary market operations or as pass-me downs.

Other products may be designed as single use ones for convenience reasons. A single use e-cigarette is used by the end-user for a short period of time and then disposed of as opposed to a multiple use product which would be recharged both with the vaping substance and with energy (in the case of a rechargeable battery).

In all such products, regardless of whether a derogation would be justified based on the Article 11(4) criteria or not, it is questionable if the end-user would actually attempt to replace the battery as the product has been designed only for a short period of use and its price shall also not motivate a replacement of the battery.

Regardless of the negative contribution of such products to waste in the European Union, it is doubtful if requiring the replaceability of the battery shall achieve an extended lifetime of the product, meaning that the burden of redesign is not expected to lead to a benefit in terms of impacts to the

environment (e.g. reduction of waste) or on society (e.g. extension of use time for the consumer).

1.5.4. Inexpensive products and the likelihood of battery replacement

In some cases, ensuring the replaceability of a battery by the end-user is of relevance for ensuring the further function of the device beyond the end-of-life of the battery. This is often the case in products that are inexpensive and/or products that have a technical function which needs to be updated from time to time to remain compatible with other devices or with connectivity. A limitation to battery replaceability can in these cases mean that once the battery is depleted the product shall lose its function and be submitted to a premature end-of-life.

Though in some cases replaceability by an independent professional may be warranted, it may in practice render the product obsolete once the battery is depleted.

For example, in an application submitted by Mattel for children's 'Hot wheels' remote-control vehicles, the applicant ensures 'at least 20 hours of playtime in standard testing conditions, which exceeds the amount of time most consumers are likely to use the toy'. This is assumed by the consultant to refer to the total amount of time that the battery would be activated during playing by a child. In other words, the consultants assume that the product is not designed for 20 hours in total (less than one day) but rather 20 hours of use that would be distributed over a longer period of a few months or a year.

In theory, a product like a remote-control car could be passed down from one child to the next or passed on through secondary sales or charity to the next user. The decision to design the car so that the battery is non-replaceable contributes to making the product lifetime a relatively short one. Subsequently, where in this case the remote-control function is considered a central function to the product, the replaceability is understood to be undermined. Whereas the idea of replaceability is intended to prevent products from becoming waste once the battery is depleted, in this case, once the battery is depleted, it is doubtful if it would be replaced (irrespective of the possibility to do so), especially if this requires sending it to an independent professional.

For example, on a retailer's website, the Matel Hot Wheels RC Toy Car ([4]) is sold for 32.99 €. If the battery is readily replaceable by the user (as in the case of the remote control) and available on the market, it can be assumed that the

[4] See details: https://www.amazon.de/Hot-Wheels-Spielzeugauto-Ferngesteuerter-Stradale/dp/B0DLDTPFPB?source=ps-sl-shoppingads-lpcontext&smid=A3JWKAKR8XB7XF&language=en_GB&th=1, last viewed 23.10.2025

battery would be replaced once depleted. If the battery is not replaceable by the end-user (as is the case in the toy car itself), at a minimum the following must be assumed to finance a repair:

- The cost of shipping the product to an independent professional and back to the consumer – For example, sending an envelope in Germany costs 0.95-2.90 € ([5]) assuming the envelope is limited in thickness (1-5 cm, depending on size). Shipping a larger product is expected to be more expensive. Shipping a small parcel will generally cost 3.50 € or more ([6]).
- The cost of the replacement battery – This could be as low as 1 € and up to a few tens of € depending on the battery type and the product.
- Additional components may need replacement as a result of the procedure, demanding an additional cost.
- The cost of replacement shall mainly be made up by the labour costs associated with the replacement. This refers to the time needed by the professional to replace the battery but also to the time needed for the logistics of receiving and resending the shipment and the time needed for billing. A cost of at least 50 € can be expected.

Looking at the various cost components and the original cost of the product, it is easy to understand why some end-consumers will prefer to dispose of the product and purchase a new one, regardless of whether the battery design would allow replacement by a professional or not. In such cases, it is thus doubtful if replaceability by an independent professional will lead to an actual replacement.

In a (2020) study that looked at the subject of obsolescence, the concept of economic obsolescence was explained to be:

> related not only to the technical possibilities of carrying out repairs, but also to the availability of repair service and especially incurring repair costs. Appreciation of costs between product replacements and repairs is in most cases the key factor for decisions pertaining to repairs and crucial for changing useful service life of products. (Prakash et al., 2020)

[5] See details: https://www.deutschepost.de/en/b/brief_postkarte.html, last viewed 28.7.2025

[6] See details: https://single-market-economy.ec.europa.eu/sectors/postal-services/parcel-delivery-eu/find-best-price-your-eu-parcel-delivery_en, last viewed 28.7.2025

In other words, the fact that the battery could be designed to be a replaceable by an independent professional will not necessarily lead to actual replacement and the related prevention of waste.

2. Assessment of applications for derogations based on Article 11(4)

2.1. Products falling under the scope of Directive 2014/34/EU ('ATEX Directive')

2.1.1. Summary of the applications

Eleven applications were submitted regarding products falling under Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU, 2014), which is usually abbreviated as ATEX Directive. The applicants were associations, producing companies and national agencies. The following Table 2-1 lists the applicants in alphabetical order, their wording of the product category and a summary of their argumentation for a derogation.

Table 2-1 – Summary of applications on products falling under the scope of the ATEX Directive received in the call for applications under Article 11(4)

Applicant	Product category	Main argumentation summary	Additional argumentation
Aava Mobile Oy	ATEX certified products (2014/34/EU)	Reference to ANNEX II of the ATEX-Directive 1.0 General requirements to points: 1.01. Principles of integrated explosion safety; 1.2.3. Enclosed structures and prevention of leaks; 1.2.6 Safe opening; 1.2.9 Flameproof enclosure systems	Reference to the JRC Report (EUR 31801 EN) from 2024 (Chapter 4)
ECOM instruments GmbH	Battery-operated mobile devices that fall under the ATEX Directive (EU) 2014/34 (e.g. tablets, smartphones and accessories such as headsets, barcode readers, etc.)	Battery replacement by end users poses a significant risk, as improper handling could lead to sparking, greatly increasing risks of explosions or fires; use of specially tested and certified batteries may be used; permanent integration in a robust, sealed housing to prevent mechanical damage, moisture ingress, and safety-critical malfunctions; replacement permitted only by authorized specialists under controlled conditions; small quantity of devices for a specialized niche market; need for ATEX compliance.	-

Applicant	Product category	Main argumentation summary	Additional argumentation
GAMBICA Association Ltd.	Products falling under the scope of Article 1 of Directive 2014/34/EU (ATEX Directive)	Specific product design to protect professional users in hazardous environments, e.g. in the energy, chemical, food, and pharmaceutical industries; strict safety requirements in harmonised EU standards under the ATEX Directive on encapsulation, non-repairable flamepaths, sealed joints, use of tested battery types and access to battery compartments restricted to qualified professionals using specialised tools; legal contradiction.	Reference to Commission guidelines concluding that the safety considerations would justify a full derogation and the safety requirements in Annex II of the ATEX Directive (1.01. Principles of integrated explosion safety; 1.2.3. Enclosed structures and prevention of leaks; 1.2.6 Safe opening; 1.2.9 Flameproof enclosure systems) and to the JRC report
Finnish Safety and Chemicals Agency Tukes	All ATEX (2014/34/EU) product	Explosion protection of ATEX products is a case where the requirements of Article 11 of the BattReg. are in violation of other product safety requirements provided for by applicable Union law; ATEX equipment only for professional use in a negligible proportion of the equipment on the market; conformity assessment of ATEX equipment often includes type approval and production quality assurance; safety requirements on insulation, material and instructions on authorized party for repair.	-
FM Approvals LLC	Products under the scope of 2014/34/EU - ATEX Directive	Reference to ANNEX II of ATEX-Directive 1.0 General requirements to the points: 1.01. Principles of integrated explosion safety; 1.2.3. Enclosed structures and prevention of leaks; 1.2.6 Safe opening; 1.2.9 Flameproof enclosure systems	Reference to ZVEI position paper and JRC report (chapter 4)
Anonymised	Anonymised	In this product group, the replacement of batteries by non-specialists poses an increased/life-threatening risk to subsequent use of the respective products, as ignition protection-related gap dimensions or tightness can no longer be fully guaranteed.	
Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services (ILNAS)	Products falling under Directive 2014/34/EU (ATEX Product Directive)	Reference to safety requirements of the ATEX Directive, in particular to Annex II point 1.2.6 requires: Safe opening, 1.2.9 Flame proofen closure systems and 1.3.1 Hazards arising from different ignition *sources*; note on harmonised standards requiring use of specific cell types and batteries and replacement instruction (manufacturer's recommended method(s) of making electrical connections to a battery).	Safety of batteries in ATEX equipment, the prevention of sparks and heat generation critical concern; ATEX certification essential for safety of personnel and equipment.

Applicant	Product category	Main argumentation summary	Additional argumentation
MSA Technologies and Enterprise Services GmbH	Products, under the Scope of 2014/34/EU (ATEX-Directive)	Product example, handheld gas detection equipment powered by specially designed/ protected batteries to be changed by authorized and special ATEX trained people; reference to ANNEX II of ATEX-Directive 1.0 General requirements to the points: 1.01. Principles of integrated explosion safety; 1.2.3. Enclosed structures and prevention of leaks; 1.2.6 Safe opening; 1.2.9 Flameproof enclosure systems	Reference to the ZVEI position paper
ORGALIM - Europe's technology industries	Products falling under the scope of the ATEX Directive (as defined in Article 1 of Directive 2024/34/EU)	Standardised design to ensure health and safety of professional users; requirements include encapsulating materials, non-repairable flamepaths, glued or cemented joints, limited range of batteries allowed for use, no access by unauthorised personnel; conflicting requirements in two pieces of legislation risking in unsafe working conditions.	Reference to ANNEX II of the ATEX-Directive and in particular to the points 1.01. Principles of integrated explosion safety, 1.2.3. Enclosed structures and prevention of leaks, 1.2.6 Safe opening and 1.2.9 Flameproof enclosure systems; reference to the recommendation of the JRC report on a full derogation (chapter 4)
Pepperl + Fuchs SE	Products, under the scope of 2014/34/EU (ATEX-Directive)	High safety level for products by ATEX Directive and harmonised standards is jeopardised; contradicting safety requirements (e.g. under ATEX prevention of easy access or access by unauthorized personnel), products not intended for consumer market.	Reference to ZVEI position paper and JRC report (chapter 4)
ZVEI e. V. Electro and Digital Industry Association	Products, under the Scope of 2014/34/EU (ATEX-Directive)	Reference to ANNEX II of ATEX-Directive 1.0 General requirements to the points: 1.01. Principles of integrated explosion safety; 1.2.3. Enclosed structures and prevention of leaks; 1.2.6 Safe opening; 1.2.9 Flameproof enclosure systems	Reference to ZVEI position paper and JRC report (chapter 4): ZVEI position paper raises health and safety requirements of ATEX Directive (encapsulating materials, non-repairable flamepaths, glued or cemented joints, limited range of batteries allowed for use) and explains contradictions to the Batteries Regulation and proposes as wording 'products, under the scope of Article 1 of Directive 2014/34/EU (ATEX Directive)'

Sources: (Aava Mobile Oy, 2025; ECOM instruments GmbH, 2025; Finnish Safety and Chemicals Agency Tukes, 2025; FM Approvals LLC, 2025; Institut Luxembourgeois de la Normalisation, 2025; MSA Technologies and Enterprise Services GmbH, 2025; ORGALIM - Europe's technology industries, 2025;

Pepperl+Fuchs SE, 2025; The GAMBICA Association Ltd, 2025; ZVEI e. V. Electro and Digital Industry Association, 2025b)

Notes:
JRC report: report of the Joint Research Centre (JRC): Spiliotopoulos, C.; Magrini, C. (2024): Technical input for the Guidelines on removability and replaceability of portable and Light Means of Transport batteries., Publications Office of the European Union, Luxembourg, 2024, doi:10.2760/564746; https://publications.jrc.ec.europa.eu/repository/handle/JRC136588

Commission guidelines: Commission Notice C/2025/214 (2025: Commission guidelines to facilitate the harmonised application of provisions on the removability and replaceability of portable batteries and LMT batteries in Regulation (EU) 2023/1542; https://eur-lex.europa.eu/eli/C/2025/214/oj

The applicants mostly referred to all products falling under the ATEX Directive which are sometimes referred to as 'Ex Products'. One applicant, ECOM instruments GmbH, a manufacturing company, only refers to 'battery-operated mobile devices that fall under the ATEX Directive (EU) 2014/34 (e.g. tablets, smartphones and accessories such as headsets, barcode readers, etc.)'. According to the applicants, products falling under the ATEX Directive are used in various industries, including the energy sector (with the emerging hydrogen industry being mentioned specifically), the food sector (with flour mills and grain silos being given as examples), and the chemical and pharmaceutical manufacturing industry. Some applicants emphasised that these products are manufactured in relatively small quantities for a specialised niche market. This was mentioned to support the argument that sustainability and waste reduction or prevention are less relevant.

The argumentation of the applicants mostly refers to the specific safety requirements in Annex II of the ATEX Directive. Under the common requirements for equipment and protective systems, the applicants emphasise the following provisions:

> 1.0 General requirements
>
> 1.01. Principles of integrated explosion safety
>
> Equipment and protective systems intended for use in potentially explosive atmospheres must be designed from the point of view of integrated explosion safety.
>
> 1.2.3. Enclosed structures and prevention of leaks
>
> Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only. If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that releases of gases or dusts cannot give rise to explosive atmospheres outside the equipment.
>
> 1.2.6 Safe opening
>
> If equipment and protective systems are in a housing or a locked container forming part of the explosion protection

> itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.
>
> 1.2.9 Flameproof enclosure systems
>
> If parts which can ignite an explosive atmosphere are placed in an enclosure, measures must be taken to ensure that the enclosure withstands the pressure developed during an internal explosion of an explosive mixture and prevents the transmission of the explosion to the explosive atmosphere surrounding the enclosure.
>
> (Directive 2014/34/EU, 2014), Annex II

These safety requirements stipulate that, for products falling under the ATEX Directive, batteries must be permanently integrated into robust, sealed housings to prevent mechanical damage, moisture ingress, and safety-critical malfunctions. The applicants emphasise the need of using encapsulating materials or non-repairable flamepaths, as well as glued or cemented joints. Only authorised specialists are permitted to replace them under controlled conditions. Furthermore, batteries are often rigorously tested and assessed before being used in the products, and only a limited range of battery types are permitted. Applicants also referred to harmonised European standards, for complying with the essential health and safety requirements of Directive 2014/34/EU; these standards were not further specified.

Several applicants referred to the report of the Joint Research Centre (JRC) (Spiliotopoulos & Magrini, 2024) on the 'Technical input for the Guidelines on removability and replaceability of portable and Light Means of Transport batteries' published in January 2024. The report has already highlighted safety considerations for equipment and protective systems intended for use in potentially explosive atmospheres under Directive 2014/34/EU, and a derogation has already been proposed by (Spiliotopoulos & Magrini, 2024).

Several applicants referred to the position paper by the German Electro and Digital Industry Association ZVEI e. V., where the argumentation as summarized above is also presented.

2.1.2. Assessment

Article 11(2)

The derogations specified in BattReg Article 11(2) for appliances specifically designed to operate primarily in an environment and for specific medical devices do not apply here. (Regulation (EU) 2023/1542, 2024)

Article 11(3)

The derogation specified in Article 11(3) is not applicable here. Neither continuity of power supply nor a permanent connection between the product and the respective portable battery are required to ensure the safety of the user and the appliance nor, for products that collect and supply data as their main function, have data integrity reasons been raised for the products falling under the scope of the ATEX Directive.

Criteria for a derogation in Article 11(4)

Article 11(4) allows for adding further products to be exempted from the removability and replaceability requirements if there are scientifically grounded concerns over the safety of end-users removing or replacing the portable battery, or in cases where there is a risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law. As the ATEX Directive provides dedicated safety requirements that explicitly require that batteries are not accessible to the end-user the second criterion of Article 11(4) is considered applicable.

The legal incoherence that would lead to a violation of the safety provision of the ATEX Directive is as follows: The provisions of the Battery Regulation require a portable battery to be readily removable by the end-user with the use of commercially available tools, without requiring the use of specialised tools. In contrast, the safety requirements for products falling under the ATEX Directive require the prevention of any ignition of explosive atmospheres. Therefore, an enclosed structure of the equipment is required as well as a safe opening, which means that the opening should only be with a special tool or by means of appropriate protection measures. A battery replacement by an end user must therefore be considered as an improper handling that could lead to sparking and provoke an ignition source.

In the JRC report (Spiliotopoulos & Magrini, 2024), safety considerations have already been brought forward for the equipment and protective systems intended for use in potentially explosive atmospheres under Directive

2014/34/EU, and a derogation has already been proposed. Spiliotopoulos & Magrini (2024) concluded that in this type of application and regardless of product type, a risk-averse approach is proposed with regards to removability and replaceability by associating such applications with the safety reasons of the derogation.

As for the wording of the derogation, most of the applicants referred in general to all ATEX products. However, the wording of one of the manufacturing companies indicates that not all ATEX products might contain portable batteries.

Article 1(1) of the ATEX Directive outlines the scope as follows:

> 1. This Directive shall apply to the following, hereinafter referred to as 'products':
>
> (a) equipment and protective systems intended for use in potentially explosive atmospheres;
>
> (b) safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;
>
> (c) components intended to be incorporated into equipment and protective systems referred to in point (a).
>
> (Directive 2014/34/EU, 2014)

Additionally, Article 1(2) of the ATEX Directive lists products where the Directive shall not apply to, e.g. medical devices or equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created. ([7])

[7] The full list is as follows:
(a) medical devices intended for use in a medical environment; (b) equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances; (c) equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas; (d) personal protective equipment covered by Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment; (e) seagoing vessels and mobile offshore units together with equipment on board such vessels or units; (f) means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by

It might be that from the products falling under the ATEX Directive, safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres (Article 1(1)(b)) also cover devices that are not battery operated, but it may also be that products cannot clearly be allocated to the subcategories. The applicants did not engage in such a discussion. Only one applicant used the term of 'battery-operated mobile devices that fall under the ATEX Directive (EU) 2014/34 (e.g. tablets, smartphones and accessories such as headsets, barcode readers, etc.)'

However, as the derogation only refers to battery removability and replacement, a broader wording of the derogation would not affect devices falling under the ATEX Directive that are not battery operated. Therefore, it is recommended to formulate a general derogation for products falling under the ATEX Directive to avoid any conflicts resulting of a too narrow formulation of the derogation.

2.1.3. Conclusion and recommendation

From the information provided by the applicants it is concluded that the second criterion of Article 11(4) on the violation of any product safety requirements provided for by applicable Union law is fulfilled. The ATEX Directive 2014/34/EU on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres provides safety requirements that do not allow removability and replaceability of batteries by end-users.

Therefore, it is recommended to add a derogation for products falling under (Directive 2014/34/EU, 2014).

public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded from the scope of this Directive; (g) the equipment covered by point (b) of Article 346(1) of the Treaty on the Functioning of the European Union.

2.2. Toys

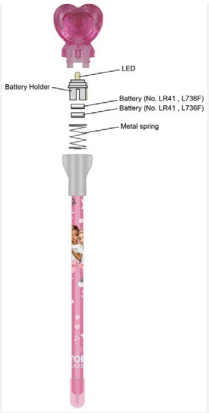
2.2.1. Summary of the applications

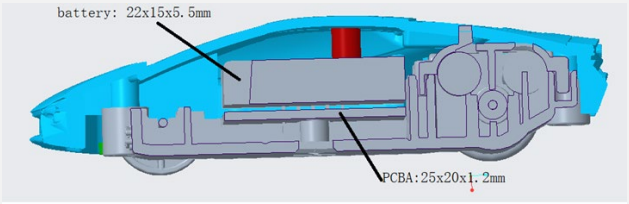
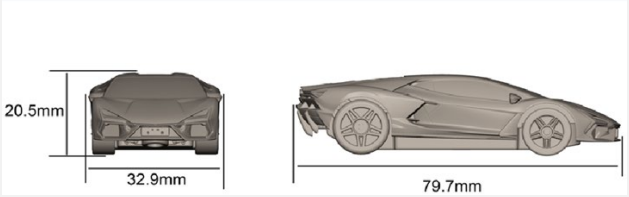
The products in four derogation applications are categorised as toys. Toys are defined as products 'designed or intended, whether or not exclusively, for use in play by children under 14 years of age' in the (Directive 2009/48/EC, 2009). ([8])

The following Table 2-2 shows the applicants, the products covered by their applications, and their main arguments.

[8] The Toy Safety Directive is supplemented by the references of the harmonised standards for toys: COMMISSION IMPLEMENTING DECISION (EU) 2023/740 of 4 April 2023 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council; https://eur-lex.europa.eu/eli/dec_impl/2023/740/oj

Table 2-2 – Summary of applications for toys received in the call for applications for derogation under Article 11(4)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Depesche Vertrieb GmbH & Co. KG	Ballpen with Unicorn Topper and LED Light	Material or size of product do not permit securing the battery compartment with safety screw; Locking solution did not meet testing standards for electronic child safety.	Could prevent children from accessing the button batteries to avoid electric shock or swallowing. For toy safety, consider: Article 10 and Annex II: Toys must prevent children from accessing small parts, including battery compartments. EN IEC 62115 (safety standard for electric toys): Emphasizes that children must not have access to button batteries to avoid electric shocks or swallowing.	 The exploded diagram additionally provided with the application does not show a unicorn topper but rather a heart-shaped topper and also shows a small pin cap.
Depesche Vertrieb GmbH & Co. KG	Mini colouring book with sound	Batteries are permanently integrated into device for safety and longevity of product	Safety: prevents small children from accidentally removing batteries and swallowing them or injuring themselves Longevity: sealed design ensures that sound module functions reliably for entire service life of colouring book	

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Mattel Europa B.V.	Product family of Hot Wheels RC 1:64 Toy Car	Space constraints, Disruption of compatibility with the 1:64 scale playsets Redesign needs re-testing and recertifications No need for consumer replacement in most cases	Lithium battery in the toy vehicle requires cutting wires to remove; conflict with harmonized standard EN IEC 62115:2020+A11:2020, PCBA (Printed Circuit Board Assembly) is an essential structural component of the RC platform. Additionally, enlarging the toy to accommodate compliance requirements for battery replacement would alter its form factor, rendering it incompatible with the Hot Wheels ecosystem, including the track sets and playsets. This incompatibility would prevent consumers from enjoying the full interactive play experience that characterizes the Hot Wheels product line, negatively impacting market competitiveness. Batteries last for the full duration of expected play, with no need for replacement in normal circumstances.	 
The LEGO Group	New interactive LEGO Brick	Design and development of small toys with electronics in a safe way, in alignment with EU and non-EU toy safety norms and standards, guarantee end-user safety.	Particularly relevant given the small size, nature and form factor of this product category, the special nature of the end-user audience (i.e. children) and the use of the toy.	

Source: (Depesche Vertrieb GmbH & Co. KG, 2025a, 2025d; Mattel Europa B.V., 2025; The LEGO Group, 2025)

Depesche Vertrieb's Ballpen with Unicorn Topper and LED Light

The applicant Depesche Vertrieb requests a derogation for the battery in an LED light within a ballpen plastic topper. From the picture provided by the applicant, it seems that the battery and LED plastic topper are glued together, which makes them sealed. The applicant explains that they tested a locking solution, but it did not meet the testing standards for electronic child safety. The material or size of the product does not permit securing the battery compartment with a safety screw. The applicant did not provide further information on the testing of the locking solution. From the picture that the applicant provided it is understood that the topper of the pen containing the LED light is made of plastic that might be prone to breaking. It can be followed that the further use of this material does not allow the battery to be covered so that it can only be removed with the aid of a tool. The applicant does not provide information as to how the battery will be made removable and replaceable by independent professionals. Overall, the argumentation in the application points to an understanding that a derogation supports a 'business as usual' scenario. (Depesche Vertrieb GmbH & Co. KG, 2025c)

Depesche Vertrieb's mini colouring book with sound

The application covers a small book containing pictures that can be coloured in. The colouring book has an integrated sound device, the nature of which is not specified. It can be assumed that the use phase of such a colouring book is very limited. The applicant also argues that this 'sealed design ensures that the sound module functions reliably for the entire service life of the colouring book.' Consequently, there is no indication that the applicant has made any effort to make the battery replaceable. (Depesche Vertrieb GmbH & Co. KG, 2025d)

The applicant further claims that the battery is permanently integrated into the device for safety of the product, which would prevent small children from accidentally removing the batteries and swallowing them or injuring themselves. Concerning the risk of swallowing, the standard for electric toys EN IEC 62115, requires that the risk is minimised

> by requiring that small part components containing batteries are not able to be removed without the aid of a tool, unless the same part prevents access to the batteries under the test conditions of this clause. Also, for batteries that are small parts, the battery cover should only be able to be removed with the aid of a tool. (*EN IEC 62115:2020*, 2020)

The risk of injury is not further specified. However, Annex II of the Toy Safety Directive mentions the risk of physical injury with regard to product stability,

ensuring that the toy can withstand stress without breaking, and with regard to the design of accessible edges, for example, and electrical properties, such as the risk of injury to the eyes from light-emitting diodes (LEDs) (damage to sight). These possibilities of injuries are not expected with this product and the applicant's claim cannot be followed.

Mattel's Hot Wheels RC 1:64 Toy Car

The Mattel application does not refer to safety considerations in the first place but to the space constraints in the toy car 'Hot Wheels RC 1:64' (Mattel Europa B.V., 2025). From Mattel's webpages it is understood that their toy cars 'Hot Wheels' exist in several dimensions, where 1:64 is the smallest scale. The basic product line is understood to not contain batteries; only the remote controlled 'RC' toy cars do. ([9])

For other electric toys, Mattel explains that they implemented pigtail lithium battery connectors that can be removed and replaced by the end consumer. In the toy car 'Hot Wheels RC 1:64', however, this would be impractical due to the toy's compact dimensions. In the current design, the battery is explained to be connected via wiring from the Printed Circuit Board Assembly (PCBA). Mattel describes that replacing the battery demands heating solder pads in the PCBA of the RC platform. Under this condition, Mattel states that 'the battery replacement process may conflict with harmonized standard EN IEC 62115:2020+A11:2020, which provides a presumption of conformity with the Directive and outlines safety requirements for electric toys.' No further details are given. (Mattel Europa B.V., 2025)

Mattel does not provide information on the possibility that independent professionals will remove and replace the battery in these toy cars. Rather, they claim that

> the battery life of Mattel products is carefully designed to align with the expected lifespan of the toy and beyond, ensuring continued usability. Mattel's quality standards aim to design batteries that last for the full duration of expected play, with no need for replacement in normal circumstances. For RC vehicles, the company ensures at least 20 hours of playtime in standard testing conditions, which exceeds the amount of time most consumers are likely to use the toy. (Mattel Europa B.V., 2025)

[9] https://shop.mattel.com/pages/hot-wheels

The LEGO Group: New interactive LEGO Bricks

The LEGO Group application covers new interactive LEGO bricks that are understood not to be on the market yet. From the pictures provided by the applicant, the LEGO Brick 2x4 has included the following complex electronics: a speaker, an accelerometer, light output and a battery that can be charged wirelessly. The LEGO Group provides a charging station so that the bricks can be charged wirelessly. The applicant points out that 'battery swapping is not needed'. No information is provided on the possibility of battery removability and replaceability by independent professionals. (The LEGO Group, 2025)

2.2.2. Assessment

Relation to existing derogations

Article 11(2)

Though there might be toys that are 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, this aspect does not apply to the toy products under assessment here. Thus Article 11(2)(b) would not apply.

Nor would the toys for which a derogation has been requested be considered as medical devices that benefit from the derogation in Article 11(2)(b).

Article 11(3)

The derogation specified in Article 11(3) does not apply for the toy applications. None of the aspects of Article 11(3) were raised.

Criteria for a derogation in Article 11(4)

There are two safety criteria given in Article 11(4), scientifically grounded concerns over the safety of end-users removing or replacing the portable battery, or in cases where there is a risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law.

The reasons and concerns raised by the applicants are related to the specific toy safety requirements set out in the Toys Directive and the standards that supplement the legislation.

The toys legislation has been revised and a provisional agreement on a regulation on the safety of toys was reached:

> Recital 20: As batteries are regulated by Regulation (EU) …/…[P.O. insert serial number for Regulation on batteries and waste batteries], the requirements regarding chemical substances in toys should not apply to the batteries included in toys. However, toys that include batteries should be designed in such a way that the batteries are difficult for children to access. In situations where, due to the nature, size or form factor of the toy, or of the small electronics contained within, it would not be possible to design the toy in a way that the internal battery would be removable and replaceable by the end-user while also ensuring the safety of the child and the safe continued use of the toy, the toy could be designed in such a way as to make the battery removable and replaceable by independent operators.'
>
> Annex II (Particular Safety Requirements), Part IV (Electrical properties), Point 10: Electric toys with batteries that constitute small parts shall be designed and manufactured in such a way as to ensure that access to the battery is prevented by requiring the use of a tool. 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.
>
> (PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS Subject: Proposal for a Regulation of the European Parliament and of the Council on the Safety of Toys and Repealing Directive 2009/48/EC (COM(2023)0462 – C9-0317/2023 – 2023/0290(COD)), 2025)

The (future) Toy Safety legislation, though referring to the Batteries Regulation, specifies product safety requirements also for batteries and also describes possible circumstances for a derogation for the removability and replaceability by the end-user, such as size and nature, and additionally requires in these cases the use of a rechargeable battery.

The derogations under Article 11 of the Batteries Regulation for toys risks to be in violation of the toy safety legislation supplemented by the references of the harmonised standards for toys. Thus, if it is to be considered to formulate a derogation for toys in order to provide legal certainty, it should refer to the provisions of the toy legislation.

2.2.3. Conclusion and recommendation

From the assessment it can be concluded that the second criterion for a derogation in Article 11(4) applies where the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable EU law. The future toys legislation (PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS Subject: Proposal for a Regulation of the European Parliament and of the Council on the Safety of Toys and Repealing Directive 2009/48/EC (COM(2023)0462 – C9-0317/2023 – 2023/0290(COD)), 2025) has specific requirements for electrical toys and will allow derogations from the obligation of battery removability and replaceability 'due to the nature, size or form factor of the toy, or of the small electronics contained within'. Furthermore, it shall require that a rechargeable battery must be used. This formulation may still require further clarification, for example in the form of a guidance document of the Commission and the Expert Group on Toy Safety ([10]) to provide a definition of terms such as 'nature' of the toy. It is recommended to address the interface to the toys legislation in a recital of the delegated act pursuant to Article 11, as also recital 38 of the Battery Regulation states on the removability and replaceability of portable batteries that 'where other Union law lays down more specific requirements, for safety reasons, regarding the removal of batteries from products, such as toys, those specific rules should apply.' However, if an additional derogation is required to provide further legal certainty for electric toys with batteries, the following formulation is proposed:

- Electric toys that constitute small parts when due to the nature, size or form of the toy, the removability and replaceability of the battery is required by independent professionals to ensure the safety of the toy, as set out in Article 10(2) of Directive 2009/48/EC.

[10] The Guidance Documents on Toy Safety are available at: https://single-market-economy.ec.europa.eu/sectors/toys/toy-safety/guidance_en, E.g. European Commission (2025): GUIDANCE DOCUMENT No 4 ON THE APPLICATION OF DIRECTIVE 2009/48/EC ON THE SAFETY OF TOYS; Grey zone problem: Is a specific product covered by the Toy Safety Directive 2009/48/EC or not?; Ref. Ares(2015)4435628 - 20/10/2015;

2.3. Medical applications

2.3.1. Summary of the application

Four applications were submitted that concern medical devices. See Table 2-3 for a short summary and the following paragraphs for additional details.

Article 11(2) already foresees derogations for some medical devices, referring to:

> (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. (Regulation (EU) 2023/1542, 2024)

However, the derogation does not cover all medical devices, and it is assumed that the devices for which requests for derogation have been made are not in scope of the existing derogation.

Table 2-3 – Summary of requests for derogation of medical devices received in the call for applications under Article 11(4)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Medical device manufacturer	Surgical utensil and endoscope washer disinfectors	Battery replacement is part of the maintenance provided		No images provided by applicant.

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Dexcom, Inc.	Stelo Glucose Biosensor System	Battery is not removable and exceeds lifetime of transmitter in which it is incorporated.	Transmitter is wearable, may be subjected to water and would benefit from derogation 11(2)(a). The request attempts to exclude device from obligations to make the battery replaceable by an independent professional.	Source: https://www.stelo.com/en-us/how-it-works
Nuova Ompi Unipersonale	On-Body Delivery Systems (OBDS) controller			Source: https://www.stevanatogroup.com/de/produkte-kompetenzen/drug-delivery-systems/vertiva/

Source: (Dexcom, Inc., 2025; Nuova Ompi Unipersonale S.r.l, 2025a)

Another application was submitted by a manufacturer of medical devices, however at later stages it was retracted for confidentiality reasons.

Manufacturer of medical devices: application for surgical utensils and endoscope washer disinfectors

A manufacturer of medical devices explains that replacing of the batteries in the above-mentioned products is part of the mandated maintenance program. The service needs to be performed by a trained service technician and not by the user as is documented in the service instructions.

Further information was not provided in the application (i.e., category of devices, reference to standards or EU legislation requiring the service to be done by an independent professional). Despite being approached with additional questions, no further data has been provided by the applicant so far.

In an exchange with an EC colleague working on the Medical Devices legislation, it was explained that the request may concern devices that need to

be validated in operation mode as they need to remain sterile for operations. The use of the battery may be needed to avoid possible memory corruption of the device settings such as the temperatures and times for sterilisation cycles and disinfection processes.

Dexcom, Inc., application for the Stelo glucose biosensor system

Dexcom, Inc., request a derogation for their Stelo glucose biosensor system, which is explained to be an integrated continuous glucose monitor for non-intensive glucose monitoring sold 'over the counter'. The device is a continuous glucose monitoring (iCGM) system that measures and displays estimated glucose values. It is intended for people who are not medicated with insulin but who need to monitor glucose in their blood to consider lifestyle and dietary strategies. This includes people diagnosed with type 2 diabetes or prediabetes or people interested in monitoring their glucose levels. The system is comprised of the sensor applicator and on-body wearable, which includes a Bluetooth transmitter, adhesive patch and sensor. The sensor is inserted by the user into subcutaneous tissue where it converts glucose into electrical current. The readings are sent to an app where they are processed and displayed to the user. The system is considered far less invasive than traditional blood glucose monitoring devices. The transmitter in the Stelo System has a lifetime of ca. 15 days after which it needs to be replaced with a new one. The transmitter incorporates a sealed portable battery, which cannot be removed to ensure device integrity. Dexcom claims that 'the transmitter battery itself has been tested and exceeds the device's lifespan.' This means that a user will never need to remove and replace the battery during the 15-day lifespan of the System. The device is not classified as a medical device or an in-vitro medical device under the MDR IVDR. (Dexcom, Inc., 2025)

The applicant contends

> it is designed and intended to operate in an environment that is regularly subject to splashing water, water streams or water immersion. The Stelo System is a wearable device that (i) is washable, rinseable, water-resistant or waterproof, (ii) is designed to be submersed up to 2.4 metres in water for 24 hours, (iii) has an Ingress Protection (IP) rating of IPX8, and (iv) is expected to be subject to water splashing, streams, or immersion on a daily basis. Further, the replaceability and removability by end-users would compromise the safety of the user or the appliance and there is no way to redesign the device with the current state of the art technology, without severely affecting its performance and functionality. (Dexcom, Inc., 2025)

This indicates that the device is already covered by derogation 11(2)(a), however the application was made to avoid the need for designing the battery to be replaceable by an independent professional. The latter request is beyond the mandate of the consultants.

Furthermore, Dexcom states that '[t]he removal of the battery would also interrupt with the System's continuous glucose monitoring, by cutting the power supply, which would compromise data integrity. This would jeopardize the ability of the device to fulfill its function of providing continuous glucose monitoring.' (Dexcom, Inc., 2025)

Nuova Ompi Unipersonale application for an On-body Delivery Injection System (OBDS) with reusable electronic unit.

The product for which the derogation is sought envisions the development of On-Body Delivery Systems (OBDS) for the subcutaneous administration of medicinal products. OBDSs are designed with a single use disposable unit (a.k.a. Pod) that contains a glass primary container filled with the medicinal product and a reusable unit (named Controller). 'The Controller contains all the elements able to energize, actuate and monitor the delivery process.' (Nuova Ompi Unipersonale S.r.l, 2025a) According to the applicant, it is coupled with each new Pod before the start and removed after the end of each therapy cycle, ready to be then connected to a new Pod for the next cycle. 'The Controller is equipped with a lithium battery.' The expected operating lifetime of the reusable electronic unit is shorter than the lifetime of the battery. 'Once the Controller reaches the End of Life condition, it cannot be used anymore.' The applicant considers the replaceability of the battery to be unnecessary due to this functionality and the understanding that the battery has a longer life than the controller. Removing and reconnecting the battery is equivalent to a reset and the controller loses its capacity to track its own operating lifetime. (Nuova Ompi Unipersonale S.r.l, 2025a)

When asked to provide further information as to what causes the device to enter the end-of-Life mode, it was explained that the battery powers all the device functions, being the only internal power source of the device.

> The lifetime of the Controller is primarily determined by the mechanical capacity of the motor to reliably perform a defined number of drug administrations over time, as well as the mechanism that transfers mechanical power from the motor to the Pod. While the controller is designed for multiple uses, it eventually reaches end-of-life when its performance can no longer be guaranteed within validated parameters. (Nuova Ompi Unipersonale S.r.l, 2025b)

The battery lifetime was however explained not to be considered as the limiting factor in this context. (Nuova Ompi Unipersonale S.r.l, 2025b)

2.3.2. Assessment

Article 11(2)

Though some of the devices mentioned may be used in an environment in which they could be exposed to water during normal use, this has not been raised by the applicants (i.e., Nuova Ompi Unipersonale and another manufacturer of medical devices) and thus Article 11(a) is assumed not to apply to these cases. Should use conditions in a wet environment be relevant, the applicants could make use of the existing derogation but would have the burden of proving their compliance with the indicators specified for this derogation under Commission Notice C/2025/214.

In the case of the Stelos System for which a derogation is requested by **Dexcom** (Dexcom, Inc., 2025), it can be understood that the device can be used while e.g. swimming or during intensive sports. Dexcom claims that the derogation applies, suggesting that the indicators apply (Dexcom, Inc., 2025). To consider if the device would be covered, the five indicators specified under Commission Notice C/2025/214 would need to be fulfilled. The assessment of the indicators is as follows:

(i) ‘specifically’: the appliance is designed with the main purpose to operate in a wet environment: FULFILLED, given that the device has an IP rating of IPX8, and (iv) is expected to be subject to water splashing, streams, or immersion on a daily basis.

(ii) ‘primarily’: the environment described is the primary environment for the majority of the active service of the appliance: FULFILLED. From an exchange of a user of a similar device placed on the market by Dexcom, it was understood that the device is attached to the users body and remains in place throughout its lifetime, meaning that it would e.g. be subject to washing and bathing as part of normal use.

(iii) ‘washable or rinseable’: the appliance is intended to be washable or rinseable: FULFILLED, given the IP rating of OPX8.

(iv) ‘compromising safety’: there is evidence in the product documentation that battery replaceability and removability by end-users would compromise the safety of the user or the appliance:
NOT FULFILLED, though the request states that ‘the replaceability and removability by end-users would compromise the safety of the user or the appliance’, this is not substantiated. The device uses a CR1216 3V

battery and it is doubtful that its removal could result in a safety risk to the user ([11]). That said, given the lifetime of the Stelo System it is unlikely that a battery would need to be fulfilled as the device lifetime is shorter than that of the battery.

(v) 'no way to redesign': the applicant claims that a redesign would not be possible 'with the current state of the art technology, without severely affecting its performance and functionality' (Dexcom, Inc., 2025). Though this is not further explained it can be followed that the device needs to remain relatively small in form, meaning that a redesign would be challenging. FULFILLED.
(Commission Notice C/2025/214, 2025)

It is thus assumed that the Stelo System would also not benefit from the derogation under Article 11(2)(a).

It is assumed that none of the devices for which a derogation is requested benefit from derogation 11(2)(b) for medical devices, because, if this were the case the applicants would have not submitted a request for derogation. Furthermore, none of the devices at hand are understood to be imaging devices or invitro diagnostic devices currently benefiting from this derogation.

Article 11(3)

The derogation specified in Article 11(3) applies in cases: 'where continuity of power supply is […] to ensure the safety of the user and the appliance or, for products that collect and supply data as their main function, for data integrity reasons'.

In the case of the application made by a manufacturer of medical devices, based on an EC representative, such devices are used for disinfection and sanitation of utensils in operating rooms. The use of the battery ensures that the device programming is not lost or impaired during device operation as this could have a detrimental effect on patients in cases where the temperature or duration of disinfection and sanitation cycles is not sufficient due to a falsely replaced battery. The devices would be understood to have the battery replaced during maintenance on a routine basis to avoid this risk to patient safety. This could be considered to be in line with Article 11(4) criteria for replaceability to undermine end-user safety, however it could also be considered that the device needs to ensure a continuity of power supply between the battery and the device to ensure its proper function of supplying the data to perform proper disinfection and sanitation cycles.

[11] See Blogspot under: https://andykong.org/blog/cgmteardown1

The case of the Stelo System produced by **Dexcom** is considered to benefit from this derogation. Data integrity would not be necessary to ensure user safety as users are not medicated with insulin and thus are not at risk in case of monitoring failure in a device with a lifetime of 15 days. Nonetheless, the device is as a product that collects and supplies data as its main function. Blood glucose monitors are specifically mentioned in the Commission Notice 2023/1542/EU.

Criteria for a derogation in Article 11(4)

Looking at the criteria listed under Article 11(4):

For surgical utensils and endoscope washer disinfectors, the applicant did not provide information that would allow assessing the criteria specified in this article.

For the Stelos System for which a derogation is requested by **Dexcom**, it can be understood that battery replaceability is not needed as the device will reach end-of-life long before the battery needs to be replaced. From an exchange with a user of a similar device, it could be understood that due to the function mechanism of the device, in which the sensor inserted into the body tissue is depleted over time, the device will indeed be disposed of long before the battery needs to be replaced. Though it can be followed in this case that the there is no need for battery replacement, the Article 11(4) criteria would not support a derogation in this case as a risk to the user is not foreseen.

Finally, for the OBDS system for which a derogation is requested by **Nuova Ompi Unipersonale**, the consultant agrees that battery replacement could undermine the initiation of the End-of-Life mode of the device, resulting in false administration of medication. Depending on the medication at hand, this could result in a safety risk for the user in some cases. As explained by the applicant, the battery lifetime is not the limiting factor to reaching this mode, but rather the mechanical capacity of the motor to reliably perform a defined number of drug administrations over time and the mechanism that transfers mechanical power from the motor to the Pod. Should one of these functions be impaired, this could result in a false administration with the risks associated above. The consultants understand the initiation of the End-of-Life mode to be intended to prevent such cases of false administration due to improper function of the various components. In a second communication round, the applicant further referred to safety risks related to cases in which the battery was to be removed by the end-user: ‘Safety risks related to premature battery removal could lead to therapy interruption if the user is unable to reconnect the battery’ (Nuova Ompi Unipersonale S.r.l, 2025b). Furthermore, safety risks and loss of data may be relevant in the case that battery reconnection would reset the internal clock and software variables used to monitor the device’s operating lifetime and therapy count. This could also lead to uncontrolled operation and false administration of

medicine. Article 11(4) is considered thus fulfilled and a derogation could thus be provided. The applicant explained that this product differs from most devices on the market that are designed to administer medicinal products insofar that the separation of the controller and the pod allows reuse of the controller over a longer period of time and thus saves resources. According to the applicant, 'Current on-body drug delivery devices (OBDS) available on the market are typically disposable'. (Nuova Ompi Unipersonale S.r.l, 2025b) This aspect could be used to make a distinction between the current product and more common alternatives

2.3.3. Conclusion and recommendation

Each of the cases of medical applications is different and requires an individual approach. None of the products is considered to benefit from BattReg Article 11(2)(a), despite this being claimed for the Stelo System of Dexcom.

Derogation 11(2)(b) is also not considered relevant for any of the devices, as none of the devices can be considered medical imaging and radiotherapy devices or in-vitro diagnostic medical devices.

The surgical utensils and endoscope washer disinfectors are considered to benefit from the derogation under Article 11(3) as a discontinuity in power supply could result in erasure of memory, which could have detrimental effects in an operation room should surgical equipment not be properly sterilised and disinfected. The Stelo System produced by **Dexcom** is also assumed to benefit from this derogation as the device is a product that collects and supplies data as its main function.

For the criteria included in Article 11(4), it is considered that the OBDS system produced by **Nuova Ompi Unipersonale** fulfils the requirements, as battery replacement is associated with a number of safety risks to the end-user. In this case, making a distinction between this product and other ones available on the market as single-use devices, it is proposed to recommend a derogation for 'Multiple use controllers of On-Body Delivery Systems for the subcutaneous administration of medicinal products'.

2.4. Apption Labs GmbH: Wireless Meat Thermometer

2.4.1. Summary of the application

Apption Labs GmbH, applied for a derogation under Article 11(1) of Regulation (EU) 2023/1542 concerning their Wireless Meat Thermometer. This product is a temperature measurement device used in cooking environments such as ovens, grills, and barbecues. It consists of two distinct components: a probe and a charger, both containing rechargeable batteries. The charger, referred to as 'Block', is an integral functional component of the entire product and is also mentioned in the application form. However, the derogation request only concerns the probe. (Apption Labs GmbH, 2025)

The probe is a sealed unit made of stainless steel and ceramic, containing a printed circuit board, sensors, antenna, and a soldered rechargeable battery (Figure 2-1). It transmits temperature data via Bluetooth to a mobile device. The charger serves multiple functions, including charging the probe, acting as a Bluetooth repeater and connecting to Wi-Fi. Some models also feature a display and are powered by either primary or secondary batteries. (Apption Labs GmbH, 2025)

Figure 2-1 – Wireless Meat Thermometer (probe)

© Apption Labs GmbH.

Source: https://assets.meater.cloud/safety-information/en/meater-plus.pdf, last viewed 06.08.2025.

The applicant argues that the battery in the probe should not be removable or replaceable by end-users due to significant safety and technical concerns. The probe is permanently sealed to prevent water and moisture ingress, which is critical for its safe operation in high-heat and wet environments. If an end-user were to attempt battery replacement, this seal would be compromised, potentially leading to malfunctions, short circuits, or even explosions. Additionally, improper battery handling could result in inaccurate temperature readings, posing a serious food safety risk from potentially misleading users into consuming undercooked meat. (Apption Labs GmbH, 2025)

The design of the probe imposes strict spatial constraints, with a diameter of only 5–6 mm and a battery size of 3.9 mm by 15 mm. The battery is soldered in place to ensure durability and sealing and cannot be accessed or replaced without specialized tools and expertise. Furthermore, the battery is engineered to last the entire lifespan of the product, with over a thousand charging cycles and no recorded replacements in nine years of market presence. This durability eliminates the need for user intervention. (Apption Labs GmbH, 2025)

Based on these arguments, Apption Labs GmbH requests a derogation from the removability and replaceability requirements, asserting that allowing end-users to access the battery would introduce unacceptable risks that can only be mitigated by professional handling. The applicant does not provide information on whether battery replacement by a trained professional would be possible. Neither the product user manual nor the company's website provides information on whether the vendor offers a battery replacement service or information for independent professionals. Instead, the applicant claims, as stated in the application form, that the battery's life expectancy typically exceeds that of the probe, meaning that no replacement is necessary during the device's entire service life. They also request that their submission be treated as confidential due to potential commercial implications. (Apption Labs GmbH, 2025)

2.4.2. Assessment

Article 11(2)

The probe component of the Wireless Meat Thermometer is intended to be operated in an environment that is regularly subject to splashing water, water streams or water immersion, and that are intended to be washable or rinseable. However, this design is primarily a functional requirement to make the appliance more convenient to use, rather than a safety feature. The applicant argues that the probe's completely sealed design, which prevents the internal battery from being replaceable, is necessary to ensure users' safety. The argument is not supported by technical explanations detailing the safety risks resulting from the end user's interaction with the probe when attempting to replace the internal battery.

The assessment of applicability of Article 11(2) to the wireless meat thermometer against indicators for granting a derogation for appliances operating in wet environments set out in the Commission Notice C/2025/214 concludes the following:

(i) ‘specifically’: the appliance is designed with the main purpose to operate in a wet environment: FULFILLED, however, There is no official IP (Ingress Protection) rating mentioned for the wireless meat

thermometer on the manufacturer's website or in the available product specifications.

(ii) 'primarily': the environment described is the primary environment for the majority of the active service of the appliance: FULFILLED,

(iii) 'washable or rinseable': the appliance is intended to be washable or rinseable: FULFILLED,

(iv) 'compromising safety': there is no evidence in the product documentation that battery replaceability and removability by end-users would compromise the safety of the user or the appliance:
NOT FULFILLED,
The applicant has not provided evidence (such as safety tests).

(v) 'no way to redesign': there is no evidence in the product documentation that there is no way to redesign the appliance with the current state of the art technology, without severely affecting the health and safety of the end-user or the performance and functionality of the product.
NOT FULFILLED. The applicant has not provided evidence (such as design studies.
(Commission Notice C/2025/214, 2025)

In conclusion, the wireless meat thermometer fulfils three out of the five indicators mentioned in Commission Notice C/2025/214. This notice clearly states that ALL of the indicators must be fulfilled in order to justify a derogation under Article 11(2). However, indicators IV and V have not been fulfilled due to a lack of evidence provided by the applicant. Hence, the conditions to grant a derogation according to Article 11(2)a are NOT FULFILLED, regardless of the product being designed for a wet environment.

Article 11(3)

The derogation specified in Article 11(3) does not apply as the Wireless Meat Thermometer does not require a continuity of power supply for safety reasons.

Criteria for a derogation in Article 11(4)

Safety of end-users removing the battery

According to Article 11(4), a derogation can be granted if the conditions detailed in Article 11(4) are met. In instances where the replacement of the battery by end-users poses a safety risk, the derogation may permit a product design that prevents the battery replacement by end-users.

The applicant explains that a safety risk to the user may arise if the probe is opened to replace the internal battery. Inexperienced users may damage sealings in the process or insert an off-spec replacement battery so that it gets exposed to moisture during use. The applicant mentions the risk of water ingress if the probe`s sealing is damaged. This would pose a risk to the internal battery`s integrity and may cause short circuit that may result in overheating. The applicant warns of a failure mode, where the battery could explode due to compromised circuitry and battery protection systems. Given the small size of the internal battery this worst-case scenario appears exaggerated. Nevertheless, water ingress in the probe`s interior must be prevented by design in order to minimise other safety risks to end-users as described below.

Product safety requirements

The applicant elaborates that the probe of the Wireless Meat Thermometer is designed to be used during cooking, frying, baking, and grilling of food at high temperatures and wet conditions. This presents a demanding environment to any electronic product containing a battery. It can be assumed that the probe's functionality will only be maintained if it is used and maintained according to the specifications detailed in the user manual. Replacement of the internal battery is not possible because this could affect the probe's sealing, and it cannot be guaranteed that the replacement battery would withstand the high temperatures. Moreover, this could lead to ingress of water, causing short circuits or malfunctions in the electronics parts. This could affect the accuracy with which the device measures the temperature of the cooked food. The applicant describes the risk of inaccurate temperature readings if the battery was replaced incorrectly. In this case, the applicant warns of a significant health risk due to inadequate pathogen elimination if the meat is undercooked. This argument appears a little bit far-fetched since food preparation is done entirely without a temperature probe in the vast majority of households.

Additional arguments pertaining to safety

The applicant does not mention the risk of chemicals leaking from damaged batteries into food as a result of improper attempts to replace the probe's internal battery. This scenario is more likely than the battery exploding due to overheating, as described above. The probe is designed for use in close proximity to food (even inside it) during food preparation at high temperatures. This means that only materials approved for food contact, such as stainless steel and a special sealant, can be used. Moreover, the compact design and watertight seal of the probe are functional prerequisites. However, replacing its internal battery requires special skills and tools that are not typically available to end users. Consequently, the probe's design must prevent any attempts to replace the battery incorrectly. Otherwise, the seal may be damaged, allowing

salty water from food to enter and damage the battery, resulting in overheating and overpressure within the probe. If the probe's sealing is damaged, leaking chemicals from a damaged battery, such as soluble cobalt compounds, lithium hexafluorophosphate, ethylene carbonate (EC), dimethyl carbonate (DMC) or diethyl carbonate (DEC), may leak from the probe`s interior and contaminate the food. Hence, the design of the probe must prevent the risk of food poisoning. This could reasonably be achieved by designing the probe so that end users cannot easily disassemble it.

Given the above-discussed safety risks to the end user and the fact that the probe's seamless design is the wireless meat thermometers unique selling point, the derogation specified in Article 11(4) is FULFILLED by the probe (but not so for the charger ‘block’).

2.4.3. Conclusion and recommendation

The arguments put forward by the applicant to justify the request for a derogation do not fulfil all five indicators set by the Commission for the existing derogation specified under Article 11(2)(a). However, according to Article 11(4), a new derogation could be considered, as there are scientifically grounded concerns over the safety of end users when removing or replacing the portable battery. This risk is clear, even though the applicant fails to describe it, instead bringing forward other irrelevant arguments. A temperature probe designed for use inside food during cooking and frying must remain securely sealed to ensure food safety, even in hot, wet conditions. Seamless sealing of the probe's interior appears to be an adequate solution to prevent chemicals from the battery leaking into food. However, this would make the internal battery irreplaceable, so a derogation appears necessary. Hence, it is recommended that a derogation be granted with the following formulation:

- Wireless Thermometer probe designed for food contact during food preparation processes.

2.5. Grundfos: Products incorporating integral batteries for the Real-Time-Clock (RTC) functionality

2.5.1. Summary of the application

The application relates to various unspecified control units for connected appliances (e.g. household pumps) (Grundfos, 2025b). It can be inferred that the applicant is referring to smart home appliances, and that 'connected' means that the appliances are connected to a data network (LAN) as well as to the power grid and water installation. It is unclear which connection technology to the LAN is used (cable, WLAN, Bluetooth or mobile). (Grundfos, 2025a)

The derogation request did not provide concrete information on the type of devices involved or their design.

In a later communication the applicant provided a picture of a device for which the derogation is requested (see Figure 2-2), explain that in the devices depicted above the battery is replaceable, however this is not the case for all devices in the portfolio. (Grundfos Holding A/S, personal communication, 12 November 2025)

Figure 2-2 – Examples of monitoring and controlling devices for pumps that contain a battery provided by the applicant

© from the applicant`s website

Source: (Grundfos Holding A/S, personal communication, 12 November 2025)

According to the applicant's derogation request, some of these devices include a real-time clock (RTC) for timekeeping purposes when not connected to the mains (in the event of a power outage or otherwise) (Grundfos, 2025b). The applicant specifies the usual use-cases of the time-keeping as follows:

1) Time scheduling work regime for the product,

2) Timestamps for alarms and notifications for diagnostics,

3) Trend data about product running hours.

(Grundfos, 2025b)

The RTC requires a buffer battery to prevent loss of the current time and date if the main power source (i.e. the host device's power source) is switched off. The battery type is typically a CR2032 coin cell, which is mounted directly on to a printed circuit board in a battery slot. The applicant explains that batteries usually have an equal or longer lifetime than the product itself.(Grundfos, 2025b)

The applicant explains that the location of the internal battery on the printed circuit board would require the end user to open the product's enclosure cover/lid to replace the battery. This is deemed to pose a safety risk due to the risk of electric shock. (Grundfos, 2025b)

2.5.2. Assessment

Article 11(2)

Article 11(2)a does not apply, as control devices containing a battery are not designed to be operated in wet environments or intended for washing or rinsing.

Article 11(2)b is also not applicable as the household appliances concerned are not medical devices.

Article 11(3)

The applicant makes no mention of the equipment relying on an uninterrupted power supply via an internal buffer battery to ensure data safety and integrity in the sense of Article 11(3).

Therefore, **Article 11(3) does not apply**.

Criteria for a derogation in Article 11(4)

Safety of end-users removing the battery

The applicant asserts that informing the end user of the possibility of replacing the internal battery would imply that the end user would need to open the cover/lid of the enclosure containing the electronics/PCB to access the battery. They explain that this would mean the product would be considered a 'detachable part' according to the technical standards used to verify product safety. (Grundfos, 2025b)

The standard EN IEC 60335-1:2023 for the safety of household and similar electrical appliances requires that detachable parts must be designed so that their removal and refitting do not compromise electrical safety. When a detachable part is removed, live parts (i.e. high voltage bearing parts electrical contacts) must not be accessible. The design must prevent accidental contact with dangerous voltages. This is typically achieved by additional barriers, interlocks, or insulation. If detachable parts are intended to be removed for maintenance, the user manual must provide clear technical instructions as well as warnings and safety instructions.

The standard EN IEC 60730-1:2024 applies for automatic electrical controls for household and similar use. This standard defines detachable parts as components of a control that can be removed by the user. When a detachable part is removed, live parts must not be accessible. The standard requires that the removal of covers or other detachable parts must not expose users to hazardous voltages or components. The standard also prescribes design solutions such as barriers or additional insulation and interlocks that disconnect power when a part is removed.

The applicant's arguments do **not qualify for a derogation** because none of the conditions related to the batteries and device enclosures are likely to pose a safety risk to end users if the above-mentioned standards are followed. Moreover, the applicant can provide technical and safety instructions to the end-user how to safely replace the battery. In fact, this is already common practice as exemplified in one of the companies own user manuals for the ‘CU 202’ controlling unit (Grundfos, 2025a).

Regarding design options that enhance the safety of end users when replacing the internal battery, standards EN IEC 60335-1:2023 and EN IEC 60730-1:2024 provide suitable solutions, including additional barriers, interlocks and insulation. However, the applicant has not explained why these design solutions would not be applicable to the products in question.

Product safety requirements

The applicant does not mention aspects relating to product safety requirements as a reason for granting the requested derogation.

Additional arguments pertaining to safety

The applicant mentions no further aspects relating to safety as a reason for granting the requested derogation.

2.5.3. Conclusion and recommendation

The Grundfos derogation request for products incorporating integral batteries for the Real-Time-Clock (RTC) functionality does not concern appliances that are subject to Article 11(2), such as products intended for use in a wet environment, or medical imaging or radiotherapy devices. Furthermore, the user safety concerns mentioned by the applicant could be addressed through redesigning the devices and providing technical and safety instructions for battery replacement in the relevant user manuals. Therefore, it is recommended that a derogation not be granted.

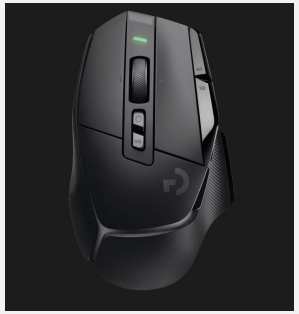
2.6. Wireless Devices Cluster (Logitech, VGE, Yamaha, LG Electronics)

2.6.1. Summary of the applications

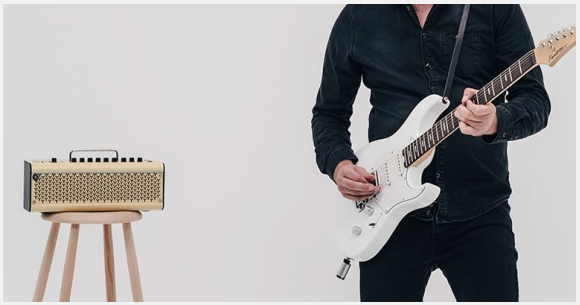
Numerous applications were made regarding various wireless devices; these have been clustered together for the purpose of the assessment. The following Table 2-4 shows the applicants, the products covered by their applications and a summary of the main arguments for derogation. More detail is summarised below the table for each of the cases.

Table 2-4 – Summary of applications for wireless products received in the call for applications for derogation under Article 11(4)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Logitech	IPX7 rated Bluetooth speakers	Consumer removal of batteries could pose severe safety risks and force Logitech to redesign its products, lowering sustainable standards.	Safety of speakers is certified under global frameworks including: IEC 62133 (safety requirements for Li-Ion batteries); IEC 62368-1 (requires hazardous energy sources (such as lithium cells) be protected against foreseeable misuse by untrained users); General Product Safety Regulation EU 2023/988	No detail is given on the exact products in question.

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Logitech	Compact wireless mouse using soft-pack lithium-ion battery.	Safety risks, certification conflicts (UL/IEC), tightly integrated battery design requiring professional replacement	See Article 11(4) of Regulation (EU) 2023/1542	 *Source*: https://www.logitechg.com/de-de/products/gaming-mice/g502-x-wireless-lightforce.910-006180.html?sp=2&searchclick=gaming
Logitech	Wireless keyboard with integrated lithium-ion battery	User access would compromise safety certifications and product durability. Professional replacement aligns with circular design principles.	See Article 11(4) of Regulation (EU) 2023/1542	*Source*: https://www.logitech.com/de-de/shop/p/mx-keys-s
Logitech	Wireless headset with sealed battery compartment.	Allowing end-user access would increase risk of battery failure, chemical exposure, and loss of certification. Professional servicing is safer and maintains compliance.	See Article 11(4) of Regulation (EU) 2023/1542	*Source*: https://www.logitech.com/de-de/shop/p/pro-x-wireless-headset.981-000907?sp=1&searchclick=Logitech%20G

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Logitech	Microform gaming devices – e.g. controllers with tightly integrated batteries.	Consumer replaceability is structurally unfeasible due to compact design; safety and certification risks are too high. Professional battery replacement is recommended.	See Article 11(4) of Regulation (EU) 2023/1542	*Source*: https://www.logitechg.com/de-de/products/gamepads/f310-gamepad.940-000135.html?sp=3&searchclick=gaming
Manufacturer of handheld video game consoles	Handheld Video Game Consoles	**Compactness and Integration:** Very compact design of handheld gaming consoles and integration of soft-pack lithium-ion batteries, makes it technically impossible to allow end-user battery replacement without compromising safety and device integrity.	VGE emphasizes that the need to maintain product robustness and compliance with certification standards (such as those for electrical safety and durability) precludes safe user access to the battery.	

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Yamaha	Audio Transmitters and Receivers	**Highly Integrated Battery Systems:** Devices use highly integrated battery systems, often with soft-pack lithium-ion batteries, to achieve the required compact form factors and performance	**Safety and Certification Risks:** The company argues that allowing end-users to replace the batteries would pose safety risks (such as battery damage, chemical exposure, or electrical faults) and could jeopardize compliance with product certification standards.	 *Source*: (Yamaha Corporation, personal communication, 29 October 2025)
Manufacturer of portable wireless speakers	Small sized portable Wireless Speakers	**Design for Compactness and Acoustic Performance:** Portable wireless speakers are engineered for high compactness and optimal sound quality, requiring soft-pack lithium-ion batteries.	**Risk to Water Resistance and Safety:** The company argues that opening the device for battery replacement could compromise its water resistance (IP rating), which is essential for safe operation—especially in environments where the speakers may be exposed to splashes or moisture.	

Source: (Logitech, 2025a, 2025b; Yamaha Corporation, 2025)

Logitech IPX7-rated portable Bluetooth speakers

Logitech explains that various standards and regulations govern the design of the battery integration into such speakers:

> These certifications include strict design requirements for electrical insulation and environmental protection. For IPX-rated devices, these protections are realized through fully sealed enclosures with no accessible seams, openings, or user-serviceable internal components. Enabling end-user battery access would compromise these sealed enclosures, introducing new seams, gaskets, and user-interfacing compartments that break the device's IPX7 rating and violate core assumptions of UL and IEC safety models. (Logitech, 2025a)

Adding battery compartments and enabling user access to batteries built into such Bluetooth speakers is explained to introduce the following risks:

> - Physical damage to batteries or components during disassembly or reinsertion.
>
> - Exposure to internal conductors, sharp edges, or live terminals.
>
> - Installation of low-quality, incompatible batteries that may overheat, swell, or fail.
>
> (Logitech, 2025a)

From the information provided by Logitech, it is clear that the current design uses soft-pack batteries. (Logitech, 2025a) This suggests that redesign may need to switch to using hard-pack batteries.

Initially, the application did not provide examples of Logitech products for which the derogation is needed. Upon browsing the Logitech website, a few Bluetooth speaker specifications were found; however, products giving detail of the IPX rating have yet to be identified.

In a later communication, Logitech explained that

> Logitech's Ultimate Ears IPX7-rated speakers are explicitly designed for outdoor and moisture-prone environments, such as pools, bathrooms, and kitchens. These use cases demand robust water resistance, which cannot be achieved with designs that compromise sealed enclosures. Enabling consumer access to the battery

> compartments in these products would introduce seams and joints that inherently violate IPX7 standards and IEC 62368-1 safety requirements. (Logitech, personal communication, 4 November 2025)

In such speakers, IPX7 certification is explained to be a key feature advertised to consumers, ensuring product durability and reliability. (Logitech, personal communication, 4 November 2025)

Logitech (Wireless Mice, Keyboards, Headsets, Gaming Devices)

Logitech claims that using soft-pack lithium-ion batteries, combined with highly compact device architecture and international certification requirements (UL/IEC), makes safe end-user battery replacement technically and safety-wise unjustifiable. The company highlights risks such as battery puncture, thermal failure, chemical exposure, and loss of certification or product durability if end-user access were enabled. Professional replacement is presented as the only viable option under current design and certification constraints (Logitech, 2025b).

In a later communication, Logitech further explained that ‘many Logitech products, such as wireless mice and headsets, are ergonomically contoured and engineered to maximize internal efficiency. In many instances, we operate with less than 1 cm of internal clearance between the battery and the device enclosure’. This compact form factor was explained to limit the ability to redesign such products. (Logitech, personal communication, 4 November 2025)

Manufacturer of (Handheld Video Game Consoles)

The applicant argues that the compactness of handheld gaming consoles, integration of soft-pack batteries, and the need to maintain product robustness and certification standards make it impossible to allow end-user battery replacement without compromising safety and device integrity. They point to risks of incorrect assembly, potential damage to sensitive electronics, or dust ingress protection. (source anonymised)

Yamaha (Audio Transmitters and Receivers)

Yamaha states that their wireless audio transmitters and receivers use highly integrated battery systems, often with soft-pack batteries, to achieve required form factors and performance. They argue that end-user battery replacement would pose safety risks, could affect product certification, and might result in loss of audio quality or device malfunction due to improper reassembly. (Yamaha Corporation, 2025)

Manufacturer of Portable Wireless Speakers)

The manufacturer notes that their small sized portable wireless speakers are designed for compactness and acoustic performance, using soft-pack lithium-ion batteries. They argue that opening the device for battery replacement could compromise water resistance (IP rating), safety, and sound quality, and that professional servicing is necessary to maintain these features. (source anonymised)

2.6.2. Assessment

Article 11(2) and 11(3)

Not applicable to any products in this cluster:
In a few of the above cases, the applications for derogation refer to the need to maintain a high IPX rating for their devices (e.g. IP67 or IPX7 both of which are relevant for products intended for use in an environment exposed to water). Nonetheless, from the argumentation made, it is not clear why the products, which are described generically and without examples of specific cases, would be exposed to a wet environment during normal use. This is particularly the case for computer mice, wireless keyboards, gaming controllers or consoles which are assumed to mainly be used inside but also for most speakers which would not necessarily be used outdoors. Though the IP rating is argued as a rating that needs to be achieved, it is not explained why this rating is necessary in the products for which the derogation is sought. It seems that none of the devices are primarily designed for operation in wet environments or intended to be washable/rinseable (Art. 11(2)(a)). Thus, despite the IP rating which may be high in some cases, the consultants assume that the existing derogation would not apply. Should some of the applications be intended for use in such conditions, the derogation listed under Article 11(2)(a) could apply if all indicators listed in Commission Notice C/2025/214 are complied with. In a later communication, Logitech referred to its Ultimate Ears IPX7-rated speakers explaining that they are explicitly designed for outdoor and moisture-prone environments (Logitech, personal communication, 4 November 2025). Information put forward does not allow such an assessment. However, in cases where the product is specifically designed for use in a wet environment and fulfils the Commission Notice C/2025/214 indicators, it could benefit from the derogation already specified under Article 11(2)(a) of the BatReg. The burden of proof in such cases would be on the manufacturer.

None of the applications for which a derogation is sought are medical devices and thus derogation 11(2)(b) does not apply.

The need for an uninterrupted connection between the battery and the device is not raised in any of the applications, neither for safety reasons nor for data integrity reasons and thus the derogation specified in Article 11(3) is understood to be irrelevant in this case.

Article 11(4)

All manufacturers in this cluster cite the use of soft-pack lithium-ion batteries, compact integrated design, and the need to maintain international safety certifications as reasons why end-user battery replacement is not feasible or safe. They reference risks such as battery puncture, loss of certification, and the potential for user error leading to product malfunction or safety hazards.

While these arguments reflect genuine technical and certification challenges, we emphasize the following points.

The mere use of soft-pack batteries for reasons of weight, form factor, or design preference is **not**, in itself, a sufficient basis for derogation under Article 11(4). A precedent to this principle can be seen in the Ecodesign Regulation 2023/1670/EU recently published for smart, mobile and cordless phones (Regulation (EU) 2023/1670, 2023). The majority of smartphones on the EU market use soft-pack batteries, and nonetheless the Regulation requires that by 20 June 2025, the replacement of such batteries meet a few criteria, including that ‘the process for replacement shall be feasible […] with no tool, a tool or set of tools that is supplied with the product or spare part, or basic tools’ (Regulation (EU) 2023/1670, 2023), and it must be possible for an amateur to carry out battery replacement. Though it is not clear if manufacturers of smartphones shall redesign products to include hard batteries, it stands to reason that if such products are required to undergo redesign to ensure battery replaceability that the same should apply for the wireless or portable products under this cluster in terms of use environment and form factor. In this respect, it should be mentioned that the Ecodesign Regulation 2023/1670/EU provides an alternative to battery replacement in the form of fulfilling certain criteria on battery and device durability. Though this approach could be valid in the case at hand, the consultant understands that such criteria could not be set under the BattReg as this would require developing criteria on a case-by-case basis. It is also not clear if durability criteria could be set for such devices under the BattReg.

In a later communication, Logitech challenges this view, explaining that the case of smartphones and tablets and the wireless products for which they request derogations is different in terms of use case and safety profiles. Logitech states:

> Smartphones are designed with user access in mind from the outset, including modularity for screens, ports, and

> batteries. Logitech's wireless devices (e.g. mice, headsets, compact gaming controllers) are not intended to be opened by users and are built around sealed, precision-engineered enclosures. The risk profile is different: Logitech's devices often use smaller form factors and tighter integration, where even minor enclosure breaches can compromise thermal insulation, electrical safety, or mechanical integrity.
>
> (Logitech, personal communication, 4 November 2025)

The consultants cannot completely follow this line of argumentation. To begin with, at least prior to the introduction of the new requirements under the Ecodesign (Regulation (EU) 2023/1670, 2023), multiple smartphone and tablet models available on the EU market did not enable simple replacement of batteries, nor of other components as suggested by Logitech. In 2021, the European Environmental Bureau even contended that 'Close to 100% of tablet and smartphone batteries are glued in place' (EEB, 2021). As for the tighter form function, this would need to be assessed on a case-by-case basis. Though current designs may be 'tight', as Logitech suggests, this would not mean in all cases that a redesign which extends the casing dimensions is not possible. Logitech refers to the case of ergonomic design for computer mice and headsets. Though it can be followed that the design of an ergonomic computer mouse may limit the possibilities of redesign as it needs to fit in its entirety in the hand of the user, this argumentation cannot be followed for all products. One could then argue that an ergonomic headset could not be redesigned since the change of dimension would affect its weight; however, headsets available on the market come in a range of weights ([12]) that undermines this line of argument. To justify a derogation, applicants must provide **product-specific, scientifically grounded evidence** and direct citations from relevant safety standards (e.g. UL/IEC 62368-1, IEC 62133) demonstrating that end-user battery replacement would genuinely pose safety risks or result in non-compliance with Union product safety law. Though various standards are referred to and it is explained that making batteries replaceable would render current designs as non-compliant, it cannot be followed that products could not be designed in a way that ensures compliance with the various safety standards while also enabling battery replacement. Arguments raised on safety refer to the current design however a redesign cannot be excluded. This may affect the size and design of compartments of various products, however neither of the applications specifies the dimensions of relevant products. Though some mention small size, actual dimensions are not provided. Looking at the various

[12] Whereas earbuds can weigh just a few ounces, one source states that gaming headsets vary in weight from 200 grams to over 500 grams (see: https://trittonaudio.com/blog/how-heavy-should-a-gaming-headset-be/).

products that exist in the various product groups suggests that most are not so small to justify miniaturisation as an argument against redesign.

In a later communication, Logitech refers more specifically to the following standards and certifications of relevance for its products:

> IEC 62368-1: Assumes user inaccessibility to internal energy sources and to hazardous components. Enabling battery access would compromise sealed enclosures (also in violation of IPX7).
>
> UL 62368-1: Assumes user inaccessibility to internal energy sources and to hazardous components. Requires fire-enclosure integrity. Replaceability would lead to loss of electrical safety under UL 62368-1 §4.2.
>
> CSA 62368-1: assume user inaccessibility to internal energy sources
>
> IEC 62133: Assumes user inaccessibility to internal energy sources. Classifies such [soft-pack] cells as 'non-user-replaceable'.
>
> IEC 62133-2
>
> UL 2054: Explicitly requires a hard-pack enclosure to contain potential venting or rupture events. Classifies such [soft-pack] cells as 'non-user-replaceable'.
>
> (Logitech, personal communication, 4 November 2025)

From the information available on these standards, it appears that the replacement of soft-pack batteries is allowed, provided the design ensures that the user cannot damage the battery during replacement. Such a design would need to fulfil various requirements and may be challenging to implement but is not considered to be impossible. Though for some products, freedom of design may be limited (i.e. due to ergonomic design form factor), the consultant assumes that this shall not be the case for all wireless products.

Granting **derogations** solely based on soft-pack battery use could incentivize manufacturers to adopt such designs to circumvent the Regulation, undermining its objectives and stifling innovation in user-friendly, sustainable battery solutions. Furthermore, in other products on the market it can already be observed that a use of soft-pack batteries does not justify non-replaceability under other EU law.

2.6.3. Conclusion and recommendation

While various manufacturers argue that the use of soft-pack lithium-ion batteries in their wireless products, combined with compact device architecture and certification requirements, currently make safe end-user battery replacement technically and safety-wise unjustifiable, the consultant notes that the mere choice of a soft-pack battery for reasons such as weight or design preference is not, in itself, sufficient grounds for a derogation under BattReg Article 11(4). Though reference is made to various safety risks and safety standards that need to be fulfilled, these are understood to be relevant for current product designs but not to exclude redesigning products in a way that would fulfil standard and legislation requirements while maintaining user safety in the case of battery replacement. It is possible in some cases that products are and need to be very small, making a redesign unfeasible; this may in particular be relevant when the design needs to be ergonomical. However, this line of argumentation cannot justify a blanket derogation for all products. In addition, some products are understood to have a high IP rating, which could be relevant for water resistance. However, the argumentation provided does not suggest that most products need to be water resistant to allow performing in a wet environment under normal use conditions. The case of the Logitech Ultimate Ears IPX7-rated speakers provides an example of a product design for a wet environment and also communicated as such to consumers. In such cases, manufacturers would have the burden of proof of fulfilling the indicators specified in Commission Notice C/2025/214 in relation to derogation 11(2)(a).

Finally, the approach applied in Ecodesign (Regulation (EU) 2023/1670, 2023) for smartphones and tablets suggests that battery replaceability may not be necessary in the case of products that show a high durability of the battery (and its integration into the products). Though this approach may also be valid for some of the wireless and portable devices, it would require specifying a minimum durability to be complied with for each product category to ensure that a derogation is not misused. Setting such criteria has not been possible based on the information provided by applicants.

It is recommended that a general derogation not be provided for wireless and/or portable products nor for any of the categories that have been referred to (i.e. computer mice and keyboards, gaming devices and consoles, Bluetooth speakers), seeing as the argumentation provided would not cover the full array of such products. Redesign is assumed to be possible in most cases in a way that would comply with standards and legislation while ensuring consumer safety if a battery is replaced. In some cases, manufacturers could look into the applicability of derogation 11(2)(a) when all indicators in Commission Notice C/2025/214 are met (Commission Notice C/2025/214, 2025).

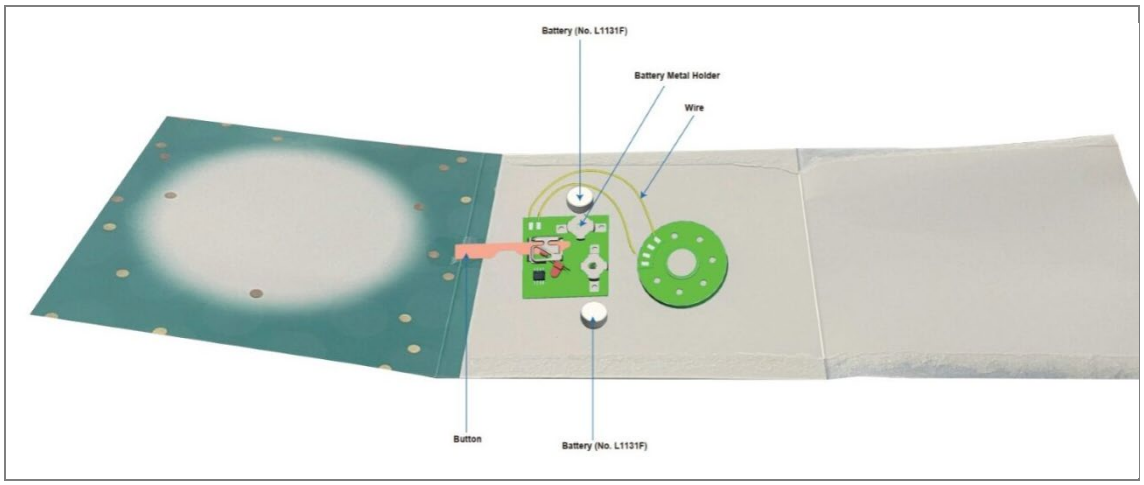
2.7. Music cards and soundboxes

2.7.1. Summary of the applications

Depesche Vetrieb requested a derogation for **music cards**, explaining that the batteries in the music cards cannot be removed as they are permanently integrated into the device to ensure the safety and longevity of the product. The sealed design also ensures the reliable function of the sound module for the entire service life of the music card ([13]) without the need to change the batteries. The design is also mentioned to prevent small children form removing the battery from the music card and swallowing it. (Depesche Vertrieb GmbH & Co. KG, 2025b)

Depesche Vertrieb provides a technical drawing of how the battery is incorporated into the music card, reproduced in Figure 2-3 below. The technical drawing shows that two batteries of type L1131f are incorporated into the products. Such batteries are button cell primary (non-rechargeable) batteries with a voltage of 1.5 V. (Depesche Vertrieb GmbH & Co. KG, 2025b)

Figure 2-3 – Technical drawing of the incorporation of the battery into the products



Source: (Depesche Vertrieb GmbH & Co. KG, 2025b)

A number of music cards marketed by Depesche Vetrieb GmbH & Co. KG can be found on Amazon's website ([14]) with various designs. The product

[13] In the application, 'colouring book' is referred to, but the consultant assumes this is a mix up with another application by the same company.

[14] See for example: https://www.amazon.de/Depesche-11661-012-Congratulations-Birthday-Matching/dp/B09RDQHK8W?ref_=ast_sto_dp, last viewed 28.7.2025

description of a card intended for a 70th birthday provides the following details: '[…] When you open the folding card, the song "Staying alive" sounds. Printed outside and inside, one side blank for personal words, messages and messages for the birthday child' (Depesche Vertrieb GmbH & Co. KG, 2025b). Prices vary but are in all cases below 20 € and often below 10 €.

A second application of the same company requests a derogation for **soundboxes** (Depesche Vertrieb GmbH & Co. KG, 2025a). The argumentation made is identical to that included for music cards. The picture of sample music boxes was also included with the application and is reproduced below.

Figure 2-4 – Technical drawing of the incorporation of the battery into the products

Source: (Depesche Vertrieb GmbH & Co. KG, 2025a)

Online prices from one website were found to be below 10 € per box ([15]).

In a later communication, the applicant further provides the following arguments:

[15] See: https://www.kaufhaus-peters.de/schreibwaren/fancy-artikel/wunscherfuller-soundboxen.html as an example.

1. Product lifespan in relation to battery lifespan: The average lifespan of music cards and music boxes is significantly shorter than the expected lifespan of the integrated battery. In practice, the product is no longer in use before the battery reaches the end of its lifespan. It is therefore not necessary to replace the battery.

2. Product safety and child protection: Music cards and music boxes are often intended for children. An accessible or removable battery poses significant safety risks, such as swallowing or improper handling of electrical components. A permanently installed battery contributes significantly to compliance with safety requirements (e.g., according to EN 71-1 or EN 62115).

3. Design and functional unit: The battery is usually an integral part of the housing and the electronic circuit. A design that allows for easy removal would require extensive design changes that would:

- jeopardize mechanical stability and safety requirements,

- impair protection against moisture and dust (e.g., IP protection),

- and significantly increase production costs and material costs without creating any ecological or functional added value.

4. Environmental aspect: Due to the small size and short service life of the products, the resource consumption associated with redesigning them for replaceability would be higher than the ecological benefits of being able to replace the battery at a later date. In addition, at the end of their service life, the products are collected as waste electrical equipment under existing take-back systems and recycled in a professional manner.

(Depesche Vertrieb GmbH & Co. KG, personal communication, 30 October 2025)

2.7.2. Assessment

Due to the similar application, price, argumentation and the identical applicant, the following assessment is considered relevant for both the music cards and

soundboxes, despite not having received documentation of how the battery is integrated into the music or soundbox.

Article 11(2)

Neither of the derogations already specified under article 11(2) apply in this case. Even though the applicant refers to protection against moisture and dust, the product is not deigned to operate in a wet environment (11(2)(a)) nor is it a medical device (11(2)(b)).

Article 11(3)

The derogation specified in Article 11(3) does not apply. The applicant did not raise the necessity of continuity of power supply and a permanent connection between the product and the respective portable battery.

Criteria for a derogation in Article 11(4)

In the case at hand, the consultants cannot follow that making the battery replaceable would comprise a safety risk for end-users removing and replacing the battery. The battery applied in the product has a voltage of 1.5 V which does not pose an electric shock risk when handled improperly. Even should the end-user attempt to replace the battery, a clear risk cannot be concluded. All the more so as such batteries can be purchased for use as replacement batteries online, suggesting that end-users are expected to be able to deal with possible emissions to arise due to false handling.

The applicant does not raise any argumentation related to product safety requirements specified in Union legislation or standards. Though a reference is made to the risk of swallowing in the case that a child should remove the battery from the product, this statement cannot be followed. The online information does not specify that the music cards are intended for children below the age of 36 months or nor are they specified to be used for playing. Both of these aspects are understood to be pre-conditions for the product to be considered a toy and to need to comply with the Toy Safety Directive 2009/48/EC. Even so, as explained in section 1.5.2, the Toys Safety Directive refers to a risk of swallowing only when a product or a part of it can be removed and swallowed in products designed for children below the age of 36 months or in products designed to be placed in the mouth during use when intended for older children. Though some of the music cards are designed for children, they are not designed as an object of play nor as an object that should be placed in the mouth during use. The designs also do not suggest that they are intended for children below the age of 36 months, and were this the case, it would need to

be specified in the product details (e.g. a warning that the product contains small parts that can be swallowed).

Though the applicant raises arguments related to the increase in production and material costs related to a product redesign and related environmental aspects, these do not relate to safety aspects and can thus not be considered in relation to the criteria specified in Article 11(4) for adding derogations in Article 11(2) from Article 11(1).

2.7.3. Conclusion and recommendation

The application does not fulfil the criteria specified in BattReg Article 11(4) for granting a derogation from the Article 11(1) requirement for portable batteries to be removable and replaceable. It is recommended that a derogation for the music card and the soundbox applications not be granted.

The consultants feel a need to mention the nature of this product in this context. A music card can be considered as a product with a short lifespan or even one intended for single use. In a later communication the applicant furthermore contends in this regard that the battery lifetime is expected to exceed that of both of these product categories (Depesche Vertrieb GmbH & Co. KG, personal communication, 30 October 2025). The main function is to convey a message from the person gifting the card to the recipient at the time the card is given and as such the former may add a written inscription to the card. The music function adds a second aspect to the experience but is a secondary function. The main function of the card shall still be intact even when the battery is depleted. In other words, it is doubtful if the end-user would attempt to replace the battery when it is depleted, regardless of whether this can be performed by the end-user or whether it requires the help of an independent professional. Even if a derogation were justified based on the Article 11(4) criteria, the cost to replace a battery would probably render replacement by an independent professional impractical, seeing as the product is relatively inexpensive. See Section 1.5.4 for a discussion on the costs of replacing batteries and how they may affect the likelihood of a replacement.

2.8. Electrical temperature control (thermostat) device

2.8.1. Summary of the application

CAREL INDUSTRIES S.p.A applied for a derogation from the Article 11(1) replaceability requirement for an electrical temperature control (thermostat) device intended for professional use in HVAC/R market. The product is a

professional electrical thermostat used in the HVAC/R market, specifically to operate temperature controls with display for commercial refrigeration applications such as food storage. It exists in two main configurations: a Front Panel version, mounted directly on the appliance's frame (see Figure 2-5 as an example); and a Split version, where the control unit is installed inside the appliance and the optional display is mounted externally. (CAREL INDUSTRIES S.p.A, 2025)

Figure 2-5 – Professional electrical thermostat iJF Panel

© CAREL INDUSTRIES SpA

Source: https://www.careluk.com/documents/10191/0/%2B0500161ML/b8d636ac-f9cc-43de-991b-781f1814a0da?version=1.0, last viewed 13.08.2025.

The primary function of the thermostat is to control the temperature of the appliance by processing data from external temperature probes and activating the cooling unit via relays. (CAREL INDUSTRIES S.p.A, 2025)

Some versions also include a secondary function: a real-time clock (RTC) that logs activities such as BLE/NFC connections, alarms, and parameter changes. This RTC is powered by a portable, non-rechargeable button-type battery (e.g. CR1220 or BR1225), which only activates in case of a main power failure to preserve log data. While the device is intended to be normally powered by a 5V supply via a connection to the refrigerators power supply, the internal battery serves to maintain the uninterrupted function of the device's internal real-time clock (RTC) and support an uninterrupted log-management that is dependent on the function of the RTC. This requires a permanent connection between the product and the battery. (CAREL INDUSTRIES S.p.A, 2025)

According to the applicant, the internal battery cannot be replaced by end-users for several technical and safety reasons:

- Cybersecurity and Firmware Protection: The product contains internal firmware uploaded during manufacturing via test points that are intentionally made inaccessible by the plastic enclosure. Allowing easy access to the battery would also expose these test points, risking firmware manipulation and violating cybersecurity requirements under the EU Cyber Resilience Act (CRA).

- Design Constraints: The battery is housed in a holder to avoid thermal stress during soldering, not to facilitate user replacement. Opening the enclosure to access the battery could damage the product and tear the label placed across the casing junction, serving as a tamper-evident seal.
- Durability and Use Case: The battery's lifespan (estimated at 14 years) exceeds the average product life (less than 11 years), making replacement unnecessary. Since the battery only supports a non-critical secondary function, its depletion does not affect the thermostat's core temperature control capabilities.
- Regulatory Compliance: Redesigning the product to allow battery replacement would compromise its compliance with CRA requirements, particularly those aimed at minimizing attack surfaces and securing digital elements.
- End-User Safety and Practicality: There are concerns about end-user safety when attempting battery replacement, and no market demand has been observed for such a feature since the product's launch in 2021.

(CAREL INDUSTRIES S.p.A, 2025)

2.8.2. Assessment

Article 11(2)

The derogations specified in BattReg Article 11(2) do not apply. The professional electrical thermostat iJF Panel is not intended to come in contact with splashing water, water streams or water immersion of relevance to the derogation specified under Article 11(2)(a). While the surface of the display is likely designed to be cleaned using water, that process is not to be based on washing or rinsing. The derogation specified under Article 11(2) (b) also does not apply, as the product is not a medical device.

Article 11(3)

The derogation specified in BattReg Article 11(3) does not apply to the professional electrical thermostat iJF Panel as the battery serves the operation of a secondary function: a real-time clock (RTC) that logs activities such as BLE/NFC connections, alarms, and parameter change. The applicant states that this secondary function is considered a non-critical feature of the product. According to Commission Notice C/2025/214, the derogation in BattReg Article 11(3) is not considered applicable for devices that deliver a data collection and supply function as an additional feature (beyond its main function) (Commission Notice C/2025/214, 2025).

The main function of this product is controlling the cooling device of a refrigerator appliance. This main function does not require a continuity of power supply for its data logging function and to maintain data integrity and data security during the operation time of a refrigerating appliance.

Against this background, it is assessed that Article 11(3) does not apply in the concrete use-context of this product.

Criteria for a derogation in Article 11(4)

1. Safety of end-users removing the battery

According to BattReg Article 11(4), a derogation can be granted if the conditions detailed in Article 11(4) are met. In instances where the replacement of the battery by end-users poses a safety risk, the derogation may permit a product design that renders the battery replacement by end-users infeasible.

The applicant does not explain the following:

1. Why the integrated portable battery is necessary for the iJF Panel to fulfil its main function, namely controlling the cooling unit.
2. How the integrated portable battery is necessary to ensure the safety of the user and the appliance during the time period where the external power source of the temperature control is off.

In contrast, the applicant clearly states that

> the portable battery currently provides to the product only the secondary function of log-management thanks to RTC. Thanks to this, even in case of battery discharge the product would still be able to perform its primary function of temperature's control. Clearly, this secondary function is not related with safety of user and appliance. (CAREL INDUSTRIES S.p.A, 2025)

There is no need for the iJF Panel to fulfil its main function (temperature control) during off-times of the refrigerator. While the device`s capability to collect and record data in periods when the refrigerator's power supply is off can be considered a safety feature, the applicant does not explain why the battery must be non-replaceable to fulfil this secondary function.

The applicant contends that there are concerns about end-user safety when attempting battery replacement, and no market demand has been observed for such a feature since the product's launch in 2021. However, detail is not provided as to such concerns and the fact that a market demand for battery

replacement has not been observed since the product launch is also not surprising given that only 4 years have passed,

Hence, the criteria 1 ‘Safety of end-users’ for a derogation in Article 11(4) does not apply.

2. Product safety requirements

The applicant raises several arguments relating to end-user related product safety aspects, as described in the application summary (see section 2.8.1). Each of these is assessed in the following:

- Cybersecurity and Firmware Protection: The design of an inaccessible plastic enclosure to prevent easy access to the test points, in order to prevent firmware manipulation and violations of cybersecurity requirements, does not provide a convincing argument for making the battery inaccessible to users. From a design point of view, a compartment for a replaceable battery could be located elsewhere in the product enclosure, meaning that replacing the battery would not expose the test points. This would require the product to be redesigned.
- Design Constraints: the arguments provided do not relate to product safety aspects that are relevant to end users. If a tamper-evident seal or label is placed across the casing junction, this does not prevent the design of a compartment for a replaceable battery, located elsewhere in the product enclosure so that a battery replacement would not damage the label or seal. Should a redesign be necessary to change the location of the battery compartment, it could also ensure that the opening to the compartment is not adjacent to the temper-evident seal.
- Durability and Use Case: This aspect does not relate to product safety aspects.
- Regulatory Compliance: The stated necessity of compliance with CRA requirements is not related to product safety aspects relating to end users in the sense of Article 11(4). The safety considerations set out in Commission Notice C/2025/214 do not address design features aimed at minimising attack surfaces and securing digital elements for the sake of data security. (Commission Notice C/2025/214, 2025)

(CAREL INDUSTRIES S.p.A, 2025)

Hence, the criteria 2 ‘product safety requirements’ for a derogation in Article 11(4) does not apply.

Additional arguments pertaining to safety

The iJF Panel is not externally powered (e.g. if the appliance is being cleaned or maintained). The secondary function of keeping time and ensuring data integrity necessitates the internal battery working. However, if the internal battery becomes exhausted after 13 years, exceeding the expected lifetime of the iJF Panel, is not a valid reason for designing it in such a way.

2.8.3. Conclusion and recommendation

The assessment of the arguments provided by the applicant, as well as the supplementary information provided with the application form, concludes that the conditions for a derogation from Article 11(4) for the CAREL INDUSTRIES electrical temperature control (thermostat) device intended for professional use in HVAC/R market are not met. Specifically, the derogation request refers to a secondary function that does not affect end-user related product safety aspects. Compliance with relevant standards (not necessarily safety-related) may not be possible with the current design; however, they could be achieved through product redesign which would also be necessary to ensure battery replaceability. Hence, it is recommended that the derogation for the professional electrical thermostat iJF Panel not be granted.

3. Assessment of applications for products designed to operate in a wet environment

The Battery Regulation Article 11(2) establishes derogations from the removability and replaceability requirements set out in Article 11(1) for portable batteries incorporated in products to be removable and replaceable by end users. For certain products where it is necessary to ensure the safety of the product user, it is sufficient that portable batteries can be replaced and removed by independent professionals with commercially available tools. This includes products specifically designed to operate primarily in a wet environment:

> (a) appliances 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.
>
> (Regulation (EU) 2023/1542, 2024), Article 11(2)(a)

A number of applications for which derogations have been requested have been assessed in relation to the applicability of the derogation listed under Article 11(2)(a), as detailed in this chapter.

3.1. Durex Pleasure Gadgets

3.1.1. Summary of the application

The applicant Reckitt Benckiser Healthcare requests a derogation for the Durex rechargeable pleasure gadget range (also termed battery powered electrical pleasure toys). These products are designed to deliver vibrations to intimate areas of the body. The applicant has chosen lithium-ion batteries due to their better performance and their small size of approximately 24-38 mm length. The battery is connected in the pleasure gadget through wire connections so that soldering is needed to replace the battery. Therefore, the applicant claims that a replacement by the end user would be impractical and that improper handling during the replacement could lead to accidental short circuits and health risks such as electrical shocks or burns and accidental fires. As the products are intended to come in contact with bodily fluids, they need to be cleaned after use with warm water and mild soap that is free from alcohol, petroleum-based solvents, or acetones; water coming into contact with to the charging interface should be prevented. Reckitt Benckiser Healthcare explains that a redesign of the product to allow a battery replacement by end-users may compromise the

hygienic design. A battery opening compartment creates crevices, gaps and seams that prevent thorough cleaning. The applicant has provided details on microbial infection risks that such a redesign would entail (Reckitt Benckiser Healthcare (UK) Limited, 2025).

The applicant also excludes that battery replacement is conducted by independent professionals, arguing that used pleasure gadgets will be classified as 'biohazard' and that privacy and discretion would result in handling being limited exclusively to end-users. Assessing this aspect is beyond the mandate of the consultant, who can only consider applicability of existing derogations or recommend including new derogations under Article 11(2) of the BattReg (Reckitt Benckiser Healthcare (UK) Limited, 2025).

3.1.2. Assessment

Article 11(2)

The applicant Reckitt Benckiser Healthcare does not refer to the existing derogation under Article 11(2)(a) on appliances 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 and no water resistance rating has been specified in the application.

However, as the products are washable and rinseable, and as for the 'wearables' product category, sweat has been considered equivalent to water splashes, the existing derogation 11(2)(a) has been checked for applicability to sex toys.

The Commission Notice C/2015/214 (2025) provides detail on the derogation listed under Article 11(2)(a) for appliances specifically designed to operate in a wet environment and provides the following indicators that are all relevant for interpreting and applying the criteria for the applicability of the derogation for such appliances:

(i) (i) 'specifically': the appliance is designed with the main purpose to operate in the environment described;

(ii) (ii) 'primarily': the environment described is the primary environment of the appliance, as Recital 39 explicitly specifies, 'for the majority of the active service of the appliance'. In other words, not just an environment in which the device may only coincidentally or accidentally operate;

(iii) (iii) 'washable or rinseable': the appliance is intended to be washable or rinseable;

(iv) (iv) ‘compromising safety’: there is evidence in the product documentation when placing the product on the market that battery replaceability and removability by end-users would compromise the safety of the user or the appliance;

(v) (v) ‘no way to redesign’: there is evidence in the product documentation when placing the product on the market that there is no way to redesign the appliance with the current state of the art technology, without severely affecting the health and safety of the end-user or the performance and functionality of the product.

(Commission Notice C/2025/214, 2025)

In most other assessments included in this study, indicators (i) and (ii) have been interpreted as environments such as a washbasin/sinks, as in the case of oral hygiene products. However, for the product category of the wearables, the contact with sweat was considered equivalent with an environment in which water splashes are common. Consequently, other body fluids could also be considered comparable. Additionally, the products may be used in humid internal body areas. With this in mind, indicator (i) and (ii) would apply in this case, and the main function of pleasure gadgets would be recognized as taking place specifically and primarily in a wet environment due to body fluids. Though Reckitt Benckiser Healthcare did not state any IPX ingress protection class numbers, some of the products are advertised with the claim to be usable under the shower. In addition, seeing as the products should be rinsed after each use, indicator (iii) also applies as the appliances are necessarily washable and rinseable.

Indicator (iv) is also assessed by the consultant to apply. Reckitt Benckiser Healthcare has brought forward concerns over the safety of end-users removing or replacing the portable battery. The battery with the wire connections needs soldering to replace the battery. The applicant describes the risk of improper handling during the replacement that leads to accidental short circuits and health risks such as for example electrical shocks or burns and accidental fires. Thus, the applicant states that battery replaceability and removability by end-users would compromise the safety of the user of the appliance.

Indicator (v) on the lacking possibility to redesign the appliance has also been addressed by the applicant. Reckitt Benckiser Healthcare explains that a battery opening compartment may create crevices, gaps and seams that may hinder thorough cleaning after use and could provide an environment where microorganisms can buildup, increasing risks of urinary tract, skin infection or skin reaction to the user.

Criteria for a derogation in Article 11(4)

Article 11(4) allows for adding further products to be exempted from the removability and replaceability requirements if there are scientifically grounded concerns over the safety of end-users removing or replacing the portable battery, or in cases where there is a risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law. The applicant Reckitt Benckiser Healthcare has brought forward as main argumentation that battery replaceability by the end-user would compromise safety and that a redesign is not possible without causing safety risks. Here, a specific aspect is that a redesign is not possible. Whereas for other product categories the small form is an argument, here, hygiene reasons impede the redesign of pleasure gadgets because a battery opening compartment may create crevices, gaps and seams that may hinder thorough cleaning after use, can trap body fluids, lubricants or water and may increase hygiene risk and microbial infection risks to end-users.

Thus, if the sex toys do not benefit from derogation 11(2)(a) as this has not been applied for by the applicant, a derogation under 11(4) could be formulated.

Another reason further limiting the likelihood of a battery replacement has been raised in the case of inexpensive products (see section 1.5.4), though this would not justify a derogation as it is not related to the criteria listed under Article 11(4). For sex toys, the applicant also stresses the need to maintain privacy and discretion of the end user, which would be in violation should the gadgets be handled by independent professionals for the sake of replacement. This aspect does not relate to the Article 11(4) criteria, nor would it be under the consultant's mandate to assess its applicability.

3.1.3. Conclusion and recommendation

The assessment concludes that pleasure gadgets (sex toys) fall under derogation 11(2)(a) as they fulfil all five indicators of (Commission Notice C/2025/214, 2025) and can be considered an appliance that operates primarily in a wet environment. Thus, there is considered to be no need for formulating an additional derogation under Article 11(2).

3.2. Waterpik Water Flossers

3.2.1. Summary of the application

The applicant Waterpik Healthcare requests a derogation for Consumer Oral Health (COH) – Waterpik Water Flossers (Product Family), which are part of the

company's consumer oral health range. Water flossers are used in wet environments such as bathrooms and sinks and in the mouth in contact with saliva. Rechargeable batteries are integrated in a sealed (Ultrasonic Welding) enclosure, including both lithium-ion and nickel-metal hydride (NiMH) chemistries depending on the model. Such batteries include flammable and corrosive substances, such as lithium electrolytes and alkaline solutions. The products are explained to be designed to maintain a minimum ingress protection rating of IPX7, ensuring safe and reliable operation in high-humidity environments. (Water Pik, 2025)

The applicant further mentions the Low Voltage Directive 2014/35/EU as applicable EU law and refers to the risk of thermal runaway, overheating, or even battery fire or explosion. The integrated lithium-ion and NiMH batteries include precision thermal protection mechanisms (overcurrent, overvoltage, and over-discharge controls, embedded safety circuitry). The applicant explains that improper handling or reassembly could result in damage to the protective circuitry, misalignment of contacts, or exposure to conductive materials (Water Pik, 2025).

3.2.2. Assessment

Article 11(2)

Though the applicant does not refer to the existing derogation 11(2)(a), the argumentation relates to the indicators given in Commission Notice C/2025/214:

(i) 'specifically': the appliance is designed with the main purpose to operate in the environment described;

(ii) 'primarily': the environment described is the primary environment of the appliance, as Recital 39 explicitly specifies, 'for the majority of the active service of the appliance'. In other words, not just an environment in which the device may only coincidentally or accidentally operate;

(iii) 'washable or rinseable': the appliance is intended to be washable or rinseable;

(iv) 'compromising safety': there is evidence in the product documentation when placing the product on the market that battery replaceability and removability by end-users would compromise the safety of the user or the appliance;

(v) ‘no way to redesign’: there is evidence in the product documentation when placing the product on the market that there is no way to redesign the appliance with the current state of the art technology, without severely affecting the health and safety of the end-user or the performance and functionality of the product.

(Commission Notice C/2025/214, 2025)

The indicators (i) to (iii) are assessed by the consultant to be fulfilled, as the water flossers are designed with the main purpose to operate in bathrooms and in oral cavities specifically and primarily and as the products will be rinsed during and after use. The Commission guidelines explicitly mention oral hygiene appliances as a representative example of products for these indicators. The water flossers have an IPX7 rating which is considered equivalent to the case of ‘water immersion’ in the Commission guidelines.

For the indicator (iv) on ‘compromising safety’, the applicant Water Pik, Inc. emphasises that the welding process applied for the sealed enclosure cannot be replicated by consumers or third parties using commercial tools. A disassembly of the sealed enclosure would permanently degrade the IPX7 ingress protection and could result in moisture ingress, internal condensation, and electrical or thermal faults especially during charging or high-drain operation. Furthermore, if end-users attempt to replace the battery, improper handling or reassembly could result in damage to the protective circuitry, misalignment of contacts, or exposure to conductive materials each of which increases the risk of thermal runaway, overheating, or even battery fire or explosion because Li-Ion and NiMH batteries contain flammable and corrosive substances, such as lithium electrolytes and alkaline solutions. (Water Pik, 2025)

Regarding the indicator (v) on ‘no way to redesign’, the applicant argues with the compliance with safety objectives under the Low Voltage Directive 2014/35/EU. Accordingly, electrical products have to be constructed to prevent hazards such as fire, overheating, and mechanical instability during foreseeable use. Enabling consumer battery access in the case of the water flossers would violate these objectives due to the inherent risks introduced during product disassembly and reassembly. (Water Pik, 2025) Should a compartment be integrated into the product to enable a battery replacement, it would introduce cervices and grooves that could allow water ingress when not closed properly, introducing safety risks to the use of the appliance and thus to the user.

3.2.3. Conclusion and recommendation

The assessment concludes that the water flosser benefits from the derogation listed under Article 11(2)(a) of the BattReg, as it is an appliance that operates primarily in a wet environment. There is thus no need for formulating an additional derogation.

3.3. Wearable devices

3.3.1. Summary of the applications

Twelve of the derogation applications describe products categorised as wearable devices, intended to be worn on the body in different ways, including on the head, wrist or hand. No common legal definition exists of wearable devices. Different sources define wearable devices or wearables as

> portable electronic devices that are worn on the body and often have sensors and connectivity to collect and transmit data. They can be in the form of smartwatches, fitness trackers, smart glasses or electronics integrated into clothing and other accessories. ([16],[17])

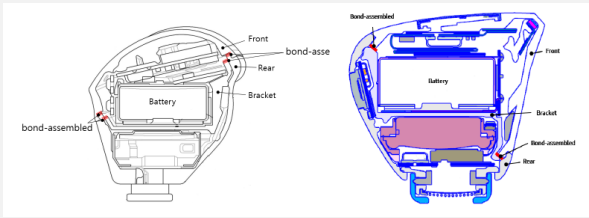
For each of these cases, Table 3-1 specifies the applicants, the products covered by their applications, and a summary of their main arguments.

[16] Internet of Things, Wearable technology, Business Innovation Observatory, European Union, February 2015

[17] Business Unicorns (last accessed 19.08.2025) https://www.business-unicorns.de/lexikon/wearable-technology#:~:text=Wearable%20Technology%20(zu%20Deutsch:%20Tragbare,Brillen%20und%20sogar%20Kleidung%20auftreten.

Table 3-1 – Summary of wearable device applications received in the call for applications under Article 11(4)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Manufacturer of wearable devices	Wearable devices intended to be worn on hand, wrist or head	A removable battery design would not allow for precise sealing and protection of the Li-ion battery, compromising water resistance	Small form factor causes high risk of damages during battery replacement, with subsequent safety risks	No picture provided. Application refers to various different products within the provided definition.
DIGITALEUROPE	Wearable devices intended to be worn on hand and wrist	Safety risks caused by improper battery replacement, non-compatible batteries	Removable battery design not feasible without undermining product functionality; ergonomic and user comfort constraints; compromised compliance with water-resistance standards; small form factor causes high risk of damage during battery replacement, with subsequent safety risks	No picture provided. Application refers to various different products within the provided definition. It must be noted that the applicant requests a derogation for the category of wearables worn on the head and wearables worn on the hand and wrist. However, detailed information and arguments have been submitted only with regards to wearables worn on the wrist or hand.
Luxottica Group S.p.A	Smart glasses	Safety risks caused by improper battery replacement, non-compatible batteries, damaged/improper re-installation of the IPX sealing Ingestion risk of small batteries	Not possible to ensure IPX4 of higher water-resistance standards with a removable battery design without compromising overall product integrity; ergonomic and user comfort constraints	 Smart glasses *Source*: (Luxottica Group S.p.A, personal communication, 3 November 2025)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Manufacturer of wearable devices	Smart glasses	Safety risks caused by improper battery replacement, non-compatible batteries, damaged/improper re-installation of the IPX sealing	Small form factor causes high risk of damages during battery replacement, with subsequent safety risks	
Samsung Electronics	Wearables intended to be worn on the head and on the hand (or on the wrist)	Safety risks caused by improper battery replacement, non-compatible batteries; removable battery design not feasible without undermining product functionality	Small form factor causes high risk of damages; not possible to ensure water-resistance (5-10 ATM or up to IPX7) standards with a removable battery design without compromising overall product integrity.	 Smart ring and its structure with battery *Source*: (Samsung Electronics, 2025)  Structure of earbuds with battery *Source*: (Samsung Electronics, 2025)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
SHOKZ (SINGAPORE) PTE LTD	Bone conduction behind-the-neck headphones	Designed for use in wet environments and resist to sweat, rain exposure and rinsing; safety risks caused by improper battery replacement; removable battery design not feasible without undermining product functionality	Battery removability and replaceability by the end-user would cause frequent manual operations whose risks would be difficult to predict and control	 The image was not provided by the applicant. The image of the product was found online, matches the description and is manufactured by the applicant. *Source*: https://shokz.com/collections/headphones-accessories, last viewed 03.10.2025
Axon Enterprise, Inc.	Body worn cameras (BWC)	Malfunction of the device caused by improper battery handling and replacement, leading to failure during life-threatening scenarios	None	 The image was not provided by the applicant. The image of the product was found online, matches the description and is manufactured by the applicant. *Source*: https://www.axon.com/products/taser-10, last viewed 03.10.2025

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
ZVEI e. V. Electro and Digital Industry Association	Appliances designed to be worn on the head (including eyes and ears) and their associated charging cases	Safety risks caused by improper battery replacement, non-compatible batteries	Increased risk of accidental ingestion of small coin batteries by children; removable battery design not feasible without undermining product functionality; ergonomic and user comfort constraints	No picture provided. Application refers to various different products within the provided definition.
Mobile & Wireless Forum (MWF)	Head-worn wearables (wireless earbuds and smart glasses)	Safety risks caused by improper battery replacement, non-compatible batteries; removable battery design not feasible without undermining product functionality; ergonomic and user comfort constraints; not possible to ensure water-resistance (IPX4 or higher) standards with a removable battery design	Violation of IEC 62133-2:2017 (Section 5.1.1), EU CLP Regulation (Annex VI), IEC 62368-1 and ANSI/UL 4200A, ISO 14971 (Risk-Benefit Thresholds).	No picture provided.

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Nothing Technology Limited	Smart Hybrid Watches	Safety risks caused by improper battery replacement, non-compatible batteries	Water- and dust-resistant properties of watches and consumers' aesthetic expectations are in conflict with battery replaceability requirements	The image was not provided by the applicant. The image of the product was found online, matches the description and is manufactured by the applicant. *Source*: https://it.nothing.tech/collections/watches, last viewed 03.10.2025
Whoop Inc	Wearable device intended to be worn on wrist or other part of the body	Safety risks caused by improper battery replacement, non-compatible batteries, variability in the IPX sealing	Ergonomic and user comfort constraints	The image was not provided by the applicant. The image of the product was found online, matches the description and is manufactured by the applicant. *Source*: https://www.whoop.com/gb/de/membership/, last viewed 13.08.2025. Image of Whoop 5.0 One

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
A manufacturer of smart watches for children	Smart watches for children	Safety risks caused by improper battery replacement, non-compatible batteries; swallowing risk for children (users) due to small batter size.	Risk of design modification by user	
A manufacturer of mart watches for children	Smart watches for children	Safety risks caused by loss of water resistance, use of non-compatible batteries	-	No picture provided.

Source: (Axon Enterprise, Inc, 2025; DIGITALEUROPE, 2025; Luxottica Group S.p.A, 2025; Mobile & Wireless Forum, 2025; Nothing Technology Limited, 2025b; Samsung Electronics, 2025; SHOKZ (SINGAPORE) PTE. LTD., 2025a; Whoop Inc, 2025; ZVEI e. V. Electro and Digital Industry Association, 2025a)

3.3.2. Assessment

Relation to existing derogations

Article 11(2)

The exemption already specified in Article 11(2)(a) for appliances 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, *may apply* to wearables if they meet IPX4 (or higher) water-resistance standards in accordance with IEC 60529 or are water-resistant according to ISO 22810 (only applicable to wrist worn wearables). As outlined in Commission Notice C/2025/214, the criteria which must be fulfilled for application of this derogation are:

(i) Wearable devices can be **specifically designed** to ensure water and dust resistance.
Assessment: Devices that meet IPX4 (or higher) water-resistance standards in accordance with IEC 60529, which according to Commission Notice C/2025/214 may be seen as equivalent to splashing water, are considered to fulfil this criterion. For wrist worn wearables complying with ISO 22810 for water resistant watches or ISO 6425 for divers' watches, the same applies.

(ii) Wrist and hand worn wearables that meet IPX4 (or higher) water resistance standards are regularly subject to water splashes in their regular intended use or as Commission Notice C/2025/214 specifies 'for the majority of the active service of the appliance', e.g. from washing of the hands, and they can hence be considered to be 'designed to operate **primarily** in an environment that is regularly subject to splashing water […]' (Commission Notice C/2025/214, 2025).
Assessment: As regards head worn wearables such as earbuds, smart glasses and headphones that are not specifically intended for swimming and therefore with a water resistance level lower than IPX8 (continuous immersion in water), it is not clear whether they would be regularly subject to water splashes. If such devices are intended to be used during sports and exposure to sweat is considered equivalent to the exposure to water splashes, then the device would be considered to meet this criterion and therefore designed to primarily operate in a wet environment. If exposure to sweat is not considered equivalent to the exposure to water splashes, the exposure to wet environments is considered for these products only coincidental or accidental.

(iii) A wearable may be considered to be **washable or rinseable** if it meets IPX5 (or higher) water-resistance standards in accordance with IEC 60529 which implies that a device can endure direct contact with water that's projected from a nozzle or 'water streams'.
Assessment: Although the requirements of IEC 60529 for testing water and dust resistance are different and do not directly correlate with the water resistance standard ISO 22810, the immersion to which 'water resistant' wrist worn wearables conforming to ISO 22810 are subjected can be considered similar to IPX7 or higher levels of water resistance. However, it is not clear how much the criterion of 'washability/rinseability' should be evaluated based on the existence of an official declaration by the manufacturer.

(iv) The applicants all provided arguments that battery replaceability and removability by end-users would **compromise the safety** of the user.
Assessment: In the cases where it is deemed that the end-user would not be able to restore the water-resistance properties of the product and that water and dust ingress could cause safety issues (e.g. short circuits), this criterion is considered to be met.

(v) The applicants claim that there is **no way to redesign** the devices so that the battery can be removed and replaced by the end-user and the device will maintain its IP rating after such replacement.
Assessment: The evidence provided by the applicants does however not indicate that redesigning the wearable device would result in the device no longer operating safely in the described environment prior to such a battery replacement.

(Commission Notice C/2025/214, 2025)

The wearables in question are not medical devices according to Article 11(2)(b).

Article 11(3)

Article 11(3) provides an exemption for certain products from the Article 11(1) provision:

> where continuity of power supply is necessary and a permanent connection between the product and the respective portable battery is required to ensure the safety of the user and the appliance
>
> or,
>
> for products that collect and supply data as their main function, for data integrity reasons.

(Regulation (EU) 2023/1542, 2024)

Initially, applicants did not raise aspects related to the derogation specified in Article 11(3) for the wearable applications. However, in a later communication, Whoop explained its understanding of this derogation on data integrity to be based on the primary function of the device being the continuous collection of data. Whoop understands the Commission's position in this case to mean that the loss of data integrity—however brief—is sufficient to conclude that the derogation can be relied upon, because it is preventing the product from operating as intended. As the continuous collection of data has for years been the primary function of the WHOOP device, WHOOP considers this to be clear guidance from the Commission that the WHOOP device benefits from the data integrity derogation under Article 11(3).

In this context, the guidance on this derogation specified under Commission Notice C/2025/214 explains that ‘the main function of the product needs to be data collection and supply’ but it also adds that ‘a loss of data integrity needs to be at stake’ (Commission Notice C/2025/214, 2025). The guidance further provides some examples: battery-powered devices used in professional weather stations or in laboratories, batteries whose main function is to power a volatile memory itself or deliver backup functions in the internal clock of a device (e.g. in cameras, processors, sensors, and medical devices), on-board equipment (OBE) which is carried or installed in vehicles and is used as part of toll services and points-of-sale hardware used by the digital payments industry. The guidance document further specifies that the derogation is not considered applicable for devices that ‘deliver a data collection and supply function, as a primary function, but do not pose a risk of data integrity loss, due to, for example, the presence of non-volatile memory in the device’ (Commission Notice C/2025/214, 2025).

In the consultant’s opinion, smart watches in general would not benefit from this derogation. Although their main function is to collect and supply data, they have internal mechanisms that ensure that data is not lost during the time that the battery needs to be recharged. In other words, a loss of data integrity is not at stake. For most smart watches, the battery is recharged through connecting the watch with a cable to an external charger. During the duration of the charging process the watch does not collect and report data; however, the data already collected remains in the device memory and is not lost. This is different from the examples given above, where the battery usually has some form of back-up function aimed at ensuring data integrity during a power shortage or while the main battery is recharged (e.g. in the camera).

The smart watch produced by Whoop poses a different case, in so far that it has been designed to avoid the need for watch removal during charging. The watch remains functional while it is being charged through the connection of a battery powered charger to it. Nonetheless, even if this is the idea behind the watch design, in such cases the user could still forget to charge or not be in proximity

of the charger when it needs to be charged. In this case the watch would have a power shortage. However, here too the watch is understood to have a mechanism that would save the collected data and avoid a loss in integrity of the data already collected. Though this may not be the normal situation of use, in the consultant's view, this is not what the legislator had in mind when developing the guidance related to this derogation.

In short, the derogation under Article 11(3) is assessed as not to apply to wearable devices, as these devices do not have a risk of data integrity loss because the device contains a form of memory.

Criteria for a derogation in Article 11(4)

There are two safety criteria given in Article 11(4): scientifically grounded concerns over the safety of end-users removing or replacing the portable battery, or in cases where there is a risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law.

The reasons and concerns raised by the applicants are related to improper replacement of batteries by the end-user resulting in a risk to the overall integrity, functionality and durability of the product. The applicants also refer to a number of cases in which the safety of the end user could be compromised, such as incorrect replacement, oxidation or contamination of the contacts due to impairment of the water and dust resistance of the watch, or the use of unqualified batteries.

While none of the applications received contain sufficient evidence of safety risks for end-users removing or replacing the portable battery, the following arguments need particular attention:

- **Small form factor**: many applicants argue that the small size of the products makes it impossible for the end-users to handle the battery and the product in a safe way. In one case, the working area has been described as being between 6-10 mm.
- **Impossibility to ensure water-resistance after end-user battery removal/replacement**: some applicants argue that some levels of water protection could not be achieved with a removable battery design because the user would not be able to correctly re-seal the device.

The applicants have not made reference to safety standards that would be violated by making the battery removable but rather to standards related to water resistance as well as water and dust ingress protection. In particular, some applicants highlighted the impossibility for the end-user to test the device after battery replacement, which would be in violation with existing standards that require after-repair testing.

3.3.3. Conclusion and recommendation

The assessment concludes that **devices to be worn on hand and wrist**, such as smart watches and smart rings, which are specifically designed to meet water-resistance requirements meeting **IP ratings equal or above IPX5** in accordance with IEC 60529 or (for wrist worn wearables) ISO 22810 **can be considered to meet the definition for a derogation in Article 11(2)(a)** 'specifically designed to operate in a wet environment', assuming that the end-user would not be able to restore the water resistance properties of the device after replacing the battery, due to the complexity of the sealings used to guarantee high water resistance levels, and subsequent water and dust ingress would likely cause short-circuits and therefore generate safety risks for the end-user (Regulation (EU) 2023/1542, 2024).

With regards to criterion iii) of Commission Notice C/2025/214 (Commission Notice C/2025/214, 2025), it should however be clarified whether such water-resistance level would be sufficient, or the washability of the product should be explicitly declared by the manufacturer.

As regards **devices to be worn on the head or body**, such as e.g. earphones, earbuds, smart glasses, which are specifically designed to meet water-resistance requirements meeting **IP ratings equal or above IPX5** in accordance with IEC 60529 or (for wrist worn wearables) ISO 22810 they **can be considered to meet the definition for a derogation in Article 11(2)(a)** 'specifically designed to operate in a wet environment' assuming that:

- Such devices can be regularly used during sports and therefore exposed to (even heavy) sweat, and that such exposure is considered equivalent to the exposure to water splashes.
- The end-user would not be able to restore the water resistance properties of the device after replacing the battery, due to the complexity of the sealings used to guarantee high water resistance levels
- Water and dust ingress would likely cause short-circuits and therefore generate safety risks for the end-user.

In such cases, Article 11(2)(a) could retain its current wording or be amended as follows to ensure clarity:

- appliances 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, **provided that the indicators (i-v) specified under Commission Notice C/2025/214, for appliances specifically designed to operate in a wet environment are fulfilled**;

Wearable devices designed to meet water-resistance requirements meeting **IP ratings equal to IPX4 or lower** in accordance with IEC 60529, are **not considered to meet the definition for a derogation in Article 11(2)(a)** for these products.

The derogation specified under Article 11(3)(a) is assessed not to apply to wearable devices with the primary function of collecting and reporting data and that include some form of memory to ensure that data is not lost during a power shortage, meaning that a risk of data loss is not applicable.

From the analysis above, it is recommended to clarify the exemption under BattReg Article 11(2)(a) being met for wearables which reach IPX5 level according to IEC 60529 or are 'water resistant' according to ISO 22810 in a revised version of Commission Notice C/2025/214 or in a recital of the delegated act pursuant to Article 11(4).

The arguments provided by the applicants are in general not considered sufficient for granting a new derogation pursuant to **Article 11(4)** related to concerns of end-user safety and need to be evaluated case by case based on the following:

- **Small form factor:** if the device is considered to be too small to allow the end-user to properly and safely handle battery replacement, then a **derogation under Article 11(4) is recommended**. Criteria which outline the characteristics of a small form factor device, as described in section 1.5.1, would need to be included in the delegated act pursuant to Article 11(4).
- **End-user safety risks due to loss of water resistance properties**: if the device is not a small form factor device and does not fall already under the exemption of Art. 11(2) a **derogation under Article 11(4) should be granted only if** it can be proved that water ingress would cause safety risks for the end user e.g. based on considerations on the battery chemistry and that the end user would not be able to restore the device's water resistance properties after battery replacement.

The following text could be used for granting a derogation to the category of wearables: 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:

- wearable appliances that meet the criteria for 'small form factor' ([18]) and/or that rely on compact, sealed construction to maintain functional integrity, including protection against water, dust, and shock, and where

[18] Criteria that should be defined and listed in the delegated act.

user access to the battery may compromise the safety, durability, or water resistance of the device.

3.4. Heart rate monitor strap

3.4.1. Summary of the application

Shokz (Singapore) requests a derogation for its product 'Heart Rate Monitor Strap'. The derogation is requested at the product category level. This implies further products developed or to be developed by the manufacturer following the same working principle with some iteration. (SHOKZ (SINGAPORE) PTE. LTD., 2025c) Products by other market actors which follow the same technical and operating principles also exist.

Figure 3-1 – Heart rate monitor strap in use

Source: (Shokz Asia, 2025)

Shokz provides the following justifications for their derogation request:

- Design considerations: The firm indicates that the Heart Rate Monitor Strap is specifically designed for sports scenarios such as swimming, running, cycling, and other similar activities. Further design considerations are waterproof capabilities to perform reliably in conditions such as heavy sweating, rain, rinsing, and submersion in water (IP 68 protection level).

- Compliance with EU Battery Regulation Exemption Criteria: The firm points to the existing derogation under Art. 11(2)(a) to claim an exemption as the product is designed for full immersion in water during normal operation. Conflict between safety risks and technical feasibility: The firm explains that designing devices for user-replaceable batteries would compromise the original sealed structure. Once the seal is broken, batteries may be exposed to moisture, which can result in short-circuiting, corrosion, and leakage. To maintain safety and performance, battery replacement should be carried out by professionals.

  (SHOKZ (SINGAPORE) PTE. LTD., 2025c)

3.4.2. Assessment

Article 11(2)

The exemption specified in Article 11(2)(a) applies to appliances designed to operate primarily in environments regularly exposed to splashing water, water streams, or water immersion, and that are intended to be washable or rinseable. The applicant indicates that the product is specifically designed for use in wet environments, including full immersion in water during activities such as swimming. As outlined in Commission Notice C/2025/214, five indicators must be fulfilled for this derogation to apply:

(i) **Specifically** designed to ensure water and dust resistance.
Assessment: The product appears to be designed to resist both water and dust. Devices that achieve IPX4 or higher water-resistance standards under IEC 60529, which the Commission Notice C/2025/214 equates to protection against splashing water, are considered to meet this criterion. The product's description suggests an IPX rating greater than 4.

(ii) Designed to 'operate **primarily** in an environment that is regularly subject to splashing water […]' (Commission Notice C/2025/214, 2025).
Assessment: The Commission Notice C/2025/214 emphasizes that exposure to water should occur for much of the device's active service life. Since these products are intended for activities like exercise and swimming, regular contact with water is a fundamental part of their normal function and a key aspect of their design and performance.

(iii) **Washable or rinseable:**
Assessment: Products may be considered washable or rinseable if they achieve IPX5 or higher water-resistance under IEC 60529, meaning the device can withstand direct contact with water projected

from a nozzle or water streams. The product description indicates an IP rating greater than 5, supporting their classification as washable or at least rinseable. The product can further be used while swimming.

(iv) Battery replaceability and removability by end-users would **compromise the safety** of the user.
Assessment: Applicants have argued that allowing end-users to replace or remove the battery could compromise safety. Whether loss of water and dust ingress protection after battery replacement by the end-user actually leads to risks such as short circuits from water ingress or dust inside the device depends on the battery chemistry and maximum voltage and therefore requires further evaluation. Nonetheless, a risk exists, and the use of the product in direct proximity to the human heart calls for a cautious approach.

(v) **No way to redesign** the devices so that the battery can be removed and replaced by the end-user.
Assessment**:** The applicants have demonstrated that it is not possible to redesign these devices so that the battery can be removed and replaced by the end-user while still maintaining the required IP rating. Although the evidence does not show that redesigning heart rate monitors for battery replacement would make the product unsafe prior to such replacement, the small size of the product suggests that end-users would likely encounter difficulties in resealing the device properly.

Depending on the IP rating of the device being above IPX5, the indicators could be considered fulfilled, meaning that the product would benefit from the derogation specified under Article 11(2)(a) of the BatReg.

Regarding the exemption specified in BattReg Article 11(2)(b), the product in question is not a medical device and would not be eligible to benefit from this derogation.

Article 11(3)

The derogation specified in Article 11(3) does not apply for the product category heart rate monitor.

Criteria for a derogation in Article 11(4)

Article 11(4) of the BattReg would only be relevant if there were uncertainty regarding the applicability of Article 11(2)(a). In this case, all five indicators are clearly met, and the consultant finds BattReg Article 11(2)(a) applicable. The

criteria listed in Article 11(4) have thus not been assessed for compliance in this case.

3.4.3. Conclusion and recommendation

Based on the assessment above, the derogation requested by SHOKZ (SINGAPORE) PTE. LTD is concluded to be justified for the following reasons:

- The product is specifically designed for use in wet environments, is intended to be washable/rinseable, and requires an IPX4 or greater protection rating for safe operation.
- The applicant has credibly argued that end-user battery replacement could compromise water ingress protection and thus electrical safety, while professional replacement can reliably maintain these safety features.

All five indicators for the applicability of Article 11(2)(a) are met, in line with existing guidance provided under Commission Notice C/2025/214. It is therefore, concluded that the existing derogation under Article 11(2)(a) is applicable in this case and thus that a new derogation would not be needed for this product category. Article 11(2)(a) could retain its current wording or be amended as follows to ensure clarity:

- appliances 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, **provided that the indicators (i-v) specified under Commission Notice C/2025/214, for appliances specifically designed to operate in a wet environment are fulfilled**;

3.5. Other watches (non-digital, non-smart)

3.5.1. Summary of the applications

In three applications, the products are categorised as watches or wearables intended to be worn on the wrist. Different to the product category of wearables, the applications were made primarily for non-smart, non-digital watches. No legal definition exists of watches. For the purpose of this document, watches are defined as: a timekeeping device worn on the wrist, designed to provide accurate timekeeping and often other functions such as indication of date, alarm, and chronograph.

For each case, Table 3-2 specifies the applicants, the products covered by their applications, and a summary of the main arguments.

Table 3-2 – Summary of applications for other (non-digital, non-smart) watches received in the call for applications under Article 11(4)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Seiko Epson Corporation	Non-digital, non-smart, wrist-worn watches	Battery replacement by the end user may compromise product integrity and end user safety due to improper installation.	Design for replaceability conflicts with design requirements for water and dust ingress protection to meet IPX4 or higher, and for water resistant watches according to ISO 22810 and diver watches according to ISO 6425.	Source:(Seiko Epson Corporation Europe BV, personal communication, 31 October 2025)
Federation of the Swiss Watch Industry FH	Watches (especially those compliant to ISO 22810 standard)	Battery replacement by the end user may compromise product integrity and end user safety due to improper installation; children could ingest button cell batteries used in wrist-worn watches if they are removable.	Design for replaceability conflicts with design requirements for water resistant watches according to ISO 22810 and divers watches according to ISO 6425.	No picture provided. Application refers to various different products within the definition of watches compliant to ISO 22810.
Additional association	Quartz watches, smart watches, stop watches, pocket watches	Battery replacement by the end user may compromise product integrity and end user safety due to improper installation.	Design for replaceability conflicts with design requirements for water resistant watches according to ISO 22810.	No picture provided. Application refers to various different products.

Source: (Federation of the Swiss Watch Industry FH, 2025; Seiko Epson Corporation, 2025)

3.5.2. Assessment

Relation to existing derogations

Article 11(2)

The exemption already specified in Article 11(2)(a) for appliances 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, *may apply* to watches if they meet IPX5 (or higher) water-resistance standards in accordance with IEC 60529 or are water-resistant according to ISO 22810 or ISO 6425. As outlined in Commission Notice C/2025/214, the five indicators which have to be fulfilled for application of this derogation are:

(i) The watch is **specifically designed** to ensure water and dust resistance to meet IPX4 (or higher) water-resistance standards in accordance with IEC 60529, which according to Commission Notice C/2025/214 may be seen as equivalent to splashing water. For watches complying with ISO 22810 for water resistant watches or ISO 6425 for divers' watches, the same applies.

(ii) Wrist worn watches are regularly subject to water splashes in their regular intended use or as Commission Notice C/2025/214 specifies 'for the majority of the active service of the appliance', e.g. from washing of the hands. Watches that meet IPX4 (or higher) water resistance standards, can hence be considered to be 'designed to operate **primarily** in an environment that is regularly subject to splashing water […]' (Commission Notice C/2025/214, 2025).

(iii) A watch may be considered to be **washable or rinseable** if it meets IPX5 (or higher) water-resistance standards in accordance with IEC 60529 which implies that a device can endure direct contact with water that's projected from a nozzle or 'water streams'. Although the requirements of IEC 60529 for testing water and dust resistance are different and do not directly correlate with the water resistance standards ISO 22810 and ISO 6425, the immersion to which 'water resistant' watches conforming to ISO 22810 and ISO 6425 are subjected can be considered similar to IPX7 or higher levels of water resistance.

(iv) The applicants all provided arguments that battery replaceability and removability by end-users would **compromise the safety** of the user.

As further discussed in the following assessment relating to Article 11(4), whether expected loss of water and dust ingress protection due to replacement of the battery by the end-user does in fact result in risks to the end-user, e.g. due to short circuits related to water ingress or dust particles inside the watch, has to be further evaluated and may depend on the battery chemistry in use.

(v) The applicants have demonstrated that there is **no way to redesign** the device so that the battery can be removed and replaced by the end-user and the device will maintain its IP rating after such replacement. The evidence provided by the applicants does however not indicate that redesigning the watch would result in the watch no longer operating safely in the described environment prior to such a battery replacement.

(Commission Notice C/2025/214, 2025)

The watches in question are not medical devices and would not be covered by Article 11(2)(b).

Article 11(3)

The derogation specified in Article 11(3) does not apply for the watches applications. None of the aspects of Article 11(3) were raised.

Criteria for a derogation in Article 11(4)

There are two safety criteria given in Article 11(4), scientifically grounded concerns over the safety of end-users removing or replacing the portable battery, or in cases where there is a risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law.

The reasons and concerns raised by the applicants are related to improper replacement of batteries by the end-user resulting in a risk to the overall integrity, functionality and durability of the product. The applicants also refer to a few cases in which the safety of the end user could be compromised, such as incorrect replacement, oxidation or contamination of the contacts due to impairment of the water and dust resistance of the watch, or the use of unqualified batteries. The applicants have not made reference to safety standards that would be violated by making the battery removable but rather to standards related to water resistance as well as water and dust ingress protection.

3.5.3. Conclusion and recommendation

The assessment concludes that watches which are specifically designed to meet water-resistance requirements meeting ISO 22810, ISO 6425 or IP ratings above IPX5 in accordance with IEC 60529 can be considered to meet the definition for a derogation in Article 11(2)(a) 'specifically designed to operate in a wet environment' (Regulation (EU) 2023/1542, 2024).

In such cases, Article 11(2)(a) could retain its current wording or be amended as follows to ensure clarity:

- appliances 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, **provided that the indicators (i-v) specified under Commission Notice C/2025/214, for appliances specifically designed to operate in a wet environment are fulfilled**;

However, watches are not considered to be washable or rinseable unless they meet the IPX5 level according to IEC 60529 or are 'water resistant' according to ISO 22810 and the evidence of redesign compromising the safety of the end user is not conclusive.

The arguments provided by the applicants are not considered sufficient for granting a new derogation pursuant to Article 11(4) related to concerns of end-user safety. It is understood that, while replacing button cell batteries from wrist worn watches can pose safety risks for the end-user if not done correctly, generally it is not inherently unsafe if done with proper precautions. Non-compliance with water resistant and diving gear accessory standards due to (i) design-changes required for replaceability of batteries; and (ii) removal of the battery by the end-user resulting in loss of the water-resistant properties are not considered a safety risk where the end-user is informed of such changes in the water-resistant properties of the watch after replacement of the battery.

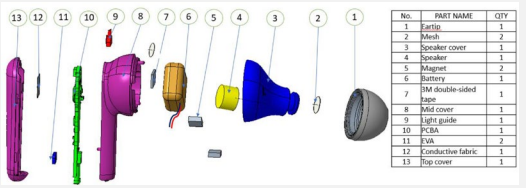
From the analysis above, it is recommended to clarify the exemption under Article 11(2)(a) being met for wearables and watches which reach IPX5 level according to IEC 60529 or are 'water resistant' according to ISO 22810 (water-resistant watches) or ISO 6425 (diver's watches) in a revised version of Commission Notice C/2025/214 or in a recital of the delegated act pursuant to Article 11(4).

3.6. Wireless earphones (earbuds)

3.6.1. Summary of the applications

Ten of the submitted applications refer to earbuds, also referred to as earphones, which are ‘relatively small sound speakers’ designed to fit into the outer ear canal for audio consumption. While differing in the manner in which earbuds are inserted or securely attached to the outer ear canal, the applications operate on similar principles. A summary of the applications is provided Table 3-3 below.

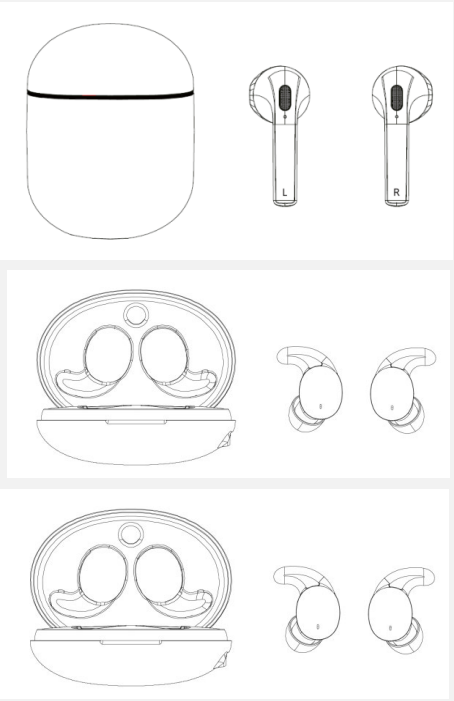
Table 3-3 – Summary of earbud applications received in the call for applications under Article 11(4)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Belkin International Inc.	True Wireless Earbuds	Ingestion risks from small-part generation and lithium-ion toxicity; compromised ingress protection (IP) ([19]) and safety of the product; shorting of battery components due to mechanical abuse.	Removal of the earbud battery would also lead to the other small parts becoming separately accessible which could be swallowed by children due to the need to modularize the product design for removal and replacement. Design for removal and replacement would lead to the possibility that users are unable to reseal the device so that it retains its water protection rating under IEC 60529. Shorting of the battery components due to mechanical abuse may lead to burns to the user´s skin and ear canal during active use. Thermal runway fires are also possible even at low water ingress levels. This is backed up by scientific experimentation based on salt water (presence of salt in human sweat alludes to similar effects on contact).	 *Source*: (Belkin International, Inc., 2025)

[19] IEC 60529 on the degrees of protection provided by enclosures (Ingress Protection code) for solid foreign objects and water. Accessible here. https://www.iec.ch/ip-ratings.

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Harman International Industries, Incorporated	TWS (True Wireless Stereo) in-ear Headphones	End-user battery exchange is impractical due to user safety and product performance reasons; ergonomic design requirements to allow product to fit securely in the outer ear-canal; space requirements to allow for the placement and secure fastening of internal components.	The manufacturer has already implemented a novel strategy that allows users to replace each earbud independently should a defect occur as well as the charging case. From mid-2026, the larger battery in the charging case will be designed for removal and replaceability. Batteries expected to outpace the product´s lifetime therefore replacement will not be necessary. Specific product features such as noise-cancelling might be negatively affected if shifted out of intended positions.	*Source*: (Harman International Industries , Incorporated, 2025)
Manufacturer of wireless earbuds	Wireless earbuds	Ingestion hazard (specifically to children); implementing user-replaceability under EU legislation could lead to design conflicts with other EU and international legislations.	The ultra-compact form of factor of earbuds does not permit the inclusion of child-resistant mechanisms such as screw-secured battery covers or dual-action release systems without compromising usability, safety and performance.	No picture provided in application
Nothing Technology Limited	Clip-on Earphones	Space constraints to allow for other components such as Bluetooth chips, processors, microphones and speakers; compromised the ingress protection (IP) and safety of the product; sealed battery to reduce consumer safety risks by ensuring product center of gravity and placement of components conform to users' outer ear canal shape.	Stable welding connections and glue fixation need to prevent battery shifting during use to avoid internal short circuits, and other safety risks to the product and user.	No picture provided in application

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Nothing Technology Limited	Open Wireless Stereo (OWS)	Space constraints to allow for other components such as Bluetooth chips, processors, microphones and speakers; compromised ingress protection (IP) and safety of the product.	None	No picture provided in application
Nothing Technology Limited	True Wireless Stereo (TWS) earbuds	Internal space constraints; need to prevent dust and moisture ingress based on IP standards; ensure ergonomic stability, comfort, and safety of users; ensure mechanical and electrical reliability.	Compact size of the product requires extremely small components leading to limited disassembly space. Improper dismantling risks damaging flexible circuit boards, wiring, or microphone components. Potential short circuits may cause fires or chemical burns. Product design and assembly is challenging for professional repairers, hence it is unlikely end-users can successfully remove and replace batteries without damaging the product and themselves.	*Source*: (Nothing Technology Limited, 2025a)

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Shenzhen DNS Industries Co., Ltd	True Wireless Stereo (TWS) earphones	The earbuds comply with a water resistance rating of IPX5 or higher according to IEC 60529. As the earbuds are seated within the ear canal and may come into contact with bodily fluids, some users might choose to clean them periodically. Small size of batteries is swallowing risk for children; conflict with existing regulatory requirements specifically IEC 62368-1:2023	End-user removal or replacement of the battery will void the IPX5 waterproof seal. This breach can result in short circuits from water or dust ingress, with the specific risk level dependent on the battery's chemical composition, max voltage/current, and other factors. IEC 62368-1:2023 requires that if the product is equipped with a removable battery and is disassembled with a tool, the disassembly force must meet 0.5Nm torque, which will break the earphones. If screws are used in the component assembly, they are required to reach 0.4 Nm after being disassembled 10 times. TWS earphones are very small; there is no space to install screws, hindering the application of this option to provide a disassembly route.	 *Source*: (Shenzhen DNS Industries Co., Ltd, personal communication, 4 November 2025)
Beyerdynamic GmbH & C0. KG	In-ear headphones and open-ear headphones worn directly on the ear	Internal space constraints; need prevent moisture ingress.	None provided by the applicant so far although requested. It is likely the applicant´s response will follow similar argumentation made by other applicants in this cluster.	None provided by the applicant.

Applicant	Product	Main argumentation summary	Additional argumentation	Picture of the product and comments
Shenzen Baseus Technology Co. Ltd ([20]).	TWS Earphones	Internal space constraints; need prevent moisture ingress.	None provided by the applicant so far although requested. It is likely the applicant´s response will follow similar argumentation made by other applicants in this cluster.	None provided by the applicant.
Shokz (Singapore) PTE LTD	TWS Earphones	Internal space constraints; small battery size is swallowing risk for children.	Prevent the ingress of sweat and moisture that could cause battery to short-circuit, corrode, or other safety hazards. Enhance reliability and durability in high-humidity and corrosive environments. Meet the practical demands of users for safety and comfort during sports activities.	None provided by the applicant.

Source: (Belkin International, Inc., 2025; Beyerdynamic GmbH & Co. KG, 2025; Harman International Industries , Incorporated, 2025; Nothing Technology Limited, 2025a; Shenzhen Baseus Technology Co., Ltd., 2025; Shenzhen DNS Industries Co., Ltd, 2025)

[20] The applicant lists several products in a single application without providing argumentation or supporting documentation. The additional products listed are wireless cameras for home security, outdoor portable speaker, headphone, rechargeable stylus, rechargeable keyboard and mouse, emergency Power Bank, and a car vacuum cleaner. In the absence of a description of the product, argumentation and supporting documentation, these products were not assessed.

Belkin International´s True Wireless Earbuds

The applicant, Belkin International, requests a derogation for the battery installed in their True Wireless Earbud. The product is specifically designed to fit into the ear canal of a wearer and is hence tightly designed for the dimensions of the human ear. Each earbud of the pair includes a very small lithium-ion battery cell, and these pairs are usually marketed and sold with a charging case that holds and recharges the earbuds when they are not actively being used. The earbud case typically includes a larger lithium-ion cell capable of charging the pair of earbuds multiple times (earbud casings are addressed in section 5.1). The applicant presents the following argumentation in support of their position:

> Removal of the earbud battery may result in the generation of small parts. Due to the modularization (redesign) required for battery removal and replacement, additional components may become detached, posing an ingestion hazard to children.
>
> The design for battery removability and replaceability can compromise the product's ingress protection (IP) rating as defined by IEC 60529. After battery replacement, users may be unable to reseal the device to its original water resistance, thereby reducing the product's safety.
>
> Mechanical abuse during battery replacement or handling can lead to short-circuiting of battery components leading to the premature end-of-life of the product. Such circuit shorting may cause burns to the user's skin and ear canal during use, and may also trigger thermal runaway events, including fire, even at low levels of water ingress (Johns & Torelli, 2023).
>
> (Belkin International, Inc., 2025)

Harman International´s True Wireless Stereo in-ear Headphones

Harman International, applies for a derogation from Art. 11(1) for the lithium battery installed in their in-ear headphones. Pictures of the product along with supporting information provided by the applicant indicate that these in-ear headphones are of similar nature to the earbuds described above. The applicant presented the following arguments to support their request:

> **Battery exchange by the end-user battery is impractical for user safety and product performance**

reasons: Providing consumers with direct access to small lithium-ion batteries introduces safety risks such as punctures and overheating, and improper installation with punctures can potentially lead to chemical leakage or ignition. To prevent moisture or water ingress, which can cause malfunctions or safety hazards, these devices are typically sealed to establish a high Ingress Protection rating using ultrasonic welding, making them impossible to open without destruction. However, if water, especially chlorinated or saline, as would be in human sweat, enters the device, the risk of overheating and other safety concerns increases.

Ergonomic design requirements to allow secure fit in the outer ear-canal: Malfunctioning due to improper battery replacement could in extreme cases lead to skin burns or even hearing loss. It is on this basis that only independent professionals should replace batteries.

Product durability: The applicant states that batteries used in their products are designed to outpace the lifetime of the overall product, thereby eliminating the need for removal or replacement. Furthermore, the batteries are designed with ‘soft packs’ containing hazardous chemicals. Should these be damaged, it would lead to leakage of chemicals that would have the effect of shortening the lifetime of the product leading to the creation of electronic waste.

Product Reliability: The internal components of TWS products are extremely small and sensitive. Even minimal contact with the printed circuit board or internal antennas during battery replacement can disrupt Bluetooth connectivity, affecting both performance and range.

Product Quality: Achieving high audio quality, effective active noise cancellation, and clear call audibility requires precise placement of two or more built-in microphones. Any slight movement or disturbance of these components can immediately and significantly degrade product performance.

Design for removal from earbud case: TWS products consist of three components: two earbuds (left and right) and a charging case. Harman has implemented a service strategy that allows consumers to replace each part independently in the rare event of a defect (this is also the

case for most manufacturers in this product category.) Beginning in the second half of 2026, the larger battery inside the charging case of new Harman products will be designed to meet requirements for removability and replaceability.

Impossibility to redesign without compromising durability and functional design: TWS in-ear headphones are engineered to be as small and lightweight as possible, leaving very limited space for internal components. Designing these products to accommodate replaceable batteries would require significantly larger enclosures, which would compromise both ergonomic fit and overall usability, as bulkier designs would not sit comfortably in the ear canal. To achieve high levels of water and dust resistance, these products are sealed using ultrasonic welding, ensuring robust IPX ratings. Introducing opening mechanisms for battery access would undermine product durability, lower ingress protection, and pose risks to both consumer safety and product performance, including potential overheating, shutdowns, and reduced battery life. Additionally, there is a risk that moisture ingress could lead to corrosion of internal components.

(Harman International Industries , Incorporated, 2025)

Manufacturer of Wireless earbuds

The manufacturers application also covers its wireless earbuds, which are similar in construction and operation to the two earbuds discussed above. The applicant presented the following arguments, paraphrased here:

- **Ingestion hazard (specifically to children):** The ultra-compact form of factor of earbuds does not permit the inclusion of child-resistant mechanisms such as screw-secured battery covers or dual-action release systems without compromising usability, safety and performance.
- **Conflicting EU regulations on product safety and eco-design**: Wireless earbuds contain compact lithium-ion batteries similar in size to button or coin cells, which are known ingestion hazards for young children and can cause severe internal injuries if swallowed. To address this risk, international safety regulations such as the EU General Product Safety Regulation (Regulation 2023/988) and U.S. Reese's Law require manufacturers to design products that prevent child access to these batteries, often mandating child-resistant features that are difficult to

implement in ultra-compact devices. As a result, non-replaceable battery designs, where the battery is permanently sealed within the housing, are recognized as the most effective and practical way to eliminate the risk of accidental ingestion and ensure compliance with safety standards. The current design of wireless earbuds fully seals the battery, making it inaccessible to users and children, and thereby meets both EU and U.S. product safety requirements.

(source anonymised)

Nothing Technology´s Clip-on Earphones

The Clip-on Earphones presented by the applicant appear to be a form of earbuds where held-in-place within the ear canal by a clip-like clasp attached to the outer earlobe. Besides this different design feature, the product functions in very much the same way as 'typical' earbuds discussed in this chapter. The applicant presented the following arguments, paraphrased here:

- **Limited internal space** must accommodate essential components such as Bluetooth chips, processors, microphones, and speakers.
- Enabling battery access could **compromise the product's ingress protection** and overall **safety**.
- Sealing the battery helps **minimize safety risks** for consumers by ensuring that the centre of gravity and component placement align with the ergonomic shape of the outer ear canal.

(Nothing Technology Limited, 2025a)

Nothing Technology, Open Wireless Stereo

Nothing Technology requests a further derogation from Art. 11(1) for its product, the Open Wireless Stereo. The product functions in a similar way to conventional earbuds with the exception that it features a curved attachment mechanism to the outer earlobe allowing the main part of the product to rest on the entrance of the ear canal. Arguments presented by the applicant in support of their request can be summarised as follows:

- Internal space is needed to accommodate critical components such as Bluetooth chips, processors, microphones, and speakers.
- Providing battery access may compromise the product's ingress protection and overall safety as mentioned by other applicants of similar products above.

(Nothing Technology Limited, 2025a)

Nothing Technology, True Wireless Stereo Earbuds

Nothing Technology also requests a derogation for their 'conventional' earbuds. Based on the pictures presented by the applicant, the product is similar to other earbuds presented for derogation in this chapter. The line of argumentation in the application is also similar to other applications, as summarised here:

- The **compact design** of the product requires extremely small components, resulting in limited space for disassembly.
- High standards for dust and moisture protection must be met to comply with **Ingress Protection requirements**.
- **Improper dismantling can damage sensitive parts** such as flexible circuit boards, wiring, or microphone components.
- The design must ensure **ergonomic stability, comfort, and user safety**, as improper handling could lead to short circuits, fires, or chemical burns.
- Mechanical and electrical **reliability** is essential, and the complexity of assembly makes battery removal and replacement challenging even for professional repairers, making it unlikely that end-users could do so without causing damage to the product or themselves.

(Nothing Technology Limited, 2025a)

Shenzhen DNS Industries, True Wireless Stereo Earbuds

Shenzhen DNS Industries requests a derogation from Art. 11(1) for their True Wireless Stereo earbuds. Based on the technical information provided by the applicant, the earbuds function in a similar nature to earbuds discussed in this chapter albeit with a different mechanism to keep the sound producing park of the earbud atop the ear canal. The applicant's line of argumentation is paraphrased below:

- Small size of batteries presents a **swallowing risk for children**, similar to arguments presented by other applicants for derogations for their earbuds.
- **Conflict with existing regulatory requirements specifically IEC 62368-1:2023** ([21]): IEC 62368-1:2023 stipulates that if a product contains a removable battery and is designed to be disassembled with a tool, the required disassembly force must reach 0.5 Nm of torque. This level

[21] IEC 62368-1:2023 is a product safety standard that classifies energy sources, prescribes safeguards against those energy sources, and provides guidance on the application of, and requirements for, those safeguards. The prescribed safeguards are intended to reduce the likelihood of pain, injury and, in the case of fire, property damage. See: https://webstore.iec.ch/en/publication/69308

> would break typical earphones. Additionally, if screws are used in the assembly, they must withstand 0.4 Nm of torque even after being removed and reinserted ten times. Due to the extremely small size of TWS earphones, there is insufficient space to accommodate screws, making this method of disassembly unfeasible.

(Shenzhen DNS Industries Co., Ltd, 2025)

Beyerdynamic GmbH &CO. KG, In-ear headphones and open-ear headphones worn directly on the ear

Beyerdynamic GmbH & CO requests a derogation from Art. 11(1) for their in-ear and open-ear headphones worn directly on the ear. While the applicant does not provide details on the technical specifications of the product, it is conceivable that they are generally similar to other earbuds described in this cluster. The applicant's line of argumentation is paraphrased below:

- It is crucial to keep headphones sealed and **free from moisture** for product safety.
- Because of their small size, replacing the 'delicate' batteries may compromise the effectiveness of the seal.

(Beyerdynamic GmbH & Co. KG, 2025)

Shokz (Singapore) PTE. LTD., TWS earbuds

The applicant, Shokz (Singapore) PTE.LTD, requests a derogation from Art. 11(1) for their True Wireless Stereo earbuds which are compact, fully wireless audio devices that use Bluetooth to deliver stereo sound. They typically include a charging case and two individual earbuds. The argumentation provided by the applicant are listed below:

> Child safety risks: Children can mistake small TWS earbuds or their batteries for candy, creating a high risk of accidental swallowing; button batteries in particular can cause severe injuries such as esophageal burns within two hours and even gastrointestinal perforation. Regulations in Europe, the US, and Australia underscore these hazards, and evidence from poison control guidance, academic reports, and news cases highlights the consequences. Designs with removable batteries raise risk by making small cells more accessible and increasing their circulation. In contrast, non-removable battery designs achieved through structural encapsulation (for example, adhesive or welding) physically isolate the battery, reduce its presence in the market, and substantially enhance product safety for children.

> General safety risks of removable battery design in TWS earbuds: Removable battery designs in TWS earbuds elevate safety risks by making cells vulnerable to damage and internal short circuits from repeated insertion and removal, especially in wet environments; this can lead to overheating or leakage, with temperatures reportedly reaching up to 130°C, creating burn hazards and compromising the device's airtight seal. Current standards may not fully capture these real-world risks: IEC 62133-2 is a one-time lab test that does not simulate frequent handling or drops and focuses on explosion/fire rather than temperature, while IEC 62368-1 requires body-contacting surfaces to stay below 43°C. Because TWS earbuds are worn on the head, a battery short circuit poses a direct threat to the face and auditory organs, making the risk profile significantly higher than for devices used away from the head.
>
> Technical and design challenges for implementing removable batteries in TWS earbuds: TWS earbuds are too compact to accommodate a removable battery without unacceptable increases in size, weight, and complexity. Adding a user-removable mechanism would require a full redesign with larger compartments, covers, fasteners, and protective elements, impairing comfort, portability, and wearability, and introducing new safety risks. Achieving water and sweat resistance would demand dual-level sealing that further enlarges the device. Reinforcing the battery module adds more bulk, undermining lightweight goals. Under current technology, the trade-off between child safety and user accessibility in battery design cannot be eliminated.
>
> Limited internal space: In TWS earbuds, individual cells lack onboard protection boards because protection circuits are integrated into the mainboard, so a single cell should not be treated as a standalone battery; instead, the entire earbud functions as the user-replaceable 'battery unit.' To meet user-replaceability requirements without redesigning internal cells, individual replacement earbuds are placed on the market, allowing users to swap the complete earbud rather than handling unprotected cells, aligning safety and regulatory compliance.

(SHOKZ (SINGAPORE) PTE. LTD., 2025b)

3.6.2. Assessment

Relation to existing derogations

Article 11(2)

As outlined in Commission Notice C/2025/214, the five indicators which have to be fulfilled for application of a derogation under Art. 11(2)(a) are:

- Specifically designed with the main purpose to operate in a wet environment: Earbuds appear to be **designed to provide water and dust resistance**. Devices that achieve IPX4 or higher water-resistance standards according to IEC 60529, which the Commission Notice C/2025/214 equates to protection against splashing water, are considered to meet this requirement. Most applicants for this product category reference IPX4 ratings or above.
- Primarily operates in wet environment: Earbuds are often exposed to water splashes during normal use, such as from drinking bottles during running or water contact during exercise. As highlighted in Commission Notice C/2025/214, these exposures occur for much of the device's active service life. Since earbuds are intended to support activities like exercise, semi-regular contact with water (e.g. sweat, rain splashes) is considered part of their normal function and a key aspect of their design and performance. However, this point is arguable as the amount of liquids with which devices come into contact may not be considered as a wet environment.
- Washable or rinseable: Earbuds may be considered washable or rinseable if they achieve IPX5 or higher water-resistance under IEC 60529, which means the device can withstand direct contact with water projected from a nozzle or from water streams. Most applicants report an IP rating of 5, which supports their classification as washable or at least rinseable. As earbuds are inserted into the outer ear canal, where they may come into contact with bodily fluids, it can be followed that some users may want to wash them from time to time.
- Compromise safety: Applicants have argued that end-user battery replaceability and removability would compromise user safety. Whether a loss of water and dust ingress protection after battery replacement by the end-user actually results in risks such as short circuits from water ingress or dust inside the device depends on the battery chemistry and maximum voltage and hence requires further evaluation. However, a risk exists and the use of the product in the inner ear warrants a cautious approach.

- No way to redesign: The applicants have shown that it is not possible to redesign these devices so that the battery can be removed and replaced by the end-user while still maintaining the IP rating. While the evidence does not show that redesigning earbuds for battery replacement would make the product unsafe before such replacement, the small size of the product suggests that end-users would likely struggle to reseal the device properly. Most applicants note that welded seals are used to ensure IPX ratings, making it difficult to maintain water and dust protection after opening (most end-users would likely not have welding instruments for example to reseal battery compartments after replacement in the product).

(Commission Notice C/2025/214, 2025)

The wearables in question are not medical devices according to Article 11(2)(b).

Article 11(3)

The derogation specified in Article 11(3) does not apply for the product category earbuds.

Criteria for a derogation in Article 11(4)

Article 11(4) sets out two safety criteria: scientifically grounded concerns regarding the safety of end-users removing or replacing the portable battery, and situations where such actions could violate product safety requirements established by Union law.

The concerns raised by applicants focus on the risk that improper battery replacement by end-users could compromise the product's integrity, functionality, and durability. Applicants also highlight scenarios where end-user safety may be at risk, such as incorrect battery replacement, short circuiting of contacts resulting from impaired water and dust ingress protection. Given the proximity of earbuds to the human body such concerns require careful consideration even if the risk might be deemed low due to the typical sizes and charge capacities of batteries used in earbuds. It should also be noted that earbuds are recharged in charging cases with significantly larger batteries. A thermal runaway in an earbud could potentially spread to its ear case causing further harm to end-users and property.

Further arguments requiring careful consideration are the small size of the batteries in the products (as well as the products themselves). The assertion being that the product and subsequent batteries are so small as to make redesign unfeasible for a form fitting into the human ear. The Toys Safety Regulation and related standards permit considering the size and nature of a device to decide if it can be redesigned to allow battery replacement with tools

or if it must only be designed to allow replacement by an independent professional (see section 1.5.1). In analogy, here too the device is considered to have a small form factor which is furthermore limited due to dimensions of the outer ear canal (i.e., the nature of the device) and thus it can be followed that a redesign may be unfeasible.

Finally, the applicants suggest that there is a risk swallowing / choking on components by children should removability and replaceability be required for the product group. The risks of swallowing or choking on batteries by children are discussed in section 1.4.2 of this report.

3.6.3. Conclusion and recommendation

The exemption already specified in Article 11(2)(a) for appliances 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, may apply to earbuds if they meet IPX4 (or higher) water-resistance standards in accordance with IEC 60529. Due to the proximity of the product category to the human body, it is conceivable that it is regularly subjected to human sweat (a somewhat saline aqueous solution). However, this is only arguable if the product can be classified as washable or rinseable achieving an IPX rating of 5 or higher.

Although not all applicants mention IPX5 ratings, it is clear they all aim for this classification. Despite this distinction, it is not clear if a derogation based on the exemption for wet environments is possible: it depends on whether the subjection of the devices to bodily fluids and occasionally also to rain splashes would be considered a wet environment. In addition, it may be that some users would rinse their ear pods from time to time to retain hygiene. If the EC aligns with this argumentation, the Commission Notice indicators for assessing the applicability of a derogation for an appliance operating in a wet environment could be considered fulfilled (Commission Notice C/2025/214, 2025), meaning that such earbuds would benefit from the existing BattReg derogation in Article 11(2)(a).

Alternatively, certain aspects of Article 11(4) may also be relevant, such as scientifically-based concerns about user safety from thermal runaway, electric shock, or compliance with product safety requirements under IEC 62368-1:2023. Given the close contact of earbuds with the human body, these safety considerations warrant careful evaluation. Due to the small form factor of earbuds, it can be followed that a redesign would not be feasible due to the small size of the product and its nature which needs to fit in the outer inner ear.

Safety concerns from the risk of children swallowing batteries and other accessible components are not considered valid in this case, given that the devices are not intended for children below the age of 36 months, nor is it

intended for larger children as a toy which is to be placed in the mouth in the course of normal use. Furthermore, were this argumentation valid, it would likely apply to the device as a whole and not be relevant only to the battery.

If ear pods can be considered to benefit from the derogation for appliances operating in a wet environment, Article 11(2)(a) could retain its current wording or be amended as follows to ensure clarity:

- Appliances 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, **provided that the indicators (i-v) specified under Commission Notice C/2025/214 for appliances specifically designed to operate in a wet environment are fulfilled**;

Alternatively, and also in the case of products that achieve an IPX4 rating or lower, a derogation could be added to Article 11(2) for:

- Wireless earphones (earbuds) that meet the criteria for ‘small form factor’.

This derogation could also be merged with a derogation for wearables, provided that one is granted using the following formulation:

- Wearable appliances that meet the criteria for ‘small form factor’ and/or that rely on compact, sealed construction to maintain functional integrity, including protection against water, dust, and shock, and where user access to the battery may compromise the safety, durability, or water resistance of the device.

3.7. Floor washing appliance

3.7.1. Summary of the application

Polti SpA requests a derogation for household electrical appliances intended for floor washing from the requirement that portable batteries be readily removable and replaceable by the end-user (Article 11(1) of Regulation (EU) 2023/1542). Instead, they seek to allow battery replacement only by independent professionals. The product family includes devices with dual-tank systems, rotating brushes, steam generators, and vacuum motors, all designed for use in wet environments with an IPX4 water protection rating. (Polti SpA, 2025)

Polti SpA raise the following main arguments, paraphrased here: (Polti SpA, 2025)

- The appliance is specifically designed for operation in wet environments and is intended to be washable/rinseable.
- It achieves and requires an IPX4 water ingress protection rating for safe and reliable use.
- Allowing end-users to replace the battery could compromise the IPX4 rating, thereby posing a risk to electrical safety.
- Only independent professionals have the expertise to maintain the IPX4 protection during battery replacement, ensuring ongoing user and product safety.
- The company references relevant safety standards (EN 60335-2-10, EN 60335-2-54) and notes that technical documentation (analyses, diagrams, test reports) can be made available upon request to support their claims.
- The application is also motivated by market trends and consumer demand for multi-functional, safe, and reliable cleaning appliances.

3.7.2. Assessment

Article 11(2)

Article 11(2)(b) does not apply as the appliances for which the derogation is sought are not medical devices.

Article 11(2)(a) provides a derogation for 'appliances 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' (Regulation (EU) 2023/1542, 2024). To clarify, if appliance would benefit from this derogation, Commission Notice C/2025/214 specifies 5 indicators to be assessed:

(i) 'specifically': the appliance is designed with the main purpose to operate in the environment described;

(ii) 'primarily': the environment described is the primary environment of the appliance, as Recital 39 explicitly specifies, 'for the majority of the active service of the appliance'. In other words, not just an environment in which the device may only coincidentally or accidentally operate;

(iii) 'washable or rinseable': the appliance is intended to be washable or rinseable;

(iv) (iv) 'compromising safety': there is evidence in the product documentation when placing the product on the market that battery replaceability and removability by end-users would compromise the safety of the user or the appliance;

(v) 'no way to redesign': there is evidence in the product documentation when placing the product on the market that there is no way to redesign the appliance with the current state of the art technology, without severely affecting the health and safety of the end-user or the performance and functionality of the product.

(Commission Notice C/2025/214, 2025)

These indicators are assessed in this case as follows:

- Indicator 1: Designed for operation in wet environments: The floor washing appliances are specifically designed for operation in environments subject to splashing water and wet cleaning. Based on the product description and reference to relevant standards (EN 60335-2-10, EN 60335-2-54), the consultant finds this criterion is met.
- Indicator 2: Intended to be washable or rinseable: The floor washing appliances are intended for continuous rinsing and cleaning with water and/or steam. The operational mode confirms the product is intended to be washable/rinseable.
- Indicator 3: Water ingress protection essential for safety: The applicant states that the IPX4 protection rating is necessary for safe operation in wet environments. The consultant agrees with this view, i.e., IPX4 is a

recognized standard for splash water protection in such appliances and is essential for safety in this context.

- Indicator 4: End-user battery replacement poses a risk as it could compromise the appliance safety: Allowing end-users to replace the battery may compromise the IPX4 rating, potentially resulting in a loss of water resistance and subsequently also a loss of electrical safety. The consultant can follow this argument, as improper resealing or assembly by untrained users is a documented risk for loss of water ingress protection and could lead to electrical hazards.
- Indicator 5: Professional replacement can reliably maintain safety: Only independent professionals have the expertise to maintain the IPX4 protection during battery replacement, ensuring ongoing product and user safety. The consultant concurs that professional servicing is standard practice for maintaining technical safety features in such appliances and can reliably ensure water resistance is maintained.

Seeing as all indicators are fulfilled, the floor washing appliances are considered by the consultant to benefit from the existing derogation listed under Article 11(1).

Article 11(3)

Article 11(3) is not applicable, as the product does not require a continuous power supply for safety, nor is its main function data collection.

Criteria for a derogation in Article 11(4)

Article 11(4) would only be relevant if there were uncertainty regarding the applicability of Article 11(2)(a). In this case, all five indicators are clearly met, and the consultant finds Article 11(2)(a) applicable. The criteria listed in Article 11(4) have thus not been assessed for compliance in this case,

3.7.3. Conclusion and recommendation

Based on the assessment above, the derogation requested by Polti SpA is considered justified by the consultant for the following reasons:

- The product is specifically designed for use in wet environments, is intended to be washable/rinseable, and requires an IPX4 protection rating for safe operation.
- The applicant has credibly argued that end-user battery replacement could compromise water ingress protection and thus electrical safety,

while professional replacement can reliably maintain these safety features.

All five indicators for the applicability of Article 11(2)(a) are met, in line with existing guidance and sector standards. It is therefore, concluded that the existing derogation under Article 11(2)(a) is applicable in this case and thus that a new derogation would not be needed for this product category.

3.8. Xiaomi: Outdoor Smart Surveillance Equipment

3.8.1. Summary of the application

The application concerns Outdoor Smart Surveillance Equipment, such as smart cameras and doorbells (Xiaomi Communications Co., Ltd., 2025). The applicant added the following particular product examples for the umbrella term used in the title:

> Outdoor Smart Camera: The outdoor smart camera is designed for outdoor use in the first place, mainly for the round-the-clock monitoring of the environment around the home. With its high-definition picture quality and infrared night vision capabilities, it can clearly capture outdoor activities, such as people walking around and vehicles entering and leaving, both during the day and at night. Once it detects any abnormal situation, it will immediately send an alarm to the user. The stored video materials can be reviewed, which safeguards the safety of family property and enables users to keep abreast of the situation outside their homes at all times.
>
> Smart Doorbell: The smart doorbell was originally designed for outdoor use, mainly for the management of visitors at the door and security protection. When someone rings the doorbell, the device will quickly send a notification to the user's mobile phone. The user can then view the situation in front of the door in real time through the mobile phone and communicate with the visitor using the two-way voice function. Its built-in camera can capture and store the images in front of the door, identify the characteristics of the visitors, effectively prevent potential risks, and provide comprehensive protection for home security.
>
> (Xiaomi Communications Co., Ltd., personal communication, 4 November 2025a)

These products are generally designed for outdoor use and offer functions such as video recording, remote viewing, night vision and clear audio communication, with features like noise reduction. These devices are built to be dust- and water-resistant (IP67 rating). They typically contain built-in rechargeable lithium batteries (not specified in more detail by the applicant) that last up to six months

per charge. The battery must retain at least 80% of its capacity after 600 charge cycles. (Xiaomi Communications Co., Ltd., 2025)

The applicant asserts that replacing the battery improperly may damage the device, shortening its lifespan and reducing its durability and reliability. It can also pose health and environmental risks, such as battery leakage, fire or the creation of more electronic waste. User errors during battery replacement may compromise the device's sealing, dustproofing and waterproofing, as well as its functionality, particularly in outdoor conditions. This can lead to interruptions in surveillance and pose safety risks. Furthermore, making batteries user-replaceable can increase manufacturing costs and lower product performance, as well as raising lifecycle costs due to premature failures. (Xiaomi Communications Co., Ltd., 2025)

A proposed exemption to Article 11(2) suggests that, due to their high waterproof rating and challenging operating environments, the batteries in such equipment should only need to be removable and replaceable by professionals, not end users. The applicant justifies this by arguing that allowing users to replace the batteries could compromise the device's high level of water resistance rating IP67 and thus negatively affect its durability after battery replacement. (Xiaomi Communications Co., Ltd., 2025)

Figure 3-2 – Outdoor Smart Camera (left) and Smart Doorbell (right)

Source: https://www.mi.com/global/product/xiaomi-outdoor-camera-bw500/ and https://www.mi.com/global/product/xiaomi-smart-doorbell-3s/ (both links provided by the applicant in (Xiaomi Communications Co., Ltd., personal communication, 4 November 2025a)

3.8.2. Assessment

Article 11(2)

Although Article 11(2)(a) is referred to by the applicant, the devices do not fulfil all the assessment criteria. The outdoor smart surveillance equipment is specifically designed to operate primarily in environments that can be regularly subject to splashing water, streams of water or immersion in water, and that are intended to be washable or rinsible. During the intended use of the devices, exposure to splashing water (rain) cannot be ruled out. Therefore, the devices are designed with an Ingress Protection IP67 rating, which provides protection against dust and water intrusion (the second digit, 7, specifies water resistance up to one metre deep for up to 30 minutes).

However, recital (39) of the BattReg specifies that 'this derogation should only apply when it is not possible, by way of redesign of the appliance, to ensure the safety of the end-user and the safe continued use of the appliance after the end-user has correctly followed the instructions to remove and replace the battery. Commission Notice C/2025/214 (Commission Notice C/2025/214, 2025) outlines the following four indicators. These are then assessed to determine whether they apply for Outdoor Smart Surveillance Equipment:

(i) 'specifically': the appliance is designed with the main purpose to operate in the environment described:
- this **criterion applies** to the Outdoor Smart Surveillance Equipment as the intended use of the devices is outdoors.

(ii) 'primarily': the environment described is the primary environment of the appliance, as Recital 39 explicitly specifies, 'for the majority of the active service of the appliance':
- this **criterion applies** to the Outdoor Smart Surveillance Equipment as the devices are likely to be exposed repeatedly (although not continuously) to rain and mist during their intended use.

(iii) 'washable or rinseable': the appliance is intended to be washable or rinseable;
- this **criterion does not apply** to the Outdoor Smart Surveillance Equipment even though, given the IP67 rating, the end-users may expose the devices to water for cleaning. However, this is not the intended use and cleaning can be done without splashing water.

(iv) 'compromising safety': there is evidence in the product documentation when placing the product on the market

that battery replaceability and removability by end-users would compromise the safety of the user or the appliance:
- this **criterion applie**s because, in their application, the applicant asserts that allowing end users to replace the battery poses a safety risk to them. The applicant specifies several risks associated with untrained battery replacement:

- Accidental short-circuiting during improper handling may result in overheating, fire, or even battery explosion.
- Additional hazards arise if incompatible battery types are used or if the battery is misaligned, which can lead to similar dangerous outcomes.
- Furthermore, there is a risk that untrained end users may make errors when reassembling the device, such as misaligning the sealing, thereby compromising the device's IP67 protection.

(i) 'no way to redesign': there is evidence in the product documentation when placing the product on the market that there is no way to redesign the appliance with the current state of the art technology, without severely affecting the health and safety of the end-user or the performance and functionality of the product.
- this **criterion does not apply** to the Outdoor Smart Surveillance Equipment as the applicant has failed to provide scientifically grounded evidence that it is not possible to redesign the devices to avoid the aforementioned safety risks. Standards EN IEC 60335-1:2023 and EN IEC 60730-1:2024 outline design options that could enhance the safety of end users when replacing the internal battery. One suitable redesign solution would be to include additional barriers, interlocks, and insulation to isolate high-voltage components from the user-accessible battery compartment. As for the risk of end users accidentally causing electrical shorts when replacing the battery, adequate design solutions are available to prevent this. These include using non-reversible connectors that only allow the battery to be inserted in one orientation, and physical guides or rails that ensure the battery can only be inserted in one position. Furthermore, providing users with a manual containing adequate safety warnings and technical instructions for replacing the battery would mitigate the aforementioned safety risks, such as electric short-circuiting and the insertion of incompatible battery types. However, the applicant has not

explained why these solutions would not be applicable to the products in question.

(Commission Notice C/2025/214, 2025)

Article 11(2)b is not applicable as the Outdoor Smart Surveillance Equipment is not a medical device.

Article 11(3)

The applicant makes no mention of the outdoor smart surveillance equipment relying on an uninterrupted power supply via an internal buffer battery to ensure data safety and integrity in the sense of Article 11(3). Therefore, **Article 11(3) does not apply**.

Criteria for a derogation in Article 11(4)

Safety of end-users removing the battery

The applicant states that accidental short-circuiting during improper handling may result in overheating, fire, or even battery explosion. Additional hazards arise if incompatible battery types are used or if the battery is misaligned, which can lead to similar dangerous outcomes.

The applicant's arguments **do not fulfil** the conditions for a derogation relating to the battery or device enclosure are expected to pose a safety risk to end users, provided that the aforementioned standards are observed, and technical design solutions are adopted to minimise the risk of electric circuits during battery replacement. Additionally, the applicant can supply technical and safety instructions to guide end users in safely replacing the battery.

Product safety requirements

The applicant also raises additional product safety concerns, specifically noting that IP67-rated devices could lose their dust and water resistance if batteries are replaced by untrained end users. This loss of protection could allow water ingress, potentially reducing the product's lifespan and creating safety hazards due to moisture-induced internal short circuits.

These arguments **do not justify a derogation** either, since technical design solutions could be adopted to ensure that the product enclosure is unlikely to be damaged during battery replacement. This would minimise the risk of electric circuits after the battery has been replaced. Options to prevent misalignment of seals include recessed sealing and locking mechanisms that require minimal

effort to disassemble and reassemble the battery enclosure. Additionally, the applicant can supply technical and safety instructions to guide end users in safely replacing the battery.

Additional arguments pertaining to safety

The applicant mentions no further aspects relating to safety.

3.8.3. Conclusion and recommendation

The derogation request does not apply to the stipulations of Article 11(2). While the Outdoor Smart Surveillance Equipment is not a medical device, the products are designed and IP-rated for wet environments (intended outdoor use). However, the user safety issues raised by the applicant can be mitigated by redesigning the devices and including technical and safety instructions for battery replacement in the user manuals. Therefore, it is recommended that a derogation not be granted.

4. Assessment of applications for products where a continuity of power supply is necessary

Article 11(3) of the Batteries Regulation specifies that

> the obligations laid down in paragraph 1 shall not apply where continuity of power supply is necessary and a permanent connection between the product and the respective portable battery is required to ensure the safety of the user and the appliance or, for products that collect and supply data as their main function, for data integrity reasons. (Regulation (EU) 2023/1542, 2024)

This chapter details the numerous applications for which derogations have been requested and assessed in relation to the applicability of the derogation listed under Article 11(3).

4.1. eCall system (vehicle)

4.1.1. Summary of the application

ACEA (2025) applied for a derogation for eCall systems in vehicles. eCall is an assistance system for motor vehicles used throughout the EU that automatically makes a free emergency call to the emergency number 112 when a vehicle is involved in a serious accident. eCall can also be activated manually by pressing a button. When eCall is activated, the system establishes a connection to the nearest emergency call centre, both by telephone and data. This allows the emergency call centre to be contacted while a minimum set of data is automatically transmitted (exact location, time of accident, vehicle registration number and direction of travel). This enables the emergency services to assess the situation more quickly and respond accordingly. eCall is mandatory for vehicle models approved for production after 31 March 2018 and applies to vehicles with up to 8 seats and light commercial vehicles. The requirements for eCall are laid down in Regulation (EU) 2015/758 from 2015 ([22]). (European Automobile Manufacturers' Association (ACEA), 2025)

[22] REGULATION (EU) 2015/758 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2015 concerning type-approval requirements for the deployment of the eCall in-vehicle system based on the 112 service and amending Directive 2007/46/EC

According to the applicant, the provisions of Article 11(3) (continuity of power supply) apply to this application. The applicant declares that replacement of the batteries in the eCall control unit by customers themselves would lead to critical risks and significantly increase the likelihood of the eCall system failing. For example, plastic mountings could break, exposing the electronic circuit board (PCB). In addition, contaminants could enter the battery connection, which could lead to short circuits or damage to the device. The applicant attaches images of the technical functional elements to substantiate these arguments. (European Automobile Manufacturers' Association (ACEA), 2025)

4.1.2. Assessment

Article 11(3)

ECall systems require a continuous power supply, as a permanent connection between the product and the respective battery is necessary to ensure the main function of the system and thus the safety of vehicle occupants in the event of a serious accident. This is also evident from the detailed technical requirements and test procedures for EC type-approval of motor vehicles with regard to their 112-based eCall vehicle systems ([23]). According to these requirements, the eCall system must remain functional even after a serious accident, i.e. even if the vehicle's electrical system has failed (or been automatically switched off), the system must be able to perform its function using its own battery.

4.1.3. Conclusion and recommendation

The arguments put forward by the applicant are comprehensive. In the event of a malfunction due to improper battery replacement, there is a risk that the eCall system will not work, which would pose a safety risk to users (in this case, vehicle occupants in the event of a serious accident). The applicant demonstrates that the Union's safety requirements would not be met if the battery were removed and replaced by a person who is not professionally qualified to do so. In this respect, the exemption provided for in Article 11(3) applies.

[23] COMMISSION DELEGATED REGULATION (EU) 2017/79 of 12 September 2016 establishing detailed technical requirements and test procedures for the EC type-approval of motor vehicles with respect to their 112-based eCall in-vehicles systems, of 112-based eCall in-vehicle separate technical units and components and supplementing and amending Regulation (EU) 2015/758 of the European Parliament and of the Council with regard to the exemptions and applicable standards

4.2. Tyre Pressure Monitoring System (vehicle)

4.2.1. Summary of the application

TPMS sensors continuously measure the air pressure in the tyres while driving. Their task is to warn the driver acoustically and visually when the pressure falls below a safe limit. Insufficient air pressure not only leads to higher friction and greater wear, but the heat generated can also cause the tyre to fail, with the risk of serious accidents. In the EU, new cars must be equipped with a tyre pressure monitoring system since 1 November 2014 ([24]).

According to the applicant ACEA, the sensors of the monitoring system are attached to the valve on the inside of the rims. In order to comply with legal requirements, tyre pressure must be continuously monitored, which means that the sensors must remain functional at all times. To ensure functionality, the battery status is also constantly monitored and the expected remaining life is calculated and displayed to the driver. According to ACEA, the battery replacement itself should be planned in accordance with the instructions in the maintenance manual. (European Automobile Manufacturers' Association (ACEA), 2025)

Another association puts forward similar argumentation to that of ACEA.

ACEM, the association for European Motorcycle Manufacturers also applies for a derogation for TPMS used in L-vehicles and refers to the same arguments. (ACEM - Association des Constructeurs Européens de Motocycles, 2025)

4.2.2. Assessment

Article 11(3)

The specific technical requirements for tyre pressure monitoring systems (TPMS) are set out in Regulation UN No. 141 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of vehicles with regard to their tyre pressure monitoring systems (UN ECE 141 (TPMS) [2018/1593], 2018). Article 5 contains the technical requirements, Annex 3 the test requirements for Tyre Pressure Monitoring

[24] REGULATION (EC) No 661/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefore.

Systems (TPMS). These requirements presuppose that a continuous power supply is guaranteed.

Regardless of this, the sensor's battery is obviously installed in such a way that it cannot be replaced at all. To our knowledge, the entire sensor, including the battery, is housed in a casing that is sealed with a type of casting resin to protect it from rain, dust, moisture and mechanical stress. We therefore assume that the system's sensor will in any case be disposed of as electronic waste together with the battery, which means that the battery will not be removed.

4.2.3. Conclusion and recommendation

The arguments put forward by the applicants are understandable in the context of the legal requirements cited above. The functionality of the TPMS requires a continuous power supply; in the event of a malfunction, there is a risk that the TPMS will not work, which would pose a safety risk to users (in this case, drivers and vehicle occupants) in an accident due to insufficient tyre pressure. In this respect, the exemption provided for in Article 11(3) applies.

4.3. Anti-theft alarm system (vehicle)

4.3.1. Summary of the application

In general, 'Anti-theft alarm systems' or more precisely 'vehicle alarm systems (VAS)' are understood to be systems that indicate break-ins or tampering with the vehicle by means of acoustic signals and, optionally, light signals. Furthermore, these systems can offer additional protection against unauthorised use of the vehicle, for example by means of an immobiliser.

Unlike the eCall and TPMS systems described above, there is currently no legal requirement for vehicles to be equipped with a VAS. However, if vehicles are equipped with a VAS, it must comply with the requirements of UN Regulation No. 163 ([25]).

ACEA, applies for a derogation and argues that the systems fall under the exemption in Article 11 (4) (Violation of existing product safety requirements) stating: 'If the system were designed to allow disassembly by the customer, its anti-theft effectiveness could be compromised, as the alarm could potentially be disabled by removing the battery.' ACEA also refers to sections 5.6 and 10.5 of UN Regulation No. 163. (European Automobile Manufacturers' Association (ACEA), 2025)

ACEM, the association for European Motorcycle Manufacturers, also applies for a derogation for batteries used in alarm systems of L-vehicles. Though the application explains briefly that the systems are subjected to extreme environmental conditions and need to be designed to ensure that manipulation of the system is easily identifiable, it does not put forward information to suggest that battery replacement would be in violation of safety requirements or that it would create a safety risk for the user. (ACEM - Association des Constructeurs Européens de Motocycles, 2025)

Another association referred to a system with the same functionality as a 'self-powered siren' and emphasises as justification for a derogation that a continuous power supply is necessary to ensure functionality. It further explains that, for safety reasons, the device is designed in such a way that the battery cannot be replaced by the end user, but only by a professional mechanic who removes and reinstalls the entire device. Replacing only the batteries would destroy the device, rendering it inoperable. Therefore, the entire device must be replaced.

[25] UN Regulation No 163 – Uniform provisions concerning the approval of vehicle alarm system and approval of a vehicle with regard to its vehicle alarm system [2021/2276]

4.3.2. Assessment

Article 11(4)

In general, UN Regulation No. 163 sets out basic provisions on the scope of application and terminology in Part I, requirements for the approval of vehicle alarm systems, and in Part II, requirements for the approval of a vehicle with regard to its alarm system.

According to Article 5.6. (Part I), the VAS, its components and the parts affected by them must be designed and installed in such a way that it is as difficult as possible to disable them or destroy them quickly and without attracting attention, e.g. with the aid of inexpensive, easily concealable tools, devices or objects that are widely available. Similarly, Article 10.5 (Part II) also stipulates that the alarm system, its components and the parts affected by them must be installed in such a way that it is as difficult as possible to disable or destroy them quickly and without attracting attention, e.g. with the aid of inexpensive, easily concealable tools, devices or objects that are widely available.

The opening clause in Article 11(4) presupposes that there are scientifically substantiated concerns regarding the safety of the removal or replacement of the portable battery by end users, or that there is a risk that the removal or replacement of the battery by end users may violate product safety requirements specified under applicable Union law. In the present case of the VAS, however, neither the arguments in the application nor the requirements of UN 163 indicate that there are scientifically substantiated concerns regarding the safety of the removal or replacement of the portable battery by end users or that there is a risk that the removal or replacement of the battery by end users may violate product safety requirements under applicable Union law.

From the special requirements set out in Article 6.1.1 of UN No. 163, it can be concluded that vehicles equipped with a VAS must be equipped with various sensors (opening of a vehicle door, bonnet and boot must be detected and indicated) or can be equipped with such sensors (monitoring of the interior and glazed area, tilt sensor to register unauthorised movement of the vehicle). Furthermore, it is clear from the requirements that this functionality requires a continuous power supply that is independent of the vehicle battery. In this respect, we believe that VAS would be classified as a derogation under Article 11 (3).

4.3.3. Conclusion and recommendation

In the VAS case discussed here, the arguments put forward by applicants ACEA and ACEM cannot be accepted. Although the functionality of the system

could indeed be impaired by improper replacement of the battery, in our view this does not constitute a violation of the existing product safety requirements under UN Regulation 163. Instead, a derogation under Article 11(3) could be applicable to VAS, as suggested by the third associations comments mentioned in the summary (see section 4.3.1).

4.4. Battery Temperature Warning System (with integrated battery) (vehicle)

4.4.1. Summary of the application

A battery temperature warning system continuously monitors the temperature of the vehicle battery. It warns the driver if the battery overheats. This is intended to prevent dangerous situations such as thermal failure of the battery or vehicle fires. Unlike the eCall system and the tyre pressure monitoring system discussed above, equipping vehicles with this warning system is not required by law.

4.4.2. Assessment

ACEA, the applicant, argues that the system falls under the exemption specified under Article 11(3) (continuity of power supply) on the grounds that replacing the battery by the end user could result in damage to the wiring or loss of contact in the cables. Any error occurring during replacement by the user could lead to a life-threatening situation before the functionality of the system has been properly checked, especially since the battery indicates that the alarm box can be supplied with 24 V without any problems. Furthermore, it cannot be guaranteed that the alarm box will be properly resealed with the prescribed torque. Finally, after installation, the alarm box must be tested and checked by an authorised service technician. (European Automobile Manufacturers' Association (ACEA), 2025)

These arguments are entirely understandable from a technical point of view, but there is neither a legal regulation nor a technical standard that bindingly specifies the requirements for battery temperature warning systems.

4.4.3. Conclusion and recommendation

Even though there are no legal regulations or technical standards specifying the requirements for battery temperature warning systems, the applicant's argument that continuity of power supply is essential for ensuring the warning function and that this would be covered by the exemption specified under Article 11(3) is justified and can be accepted.

4.5. Electronic control units (ECUs) (vehicle)

In addition to the systems in the automotive sector discussed so far, ACEA has submitted a collective application for electronic control units (ECUs) as a whole. We understand the explicitly mentioned applications ([26]) to be merely examples. The application is understood by the consultants as a claim that ECUs should generally be exempted from the requirements of the Battery Regulation on the basis of Articles 11(3) and 11(4). (European Automobile Manufacturers' Association (ACEA), 2025)

Even if ACEA's argumentation is entirely valid for the applications mentioned as examples, we do not believe that a general exemption for an entire product group can be claimed in this case, as the requirements vary considerably from application to application and must be assessed on a case-by-case basis.

For example, in some cases, ACEA mentions legislation that requires integrating certain systems into the vehicle. However, it is not explained if and why battery replacement would be non-compliant with such legislation nor whether this could comprise a safety risk to the user (e.g. warning devices, event data recorders). Other cases are explained to be covered by Article 11(3) of the BattReg (e.g. on-board computers).

Though ACEA provides argumentation for a few examples, the list is furthermore understood to not be exhaustive, so that it can not be ensured whether all cases would be justified.

Sections 4.6 to 4.10 assess the individual cases presented in the document following a case-by-case approach.

4.6. ISA speed intelligent box (vehicle)

4.6.1. Summary of the application

From July 2024, all newly registered vehicle models must be equipped with the Intelligent Speed Assistance (ISA) system. This system is designed to ensure that drivers comply with speed limits, thereby improving road safety and reducing the number of accidents and fatalities.

[26] Intelligent speed assistance map unit, on-board computers and devices integrated into cockpits, event data recorder, warning devices, and tachographs.

Technically speaking, the ISA speed assistant recognises the applicable speed limit either using a video camera that reads traffic signs and/or using GPS data from digital road maps. If the driver exceeds the prescribed speed limit, the system emits an acoustic/visual warning or actively intervenes. There are currently three different feedback methods for informing the driver about a speed limit and/or if the limit is exceeded; the choice of feedback method is left to the manufacturers:

- Method 1 'Open ISA': Here, only a visual or acoustic warning is given, i.e. the driver decides for themselves how to proceed.
- Method 2 'Semi-open ISA': The ISA system increases the resistance of the accelerator pedal to inform the driver about the speed limit.
- Method 3 'Closed ISA': If the speed is exceeded, ISA automatically reduces engine power by gently throttling and brakes the vehicle to the applicable speed limit.
- ('Intelligent Speed Adaptation (ISA)', n.d)

In its application, ACEA states that the Intelligent Speed Assistance (ISA) card provides map information in accordance with Regulation (EU) 2021/1958. The device requires a continuous battery supply to store its internal data when the vehicle's ignition is switched off and on again. It is located in the cockpit module and is generally not intended to be replaced by the vehicle user. Attempting to remove or replace the battery could damage the wiring harnesses that are part of the cockpit equipment and/or the battery connection itself. Improper replacement also carries the risk of malfunction, which may result in non-compliance with legal requirements. (European Automobile Manufacturers' Association (ACEA), 2025)

A company also in support of this derogation argues that the replacement of the battery by the end-user may cause several risks which are in violation of the GSR safety requirements.

4.6.2. Assessment

Both applicants argue that ISA complies with legal safety requirements. ACEA also describes the need for an independent power supply for reasons of data integrity. Both lines of argument can be derived from the legal requirements for ISA described above.

4.6.3. Conclusion and recommendation

The arguments put forward by the applicants are comprehensive. In the event of a malfunction due to improper battery replacement, there is a risk that the

ISA system will not work, which would pose a safety risk to users. The applicant demonstrates that the Union's safety requirements would not be met if the battery were removed and replaced by a person who is not professionally qualified to do so. In this respect, the exemption provided for in Article 11(3) applies.

Nevertheless, one must bear in mind that the ISA system only has to recognise 90% of the speed limits indicated by traffic signs. Furthermore, drivers are legally permitted to bypass or switch off the system and, in legal disputes to date, the courts (in Germany) have ruled that drivers cannot rely on the ISA system but are themselves responsible for complying with speed limits at all times.

4.7. Tachographs (vehicle)

4.7.1. Summary of the application

Tachographs ensure compliance with the rules on driving and rest periods in accordance with Regulation (EU) 2016/799. These devices record driving times, rest periods and vehicle speed. They are designed to contribute to the safety of drivers and road users by preventing driver fatigue.

Member States are responsible for authorising, regularly checking and certifying the bodies authorised to install, check, inspect and repair tachographs. These certified bodies ensure that tachographs are properly installed and maintained in order to comply with legal standards. In addition to the initial installation, the tachograph is subject to regular inspections by these certified bodies. These inspections ensure, among other things, that the seals on the tachograph are correctly affixed and in good condition so that the device remains tamper-proof and fully functional.

4.7.2. Assessment

This application is part of a collective application submitted by ACEA for ECU. ECUs with built-in batteries are crucial for the safety of both the user and the vehicle. According to ACEA the applications are also subject to existing product safety requirements at UN and EU level and should therefore be exempted from the replaceability requirements. (European Automobile Manufacturers' Association (ACEA), 2025)

The specific requirements for tachographs under Regulation (EU) 2016/799 are extremely extensive and cover more than 500 pages. This makes it difficult to provide a comprehensive and exhaustive evaluation within the scope of this study. For the purposes of the assessment, therefore, the regulated aspects that are particularly relevant in view of the exceptions in Article 11 have been selected. Essentially, tachographs must record and store a large number of driving parameters, which must be independent of the main battery power supply and must be stored in a tamper-proof manner. In this respect, the conditions set out in Article 11(3) apply in any case.

4.7.3. Conclusion and recommendation

The arguments put forward by the applicant are comprehensive. In the event of a malfunction due to improper battery replacement, there is a risk that the tachographs will not work reliably, which would pose a safety risk to users (in

this case, to the safety of drivers and other road users). The applicant demonstrates that the Union's safety requirements would not be met if the battery were removed and replaced by a person who is not professionally qualified to do so. In this respect, the exemption provided for in Article 11(3) applies.

4.8. Warning devices (vehicle)

4.8.1. Summary of the application

Warning devices are important safety features in vehicles designed to help prevent or minimise injuries or damage in the event of a fire or other dangerous situations. UN Regulation No. 107 ([27]) relates to vehicles of category M_2 or M_3 (i.e. vehicles for passenger transport, such as buses and coaches) and stipulates that vehicles must be equipped with suitable warning devices that can detect smoke and fire hazards and alert occupants to ensure safety in emergencies. These warning systems are designed to meet strict performance criteria and function reliably under various conditions.

4.8.2. Assessment

This application is part of a collective application submitted by ACEA for ECU. According to ACEA, ECUs with built-in batteries are generally crucial for the safety of both the user and the vehicle. They are also subject to existing product safety requirements at UN and EU level and should therefore be exempted from the replaceability requirements. (European Automobile Manufacturers' Association (ACEA), 2025)

UN Regulation No. 107, designated by ACEA for this application, contains very different requirements for vehicles in categories M2 and M3 (e.g. regarding seats, distances between seats, the design of steps in double-decker buses, etc.), without any direct reference to batteries or the removal and replacement of batteries. It is possible that ACEA's application refers to the specific requirements for protection against fire hazards (Article 7.5.). For example, in vehicles where the engine is located behind the driver's compartment, the driver's compartment must be equipped with an alarm system that alerts the driver about overheating in the engine compartment and in each individual compartment containing an internal combustion heater by means of both an audible and a visual signal. The alarm system must be designed to detect a temperature exceeding the normal operating temperature in the engine compartment and in each individual compartment in which a combustion heater is located. Finally, the alarm system must be operational from the moment the engine start device is activated until the engine stop device is activated,

[27] Regulation No 107 of the Economic Commission for Europe of the United Nations (UNECE) — Uniform provisions concerning the approval of category M2 or M3 vehicles with regard to their general construction [2015/922]

regardless of the position of the vehicle. However, it is not clear to what extent these requirements affect the possibility of removing and replacing batteries.

4.8.3. Conclusion and recommendation

Based on the arguments put forward by the applicant and the specific requirements of UN Regulation No. 107 for warning systems, the consultants see no connection with the issue of removability and interchangeability with batteries. It is therefore not possible to classify the application under the opening clauses of Article 11.

4.9. Event Data Recorder (EDR) (vehicle)

4.9.1. Summary of the application

According to the definition in UN Regulation No. 160, an event data recorder (EDR) is a device or function in a vehicle that records the vehicle's dynamic time series data during the period immediately preceding an event (e.g. vehicle speed in relation to time) or during an accident (e.g. delta-V versus time) for retrieval after the accident. Event data recorders are therefore important components of vehicles for recording and storing data on vehicle operation, especially in the event of significant events such as accidents. The systems are designed to provide data that can be used for analysis and investigation after a collision or other critical events to ensure transparency and support safety improvements.

This application is part of a collective application submitted by ACEA for ECU. ECUs with built-in batteries are crucial for the safety of both the user and the vehicle. According to ACEA they are also subject to existing product safety requirements at the UN and EU level and should therefore be exempted from the replaceability requirements. (European Automobile Manufacturers' Association (ACEA), 2025)

4.9.2. Assessment

The applicant emphasises that compliance with type approval requirements, in particular in accordance with UN Regulation No. 160 and GSR II, is essential. These regulations stipulate that vehicles must be equipped with an EDR capable of recording and storing data related to accidents even after an accident has occurred. The recorded data may include critical parameters such as vehicle speed, braking, steering movements and the severity of the accident. (European Automobile Manufacturers' Association (ACEA), 2025)

By ensuring data recording during these events, the EDR contributes to both vehicle safety and regulatory compliance by providing important information that can be used to understand the circumstances of the accident.

4.9.3. Conclusion and recommendation

The arguments put forward by the applicant are comprehensive. In the event of a malfunction due to improper battery replacement, there is a risk that the EDR will not work reliably, which would pose a safety risk to users. The applicant demonstrates that the Union's safety requirements would not be met if the

battery were removed and replaced by a person who is not professionally qualified to do so. In this respect, the exemption provided for in Article 11 (3) applies.

4.10. On-board computers and devices integrated in cockpits (vehicle)

4.10.1. Summary of the application

On-board computers are generally considered important components for the overall operation and safety of vehicles. They are responsible for processing data from various systems and ensuring important vehicle functions. One relevant function is to ensure the visibility of warning lights in the instrument cluster so that safety indicators are clearly displayed to the driver in the event of a malfunction or danger.

The on-board computer unit (ICUC) is powered by the vehicle battery, with the real-time clock (RTC) continuously supplied with voltage to ensure accurate time measurement even when the ignition is switched off (in vehicles with combustion engines). This ensures that time-critical processes such as logging and diagnostics are always up to date. An important aspect is the possible isolation of the system due to environmental factors such as moisture and dust accumulation, as these factors could interfere with the internal circuits and potentially lead to malfunctions or failures. Proper sealing and protection of the unit are essential, in the applicant's view, to ensure reliable operation under various environmental conditions. (European Automobile Manufacturers' Association (ACEA), 2025)

This application is also part of a collective application submitted by ACEA for ECU. ECUs with built-in batteries are crucial for the safety of both the user and the vehicle. According to ACEA they are also subject to existing product safety requirements at UN and EU level and should therefore be exempted from the replaceability requirements. (European Automobile Manufacturers' Association (ACEA), 2025)

4.10.2. Assessment

ACEA, as the applicant, points out that an important function of on-board computers is to ensure the visibility of warning lights in the instrument cluster in accordance with UN Regulation No 121, so that safety indicators are clearly displayed to the driver in the event of a malfunction or danger. (European Automobile Manufacturers' Association (ACEA), 2025)

Generally, UN Regulation No. 121 applies to vehicles of categories M and N (1). It specifies requirements for the location, identification, colour and illumination of motor vehicle hand controls, tell-tales and indicators. It is designed to ensure

the accessibility and visibility of vehicle controls, tell-tales and indicators, and to facilitate their selection under daylight and night-time conditions, in order to reduce the safety hazards caused by the diversion of the driver's attention from the driving task and by mistakes in selecting controls.

None of these extensive requirements appear to be related to the issue of battery interchangeability or to the extent to which battery replacement can constitute compliance with the requirements of the regulation.

4.10.3. Conclusion and recommendation

Based on the arguments put forward by the applicant and the specific requirements of UN Regulation No. 121 with regard to the visibility of warning lights in the instrument cluster, the consultants see no connection with the issue of removability and interchangeability with batteries. It is therefore not possible to classify the application under the opening clauses of Article 11 of the Batteries Regulation.

4.11. Quantum Key Distribution (QKD) System

4.11.1. Summary of the application

Quantum Key Distribution (QKD) applies quantum effects to allow two remote parties to agree on a secret key via an insecure telecommunications channel. It is a proposed solution for quantum-safe key agreement and comprises protocols that exploit quantum-physical phenomena for secure key agreement. In a QKD protocol, quantum states are exchanged or distributed and measured by the remote parties. After post-processing, a secret key is derived from the measurements. This allows the remote parties to detect a third-party eavesdropper by comparing parts of the measurement results, as the quantum state will change if there is any non-trivial interaction with it. (ANSSI et al., n.s)

This technology is under development, as large-scale fault-tolerant quantum computers are expected to become available in the future and will be able to decipher most of the public-key cryptography that digital infrastructure is currently based on. The applicant states that

> The theoretical security of QKD protocols is based on quantum-physical principles, whereas post-quantum and classically secure public-key cryptography are based on the assumed hardness of certain mathematical problems. This implies that, at least in theory, QKD protocols are secure even against computationally unbounded attackers or in the event of future algorithmic breakthrough. (ANSSI et al., n.s)

Using QKD requires specialised hardware such as single-photon sources and detectors to transmit quantum states via fibre-optic cables. (ANSSI et al., n.s)

In some QKD systems, time synchronization is used to allow the remote users to assign an absolute timestamp to every detection and to reconstruct time-correlated events. In such systems a real-time clock (RTC) will be used on either end, and allows exactly correlated events between the two remote users to be identified. (Pelet et al., 2025)

A manufacturer of similar systems requested a derogation from Article 11(1), explaining that to power the RTC on which the synchronisation process relies, an internal battery is used as a buffer to power the RTC in case of a power failure. The battery is thus critical to allow storing important system data such as the date and time and various hardware configurations. This allows the system to restart after a power shortage while ensuring the proper system function. The

battery is intended to only be replaced by authorised service support teams and cannot be replaced by an amateur.

The RTC serves the following functions: The timestamp detects the correct time intervals for transmitting the quantum key at extremely high speeds and synchronises the sender and receiver. Accurate timing reduces errors and ensures data integrity, as only photons arriving within the expected time slots are considered valid, thereby reducing false positives caused by background noise or stray photons. Furthermore, a synchronised real-time clock contributes to the security of the key exchange, as it is necessary for detecting eavesdropping attempts, which often introduce timing discrepancies. For this reason, the QKD system can be considered a product whose main function is to collect and supply data for reasons of data integrity.

4.11.2. Assessment

As the applicant has requested to keep the application confidential, the documentation of the assessment in the public report only includes the part critical to derogating this product from Article 11(1).

Article 11(2)

Text removed due to confidentiality.

Article 11(3)

According to the stipulation of Article 11(3), the requirement to design a product in such a way that batteries are readily removable and replaceable by the end-user (Article 11(1)) do not apply for products that require continuity of power supply in form of a permanent connection between the product and the portable battery for data integrity reasons. In this case, no derogation according to Article 11(4) is needed nor can such a derogation be granted by the Commission.

The same situation applies to the QKD system. Continuity of the power supply is necessary for reasons of data integrity, which the applicant refers to as 'safety' (in the sense of data safety rather than end-user safety).

Hence, it can be concluded that the QKD system is exempted from the stipulation of Article 11(1) and does not require a derogation. To that end, the applicant's request for a derogation is superfluous.

Criteria for a derogation in Article 11(4)

Text removed due to confidentiality.

4.11.3. Conclusion and recommendation

The QKD system is exempted from terms under BattReg Article 11(1) and does not require a derogation because it requires continuity of power supply using a permanent connection between the product and the portable battery for data integrity reasons. For this reason, the applicant's request for a new derogation is unnecessary. However, the product benefits from Article 11(3), which provides an exemption for products requiring a continuous power supply for reasons of data integrity.

4.12. Request on temperature sensor: ‘AiroSensor’

4.12.1. Summary of the application

The SenseAnywhere® AiroSensor is a wireless data logger used for monitoring temperature and humidity in use cases where continuous data collection is important, such as storage and transport of temperature-sensitive goods. It is suitable for applications like refrigerated transport, storage containers, warehouses and incubators. The device is designed to operate without maintenance for its full lifetime, providing uninterrupted data logging that supports compliance with regulatory requirements (SenseAnywhere® B.V., personal communication, 4 November 2025; SenseAnywhere B.V., 2025).

The AiroSensor data logger continuously records temperature and humidity and intermittently transmits the data wirelessly to an access point that is connected to the Internet. The communication between AiroSensor and the access point works at radiofrequencies (RF) of 868 MHz or 915 MHz. For this purpose, the device features an RF antenna that is powered by its internal primary (i.e. non rechargeable) battery, which is engineered to last for at least ten years or approximately one million messages without replacement. This long battery life is made possible by an energy-efficient protocol, hardware design, and firmware architecture that together minimise power consumption. (SenseAnywhere® B.V., personal communication, 4 November 2025, personal communication, 4 November 2025)

The AiroSensor is housed in a sealed plastic casing designed for durability and ease of cleaning (Figure 4-1). The device is suitable for use in damp (though not humid) environments, such as food containers. It has an IP67 rating, which indicates enhanced protection against moisture and dust ingress (SenseAnywhere® B.V., n.d.)

The AiroSensor is designed to function reliably for ten years without any battery replacement. The battery is intentionally not user-replaceable, enabling a long-term, maintenance-free ‘set-and-forget’ operating model. This is a deliberate design choice and a central differentiator of the AiroSensor compared to traditional data loggers that require periodic servicing and battery changes. (SenseAnywhere® B.V., personal communication, 4 November 2025)

According to SenseAnywhere B.V., a lifespan of at least ten years offers several advantages for professional users:

- Significantly lower total cost of ownership, as no replacement parts, labour, service visits, or downtime are required

- Operational continuity, because the device does not need to be retrieved, opened, or re-installed during its lifetime
- Greater data integrity, as there are no monitoring gaps caused by low-battery shutdowns or replacement errors
- Improved sustainability, because long-life sealed batteries reduce electronic waste and prevent disposal of thousands of short-lived lithium batteries
- Simplified logistics, ideal for high-volume deployments (e.g. pharma distribution, cold-chain networks, warehouses) where manual maintenance is impractical

(SenseAnywhere® B.V., personal communication, 4 November 2025)

In sectors with strict regulatory requirements—such as pharmaceuticals, food logistics, and medical storage—uninterrupted temperature data is critical. The sealed, tamper-proof battery design ensures a permanent power connection and thus safeguards continuous data integrity. (SenseAnywhere® B.V., personal communication, 4 November 2025)

SenseAnywhere B.V. applies for an exemption from certain provisions concerning the requirement for battery removability in electronic products (SenseAnywhere B.V., 2025). The applicant justifies their application by presenting the following arguments: Product integrity and reliability are engineered features of the sensors, achieved through a seamlessly sealed (i.e. ultrasonically welded) PC/ABS plastic casing. This sealed casing provides a mechanically robust and tamper-proof design that prevents unauthorised access to the temperature logger. It also ensures effortless use of the device and eliminates the need for battery maintenance. (SenseAnywhere B.V., 2025)

Figure 4-1 – SenseAnywhere AiroSensor

Source: (SenseAnywhere® B.V., personal communication, 4 November 2025)

4.12.2. Assessment

Article 11(2)

Article 11(2)a is generally applicable in the sense that the sensor devices containing a battery are designed to be operated in damp (if not humid) environments. Nevertheless, the device is not designed to withstand constant exposure to splashing water for longer periods of time, streams of water or immersion in water, although it can be cleaned in wet conditions. Its IP67 rating indicates this property.

The applicant does not provide any arguments relating to user safety to suggest that there would be a safety risk if the end user attempted to replace the AiroSensor's battery. Although the applicant explains that designing the AiroSensor to allow end users to replace the battery would make the device less secure, this argument is not relevant to user safety as defined in Article 11(2). Therefore, a derogation under Article 11(2) does not appear justifiable.

Article 11(2)b is not applicable as the devices concerned are not considered to be medical devices.

Article 11(3)

Article 11(3) can be interpreted as applying to the AiroSensor, given that the device is designed to provide continuous and secure data logging of temperature and humidity in settings, that require such proof of uninterrupted cooling during logistics. This is particularly true when it comes to transporting and storing food or pharmaceutical products. Such logistical processes require continuous measurement and data logging, as well as the ability to retrieve the log file. To maintain a level of security as regulatory demands require, the

devices used for this purpose must be tamper-proof to a certain extent. Moreover, practical necessities during professional logistics set the demand for ease of handling of the data logging device, i.e. keeping maintenance costs low.

For this reason, the AiroSensor is a product designed primarily to collect and supply data to ensure data integrity. In this sense, Article 11(3) exempts the product from the requirements of Article 11(1) for product design that facilitates the end-user removing and replacing batteries. Hence, the conditions laid out in Article 11(3) support the applicants demand for an exemption, and no derogation is needed.

Criteria for a derogation in Article 11(4)

1: Safety of end-users removing the battery

The applicant does not claim or provide evidence of any safety risks to end users in the event of a battery replacement. Since the sensor runs on low voltage provided by the portable battery, there is no risk of electric shock.

Assessment: A possible battery replacement will not affect the safety of end users. Therefore, there is no justification for a derogation on this basis.

2. Product safety requirements

The applicant does not claim or provide evidence of any safety risks to the product itself in the event of a battery replacement. The main argument, mentioned by the applicant is that there is no need to exchange the battery during the product`s comparable long lifetime. Replacements of the battery could not be performed by end-users because they usually cannot renew the weld-sealed casing. Otherwise, designing the AiroSensor with a replaceable battery would compromise its mechanical robustness and reliability and also compromise data security and integrity. Redesigning the product with a replaceable battery is deemed unnecessary, given the long battery lifetime in the first place.

Assessment: Product safety requirements are not considered to be a sufficiently strong justification for a derogation.

3. Additional arguments pertaining to safety

The applicant explains that replacing the battery yourself could damage the sensor device's seal, causing corrosion to the electronic parts, including the battery. This could result in the temperature sensor malfunctioning and failure in

cold chain monitoring. Although the applicant asserts that the failure rate of current AiroSensors (with non-replaceable batteries) is below 0.5% over the product's lifetime, technical evidence was initially not provided to support the claim stated above of a corrosion risk and its impact.

In a later communication, the applicant asserted that, although the product is sealed and rated IP67, it does not mean that moisture cannot form on the electronics or electrical contacts. The air enclosed within the device contains water vapor, and when the temperature drops below the dew point, condensation can occur. Over time, such condensation may lead to corrosion. To minimize this risk, all components—including the battery—are soldered in place, and all electronic parts are protected with a conformal coating. Battery contacts, which are required for replaceable batteries remain particularly susceptible to corrosion; removability will have an impact on the reliability of the temperature monitoring function. (SenseAnywhere® B.V., personal communication, 4 November 2025)

The consultant assesses that other safety requirements are not considered to be a sufficiently strong justification for a derogation.

4.12.3. Conclusion and recommendation

Given that the primary function of the AiroSensor is to provide reliable, tamper-proof temperature monitoring in sensitive areas where an uninterrupted cooling chain is essential, it can be concluded that a continuous power supply is required through a permanent connection between the product and the portable battery in order to ensure data integrity. Redesigning the product to facilitate battery replacement by end users would compromise its primary function of collecting and supplying temperature data. For this reason, it falls under the exemption stipulated by Article 11(3) in the Batteries Regulation.

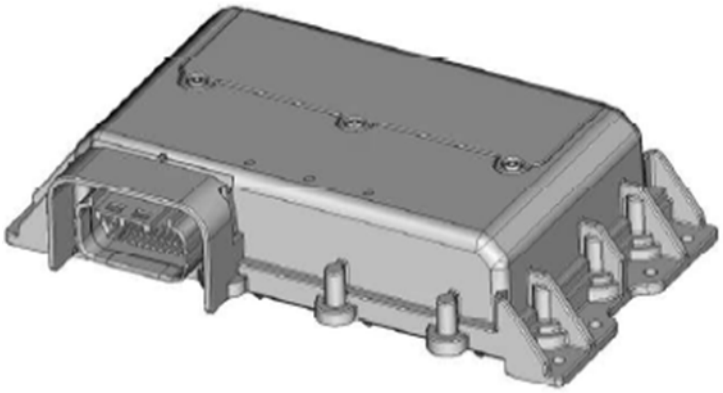
4.13. Kubota Corporation—Telematics units installed in Agricultural and Construction machines

4.13.1. Summary of the application

The application covers generic telematics units for agricultural and construction machinery manufactured by, or placed on the market under, the applicant's brand (Kubota Corporation, 2025). The application does not specify which telematics units contain a portable battery, nor does it provide information about the battery type. From the application's description, it can be inferred that the derogation request does not concern the starter battery of agricultural and construction machines. The telematics units seem to contain a separate battery, which appears to be much smaller and incorporated into the housing of the respective telematics unit. This unit is then integrated into the agricultural and construction machines. This location is usually inaccessible to users of these machines. These telematics units are designed to be accessible only by professionals in authorised workshops, in order to prevent system malfunctions and ensure correct machine configuration. (Kubota Corporation, 2025)

According to the application, the battery in the telematics unit is designed to buffer power fluctuations that occur regularly when the machine is started. At this time, a temporary voltage drop occurs in the power supply via the starter battery. Based on this, the applicant argues that the main function of the portable battery in the telematics unit is to ensure continued operation during power loss and maintain data integrity. Furthermore, the telematics unit provides alerts if it is disconnected from the agricultural or construction machine. This is argued to be an important secondary function, used for maintenance, theft tracking and tamper protection. The applicant asserts that if the battery fails or is replaced incorrectly by untrained end users, the telematics unit may not function properly, thus compromising the durability, security and data protection of the machine. (Kubota Corporation, 2025)

Figure 4-2 – Schematic of the telematics Module



Source: (Kubota Corporation, personal communication, 12 November 2025)

In a later communication, the applicant clarifies several specific design aspects of the telematics units and provides confidential technical documentation (Kubota, personal communication, 4 November 2025). The application for derogation concerns the product shown in Figure 4-2, a device (or unit) called Direct Control Unit (DCU) that can also be attached outside the body of a vehicle. The DCU therefore may be exposed to humid or wet outdoor conditions at least in some application scenarios. Thus, it requires a IP66K rating that must be maintained during the whole service life of that specific DCU device. The applicant argues that replacing the internal battery requires special tools to facilitate torque management of the screws holding the device in place, even in conditions involving heavy vibration, such as with construction machines.

4.13.2. Assessment

Article 11(2)

Parts of the telematics units are designed for use in wet surroundings, and they can be exposed to splashing water (rain). Hence, Article 11(2)a is applicable.

Article 11(2)b is also not applicable as the telematics units are not intended to be installed in medical devices.

Article 11(3)

According to Article 11(3), products do not have to be designed so that batteries can be easily removed and replaced by the end user if this would affect data integrity. This exemption applies to products that require a continuous power supply in the form of a permanent connection between the product and the portable battery. No derogation under Article 11(2) is therefore required in this case.

The applicant asserts that the telematics units rely on an uninterrupted power supply via an internal buffer battery to ensure data safety and integrity in the event of a voltage drop through the starter battery when the machine is started up at regular occurrence (Kubota Corporation, 2025). This situation imposes the need for the telematics units to rely on an independent power source to buffer the temporary voltage drop. An internal battery is a technical solution that would enable this and preserve uninterrupted function and maintain data integrity.

However, the applicant's argument falls short of providing a plausible explanation as to how the devices' data integrity would be affected if the end user replaced the internal battery at longer intervals, such as every few years, once the original portable battery's capacity has depleted and it reaches the end of its life. Such a replacement would obviously not be undertaken at the moment of starting the machine, so it is very unlikely that a power drop in the starter battery would coincide with the replacement of the internal battery. For this reason, the argument that maintaining data integrity, being a prerequisite for derogating from the provisions of Article 11(1), seems far-fetched.

Therefore, from the consultant's assessment, the exemption for data integrity reasons is not applicable under BattReg Article 11(3).

Criteria for a derogation in Article 11(4)

1: Safety of end-users removing the battery

The applicant has not provided any information on the potential safety risks to end users when attempting to replace the internal battery of the telematics units.

It can be inferred that a battery replacement would rather be inconvenient for end-users as the telematics units are usually not easily accessible within agricultural and construction machinery. This is however not a safety concern and thus not a reason for a derogation to be granted.

Another point raised by the applicant is that the battery in the telematics unit should only be removable and replaceable by independent professionals. It can be assumed that agricultural and construction machinery is used by professionals and is not operated by private end users. The reality of agricultural and construction businesses implies that such machinery is usually subject to professional servicing and maintenance schemes, often offered by the machinery's manufacturer or professional maintenance contractors. For reasons of economic efficiency, professional users of such machines are unlikely to take the time to replace the internal battery in the telematics unit themselves, given that the function provided by these devices is not the main function of the machines. Thus, even if the internal battery were designed to be

replaced by end users, this scenario is far from typical in agricultural and construction businesses. This is however not a consideration related to the safety of end-users and thus not a reason for a derogation to be granted.

The safety of end-users is not considered a valid reason for granting a derogation.

2. product safety requirements

The applicant further mentions aspects relating to product safety:

- For the DCU unit of the telematics unit, product safety would be compromised if untrained end-users were to replace the internal battery without access to special tools. This is due to the heavy duty use conditions (wet surroundings and vibrations) (Kubota, personal communication, 4 November 2025).

Product safety requirements are a reason to grant a derogation for the DCU unit of the telematics module. Other components of the telematics unit (e.g. components that may contain internal batteries) are not subject to the requested derogation.

The applicant's arguments do not relate to end user safety in the process of replacing the battery. In particular, the product safety requirements of the Low Voltage Directive (LVD) 2014/35/EU apply to voltages upwards of 50 V AC or more, or 75 V DC or more. Although no data on the voltage rating of this telematics unit is provided, it can be assumed to be 12 V DC. Battery replacement would be carried out by end users while the unit is switched off or disconnected from the power supply, so there is no risk of electric shock. If the units were to contain high voltage bearing parts during off-mode (such as capacitors), the protection against access to hazardous live parts can be achieved by means of enclosures or barriers (compare EN 62368-1) that separate the battery from high voltage bearing parts.

Arguments relating to the tamper-proofing of telematics units are not considered to be relevant hinderances to the design of products with replaceable batteries. In the event of theft, it is reasonable to assume that the perpetrator would overcome any technical barriers to disable the telematics unit.

Additional arguments pertaining to safety

The applicant states that product safety requirements rule out designing the DCU unit in a way that allows untrained end users to replace the internal battery without access to special tools. Instead, they argue that only maintenance personnel of dealers or distributors who are certified by the applicant should replace the internal battery, as they have access to the necessary expertise and

tools. (Kubota, personal communication, 4 November 2025). This argument can be partly accepted, since in the construction or agricultural industries, it is uncommon for end users, i.e. machine operators, to be responsible for maintaining sub-assemblies of machines. It is more common for machines to be serviced by maintenance personnel from specialised contractors or service providers commissioned by the original manufacturer.

4.13.3. Conclusion and recommendation

Additional arguments and documents provided by the applicant clarify that the device complies with the Article 11(4) criteria. The suggested derogation implies that the DCU unit must be designed in such a way as to enable service providers certified by the applicant, as well as independent repair professionals, to replace the battery. The applicant should note that if the portable battery of the DCU unit cannot be replaced by the end-user, the manufacturer must ensure that independent repair professionals have access to the necessary information, tools, and spare parts to carry out the replacement (Article 11(2)).

It is therefore recommended that a derogation be granted for the DCU unit of the telematics module. A derogation could be formulated as follows:

‘Direct Control Unit of a telematics module intended for installation on the exterior of agricultural and construction machinery.’

4.14. Veterinary in vitro diagnostic medical devices by Zoetis Inc.

4.14.1. Summary of the application

The company Zoetis Inc. requests a derogation for 'all veterinary in vitro diagnostic medical devices equivalent to the already existing derogation of in vitro diagnostic medical devices, as defined in Article 2, point (2), of Regulation (EU) 2017/746. In the alternative, we are requesting a derogation for at least those veterinary in vitro diagnostic medical devices that are intended to be plugged into the wall plug for power and use only a button cell to support the Real Time Clock (RTC).' The applicant points out that veterinary in vitro diagnostic medical devices are not covered by EU Regulation 2017/746/EU as they are not intended for humans but for animals. Zoetis argues that veterinary in vitro diagnostic medical devices and human in vitro diagnostic medical devices are technically and scientifically equivalent and that the only difference is their intended use. (Zoetis Belgium S.A., 2025) ([28])

Regarding the products covered by the request, Zoetis explains that

> the majority of the Zoetis veterinary in vitro diagnostic medical devices are small or medium desktop analysers that provide fast and accurate diagnoses at the point-of-care (equivalent to "near-patient testing" as defined in Regulation (EU) 2017/746). The rest of the Zoetis products are battery-operated, hand-held devices. (Zoetis Belgium S.A., 2025)

Zoetis provides the following examples of veterinary in vitro diagnostic medical devices that all refer to connected appliances but does not provide examples of the battery-operated, hand-held devices. (Zoetis Belgium S.A., 2025)

[28] European headquarters of Zoetis Inc.

Table 4-1 – Examples of veterinary in-vitro diagnostic medical devices

Product	Functionality	Picture of the product and comments
VetScan VS2 Analyzer *	Quantitative in vitro determinations of clinical chemistry analytes in heparinized whole blood, heparinized plasma, or serum	*Source*: Vetscan VS 2 Operator's Manual, PN 51884900
VetScan HM5 hematology analyzer **	Compact, fully automated cell counter for in-vitro diagnostic used in e.g. veterinary clinics or research laboratories, universities and pharmaceutical/biotech companies	*Source*: Vetscan HM5 Hematology System Original User's Manual, PN: 790-7013 Rev. F
Vetscan OptiCell ***	Point-of-case diagnostic hematology analyzer Artificial Intelligence (AI) driven cellular classification technology facilitates an automated complete blood count (CBC) analysis of 22 parameters using venous whole blood samples (K2/K3 EDTA anticoagulated) in validated species via a cartridge-based system.	: *Source*: Vetscan OptiCell User Manual, PN: 69896.1

Source: (Zoetis Belgium S.A., 2025) and (Zoetis Belgium S.A., personal communication, 3 November 2025)

The webpage of Zoetis was checked for examples of battery-operated, hand-held devices. For example, the Vetscan® UA ([29]) is specified as 'analyser with rechargeable battery, USB-powered printer, AC power supply'. When asked for further information, the applicant explained that for the battery-operated handheld devices, the rechargeable batteries are removable and replaceable by the end-user.

[29] https://www2.zoetis.de/diagnostik/vetscan-ua

Table 4-2 – Example of a handheld in vitro diagnostic medical device

Product	Functionality	Picture of the product and comments
Vetscan® UA *	Urinary tract, kidney and metabolic screening	*Source*: *: Vetscan UA User's Manual, PN: 1550-7005 Rev. B

Source : (Zoetis Belgium S.A., 2025)

Concerning arguments related to Real Time Clock (RTC), no details have been brought forward by the applicant. When asked for more information, the applicant explained that accurate date and time documentation is crucial in medical diagnostics, as an incorrect timestamp could compromise patient records and hinder monitoring. To ensure accuracy, devices use a real-time clock (RTC), which tracks date and time, and which is integrated in any device with a calendar or clock function. The RTC requires power to operate; if power is lost, it may stop and be reset. To prevent this, RTCs are typically connected to a battery (often a button cell), which only powers the RTC during outages, not the entire device. (Zoetis Belgium S.A., personal communication, 3 November 2025)

4.14.2. Assessment

Article 11(2)

With regards to the existing derogations under Article 11(2)(b) for 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, Zoetis claims that the Vetscan veterinary devices are technically and scientifically equivalent to devices intended for human use.

The argumentation of the applicant can be followed as all devices shown in the summary of the applications are examples for which the same functionalities are also applied for human use (blood or urine chemistry diagnostic, for example). Furthermore, one additional document provided by the applicant, a

test certificate issued by a IECEE National Certification Body (NCB) indicates as manufacturer of the devices the company Abaxis, that promotes these devices for human use. According to the applicant, Abaxis is 100% owned by Zoetis. (Zoetis Belgium S.A., personal communication, 3 November 2025)

In the veterinary sector, Regulation 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products (Regulation (EU) 2019/6, 2019) only covers medicinal products. EU legislation addresses medical devices for humans but medical devices for veterinary use are not covered by a legal act. Consequently, medical devices for veterinary use do not have to meet the requirements for the CE marking of medical devices for human use. (Danish Medicines Agency, 2019) They will also not have to be registered in the European database on medical devices (EUDAMED).(European Commission, n.d.) Therefore, the existing derogation under 11(2)(b) does not apply here.

Article 11(3)

Arguments raised by the applicant are linked to Article 11(3) that applies in cases 'where continuity of power supply is […] to ensure the safety of the user and the appliance or, for products that collect and supply data as their main function, for data integrity reasons' (Regulation (EU) 2023/1542, 2024). The use of the battery here ensures that the device time programming is not lost or impaired during device operation as this would compromise data by incorrect saving in the patient record. If the device fails to maintain accurate time-stamped data due to power loss, there is a significant risk that the progress of a patient's treatment cannot be properly monitored. Such gaps or errors in data could lead to inappropriate clinical decisions, missed interventions, or an inability to track improvements or deteriorations in the animal patient's condition. Ultimately, this could have serious, potentially detrimental consequences for animal patient health and safety.

For these veterinary devices, data collection and supply are the primary functions and the RTC is a main part within the data collection for which the requirement for uninterrupted power—enabled by a battery—is not a design aspect but a safeguard for data integrity. In this context, the derogation provided under Article 11(3) applies in this case, as it directly addresses the risk of compromised data quality. So, it can be concluded that data integrity considerations apply here.

Article 11(4) criteria

The argumentation of the applicant on the equivalence of the devices can be followed as all devices shown in the summary of the applications are examples for which the same functionalities are also applied for human use (blood or

urine chemistry diagnostic, for example). Furthermore, one additional document provided by the applicant, a test certificate issued by a IECEE National Certification Body (NCB) indicates as manufacturer of the devices the company Abaxis, ([30]) that promotes these devices for human use. According to the applicant, Abaxis is 100% owned by Zoetis. Taking this equivalence into consideration, the same safety and maintenance requirements that apply to (human) medical devices would then also apply for the veterinary in vitro medical devices. According to the applicant, this includes the requirement that the devices must not be opened by end users, but only by specialists as otherwise, the calibration of the devices would be compromised.

This issue relates to the criterion outlined in Article 11(4), which addresses the risk that the removal or the replacement of the battery by end-users would be in violation of any product safety requirements provided for by applicable Union law. However, since there is currently no Union legislation specifically governing veterinary medical devices, the safety standards referenced by the applicant—such as the EN 61010 series (Safety requirements for electrical equipment for measurement, control, and laboratory use) and EN 60601-1 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)—are not legally binding in the veterinary sector. As a result, compliance with these standards is voluntary for veterinary medical devices, and their application does not fulfil a legal requirement under Union law. Therefore, a derogation could also refer to the equivalence of these devices in order for the safety requirements to be considered binding.

4.14.3. Conclusion and recommendation

The application of Zoetis can be followed for the veterinary in vitro diagnostic medical devices that are intended to be plugged into a wall plug for power and use only a button cell to support the Real Time Clock (RTC). It is concluded that Article 11(3) applies because, for RTC needs, these devices require an uninterrupted power supply that can be ensured by a battery, allowing accurate data collection and supply for measurements from veterinary in vitro diagnostic devices. Loss of power could compromise time-stamped patient records, leading to gaps in treatment monitoring and to potentially harmful consequences for animal health and safety. It is therefore concluded that the derogation according to Article 11(3) applies.

[30] https://www.abaxis.com/products/

5. Assessment of products that may be a battery in their own right

A few applications were submitted where the assessment considered whether the device can be considered as a battery rather than as an appliance in which a battery is integrated. These cases are detailed in the following chapter.

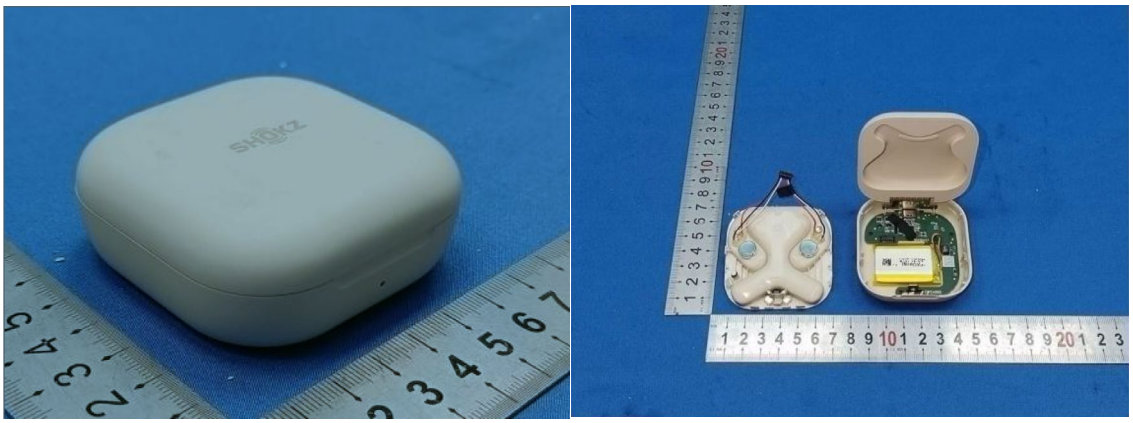
5.1. Wireless earphone (earbud) casings

5.1.1. Summary of the application

Shokz (Singapore) (Shokz Asia, 2025) requests a derogation for its product 'True Wireless Stereo earphone casing' (also referred to as 'earbud casings'). The derogation is asked for at the product category level, which implies further products developed or to be developed by the manufacturer following the same working principle. Products by other market actors which follow the same technical and operating principles are also in existence.

The applicant describes the product as a 'True Wireless Stereo' (TWS) charging case, meaning a portable device that stores and charges a pair of 'True Wireless' earbuds. (Shokz Asia, 2025)

Figure 5-1 – External (R) and internal view of wireless earbuds



Source: (Shokz Asia, 2025)

The applicant Shokz provides the following line of argument for the potential derogation:

- Charging Case Replacement Meets User-Replaceable Battery Requirement: the applicant believes that offering the charging cases as standalone products for users to

purchase and replace should be regarded as meeting the EU Battery Regulation's requirement for 'batteries replaceable by end-users.' Typically, a TWS charging case consists of a battery, circuitry, and housing, and functions as a dedicated energy unit for the earbuds. The applicant indicates that the charging case has the following characteristics:

  - Functionally equivalent to a battery: The primary purpose of the charging case is to repeatedly recharge the earbuds, which is essentially the same function as a replaceable battery.
  - Independently replaceable and available for purchase: When the battery performance degrades, users can directly replace the entire charging case.

- User-friendly and safe operation: The applicant states that replacing the entire case is simpler and safer than replacing the internal battery, thereby minimizing safety risks associated with improper handling.
- Industry-wide precedent: The applicant states that this approach is widely adopted across the TWS industry and well accepted by consumers. Brands such as Apple (AirPods) and Samsung (Galaxy Buds) have similar products currently on the market.
- Charging case recognized as a battery in international legislation: The applicant states that in several international regulatory frameworks, the earbud charging case is often classified as a battery due to its structural and functional characteristics. The applicant lists some international legislations to support this assertion such as:
  - PSE (Product Safety of Electrical Appliances & Materials — Japan): An approved test report of the product conducted by the firm SGS under the framework of the Japanese PSE regulation indeed classified the product as a 'rechargeable Li-ion battery'.
  - UN38.3 Transport Regulation: UN38.3 defines a battery as follows:

    > two or more cells or batteries which are electrically connected together and fitted with devices necessary for use, for example, case, terminals, marking or protective devices. Units which have two or more cells that are commonly

> referred to as ‘battery packs’, ‘modules’ or ‘battery assemblies’ having the primary function of providing a source of power to another piece of equipment are for the purposes of the Model Regulations and this Manual treated as batteries.

(Shokz Asia, 2025)

5.1.2. Assessment

Article 11(2)

Neither of the derogations already specified under article 11(2) apply in this case. The product is not deigned to operate in a wet environment (11(2)(a)) nor is it a medical device (11(2)(b)).

Article 11(3)

The derogation specified in Article 11(3) does not apply. The applicant did not raise the necessity of continuity of power supply and a permanent connection between the product and the respective portable battery.

Criteria for a derogation in Article 11(4)

While the applicant mentions safety to end-users as a justification for its application, there are no further details provided on the nature and severity of the safety risk. An analysis of a similar product sold by the applicant indicates that lithium-ion batteries with a capacity of about 3.5V-5V are used. This is not enough to pose the risk of an electric shock to the consumer should batteries be damaged during removal and replacement (eszoneo, 2025). However, there is a chance of chemical burns and fire if terminals are damaged (Lisbona & Snee, 2011). Damaged Lithium-ion batteries can ignite (thermal runaway) which is challenging to put out without specialized solutions and training not likely available to the ordinary end-user.

Additional aspects

The applicant believes that offering the charging case as a standalone product for users to purchase and replace should be regarded as meeting the EU Battery Regulation’s requirement for batteries replaceable by end-users. In other words, the applicant sees the charging case as a battery in its own right,

making reference to the primary purpose of the charging case being to repeatedly recharge the earbuds, which is essentially the same function as a replaceable battery.

In the consultant's view, though the charging case also has the function of storing the earbuds, is in providing the charging function for them. Though it may use same energy to indicate its own charging level, this is intended for the user to be able to consider the functionality of the casing for the purpose of charging the earbuds. Though such cases are not referred to in the BattReg nor in Commission Notice C/2025/214, in Article 3(26) of the BattReg it defines an 'appliance' as 'any electrical or electronic equipment, as defined in Article 3(1), point (a), of Directive 2012/19/EU, which is fully or partly powered by a battery or is capable of being so' (Regulation (EU) 2023/1542, 2024). In that respect, whereas the earbuds are to be considered as an appliance, the casing could indeed by viewed as the battery with which they can be charged.

5.1.3. Conclusion and recommendation

Based on the definition of a 'battery' provided in Art. 3(1) and supported by the international regulation UN38.3, it can be argued that indeed the casing as described by the applicant can be viewed as a battery in and of itself with the primary purpose of charging earphones. The case appears to serve the purpose of a battery with an internal battery management system (BMS) to indicate the state of charge to the user. It effectively functions in the same manner as a power bank.

Based on the risks to end-users through fires as a result of damaged terminals during replacement, a derogation is recommended as described in Article 11(4) with a threshold based on the typical battery capacities of earphone charging cases (between 300-600 mAh ([31])). The operations and working principle described by the applicant also apply for several other products on the market. Removal and replacement of these batteries might pose a significant risk to large sections of the population who typically use such cases and store them on their persons, homes and travelling bags.

A formulation for derogation that may impact the product category and not only this application could be formulated as follows:

- Casings—comprising battery, circuitry, and housing—which function as a dedicated energy unit for wireless earbuds, are exempt from the obligations described in Art. 11 (1) provided the maximum battery capacity does not exceed 600 mAh.

[31] This threshold is based on an analysis of a small sample of earphone casings placed on the EU market.

Alternatively, the EC may consider the casing to be a battery in its own right, in which case it would not be in the scope of Article 11, making a derogation redundant.

5.2. Powerbank

5.2.1. Summary of the application

The firm Xiaomi Communications Co., Ltd. requests a derogation from the requirements of Art. 11(1) for their power bank product series (Xiaomi, 2025). The firm describes the product as follows:

> This product is designed for portability and daily convenience, featuring a compact form and a durable, fireproof casing that resists wear and stains. It includes a power display for easy monitoring of remaining charge and offers multiple mainstream output ports to ensure compatibility with most electronic devices. High-capacity batteries are used to ensure stable and efficient power delivery, while comprehensive safety mechanisms such as over-current, over-voltage, and short-circuit protection, guarantee safe and reliable charging. (Xiaomi, 2025)

According to the applicant, the power bank is a rechargeable lithium-ion battery equipped with supporting circuitry, ports, and indicators, designed to meet a wide range of user needs (see Figure 5-2). It is intended as a portable power source for mobile electronics, providing charging for smartphones, tablets, wireless earphones, and similar devices. (Xiaomi, 2025)

Figure 5-2 – Example of a power bank

Source: Specified by applicant in a later communication (Xiaomi Communications Co., Ltd., personal communication, 4 November 2025b) as The Product link: **https://www.mi.com/global/product/xiaomi-212w-hypercharge-power-bank-25000/**

The main arguments that the applicant used in their request for a derogation are as follows:

- The power bank is itself a portable battery and not a product incorporating a portable battery as defined in Art. 3(9). While the power bank may include auxiliary components to enhance user friendliness (state of charge, state of health, charging ports, etc), replacing the internal battery would require replacing the entire product both in a practical and economic sense.
- Enforcing an end-user battery replaceability requirement on power banks would defeat the purpose of the provision. It does not yield the intended sustainability benefits of prolonging device life, since the act of battery replacement in this case is functionally equivalent to replacing the entire device. Instead, such a requirement could lead to additional design complexity, safety risks, and environmental burden without meaningful gains in repairability or product lifespan.
- On safety concerns pertaining to the end-user and product, the following further justifications are provided:
    - Use of improperly installed batteries: the applicant states that the power bank may be dropped or immersed in sweat subjecting the product to wet conditions. This may lead to poor contacts in internal circuits and presents a short circuit risk when batteries have been replaced (improperly).
    - Unclean environment for maintenance: The applicant asserts that battery replacement conducted by non-professionals may occur in uncontrolled, unclean environments. Should dust ingress occur, poor contacts could lead to short circuits.
    - Overheating/fire/explosion risk: Should end-users replace batteries with poor quality or non-compliant ones, product performance cannot be guaranteed.
    - Compact product design: The battery and internal structural components are closely integrated to prevent connections from loosening. Should end-users be allowed access to these components, the compactness of the internal structure and battery cannot be assured.

  - The casing of the product has some fireproof/fire supressing functionalities that may be reduced with improper battery replacement.
  - During the battery replacement process, punctures to battery cells/modules may lead to hazardous materials leaks, posing a risk to the user's health and personal safety.

- Increased volume and weight of the product: Redesign of the product to allow for battery removal and replacement would require additional space and further material use, countering the tenets of ecological design.
- Adverse impact on product lifecycle costs and the generation of further electronic waste: The applicant states that design for removal and replacement may result in premature failure and subsequently a reduced overall product lifetime. When end users purchase replacement products, this would generate more electronic waste. The core component of the power bank is the rechargeable lithium-ion battery itself, which constitutes the vast majority of the product's overall cost. In contrast, peripheral components such as the outer shell and integrated charging cables represent only a minor portion of the total material and manufacturing expenses.
- Finally, the applicant states that implementing a battery replacement design would not only introduce additional complexity and safety concerns, but it would also increase the cost for consumers.

(Xiaomi, 2025)

Another application presenting similar argumentation was submitted by a different company also requesting a derogation for a powerbank. They, however, do not provide a description of their product nor any additional information in support of their application. Their data is thus not reproduced in this report. Nevertheless, the conclusions of this chapter would apply to the second application as well, including the proposed wording for a potential derogation.

5.2.2. Assessment

Article 11(2)

Neither of the derogations already specified under article 11(2) apply in this case. The product is not designed to operate in a wet environment under

normal use, even if it may be accidentally exposed to wet environments from time to time (11(2)(a)) nor is it a medical device (11(2)(b)).

Article 11(3)

The derogation specified in Article 11(3) does not apply. The applicant did not raise the necessity of continuity of power supply and a permanent connection between the power bank and its battery.

Criteria for a derogation in Article 11(4)

Article 11(4) sets out two safety criteria: first, scientifically grounded concerns regarding the safety of end-users when removing or replacing the portable battery; and second, situations in which such actions could violate product safety requirements established by Union law. The concerns raised by the applicant focus on the risk that improper battery replacement by end-users could compromise the product's integrity, functionality, and durability.

In addition, the applicant highlights scenarios where end-user safety may be at risk, including incorrect battery replacement, shorting of contacts, and accidental puncture of battery cells or modules. These situations can result in fire risks through thermal runaway, as well as the leakage of hazardous battery materials. There are, in fact, several safety issues associated with power banks and the protection of end-users, particularly given the current designs that do not allow for removal or replacement. The most notable and recent cases are as follows:

- Anker PowerCore 10000 Recall (2025): Over 1.1 million Anker PowerCore 10000 power banks (model A1263) were recalled in the U.S. after 19 reports of fires and explosions. These incidents included two cases of minor burn injuries and property damage totalling more than $60,000. The U.S. Consumer Product Safety Commission (CPSC) urged consumers to stop using these devices immediately. The recall covered devices sold between June 2016 and December 2022 (Murphy & Fox Business, 2025).
- Incident in Japan: A traveller reported their power bank exploded while charging in a hotel room, causing $8,000 in damages. This is one of several incidents globally where lithium-ion batteries in power banks have caused fires, injuries, and significant property damage (Manufacturing Tomorrow, 2025).
- Baseus Power Bank Issues: Another brand, Baseus, received 76 reports involving their portable chargers, including 72 cases of battery bulging and four fires. Some incidents caused injuries and property damage,

prompting recalls and warnings from safety authorities (in this case the Australian Competition and Consumer Commission) (ACCC, 2025).

Based on current design which hinders the removal and replacement of batteries in power banks, significant incidents of fire, explosions and leakages still occur. This signifies the instability of the technology. It is therefore conceivable that should end-users be allowed access to batteries for the purpose of removal and replacement, such incidents may increase.

Additional aspects:

The applicant considers the power bank to be in itself a portable battery and not a product incorporating a portable battery. This is substantiated by its explanation that, replacing the internal battery would require replacing the entire product both in a practical and economic sense. Xiaomi argues that replacement of the battery within the product would not yield the intended sustainability benefits of prolonging device life, since the act of battery replacement in this case is functionally equivalent to replacing the entire device (Xiaomi, 2025)

The consultant agrees with this interpretation of the intention of Article 11(1). Article 11(1) of the BattReg is understood to have the intention of ensuring that batteries integrated into appliances are removable to allow separate waste management and that they are replaceable (preferably by the end-user) to prevent the need for scrapping the device once the battery has been depleted. In the case of powerbanks, the battery is understood to be dominant in the appliance in terms of use of resources. An end-user would be expected to replace the whole device once the battery becomes weaker and not to pursue a replacement of the battery, either individually or with the service of an independent professional. Furthermore, similar to other batteries, a power bank is often equipped with indicators for the battery's state of health and charge.

Furthermore, Article 3(26) of the BattReg defines an 'appliance' as 'any electrical or electronic equipment, as defined in Article 3(1), point (a), of Directive 2012/19/EU, which is fully or partly powered by a battery or is capable of being so' (Regulation (EU) 2023/1542, 2024). In this sense, the powerbank can be viewed as a battery with the main function of powering appliances.

Though determining this aspect is beyond the mandate of the consultant, there appears to be merit in considering a power bank as a battery in its own right, in which case Article 11 would not apply as replaceability is enabled through replacement of the product as is the case with other batteries.

5.2.3. Conclusion and recommendation

The assessment of the application submitted for derogation from Article 11(1) for powerbanks can be viewed in two possible ways.

First, the question is raised whether a power bank should be regarded as a portable battery in its own right instead of as a product into which a battery is incorporated. There is a case to be made for this perspective, as the indicators for the battery's state of health and charge are similar to functionalities found in other batteries; for example, lead-acid batteries often feature a non-electronic display of their state of health. The case can be made that the product is in fact a battery, as all its functions are tailored to simply charge a device repeatedly (see Article 3 (1)(1)).

Alternatively, the safety concerns raised by the applicant are acknowledged, as these are significant. It is plausible that designing power banks for removal and replaceability could increase the likelihood of damage to battery modules and cells. Considering the widespread use of power banks, including in sensitive settings such as on flights, these safety concerns warrant careful attention and priority.

If a derogation is granted for the product group 'Power Banks', it would be advisable to include a condition that limits eligibility to:

- power banks that meet the definition of a portable battery under Article 3(9), specifically those not exceeding 5 kg in weight.

A derogation could also be formulated to address similar products with the main functionality of storing energy for the purpose of charging other devices such as the jump starter applications addressed under section 5.3. The following formulation could be used for this purpose:

- Appliances with batteries not exceeding 5 kg in weight, specifically designed with an internal storage, consisting of one or more non-rechargeable or rechargeable battery cells, modules or packs, and with the primary function of delivering electrical energy to another product or products.

5.3. Jump Starter

5.3.1. Summary of the application

A manufacturer of jump starters requests a derogation from the requirements of Art. 11(1) for a vehicle battery jump starter that can be used to jump start a 12/24 volt vehicle dependent on product type.

The applicant explains that the product is a vehicle battery jump starter for 12 V or 24 V vehicles, whose primary function is to deliver a short burst of very high current to start a vehicle with a depleted battery. They note that while this core purpose aligns it with a starter-type battery, many jump starters additionally include features like a powerbank function or a small light. In the applicants view, these added functions could bring the device within the 'portable battery' category and trigger Article 11(1) requirements for end-user replaceability with household tools. (Source anonymised)

The applicants state that the jump starters use lithium cells designed for extremely high discharge rates—potentially several thousand amps—for brief periods. They argue that enabling end-users to open the enclosure and replace the battery at home would introduce significant safety risks, including:

- Accidental short circuits with tools, leading to sparks and burns.
- Fire or explosion due to mishandling, mechanical damage, or water ingress.
- Replacement of an already damaged battery, which they consider likely to escalate the above hazards.
- Improper reassembly, which they claim could harm the product and potentially damage vehicle electronics during use.

(Source anonymised)

The applicant further contends that redesigning the product to support 'safe' user replacement would necessitate additional protective features, connectors, and structural elements. According to them, this would increase the product's size, cost, and material use, undermining practicality and affordability. (Source anonymised)

While acknowledging the policy goal of extending product life through battery replacement, the applicant proposes an alternative compliance approach: batteries would be replaceable only via authorized repair centres. They assert that this would ensure safe handling and testing, mitigate risks to users and vehicles, and enable proper disposal of spent batteries. (Source anonymised)

On this basis, the applicant seeks a derogation from Article 11(1) for this product type, arguing that the safety and design burdens of end-user replaceability are disproportionate given the jump starter's high-current, vehicle-starting application.

Another manufacturer of jump starters sent an application on their own with the exact same argumentation and for the exact same product, which is therefore not assessed separately.

5.3.2. Assessment

Legal context and relevant definitions

As stated in the application, the product is designed to enable vehicle engine start-up and is therefore, in the applicant's view, comparable to an 'SLA battery'; they likely meant to refer to an SLI battery (starting, lighting, ignition) as defined under Article 3(12) of the EU Battery Regulation. SLI batteries are explicitly excluded from the removability obligations set out in Article 11(1), meaning no derogation under Article 11(2) would be required if the battery falls into this category.

In turn, Article 3(12) defines an SLI battery as one 'specifically designed to supply electric power for starting, lighting, or ignition and that can also be used for auxiliary or backup purposes in vehicles, other means of transport or machinery.' (Regulation (EU) 2023/1542, 2024)

If the battery does not meet this definition, it must be classified as a portable battery in line with Article 3(9), provided it meets the general criteria (sealed, ≤5 kg, not specifically designed for industrial use, and not falling into another battery category).

Importantly, in cases where a battery could fall under more than one category, Article 1(3) requires classification according to the strictest applicable requirements — which, for Chapter II obligations such as removability, would be the portable battery category.

This classification step is thus central to determining the admissibility and relevance of the requested exemption.

Functional and design purpose of jump starters

The applicant describes the product as a portable jump starter designed to deliver a high-current burst—potentially several thousand amperes—over a short period to start a car with a depleted battery. The product is constructed

using one or more lithium batteries and is used by externally connecting it to the vehicle's terminals in case of a depleted vehicle battery. (Source anonymised)

The jump starter is connected externally to the vehicle's battery terminals and delivers a short burst of high current designed to enable engine start when the vehicle's own battery is depleted. It does not recharge the battery beforehand, nor does it replace or integrate into the vehicle's electrical system. Rather, it serves as a temporary auxiliary device used in exceptional situations where the main battery cannot provide sufficient power to initiate the starting process.

Furthermore, the definition of an SLI battery includes the requirement that the battery 'can also be used for auxiliary or backup purposes in vehicles, […]' (Regulation (EU) 2023/1542, 2024). This reinforces the interpretation that an SLI battery is typically embedded in, or forms part of, the vehicle's own systems. The battery in a jump starter, by contrast, is externally connected to a vehicle, operates independently of the vehicle's internal electronics for its auxiliary features, and is not used for continuous backup or auxiliary support within the vehicle. Instead, its auxiliary features—such as USB charging or lighting—serve external devices and are unrelated to the functioning of the vehicle.

Therefore, while the product is indeed designed to facilitate starting a vehicle, its functionality is distinct from that of a battery 'in' the vehicle. The device neither replaces nor continuously supports the vehicle's SLI battery system. It merely enables occasional intervention when the primary battery fails.

Moreover, the usage profile of the device further supports this distinction. Unlike SLI batteries, which are actively engaged during each vehicle start cycle, jump starters are used typically only in emergency scenarios. Their predominant functions, especially in consumer-oriented models, may increasingly lie in their use as power banks or portable energy sources—activities fully aligned with the definition of portable batteries.

Classification

Based on the functional and design characteristics assessed above, the embedded battery in the jump starter is not to be classified as an SLI battery under Article 3(12) of the Battery Regulation. While the product's primary emergency function is to support engine starting, the battery:

- is not integrated into the vehicle;
- and cannot fulfil auxiliary or backup functions within the vehicle.

Moreover, the product's multifunctional use—including its ability to charge external devices and function as a power bank—points toward a consumer-oriented, general-purpose design. These features, alongside the absence of

vehicle integration, support the **classification of the battery as a portable battery** under Article 3(9).

Accordingly, the product falls within the scope of Article 11(1), and the requirement for end-user removability and replaceability applies. Therefore, a justification for derogation under Article 11(4) must be assessed.

Article 11(2)

Neither of the derogations already specified under article 11(2) apply in this case. The product is not designed to operate in a wet environment under normal use, even if it may be accidentally exposed to wet environments from time to time (11(2)(a)) nor is it a medical device (11(2)(b)).

Article 11(3)

The derogation specified in Article 11(3) does not apply. The applicant did not raise the necessity of continuity of power supply and a permanent connection between the power bank and its battery.

Criteria for derogation from Article 11(4)

The applicant lists several safety risks, including short-circuiting with tools, risk of fire or explosion through battery damage, water ingress, and the possibility of damage to vehicle electronics if reassembly is done incorrectly. While these claims outline plausible hazards, the application provides no supporting test data, citations from safety standards, or detailed risk analysis as required by the Commission's guidance.

Nevertheless, the product's technical function warrants careful consideration. The jump starter is designed to deliver high current—reportedly several hundred to over one thousand amperes—for a short period to assist in starting an internal combustion engine. While this level of current is significantly higher than that found in typical portable consumer electronics, it should be noted that no source is cited by the applicant to substantiate the actual current range or battery configuration.

Jump starters operate at voltages around 12V and are designed to deliver high instantaneous current to a vehicle's starter circuit. This places them closer, in terms of risk profile, to certain industrial or automotive applications—even though the device as a whole can be classified as a portable battery under Article 3(9) (as established in the previous chapter).

Given the absence of product-specific test data, we rely on comparative safety cases, particularly those concerning high-capacity lithium-ion battery devices.

As seen in the 2025 recall of the Anker PowerCore 10000 (Murphy & Fox Business, 2025) and Baseus power banks (ACCC, 2025), fire and explosion incidents have occurred due to cell defects, overcharging, or internal damage. These cases demonstrate that even enclosed designs with non-removable batteries can present significant fire hazards. It is conceivable that allowing end-users to access and replace high-current jump starter batteries—without sufficient training, protective equipment, or appropriate safety design—could increase the risk of battery damage during disassembly or reassembly, potentially leading to thermal runaway or fire.

However, the Commission Notice C/2025/214 (2025) (p. 8) on Article 11(4) provides a stricter evidentiary standard: the applicant must demonstrate, with scientific and technical evidence, that the safety risk cannot be mitigated through alternative design and that compliance with other safety regulations would be jeopardised by battery removability.

The applicant further argues that design changes to enable battery replacement would increase product size, weight, and material use—adding cost and complexity. However, design inconvenience or cost is not, by itself, a sufficient justification under Article 11(4). A claim that redesign is ‘not justified’ (source anonymised) due to the infrequent use of jump starters (and thus rare battery replacements) is also unconvincing from a regulatory perspective: the frequency of replacement does not override the requirement for end-user accessibility unless safety risks are clearly demonstrated and evidenced.

While the jump starter's high-current function makes it riskier than standard portable devices, certain risks—such as thermal runaway and fire—are shared with other lithium-ion battery products, including power banks. In the power bank assessment, it was acknowledged that redesigning such products for removability could increase the likelihood of battery damage and safety incidents—especially given their use in sensitive contexts (e.g. air travel). While jump starters are not used in the same frequency or context, a parallel may be drawn: granting a narrowly defined derogation may be justified if high discharge rates, compact design, and technical constraints can be shown to elevate end-user risk during battery removal.

Additional aspects

The applicant argues that the jump state may be considered as an SLI battery as its is designed to serve the purpose of starting a vehicle. In addition, it can be understood that in some cases the device will have additional functions integrated into it such as serving as a power bank. Though the assessment shows that the device being an SLI battery is arguable, it could still be considered that it may be a (portable) battery in its own right as its main function is externally charging a vehicle so that it can be started and on occasion it may have an additional function of serving as a powerbank. Looking at the

assessment of powerbanks (see section 5.2) suggests considering the definition for an appliance of the BattReg, which is stipulated in Article 3(26). It defines an 'appliance' as 'any electrical or electronic equipment, as defined in Article 3(1), point (a), of Directive 2012/19/EU, which is fully or partly powered by a battery or is capable of being so' (Regulation (EU) 2023/1542, 2024). In other words, the jump started could be considered as a device designed to either power a vehicle or to power other devices, however, in any case having the function of a battery of storing and power to other devices.

Though determining this aspect is beyond the mandate of the consultant, there appears to be merit in considering a jump starter as a battery in its own right, in which case Article 11 would not apply as replaceability is enabled through replacement of the product as is the case with other batteries.

5.3.3. Conclusion and recommendation

The safety concerns raised by the applicant are credible in principle and are consistent with known risks associated with high-current lithium-ion batteries. While the application lacks scientific studies, test data or references to relevant safety standards, the described hazards—short-circuiting, thermal runaway, and fire risks during battery handling—are well-recognised in the literature and known from similar products. It is plausible that allowing untrained users to access or replace batteries in high-current devices like jump starters could increase risk, particularly if protective circuitry, insulation, or assembly tolerances are compromised. This warrants careful regulatory consideration, especially given the operating environment of such products (e.g. near vehicle fuel systems).

At the same time, the evidentiary bar set by Article 11(4) has not been met. The application does not:

- Demonstrate that battery removability would render the product non-compliant with Union safety law;
- Provide product-specific test results, incident statistics, or safety certification references;
- Substantiate that safe redesigns are technically infeasible or would violate existing standards.

(Regulation (EU) 2023/1542, 2024)

From a regulatory standpoint, this creates a grey zone. While the evidence is insufficient for granting a derogation outright under Article 11(4), the identified risks are non-trivial and credible, especially when compared to lower-current consumer devices.

A further possible approach would be to consider the jump starter as a kind of powerbank, seeing as its main function is delivering electrical energy to other products. In this case it should be dealt with in the same manner as powerbanks (see section 5.1), i.e. either benefiting from the same derogation or being viewed as a battery and thus not in scope of the Article 11 provisions. In the former case, the following derogation formulated for powerbanks would then also apply to a jump starter:

- Appliances with batteries not exceeding 5 kg in weight, specifically designed with an internal storage, consisting of one or more non-rechargeable or rechargeable battery cells, modules or packs, and with the primary function of delivering electrical energy to another product or products.

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