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NOTE

From:	General Secretariat of the Council
То:	Delegations
No. Cion doc.:	13944/20 + ADD 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020
	- Presidency compromise text

Delegations will find in Annex a compromise text on the above Commission proposal.

This text has been prepared by the Presidency on the basis of a non-paper circulated during the first semester (as regard Chapter II) and non-papers circulated in July and September (Chapters I, III to VI.A, VIII to XIII), taking also into account oral and written comments by delegations.

A compromise proposal on Chapter VII is still being prepared and is therefore not included in this text. Those parts of the text which relate to Chapter VII are left in square-brackets and will have to be revised and discussed once the revised version of Chapter VII will be circulated.

Changes to the Commission proposal are highlighted as follows: new text is set out in **<u>bold</u> <u>underlined</u>**, while strikethrough indicates deletions.

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020

(Text with EEA relevance)

HAVE ADOPTED THIS REGULATION:

Chapter I General provisions

Article 1 Subject matter and scope

- This Regulation establishes requirements on sustainability, safety, labelling and information to allow the placing on the market or putting into service of batteries, as well as <u>[minimum]</u> requirements for the collection, treatment and recycling of waste batteries.
- 1a. This Regulation lays down the supply chain due diligence obligations of economic

 operators placing batteries on the market or putting them into service and requirements

 for green public procurement when procuring batteries or products containing

 batteries.
- This Regulation shall apply to all <u>types of</u> batteries, namely portable batteries, automotive batteries, <u>light means of transport batteries</u>, electric vehicle batteries and industrial batteries, regardless of their shape, volume, weight, design, material composition, <u>type</u>, <u>chemistry</u>, use or purpose. It shall also apply to batteries <u>designed to be or</u> incorporated in or added to other products.

<u>Article 1a</u>

Exemptions

- 3. This Regulation shall not apply to batteries in:
 - (a) equipment connected with the protection of Member States' essential security interests, arms, munitions and war material, with the exclusion of products that are not intended for specifically military purposes; and
 - (b) equipment designed to be sent into space.
- 3a. For batteries with external storage, and for industrial batteries and electric vehiclebatteries with internal storage and a nominal energy below or equal to 2 kWh, thefollowing provisions shall not apply:
 - (a) <u>sustainability requirements set out in Articles 7, 8 and 10;</u>
 - (b) <u>requirements on access to information set out in points (f), (g) and (h) of Article</u> <u>13a(5);</u>
 - (c) information on the state of health requirements set out in Article 14;
 - (d) <u>due diligence obligations set out in Articles 45a to 45f;</u>
 - (e) [requirements related to the repurposing and remanufacturing set out in Article 59;]
 - (f) <u>requirements on electronic availability of information and data set out in Article</u> <u>64; and</u>
 - (g) <u>requirements on battery passport set out in Article 65.</u>

Definitions

For the purposes of this Regulation, the following definitions shall apply:

 (1) 'battery' means any source of electrical energy generated by direct conversion of chemical energy, having internal or external storage, and consisting of one or more non-rechargeable or rechargeable battery cells, or of groups modules or packs of them;

(1a) 'battery pack' means any set of battery cells that are connected together or encapsulated within an outer casing, so as to form a complete unit that the end-user is not intended to split up or open;

- (2) 'battery cell' means the basic functional unit in a battery constituted by electrodes, electrolyte, container, terminals and, if applicable, separators, and containing the active materials the reaction of which generates electrical energy;
- (3) 'active materials' means material which reacts chemically to produce electric energy when the battery cell discharges or to store electric energy when the battery is being charged;
- (4) 'non-rechargeable battery' means a battery that is not designed to be electrically recharged;
- (5) 'rechargeable battery' means a battery that is designed to be electrically recharged;
- (6) 'battery with internal<u>external</u> storage' means a battery with no attached external devices to store energymeans a battery designed to have the energy stored exclusively in one or more attached external devices;
- (7) 'portable battery' means any battery that:
 - is sealed;
 - weighs below <u>or equal to</u> 5 kg;
 - is not designed <u>exclusively</u> for industrial purposes; and

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 is neither an electric vehicle battery, nor a lights means of transport battery, nor an automotive battery;

Portable battery includes any battery incorporated in or designed for products that are considered as toys within the meaning of the Toy Safety Directive 2009/48/EC.

- (8) 'portable batteries of general use' means <u>rechargeable and non-rechargeable</u> portable batteries <u>specifically produced to be interoperable and</u> with the <u>following</u>-common formats, <u>such as</u>: 4,5 Volts (3R12), D, C, AA, AAAA, AAAA, A23, 9 Volts (PP3);
- (9) 'light means of transport <u>battery</u>' means wheeled vehicles that have an electric motor of less than 750 watts, on which travellers are seated when the vehicle is moving and that can be powered by the electric motor alone or by a combination of motor and human power <u>means</u> any battery with a weight below or equal to 25 kg, designed to provide traction to wheeled vehicles that can be powered by the electric motor alone or by a combination of motor and human power, including vehicles of type-approved categories in the meaning of Regulation (EU) No 168/2013;
- (10) 'automotive-<u>SLI</u> battery' means any battery <u>used onlydesigned to supply electric power</u> for automotive-starter, lighting, or-ignition, power<u>auxiliary or back-up purposes in vehicles</u>, <u>other means of transport or machinery</u>;
- (11) 'industrial battery' means any battery designed for industrial uses and any other battery excluding portable batteries, <u>light means of transport batteries</u>, electric vehicle batteries and automotive batteries;
- (12) 'electric vehicle battery' means any battery specifically designed to provide traction to
 <u>hybrid or electric vehicles of categories M, N or O in the meaning of Regulation (EU)</u>
 <u>2018/858 or any battery with a weight above 25 kg, designed to provide traction to</u>
 <u>vehicles of category L in the meaning of Regulation (EU) No 168/2013</u>to hybrid and
 <u>electric vehicles for road transport;</u>

(13) 'stationary battery energy storage system' means a rechargeable industrial battery with internal storage specifically designed to store and deliver electric energy <u>from and</u> into the grid <u>or store and deliver electric energy to end-user</u>, regardless of where and by whom this battery is being used;

(13a) 'nominal energy' means the amount of energy that can be withdrawn from the battery at a particular constant current, starting from a fully charged state;

- (14) 'placing on the market' means <u>the first making available of</u> a battery for the first time on the Union market;
- (15) 'making available on the market' means any supply of a battery for distribution or use on the <u>Union</u> market in the course of a commercial activity, whether in return for payment or free of charge;
- (16) 'putting into service' means the first use, for its intended purpose, in the Union, of a battery;
- (17) 'battery model' is any manufactured battery that is manufactured produced in series;

(17a) 'battery presenting a risk' means a battery having the potential to affect adversely

health or safety of persons, property or the environment to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the battery concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

(18) 'carbon footprint' means the sum of greenhouse gas (GHG) emissions and GHG removals in a product system, expressed as carbon dioxide (CO2) equivalents and based on a Product Environmental Footprint (PEF) study using the single impact category of climate change-;

- (19) 'economic operator' means the manufacturer, the <u>manufacturer's</u> authorised representative, the importer, the distributor or the fulfilment service provider <u>or any other natural or legal</u> <u>person</u> who is subject to obligations in relation to manufacturing batteries, making them available or placing them on the market, <u>including on-line placing on the market</u>, or putting them into service in accordance with the present Regulation;
- [(20) 'independent operator' means a natural or legal person, other than an authorised dealer <u>a</u> <u>distributor</u> or repairer or remanufacturer, who is independent from the manufacturer and the producer and is directly or indirectly involved in the repair, maintenance or repurposing of batteries, and include waste management operators, repairers, manufacturers or distributors of repair equipment, tools or spare parts, as well as publishers of technical information, operators offering inspection and testing services, operators offering training for installers, manufacturers and repairers of equipment for alternative-fuel vehicles;]
- (21) 'QR code' means a matrix barcode that links to information about a battery model;
- (22) 'battery management system' means an electronic device that controls or manages the electric and thermal functions of the battery, that manages and stores the data on the parameters for determining the state of health and expected lifetime of batteries laid down in Annex VII and that communicates with the vehicle or appliance in which the battery is incorporated;
- (23) 'appliance' means any electrical or electronic equipment, as defined by Directive 2012/19/EU, which is fully or partly powered by a battery or is capable of being so;
- (24) 'state of charge' means the available capacity in a battery expressed as a percentage of rated capacity as defined by the manufacturer;
- (25) 'state of health' means a measure of the general condition of a rechargeable battery and its ability to deliver the specified performance compared with its initial condition;
- [(25a)'preparing for repurpose' means any operation, such as checking, cleaning orrepairing operation, by which a battery that have become waste is prepared so that it can beused for a different purpose or application than the one that the battery was originallydesigned for;]

[(26) 'repurposing' means any operation that results in parts or the complete battery being used for a different purpose or application than the one that the battery was originally designed for;]

[(26a) 'remanufacturing' means any operation, such as disassembly and checking, cleaning or repairing operation on used battery packs, battery modules or battery cells, by which a battery is disassembled and its parts are prepared so that they can be used to remanufacture a new battery, for original or a different purpose;]

- (27) 'manufacturer' means any natural or legal person who manufactures a battery or has a battery designed or manufactured, and markets that battery <u>or puts it into service</u> under its own name or trademark;
- (28) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, process or service;
- (29) 'harmonised standard' means a standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;
- (30) 'CE marking' means a marking by which the manufacturer indicates that the battery is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;
- (31) 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;
- (32) 'national accreditation body' a national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;
- (33) 'conformity assessment' means the process demonstrating whether the sustainability, safety-<u></u>, and-labelling <u>and information</u> requirements of this Regulation, relating to a battery have been fulfilled;
- (34) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

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- (35) 'notified body' means a conformity assessment body notified in accordance with Article 22
 <u>Chapter V of this Regulation;</u>
- (36) 'supply chain due diligence' means the obligations of the economic operator-which places a rechargeable industrial battery or an electric-vehicle battery on the market, in relation to its management system, risk management, third party verifications-<u>and surveillance</u> by notified bodies and disclosure of information with a view to identifying and addressing actual and potential risks linked to the sourcing, processing and trading of the raw materials required for battery manufacturing;
- [(37) 'producer' means any manufacturer, importer or distributor <u>natural or legal person</u> who, irrespective of the selling technique used, including by means of distance contracts as defined in Article 2(7) of Directive 2011/83/EU, supplies a battery for the first time for distribution or use, including when incorporated into appliances or vehicles, within the territory of a Member State on a professional basis;<u>alternatively:</u>

(i) is established in a Member State and manufactures batteries under its own name or trademark, or has batteries designed or manufactured and supplies them for the first time under its own name or trademark, including those incorporated in appliances, light means of transport or vehicles, within the territory of that Member State;

(ii) is established in a Member State and resells within the territory of that Member State, under its own name or trademark, batteries, including those incorporated in appliances, light means of transport or vehicles, manufactured by others. A reseller is not regarded as the 'producer' if the brand of the producer appears on the batteries, as provided for in point (i);

(iii) is established in a Member State and supplies for the first time on a professional basis, batteries, including those incorporated in appliances, light means of transport or vehicles, from a third country or from another Member State;

(*iv*) sells batteries, including those incorporated in appliances, light means of transport or vehicles, by means of distance communication directly to private households or to users other than private households in a Member State, and is established in another Member State or in a third country;]

- [(37a) 'producer's authorised representative' means any natural or legal person that is established in the Member State, where the producer is established, and who has received a written mandate from a producer to act on its behalf in relation to specified tasks with regard to the producer's obligations under the requirements of Chapter VII of this <u>Regulation;]</u>
- [(37b)'extended producer responsibility scheme' means a set of measures taken by MemberStates to ensure that producers of batteries bear financial responsibility or financial and
organisational responsibility for the management of the waste stage of a battery0s life
cycle;]
- [(38) 'producer responsibility organisation' means a legal entity that financially or <u>financially and</u> operationally organises the fulfilment of extended producer responsibility obligations on behalf of several producers;]
- [(39) 'waste battery' means any battery which is waste within the meaning of Article 3(1) of Directive 2008/98/EC;]
- [(40) 'reuse' means <u>any operation by which a battery that is not waste is used again for the same</u> <u>purpose for which it was conceived</u>the complete or partial direct re-use of the battery for the original purpose the battery was designed for;]

- (41) 'hazardous substance' means any <u>a</u> substance <u>classified as a hazardous as a consequence of fulfilling</u>which fulfils the criteria <u>laid down for any of the following hazard classes or categories set out in <u>Parts 2 to 5 of the</u> Annex I of Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹:</u>
 - (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
 - (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
 - (c) hazard class 4.1;
 - (d) hazard class 5.1;
- [(42) 'treatment' means any activity carried out on waste batteries after they have been handed over to a facility for sorting, or preparing for re-use, preparing for repurposing, preparing for remanufacturing or preparation for recycling;]
- [(43) 'voluntary collection points' means any non-profit, commercial or other economic undertaking or public body involved on their own initiative in the separate collection of waste portable batteries, by collecting the waste portable batteries it generates or which are generated by other end-users before they are picked up by waste management operators for subsequent treatment;]
- [(44) 'waste management operator' means any natural or legal person dealing on a professional basis with the separate collection, sorting, or treatment of waste batteries;]

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Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)

- [(45) 'permitted facility' means any facility that is permitted in accordance with Directive 2008/98/EC to carry out the treatment or recycling of waste batteries;]
- [(46) 'recycler' means any natural or legal person established in the Union who carries out recycling processes in a permitted facility;]
- [(47) 'lifetime' of a battery means the period of time that starts when the battery is placed on the market<u>manufactured</u>, and ends when the battery becomes waste;]
- [(48) 'level of recycling' means, for a given Member State in a given calendar year, the percentage obtained by dividing the weight of waste batteries that undergo treatment and recycling in accordance with Article 56 of this Regulation in that calendar year, by the weight of waste batteries collected in accordance with Articles 48 and 49 of this Regulation;]
- [(49) 'recycling process' means any recycling operation of waste batteries, excluding sorting or <u>and</u> preparation for recycling, that may be carried out in a single or several permitted facilities;]
- [(50) 'recycling efficiency' of a recycling process means the ratio obtained by dividing the mass of output fractions accounting for recycling by the mass of the <u>sorted</u> waste batteries input fraction, expressed as a percentage;]
- (51) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (52) 'national authority' means an approval authority or any other authority involved in and responsible for market surveillance as set out in Chapter VI-<u>IX</u> or border control in a Member State in respect of batteries;
- (53) '<u>manufacturer's</u> authorised representative' means any natural or legal person established in the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the requirements of <u>Chapter IV and VI of</u> this Regulation;

- (54) 'importer' means any natural or legal person established within the Union who places a battery from a third country on the Union-market;
- (55) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a battery available on the market;
- (56) 'risk' means the combination of the probability of <u>an</u> occurrence of <u>a hazard causing</u> harm <u>to human health or safety of persons, to property or to the environment</u> and the <u>degree of</u> severity of that harm-limited to human health or safety of persons, to property or to the <u>environment</u>.

[The definitions of 'waste', 'waste holder', 'waste management', <u>'prevention',</u> 'collection', 'separate collection', <u>['extended producer responsibility scheme'], 'prevention',</u> 'preparing for reuse', '<u>material</u> recovery' and 'recycling' laid down in Article 3 of Directive 2008/98/EC shall apply.]

The definitions of <u>'end-user'</u>, 'market surveillance', 'market surveillance authority', <u>'non-</u> <u>compliance'</u>, 'fulfilment service provider', 'corrective action', <u>'end-user'</u>, 'recall' and 'withdrawal' laid down in Article 3 of Regulation (EU) 2019/1020 shall apply.

The definitions of 'independent aggregator'<u>and</u> 'market participant' <u>and 'energy storage'</u> laid down in Article 2 of Directive (EU) 2019/944 shall apply.

Article 3

Free movement

 Member States shall not, for reasons relating to sustainability, safety, labelling and information requirements of batteries or management of waste batteries covered by this Regulation, prohibit, restrict or impede the making available on the market or the putting into service of batteries that comply with this Regulation.

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2. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not prevent the showing of batteries, which do not comply with this Regulation, provided that a visible sign clearly indicates that such batteries do not comply with this Regulation and that they are not for sale-made available on the market or put into service until they have been brought into conformity.

Article 4

Sustainability, safety, labelling and information requirements for batteries

- 1. Batteries shall only be placed on the market or put into service if they meet:
 - (a) the sustainability and safety requirements set out in Chapter II;<u>Articles 6 to 10 and 12;</u>
 <u>and</u>
 - (b) the labelling and information requirements set out <u>in</u> Chapter III.
- 2. For any aspects not covered by Chapters II and III, batteries shall not present a risk to human health, to safety **of persons**, to property or to the environment.

Article 5

Competent authority.

- 1. Member States shall designate one or more competent authorities responsible for carrying out obligations arising from Chapter VII and monitoring and verifying compliance of the producers and producer responsibility organisations with the requirements of that Chapter.
- 2. Member States shall lay down the details of the competent authority's or authorities' organisation and operation, including the administrative and procedural rules to ensure:
 - (a) the registration of producers in accordance with Article 46;
 - (b) the authorisation of producers and producer responsibility organisations in accordance with Article 47 and the authorisation and monitoring regarding the requirements under Article 48;

- (c) the oversight of implementation of extended producer responsibility obligations in accordance with Article 47;
- (d) the collection of data on batteries in accordance with Article 61;
- (e) making information available in accordance with Article 62.

3. By [18 months after the date of entry into force of this Regulation], Member States shall notify the Commission of the names and addresses of the competent authorities designated pursuant to paragraph 1. Member States shall inform the Commission without undue delay of any changes to the names or addresses of those competent authorities.

Chapter II Sustainability and safety requirements

Article 6 Restrictions of hazardous substances

- In addition<u>Without prejudice</u> to the restrictions set out in Annex XVII of Regulation (EC) No 1907/2006, batteries shall not contain hazardous substances for which Annex I contains a restriction unless they comply with the conditions of that restriction.
- 2. When there is an unacceptable risk to human health or the environment, arising from the use of a substance in the manufacture of batteries, or from a substance present in the batteries when they are-placed on the market, or during their subsequent life cycle stages, including the waste phase, that needs to be addressed on a Union-wide basis, the Commission shall, adopt a delegated act in accordance with the procedure referred to in Article 73 where appropriate, make legislative proposals to amend the restrictions in Annex I, pursuant to the procedure laid down in Article 71.
- 3. In adopting a delegated act <u>making legislative proposals</u> referred to in paragraph 2, the Commission shall take into account the socio-economic impact of the restriction, including the availability of alternatives for the hazardous substance.

- Restrictions adopted pursuant to paragraph 2 shall not apply to the use of a substance in scientific research and development (of batteries) as defined in Article 3(23) of Regulation (EC) No 1907/2006.
- 5. If a restriction adopted pursuant to paragraph 2 shall not apply to product and process oriented research and development, as defined in Article 3(22) of Regulation (EC) No 1907/2006, this exemption, as well as the maximum quantity of the substance exempted, shall be specified in Annex I.

5a. In case Annex XVII of Regulation (EC) No 1907/2006 is amended the Commission shall, where appropriate, propose amendments to this Regulation.

Article 7

Carbon footprint of electric vehicle batteries and rechargeable-industrial batteries

- 1. From either 1 July 2024[30/66 months after the start of application of this Regulation] or [12 months] after the adoption of the delegated and implementing acts referred to in points (a) and (b) of the third subparagraph, whichever is the latest, Eelectric vehicle batteries and rechargeable-industrial batteries with internal storage and a capacitynominal energy above 2 kWh shall be accompanied by technical-documentation that includes, for each battery model and batch per manufacturing plant, a carbon footprint declaration drawn up in accordance with the delegated act referred to in the second sub-paragraph and containing, at least, the following information:
 - (a) administrative information about the producer<u>manufacturer</u>;
 - (b) information about the battery <u>model</u> for which the declaration applies;
 - (c) information about the geographic location of the battery manufacturing facility;
 - (d) the total-<u>life-cycle</u> carbon footprint of the battery, calculated as kg of carbon dioxide equivalent;
 - (e) the carbon footprint of the battery differentiated per life cycle stage as described in point 4 of Annex II;

- (f) the independent third party verification statement proof of third party verification by a <u>notified body;</u>
- (g) a web link to get access to a public version of the study supporting the carbon footprint declaration results values referred to in points (d) and (e).

The carbon footprint declaration requirement in the first subparagraph shall apply as of 1 July 2024 to electric vehicle batteries and to rechargeable industrial batteriesshall be drawn up in the language or languages required by the Member State in which the battery is placed or made available on the market or put into service and shall be accessible through the QR code referred to in Article 13(5).

The Commission shall, no later than 1 July 2023[18/42 months after the start of application] of this Regulation], adopt:

- (a) a delegated act in accordance with Article 73 to supplement this Regulation by establishing the methodology to calculate the total-values of carbon footprint of the battery referred to in point (d) and (e) of the first sub-paragraph, in accordance with the essential elements set out in points 1 to 7 of Annex II;
- (b) an implementing act establishing the format for the carbon footprint declaration referred to in the first subparagraph. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(3).

The Commission shall be empowered to adopt delegated acts in accordance with Article 73 to amend the information requirements set out in the first subparagraph.

2. From either 1 January 2026[48/84 months after the start of application of this Regulation] or [12 months] after the adoption of the delegated and implementing acts referred to in points (a) and (b) of the third subparagraph, whichever is the latest, Eelectric vehicle batteries and rechargeable-industrial batteries with internal storage and a capacitynominal energy above 2 kWh shall bear a conspicuous, clearly legible and indelible label indicating the carbon footprint performance class that the individual battery the relevant battery model and batch per manufacturing plant corresponds to.

In addition to the information set out in paragraph 1, For batteries referred to in first subparagraph, the technical documentation referred to in Annex VIII shall demonstrate that the carbon footprint declared and the related classification into a carbon footprint performance class have been calculated in accordance with the methodology set out in the delegated acts adopted by the Commission pursuant to the fourth-point (a) of third subparagraph.

The carbon footprint performance class requirements in the first subparagraph shall apply as of 1 January 2026 for electric vehicle batteries and for rechargeable industrial batteries.

The Commission shall, no later than 31 December-2024[36/60 months after the start of application of this Regulation], adopt:

- (a) a delegated act in accordance with Article 73 to supplement this Regulation by establishing the carbon footprint performance classes referred to in the first subparagraph. In preparing that delegated act, the Commission shall take into account the relevant essential elements<u>conditions</u> set out in <u>point 8 of</u> Annex II;
- (b) an implementing act establishing the formats for the labelling referred to in the first subparagraph and the format for the declaration on the carbon footprint performance class referred to in the second subparagraph. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(3).

The Commission shall, in accordance with the conditions set out in point 8 of Annex II, review the number of performance classes and the thresholds between them every three years and, where appropriate, adopt delegated acts in accordance with Article 73 to amend them in a view of keeping them representative of the market reality and its expected development.

3. From either 1 July 2027[66/90) months after the start of application of this Regulation] or [12 months] after the adoption of the delegated act referred to in the second subparagraph, whichever is later, Efor electric vehicle batteries and rechargeable-industrial batteries with internal storage and a capacitynominal energy above 2 kWh-shall, for each battery model and batch per manufacturing plant, be accompanied by the technical documentation referred to in Annex VIII shall demonstrateing that the declared- life cycle carbon footprint value for the relevant battery model and batch per manufacturing plant, is below the maximum threshold established in the delegated act adopted by the Commission pursuant to the third subparagraph.

The requirement for a maximum life cycle carbon footprint threshold in the first subparagraph shall apply as of 1 July 2027[66 months after start of application of the Regulation] for electric vehicle batteries and for rechargeable industrial batteries.

The Commission shall, no later than 1 July 2026[54/78 months after the start of application of this Regulation], adopt a delegated act in accordance with Article 73 to supplement this Regulation by determining the maximum life cycle carbon footprint threshold referred to in the first subparagraph. In preparing that delegated act, the Commission shall take into account the relevant essential elementsconditions set out in point 9 of Annex II.

The introduction of a maximum life cycle carbon footprint threshold shall trigger, if necessary, a reclassification of the carbon footprint performance classes of the batteries referred to in paragraph 2.

Recycled content in industrial batteries, electric vehicle batteries and automotive batteries

1. From <u>either</u> 1 January 2027[60/72 months after the start of application of this Regulation] or [12 months] after the adoption of the delegated act referred to in second subparagraph, whichever is later, industrial batteries, electric vehicle batteries and automotive batteries with internal storage and a capacitynominal energy above 2 kWh that contain cobalt, lead, lithium or nickel in active materials shall be accompanied by technical documentation containing information about the amount share of, respectively, cobalt, lead, lithium or nickel recovered from waste present in active materials, and share of lead recovered from waste present in battery, in each battery model and batch per manufacturing plant.

By 31 December-2025[48 months after the start of application of this Regulation], the Commission shall adopt an implementing delegated act in accordance with Article 73 to supplement this Regulation by laying down establishing the methodology for the calculation and verification of the amount share of cobalt, lead, lithium or nickel recovered from waste present in active materials, and share of lead recovered from waste present in battery, in the batteries referred to in the first subparagraph, and the format for the technical documentation. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(3).

2. From 1 January-2030[96 months after the start of application of this Regulation], for industrial batteries, electric vehicle batteries and automotive batteries with internal storage and a capacitynominal energy above 2 kWh that contain cobalt, lead, lithium or nickel in active materials, shall be accompanied by technical documentation referred to in Annex <u>VIII shall</u> demonstrateing that those batteries contain the following minimum share of, respectively, cobalt, lead, lithium or nickel recovered from waste present in active materials, and share of lead recovered from waste present in battery, in each battery model and batch per manufacturing plant:

- (a) 12% cobalt;
- (b) 85% lead;

- (c) 4% lithium;
- (d) 4% nickel.
- 3. From 1 January-2035[156 months after the start of application of this Regulation], for industrial batteries, electric vehicle batteries and automotive batteries with internal storage and a capacitynominal energy above 2 kWh that contain cobalt, lead, lithium or nickel in active materials, shall be accompanied by a technical documentation referred to in Annex VIII shall demonstrateing that those batteries contain the following minimum share of, respectively, cobalt, lead, lithium or nickel recovered from waste present in active materials, and share of lead recovered from waste present in battery, in each battery model and batch per manufacturing plant:
 - (a) 20% cobalt;
 - (b) 85 % lead;
 - (c) 10% lithium;
 - (d) 12% nickel.
- 4. Where justified and appropriate due to the availability of cobalt, lead, lithium or nickel recovered from waste, or the lack thereof, <u>or other considerable changes in battery</u> <u>technologies impacting the type of materials recovered,</u> the Commission shall be empowered to adopt, by 31 December-2027[72 months after the start of application of this <u>Regulation</u>], a delegated act<u>s</u> in accordance with Article 73, to amend the targets laid down in paragraphs 2 and 3.

Performance and durability requirements for portable batteries of general use

- From <u>either 1 January 2027[60/72 months after the start of application of this Regulation]</u> or [12 months] after the adoption of the delegated act referred to in paragraph 2, whichever is later, portable batteries of general use shall meet the <u>minimum</u> values for the electrochemical performance and durability parameters set out in Annex III as laid down in the delegated act adopted by the Commission pursuant to paragraph 2.
- By 31 December-2025[48 months after the start of application of this Regulation], the Commission shall adopt a delegated act in accordance with Article 73 to supplement this Regulation by establishing minimum values for the electrochemical performance and durability parameters laid down in Annex III that portable batteries of general use shall attain.

The Commission is shall be empowered to adopt delegated acts in accordance with Article 73 to amend the electrochemical performance and durability parameters laid down in Annex III in view of technical and scientific progress.

In preparing the delegated act referred to in the first subparagraph, the Commission shall consider the need to reduce the life cycle environmental impact of portable batteries of general use and take into consideration relevant international standards and labelling schemes. The Commission shall also ensure that the provisions laid down by that delegated act do not have a significant negative impact on the functionality of those batteries or the appliances into which those batteries are incorporated, the affordability and the cost for end-users and the industry's competitiveness. No excessive administrative burden shall be imposed on manufacturers of the batteries and the appliances concerned.

3. By 31 December-2030[108/48 months after the start of application of this Regulation], the Commission shall assess the feasibility of measures to phase out the use of non-rechargeable portable batteries of general use in view of minimising their environmental impact based on the life cycle assessment methodology. To that end, the Commission shall submit a report to the European Parliament and to the Council and consider-takeing the appropriate measures, including, if appropriate, the adoption of legislative proposals.

Performance and durability requirements for <u>light means of transport batteries</u>, rechargeable industrial batteries and electric vehicle batteries

 From [12 months after entry into forcestart of the Regulation of application of this <u>Regulation</u>], light means of transport batteries, rechargeable-industrial batteries and electric vehicle batteries with internal storage and a capacity<u>nominal energy</u> above 2 kWh shall be accompanied by a technical-documentation containing values for the electrochemical performance and durability parameters laid down in Part A of Annex IV.

For batteries referred to in first subparagraph **F**the technical documentation referred to in the first subparagraph<u>Annex VIII</u> shall also-contain an explanation of the technical specifications, standards and conditions used to measure, calculate or estimate the values for the electrochemical performance and durability parameters. That explanation shall include, at least, the elements laid down in Part B of Annex IV.

- 2. From <u>either 1 January-2026[48 months after the start of application of this Regulation] or</u> [12 months] after the adoption of the delegated act referred to in paragraph 3, whichever is later, rechargeable industrial batteries with internal storage and a capacity<u>nominal energy</u> above 2 kWh shall meet the minimum values laid down in the delegated act adopted by the Commission pursuant to paragraph 3 for the electrochemical performance and durability parameters set out in Part A of Annex IV.
- 3. By 31 December-2024[36 months after the start of application of this Regulation], the Commission shall adopt a delegated act in accordance with Article 73 to supplement this Regulation by establishing minimum values for the electrochemical performance and durability parameters laid down in Part A of Annex IV that rechargeable light means of transport batteries and industrial batteries with internal storage and <u>a</u> capacity<u>nominal</u> <u>energy</u> above 2 kWh shall attain.

In preparing the delegated act referred to in the first subparagraph, the Commission shall consider the need to reduce the life cycle environmental impact of rechargeable industrial batteries with internal storage and a capacity above 2 kWh and ensure that the requirements laid down therein do not have a significant negative impact on the functionality of those batteries or the appliances into which those batteries are incorporated, its affordability and industry's competitiveness. No excessive administrative burden shall be imposed on manufacturers of the batteries and the appliances concerned.

- 3a. The Commission shall be empowered to adopt delegated acts in accordance with Article73 to amend the electrochemical performance and durability parameters laid down inAnnex IV in view of market development and technical and scientific progress.
- 3b. The Commission shall be empowered to adopt delegated acts to supplement thisRegulation by establishing minimum values for the electrochemical performance anddurability parameters laid down in Part A of Annex IV for light means of transportbatteries.

Article 11 Removability and replaceability of portable batteries

 From either 1 January [24 months after start of application of this Regulation] or [6 months] after the publication of the guideline referred to in paragraph 3, whichever is later, Pportable batteries batteries incorporated in appliances or products shall be readily removable and replaceable by the end-user or by independent operators during the lifetime of the appliance, if the batteries have a shorter lifetime than the appliance, or at the latest at the end of the lifetime of the appliance.

A <u>portable</u> battery is readily replaceable where, after its removal from an appliance <u>or</u> <u>product</u>, it can be substituted by a similar battery, without affecting the functioning or the performance of that appliance.

2. The obligations set out in paragraph 1 shall not apply where

- (a) continuity of power supply is necessary and a permanent connection between the appliance and the portable battery is required for safety, performance, medical or data integrity reasons.; or
- (b) the functioning of the battery is only possible when the battery is integrated into the structure of the appliance.
- By [18 months after start of application of this Regulation], ^Tthe Commission shall adopt publish guidelinesguidance-to facilitate harmonised application of the derogations set out in paragraph 2.

Safety of stationary battery energy storage systems

- Stationary battery energy storage systems shall be accompanied by technical documentation demonstrating that they are safe during their normal operation and use, including evidence that they have been successfully tested, at a minimum for the safety parameters laid down in Annex V, for which state-of-the-art testing methodologies should be used.
- The Commission is shall be empowered to adopt delegated acts in accordance with Article 73 to amend the safety parameters laid down in Annex V in view of technical and scientific progress.

2a. The technical documentation referred to in Annex VII shall include at least:

- (a) an assessment of possible additional safety hazards, not addressed in Annex V, of the specific battery energy storage system, based on its technology and the specific application and environment of the battery energy storage system. The documentation should be reviewed if a battery is refurbished and reused for another application or in another environment,
- (b) <u>evidence that the additional hazards have been successfully mitigated and tested</u> <u>for which state-of-the-art testing methodologies should be used;</u>

(c) <u>mitigation instructions in case the identified hazards addressed in Annex V may</u> <u>occur, for example a fire or explosion.</u>

Chapter III Labelling and information requirements

Article 13

Labelling and marking of batteries

- From 1 January-2027[60 months after the start of application of this Regulation], all batteries shall be marked with a label containing the information laid down in Part A of Annex VI.
- From 1 January-2027[60 months after the start of application of this Regulation], nonrechargeable portable batteries and automotive batteries shall be marked with a label containing information on their capacity.
- <u>From 1 January ... [60 months after the start of application of this Regulation]</u>, and
 <u>rechargeable</u> portable batteries shall be marked with a label containing information on their minimum average duration when used in specific applications.
- 3. From 1 July-2023[18 months after the start of application of this Regulation], all batteries shall be labelled-marked with the symbol indicating 'separate collection' in accordance with the requirements laid down in Part B of Annex VI.

The symbol shall cover at least 3 % of the area of the largest side of the battery up to a maximum size of 5×5 cm.

In the case of cylindrical battery cells, the symbol shall cover at least 1,5 % of the surface area of the battery and shall have a maximum size of 5×5 cm.

Where the size of the battery is such that the symbol would be smaller than 0.5×0.5 cm, the battery does not need to be marked but a symbol measuring at least 1×1 cm shall be printed on the packaging **and on the documents accompanying the battery**.

From 1 July-2023[18 months after the start of application of this Regulation], all batteries containing more than 0,0005 % mercury or more than 0,002 % cadmium or more than 0,004 % lead, shall be marked with the chemical symbol for the metal concerned: Hg or Cd or Pb.

The symbol indicating the heavy metal content shall be printed beneath the symbol shown in Part B of Annex VI and shall cover an area of at least one-quarter the size of that symbol.

- 4a. From 1 January ... [48 months after the start of application of this Regulation], industrial batteries and electric vehicle batteries with a nominal energy above 2 kWh shall be marked with a label containing the information in accordance with Article 7(2).
- 5. Batteries From 1 January ... [12 months after the start of application of this Regulation], all batteries shall be marked with a QR code in accordance with Part C of Annex VI. which QR code shall provide access to the following information of the respective battery model,: specified in Article 13a.
 - (a) from 1 January 2027, for all batteries the information referred to in paragraph 1;
 - (b) from 1 January 2027, for portable and automotive batteries the information referred to in paragraph 2;
 - (c) from 1 January 2023, for all batteries the symbol referred to in paragraph 3;
 - (d) from 1 January 2023, for batteries containing more than 0,002 % cadmium or more than 0,004 % lead, the symbol referred to in paragraph 4;
 - (e) from [12 months after the entry into force of this Regulation], for rechargeable industrial batteries and electric vehicle batteries the report referred to in Article 39(6);

- (f) from 1 July 2024, for electric vehicle batteries and for rechargeable industrial batteries with internal storage and a capacity above 2 kWh the carbon footprint declaration referred to in Article 7(1);
- (g) from 1 January 2026, for electric vehicle batteries and for rechargeable industrial batteries with internal storage and a capacity above 2 kWh the carbon footprint performance class referred to in Article 7(2);
- (h) from 1 January 2027, for rechargeable industrial batteries, automotive batteries and electric vehicle batteries with internal storage and a capacity above 2 kWh the amount of cobalt, lead, lithium or nickel recovered from waste and present in active materials in the battery, in accordance with Article 8;
- (i) from 1 January 2023, for all batteries the declaration referred to in Article 18;
- (j) from 1 July 2023, for all batteries the information referred to in points (a) to (f) of Article 60(1).

5a. From 1 January ... [48 months after the start of application of this Regulation], each individual industrial and electric vehicle batteries with a nominal energy above 2 kWh shall be marked with a unique identifier in accordance with Article 65(2).

- 6. Labels, and QR code and unique identifier referred to in paragraphs 1 to 5-7 shall be printed or engraved visibly, <u>clearly</u> legibly and indelibly on the battery. Where this is not possible or not warranted on account of the nature and size of the battery, labels and QR code shall be affixed to the packaging and to the documents accompanying the battery.
- 7. The Commission shall, by 31 December-2025[48 months after the start of application of this <u>Regulation</u>], adopt implementing acts to establish harmonised specifications for the labelling requirements referred to in paragraphs 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3).

[7a. In case that a battery has been repurposed or remanufactured in such a way that there is a change of any of the information in accordance with this Article, the label or the marking of the initial battery shall be replaced with a new label or marking containing the information relevant for its second life as a repurposed or remanufactured battery.]

<u>Article 13a</u>

Information, accessible electronically through QR code

<u>**OR code, referred to in Article 13(5), shall provide access to the following information** <u>**of the**</u> <u>**respective battery model**</u>:</u>

- (a) from 1 January <u>2027[60 months after the start of application of this Regulation]</u>, for all batteries the information referred to in <u>paragraph Article 13(1)</u>;
- (b) from 1 January-2027[60 months after the start of application of this Regulation], for portable <u>batteries</u> and automotive batteries the information referred to <u>specified</u> in paragraph-<u>Article 13(2);</u>
- (c) from 1 January-2023[12 months after the start of application of this Regulation], for all batteries the symbol referred to in paragraph-<u>Article 13(3)</u>;
- (d) from 1 January-2023[12 months after the start of application of this Regulation], for batteries containing more than 0,0005 % mercury or more than 0,002 % cadmium or more than 0,004 % lead, the symbol referred to in paragraph <u>Article 13(4)</u>;
- (e) from [12 months after the entry into forcestart of application of this Regulation], for rechargeable industrial batteries and electric vehicle batteries the report referred to in Article 39(6)45e(6a);
- (f) from 1 July-2024[30 months after the start of application of this Regulation], for industrial electric vehicle batteries and for rechargeable industrial electric vehicle batteries with internal storage and a capacitynominal energy above 2 kWh the carbon footprint declaration referred to in Article 7(1);

- (g) from 1 January-2026[48 months after the start of application of this Regulation], for industrial electric vehicle batteries and for rechargeable industrial electric vehicle batteries with internal storage and a capacitynominal energy above 2 kWh the carbon footprint performance class referred to in Article 7(2);
- (h) from 1 January-2027[60 months after the start of application of this Regulation], for rechargeable-industrial batteries, automotive batteries and electric vehicle batteries with internal storage and a capacity<u>nominal energy</u> above 2 kWh the <u>amount share</u> of cobalt, lead, lithium or nickel recovered from waste and present in active materials in the battery, in accordance with Article 8;
- (i) from 1 January-2023[12 months after the start of application of this Regulation], for all batteries the <u>EU</u> declaration <u>of conformity</u> referred to in Article 18;
- (j) from 1 July-2023[18 months after the start of application of this Regulation], for all batteries the information referred to in points (a) to (f) of Article 60(1).

Information on the state of health and expected lifetime of batteries

- Rechargeable i<u>I</u>ndustrial batteries and electric vehicle batteries with internal storage and a capacity<u>nominal energy</u> above 2 kWh shall that include a battery management system <u>shall</u> containing in their battery management system up-to-date data on the parameters for determining the state of health and expected lifetime of batteries as laid down in Annex VII.
- Access<u>Read-only access</u> to the data in the battery management system referred to in paragraph 1 shall be provided, respecting intellectual property rights of battery <u>manuracturer</u>, on a non-discriminatory basis to the legal or natural person who has legally purchased the battery or any third party acting on their behalf at any time for the purpose of:
 - (a) evaluating the residual value of the battery and capability for further use, based on the estimation of the state of health;

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(b) facilitating the reuse, repurposing or remanufacturing of the battery;

(c) making the battery available to independent aggregators or market participants through energy storage.

2a. The Commission shall be empowered to adopt a delegated act in accordance with Article 73 to supplement this Regulation by establishing the requirements for the data and laying down the methodology for estimating the state of health of batteries.

3. The provisions of this Article shall apply in addition to those laid down in Union law on type approval of vehicles.

Chapter IV Conformity of batteries

Article 15

Presumption of conformity of batteries Harmonised standards

- For the purposes of compliance and verification of compliance <u>of batteries</u> with the requirements set out in Articles 9, 10, 12, 13(2) and [59(5)(a)] of this Regulation, <u>test</u>, measurements and calculations shall be made using a reliable, accurate and reproducible method<u>s</u>, which takes into account the generally recognised state-of-the-art methods, and whose results are deemed to be of low uncertainty, including methods set out in standards, the reference numbers of which have been published for that purpose in the Official Journal of the European Union.
- 2. Batteries which are tested followingin conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements referred toset out in Articles 9, 10, 12, 13(2) and [59(5)(a)] to the extent that those requirements are covered by such harmonised standards or parts thereof, and, if applicable, to the extent that the minimum values established for those requirements are attained.

3. Batteries which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Article 12 to the extent that those requirements are covered by such harmonised standards.

Article 16 Common specifications

- The Commission shall be empowered to adopt implementing acts laying down common specifications for the requirements set out in Articles 9, 10, 12, 13(2), [59(5)(a)]-or tests referred to in Article 15(2), where <u>at least one of the following conditions have been</u> <u>fulfilled</u>:
 - (a) those requirements or tests are not covered by harmonised standards or parts-thereof, the references of which have been published in the Official Journal-of the European Union; or

(aa) the request has not been accepted by any of the European standardisation organisations; or

- (b) the Commission observes undue delays in the adoption of requested-harmonised standards, or considers that relevant harmonised standards are not sufficient; or
- (c) the Commission has decided in accordance with the procedure referred to in Article 11(5) of Regulation (EU) No 1025/2012 to maintain with restriction or to withdraw the references to the harmonised standards or parts thereof by which those requirements or tests are covered.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3).

Batteries which are tested followingin conformity with common specifications or parts thereof shall be presumed to be in conformity with the requirements set out in Articles 9, 10, 12, 13(2) and [59(5)(a)] to the extent that those requirements are covered by those common specifications or parts thereof, and, if applicable, to the extent that the minimum values established for those requirements are attained.

3. Batteries which are in conformity with common specifications or parts thereof shall be presumed to be in conformity with the requirements set out in Article 12 to the extent that those requirements are covered by those common specifications or parts thereof. <u>The</u> <u>Commission shall amend or repeal implementing acts refered to in paragraph 1 within a</u> <u>reasonable period after publication of reference numbers of harmonised standards or</u> <u>parts thereof, covering the requirements or tests refered to in paragraph 1, in the</u> <u>Official Journal of the European Union, in order to allow manufacturers to take into</u> <u>account the changes as referred to in Article 38(6).</u>

Article 17 Conformity assessment procedures

- Before a battery is placed on the market or put it into service, the manufacturer or its authorised representative shall ensure that an assessment of the product's conformity with the requirements of Chapters II and III of this Regulation is carried out.
- Conformity assessment of batteries with the requirements set out in Articles 6, 9, 10, 11, 12, 13, and 14 shall be carried out in accordance with the procedure <u>'Module A Internal</u> production control', set out in Part A of Annex VIII.
- Conformity assessment of batteries with requirements set out in Articles 7, <u>and 8 and 39</u> shall be carried out in accordance with the <u>following procedures:</u>
 - (a) 'Module D1 Quality assurance of the production process' set out in Part B of Annex VIII; or
 - (b) 'Module G Conformity based on unit verification' set out in Part C of Annex <u>VIII</u>.
- 4. The Commission is shall be empowered to adopt delegated acts in accordance with Article 73 to amend Annex VIII by introducing additional verification steps in the conformity assessment modules or by replacing those modules set out in Annex VIII by other modules set out in Decision No 768/2008/EC, if necessary after adapting them to the specific requirements for batteries.

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 Records and correspondence relating to the conformity assessment <u>procedures</u> of batteries shall be drawn up in <u>an-the</u> official language <u>or languages</u> of the Member State where the notified body carrying out the conformity assessment procedures referred to in paragraphs 1 and 2-is established, or in a language accepted by that body.

Article 18 EU declaration of conformity

- The EU declaration of conformity shall state that the fulfilment of the requirements set out in <u>Chapters II and III Articles 6 to 10 and 12 to 14 has been demonstrated.</u>
- 2. The EU declaration of conformity shall have the model structure set out in Annex IX, shall contain the elements specified in the relevant modules set out in Annex VIII and shall be continuously-updated, if necessary. It shall be translated into the language or languages required by the Member State in which the battery is placed or made available on the market or put into service. It shall be drawn up in electronic form and where requested, it shall be provided in paper form.
- 3. Where a battery model is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall state the Union acts concerned and their publication references. It may be a dossier made up of relevant individual EU declarations of conformity.

Article 19 General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Rules and conditions for affixing the CE marking

- 1. The CE marking shall be affixed visibly, legibly and indelibly to the battery. Where that is not possible or not warranted due to the nature of the battery, it shall be affixed to the packaging and to the documents accompanying the battery.
- 2. The CE marking shall be affixed before the battery is placed on the market <u>or put into</u> <u>service</u>.
- 3. The CE marking shall be followed by the identification number of the notified body-that has carried out the conformity assessmentwhere required under Annex VIII, Part B. That identification number shall be affixed by the notified body itself or, under its instructions, by the manufacturer or by the manufacturer's its authorised representative.
- 4. The CE marking and the identification number referred to in paragraph 3 shall-may be followed, if applicable, by any labelling pictogram or other mark indicating a special risk, use or other any danger linked to the use, storage, treatment or transport of the battery.
- 5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Chapter V

Notification of conformity assessment bodies

Article 21

Notification

Member States shall notify the Commission and the other Member States of conformity assessment bodies authorised to carry out conformity assessment-in accordance with this Regulation.

Notifying authorities

- 1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article $\frac{2527}{2}$.
- 2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
- 3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 23. In addition, it shall have arrangements to cover liabilities arising out of its activities.
- 4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 23 Requirements relating to notifying authorities

- A notifying authority shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid conflicts of interest with notified bodies and conformity assessment bodies applying for notification in accordance with Article 28.
- 1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
1a. A notifying authority shall be organised and operated so as to safeguard the objectivityand impartiality of its activities.

- 2. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment of the conformity assessment bodies applying for notification in accordance with Article 28.
- 3. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
- A notifying authority shall safeguard the confidentiality of the information it obtains. However, it shall, upon request, exchange information on notified bodies with the Commission as well as with notifying authorities of other Member States and other relevant national authorities.
- 5. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 24

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 25

Requirements relateding to notified bodies

- 1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
- 2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

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- 3. A conformity assessment body shall be a third-party body independent from any and all business ties and from the battery batteries model it assesses, in particular from battery manufacturers, the battery manufacturers' trade partners, shareholding investors on the battery manufacturers' plants and from other notified bodies and the notified bodies' business associations, parent companies or subsidiaries.
- 4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, <u>importer, distributor,</u> installer, purchaser, owner, user or maintainer of the batteries which they assess, nor the representative of any of those parties. This shall not preclude the use of <u>assessed</u> batteries that are necessary for the operations of the conformity assessment body or the use of <u>such</u> batteries for personal purposes.
- A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, installation, use or maintenance of those batteries, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.
- A conformity assessment body shall ensure that the activities of its parent or sister companies, subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.
- 5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of its conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

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6. A conformity assessment body shall be capable of carrying out all the conformity assessment activities mentioned <u>tasks assigned to it</u> in Annex VIII and <u>Article 45d</u> in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times, and for each conformity assessment procedure <u>set out in Annex VIII and</u> <u>Article 45d, and each battery model for the batteries</u> in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) in-house personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities<u>tasks;</u>
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;
- (c) appropriate policies and procedures to distinguish between activities that it carries out as a notified body and other activities;
- (d) procedures for the performance of conformity assessment activities <u>tasks</u> which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the battery technology in question and the mass or serial nature of the production process.

A conformity assessment body shall <u>have the means necessary to perform the technical</u> <u>and administrative tasks connected with the conformity assessment activities in an</u> <u>appropriate manner and shall have access toat all times have access to all necessary</u> testing equipment or facilities needed for each conformity assessment procedure and each <u>battery model in relation to which it has been notified</u>.

- 7. The personnel responsible for carrying out conformity assessment tasks shall have the following:
 - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

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- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the requirements <u>and obligations</u> set out in-<u>Chapters II and III</u> <u>Articles 6 to 10 and 12 to 14 and in Articles 45a to 45e</u>, of the applicable harmonised standards referred to in Article 15 and common specifications referred to in Article 16 and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.
- 8. The impartiality of a conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities <u>tasks</u> shall be guaranteed.

The remuneration of the top level management and the personnel responsible for carrying out the conformity assessments activities <u>tasks</u> shall not depend on the number of conformity assessments carried out or on the results of those assessments.

- A conformity assessment body shall take out liability insurance unless liability is assumed by the state in accordance with national law in the <u>notifying</u> Member <u>sS</u>tate where its activities are carried out, or that <u>the</u> Member State itself is directly responsible for the conformity assessment.
- 10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment activities <u>tasks</u> in accordance with Annex VIII and Article 45d, except in relation to the competent <u>notifying authority and national</u> authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
- 11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment activities <u>tasks</u> are <u>is</u> informed of, the relevant standardisation activities and the activities of the notified body coordination group established pursuant to Article 37 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 26 Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in Article 25 in so far as the applicable harmonised standards cover those requirements.

Article 27

Subsidiaries of and subcontracting by notified bodies

- 1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 25 and shall inform the notifying authority accordingly.
- 2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established
- 3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client. The establishment and the supervision of internal procedures, general policies, codes of conduct or other internal rules, the assignment of personnel to specific tasks and the decision on certification may not be delegated to a subcontractor or a subsidiary.
- 4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex VIII.

Article 28 Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

- 2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment <u>module or modules</u> set out in Annex VIII <u>and the procedure set out in Article 45d,</u> and of the <u>battery modelbatteries</u> for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, <u>where applicable,</u> issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 25.
- 3. Where the conformity assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 25, including appropriate documentation demonstrating that the conformity assessment body is independent in the meaning of paragraph 3 of that Article.

Article 29 Notification procedure

- 1. A notifying authority may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 25.
- 2. The notifying authority shall send a notification to the Commission and the other Member States of each conformity assessment body referred to in paragraph 1 using the electronic notification tool developed and managed by the Commission.
- The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules <u>and the procedure set out in Article 45d</u>, and the batteries concerned and the relevant attestation of competence.
- 4. Where a notification is not based on an accreditation certificate as referred to in Article 28(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 25.

- 5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the notification where it includes an accreditation certificate referred to in Article 28(2) or within two months of the notification where it includes documentary evidence referred to in Article 28(3) paragraph 4. Only such conformity assessment body shall be considered as notified body for the purposes of this Regulation.
- 6. The notifying authority shall inform the Commission and the other Member States of any subs<u>s</u>equent relevant changes to the notification referred to in paragraph 2.

Article 30 Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

 The Commission shall make publicly available the list of notified bodies <u>under this</u> <u>Regulation</u>, including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 31 Changes to notifications

 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 25 or that it is failing to fulfil its obligations the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 32 Challenge of the competence of notified bodies

- 1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
- 2. The notifying authority shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.
- 3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
- 4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting requiring the notifying authority <u>Member State</u> to take the necessary corrective action, including withdrawal of the notification if necessary. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article74(2).

Article 33 Operational obligations of notified bodies

 A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Annex VIII and the procedure set out in Article 45d, as determined by its scope of notificaton.

2. A notified body shall perform its activities <u>carry out procedures referred to in paragraph 1</u> in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the battery to be assessed and the mass or serial nature of the production process.

In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the battery with this Regulation.

- 3. Where a notified body finds that the <u>applicable</u> requirements set out in <u>Chapters II and III</u> <u>Articles 6 to 10 and 12 to 14</u>, <u>in corresponding</u> harmonised standards referred to in Article 15, common specifications referred to in Article 16 or other technical specifications have not been met by a manufacturer, it shall require that manufacturer <u>or the relevant economic</u> <u>operator</u>, to take appropriate corrective action in view of a second and final <u>conformity</u> <u>assessment</u>certification decision, unless the deficiencies cannot be remedied, in which case <u>it</u> <u>shall not issue</u> the certificate <u>of conformity or approval decision</u> cannot be issued.
- 4. Where, in the course of the monitoring of conformity following the issue of a certificate of conformity or the adoption of an approval decision, a notified body finds that a battery or the supply chain due diligence policies no longer complies comply, it shall require the manufacturer to take appropriate corrective action and shall suspend or withdraw the certificate of conformity or the approval decision, if necessary.
- Where corrective action is not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates of conformity or<u>the</u> approval decisions, as appropriate.

Article 34 Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against the decisions of notified bodies is available.

Article 35 Information obligation on notified bodies

- 1. A notified body shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval decision;
 - (b) any circumstances affecting the scope of, or the conditions for, its notification;
 - (c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;
 - (d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.
- 2. A notified body shall provide other notified bodies carrying out similar conformity assessment activities <u>or third-party verification activities referred to in Article 45d</u> covering the same batteries with relevant information on issues relating to negative and, on request, positive conformity assessment results, <u>or approval decisions that have been</u> <u>refused, withdrawn, suspended or otherwise resticted, and, upon request, of approval decisions issued</u>.

Article 36 Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.



Article 37 Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between notified bodies are put in place and properly operated in the form of a sectoral group or groups of notified bodies.

A n<u>N</u>otified bod<u>iesy</u> shall participate in the work of that group-or those groups, directly or by means of designated representatives.

Chapter VI

Obligations of economic operators other than the obligations in Chapters <u>VI.A and VII</u>

Article 38 Obligations of manufacturers

1. When placing a battery on the market or putting it into service, including for the manufacturers' own purposes, manufacturers shall ensure that the battery:

- (a) has been designed and manufactured in accordance with the requirements set out in Articles 6 to <u>10, Article</u>12-and Article 14, <u>and is accompanied by instructions</u> <u>and safety information provided under those articles in a language or</u> <u>languages, which can be easily understood by end-users, as determined by the</u> <u>Member State in which the battery is to be placed on the market or put into</u> <u>service</u>; and
- (b) is labelled in accordance with the requirements set out in Article 13.
- 2. Before placing a battery on the market or putting it into service Mm anufacturers shall draw up the technical documentation referred to in Annex VIII for the battery and carry out the relevant conformity assessment procedure, as applicable and referred to, in paragraphs 2 and 3 of Article 17, or have it carried out before placing a battery on the market or putting it into service.

- 3. Where compliance of a battery with the applicable requirements has been demonstrated by the relevant conformity assessment procedure referred to in paragraphs 2 and 3 of Article 17, manufacturers shall draw up an EU declaration of conformity in accordance with Article 18 and affix the CE marking in accordance with Articles 19 and 20.
- 4. Manufacturers shall ensure that an EU declaration of conformity is drawn up in accordance with Article 18 in a language which can be easily understood by consumers and other endusers for each battery that they place on the market or put into service.

However, where several batteries are delivered simultaneously to a single user, the batch or consignment concerned may be accompanied by a single copy of the EU declaration of conformity.

- 5. Manufacturers shall keep the technical documentation referred to in Annex VIII and the EU declaration of conformity at the disposal of the market surveillance authorities and national authorities for 10 years after the battery has been placed on the market or put into service.
- 6. Manufacturers shall ensure that procedures are in place for a battery that is part of a series production to remain in conformity with this Regulation. In doing so, manufacturer shall adequately take in to account Cchanges in the production process or in battery design or characteristics and changes in the harmonised standards referred to in article 15, common specifications referred to in Article 16 or other technical specifications by reference to which the conformity of the battery is declared or by application of which its conformity is verified shall trigger a re-examination of the conformity assessment in accordance with the relevant conformity assessment procedure referred to in paragraphs 2 and 3 of Article 17.
- 7. Manufacturers shall ensure that the battery is labelled in accordance with the requirements in paragraphs 1 to <u>7</u>8 of Article 13.

- 8. Manufacturers shall indicate <u>on the battery</u> their name, registered trade name or registered trade mark, and the postal address and web address <u>or e-mail address, indicating a single contact point,</u> at which they can be contacted <u>or, where that is not possible,</u> on the <u>its</u> packaging of the battery or in a document accompanying the battery. The postal address shall indicate a single point at which the manufacturer can be contacted. Such information <u>The contact details</u> shall be in a language <u>or languages, which can be</u> easily understood by end-users and market surveillance authorities, <u>as determined by the Member State in</u> which the battery is to be placed on the market or put into service, and shall be clear, understandable and legible.
- 9. Manufacturers shall ensure that each battery that they place on the market or put into service is accompanied by instructions and safety information in accordance with Articles 6 to 12 and Article 14.
- Manufacturers shall provide access to the data on the parameters in the battery management system referred to in paragraph 1 of Article 14 [and paragraphs 1 and 2 of Article 59], in accordance with the requirements laid down in those Articles.
- 10a.Depending on the risks presented by a battery, manufacturers shall, to protect the
human health and safety of consumers, carry out sample testing of marketed
batteries, investigate, and, if necessary, keep a register of complaints, of non-
conforming batteries and battery recalls, and shall keep distributors informed of such
monitoring.
- 11. Manufacturers who consider or have reason to believe that a battery which they have placed on the market or put into service is not in conformity with <u>anv of</u> the <u>applicable</u> requirements set out in <u>Chapters II and III Articles 6 to 10 or 12 to 14</u> shall immediately take the corrective action necessary to bring that battery into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the battery presents a risk, manufacturers shall immediately inform the national <u>market surveillance</u> authority of the Member State in which they made the battery available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective action taken.

12. Manufacturers shall, further to a reasoned request from a national authority-, provide it that authority with all the information and technical-documentation necessary to demonstrate the conformity of the battery with the requirements set out in Chapters II and III Articles 6 to 10 and 12 to 14, in a language, which can be easily understood by that authority. That information and the technical-documentation shall be provided in either paper or electronic format. Manufacturers shall cooperate with the national authority, at its request, on any action taken to eliminate the risks posed by a battery which they have placed on the market or put into service.

Article 39

Obligation for economic operators that place rechargeable industrial batteries and electric-vehicle batteries with internal storage and a capacity above 2 kWh on the market to establish supply chain due diligence policies

- 1. As of [12 months after the entry into force of the Regulation] the economic operator that places rechargeable industrial batteries and electric-vehicle batteries with internal storage and a capacity above 2 kWh on the market shall comply with the supply chain due diligence obligations set out in paragraphs 2 to 5 of this Article and shall keep documentation demonstrating its respective compliance with those obligations, including the results of the third-party verification carried out by notified bodies.
- 2. The economic operator referred to in paragraph 1 shall
 - (a) adopt, and clearly communicate to suppliers and the public, a company policy for the supply chain of raw materials indicated in Annex X, point 1;
 - (b) incorporate in its supply chain policy standards consistent with the standards set out in the model supply chain policy in Annex II to the OECD Due Diligence Guidance;

- (c) structure its respective internal management systems to support supply chain due diligence by assigning responsibility to senior management to oversee the supply chain due diligence process as well as maintain records of those systems for a minimum of five years;
- (d) establish and operate a system of controls and transparency over the supply chain, including a chain of custody or traceability system or the identification of upstream actors in the supply chain.

Such a system shall be supported by documentation that provides the following information:

(i) description of the raw material, including its trade name and type;

- (ii) name and address of the supplier that supplied the raw material present in the batteries to the economic operator that places on the market the batteries containing the raw material in question;
- (iii) country of origin of the raw material and the market transactions from the raw material's extraction to the immediate supplier to the economic operator;
- (iv) quantities of the raw material present in the battery placed on the market, expressed in percentage or weight.

The requirements set out in the current point (d) may be implemented through participation in industry-led schemes.

(e) incorporate its supply chain policy into contracts and agreements with suppliers, including their risk management measures;

- (f) establish a grievance mechanism as an early-warning risk-awareness system or provide such mechanism through collaborative arrangements with other economic operators or organisations, or by facilitating recourse to an external expert or body, such as an ombudsman.
- 3. The economic operator referred to in paragraph 1 shall
 - (a) identify and assess the adverse impacts associated to the risk categories listed in Annex X, point 2, in its supply chain on the basis of the information provided pursuant to paragraph 2 against the standards of their supply chain policy;
 - (b) implement a strategy to respond to the identified risks designed so as to prevent or mitigate adverse impacts by:
 - (i) reporting findings of the supply chain risk assessment to senior management designated for that purpose;
 - (ii) adopting risk management measures consistent with Annex II to the OECD Due Diligence Guidance, considering their ability to influence, and where necessary take steps to exert pressure on suppliers who can most effectively prevent or mitigate the identified risk;
 - (iii) implementing the risk management plan, monitoring and tracking performance of risk mitigation efforts, reporting back to senior management designated for this purpose and considering suspending or discontinuing engagement with a supplier after failed attempts at mitigation, based on relevant contractual arrangements in line with the second subparagraph to paragraph 2 above;
 - (iv) undertaking additional fact and risk assessments for risks requiring mitigation, or after a change of circumstances.

If the economic operator referred to in paragraph 1 pursues risk mitigation efforts while continuing trade or temporarily suspending trade, it shall consult with suppliers and with the stakeholders concerned, including local and central government authorities, international or civil society organisations and affected third parties, and agree on a strategy for measurable risk mitigation in the risk management plan.

The economic operator referred to in paragraph 1 shall identify and assess the probability of adverse impacts in the risk categories listed in Annex X, point 2, in its supply chain based on available reports by third-party verification done by a notified body concerning the suppliers in that chain, and, by assessing, as appropriate, its due diligence practices. Those verification reports shall be in accordance with the first subparagraph in paragraph 4. In the absence of such third-party verification reports concerning suppliers, the economic operator referred to in paragraph 1 shall identify and assess the risks in its supply chain as part of its own risk management systems. In such cases, economic operators referred to in paragraph 1 shall carry out third party verifications of its own supply chains due diligence via a notified body in accordance with the first subparagraph in paragraph 4.

The economic operator referred to in paragraph 1 shall report the findings of the risk assessment referred to in the third subparagraph to its senior management designated for that purpose and a response strategy designed to prevent or mitigate adverse impacts shall be implemented.

4. The economic operator referred to in paragraph 1 shall have their supply chain due diligence policies verified by a notified body ("third-party verification").

The third-party verification by a notified body shall:

 (a) include in its scope all activities, processes and systems used by economic operators to implement their supply chain due diligence requirements in accordance with paragraphs 2, 3 and 5;

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- (b) have as its objective the determination of conformity of the supply chain due diligence practices of economic operators placing batteries on the market with paragraphs 2, 3 and 5;
- (c) make recommendations to the economic operators that place batteries on the market on how to improve their supply chain due diligence practices;
- (d) respect the audit principles of independence, competence and accountability, as set out in the OECD Due Diligence Guidance;
- 5. The economic operator referred to in paragraph 1 shall make available upon request to Member States' market surveillance authorities the reports of any third-party verification carried out in accordance with paragraph 4 or evidence of compliance with a supply chain due diligence scheme recognised by the Commission in accordance with Article 72.
- 6. The economic operator referred to in paragraph 1 shall make available to its immediate downstream purchasers all information gained and maintained pursuant to its supply chain due diligence policies with due regard for business confidentiality and other competitive concerns.

The economic operator referred to in paragraph 1 shall on an annual basis, publicly report as widely as possible, including on the internet, on its supply chain due diligence policies. That report shall contain the steps taken by that economic operator to comply with the requirements set out in paragraphs 2 and 3, including findings of significant adverse impacts in the risk categories listed in Annex X, point 2, and how they have been addressed, as well as a summary report of the third-party verifications carried out in accordance with point 4, including the name of the notified body, with due regard for business confidentiality and other competitive concerns.

Where the economic operator referred to in paragraph 1 can reasonably conclude that the raw materials listed in Annex X, point 1, that are present in the battery are derived only from recycled sources, it shall publicly disclose its conclusions in reasonable detail, with due regard for business confidentiality and other competitive concerns.

- 7. The Commission shall develop guidance as regards the application of the due diligence requirements defined in paragraphs 2 and 3 of this Article, with regard to the social and environmental risks referred to in Annex X, point 2, and particularly in line with the international instruments referred to in Annex X, point 3.
- 8. The Commission is empowered to adopt delegated acts in accordance with Article 73 to:
 - (a) Amend the lists of raw materials and risk categories in Annex X in view of scientific and technological progress in battery manufacturing and chemistries and amendments to Regulation (EU) 2017/821;
 - (b) amend the obligations on the economic operator referred to in paragraph 1 set out in paragraphs 2 to 4 in view of amendments to Regulation (EU) 2017/821 and changes to the due diligence recommendations set out in Annex I to the OECD Due Diligence Guidance.

Article 40

Obligations of *manufacturer's* authorised representatives

- Where the manufacturer of a battery is not established in a Member State, the battery may only be placed on the Union market if the manufacturer designates a sole authorised representative.
- The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all batteries of the same battery model<u>A manufacturer may, by a written mandate, designate an authorised representative</u>.

- 3. The obligations laid down in Article 38(1) and Articles 45a to 45e and the obligation to draw up technical documentation shall not form part of the authorised representative's mandate.
- An manufacturer's authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The authorised representative shall provide a copy of the mandate to the competent authority, upon request. The mandate shall allow the manufacturer's authorised representative to do at least the following:
 - (a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
 - (b) keep the EU declaration of conformity, and the updated technical documentation and the verification report and approval decision referred to in paragraph 4a of Article 45d and the audit reports referred to in paragraph 1a of Article 45a at the disposal of market surveillance national authorities for 10 years after the battery has been placed on the market or put into service;
 - (c) further to a reasoned request from a national authority, provide that authority with all the information and <u>technical</u> documentation necessary to demonstrate the conformity of <u>the a</u> battery with the requirements set out in Articles 6 to 10 and <u>12 to 14 in a language, which can be easily understood by that authority. That</u> <u>information and the technical documentation shall be provided in either paper</u> <u>or electronic format</u>;
 - (d) cooperate with the national authorities, at their request, on any action taken to eliminate the risks posed by batteries covered by the authorised representative's mandate;.
 - (e) fulfil the manufacturer's obligations under Chapter V
 - (f) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.

Article 41

Obligations of importers

- 1. Importers shall only place on the market or put into service a battery which is compliant with the <u>applicable</u> requirements of <u>Chapters II and IIIArticles 6 to 10 and 12 to 14.</u>
- Before placing a battery on the market or putting it into service, importers shall <u>verify</u> <u>that:</u>
 - (a) verify that the EU declaration of conformity and technical documentation referred to in Annex VIII have been drawn up and the relevant that an appropriate conformity assessment procedure, as applicable and referred to in paragraphs 2 and 3 of Article 17, has been carried out by the manufacturer;-
 - (b) They shall verify that the manufacturer has drawn up the technical documentation referred to in Annex VIII, that the battery bears the CE marking referred to in Article 19, and that the battery is labelled in accordance with Article 13 and the QR code referred to in Article 13(5),
 - (c) the battery is accompanied by the required documents and by instructions and safety information in a language or languages, which can be easily understood by end-users, as determined by the Member State in which the battery is to be made availabe on the market; and
 - (d) that the manufacturer has complied with the obligations requirements set out in paragraphs 7, 8 and 9 of Article 38(8).

Where an importer considers or has reason to believe that a battery is not in conformity with the <u>applicable</u> requirements set out in <u>Chapters II and III Articles 6 to 10 and 12 to</u> <u>14</u>, the importer shall not place <u>itthe battery</u> on the market or put it into service until it has been brought into conformity. Furthermore, where the battery presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.



- 3. Importers shall indicate on the battery their name, registered trade name or registered trade mark, and the postal address-at which they can be contacted and web address or e-mail address, indicating a single contact point, at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the battery. The contact details shall be in a language or languages, which can be easily understood by consumers, other end-users and the market surveillance authorities, as determined by the Member State in which the battery is to be made availabe on the market, and shall be clear, understandable and legible.
- Importers shall ensure the manufacturer has fulfilled its obligations under paragraphs 7, 9 and 10 of Article 38.
- Importers shall ensure that, while a battery is under their responsibility, storage or transport conditions do not jeopardise its compliance with the <u>applicable</u> requirements set out in <u>Chapters II and III Articles 6 to 10 and 12 to 14</u>.
- 6. When deemed appropriate with regard to <u>Depending on</u> the risks presented by a battery, importers shall, to protect the human health and safety of consumers, carry out sample testing of marketed batteries, investigate, and, if necessary, keep a register of complaints, of non-conforming batteries and battery recalls, and shall keep distributors informed of such monitoring.
- 7. Importers who consider or have reason to believe that a battery, which they have placed on the market or put into service, is not in conformity with the <u>applicable</u> requirements set out in <u>Chapters II and III</u> <u>Articles 6 to 10 and 12 to 14</u>, shall immediately take the corrective action necessary to bring that battery into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the battery presents a risk, importers shall immediately inform the <u>national-market surveillance</u> authority of the Member State in which they made the battery available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective action taken.
- 8. Importers shall keep the technical documentation referred to in Annex VIII and a copy of the EU declaration of conformity at the disposal of the national authorities and market surveillance authorities for 10 years after the battery has been placed on the market or put into service.

9. Importers shall, further to a reasoned request from a national authority, provide it-that authority with all the information and technical documentation necessary to demonstrate the conformity of a battery with the applicable requirements set out in Chapters II and III Articles 6 to 10 and 12 to 14, in a language or languages, that which can be easily understood by that authority. That information and the technical documentation shall be provided either in paper or electronic format. Importers shall cooperate with the national authority, at its request, on any action taken to eliminate the risks posed by batteries, which they have placed on the market or put into service.

Article 42

Obligations of distributors

- 1. When making a battery available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
- 2. Before making a battery available on the market, distributors shall verify that:
 - (a) the manufacturer, the manufacturer's authorised representative, importer or other distributors are registered on the territory of a Member State in accordance with Article 46 for the battery there is a producer or producer responsibility organisation registered in the register of producers referred to in Article 46;
 - (b) the battery bears the CE marking referred to in Article 19, that the battery is labelled in accordance with Article 13 and the QR code referred to in Article <u>13(5);</u>
 - (c) <u>the</u> battery is accompanied by the required documents in a language which can be easily understood by the consumers and other end-user in the Member State in which the battery is to be made available on the market and by instructions and safety information in language or languages, which can be easily understood by end-users and the market surveillance authorities, as determined by the Member State in which the battery is to be made available on the market or put into service; and

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- (d) the manufacturer and the importer have complied with the requirements set out in paragraphs 7, 9 and 10 of Article 38(8) and Article 41(3) and (4) respectively.
- 3. Where a distributor considers or has reason to believe that a battery is not in conformity with <u>any of</u> the <u>applicable</u> requirements set out in <u>Chapters II and III</u> <u>Articles 6 to 10 or</u> <u>12 to 14 or for the battery there is no producer or producer responsibility</u> <u>organisation registered in the register of producers referred to in Article 46</u>, the distributor shall not make the battery available on the market until it has been brought into conformity. Furthermore, where the battery presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the relevant market surveillance authorities.
- Distributors shall ensure that, while a battery is under their responsibility, storage or transport conditions do not jeopardise its compliance with the <u>applicable</u> requirements set out in <u>Chapters II and III</u> <u>Articles 6 to 10 and 12 to 14</u>.
- 5. Distributors who consider or have reason to believe that a battery, which they have made available on the market, is not in conformity with <u>any of</u> the <u>applicable</u> requirements set out in <u>Chapters II and III Articles 6 to 10 or 12 to 14</u> shall make sure that the corrective action necessary to bring that battery into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the battery presents a risk, distributors shall immediately inform the national authority of the Member States in which they made the battery available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective action taken.
- 6. Distributors shall, further to a reasoned request from a national authority-provide it-that authority with all the information and the technical documentation necessary to demonstrate the conformity of a battery with the applicable requirements set out in Chapters II and III-Articles 6 to 10 and 12 to 14 in a language, that which can be easily understood by that authority. That information and the technical documentation shall be provided in paper or electronic format. Distributors shall cooperate with the national authority, at its request, on any action taken to eliminate the risks posed by batteries that they have made available on the market.

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Article 43 Obligations of fulfilment service providers

Fulfilment service providers shall ensure that, for batteries that they handle, the conditions during warehousing, packaging, addressing or dispatching, do not jeopardise the batteries' compliance with the requirements set out in <u>Chapters II and III Articles 6 to 10 and 12 to 14</u>.

Article 44

Case in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and that importer or distributor shall be subject to the obligations of the manufacturer under Article 4038, where

- (a) a battery is placed on the market or put into service under that importer's or distributor's own name or trademark; or
- (b) a battery already placed on the market or put into service is modified by that importer or distributor in such a way that compliance with the requirements of this Regulation may be affected; or
- (c) the purpose of a battery already placed on the market or put into service is modified by that importer or distributor.

Article 45

Identification of economic operators

Upon a request of a market surveillance authority or a national authority, for a period of 10 years after the placing on the market of a battery, economic operators <u>and independent operators</u> <u>referred to in Article 44a</u> shall provide information on the following:

- (a) the identity of any economic operator that has supplied them with a battery;
- (b) the identity of any economic operator to which they have supplied a battery, as well as the quantity and exact models.

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Chapter VI.A

Obligations of economic operators on supply chain due diligence policies

Obligation for economic operators that place rechargeable industrial batteries and electricvehicle batteries with internal storage and a capacity above 2 kWh on the market to establish supply chain due diligence policies Supply chain due diligence policies

- (39)1. As of [12-36 months after the start -of the Regulation of application of this Regulation], the economic operator that places rechargeable industrial batteries and electric-vehicle batteries with internal storage and a capacity nominal energy above 2 kWh on the market or puts them into service shall comply with the supply chain due diligence obligations set out in paragraphs 1a and 1b and paragraphs 2 to 5of this Articles 45b to 45e and shall, to that end, set up and implement supply chain due diligence policies.
 - 1a.The economic operator referred to in paragraph 1 shall have its supply chain duediligence policies verified by a notified body ('third-party verification') in accordancewith Article 45d and periodically audited by the notified body to make sure that thesupply chain due diligence policies are maintained and applied in accordance with therequirements set out in Articles 45b, 45c and 45e. The notified body shall provide theaudited economic operator with an audit report.
 - <u>The economic operator referred to in paragraph 1</u> shall keep documentation demonstrating its respective compliance with <u>those the</u> obligations <u>set out in Articles 45b</u> <u>to 45e</u>, including the <u>results of the third party</u> verification <u>report and approval decision</u> <u>carried out by notified bodies</u> <u>referred to in 45d and the audit reports referred to in</u> <u>paragraph 1a, for ten years after the last battery under the relevant supply chain due</u> <u>diligence policies has been placed on the market or put into service</u>.

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- (39)7. By [... months after the start of application of this Regulation], Fthe Commission shall develop guidance publish guideline as regards the application of the due diligence requirements defined in paragraphs <u>Articles 245b</u> and <u>345c</u> of this Article, with regard to the social and environmental risks referred to in Annex X, point 2, and particularly in line with the international instruments referred to in Annex X, point 3.
- (39)8. The Commission is shall be empowered to adopt delegated acts in accordance with Article 73 to:
 - (a) Amend amend the lists of raw materials in Annex X, point 1, and risk categories in Annex X, point 2, in view of scientific and technological progress in battery manufacturing and chemistries and amendments to Regulation (EU) 2017/821;.
 - (b) amend the obligations on the economic operator referred to in paragraph 1 set out in paragraphs 2 to 4 in view of amendments to Regulation (EU) 2017/821 and changes to the due diligence recommendations set out in Annex I to the OECD Due Diligence Guidance.

<u>Article 45b</u>

Economic operator's management system

- (39)2. The economic operator referred to in paragraph 1<u>Article 45a</u> shall:
 - (a) adopt, and clearly communicate to suppliers and the public, a company <u>supply chain</u> <u>due diligence</u> policy for the supply chain of raw materials indicated in Annex X, point 1;
 - (b) incorporate in its supply chain <u>due diligence</u> policy standards consistent with the standards set out in the model supply chain policy in Annex II to the OECD Due Diligence Guidance, <u>and take into account other international due diligence</u> <u>standards, such as United Nations Guiding Principles on Business and Human Rights and OECD Guidelines for Multinational Enterprises;</u>

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- (c) structure its respective internal management systems to support supply chain due diligence by assigning responsibility to <u>the most</u> senior management <u>level of the</u>
 <u>economic operator</u> to oversee the supply chain due diligence <u>process policy</u> as well as maintain records of those systems for a minimum of <u>five ten</u> years;
- (d) establish and operate a system of controls and transparency over the supply chain, including a chain of custody or traceability system or the identification of upstream actors in the supply chain.

Such a system shall be supported, with due regard for multilateral confidentiality agreements along the supply chain, by documentation that provides the following information:

- (i) description of the raw material, including its trade name and type;
- (ii) name and address of the supplier that supplied the raw material present in the batteries to the economic operator that places on the market the batteries containing the raw material in question;
- (iii) country of origin of the raw material and the market transactions from the raw material's extraction to the immediate supplier to the economic operator <u>that</u> <u>places the battery on the market;</u>
- (iv) quantities of the raw material present in the battery placed on the market <u>or put</u> <u>into service</u>, expressed in percentage or weight-<u>:</u>

(v) available third-party verification reports done by a notified body and concerning the-up-stream suppliers.

The requirements set out in the current point (d) may be implemented through participation in industry-led schemes.

 (e) incorporate its supply chain <u>due diligence</u> policy into contracts and agreements with suppliers, including their-risk management measures;

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(f) establish a grievance mechanism as an early-warning risk-awareness system or provide such mechanism through collaborative arrangements with other economic operators or organisations, or by facilitating recourse to an external expert or body, such as an ombudsman<u>or an OECD national contact point to the OECD</u> <u>Guidelines for Multinational Enterprises</u>.

<u>Article 45c</u> <u>Risk management plan</u>

- (39)3. The economic operator referred to in paragraph 1<u>Article 45a</u> shall:
 - (a) <u>identify risks in its supply chain, associated to the risk categories listed in Annex</u>
 <u>X, point 2, including as described in the OECD Due Diligence Guidance for</u>
 <u>Responsible Business Conduct, Chapter II, or in a equivalent way;</u>
 - (b) identify and assess the adverse impacts associated to the risk, referred to in point (a)-categories listed in Annex X, point 2, in its supply chain on the basis of the information provided pursuant to paragraph 2<u>Article 45b and any other relevant</u> information that is either publicly available or provided by stakeholders, against the standards of their its supply chain policy;
 - (bc) <u>design and implement a strategy to respond to the identified risks designed so as to</u> prevent or mitigate adverse impacts by:
 - (i) reporting findings of the supply chain risk assessment to <u>the most</u> senior management designated for that <u>purpose</u> level of the economic operator assigned in accordance with point (c) of Article 45b;
 - (ii) adopting risk management measures consistent with Annex II to the OECD Due Diligence Guidance, considering their ability to influence, and where necessary take steps to exert pressure on suppliers who can most effectively prevent or mitigate the identified risk;

- (iii) <u>designing and</u> implementing the risk management plan, monitoring and tracking performance of risk mitigation efforts, reporting back to <u>the most</u> senior management designated for this purpose <u>level of the economic</u> <u>operator assigned in accordance with point (c) of Article 45b</u>, and considering suspending or discontinuing engagement with a supplier after failed attempts at mitigation, based on relevant <u>contractual contracts and</u> arrangements in line with the second subparagraph <u>referred</u> to <u>in point (e) of Article 45b</u>, above;
- (iv) undertaking additional fact and risk assessments for risks requiring mitigation, or after a change of circumstances.
- 3a. If the economic operator referred to in paragraph 1<u>Article 45a</u> pursues risk mitigation efforts while continuing trade or temporarily suspending trade, it shall consult with suppliers and with the stakeholders concerned, including local and central government authorities, international or civil society organisations and affected third parties, and agree on a strategy for measurable risk mitigation in the risk management plan referred to in point (c)(iii).
- 3b. The economic operator referred to in paragraph 1<u>Article 45a</u> shall identify and assess the probability of adverse impacts in the risk categories listed in Annex X, point 2, in its supply chain based on available reports by third-party verification reports done by a notified body <u>and</u> concerning the suppliers in that chain, and, by assessing, as appropriate, its <u>their</u> due diligence practices. Those verification reports shall be in accordance with the first subparagraph in paragraph 4<u>Article 45d</u>. In the absence of such third-party verification reports concerning suppliers, or in case such third-party verification reports concerning suppliers are not in accordance with Article 45d, the economic operator referred to in paragraph 1<u>Article 45a</u> shall identify and assess the risks in its supply chain as part of its own risk management systems. In such cases, economic operators referred to in paragraph 1<u>Article 45a</u> shall carry out third party verifications of its own supply chains due diligence via a notified body in accordance with the first subparagraph in paragraph 4<u>Article 45a</u>.

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3c. The economic operator referred to in paragraph 1<u>Article 45a</u> shall report the findings of the risk assessment referred to in the third subparagraphparagraph 3b to its most senior level management designated for that purpose assigned in accordance with point (c) of <u>Article 45b</u>, and a response strategy designed to prevent or mitigate adverse impacts to respond to the identified risks, referred to in point (c), shall be implemented.

<u>Article 45d</u> <u>Third-party verification of supply chain due diligence policies</u>

(39)4. The economic operator referred to in paragraph 1 shall have their supply chain due diligence policies verified by a notified body ("third-party verification").

The third-party verification by a notified body shall:

- (a) include in its scope all activities, processes and systems used by economic operators to implement their supply chain due diligence requirements in accordance with paragraphs 2, 3 and 5<u>Artices 45a, 45b and 45e;</u>
- (b) have as its objective the determination of conformity of the supply chain due diligence practices of economic operators placing batteries on the market with paragraphs 2, 3 and 5<u>Artices 45a, 45b and 45e;</u>

(b bis) where relevant, carry out checks on undertakings and gather information from stakeholders;

- (c) make recommendations to the economic operators that place batteries on the market on how to improve their supply chain due diligence practices;
- (d) respect the audit principles of independence, competence and accountability, as set out in the OECD Due Diligence Guidance;



4a.The notified body shall issue a verification report that records the activitiesundertaken in accordance with the paragraph 4 and their outcomes. Where thesupply chain due diligence policies of the economic operator referred to in paragraph4 comply with the obligations set out in Articles 45a and 45c, the notified body shallissue an approval decision.

<u>Article 45e</u> <u>Disclosure of information on supply chain due diligence policies</u>

- (39)5. The economic operator referred to in paragraph 1-Article 45a shall make available upon request to Member States' market surveillance authorities or national authorities the reports of any third-party-verification report carried outor approval decision issued in accordance with paragraph 4-Article 45d, the audit reports referred to in paragraph 1a of Article 45a or and available evidence of compliance with a supply chain due diligence scheme recognised by the Commission in accordance with Article 7245f.
- (39)6. The economic operator referred to in paragraph 1-<u>Article 45a</u> shall make available to its immediate downstream purchasers all <u>relevant</u> information gained and maintained pursuant to its supply chain due diligence policies with due regard for business confidentiality and other competitive concerns.
- <u>6a.</u> The economic operator referred to in paragraph 1-<u>Article 45a</u> shall on an annual basis, review and make publicly report-available as widely as possible, including on the internet, report on its supply chain due diligence policies. That report shall contain the <u>data and information on</u> steps taken by that economic operator to comply with the requirements set out in paragraphs 2 and 3<u>Articlec 45a and 45c</u>, including findings of significant adverse impacts in the risk categories listed in Annex X, point 2, and how they have been addressed, as well as a summary report of the third-party verifications carried out in accordance with point 4<u>Article 45d</u>, including the name of the notified body, with due regard for business confidentiality and other competitive concerns.

<u>6b.</u> Where the economic operator referred to in paragraph 1-<u>Article 45a</u> can reasonably conclude that the raw materials listed in Annex X, point 1, that are present in the battery are derived only from recycled sources, it shall publicly disclose its conclusions in reasonable detail, with due regard for business confidentiality and other competitive concerns.

Article 72<u>45f</u> Supply-<u>Recognition of supply</u> chain due diligence schemes

- Governments, industry associations and groupings of interested organisations-<u>that have</u> developed and oversee due diligence schemes ("scheme owners") may apply to the Commission to have their supply chain due diligence schemes recognised by the Commission. The Commission is-<u>shall be</u> empowered to adopt implementing acts establishing the information requirements that the application to the Commission shall contain. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3).
- 2. Where, on the basis of the evidence and information provided pursuant to the first subparagraph 1, the Commission determines that the supply chain due diligence scheme referred to in paragraph 1, enables that economic operators- to comply with <u>fulfil</u> the requirements set out in Articles <u>39 45a to 45c and 45e</u> of this Regulation, it shall adopt an implementing act granting that scheme a recognition of equivalence with the requirements set out in this Regulation. The OECD Secretariat shall, as appropriate, be consulted prior to the adoption of such implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3).

When making a determination on the recognition of a due diligence scheme, the Commission shall take into account the diverse industry practices covered by that scheme and shall have regard to the risk-based approach and method used by that scheme to identify risks.

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- 3. The Commission is shall be empowered to adopt implementing acts setting out the criteria and the methodology according to which the Commission shall determine, in accordance with paragraph 2, whether supply chain due diligence schemes ensure that economic operators fulfil the requirements set out in Articles 3945a to 45c and 45e of this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3). The Commission shall also, as appropriate, periodically verify that recognised supply chain due diligence schemes continue to fulfil the criteria that led to a recognition of equivalence decision adopted pursuant to paragraph 2.
- The owner of a supply chain due diligence scheme for which the recognition of equivalence was granted in accordance with paragraph 2 shall inform the Commission without delay of any changes or updates made to that scheme. <u>The Commission shall assess whether such changes or updates affect the basis for the recognition of equivalence of that scheme and take appropriate action.</u>
- 5. If there is evidence of repeated or significant cases where economic operators implementing a scheme recognised in accordance with paragraph 2 have failed to fulfil the requirements set out in Article 39-45a to 45c and 45e of this Regulation, the Commission shall examine, in consultation with the owner of the recognised scheme, whether those cases indicate deficiencies in the scheme.
- 6. Where the Commission identifies a failure to comply with the requirements set out in Articles <u>3945a to 45c and 45e</u> of this Regulation or deficiencies in a recognised supply chain due diligence scheme, it may grant the scheme owner an appropriate period of time to take remedial action.

- 7. Where the scheme owner-fails or refuses to take the necessary remedial action, and where the Commission has determined that the failure or deficiencies referred to in paragraph 6 compromise the ability of the economic operator referred to in Article 3945a(1) implementing a scheme to comply with the requirements set out in Articles 3945a to 45c and 45e of this Regulation or where repeated or significant cases of non-compliance by economic operators implementing a scheme are due to deficiencies in the scheme, the Commission shall adopt an implementing act withdrawing the recognition of equivalence of the scheme. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3).
- 8. The Commission shall establish and keep up-to-date a register of recognised supply chain due diligence schemes. That register shall be made publicly available on the internet.

Chapter VII End-of-life management of batteries

[...]

Chapter VIII

Electronic exchange of information <u>on industrial batteries and electric</u> <u>vehicle batteries with a nominal energy above 2 kwh</u>

Article 64

Electronic exchange system

 By 1 January-2026[48 months after the start of application of this Regulation], the Commission shall set up the electronic exchange system for battery information <u>"The</u> <u>European Electronic Exchange System" (hereafter:</u> "the system").

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- 2. The system shall contain the information and data on rechargeable-industrial batteries and electric vehicle batteries with internal storage and a capacity<u>nominal energy</u> above 2 kWh as laid down in Annex XIII. That information and data shall be sortable and searchable, respecting open standards for third party use.
- 3. The economic operators that place <u>a rechargeable an</u> industrial batter<u>iesy</u> or an electric vehicle batter<u>iesy</u> with <u>internal storage a nominal energy above 2 kWh</u> on the market <u>or put it into service</u> shall make the information referred to in paragraph 2 available electronically in a machine readable format using interoperable and easily accessible data services in the format established in accordance with paragraph 5.
- 4. The Commission shall, after a review in accordance with Article $62(5\underline{4})$, publish through the <u>System system</u> the information referred to in Article 62(1) as well as the assessment referred to in Article $62(5\underline{4})$.
- The Commission shall, by 31 December-2024[36 months after the start of application of this Regulation], adopt implementing acts to establish:
 - (a) the architecture of the system, based, where applicable, on the European
 <u>Commission's Connecting Europe Facility principles for the eDelivery Network;</u>
 - (b) the format in which the data and information referred to in paragraph 2 shall be made available;
 - (c) the rules for accessing, sharing, managing, exploring, publishing and reusing of the information and data in the system.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3).
Article 65

Battery passport

- By From either 1 January-2026[48 months after the start of application of this Regulation] or [12 months] after adoption of implemening acts referred to in paragraph 7, whichever is later, each industrial battery and electric vehicle battery with a nominal energy above 2 kWh placed on the market or put into service and whose capacity is higher than 2 kWh-shall have an electronic record ("battery passport").
- 2. The battery passport shall be unique for each individual battery referred to in paragraph 1 and shall be identified through a unique identifier that the economic operator placing the battery on the market **or putting it into service** shall attribute to it and which shall be printed or engraved on it.
- 3. The battery passport shall be linked to the information about the basic characteristics of each battery type and model stored in the data sources of the System established pursuant to Article 64. Each individual battery passport shall consist of a combination of data common to its battery model and data specific to its particular usage, providing, at least, the following information:
 - (a) common information on the battery model referred to in Article 64(2) and <u>Annex XIII;</u>
 - (b) information on the status of the battery, defined as 'original', ['repurposed', <u>'remanufactured' or 'waste'];</u>
 - (c) information about the values for performance and durability parameters referred to in Article 10(1), when the battery is placed on the market or put into service and when it is subject to changes in its status;
 - (d) specific data to each individual battery, including the number of charging anddischarging cycles and negative events, as well as periodically recordedinformation on the operating environmental conditions, including temperature,and on the state of charge.

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The economic operator that places an industrial battery or an electric vehicle battery with a **nominal energy above 2 kWh** on the market **or put it into service** shall ensure that the data included in the battery passport is <u>are</u> accurate, complete and up-to-date.

- The <u>economic operators referred to in paragraph 3 shall make the</u> battery passport shall be accessible online, through electronic systems interoperable with the System system established pursuant to Article 64. <u>The information and data in the battery</u> passport shall be sortable and searchable, respecting open standards for third party <u>use.</u>
- 5. The battery passport shall allow access to information about the values for performance and durability parameters referred to in Article 10(1), when the battery is placed on the market and when it is subject to changes in its status.
- [6. When the change in the status <u>of a battery reffered to in paragraph 1</u> is due to repairing or repurposing <u>or remanufacturing</u> activities, the responsibility for the battery record in the battery passport shall be transferred to the economic operator that is considered to place the <u>repurposed or remanufactured</u> industrial battery or the <u>repurposed or</u> <u>remanufactured</u> electric vehicle battery on the market or that-puts it into service. <u>This</u> <u>battery record shall be considered as a new battery passport and shall be linked to the</u> <u>battery passport or passports of the previous battery or batteries, that are sources of parts</u> <u>or modules, used in the repurposed or remanufactured battery.</u>
- 6a. When there is a change of a status of a battery to a waste battery, the responsibility for the battery record in the battery passport shall be transferred to the producers or, where appointed in accordance with Article 47(2), producer responsibility organisations acting on their behalf.]
- 6b.The Commission is shall be empowered to adopt a delegated act in accordance withArticle 73 to amend or supplement the information that the battery passport shallprovide in view of technical and scientific progress.
- The Commission shall, by 31 December ... [36 months after the start of application of this Regulation], adopt implementing acts to establish:

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- (a) the architecture of an open network for the data exchange needed for the battery passport, based, where applicable, on the European Commission's <u>Connecting Europe Facility principles for the eDelivery Network;</u>
- (b) the format in which the data and information referred to in paragraph 3 shall be made available;
- (b) the rules for accessing, sharing, managing, exploring, publishing and reusing of the information and data accessible through the battery passport.

Those implementing acts shall be adopted **by** [*36 months after the start of application of this Regulation*] in accordance with the examination procedure referred to in Article 74(3).

Chapter IX

Union market surveillance, control of batteries entering the Union market and Union safeguard procedures

Article 66

Procedure at national level for dealing with batteries presenting a risk

1. Without prejudice to Article 19 of the Regulation (EU) 2019/1020, Wwhere the market surveillance authorities of one Member State have sufficient reason to believe that a battery covered by this Regulation presents a risk to human health or safety of persons, to property or to the environment, they shall carry out an evaluation in relation to the battery concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market survceillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the battery does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action, within a reasonable period prescribed by the market surveillance authorities and commensurate with the nature of the risk, to bring the battery into compliance with those requirements, to withdraw it from the market, or to recall it. within a reasonable period which is commensurate with the nature of the risk referred to in the first subparagraph.

The market surveillance authorities shall inform the relevant notified body accordingly.

- 2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.
- 3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the concerned batteries that the economic operator has made available on the market throughout the Union.
- 4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the batteries being made available on their national market, to withdraw the battery from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

- 5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant battery, the origin of that battery, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:
 - (a) failure of the battery to meet any of the applicable requirements set out in Chapter II or III Articles 6 to 10 or 12 to 14 of this Regulation;
 - (b) shortcomings in the harmonised standards referred to in Article 15;
 - (c) shortcomings in the common specifications referred to in Article 16.
- 6 Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the battery concerned, and, in the event of disagreement with the adopted national measure, of their objections.
- 7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by market surveillance authorities a Member State, that measure shall be deemed justified.
- 8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the battery from the market, are taken in respect of the battery concerned without delay.

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Article 67 Union safeguard procedure

Where, on completion of the procedure set out in Article 66(3) and (4), objections are raised against a measure taken by <u>market surveillance authorities</u> Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide by means of an implementing act adopt an implementing act in the form of a decision determining whether the national measure is justified or not.

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(3).

2. The Commission shall address its decision to all Member States and shall without delay communicate it to them and the relevant economic operator or operators.

If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant battery is withdrawn from their market, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

- 3. Where the national measure is considered justified and the non-compliance of the battery is attributed to shortcomings in the harmonised standards referred to in Article 15 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.
- 3a.Where the national measure is considered justified and the non-compliance of the
battery is attributed to shortcomings in the common specifications referred to in
Article 16, the Commission shall, without delay, adopt implementing acts amending
or repealing the common specifications concerned.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(3).

Article 68 *Compliant batteries which present a risk*

- 1. Where, having carried out an evaluation under Article 6766(1), a Member State finds that although a battery is in compliance with the <u>applicable</u> requirements set out in Chapters II and III Articles 6 to 10 and 12 to 14, it presents a risk to the human health or safety of persons, to the protection of property or to the environment, it shall <u>without delay</u> require the relevant economic operator to take all appropriate measures, within a reasonable period prescribed by the market surveillance authorities and commensurate with the <u>nature of the risk</u>, to ensure that the battery concerned, when <u>placed made available</u> on the market, no longer presents that risk, to withdraw the battery from the market or to recall it, within a reasonable period which is commensurate with the nature of that risk.
- 2. The economic operator shall ensure that corrective action is taken in respect of all the concerned batteries that the economic operator has made available on the market throughout the Union.
- 3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the batteries concerned, the origin and the supply chain of the battery, the nature of the risk involved and the nature and duration of the national measures taken.
- 4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not and, where necessary, ordering proposing appropriate measures.
- 5. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 74(3).

- 6. On duly justified imperative grounds of urgency relating to the protection of human health and safety of persons, and to the protection of property or to the environment, the Commission shall adopt an immediately applicable implementing act in accordance with the procedure referred to in Article 74(34).
- 7. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 69 Other <u>Formal</u> non-compliance

- Without prejudice to Article 66, where a Member State finds that a battery falling outside the scope of Article 68 is non-compliant with this Regulation or an economic operator has infringed an obligation set out in this Regulation, shall require the relevant economic operator to put an end to the non-compliance concerned. Such non compliances shall include the following makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
 - (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Regulation;
 - (b) -the CE marking has not been affixed;
 - (c) the identification number of the notified body, where required under Annex VIII involved in the production control phase, has been affixed in violation of Article 20 or has not been affixed;
 - (d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;
 - (e) the EU declaration of conformity is not accessible via the QR code referred to in Article 13(5) does not provide access to the regired information in accordance with Article 13(5)on the battery;

- (f) the technical documentation is not available, is not complete or contains errors;
- (g) the information referred to in paragraphs 7, 9 and 10 of Article 38(8) or Article 41(3) and (4) is absent, false or incomplete or, in the case of the instructions for use, not translated into a language accepted by the Member States where the battery is placed on the market or made available;
- (h) any other administrative requirement provided for in Article 38 or Article 40 <u>41</u> is not fulfilled;

<u>Article 69a</u>

Other non-compliance

- 1.
 Without prejudice to Article 66, where a Member State finds that a battery is noncompliant with this Regulation or an economic operator has infringed an obligation set out in this Regulation, it shall require the relevant economic operator to put an end to the non-compliance concerned. Such non compliances shall include the following:
 - the requirements for safe operation and use of stationary battery energy storage systems set out in Article 12 are not respected;
 - (j) <u>anv of</u> the sustainability and safety requirements set out in Articles 6 to 12 in Chapter II and <u>or any of</u> the labelling and information requirements set out in Articles 13 and <u>to</u> 14 in Chapter III are not fulfilled;
 - (k) the requirements related to the supply chain due diligence policy in Article 39 are not fulfilled;
 - [(1) any of the obligations on extended producer responsibility referred to in Article [...] is not fulfilled;]
 - (m) any of the requirements on electronical availability of information set out in <u>Article 64(3) is not fulfilled</u>.

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<u>Article 69b</u>

Non-compliance with supply chain due diligence obligations

- 1.Without prejudice to Article 66, where a Member State finds that an economic
operator has infringed an obligation on supply chain due diligence set out in Articles
45a to 45c of this Regulation, it shall require the relevant economic operator to put an
end to the non-compliance concerned.
- 2. Where the operator does not put an end to the non-compliance referred to in point (k) of paragraph 1, a notice of remedial action shall be issued.
- 3. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the battery being made available on the market or ensure that it is recalled or withdrawn from the market. In case of the non-compliance referred to in point (k) of paragraph 1, this paragraph shall apply as a last resort if the non-compliance is serious and persists after the issuing of a notice of remedial action as referred to in paragraph 2.

Chapter X

Green public procurement, procedure for amending restrictions on hazardous substances and Commission recognition of supply chain due diligence schemes

Article 70 Green public procurement

- Contracting authorities, as defined in Article 2(1) of Directive 2014/24/EU or Article 3(1) of Directive 2014/25/EU, or contracting entities, as defined in Article 4(1) of Directive 2014/25/EU shall, when procuring batteries or products containing batteries in situations covered by those Directives, take account of the environmental impacts of batteries over their life cycle with a view to ensure that such impacts of the batteries procured are kept to a minimum.
- 2. From either 1 January [12 months after the start of application of this Regulation] or [12 months] after adoption of delegated acts referred to in paragraph 3, whichever is later, Tthe obligation set out in paragraph 1 shall apply to any contracts entered into by contracting authorities or contracting entities for the purchase of batteries or products containing batteries and shall mean that these contracting authorities and contracting entities are obliged to include technical specifications and award criteria-based on Articles 7 to 10 to ensure that a product is chosen among products with significantly lower environmental impacts over their lifecycle.
- 3. The Commission shall, by 31 December-2026[60 months after the start of application of this Regulation], adopt delegated acts in accordance with Article 73 supplementing this Regulation by establishing minimum mandatory green public procurement criteria or targets based on the requirements set out in Articles 7 to 10.

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Article 71

Procedure for amending restrictions on hazardous substances

- 1. If the Commission considers that the use of a substance in the manufacture of batteries, or the presence of a substance in the batteries when they are placed on the market, or during their subsequent life cycle stages, including the waste phase, poses a risk to human health or the environment that is not adequately controlled and needs to be addressed on a Unionwide basis, it shall request the European Chemicals Agency (the 'Agency') to prepare a dossier that conforms to the requirements of point (3) of Part II of Annex XV to Regulation (EC) No 1907/2006 ('restriction dossier'). The restriction dossier shall include a socioeconomic assessment, including an analysis of alternatives.
- 2. The Agency shall publish without delay the intention of the Commission to initiate such restriction process life cycle for a substance, and shall inform stakeholders concerned.
- 3. Within 12 months of the receipt of the request from the Commission in paragraph 1 and if the restriction dossier prepared by the Agency pursuant to that paragraph demonstrates that action is necessary on a Union-wide basis, the Agency shall suggest restrictions in order to initiate the restriction process described in paragraphs 4 to 14.
- 4. The Agency shall make publicly available on its website the restriction dossier, including the restrictions suggested pursuant to paragraph 3, without delay, clearly indicating the date of publication. The Agency shall invite all interested parties to submit individually or jointly, within four months of the date of publication, comments on the restriction dossier.
- 5. Within 12 months of the date of publication referred to in paragraph 4, the Committee for Risk Assessment, set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006, shall adopt an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the restriction dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission, and the views of interested parties referred to in paragraph 4.

- 6. Within 15 months of the date of publication referred to in paragraph 4, the Committee for Socio-economic Analysis, set up pursuant to Article 76(1)(d) of Regulation (EC) No 1907/2006, shall adopt an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to paragraph 4, if there are any.
- 7. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from the publication of that draft opinion.
- 8. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 7. This opinion shall take account of the comments of interested parties submitted under paragraphs 4 and 7.
- 9. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions suggested, the Agency shall postpone the deadline for the opinion of the Committee for Socio-economic Analysis by a maximum of 90 days.
- 10. The Agency shall submit to the Commission without delay the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to the request made by the Commission under paragraph 1. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested pursuant to paragraph 3, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadline set in paragraphs 5 and 6 the Agency shall inform the Commission accordingly, stating the reasons.
- 11. The Agency shall publish the opinions of the two Committees on its website without delay.

- 12. The Agency shall provide the Commission on request with all documents and evidence submitted to or considered by it.
- 13. If the Commission concludes that the conditions laid down in Article 6(2) are fulfilled, it shall adopt a delegated act pursuant to Article 6(2). This delegated act shall be adopted without undue delay following the receipt of the opinion of the Committee for Socio-economic Analysis referred to in paragraph 8 or after the deadline set out under paragraphs 6 and 9, as applicable, if that Committee does not adopt an opinion.
- 14. Where the Committees for Risk Assessment and Socio-economic Analysis provide an opinion pursuant to paragraphs 5 and 6, they shall make use of rapporteurs as specified in Article 87 of Regulation (EC) No 1907/2006. The rapporteurs or co-rapporteurs concerned, or their employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements related to restrictions established by the Management Board, set up pursuant to Article 76(1)(a) of Regulation (EC) No 1907/2006. Where the persons concerned fail to fulfil their duties, the Executive Director of the Agency has the right to terminate or suspend the contract or withhold remuneration.

Chapter XI

Delegated powers and committee procedure

Article 73 Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

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- 2. The power to adopt delegated acts referred to in Articles 6(2), 7(1), (2) and (3), 8(4), 9(2), 10(3), 12(2), 17(4), 27(3), 3945a(8), [55(4), 56(4), 57(65), 58(3)] and 70(23) shall be conferred on the Commission for a period of five years from [date of entry into forcethe start of application of this Regulation]. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.
- 3. The delegation of power referred to in Articles 6(2), 7(1), (2) and (3), 8(4), 9(2), 10(3), 12(2), 17(4), 27(3), 3945a(8), [55(4), 56(4), 57(65), 58(3)] and 70(23) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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6. A delegated act adopted pursuant to Articles 6(2), 7(1), (2) and (3), <u>8(4)</u>, 9(2), 10(3), 12(2), 17(4), <u>27(3)</u>, <u>3945a</u>(8), [55(4), 56(4), 57(65), 58(3)] and 70(23) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 74

Committee procedure

- The Commission shall be assisted by a committee established by Article 39 of Directive 2008/98/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
- 3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

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Chapter XII

Amendments

Article 75

Amendments to Regulation (EU) 21092019/1020

<u>1.</u> Regulation (EU) 2019/1020 is amended as follows:

(1) in Article 4(5), the text "(EU) 2016/425(35) and (EU) 2016/426(36)" is replaced by the following:

"(EU) 2016/425 (*), (EU) 2016/426 (**) and [(EU) 2020[*year of adoption of this* <u>*Regulation*]</u>/...(***)]

* Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

** Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99).

*** [*Regulation of the European Parliament and of the Council on batteries and waste batteries, amending Regulation (EU) No 2019/1020 and repealing Directive 2006/66/EC* (For the Publications Office to fill in the OJ publication details)]";

(2) in Annex I, the following point 71 is added to the list of Union harmonisation legislation:

'71. Regulation of the European Parliament and of the Council on batteries and waste batteries, amending Regulation (EU) No 2019/1020 and repealing Directive 2006/66/EC (the Publications Office to fill in the OJ publication details);

Chapter XIII Final provisions

Article 76 Penalties

By 1 January ... [*the date of start of application of this Regulation*] Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Article 77 Review

- By 31 December-2030[108 months after the start of application of this Regulation], the Commission shall draw up a report on the application of this Regulation and its impact on the environment and the functioning of the internal market.
- Taking account of technical progress and practical experience gained in Member States, the Commission shall in its report include an evaluation on the following aspects of this Regulation:
 - (a) sustainability and safety requirements set out in Chapter II;
 - (b) labelling and information requirements set out in Chapter III;
 - (c) supply chain due diligence requirements set out in Articles 39 and 7245a to 45f;
 - (d) measures regarding end-of-life management of batteries -set out in Chapter VII and

(e) measures regarding electronic exchange of information and battery passport set out in Chapter VIII.

Where appropriate, the report shall be accompanied by a legislative proposal for amendment of the relevant provisions of this Regulation.

Article 78 Repeal and transitional rules

Directive 2006/66/EC is repealed with effect from 1 <u>JanuaryJuly 2023[24 months after the start of</u> <u>the applicaton of this Regulation]</u>; however, its:

- (a) Article 10(3), Article 12(4) and Article 12(5) shall continue to apply until 31 December 2023[24 months after the start of the application of this Regulation], except as regards the transmission of data to the Commission which shall continue to apply until 31 December 2025[48 months after the start of application of this <u>Regulation</u>];
- (b)Article 12(4) and Article 12(5) shall continue to apply until 31 December2024[36 months after the start of application of this Regulation], except as regardsthe transmission of data to the Commission which shall continue to apply until31 December 2026[60 months after the start of application of this Regulation];
- (bc) Article 21(2) shall continue to apply until 31 December-2026[60 months after the start of application of this Regulation].

References to the repealed Directive shall be construed as references to this Regulation.

Article 79 Entry into force and application

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

It shall apply from 1 January-2022 [of the first calendar year after the date of entry into force of this Regulation].

<u>Chapter VII shall apply form 1 January ... [24 months after the start of application of this</u> <u>Regulation].</u>

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

Done at Brussels,

For the European Parliament The President For the Council The President

ANNEX I

Restrictions on hazardous substances

Designation of the substance or group of substances	Conditions of restriction
1. MercuryCAS No. 7439-97-6EC No. 231-106-7 and itscompounds	 Batteries, whether or not incorporated into appliances, shall not contain more than 0,0005 % of mercury (expressed as mercury metal) by weight. Batteries used in vehicles to which
	Directive 2000/53/EC applies shall not contain more than 0,1% of mercury (expressed as mercury metal) by weight in homogeneous material.
2. Cadmium CAS No. 7440-43-9 EC No. 231-152-8 and its compounds	1. Portable batteries, whether or not incorporated into appliances, shall not contain more than 0,002% of cadmium (expressed as cadmium metal) by weight.
	2. The restriction set out in point 1 shall not apply to portable batteries intended for use in:
	(a) emergency and alarm systems, including emergency lighting;(b) medical equipment.
	3. Batteries used in vehicles to which Directive 2000/53/EC applies shall not contain _more than 0,01% of cadmium (expressed as cadmium metal) by

	weight in homogeneous material.
4.	The restriction set out in point 3 does
	not apply to vehicles that benefit from an exemption on the basis of Annex II
	to Directive 2000/53/EC.

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ANNEX II

Carbon footprint

1. Definitions

For the purposes of this Annex, the following definitions shall apply:

- (a) 'Activity data' means the information associated with processes while modelling Life
 Cycle Inventories (LCI). The aggregated LCI results of the process chains that represent
 the activities of a process are each multiplied by the corresponding activity data and then
 combined to derive the footprint associated with that process;
- (b) 'Bill of materials' means list of the raw materials, sub-assemblies, intermediate assemblies, sub-components, parts and the quantities of each needed to manufacture the product in scope of the study;
- (c) 'Company-specific data' refers to directly measured or collected data from one or multiple facilities (site-specific data) that are representative for the activities of the company. It is synonymous to "primary data";
- (d) 'Functional unit' means the qualitative and quantitative aspects of the function(s) and/or service(s) provided by the product being evaluated;
- (e) 'Life cycle' means the consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal (ISO 14040:2006 <u>or equivalent</u>);
- (f) 'Life cycle inventory (LCI)' means the combined set of exchanges of elementary, waste and product flows in a LCI dataset;
- (g) 'Life cycle inventory (LCI) dataset' means a document or file with life cycle information of a specified product or other reference (e.g., site, process), covering descriptive metadata and quantitative life cycle inventory. A LCI dataset could be a unit process dataset, partially aggregated or an aggregated dataset;

- (h) 'Reference flow' means the measure of the outputs from processes in a given product system required to fulfil the function expressed by the functional unit (based on ISO 14040:2006<u>or equivalent</u>);
- (i) 'Secondary data' means data not from a specific process within the supply-chain of the company performing a carbon footprint study. This refers to data that is not directly collected, measured, or estimated by the company, but sourced from a third party LCI database or other sources. Secondary data includes industry average data (e.g., from published production data, government statistics, and industry associations), literature studies, engineering studies and patents, and may also be based on financial data, and contain proxy data, and other generic data. Primary data that go through a horizontal aggregation step are considered as secondary data;
- (j) 'System boundary' means the aspects included or excluded from the life cycle study.

Additionally, the harmonised rules for the calculation of the carbon footprint of batteries shall include any further definition necessary for their interpretation.

2. Scope

This Annex provides essential elements on how to calculate the carbon footprint.

The harmonised calculation rules referred to in Article 7(1) shall build on the essential elements included in this Annex, be in compliance with the latest version of the Commission Product Environmental Footprint² (PEF) method and relevant Product Environmental Footprint Category Rules (PEFCRs)³ and reflect the international agreements and technical/scientific progress in the area of life cycle assessment⁴.

The calculation of the life cycle carbon footprint shall be based on the bill of material, the energy, and auxiliary materials used in a specific plant to produce a specific battery model. In particular, the electronic components (e.g. battery management units, safety units) and the cathode materials have to be accurately identified, as they may become the main contributor for the battery carbon footprint.

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² https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013H0179&from=EN

³ https://ec.europa.eu/environment/eussd/smgp/pdf/PEFCR_guidance_v6.3.pdf

⁴ See https://ec.europa.eu/environment/eussd/smgp/dev_methods.htm

3. Functional unit and reference flow

The functional unit is further defined as one kWh (kilowatt-hour) of the total energy provided over the service life by the battery system, measured in kWh. The total energy is obtained from the number of cycles multiplied by the amount of delivered energy over each cycle.

The reference flow is the amount of product needed to fulfil the defined function and shall be measured in kg of battery per kWh of the total energy required by the application over its service life. All quantitative input and output data collected by the manufacturer to quantify the carbon footprint shall be calculated in relation to this reference flow.

4. System boundary

Life cycle stage	Short description of the processes included
Raw material acquisition and pre-processing	Includes mining and pre-processing, up to the
	manufacturing of battery cells and batteries
	components (active materials, separator,
	electrolyte, casings, active and passive
	battery components), and electric/electronics
	components.
Main product production	Assembly of battery cells and assembly of
	batteries with the battery cells and the
	electric/electronic components
Distribution	Transport to the point of sale
End of life and recycling	Collection, dismantling and recycling

The following life cycle stages and processes shall be included in the system boundary:

The following processes shall be excluded:

• Manufacturing of equipment for batteries assembly and recycling, as impacts have been calculated as negligible in the PEFCRs for high specific energy rechargeable batteries for mobile applications;

• Battery assembly process with the original equipment manufacturer (OEM) system components. It mainly corresponds to mechanical assembly, and it is included inside the OEM equipment or vehicle assembly line. The specific energy or material consumption for this process are negligible when compared to the manufacturing process of OEM components.

The use phase should be excluded from the lifecycle carbon footprint calculations, as not being under the direct influence of manufacturers unless it is demonstrated that choices made by battery manufacturers at the design stage can make a non-negligible contribution to this impact.

5. Use of company specific and secondary datasets

Due to the high number of battery components and the complexity of the processes, the economic operator shall limit, where justified, the use of company specific data to process and component analysis to the battery-specific parts.

In particular, all activity data related to the battery's anode, cathode, electrolyte, separator and cellcasing shall refer to a specific battery model produced in a specific production plant (i.e., no default activity data shall be used). The battery-specific activity data shall be used in combination with the relevant Product Environmental Footprint compliant secondary datasets.

As the carbon footprint declaration shall be specific to a model battery produced in a defined production site, sampling of data collected from different plants producing the same battery model should not be allowed.

A change in the bill of materials or energy mix used to produce a battery model requires a new calculation of the carbon footprint for that battery model.

The harmonised rules to be elaborated via a delegated act <u>referred to in Article 7(1)</u> shall include detailed modelling of the following lifecycle stages:

- Raw material acquisition and pre-processing stage:
- Production stage:
- Distribution<u>:</u>

- Own electricity production <u>:</u>
- End of life stage.

6. Carbon footprint impact assessment

The carbon footprint of the battery shall be calculated using the "climate change" life cycle impact assessment method recommended in the 2019 Joint Research Centre (JRC) report available at https://eplca.jrc.ec.europa.eu/permalink/PEF_method.pdf.

The results shall be provided as characterised results (without normalisation and weighting). The list of characterization factors to be used is available at https://eplca.jrc.ec.europa.eu/EnvironmentalFootprint.html.

7. Offsets

Offsets are calculated relative to a baseline that represents a hypothetical scenario for what emissions would have been in the absence of the mitigation project that generates the offsets.

Offsets shall not be included in the carbon footprint declaration, but may be reported separately as additional environmental information and used for communication purposes.

8. Carbon footprint performance classes

Depending on the distribution of the values of the batteries' carbon footprint declarations placed in <u>on</u> the <u>EU internal</u> market, a meaningful number of classes of performance will be identified, with category A being the best class with the lowest carbon footprint life cycle impact, to allow for market differentiation <u>of industrial batteries and electric vehicle batteries with a nominal energy above 2 kWh</u>.

The identification of the threshold for each class of performance, as well as their width, will be based on the distribution of performances of the <u>industrial batteries and electric vehicle</u> batteries <u>with a nominal energy above 2 kWh</u> placed on the market <u>or put into service, respectively</u>, in the previous 3 years, the expected technological improvements, and other technical factors to be identified.

The Commission shall review the number of performance classes and the thresholds between them every three years in order to keep them representative of the market reality and its expected development.

9. Maximum carbon thresholds

Based on the information collected through the carbon footprint declarations <u>of industrial batteries</u> <u>and electric vehicle batteries with a nominal energy above 2 kWh</u> and the relative distribution of the carbon footprint performance classes of <u>their</u> battery models placed on the market<u>or put into</u> <u>service</u>, and taking into account the scientific and technical progress in the field, the Commission will identify maximum lifecycle carbon footprint thresholds for rechargeable <u>electric</u> vehicle <u>industrial</u> and <u>electric vehicle <u>industrial</u> batteries <u>with a nominal energy above 2 kWh</u>, further to a dedicated impact assessment to determine those values.</u>

In proposing maximum carbon footprint thresholds <u>referred to in first subparagraph</u>, the Commission will take into account the relative distribution of the carbon footprint values <u>of the</u> <u>industrial batteries and electric vehicle batteries with a nominal energy above 2 kWhin</u> <u>batteries</u> on the market, the extent of progress in the reduction of carbon footprint of batteries placed on the Union market and the effective and potential contribution of this measure to the Union's objectives on sustainable mobility and climate neutrality by 2050.

ANNEX III

Electrochemical performance and durability parameters for portable batteries of general use

- 1. Battery capacity, electric charge which a battery can deliver under a specific set of conditions.
- 2. Minimum average duration, minimum average time on discharge when used in specific applications, depending on the type of battery.
- Shelf life (dDelayed discharge performance), the relative decrease of the minimum average duration, with the initially measured capacity as the reference point, after a defined period of time and specific conditions.
- 4. Endurance in cycles (for rechargeable batteries), the capacity of the battery after a preestablished number of charge and discharge cycles.
- 5. Resistance to leakage, i.e. resistance to unplanned escape of electrolyte, gas or other material (poor, good or excellent).



ANNEX IV

Electrochemical performance and durability requirements for rechargeable <u>light</u> means of <u>transport batteries</u>, industrial batteries and electric vehicle batteries <u>with a nominal</u> <u>energy above 2 kWh</u>

Part A

Parameters related to the electrochemical performance and durability

- 1. Rated capacity (in Ah) and capacity fade (in %).
- 2. Power (in W) and power fade (in %).
- 3. Internal resistance (in \Box) and internal resistance increase (in %).
- 4. Energy round trip efficiency and its fade (in %).
- 5. An indication of their expected life-time under the conditions for which they have been designed.

`Rated capacity' means the total number of ampere-hours (Ah) that can be withdrawn from a fully charged battery under specific conditions.

Capacity fade' means the decrease over time and upon usage in the amount of charge that a battery can deliver at the rated voltage, with respect to the original rated capacity declared by the manufacturer measured capacity.

Power' means the amount of energy that a battery is capable to provide over a given period of time.

Power fade' means the decrease over time and upon usage in the amount of power that a battery can deliver at the rated voltage.

'Internal resistance' means the opposition to the flow of current within a cell or a battery, that is, the sum of electronic resistance and ionic resistance to the contribution to total effective resistance including inductive/capacitive properties.

Energy round trip efficiency means the ratio of the net energy delivered by a battery during a discharge test to the total energy required to restore the initial State of Charge by a standard charge.

Part B

Elements for explanation of the measurements made for parameters listed in Part A

- 1. Applied discharge rate and charge rate.
- 2. Ratio between maximum allowed battery power (W) and battery energy (Wh).
- 3. Depth of discharge_in the cycle-life test.
- 4. Power capability at 80% and 20% state of charge.
- 5. Any calculations performed with the measured parameters, if applicable.



ANNEX V

Safety parameters

1. Thermal shock and cycling

This test shall be designed to evaluate changes in the integrity of the battery arising from expansion and contraction of cell components upon exposure to extreme and sudden changes in temperature and potential consequences of such changes. During a thermal shock the battery shall be exposed to two temperature limits and held at each temperature limit for a specified period of time.

2. External short circuit protection

This test shall evaluate the safety performance of a battery when applying an external short circuit. The test can evaluate the activation of the overcurrent protection device or the ability of cells to withstand the current without reaching a hazardous situation (e.g. thermal runaway, explosion, fire). The main risk factors are heat generation at cell level and electrical arcing which may damage circuitry or may lead to reduced isolation resistance.

3. Overcharge protection

This test shall evaluate the safety performance of a battery in overcharge situations. The main safety risks during overcharge are the decomposition of the electrolyte, cathode and anode breakdown, exothermic decomposition of the solid electrolyte interphase (SEI) layer, separator degradation, and the Li<u>thium</u> plating, which can lead to self-heating of the battery and thermal runaway. The factors affecting the outcome of the test shall include, at least, the charging rate and the finally reached state-of-charge (SOC). The protection can be ensured by either voltage control (interruption after reaching the limit charging voltage) or current control (interruption after exceeding maximum charging current).

4. Over-discharge protection

This test shall evaluate the safety performance of a battery in over-discharge situations. Safety risks during over-discharge include polarity reversal leading to oxidation of the anode current collector (Copper) and to plating on the cathode side. Even minor over-discharge may cause dendrite formation and finally short circuit.

5. Over-temperature protection

This test shall evaluate the effect of temperature control failure or failure of other protection features against internal overheating during operation.

6. Thermal propagation

This test shall evaluate the safety performance of a battery in thermal propagation situations. A thermal runaway in one cell can cause a cascading reaction through the entire battery which can be composed of numerous cells. It can lead to severe consequences including a significant gas release. The test shall take into account the tests under development for transport applications by ISO and UN GTR.

7. Mechanical damage by external forces (drop and impact)

These tests shall simulate one or more situations in which a battery accidentally drops or is impacted by a heavy load and remains operational for the purpose for which it was designed. The criteria to simulate these situations should reflect real life uses.

8. Internal short circuit

This test shall evaluate the safety performance of a battery in internal short-circuit situations The occurrence of internal short circuits, one of the main concerns for battery manufacturers, potentially leads to venting, thermal runaway, along with sparking which can ignite the electrolyte vapours escaping from the cell. The generation of these internal shorts can be triggered by manufacturing imperfections, presence of impurities in the cells or dendritic growth of lithium, and leads to most of in-field safety incidents. Multiple internal short circuits scenarios are possible (e.g. electrical contact of cathode/anode, aluminium current collector/copper current collector, aluminium current collector /anode) each with a different contact resistance.

9. Thermal abuse

During this test, the battery shall exposed to elevated temperatures (in IEC 62619 this is 85 °C) which can trigger exothermal decomposition reactions and lead to a thermal runaway of the cell.

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10. <u>Fire test</u>

The risk of explosion shall be assessed by exposing the battery to fire.

Proper considerations to the risk of toxic gases emitted from non-aqueous electrolytes should be made for all safety parameters listed in points 1 to $9\underline{10}$.



ANNEX VI

Labelling requirements

Part A

General information about batteries

Information on the label of batteries:

- 1. the manufacturer's name, registered trade name or trade mark;
- 2. the battery type, <u>and</u> batch or serial number of the battery or other element allowing its unequivocal identification;
- 3. battery model identifier;
- 4. date of manufacturing place (geographical location of a battery manufacturing facility) and date (month and year);
- 5. date of placing on the market<u>weight;</u>
- 6. chemistry;
- 7. hazardous substances contained in the battery other than mercury, cadmium or lead;
- 8. critical raw materials contained in the battery;
- 9. <u>usable extinguishing agent.</u>



Part B Symbol for separate collection of batteries



Part C QR code

The QR code shall be 100% black of a high colour contrast and of a size that is easily readable by a commonly available QR reader, such as those integrated in hand-held communication devices.

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ANNEX VII

Parameters for determining the state of health of batteries and expected lifetime of <u>industrial batteries and electric vehicle</u> batteries

Parameters for determining the state of health of batteries:

- 1. Remaining capacity;
- 2. Overall capacity fade;
- 3. Remaining power capability and power fade;
- 4. Remaining round trip efficiency;
- 5. Actual cooling demand;
- 6. Evolution of self-discharging rates;
- 7. Ohmic resistance and/or electrochemical impedance.

Parameters for determining the expected lifetime of batteries:

- 1. The dates of manufacturing of the battery and or, if applicable, the date of putting into service;
- 2. Energy throughput;
- 3. Capacity throughput.



ANNEX VIII

Conformity assessment procedures

Part A

MODULE A - INTERNAL PRODUCTION CONTROL

1. Description of the module

Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares <u>on his sole</u> <u>responsibility</u> that the batter<u>yies concerned</u> satisf<u>yies</u> the requirements set out in Articles 6, 9, 10, 11, 12, 13 and 14 that apply to them.

2. Technical documentation

The manufacturer shall draw up the technical documentation. The documentation shall make it possible to assess the battery's conformity with the relevant requirements referred to in point 1, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use<u>operation</u> of the battery. The technical documentation shall contain, where applicable, at least the following elements:

- (a) a general description of the battery and its intended use;
- (b) conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc;
- descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (b) and the operation of the battery;

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(ca) a specimen of the labelling required in accordance with Article 13;



- (d) a list harmonised standards, common specifications or other relevant technical specifisations which includes:
 - (i) <u>a list of</u> the harmonised standards referred to in Article 15, applied in full or in part, incuding an indication of which parts have been applied;
 - (ii) <u>a list of</u> the common specifications referred to in Article 16, applied in full or in part, incuding an indication of which parts have been applied;
 - (iii) <u>a list of</u> other relevant technical specifications used for measurement or calculation purposes;
 - (iv) an indication of which parts of the harmonised standards referred to in point (i) and the common specifications referred to in point (ii) that have been applied;
 - (v) where the harmonised standards referred to in point (i) and the common specifications referred to in point (ii)-have not been applied or are not available, a description of the solutions adopted to meet the <u>applicable</u> requirements referred to in point 1-<u>or to verify the compliance of batteries with those requirements:</u>

(da)results of design calculations made, examinations carried out, technical ordocumentary evidence used, etc.; and

(e) test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the **manufactured** batteryies with the technical documentation referred to in point 2 and with the **applicable** requirements referred to in point 1.

4. CE marking and EU declaration of conformity

The manufacturer shall affix the CE marking to each individual packaging of the battery model that satisfies the <u>applicable</u> requirements referred to in point 1, or, where <u>that is not possible or not</u> <u>warranted due to the nature of the battery, it is supplied without to the packaging, in a and the</u> document<u>s</u> accompanying the battery-model.

The manufacturer shall draw up an EU declaration of conformity for each battery model in accordance with Article 18 and keep it together with the technical documentation at the disposal of the national authorities for ten years after the last battery belonging to the respective battery model has been placed on the market <u>or put into service</u>.

A copy of the EU declaration of conformity shall be made available to the relevant <u>national</u> authorities of the Member States upon request.

5. <u>Manufacturer's</u> Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his or her <u>the manufacturer's</u> authorised representative, on his or her <u>its</u> behalf and under his or her <u>the manufacturer's</u> responsibility, provided that they are specified in the mandate.

Part B

MODULE A1 - INTERNAL PRODUCTION CONTROL PLUS SUPERVISED VERIFICATION

1. Description of the module

Internal production control plus supervised verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares that the battery satisfy the requirements set out in Articles 7, 8 and 39 that are applicable.

2. Technical documentation

The manufacturer shall draw up the technical documentation. The documentation shall make it possible to assess the battery's conformity with the requirements referred to in point 1, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements referred to in point 1 and cover, as far as relevant for the assessment, the design, manufacture and operation of the battery. The technical documentation shall contain, wherever applicable, at least the following elements:

- (a) a general description of the battery;
- (b) conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits.;
- (c) descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (b) and the operation of the battery;test reports.

3. Manufacturing

The manufacturer or the importer that places the battery on the Union market shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the applicable requirements referred to in point 1.

4. Product and information checks

For each battery model, and where applicable, for each batch that the manufacturer or the importer places on the Union market, the mentioned economic operator shall carry out one or more tests on one or more specific aspects of the battery model or batch of batteries order to verify conformity with the corresponding requirements referred to in point 1. For large battery batches, the manufacturer, the authorised representative or the importer shall choose a statistically representative sample of batteries.

The manufacturer, or the importer that places the battery model on the Union market, shall submit the information and documents referred to in Articles 7, 8 and 39 of this Regulation to the notified body for verification of compliance with the applicable requirements and obligations in those Articles, as well as in applicable implementing measures.

5. CE marking and EU declaration of conformity

The manufacturershall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each battery, or to the packaging thereof, that satisfies the applicable requirements of this Regulation.

The manufacturer shall draw up a an EU declaration of conformity for each battery model in accordance with Article 18 and keep it together with the technical documentation at the disposal of the national authorities for ten years after the last battery belonging to the respective model has been placed on the market.

A copy of the EU declaration of conformity shall be made available to the relevant authorities of Member States upon request.

6. Authorised representative

The manufacturer's obligations set out in points 4 and 5 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

MODULE D1 - QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. **Description of the module**

Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the products <u>batteries</u> concerned satisfy the requirements of the legislative instrument set out in Articles 7 and 8 that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the **product's**-**<u>battery's</u>** conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product <u>battery</u>. The technical documentation shall, where ver applicable, contain at least the following elements:

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(a) a general description of the product battery and its intended use,

- (b) conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,
- (c) descriptions and explanations necessary for the understanding of those-the drawings and schemes referred to in point (b) and the operation of the product battery,

(d) a specimen of the labelling required in accordance with Article 13,

- (e) a list of the harmonised standards <u>referred to in Article 15</u> and/or other relevant technical<u>the common</u> specifications <u>referred to in Article 16</u> the references of which have been published in the Official Journal of the European Union, applied in full or in part, and, descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In <u>in</u> the event of partly applied harmonised standards <u>and/or common specifications</u>, <u>an indication of</u> <u>which parts</u> the technical documentation shall specify the parts which have been applied,
- (f)a list of other relevant technical specifications used for measurement or calculationpurposes and descriptions of the solutions adopted to meet the applicable requirementsreferred to in point 1 or to verify the compliance of batteries with those requirements,where harmonised standards and/or common specifications have not been applied orare not available,
- (g) results of design calculations made, examinations carried out, <u>technical or documentary</u> <u>evidence used, etc., and</u>
- (h) a study supporting the carbon footprint values referred to in Article 7(1) and the carbon footprint class referred to in Article 7(2), containing the calculations made in accordance with the methodology set out in the delegated act adopted by the <u>Commission pursuant to point (a) of Article 7(1) and the evidence and information</u> <u>determining the input data for those calculations.</u>
- (i) a study supporting the recycled content share referred to in Article 8, containing the calculations made in accordance with the methodology set out in the delegated act adopted by the Commission pursuant to second subparagraph of Article 8(1) and the evidence and information determining the input data for those calculations;

(j) test reports.

3. Availability of technical documentation

The manufacturer shall keep the technical documentation at the disposal of the relevant-national authorities for 10 years after the product<u>battery</u> has been placed on the market.

4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products <u>batteries</u> concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

5. Quality system

5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products <u>batteries</u> concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the **manufacturer's** authorised representative, his name and address as well,
- (b) a written declaration that the same application has not been lodged with any other notified body,
- (c) all relevant information for the product <u>battery categorytype</u> envisaged,
- (d) the documentation concerning the quality system <u>referred to in point 5.2</u>,
- (e) the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the products <u>batteries</u> with the requirements of the legislative instrument <u>referred to in point 1</u> that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.



It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

(b) the procedures for documenting and monitoring the parameters and data necessary for calculating and updating the recycled content share referred to in Article 8 and, where applicable, the carbon footprint values and class referred to in Article 7,

- (c) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- (d) the examinations, calculations, measurements and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- (e) the quality records, such as inspection reports and <u>calculation, measurement and</u> test data, calibration data, qualification reports on the personnel concerned, etc.,
- (f) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument referred to in point 1. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant applicable requirements of the legislative instrument referred to in point 1 and to carry out the necessary examinations, calculations, measurements and tests with a view to ensuring compliance of the product battery with those requirements. The auditing team shall check the reliability of data used for the calculation of the recycled content share referred to in Article 8 and, where applicable, the carbon footprint values and class referred to in Article 7 as well as the proper implementation of the relevant calculation methodology.

The decision <u>of the notified body</u> shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether reassessment is necessary.

It-<u>The notified body</u> shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.



6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation <u>referred to in point 5.2</u>,

(b) the technical documentation referred to in point 2,

(c) the quality records, such as inspection reports and <u>calculation, measurement and</u> test data, calibration data, qualification reports on the personnel concerned, etc.

6.3. The notified body shall carry out periodic audits <u>at least once a year</u> to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. <u>During such audits the notified body shall check at least the reliability of data</u> <u>used for the calculation of the recycled content share referred to in Article 8 and, where</u> <u>applicable, the carbon footprint values and class referred to in Article 7 as well as the proper implementation of the relevant calculation methodology.</u>

6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out **product <u>examinations</u>**, **calculations**, **measurements and** tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. Conformity-<u>CE</u> marking and <u>EU</u> declaration of conformity

7.1. The manufacturer shall affix the required conformity <u>CE</u> marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual product <u>battery</u> that satisfies the applicable requirements of the legislative instrument referred to in point 1, or, where that is not possible or not warranted due to the nature of the battery, to the packaging and the documents accompanying the battery.

7.2. The manufacturer shall draw up a written an EU declaration of conformity for each product **<u>battery</u>** model in accordance with Article 18 and keep it at the disposal of the national authorities for 10 years after the product last battery belonging to the respective battery model has been placed on the market. The <u>EU</u> declaration of conformity shall identify the product battery model for which it has been drawn up.

A copy of the <u>**EU**</u> declaration of conformity shall be made available to the <u>relevant national</u> authorities upon request.

8. Availability of quality system documentation

The manufacturer shall, for a period ending at least of 10 years after the product battery has been placed on the market, keep at the disposal of the national authorities:

- (a) the <u>quality system</u> documentation referred to in point 5.42,
- (b) the change referred to in point 5.5, as approved,
- (c) the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

9. Information obligations of the notified body

Each notified body shall inform its notifying authorit<u>y</u>ies of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorit<u>y</u>ies the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, **withdrawn**, suspended or withdrawn **otherwise restricted**, and, upon request, of quality system approvals which it has issued.

10. Manufacturer's Authorised representative

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his-the manufacturer's authorised representative, on his-the manufacturer's behalf and under his-the manufacturer's responsibility, provided that they are specified in the mandate.

<u>Part C</u>

MODULE G - CONFORMITY BASED ON UNIT VERIFICATION

1. **Description of the module**

Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the product-battery concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of the legislative instrument set out in Articles 6 to 10 and 12 to 14 that apply to it.

2. Technical documentation

<u>2.1.</u> The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the **product's <u>battery's</u>** conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the <u>product battery</u>. The technical documentation shall, wherever applicable, contain-at least the following elements:

- (a) a general description of the product <u>battery and its intended use</u>,
- (b) conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,
- (c) descriptions and explanations necessary for the understanding of those the drawings and schemes referred to in point (b) and the operation of the product battery,

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(d) a specimen of the labelling required in accordance with Article 13,

a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

- (e)a list of the harmonised standards referred to in Article 15 and/or the commonspecifications referred to in Article 16 applied, and, in the event of partly appliedharmonised standards and/or common specifications, an indication of which partshave been applied,
- (f)a list of other relevant technical specifications used for measurement or calculationpurposes and descriptions of the solutions adopted to meet the applicable requirementsreferred to in point 1 or to verify the compliance of batteries with those requirements,where harmonised standards and/or common specifications have not been applied orare not available,
- (g) results of design calculations made, examinations carried out, technical or documentary evidence used, etc., and
- (h) a study supporting the carbon footprint values and class referred to in Article 7, containing the calculations made in accordance with the methodology set out in the delegated act adopted by the Commission pursuant to point (a) of the third subparagraph of Article 7(1) and the evidence and information determining the input data for those calculations,
- (i) a study supporting the recycled content share referred to in Article 8, containing the calculations made in accordance with the methodology set out in the delegated act adopted by the Commission pursuant to second subparagraph of Article 8(1) and the evidence and information determining the input data for those calculations;

TREE.1.A

(i) test reports.

<u>2.2.</u> The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product <u>battery</u> has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured **product <u>battery</u>** with the applicable requirements of the legislative instrument <u>referred to in point 1</u>.

4. Verification

<u>4.1.</u> A notified body chosen by the manufacturer shall carry out appropriate examinations<u></u> **<u>calculations, measurements</u>** and tests, set out in the relevant harmonised standards <u>referred to in</u> <u>**Article 15**</u> and/or technical common specifications <u>referred to in Article 16</u>, or equivalent tests, to check the conformity of the <u>product battery</u> with the applicable requirements of the legislative instrument <u>referred to in point 1</u>, or have them carried out. In the absence of such a harmonised standard and/or technical <u>common</u> specification the notified body concerned shall decide on the appropriate <u>examinations, calculations, measurements and</u> tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations, <u>calculations</u>, <u>measurements</u> and tests carried out and shall affix its identification number to the approved <u>product battery</u>, or have it affixed under its responsibility.

<u>4.2.</u> The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the **product** <u>**battery**</u> has been placed on the market.

5. Conformity-<u>CE</u> marking and <u>EU</u> declaration of conformity

5.1. The manufacturer shall affix the required conformity <u>CE</u> marking set out in the legislative instrument and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product <u>battery</u> that satisfies the applicable requirements of the legislative instrument referred to in point 1, or, where that is not possible or not warranted due to the nature of the battery, to the packaging and the documents accompanying the battery.

5.2. The manufacturer shall draw up a written <u>an EU</u> declaration of conformity <u>in accordance</u> <u>with Article 18 for each battery</u> and keep it at the disposal of the national authorities for 10 years after the <u>product battery</u> has been placed on the market. The <u>EU</u> declaration of conformity shall identify the <u>product battery</u> for which it has been drawn up.

A copy of the <u>EU</u> declaration of conformity shall be made available to the <u>relevant</u> <u>**national**</u> authorities upon request.

6. <u>Manufacturer's Aa</u>uthorised representative

The manufacturer's obligations set out in points 2<u>.2, 4.2</u> and 5 may be fulfilled by <u>his-the</u> <u>manufacturer's</u> authorised representative, on <u>his-the manufacturer's</u> behalf and under <u>his-the</u> <u>manufacturer's</u> responsibility, provided that they are specified in the mandate.

ANNEX IX

EU Declaration of conformity No<u>*</u> ...

- 1. Battery model (product, type, batch or serial number):
- 2. Name and address of the manufacturer and, where applicable, his authorised representative.
- 3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
- 4. Object of the declaration (identification of the battery allowing traceability): description of the battery.
- 5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: ... (reference to the other Union acts applied).
- 6. References to the relevant harmonised standards or the common specifications used or references to the other technical specifications in relation to which conformity is declared:
- 7. The notified body ... (name, address, number) ... performed ... (description of intervention) ... and issued the certificate(s): ... (details, including its date, and, where appropriate, information on the duration and conditions of its validity).
- 8. Additional information

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature)

* (unique identification of the declaration)

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ANNEX X

List of raw materials and risk categories

- 1. Raw materials:
 - (a) cobalt;
 - (b) natural graphite;
 - (c) lithium;
 - (d) nickel;
 - (e) chemical compounds based on the raw materials listed in points (a) to (f<u>d</u>) which are necessary for the manufacturing of the active materials of batteries.
- 2. Social and environmental risk categories:

(a)environment, incuding but not limited to:

(i) air, including but not limited to air pollution;

(ii) water, including seabed and marine environment and including but not limited to water pollution, water quantities (flooding or draughts) and access to water;

(iii) soil, including but not limited to soil contamination, soil erosion and land degradation;

(iv) biodiversity, including but not limited to damage to habitats, wildlife, flora and ecosystem services;

human rights;

(b) labour rights and industrial relations, including but not limited to:

(i) occupational health and safety;

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<u>(ii) child labour,</u>

(iii) forced labour,

(iv) discrimination,

(v) trade union freedoms;

(f) , including child labour;

(c)human rights recognised in international law;

(d) community life.

3. The international instruments covering the risks referred to in point 2 include:

(a-a) UN Guiding Principles on Business and Human Rights;

(a-b) OECD Guidelines for Multinational Enterprises;

(a) Ten Principles of the United Nations Global Compact;

(b) UNEP Guidelines for Social Life Cycle Assessment of Products;

(c)Convention on Biological Diversity Decision COP VIII/28- Voluntary guidelines on Biodiversity-Inclusive impact assessment;

(d) ILO Tripartite Declaration of-Principles concerning Multinational Enterprises and Social Policy;

(e-a) Eight fundamental ILO Conventions,

(e-b) ILO Declaration on Fundamental Principles and Rights at Work;

(e-c) The International Bill of Human Rights, including the international covenant on Civil and Political Rights and the International Covenant on Economic, Social and <u>Cultural Rights;</u> (e) OECD Due Diligence Guidance for Responsible Business Conduct; and

(f) OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas:

(g)The International Bill of Human Rights, including the international covenant on Civil and Political Rights and the International Covenant on Economic, Social and <u>Cultural Rights</u>.



ANNEX XI

Calculation of collection rates of waste portable batteries

- 1. Producers or, where appointed in accordance with Article 47(2), producer responsibility organisations acting on their behalf, and Member States shall calculate the collection rate as the percentage obtained by dividing the weight of waste portable batteries excluding waste batteries from light means of transport, collected in accordance with Article 48 and Article 55, respectively, in a given calendar year in a Member State by the average weight of such batteries that producers either sell directly to end-users or deliver to third parties in order to sell them to end-users in that Member State during that year and the preceding two calendar years.
- 2. Producers or, where appointed in accordance with Article 47(2), producer responsibility organisations acting on their behalf, and Member States shall calculate the annual sales of portable batteries, excluding-_batteries from light means of transport, to end-users in a given year, as the weight of such batteries made available on the market-_for the first time within the territory of the Member State in the year concerned, excluding any portable batteries that have left the territory of that Member State in that year before being sold to the end-_users.
- 3. For each battery, only the first time it is made available on the market in a Member State shall be counted.
- 4. The calculation provided for in points 21 and 32 shall be based on collected data or statistically significant estimates based on collected data.]

ANNEX XII

Treatment and recycling requirements

Part A

Treatment requirements

- 1. Treatment shall, as a minimum, include removal of all fluids and acids.
- 2. Treatment and any storage, including temporary storage, at treatment facilities shall take place in sites with impermeable surfaces and suitable weatherproof covering or in suitable containers.
- 3. Waste batteries in treatment facilities shall be stored in such a way that waste batteries are not mixed with waste from conductive or combustible materials.
- 4. Special precautions and safety measures shall be in place for the treatment of waste lithium based batteries that shall be protected from exposure to excessive heat, water, or any crushing or physical damage during handling, sorting and storage.

Part B

Recycling efficiencies

- 5. No later than 1 January-2025[36 months after the start of application of this Regulation], recycling processes shall achieve the following minimum recycling efficiencies:
 - (a) recycling of 75 % by average weight of lead-acid batteries;
 - (b) recycling of 65 % by average weight of lithium-based batteries;
 - (c) recycling of 50 % by average weight of other waste batteries.
- 6. No later than 1 January-2030[96 months after the start of application of this Regulation], recycling processes shall achieve the following minimum recycling efficiencies:
 - (a) recycling of 80 % by average weight of lead-acid batteries;
 - (b) recycling of 70_% by average weight of lithium-based batteries.



Part C

Levels of recovered materials

- No later than 1 January-2026[48 months after the start of application of this Regulation],
 all recycling processes shall achieve the following levels of materials recovery:
 - (*a*) 90 % for cobalt;
 - *(b)* 90 % *for copper;*
 - *(c)* 90 % *for lead;*
 - (d) 35% for lithium;
 - (e) 90 % for nickel.
- 8. No later than 1 January-2030[96 months after the start of application of this Regulation], all recycling processes shall achieve the following levels of materials recovery:
 - (*a*) 95 % for cobalt;
 - *(b)* 95 % *for copper;*
 - (c) 95 % for lead;
 - (*d*) 70 % for lithium;
 - (e) 95 % for nickel.]



ANNEX XIII

Information to be stored in the European Electronic Exchange System

Information and data shall be treated in accordance with Commission Decision (EU, Euratom) 2015/443⁵. The specific cyber-security arrangements of Commission Decision (EU, Euratom) 2017/46⁶ and its implementing rules shall apply. The confidentiality level shall reflect the consequential harm that may result from disclosure of the data to unauthorised persons.

1. PUBLICLY ACCESSIBLE PART OF THE SYSTEM

Information to be stored and made available in the publicly accessible part of the system by the economic operator that places a battery on the market:

- (a) Battery manufacturer, including manufacturer's name, registered trade name or trade mark;
- (b) Battery type;
- (c) General description of the model, sufficient for it to be unequivocally and easily identified, including the date of placing in the market;
- (d) Manufacturing place <u>(geographical location of a battery manufacturing facility)</u> and date <u>(month and year);</u>
- (e) Battery <u>Material</u> composition <u>of the battery</u>, including critical raw materials;
- (f) Carbon footprint information in the units indicated in the relevant implementing measure(s)referred to in Articles 7(1) and 7(2);



 ⁵ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission
 (OJ L 72, 17.3.2015, p. 41)

 ⁶ Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission (OJ L 6, 11.1.2017, p. 40)

- (g) Information on responsible sourcing as indicated in the relevant implementing measure(s)
 report on its supply chain due diligence policies referred to in Article 45f(6a);
- (h) Recycled content information as indicated in the relevant-implementing measure(s)<u>acts</u> referred to Article 8(1);
- (i) Rated capacity (in Ah);
- (j) Minimal, nominal and maximum voltage, with temperature ranges when relevant;
- (k) Original power capability (in Watts) and limits, with temperature range when relevant ;
- (1) Expected battery lifetime expressed in cycles, and reference test used ;
- (m) Capacity threshold for exhaustion (only for EVelectric vehicle batteries);
- (n) Temperature range the battery can withstand when not in use (reference test);
- (o) Period for which the commercial warranty for the calendar life applies;
- (p) Initial round trip energy efficiency and at 50% of cycle-life;
- (q) Internal battery cell and pack resistance;
- (r) C-rate of relevant cycle-life test;

(s) <u>Weight of the battery pack.</u>

2. REQUIREMENTS FOR THE PART OF THE SYSTEM ACCESSIBLE ONLY TO ACCREDITED ECONOMIC OPERATORS AND THE COMMISSION

The part of the system that shall be accessible only to accredited <u>[repairers, independent</u> <u>operators carrying out repurposing or remanufacturing operations]</u> remanufacturers, secondlife operators and recyclers shall contain:

- (a) Detailed composition, including materials used in the cathode, anode and electrolyte;
- (b) Part numbers for components and contact details of sources for replacement spares;



- (c) Dismantling information, including at least:
 - Exploded diagrams of the battery system/pack showing the location of battery cells,
 - Disassembly sequences,
 - Type and number of fastening techniques to be unlocked,
 - Tools required for disassembly,
 - Warnings if risk of damaging parts exist,
 - Amount of cells used and layout;
- (d) Safety measures.
- 3. REQUIREMENTS FOR THE PART OF THE SYSTEM ACCESSIBLE ONLY TO NOTIFIED BODIES, MARKET SURVEILLANCE AUTHORITIES AND THE COMMISSION
 - a) Results of tests reports proving compliance with the requirements laid out in this Regulation,- and its implementing or delegated measures.

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