BALIHT

REPORT ON TOXICOLOGY SAFETY AND REGULATORY

31 MARCH 2023

WP6 REGULATORY, TOXICOLOGY, ENVIRONMENTAL AND SOCIAL LIFE CYCLE ANALYSIS.

DELIVERABLE D6.8

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 875637.

Project information	
Grant Agreement nº	875637
Project Acronym	BALIHT
Project Title	Development of full lignin based organic redox flow battery suitable to work in warm environments and heavy multicycle uses
Funding scheme	H2020-LC-BAT-2019-2020
Start date of project	1 December 2019
Duration of project	42 months

Deliverable information	
Deliverable nº and name	D6.8 Report on toxicology, safety and regulatory analysis
Due date of D.	Month 34, 31 Sep 2022
Actual date of D.	Month 40, 31 March 2023
Participant responsible	ULEI

Date of the last version of the Annex I against which the assessment will be made	24 March 2022
Project coordinator	AIMPLAS
Project website address	www.baliht.eu

Dissemination Level		
PU	Public	✔
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

DELIVERABLE REPORT

Document history

Version	Issue date	Content and changes	Editor Partner
1.0	17-03-2023	First version, based on input provided by partners	ULEI
2.0	30-03-2023	Final version	ULEI

Peer-reviewed by

Partner	Editor and Reviewers
COBRA	Thomas Hoole
AIMPLAS	Marta Pérez and Carla De Juan
CMBlu	Simon Budde and Christoph Hengst

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LIST OF ABBREVIATIONS

Abbreviation	Definition
AI	Artificial Intelligence
BESS	Battery energy storage systems
BIG	Battery Interface Genome
CLP	Classification, Labelling, Packaging
DNEL	Derived No Effect Level
ECHA	European Chemical Agency
EMS	Energy management system
EoL	End-of-Life
EPR	Extended Producer Responsibility
EV	Electric Vehicles
LCA	Life Cycle Assessment
MAP	Materials Acceleration Platform
ORFB	Organic Redox Flow Battery
PBT	Persistent, Bioacumulative, Toxic
PMT	Persistent, Mobile and Toxic
PNEC	Predicted No-Effect Concentration
PPORD	Product and Process-related Research and Development
REACH	Regulation (EC) No 1907/2006 ("Registration, Evaluation, Authorisation and Restriction Of Chemicals")
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
SVHC	Substance Of Very High Concern
TRL	Technology Readiness Level
vPvB	very Persistent very Bioaccumulative
vPvM	very Persistent very Mobile
WP	Work Package

Executive Summary

This deliverable report fulfills the objectives of WP6 Task 6.5, which is stated in the project proposal as *the verification that the products comply with the existing regulatory landscape for the use of lignin-based electrolytes and other RFB components. Throughout the project a regular compliance check will also be performed to warrant that the final products within their envisaged applications fulfil all relevant EC Directives and regulations. The assessment should be performed before the scale-up begins in order to enable any processing/product specification changes. Input from all partners is required. A regulatory compliance report will be written to make sure that the products and technologies also fulfil all standards & legislation in force with regards to safety criteria.*

In this final report, we adopt a forward-looking compliance risk and opportunities approach rather than providing a definite legal assessment. This is in order to allow for the existing flexibility in design choices as the Organic Redox-flow Battery (ORFB) technology proposed by BALIHT advances to the next Technology Readiness Levels (TRL) until it reaches market-readiness. We include within the scope of the analysis highly-relevant policy proposals that are in the regulatory landscape and may become mandatory or achieve consensus amongst European stakeholders in the near future. The report focuses on high-level regulatory requirements applicable at the EU level and does not go into national-level specific requirements. It mainly focuses on specific technical and operational requirements of the battery's life cycle, largely leaving out requirements of an administrative nature such as labeling and conformity assessment.

Our key findings are summarized in the Table 1 below. Overall, we found the BALIHT design in its current form to be very well-placed to meet and exceed relevant safety and sustainability thresholds and expectations found in the policy landscape. Five key recommendations emerged from the analysis:

1. From the screening of substances involved in the life cycle of the battery, several substances meeting the criteria for substances of very high concern (SVHC) according to REACH regulation were found in the production of precursors for electrolyte's synthesis and in the paint layer of the electrodes. All substances meeting SVHC's criteria could potentially be classified as SVHC by ECHA in the future. While SVHC use is not necessarily forbidden, it is subject to important restrictions and thus careful monitoring and targeting for elimination in the supply chain is warranted, in line with EU's Chemical Strategy for Sustainability ambitions.

2. Monitor forthcoming amendments to the proposed Battery Regulation and the subsequent delegated acts, in particular those related to additional substances of concern that may be regulated, social and environmental due diligence requirements, and carbon footprint reporting and corresponding classification of batteries.

3. Prioritize research on End-of-Life (EoL) strategies for the organic negolyte that meet the requirements of the draft Battery Regulation. Such strategies must especially aim to avoid or reduce the fraction incinerated to a minimum, even if such incineration is coupled to an energy recovery operation. As there are indications that

   the hexacyanoferrate-based posolyte may be easier to reuse at the battery's EOL, continue to concretize and document pertinent treatment/reuse methods.

4. Continue to strengthen the BALIHT battery's competitiveness by enhancing the robustness of Life Cycle Assessment (LCA) and chemical risk assessment data and calculations. Deliverables 6.1 (Environmental LCA),

6.2 (Social LCA) and 6.6 (Report on Toxicology and Safety Aspects) will provide clear indications as to how to reduce uncertainty in these assessments.

5. Push for greater clarity, and if possible, tailor due diligence requirements to better distinguish when conflict/critical materials are not present in the battery.

6. Closely monitor the potential entry into force of the following safety testing requirements and conduct the relevant tests for market-ready designs: (i) thermal shock and cycling; (ii) external short circuit protection; (iii) overcharge protection; (iv) over-discharge protection; (v) over-temperature protection; (vi) thermal propagation protection; (vii) mechanical damage by external forces; (viii) internal short circuit; (ix) thermal abuse including fire test and risk of explosion; and (x) emission of gases, including under the extreme conditions described in (i)-(ix).

Table 1 Safety and sustainability regulatory compliance risks and opportunities for the BALIHT battery

Sustainability / Safety dimension	**Regulation / framework**	**Status of instrument**	**Risks**	**Opportunities**
Safety	Draft Battery Regulation (2020)	Proposed – advanced stage Mandatory	Currently, the definition of energy storage system excludes those with external storage. If this were to change to include ESS with external storage such as BALIHT, safety testing requirements would become applicable. Tests of the prototype for safety during operation have not been conducted to our knowledge, therefore we cannot establish potential for compliance. See section 2.4.5.	The experience of the BALIHT project could help with the designation of appropriate operational safety tests for 'stationary battery energy storage system' with external energy storage.
Social	Draft Battery Regulation (2020)	Proposed – advanced stage Mandatory	Due diligence exemptions for conflict/critical materials are not clearly established in the proposed regulation. This may unnecessarily introduce important administrative costs for the implementation and maintenance of a management system for batteries that avoid the risks by excluding these materials from their designs.	Social indicators obtained in the social-LCA conducted in deliverable 6.2 indicate no issues of concern in relation to conflict or critical minerals, particularly in comparison with competing battery technologies such as lithium-ion or vanadium redox-flow.
Environmental / circularity	Draft Battery Regulation (2020)	Proposed – advanced stage Mandatory	It is still not clear what EoL alternatives will be feasible in the near future (technically and economically) for some components, namely the negolyte and the membrane.	Due to its modular nature with external storage, the BALIHT battery is better placed than non-modular designs to enhance extended life, remanufacturing, repurposing and reuse.
	Draft Battery Regulation (2020)	Proposed – advanced stage Mandatory		Material-specific recycling requirements focus on cobalt, lead, lithium, and nickel in active materials, giving the BALIHT design a competitive advantage.

Sustainability / Safety dimension	Regulation / framework	Status of instrument	Risks	Opportunities
Economic	Draft Battery Regulation (2020)	Proposed – advanced stage Mandatory		The BALIHT design is likely to be favoured by green procurement practices by EU institutions as established in Chapter X Article 7 for batteries that can demonstrate a significantly lower impact.
	Batteries Directive (2006) Draft Battery Regulation (2020) Waste Framework Directive (2008)	In place – Mandatory Proposed – advanced stage Mandatory In place – Mandatory	Extended Producer Responsibility / EOL obligations adds to Levelized Cost of Storage (LCOS). In particular, handling of hazardous liquid waste from electrolyte may introduce important costs at the batteries' EoL.	

1. Introduction

1.1. Regulatory landscape

Starting from the Batteries Directive of 2006, we surveyed current and proposed legislation and frameworks on batteries and the wider green energy policy landscape that ultimately has led to the most recent policy development, the Draft Battery Regulation of 2020, still waiting for final approval. The EU Green Deal -the new comprehensive growth strategy of the EU- is the backbone of the prolific policy context encompassing green energy and batteries. The Green Deal aims at transforming the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy in which economic growth is decoupled from resource use and net emissions of greenhouse gases are eliminated by 2050. Sustainability is thus a core value of this Green Deal, with an essential role assigned to renewable energy sources. The Green Deal lays the basis for an extensive sustainability policy framework, initiating many of the policies discussed in this document, such as the Circular Economy Action Plan and the Chemicals Strategy for Sustainability, and legislations such as the Battery Regulation. An overview of policy documents relevant to the BALIHT project, sorted by time of publication and thematic focus is presented in Figure 1. In the remainder of this document, these relevant policies and regulations are described, organized by theme (batteries, circularity and materials safety).

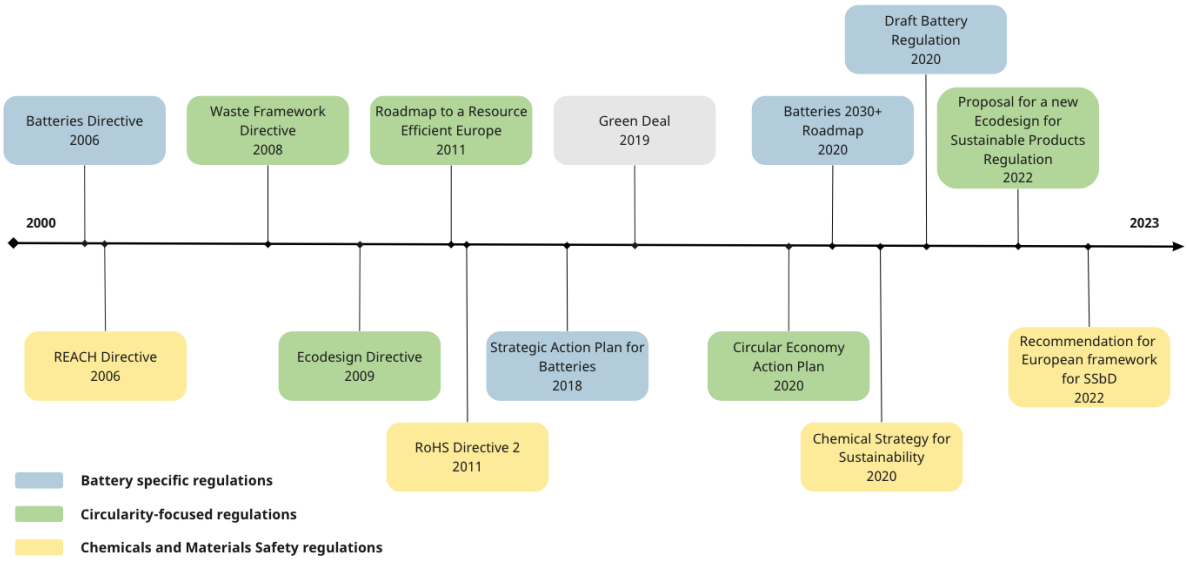

Figure 1: Policy timeline of the policies relevant to the BALIHT project

Table 2 List of policy documents included in this analysis

DATE	Document	Link
2006	Batteries Directive	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32006L0066
2006	REACH Regulation	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1907
2008	Waste Framework Directive	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20180705
2009	Eco-design Directive	https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32009L0125
2011	Roadmap to a Resource Efficient Europe	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011DC0571
2011	RoHS Directive 2	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011L0065-20160715
2018	Strategic Action Plan for Batteries	https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52019DC0176
2019	European Green Deal	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52019DC0640
2020	Draft Battery Regulation	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_5469_2023_INIT&qid=1675069045839&from=EN
2020	Circular Economy Action Plan	https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN
2020	Battery 2030+ Roadmap	https://battery2030.eu/
2020	Chemical Strategy for Sustainability	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN
2022	Proposal for a Regulation on establishing a framework for setting eco-design requirements for sustainable products	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0142
2022	Recommendation on establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials.	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022H2510

2. Battery-specific regulations and policy instruments

2.1. Batteries Directive (2006)

This document establishes rules regarding the placing on the market of batteries, with the restriction of hazardous substances, and regarding the EoL management, with collection schemes and recycling efficiencies. The directive addresses all batteries, regardless of the size and type. In the following paragraphs, the articles containing information relevant to the BALIHT project are briefly summarized and the ORFB prototype is found to be compliant with the regulation. However, since the Battery Directive is currently being replaced, it is necessary to also identify prospective regulatory risks. The new Battery Regulation will be described later in the document.

2.1.1. Definitions

The BALIHT prototype is addressed by the regulation under the definition of *industrial battery* as it is *designed for exclusively industrial or professional uses:*

- *'industrial battery or accumulator' means any battery or accumulator designed for exclusively industrial or professional uses or used in any type of electric vehicle (Article 3.6).*

2.1.2. Restricted substances

The directive prohibits the placing on the market of batteries containing mercury and cadmium above certain thresholds. For non-portable batteries, Article 4 only restricts the content of Mercury (expressed as mercury metal by weight) to 0,0005 %.

2.1.3. Battery end-of-life management

According to Article 8, producers of industrial batteries are required to take back waste batteries from end-users, regardless of chemical composition and origin. Producers are also required to organise the treatment and recycling of waste batteries, collected as prescribed in Article 8, and that the treatment and recycling schemes shall comply with EU and international legislation in terms of health, safety, and waste management and with the minimum requirements established in Annex III (Article 12). Furthermore, that producers are required to cover the cost of the collection, treatment and recycling of industrial batteries (Article 6). However, according to Article 18, small producers may be exempted from this obligation if the exemption does not impede the proper functioning of the collection and recycling schemes.

Annex III defines the minimum requirements for the treatment (part A) and the minimum recycling efficiency (part B) for all battery types. The minimum requirements for treatment are the removal of all fluids and acids and the storage of waste batteries in appropriate facilities, equipped with impermeable surfaces/covers/containers. The minimum recycling efficiency requirements to achieve by 2010 are:

- Recycling of 65 % by average weight of lead-acid batteries and accumulators, including recycling of the lead content to the highest degree that is technically feasible while avoiding excessive costs;
- Recycling of 75 % by average weight of nickel-cadmium batteries and accumulators, including recycling of the cadmium content to the highest degree that is technically feasible while avoiding excessive costs; and
- Recycling of 50 % by average weight of other waste batteries and accumulators.

Disposal in landfill or by incineration of waste industrial batteries is prohibited, with the exception of residues of batteries that have undergone treatment and recycling in accordance with Article 12 (Article 14).

2.2. Strategic Action Plan for Batteries (2018)

This plan is an Annex of the Sustainable Mobility plan, and therefore lays an emphasis on batteries for electric vehicles (EV), but the proposed strategy also applies to batteries more generally. The plan aims to: secure access to raw materials; support EU battery cell manufacturing and a full competitive value chain in Europe; strengthen industrial leadership through EU research and innovation; develop and strengthen a highly skilled workforce; support the sustainability of the EU battery cell manufacturing; and ensure consistency with the broader enabling and regulatory framework.

2.3. Batteries 2030+ Roadmap (2020)

This Roadmap is a research initiative funded by the European Commission (under Horizon 2020), aimed at inventing the sustainable batteries of the future, supporting the EU Green Deal goals. The Roadmap aims at developing ultra-high performance batteries that are safe, affordable and sustainable and have a long lifetime; it aims at providing new tools and technologies throughout the whole value chain of the EU battery industry; and it aims at enabling long-term European leadership in existing markets (e.g. stationary storage) and emerging sectors (e.g. robotics).

The Roadmap distinguished three overarching themes, with particular research areas:

- Theme I. Accelerated discovery of battery interfaces and materials.
    - Using the possibilities of AI, a Battery Interface Genome (BIG) and Materials Acceleration Platform (MAP) will be developed to accelerate the development of novel battery materials.
- Theme II: Integration of smart functionalities.
    - Embedded sensors will enable the continuous monitoring of battery health and safety status, and self-healing batteries will be developed.
- Theme III: Cross-cutting areas.
    - Manufacturability and recyclability need to be addressed early in the discovery process, using digitalization tools to replace classical trial-and-error approaches for manufacturing.

2.4. Battery Regulation (2020) – draft

The proposed new Battery Regulation aims to address three key issues. The first is the lack of framework conditions providing incentives to invest in production capacity for batteries. Due to differing regulatory frameworks, there is no level playing field in the internal market. The second problem is the sub-optimal functioning of recycling markets and the insufficiently closed material loops. The third links to the social and environmental risks that are currently not covered by the EU environmental law, such as the lack of transparency on sourcing raw materials.

Although the regulation has yet to be adopted, our analysis will focus on the most recent policy development, the final compromise text, published by the Council of the EU on the 18 of January 2023.[1] The text defines a number of

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_5469_2023_INIT&qid=1675069045839&from=EN

safety and sustainability requirements for batteries as well as the need to publicly divulge this information through 'battery passports'. The articles of the regulation containing information relevant to the BALIHT project are briefly summarized in the following paragraphs.

2.4.1. Definitions (Chapter 1. Article 2)

Two definitions established in the draft regulation are especially relevant to determine applicability of some key requirements to the BALIHT battery:

- *'Battery with external storage' means a battery designed to have the energy stored exclusively in one or more attached external devices.*
- *'Stationary battery energy storage system' means an industrial battery with internal storage specifically designed to store and deliver electric energy from and into the grid or store and deliver electric energy to end-user, regardless of where and by whom this battery is being used'.*

2.4.2. Restricted substances (Chapter 2, Article 6 and Annex I)

Pursuant to Annex XVII of Regulation (EC) No 1907/2006 ("REACH" regulation, see Section 4.1 in this report), batteries shall not contain substances for which Annex I of this draft regulation contains a restriction unless they comply with the conditions of that restriction. For non-portable batteries, Annex I only restricts the content of Mercury (expressed as mercury metal by weight) to 0,0005%.

For monitoring: By 31 December 2027, the Commission is expected to prepare a report on substances of concern, meaning substances having adverse effect on human health or the environment or hampering recycling for safe and high quality secondary raw materials, contained in batteries, or used in their manufacturing. Follow-up measures, including the adoption of the delegated acts governing the use of these substances, may derive from this report.

2.4.3. Carbon footprint (Chapter 2. Article 7 and Annex II)

The draft regulation establishes the requirements for a mandatory carbon footprint declaration, which generally follows the same methodological principles as the Product Environmental Footprint methods applied in the LCA report of the BALIHT Project (WP6, deliverable 6.1). The carbon footprint will be calculated as *kg of carbon dioxide equivalent per one kWh of the total energy provided by the battery over its expected service life*; and must be reported differentiated per life cycle stage as described in point 4 of Annex II, i.e. "Raw material acquisition and pre-processing", "Main product production", "Distribution", and "End-of-life and recycling".

The Commission will establish battery performance classes based on maximum carbon thresholds, requiring that batteries are classified accordingly as a precondition for placement on the market. For rechargeable industrial batteries with a capacity above 2 kWh, the technical documentation referred to in Annex VIII shall demonstrate that the declared life cycle carbon footprint value for the relevant battery model per manufacturing plant, is below the maximum threshold established in the delegated act adopted by the Commission pursuant to the third subparagraph.

For monitoring: The Commission shall, no later than 66 months after entry into force of the Regulation for industrial batteries with external storage, adopt a delegated act in accordance with Article 73 to supplement this Regulation by establishing the methodology for calculation and verification of the carbon footprint of the battery in accordance with the essential elements already set out in Annex II.

A requirement for a maximum life cycle carbon footprint threshold shall apply as of 120 months after entry into force of the Regulation or 18 months after entry into force either of the delegated act or of the implementing act respectively referred to in points (a) and (b) of the third subparagraph, whichever is the latest, for rechargeable industrial batteries with external

storage.

2.4.4. Mandatory recycled content (Chapter 2. Article 8)

The draft regulation establishes mandatory levels of recycled content in newly manufactured batteries, specifically cobalt, lead, lithium or nickel in active materials. However, this requirement does not apply to 'batteries with *exclusively* external storage' as is the case of BALIHT. Future revisions are anticipated in this article, yet they refer to target materials and quantities rather than expanding the scope to include batteries with exclusively external storage.

2.4.5. Safety during operation (Chapter 2, Article 12)

Stationary battery energy storage systems must be successfully tested using state-of-the-art methods for the parameters laid down in Annex V, namely: (i) thermal shock and cycling; (ii) external short circuit protection; (iii) overcharge protection; (iv) over-discharge protection; (v) over-temperature protection; (vi) thermal propagation protection; (vii) mechanical damage by external forces; (viii) internal short circuit; (ix) thermal abuse including fire test and risk of explosion; and (x) emission of gases, including under the extreme conditions described in (i)-(ix).

To monitor: To our knowledge, at the time of this report's completion, the BALIHT battery prototype had not been subject to the tests (i)-(x) described above. Strictly following the text's definitions, this requirement only applies for Energy Storage Systems with internal storage. However, we recommend these tests are conducted as soon as possible as it is possible that the terms in the regulation are redefined to include the possibility of ESS with external storage.

2.4.6. Supply-chain due diligence for raw materials (Chapter 6. Article 45b)

Economic operators (those legally responsible for the manufacture, distribution, commercialization, operation and EoL management of batteries) are required to adopt and clearly communicate a supply chain due diligence policy concerning raw materials and their associated social and environmental risk categories (Annex X). This requirement does not apply to economic operators that had a net turnover of less than EUR 40 million in the financial year preceding the last financial year, and that are not part of a group, consisting of parent and subsidiary undertakings, which, on a consolidated basis, exceeds the limit of EUR 40 million.

The due diligence policy must be supported by a management system, which includes establishment and operation of risk controls and transparency over the battery's value chain, including a chain of custody or traceability system which identifies upstream actors in the supply chain. Relevant elements of the management system must be documented and verified by third-parties.

In addition to this, economic operators will be required to develop and implement a risk management plan which produces strategies to respond to the identified risks so as to prevent, mitigate and otherwise address adverse impacts. The nature of the risks addressed are listed in Annex X and include a broad range of social and environmental risks.[2]

This element in the draft regulation appears to be centered on materials listed in Annex X, namely cobalt, natural graphite, lithium, nickel, and chemical compounds based on these which are necessary for the manufacturing of the active materials of batteries. No specification as to minimum quantities is given, and -more importantly- the text is

[2] Note: the relevant indicators have been comprehensively assessed (in a prospective way) for the BALIHT battery in both the environmental LCA (Deliverable 6.1) and the social LCA (Deliverable 6.2).

not clear on whether only conflict materials require full supply chain due diligence including chain-of-custody tracing to source.

To monitor: obtain additional clarity on (and recommend if possible) conditions for applicability of specific requirements based on types of materials. Additional materials may be added to those listed in Annex X. Battery End-of-Life management (Chapter 7).

Article 47 establishes clear obligations following the principles of Extended Producer Responsibility (EPR). Producers must cover the costs of collection, transport, and treatment of waste batteries; compositional surveys of collected mixed municipal waste; information on prevention and waste management; data gathering and reporting to the competent authorities. Producers are also required to take back free of charge, all waste batteries from end-users (directly or through an authorized representative).

Article 57 sets minimum recycling efficiency requirements to go into force by 2025:

- (a) Recycling of 75 % by average weight of lead-acid batteries.
- (b) Recycling of 65 % by average weight of lithium-based batteries.
- (ba) Recycling of 80 % by average weight of nickel-cadmium batteries.
- **(c) Recycling of 50 % by average weight of other waste batteries.**

According to the BALIHT proposal, cost-efficient decommissioning and recycling techniques are being identified, with the aim of reusing or recycling at least 80% of the materials of the battery, potentially exceeding the circularity requirements set by this regulation.

In order to prioritize re-use, repurpose and recycling, collected waste batteries *shall not be disposed of or be the subject of an energy recovery operation* (Article 56).

3. Waste and circularity-focused regulations and policy instruments

3.1. Waste Framework Directive (2008)

The Directive, published in 2008 and last amended in 2018, lays the basis for an EU circular economy. In Article 4, a waste hierarchy is defined, with prevention as first priority, followed by re-use, recycling, incineration and finally landfill disposal. The organic negolyte of BALIHT's ORFB was identified as suitable to generate heat at the end of life from the start of the project (BALIHT proposal). However, in view of the waste hierarchy established by Article 4 of Directive 2008/98/EC (Waste Framework directive), which prioritizes prevention, preparing for re-use and recycling, different EoL strategies should also be researched for the electrolytes.

Furthermore, the principle of EPR, a further extension of the polluter-pays principle, is introduced with Article 8, to support the design and production of resource-efficient goods. EPR means that the producer of a product has the responsibility to organize and pay for the waste handling of their product, a principle already established for industrial batteries by the Battery Directive of 2006.

The Directive also emphasizes the obligation to handle waste in such a way that does not have a negative impact on the environment or human health and, in particular (Article 13):

- (a) Without risk to water, air, soil, plants or animals;
- (b) Without causing a nuisance through noise or odours; and
- (c) Without adversely affecting the countryside or places of special interest.

Hazardous waste shall not be mixed with other waste, hazardous or not (Article 18) and shall be identified, labelled and packaged in accordance with international and Community standards (Article 19). Article 7 addresses the intention of compiling a 'list of waste', binding as to what is to be considered hazardous waste. According to the list (Commission Decision 2014/955/EU)[3], separately collected electrolyte from batteries and accumulators is classified as hazardous waste (Chapter 16 06 06*). The classification of the electrolytes as hazardous waste has regulatory and economic consequences for the BALIHT project and should be considered during the development of EoL strategies for the electrolytes.

3.2. Ecodesign Directive (2009)

This directive describes ecodesign as a preventive approach, which optimizes the environmental performance of products while maintaining their functional qualities. It advocates for taking action during the design phase of products, since the pollution caused during a product's life cycle is determined at that stage. The Directive is specifically aimed at stimulating energy efficiency in products are goods that have an impact on energy consumption during use, such as windows or shower heads. This Directive does not apply to batteries. However, it lays the basis for Ecodesign in EU legislation. This principle is developed further and applied to a broad range of products in the proposal for a new Regulation Proposal on establishing a framework for setting ecodesign requirements for sustainable products, published on 30 March 2022, which is described in the following section.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014D0955

3.3. Proposal for a Regulation on establishing a framework for setting ecodesign requirements for sustainable products (2022)

The objective of this Proposal is to establish *a framework for setting ecodesign requirements, creating a digital product passport, and prohibiting the destruction of unsold consumer products (p.10)*.

The Proposal also expands the definition of *substances of concern,* including substances that negatively affects the re-use and recycling of the other materials in the product (Chapter I, Article 2(28)). The other *substances of concern* are SVHC (according to the definition of REACH, Article 57) and the substances classified in the Annex VI of the CLP Regulation in one of the following hazard categories: carcinogenicity categories 1 and 2, germ cell mutagenicity categories 1 and 2, reproductive toxicity categories 1 and 2, […] Persistent, Bioacumulative, Toxic (PBTs), very Persistent very Bioaccumulative (vPvBs), Persistent, Mobile and Toxic (PMT), very Persistent very Mobile (vPvM), Endocrine disruption, respiratory sensitisation category 1, skin sensitisation category 1, chronic hazard to the aquatic environment categories 1 to 4, hazardous to the ozone layer, specific target organ toxicity (repeated exposure categories 1 and 2 and single exposure categories 1 and 2).

Chapter II of the Regulation establishes general ecodesign requirements:

- Regulate product durability, reusability, upgradability, reparability, the presence of substances of concern, and their energy and resource efficiency;
- Increase recycled content in products;
- Enable remanufacturing and high-quality recycling;
- Reduce carbon and environmental footprints.

Digital product passports (Chapter III) and eco-labels (Chapter IV) are also set as ecodesign requirements by this legislation. Article 20 (Chapter VI) enforces transparency requirements for economic operators discarding unsold products and establishes the possibility of adopting delegated acts to prohibit their destruction.

The proposal not only establishes a framework for setting ecodesign requirements, but, according to Article 4, it empowers the Commission to adopt delegated acts to actually set product-specific requirements. This Regulation, however, is meant to be applied *to products not covered by existing legislation, or when legislation does not sufficiently address the sustainability of those products; product-specific requirements […] included in delegated acts […] cannot supersede requirements set through legislative acts such as directives or regulations (although they can be more specific), following the principle of the hierarchy of norms* (Explanatory memorandum, p.2). In the case of batteries, the Battery regulation will be addressing the eco-design principles put forward by this Proposal.

3.4. Roadmap to a Resource Efficient Europe (2011)

This Roadmap provides a foundation for a competitive economy with sustainably managed resources, while protecting the climate and environment. Resource-efficiency is necessary to achieve this. Consumers should be able to choose the most resource-efficient products, through appropriate price signals and clear environmental information. Companies should benchmark their lifecycle resource efficiency, and economic growth and wellbeing should be decoupled from resource inputs. Waste should be treated as a resource, with recycling and re-use being economically attractive. These milestones were set for 2020, but they are still relevant today.

3.5. Circular Economy Action Plan (2020)

The EU Circular Economy Action Plan describes the pathway to economic growth from resource use and a climate neutral economy by 2050. In the future, products should be durable; reusable; upgradeable; and reparable. The use of hazardous chemicals should be prevented, and energy and resource efficiency should be increased. Products should increase the recycled content, while ensuring performance and safety. Remanufacturing and high-quality recycling should be enabled. At the same time, carbon and environmental footprints should be reduced. Single-use or destroying of unsold durable goods should be banned, and circular business models should be incentivized. Digital solutions must be implemented, and products with high sustainability performance should be incentivized. Certain product groups are identified as a key priority, such as batteries and vehicles, based on their environmental impact and circularity potential. This priority classification is the reason the new Battery Regulation was proposed.

4. Chemicals and materials safety regulations and policy instruments

The regulations that are relevant in the safety of the chemicals and materials in the BALIHT battery are the REACH regulation (2006), which regulates the registration, evaluation, authorization and restriction of chemicals, the Chemicals Strategy for Sustainability (2020), which focuses on safe and sustainable by design of chemicals, and the RoHS directives (2002 and 2011), which restrict hazardous substances in electrical and electronic equipment. The most recent development in terms of safety regulations is the recommendation (December 2022) of the European Commission for a European framework to assess the safety and sustainability of chemicals and materials. The proposal underlines the importance of establishing a European baseline for the evaluation of human health and environmental concerns.

4.1. REACH Regulation (2006)

REACH regulates the registration, evaluation, authorization and restriction of chemicals. In 2008, the Regulation was complemented with the CLP regulation, a system of classification, labelling and packaging of chemical substances and mixtures.

Protecting human health and the environment is a core principle. Manufacturers and importers are required to register chemicals by performing risk assessments and submitting relevant information to the European Chemicals Agency. The Agency is in charge of the evaluation of the registrations and the authorization or restriction of the chemicals. One of the key objectives of REACH is to encourage the replacement of substances of high concern with less dangerous substances, if suitable economically and technically-viable alternatives are available. The Regulation establishes that the responsibility for the determination of the risks of these substances lies with the manufacturers or importers, who should ensure that exposure to substances throughout the whole life cycle is below the threshold level beyond which adverse effects may occur.

4.1.1. Registration

The registration of chemicals under REACH is compulsory for every manufacturer or importer when the substance is produced in quantities of 1 ton or more per year (Article 6, Title II, Chapter 1). In the BALIHT project, four compounds were synthesized by CMBlu for the negolyte, since they are not available on the market. Due to the manufacturing of chemicals, Article 6 is relevant to the BALIHT project; however, the production is currently well below the minimum threshold. Furthermore, according to Article 9 (Title II, Chapter 1), Product and Process-related Research and Development (PPORD) may be exempted from the full obligation for a period of 5 years in which the substance is yet to be placed on the market and available only to a limited number of customers. Even as a downstream user, in the case of the reactants used in the synthesis of the electrolytes, BALIHT is exempted from registration, provided that the risks to human health and the environment are appropriately managed.

Producers and importers of articles are required to register any substance contained in the article if *the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year* and *the substance is intended to be released under normal or reasonably foreseeable conditions of use* (Article 7, Title II, Chapter 1).

Producers and importers of articles are also required to notify ECHA, if a substance meets the criteria for the classification as SVHC (Title VII, Chapter I, Article 57) and is identified by ECHA as SVHC in accordance with Article 59(1)

and if *the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year* and *the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w)*. However, the notification is not required if the producer can exclude the possibility of release into the environment *under normal or reasonably foreseeable conditions of use, including disposal.* In this case, the producer *shall supply appropriate instructions to the recipient of the article*.

As the manufacturer of an article (the ORFB), the BALIHT consortium is not required to register any substance since none reaches the minimum threshold of 1 tonne or is *intended to be released*.

Polymers are exempted from registration and evaluation under REACH until *a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established* (Title XV, Article 138, p. 99). However, monomers or other substances need to be registered if produced in quantities of 1 tonne or more per year and if the polymer consists of 2 % weight by weight of such monomer/substance (Article 6).

For monitoring: SVHC's presence and quantity needs to be monitored. Several substances in the battery could potentially be classified as SVHC in the future. If the exemption of polymers is lifted more SVHC could be identified. Furthermore, the criteria for the classification are periodically revised and new criteria could be introduced.

For monitoring: The registration of substances becomes necessary when the PPORD period (5 years + max. 5 years extension) expires.

4.1.2. Evaluation

The evaluation process conducted by ECHA consists of the examination of testing proposals and the compliance check of registrations (Title VI, Chapter I, Article 40-41). The registrants may be required to submit further information (Article 46).

4.1.3. Authorization

The authorisation shall be granted, after considering the opinion of the ECHA's *Committee for Risk Assessment,* if the risks to human health and the environment can be managed in accordance to section 6.4 of Annex I, i.e., if the exposure levels do not exceed the Derived No-Effect Limit (DNEL) or the Predicted No-Effect Concentration (PNEC), and if *the likelihood and severity of an event occurring due to the physicochemical properties of the substance is negligible* (Title VII, Chapter II, Article 60).

The authorisation process is responsible for the good functioning of the internal market as well as for the the proper management of risks from SVHC. The criteria for the classification of substances as SVHC by ECHA acc. Art. 59 are laid out in Article 57: *(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC; (b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC; (c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC; (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII; (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; (f) substances - such as those having endocrine disrupting properties […] - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e).*

For SVHC, the authorization may be granted if it is shown that *socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies* (Title VII, Chapter II, Article 60).

The Regulation includes in Annex XVII a list of restricted substances under Article 67 (Title VIII, Chapter I) and the conditions of the restriction, including whether the restriction is not applied to R&D or whether there is a maximum exempted quantity. Annex XVII shall be amended *when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances* (Title VIII, Chapter II, Article 68).

4.2. RoHS Directive (2011)

The Restriction of Hazardous Substances in Electrical and Electronic Equipment was first implemented by the directive of 2002; RoHS 1 was subsequently repealed by RoHS 2, i.e., the RoHS directive of 2011, amended in 2017, discussed in this document. RoHS 2 restricts the use of ten substances: lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

Recital 14 of RoHS 2 specifically states that the directive *shall apply without prejudice to Union legislation on safety and health requirements and specific Union waste management legislation, in particular Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators* (Batteries Directive). Therefore, batteries do not fall within the scope of RoHS.

4.3. Chemicals for Sustainability Strategy (2020)

This strategy adds to the REACH regulation and the CLP regulation with a specific attention for chemicals that enable the green and digital transitions and protecting the environment and human health. Substances of concern should be minimized or substituted as much as possible, and the SVHC under REACH must be phased out for non-essential use. This strategy proposes the use of chemicals in such a way their contribution to society is maximized, while harm to the planet and to humans is avoided. Safe- and sustainable-by-design chemicals are considered key to achieve these goals. In this strategy, a move towards toxic-free material cycles and clean recycling is proposed. The strategy has encouraged ongoing revisions to the REACH regulation and the CLP regulation.

4.4. Recommendation on a European framework for SSbD chemicals and materials (2022)

The objective of the proposal is to advance a European baseline for the evaluation of human health and environmental concerns. The Recommendation establishes a testing period for a Safe and Sustainable by design (SSbD) framework with a voluntary reporting mechanism, followed by a revision process to include relevant feedback.

The SSbD framework consists of a two stages iterative approach: the (re-)design stage and the safety and sustainability assessment. Different design levels can be covered in the first stage (Annex, par. 3):

- *molecular design, to design new chemicals and materials based on their chemical structure;*
- *process design, to make the production process safer and more sustainable, both for chemicals and materials being developed and for existing chemicals and materials;*
- *product design, where the results of the SSbD assessment support the selection of the chemicals or materials to meet the functional demands of the final product in which they are used.*

At this stage, several guiding principles are proposed to support SSbD: material efficiency, minimise the use of hazardous chemicals or materials, design for energy efficiency, use renewable sources, prevent and avoid hazardous emissions, design for end of life, consider the whole life cycle. The second stage is required to determine the level of safety and sustainability performance achieved by the design. The assessments consists of 4 steps: Hazard assessment (focused on the intrinsic properties of the chemicals), Human health and safety aspects of production and processing, including waste treatment (focused on risks to workers), Human health and environmental aspects in the final application phase (focused on any risk to human health or the environment), Environmental sustainability assessment (focused on LCA and assessing several impact categories). Although socio-economic assessments are envisioned by the SSbD phylosophy, further steps are currently not included in the framework; however, they are up for discussion for the reviewing process.

According to the SSbD framework, three categories of hazardous substances should be distinguished: most harmful substances according to the Chemicals Strategy for Sustainability, including SVHC identified with the criteria in Article 57 of REACH and and identified in accordance with REACH Art. 59(1), substances of concern (Article 2(28) of the ecodesign proposal for sustainable products, excluding SVHC) and other hazards (all other hazard classes). In light of these definitions, the hazard status of the compounds involved in the whole life cycle of the electrolytes of the BALIHT prototype is depicted in Figure 2 and the hazard status of the compounds present in other battery components is shown in Table 3. The precursors for DHPS are reported by CMBlu in D5.2, while the precursors for DCDHAQ and FAT are assumed from syntheses reported in literature.

The other steps of the safe and sustainable by design framework were also applied to BAHLIT battery case study under the WP6 deliverables (see D6.6 for step 1-3, D6.1 for step 4, D6.2 for the additional steps of Social-LCA).

Table 3: REACH hazard assessment of the chemicals, present in other components of the BALIHT battery

Compound	Human health hazards	Environmental hazards	Physical hazards	Source
Polymeric membrane	*Exempted*	*Exempted*	*Exempted*	-
Polymeric component 1 (for electrode paint)	*Exempted*	*Exempted*	*Exempted*	-
Component 2 (for electrode paint)	*Data conclusive but not sufficient for classification* (according to CLP notifications, may cause cancer, damage to organs, eye irritation)	*Data conclusive but not sufficient for classification*	*Data conclusive but not sufficient for classification*	*ECHA*
Other polymers (tanks, …)	*Exempted*	Exempted	*Exempted*	-

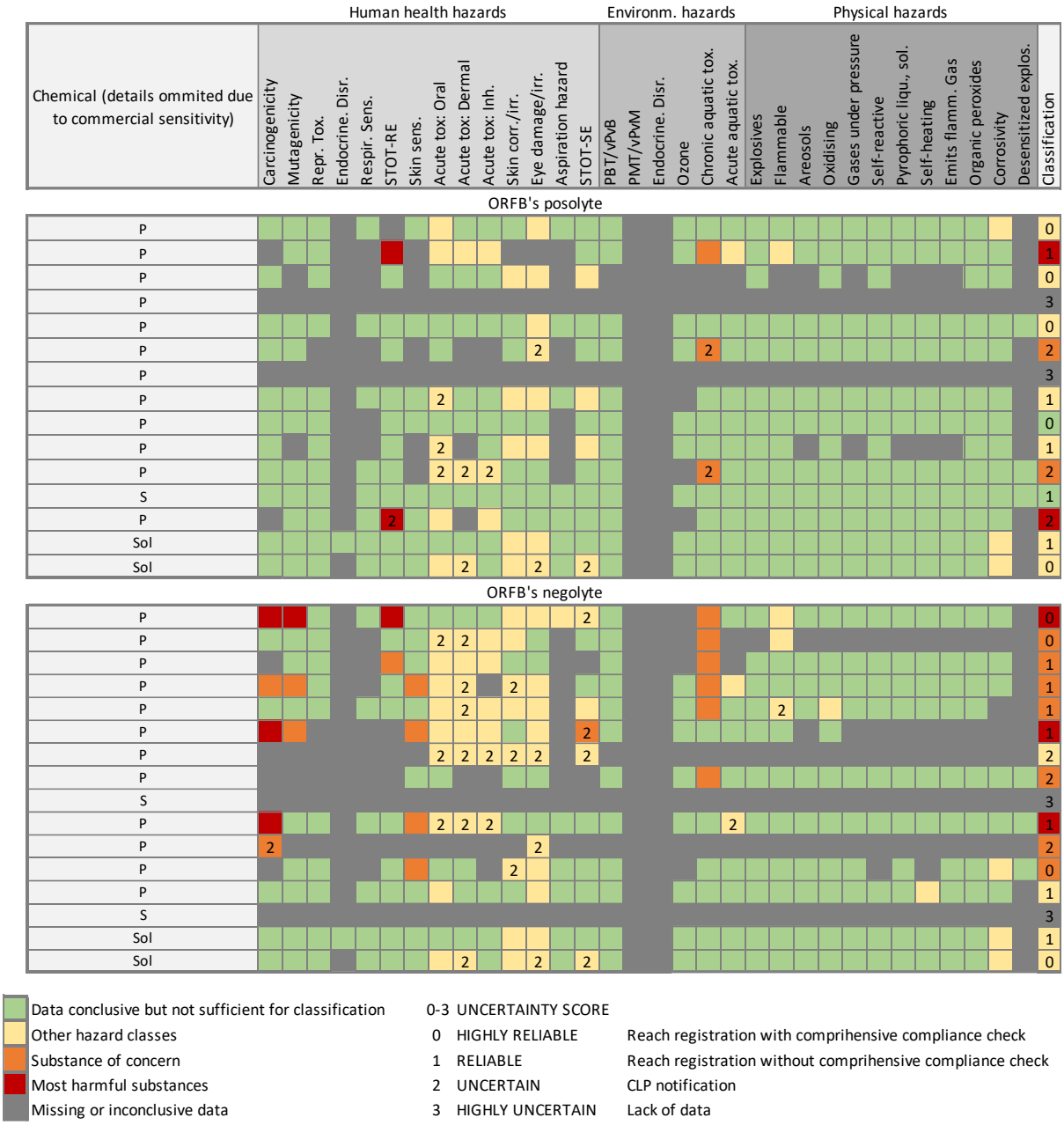

Figure 2: REACH hazard assessment of the chemicals involved in the life cycle of the electrolytes of the BALIHT battery (P: precursor, S: shuttle, Sol: solvent)

5. Regulatory risks and opportunities for the BALIHT battery

Based on the battery design proposed in BALIHT and the work conducted in WP6, it is apparent that the BALIHT battery is well-placed to meet the requirements of current legislation, particularly in terms of safety and sustainability (see Deliverables 6.1, 6.2 and 6.6). It is important to continue monitoring, as the policy landscape around sustainable energy systems, and batteries in particular, is very dynamic at present and future developments hold uncertainty. Furthermore, key aspects are set out to be determined in subsequent delegated acts; e.g. the establishment of maximum carbon footprint thresholds and the corresponding classes in the proposed Battery Regulation. Therefore, the analysis of regulatory compliance risks and opportunities is focused on upcoming policies such as the Draft Battery Regulation.

5.1. Battery-specific regulations

The introduction of *'batteries with external storage'*, such as the BALIHT battery, in the most recent version of the Battery Regulation allows for a more accurate distinction between types of batteries. However, *'batteries with external storage'* are deliberately excluded from the definition of '*stationary battery energy storage system'*, which is instead the intended application for the BALIHT battery (Article 2). Such a mismatch between the intended application of the battery and the definition of this application by the regulation might lead to confusion regarding whether certain requirements are applicable or not. Article 12, for example, explicitly addresses the safety requirements of stationary battery energy storage systems, establishing safety parameters (Annex V) to be included in a safety technical report available for users. In this instance, the inclusion of *'batteries with external storage'* in the definition of '*stationary battery energy storage system'* would require the introduction of tailor-made safety parameters, considering the technological differences between batteries with internal and external storage. Further research is required to determine relevant parameters since, currently, battery risks are modelled primarily around LIBs and very few risk assessments of RFBs or other less common battery types are available.

The calculation of the carbon footprint as described in the Battery Regulation is at the moment generic and does not distinguish between specific use battery cases / applications, such as energy arbitrage or frequency regulation. In order to understand whether a product is desirable or not in terms of carbon emissions, it is essential to clearly define its intended use so that it can be compared with realistic alternatives. As opposed to, e.g., energy generation systems such as photovoltaics or wind power whose sole purpose is to generate electricity, batteries have a broad range of applications that vary substantially in nature, yet these are not taken into account in carbon footprint calculations. The functional unit -which constitutes the basis for the assessment- is currently defined as *one kWh (kilowatt-hour) of the total energy provided over the service life by the battery system, measured in kWh*, which presupposes a simplified and single application.

Furthermore, the explicit exclusion of the use phase in the carbon footprint calculations results in that energy losses during battery cycling are disregarded from the analysis. This may reflect unfairly on battery designs that offer superior roundtrip efficiencies. For example, a battery may incur in higher carbon emissions during its manufacturing than a competing alternative, but if its superior efficiency results in less energy losses during charge/discharge cycles, its total life cycle emissions may be lower. In its present form, the proposed carbon footprint calculation method would not capture this important aspect.

5.2. Circularity-focused regulations

In the Battery Regulation, both minimum recycled content requirements and performance/durability requirements are not specified for *'batteries with external storage'.* Therefore, no risks of not compliance can be expected in the immediate future. However, the exclusion of these batteries in the legislation is a direct consequence of the low level of maturity of the external storage technology, and the introduction of ad hoc requirements can be expected as the technology progresses towards market-scale deployment. Maximizing recyclability and lifetime of the battery is therefore essential to anticipate future regulatory requirements.

Under the EPR, producers are required to cover the costs for collection, transport, and treatment of waste batteries. However, batteries with external storage such as the BALIHT battery, are modular. Each component, separately produced, can reach EoL at a different time. Therefore, the economic operator to which the EPR is assigned, i.e., component manufacturer or battery manufacturer, needs to be clearly defined.

The upcoming Battery Regulation *(Article 56.1, p. 216)* establishes that *collected waste batteries shall not be disposed of or be the subject of an energy recovery operation.* The battery is again viewed as a whole, with each component reaching EoL at the same time. This is not the case for batteries with external storage such as BALIHT's ORFB and it is not clear whether the proscription would apply to waste electrolytes that have undergone wastewater treatment. As a matter of fact, the Battery Directive allows incineration with heat recovery, if the battery has undergone treatment and recycling in accordance with Article 12, i.e., if fluids and acids have been separated and 50% of the battery by weight has been recycled.

5.3. Chemicals and materials safety regulations

Several potential SVHC were found along the supply chain of the ORFB and many more are included in the definition of substances of concern according to the Article 2(28) of the ecodesign proposal for sustainable products. While SVHC use is not necessarily forbidden, it is subject to important restrictions and thus careful monitoring and targeting for elimination in the supply chain is warranted, in line with EU's Chemical Strategy for Sustainability ambitions.