

POLICY BRIEF: EU LEGISLATION ON CHEMICALS AND MATERIALS SAFETY

OVERVIEW OF CURRENT EU LEGISLATION ON CHEMICALS AND MATERIALS SAFETY

Our partners conducted a thorough analysis of the current EU legislation for the chemicals and materials safety landscape. This Policy Brief will address the main elements of this analysis and highlight the compliance of BALIHT's prototype.

GOAL AND OBJECTIVES OF THE CURRENT EU LEGISLATION ON CHEMICALS AND MATERIALS SAFETY

The European Union has built up a legislative framework on chemicals and materials which requires particular attention due to hazardous and complex features. The *Regulation on the registration, evaluation, authorization and restriction of chemicals (REACH 2006)* laid the ground for the current European chemicals framework, before being enhanced of the *Classification, Labelling and Packaging (CLP) regulation (2008)*. Then, the *Restriction of Hazardous Substances Directive (2011)* restricts the use of substances such as lead, cadmium, and mercury in electrical and electronic equipment. The Commission released a Communication on *Chemicals for Sustainability Strategy (2020)* aligned with the objective the *green and digital transition*. Finally, the last piece of the EU landscape is the *Recommendation on a European framework for Safe-and-Sustainable-by-Design (SSbD) chemicals and materials (2022)*. This recommendation sets up a testing period for a SSbD framework with a voluntary reporting mechanism to tackle human health and environmental concerns at the beginning of the R&D process.

GENERAL IMPLEMENTATION AND PRACTICE OF THE LEGISLATION

Along with the European Chemicals Agency, *REACH (2006)* aims at protecting human health and the environment from hazardous chemicals. Legal provisions encourage the replacement of substances of high concern with less dangerous chemicals. The responsibility for determining the risks lies with the manufacturer or importer, throughout the whole life cycle.

The registration part of the legislation is required for every manufacturer if the substance is produced in quantities of 1 ton or more per year.

Manufacturers are required to notify ECHA if a chemical meet the criteria of substances of very high concern (SVHC) and if it is present in a concentration of 0,1% weight by weight.

To obtain the authorization, the ECHA's Committee for Risk Assessment has to give its opinion. Exposure levels cannot exceed the Derived No-Effect Limit (DNEL) nor the Predicted No-Effect Concentration (PNEC).

The *Chemicals for Sustainability Strategy (2020)* complements the *REACH regulation (2006)* and the *CLP regulation (2008)*. It states that substances of concern should be phase out for non-essential use. The contribution of chemicals to society has to be maximized without harming humans or the environment.

Finally, the *Recommendation on a European framework SSbD for chemicals and materials (2022)* aims at generalising the use of SSbD. This methodology is split into a (re)design stage and a safety and sustainability assessment. This should ensure better design for chemicals and materials to avoid any harm to society.

The *Recommendation* distinguishes three categories of hazardous chemicals: the most harmful substances (including but not limited to SVHC), substances of concern and other hazards.

IMPLEMENTATION AND PRACTICE OF THE LEGISLATION APPLIED TO BALIHT'S PROTOTYPE

Given the components of the BALIHT's prototype, it falls under the scope of the *REACH regulation (2006)*. The project would be subject to the registration of chemicals when the production will exceed 1 ton per year. This means that as of today, BALIHT is exempted from registration, given that risks to human health and to the environment are well-managed. Also, polymers, which are essential for the prototype, are not under the scope of the *REACH regulation (2006)*.

The *Restriction of Hazardous Substances in Electrical and Electronic Equipment directive (2011)* does not apply to batteries. Health requirements, waste management and safety concerns are covered directly by the batteries legislation.

The Safe-and-Sustainable-by-Design approach has already been applied to BALIHT's prototype in the early phases of development.

As some potential SVHC have been found in the BALIHT's prototype supply chain, thorough monitoring should be conducted to prevent and anticipate on possible legal requirements and disclosure to the European Chemicals Agency.