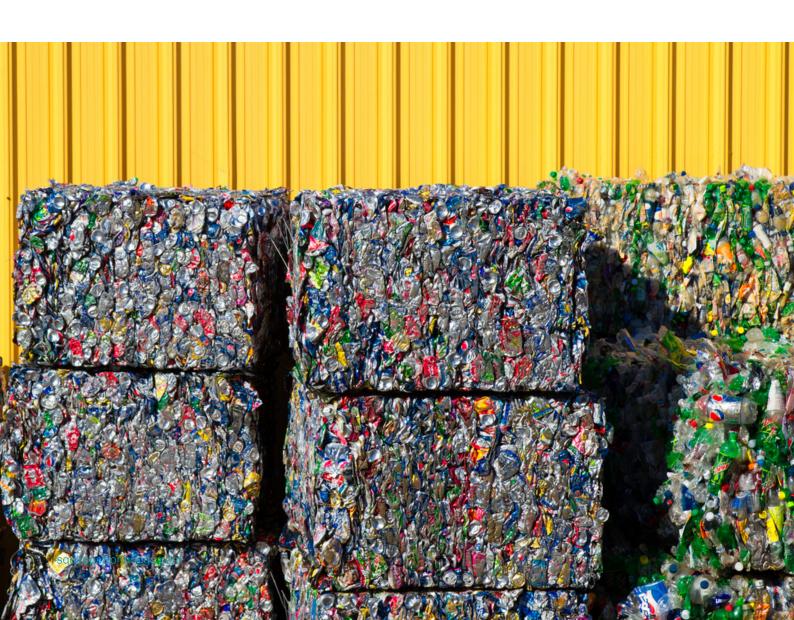


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Sustainability Outlook European Union

June 2021



Slovenian Council Presidency outlines sustainability policy priorities

At the start of July, Slovenia took over the presidency of the EU Institution representing the Member States from Portugal, which rotates every six months. France will follow in that role at the start of 2022. Among the priorities of the Slovenian Presidency are the effective implementation of the Next Generation EU (NGEU) and the Recovery and Resilience Facility (RRF), which provide overall €750 billion EU **funding to help recover from the COVID-19 crisis**, with the aim of accelerating the green and digital transition to create jobs and protect the environment. Slovenia would also strive for the transposition of the set **climate** objectives into **binding EU legislation**. According to Slovenia's Minister for Environment, starting the debate of the "Fit for 55 Package" (please see frESH Law Horizons October 2020) will be among the priorities. In that package, the Commission will make multiple legislative proposals to achieve a climate-neutral Europe by 2050, including renewable energy, energy efficiency and energy performance of buildings, as well as energy taxation and emissions trading, on 14 July. However, the new Presidency is reportedly realistic about the limited prospects of the Council already agreeing on its position on the package this year, which another highranking Slovenian official characterised as a legislative "tsunami". The official Presidency programme mentions that the UNFCCC COP-26 climate summit in Glasgow in October 2021 would provide an additional opportunity for the EU to show its determination and convince the rest of the world that climate action must be taken now. Slovenia wants to return to in-person meetings, with 45 meetings of ministers and leaders in Brussels and more than 1,600 working meetings planned over the next six months.



Following a political agreement that the Council and the European Parliament (EP) reached in April (please see frESH Law Horizons April 2021), the institutions adopted the European Climate Law. It passed the EP with 442 votes in favour, 203 against and 51 abstentions, with **strong support from** the major political groups Renew Europe (RE), the European People's Party (EPP) and the Socialist & Democrats (S&D). However, the Greens said the law was not ambitious enough and voted against it, joining the far-right Identity and Democracy group (ID). The Left reportedly also strongly opposed the legislation. In addition to the goal of climate neutrality and an aspirational goal for the Union to strive to achieve negative emissions after 2050, the European Climate Law sets a binding EU target of a reduction of net greenhouse gas emissions (emissions after deduction of removals) by at least 55% by 2030 compared to 1990. In order to ensure that sufficient efforts to reduce and prevent emissions are deployed until 2030, the climate law introduces a limit of 225 Mt of CO2 equivalent to the contribution of removals to that target. The EU will also aim to achieve a higher volume of carbon net sink by 2030. It tasks the European Commission with proposing an intermediate climate target for 2040, if appropriate, at the latest within six months after the first global stocktake carried out under the Paris Agreement. At the same time, the Commission has the task of publishing an indicative EU greenhouse gas budget for 2030 to 2050, together with its underlying methodology. The Regulation will enter into force after its publication in the Official Journal.











European Commission plans carbon border adjustment mechanism (CBAM) for imports of iron, steel, cement, fertilisers, aluminium and electricity

Ahead of the publication of the "Fit for 55 package" of legislative proposals, expected for 14 July 2021, an undated draft proposal for a regulation on CBAM (including Annexes) was leaked to the press. The products within the scope of the CBAM are enumerated in Annex I. Regarding **electricity**, the draft notes that discussions between Commission services are ongoing on how to address the imports from countries with which the Internal Energy Market is or will soon be coupled. Annex II would exclude the EFTA countries (but not the UK) from the scope of the CBAM. Importers would have to seek authorisation from a CBAM authority, **buy certificates** covering their yearly imports from that authority and surrender them. The number of certificates needed would depend on the emissions embedded in the imports, as declared by the importer and verified by an independent certifier (on the basis of the approach laid out in Annex III). The importer would be allowed to claim a reduction in the number of certificates corresponding to the carbon price paid in the country of origin for the declared emissions. The CBAM Authority would calculate the price of those certificates as the average of the closing prices of all auctions of EU ETS allowances conducted in appointed auctioning platforms during each calendar week. The draft discusses a phase-in period starting in 2023 and full implementation from 2026.

European Commission proceeds with infringement procedures against 18 Member States due to their failure to comply with EU waste law

The Commission <u>announced</u> that it has issued so-called reasoned opinions urging certain Member States to implement EU waste legislation. Member States had to transpose multiple Directives from the 2015 Circular Economy Package into their national law by July 2020. The Commission is pursuing 17 Member States (Austria, Belgium, Czech Republic, Estonia, Greece, Spain, Finland, France, Croatia, Lithuania, Luxembourg, Latvia, Malta, Poland, Romania, Slovenia and Slovakia) for their failure to transpose correctly the amendments to the **Waste Framework Directive** by Directive 2018/851.

The Commission urged 13 Member States (Austria, Estonia, Greece, Spain, Finland, France, Croatia, Lithuania, Luxembourg, Malta, The Netherlands, Poland and Romania) to correctly transpose amendments to the **Packaging and Packaging Waste Directive** by Directive 2018/852. Regarding the amendments to the **Landfill Directive** by Directive 2018/850, the Commission is pursuing 13 Member States (Austria, Belgium, Czech Republic, Estonia, Greece, Finland, France, Croatia, Luxembourg, Latvia, Malta, Romania and Slovakia). It urged seven Member States (Belgium, Greece, Finland, Croatia, Luxembourg, Malta and Slovakia) to act regarding certain waste streams (end-of-life vehicles (**ELV**), batteries and accumulators and waste electrical and electronic equipment (**WEEE**)).

The reasoned opinions that the Commission issued is the second formal step during an infringement procedure that the Commission has to open when it considers that a Member State has failed to fulfil an obligation under the EU Treaties. It follows on informal administrative letters and a so-called letter of formal notice, and is the **last step before the Commission may refer the Member State to the Court of Justice** of the European Union, to eventually induce compliance, in particular through coercive and punitive fines. The Commission has given the Member States the standard two months to reply. Despite the fact that not all Member States have implemented the changes adopted in 2018, the Commission has already been revising the Packaging and Packaging Waste Directive again.

Stakeholders comment on Commission plans for REACH and CLP

The European Commission received 325 comments on the REACH inception impact assessment (IIA) and more than 180 on the CLP IIA. The IIAs lay out the Commission's plans for the revision of the two major pieces of EU chemicals legislation, implementing the Chemicals Strategy for Sustainability (CSS) (please see fresh Law Horizons March 2021). Member States, including Germany, Sweden and Belgium, expressed strong opposition to repealing the authorisation title in REACH.

Numerous trade associations commented, including the **American Chemistry Council** (ACC), which commented that the generic approach to risk assessment extends a hazard-based regulatory system, which is not warranted. The REACH IIA overstated the speed at which companies will be able to innovate. The Commission should address the global implications of proposed actions, such as generic risk assessments, the introduction of the mixture assessment factor (MAF) and additional data and registration requirements. On the CLP, ACC stressed the benefits of global harmonisation with UN Globally Harmonized System of Classification and Labelling (GHS), while recognising the nuances of implementing CLP in a fit-for-purpose way that makes sense for the European market.

The **European Chemical Industry Council** (Cefic) identified several areas for improvement in the current legislation, including simplification of authorisation and substance evaluation procedures, and policy coherence between REACH and product policies (RoHS, Ecodesign, etc.). It highlighted the need to build on lessons learned for non-polymer substances to develop a robust and proportionate approach for the registration of certain polymers. Cefic also argued that there is a need to harmonise the CLP with the GHS, as well as to clarify obligations to classify mixtures and some complex substances.

The German *Verband der Chemischen Industrie* (VCI) held that the goals of the CSS should be achieved primarily within the framework of the existing legislation. Any further development should be based on comprehensive scientific assessments, risk assessments and the involvement of stakeholders (as elements of the precautionary principle, according to the VCI). Any foreseen option should not exclude the use of hazardous substances from the very start; rather, an open-ended evaluation should be conducted, as the functionality or reactivity of chemical substances needed for certain uses and processes are often inextricably linked to their hazardous properties. On the CLP, VCI opined that introducing new hazard classes, e.g. for endocrine disruptors, seems to be based on a general misunderstanding of the GHS, and unnecessary, as the proposed new hazard classes and criteria did not meet the OECD definition of "hazard".

<u>PlasticsEurope</u> called for new information requirements in REACH to be defined on the basis of science and within the limits of current technology, using reliable, validated and internationally accepted test methods or weight of evidence. It indicated that a MAF is not needed for all substances, as combined exposure is attributable to a comparably small number of chemicals. The **American Chamber of Commerce to the EU** (<u>AmChamEU</u>) said that the revision of REACH should avoid an unjustified overhaul of EU chemicals legislation, as this would result in lack of regulatory predictability and severe investment uncertainty.











European Commission amends REACH Annexes to clarify them

Annexes VII to X to REACH set out standard information requirements, Annex XI sets out the general rules for adaptation of the standard **testing** regime for those Annexes. In June 2019, the Commission and the European Chemicals Agency (ECHA) had concluded in the REACH Evaluation Joint Action Plan that the Commission should amend certain provisions in these Annexes to provide more clarity on the obligations of registrants and on the corresponding role and responsibilities of ECHA. Amendments foreseen in Commission Regulation 2021/979 now address the following aspects: toxicological information, physicochemical properties, existing data, "weight of evidence," structural similarity, substance-tailored exposure-driven testing, waivers for conducting relevant studies and rules for the adaptation of the standard testing regime. The changes will apply from January 2022.

The Commission is also consulting on another draft Regulation, which serves the same general purpose. That Regulation would amend certain rules on the standard information requirements set out in Annexes VII to X to REACH to align them with the terminology used in CLP Regulation 1272/2008, specific rules on the standard information on **mutagenicity and aquatic toxicity**, and information requirements on testing for mutagenicity. The draft is open for comments until 19 July 2021.

European Commission is working on restriction roadmaps

The Commission submitted a "Proposal for a Restrictions Roadmap under the Chemical Strategy for Sustainability" (CSS) to the 40th Meeting of Competent Authorities for REACH and CLP (CARACAL) in June 2021. The Roadmap aims at providing the cornerstone for the multi-annual planning under REACH restrictions and substances on the so-called Authorisation List. It would do so in the form of a "rolling" list, which will be regularly updated, with a time horizon up to 2025-2027, until the generic approach to risk management fully applies. The rolling list would consist of three pools of substances: (1) substances already on the registry of intention (Rol) for restrictions; (2) substances under consideration for a restriction proposal; and (3) potential restrictions where harmonised classification and labelling (CLH) or candidate listing are part of the "foreseen regulatory needs" assessed by ECHA along with restriction. The draft Roadmap prioritises carcinogenic, mutagenic and reprotoxic substances (CMRs), endocrine disruptors, persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances, immunotoxicants, neurotoxicants, substances toxic to specific organs and respiratory sensitisers for (group) restrictions under REACH. The Commission encourages national competent authorities to actively support the roadmap by working with ECHA and the Commission on preparing restriction proposals. The Roadmap does not affect the Member States' right of initiative as regards proposing new restrictions also for substances that are not included in the Roadmap.

ECHA publishes report on the operation of REACH and CLP

The European Chemicals Agency published its third report covering five years of operation of the two major pieces of EU chemicals regulation. It addresses the impact of REACH and CLP on health and safety for workers, consumers, environmental protection and functioning of the internal market, as well as innovation and information on possible alternative methods to animal testing. The report also covers **operational aspects**, in terms of dossier preparation and submission, screening and prioritisation, evaluation, harmonised classification and labelling, restrictions, authorisation, safe and sustainable use of chemicals. ECHA addresses the CSS in the report and welcomes the proposal in the Strategy for the Commission to mandate ECHA to prepare dossiers for harmonised classification. According to the report, REACH and CLP have advanced worker and consumer health and environmental protection, as well as promoted innovation and competitiveness in the EU market. However, the report highlights some **room for improvement**, including links between the legislation governing chemicals, and companies improving the information that they submit. The report highlights "significant discrepancies" between the data provided as part of the registration process and that provided during public consultations on specific risk management measures.



The Commission requested ECHA to prepare an evaluation report to assist it with its review of the existing derogation from the restriction of cadmium and its compounds in mixtures and articles containing recovered polymers or copolymers of vinyl chloride (PVC) in Annex XVII to REACH. The restriction includes a generic concentration limit value of 0.01% weight by weight for cadmium compounds (as cadmium). However, certain mixtures and articles containing recycled PVC are allowed to be placed on the market with a higher cadmium concentration 0.1%. ECHA concludes that the current limit value associated with the derogation for recovered PVC articles could be reduced, for example to 0.08%, without major impacts on current recycling rates nor costs to industry. However, reducing the limit would not improve product safety nor environmental protection, and any potential decline in recycling - as a result of a tighter limit - could actually lead to an increase in releases of cadmium to the environment as greater quantities of PVC are disposed of as waste, rather than being recycled. Based on ECHA's evaluation, the Commission will consider whether to request ECHA to prepare an Annex XV dossier to launch the procedure to amend the existing derogation.









Assessment Group on Glyphosate submits draft renewal assessment report

According to a summary document, National competent authorities of France, Hungary, Sweden and the Netherlands, appointed by the European Commission to act jointly as rapporteurs and forming the Assessment Group on Glyphosate (AGG), concluded that glyphosate meets the approval criteria for active substances set in Plant Protection Products Regulation (PPPR) 1107/2009. The AGG also proposes that the classification of glyphosate for Eye Damage Category 1 (H318) "causes serious eye damage" and Aquatic Chronic 2 (H411) "toxic to aquatic life with long lasting effects" should be maintained under the Classification, Labelling and Packaging (CLP) Regulation 1272/2008. It does not consider that glyphosate fulfils the criteria for classification with respect to specific target organ toxicity (STOT), carcinogenity and reproductive toxicity.

The draft report consists of 11,000 pages, which is substantially more than usual. The European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), will publish the draft report and harmonised classification and labelling (CLH) dossier, respectively, and organise parallel public consultations, starting in the first week of September 2021 and lasting for 60 days. Thereafter, EFSA will conduct a risk assessment, and ECHA's Committee for Risk Assessment (RAC) will opine on hazardous properties for the purpose of the CLH. Finally, the European Commission will adopt a proposal for decision regarding renewal of the approval as active substance and, if relevant, the classification. The PPPR requires that the approval of all active substances must be periodically reviewed. The current authorisation of glyphosate – the most widely used herbicide in the world – will expire in December 2022. Until then, it may be used as an active substance in PPP, subject to each product being authorised by national authorities following a safety evaluation.

EFSA consults on draft scientific criteria for grouping chemicals

The European Food Safety Authority published draft "Scientific Committee" guidance document on chemicals into assessment groups to multiple chemicals." Its goal is to provide harmonised and flexible methodologies. The guidance will not be binding, but the described methods can be implemented across EFSA in a fit for purpose manner. The draft proposes to use "hazard-driven" criteria to define groups of chemicals based in the first instance on toxicity information about their behaviour in humans. If this kind of information is lacking, they can be grouped based on their common effects on humans, e.g. all the relevant chemicals that damage the liver. Furthermore, the draft presents both risk-based (i.e. taking account of both their hazardous properties and human exposure to them), or solely exposure-driven methods to prioritise chemical groups, as well as the combined risk based approach (i.e. using hazard metrics for a common effect or target organ and exposure metrics of the individual chemicals). When hazard metrics are available for a common effect or target organ, a combined risk-based approach can be adopted. When hazard metrics are only accessible for the respective critical effect, a risk-based approach for single chemicals can be used. Finally, if hazard information is not readily accessible, an exposuredriven approach aiming at assessing co-exposure to chemicals can be applied. The guidance will also follow-up to EFSA's "MixTox" guidance, which created the methodological framework to assess combined exposure to multiple chemicals. Interested parties are invited to comment by 10 July 2021.

The European Commission and the Committee of the Regions launch Zero Pollution Stakeholder Platform

The Platform will assist with the implementation of the **EU Action Plan** "Towards **Zero Pollution** for Air, Water and Soil". The Action Plan was adopted in May 2021 and is a key deliverable of the European Green Deal. It sets out an integrated vision for 2050 to reduce pollution to levels that are no longer harmful to human health and natural ecosystems, as well as intermediary targets for 2030, and actions to achieve the objectives. Reducing pollution requires clean choices for regional and urban mobility and energy, and investments in buildings and infrastructure, as well as overall spatial planning. All these decisions affect the health and wellbeing of citizens. The platform will help deliver on initiatives and actions in the plan by bringing together actors from different communities and areas of expertise to tackle interrelated challenges, defining a common vision on how to achieve zero pollution objectives, and developing and sharing good practices.



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