

Sustainability Outlook European Union

December 2021

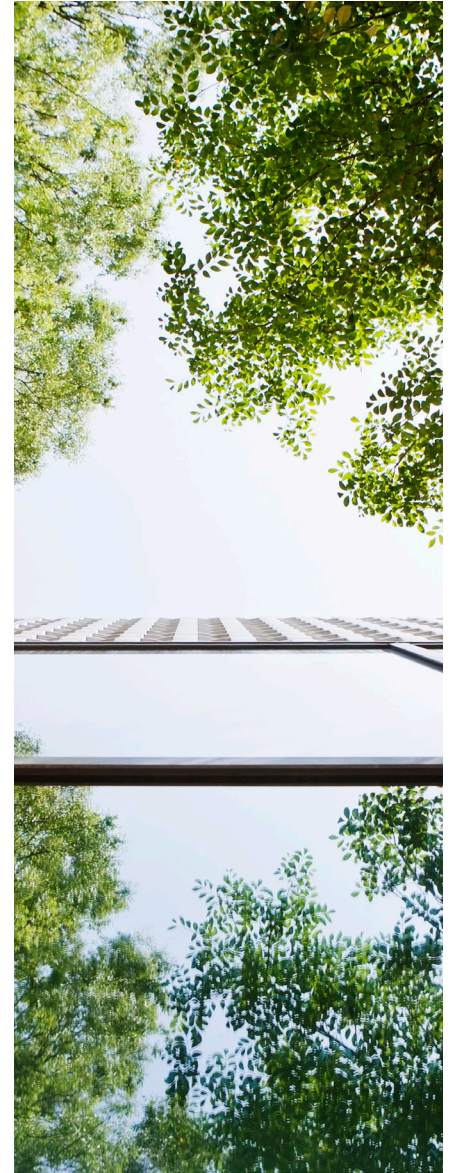


European Commission proposes new rules to boost renovation and decarbonisation of buildings.

The Commission presented its [proposal](#) for a revised **Energy Performance of Buildings Directive** (EPBD). Commission Executive Vice-President for the European Green Deal, Frans Timmermans, [commented](#) that the renovation of homes and other buildings supports economic recovery and creates new job opportunities. By targeting the obstacles to renovation and providing financial support for the necessary upfront investment, the proposal aims to boost the rate of energy renovation across the EU. Its focus on the worst performing buildings prioritises the most cost-effective renovations and helps fight energy poverty. Lower energy bills would lead to investments paying for themselves.

The proposal foresees that as of **2030, all new buildings must be zero-emission**, with all **new public buildings having to be zero-emission already as of 2027**. The proposed definition of “zero-emission building” corresponds to a building with a very high energy performance, where the very low amount of energy still required is fully covered by energy from renewable sources generated onsite, from a renewable energy community or from a district heating and cooling system. The proposal requires that the **worst-performing 15% of the building stock** (corresponding to energy performance grade G) **of each Member State is upgraded** to at least grade F. The deadline for this is 2027 for non-residential buildings and 2030 for residential buildings. The role of **Energy Performance Certificates (EPC)** would be strengthened and EPC would have to contain clearer information. EPC would be required for buildings undergoing major renovation, buildings for which a rental contract is renewed and all public buildings. Member States would be required to establish a **national building renovation plan** to ensure the renovation of the national stock of residential and non-residential buildings, both public and private, into a highly energy efficient and decarbonised building stock by 2050. Such plans would need to include an overview of the national building stock, a roadmap with nationally established targets and measurable progress indicators, an overview of implemented and planned policies and measures, and an outline of the investment needs for the implementation.

Stakeholders may provide [feedback](#) on the proposal until 14 February 2022. The Commission has sent its proposal to the Council and European Parliament. It will go through the ordinary legislative procedure.





European Commission sets policy on removing, recycling and sustainably storing carbon.

The Commission [presented](#) a [communication](#) on sustainable carbon cycles. As in a leaked draft (please see [Sustainability Outlook November 2021](#)), the Commission plans to achieve its climate objectives through three key actions: **reducing the reliance on carbon, recycling carbon from waste** and **upscaling carbon removal solutions** that capture CO₂ from the atmosphere and store it for the long term. Carbon storage must ensure no negative impact on biodiversity or ecosystem deterioration.

The communication focuses on action to upscale **carbon farming** to increase carbon sequestration, including **blue carbon initiatives** (carbon sequestration by oceanic and coastal ecosystems, such as algae). It also foresees actions to develop an internal market for the sustainable capture, recycling, transport and storage of carbon. The Commission will support technologies such as carbon capture and use (**CCU**), carbon capture and storage (**CCS**) and carbon removal, using the **Innovation Fund**.

Regarding **recycled carbon**, the Commission advocates for technological solutions for CCU and the production of sustainable synthetic fuels or other non-fossil based carbon products. It proposes that **at least 20% of carbon used in the chemical and plastic products should be from sustainable non-fossil sources by 2030**.

The Commission confirms that it will develop a legislative proposal on the **certification of carbon removals** based on scientifically robust carbon accounting rules and requirements to monitor and verify those removals. The Commission will formally start this initiative in January 2022.

Two staff working documents accompany the communication. One provides an overview of [carbon farming](#), including definition, advantages and challenges and ways to upscale carbon farming, such as public funding or the improvement of monitoring, reporting and verification methodologies. The second is a [technical assessment](#) of “sustainable carbon cycles for a 2050 climate-neutral EU” and provides insights on the different actions to achieve the climate objectives, as well as information of carbon sequestration in EU ecosystems.

European Commission presents new regime on recycled plastic food contact material and articles.

The Commission [presented](#) a draft Commission Regulation on recycled plastic materials and articles intended to come into contact with foods, repealing Regulation 282/2008. It also organised two webinars ([general points](#) and for [recyclers](#)) to explain the draft new provisions.

They take a partially different approach from the existing regime and introduce new definitions and requirements for the placing on the market of recycled plastic food contact materials (FCMs), the development and operation of **recycling processes** to produce that plastic, and the use of recycled plastic FCMs.

The draft regulation does not explicitly mention or define **chemical recycling**. However, it provides that “the Regulation shall **not apply to the use of plastic waste** to manufacture substances included in the Union list of authorised substances [...]”

The draft regulation allows recycled materials and articles on the market if they are manufactured using one of the following options: **suitable technologies** or **novel technologies**, being subject to specific conditions. Annex I provides the different types of suitable technologies. First, **mechanical recycling of PET**, whose input is post-consumer waste containing a maximum of 5% materials and articles not used in contact with food, allows for and requires the **authorisation** of individual recycling processes. Second, closed-loop recycling applies to all polymers manufactured as primary materials in compliance with Regulation 10/2011 on plastic materials and articles intended to come into contact with food, and whose input may not be polymers collected in mixed form or from consumers. It requires a recycling scheme (which organises use and collection to control contamination), but **no authorisation**.

The regulation provides detailed requirements for **documentation, instruction and labelling** of the individual batches of recycled plastic or recycled materials and articles, as well as for waste collection, **decontamination**, post-processing and use of recycled plastics and **operation of recycling schemes**. It provides several **registration requirements**, such as the inclusion of authorised recycling processes, recyclers, recycling installations, recycling schemes, recycling facilities and **novel recycling technologies** in a public **union register**. Recyclers must draw up the **compliance monitoring summary sheet** (CMSS) for each **decontamination installation** under their control (see [draft guidelines](#)).

Pending applications for authorisation will in principle be repealed. However, applications under the existing regime for PET will result in authorisation decisions for individual recycling processes, on the basis of the new Regulation. If an application is submitted up to six months after its entry into force, the process can remain on the market until the authorisation decision.

The [feedback period](#) for the draft runs until 18 January 2022. Then a committee composed of Member State representatives/experts will vote on it, which will be followed by three months of scrutiny by the Council and the European Parliament. After that, the Commission will adopt its proposal and it will enter into force.





European Commission formally starts initiative on microplastics releases.

The Commission [launched](#) a call for evidence for an upcoming law aiming to tackle microplastics that are unintentionally released into the environment. This initiative, already foreseen in the [new Circular Economy Action Plan](#) (CEAP 2.0), will focus on **labelling, standardisation, certification and regulatory measures**, addressing the main sources of these microplastics. The Commission aims to correct failures such as the absence of market incentives for operators to take measures and the absence of an EU comprehensive approach. The initiative addresses the largest microplastics contributors in the EU (nearly 2/3 of total emissions): **tyre abrasion, pre-production plastic pellets and synthetic textiles** during their entire life cycle. **Ecodesign requirements**, including new materials, will be considered for tyre abrasion and synthetic textiles, as well as the development of a standard on tyre abrasion. The Commission will assess the introduction of a regulatory system of **liability and compensation** to remediate environmental damage caused by **pellet losses**, as well as to require the supply chain to adhere to best practice measures to prevent them, including third-party, independent auditing and certification. For synthetic **textiles**, it will consider measures such as the establishment of take back systems, facilitating the uptake of recycled content, applying filters to washing machines or other appliances, as well as setting minimum sustainability and/or information requirements, and labelling products according to their level of microplastics emission. The Commission will also assess the development of voluntary industry approaches.

The call for evidence is [open for feedback](#) until 18 January 2022. The Commission plans a public consultation in Q1 2022. The Commission also invited stakeholders to register their interest in a study aimed at identifying policy options that could reduce these microplastics releases in the environment (see [Sustainability Outlook September 2021](#)). It plans to propose a regulation in Q4 2022.



Member States veto delegated act on sorting and recycling of waste.

The Council adopted an [objection](#) to the Commission delegated decision on harmonised rules for the calculation, verification and reporting of the weight of materials or substances removed after a sorting operation and not subsequently recycled, based on **average loss rates (ALR)**. The Commission adopted its delegated decision in late August (see [Sustainability Outlook September 2021](#)), based on Waste Framework Directive 2008/98 (WFD). The decision provides that Member States must establish an effective system of quality control and traceability of municipal waste to ensure that they can calculate the weight of the waste generated and that it is prepared for re-use or recycled. The Council extended the scrutiny period of two months for itself and the European Parliament by two months. According to a [note](#) from the General Secretariat of the Council, Member States were concerned that the **scope of the delegated act exceeded the mandate given to the Commission**, in particular, regarding the **obligation** that **information** about ALR for each waste treatment facility producing sorted waste is available and easily accessible to the public. Following the objection raised by the Council, the Commission is expected to redraft its delegated decision in the coming months, taking into account the concerns raised by the Council.

First technical taxonomy criteria enter into force.

Commission Delegated Regulation 2021/2139 was [published](#) in the Official Journal of the European Union. The European Commission adopted the delegated act in June 2021. This was followed by a scrutiny period for the European Parliament and the Council, which the latter extended by two months. However, [neither EU co-legislator decided to object](#) to the delegated act.

Under Taxonomy Regulation 2020/852, an **economic activity qualifies as environmentally sustainable, for the purpose of establishing the degree to which an investment in the economic activity is environmentally sustainable, only if it complies with technical screening criteria** (TSC) established by the Commission (among other things). The Delegated Regulation sets out the TSC for determining whether an economic activity contributes substantially to **climate change mitigation** or **climate change adaptation**; and whether, at the same time, it does no significant harm (DNSH) to any of the other environmental objectives under the Taxonomy Regulation. These other objectives are: sustainable use and protection of water and marine resources; transition to a circular economy; pollution prevention and control; and protection and restoration of biodiversity and ecosystems.

The TSC cover the following categories of **activities**: forestry; environmental protection and restoration activities; manufacturing; energy; water supply, sewerage, waste management and restoration; transport; construction and real estate activities; information and communication; and professional and technical activities. In addition, the TSC for climate change adaptation covers financial and insurance activities; education; residential care activities; and arts, entertainment and recreation. These TSC came into force on **1 January 2022**.

The Commission will address the TSC for the other environmental objectives in further delegated acts in 2022. In summer 2021, the Technical Working group of the Commission Platform on Sustainable Finance issued draft recommendations regarding those environmental objectives (see [Sustainability Outlook August 2021](#)). In the meantime, the Commission [announced](#) that Commission has begun expert consultations on a complementary Delegated Act covering certain nuclear and gas activities. These have proven particularly controversial.





European Commission proposes new rules against environmental crime.

The Commission [adopted](#) a proposal for a directive on the protection of the environment through criminal law, replacing Environmental Crime Directive 2008/99 (ECD). It also published a [communication](#) on “stepping up the fight against environmental crime”:

The ECD has provided that a set of environmental offences are considered as crimes in all EU Member States. Under the ECD, national legislation must include provisions on criminal sanctions. However, the ECD has not prescribed the levels and types of sanctions. The Commission [explained](#) that the evaluation of the ECD showed that only a low number of environmental crime cases are successfully investigated, prosecuted and punished, as well as non-effective cooperation between Member States (see also [frESH Law Horizons November 2020](#)). Therefore, the proposal focuses on **updating the list of criminal offences**, strengthening the **provisions on criminal sanctions** (types and levels), and strengthening **enforcement across Member States**.

In addition to the current crimes, the Commission proposed **new categories of criminal offences** regarding timber trade; ship recycling; water abstraction from ground or surface water; serious breaches of EU chemical legislation, rules on fluorinated greenhouse gases, legislation on invasive alien species; serious circumvention of requirements relating to environmental impact assessments; and source discharge of polluting substances from ships. The proposal clarifies key concepts such as “**substantial damage**”, in order to increase legal certainty and a harmonised application of the new Directive across the EU. Elements such as the duration, severity, spread or reversibility of the damage would be taken into account when assessing the substantial nature of the damage.

The provisions on penalties specify the **term of imprisonment** of individual persons for certain offences (e.g. maximum term of at least 10 years for offences that cause or are likely to cause death or serious injury to any person). The new rules propose **additional sanctions**, such as **withdrawal of permits, disqualifications**, fines and exclusion from access to public funding. **Sanctions of legal persons** liable for the offences can be of criminal or non-criminal nature (e.g. obligation to install due diligence schemes for enhancing compliance with environmental standards). Offences under the scope of the ECD must be punishable by **fine**. The maximum fine must not be less than **3-5%** (depending on the offence) of the total **worldwide turnover** of the legal person in the business year preceding the fining decision. The proposal includes **mitigating and aggravating circumstances** to modulate the sanction: severity of the damage done, involvement of organised crime or restoring nature to its previous condition. Regarding **enforcement**, the proposal includes obligations for Member States to provide for adequate training, resources, cooperation, communication and information sharing among enforcers.

The Commission has submitted its legislative proposal to the European Parliament and the Council. It will follow the ordinary legislative procedure.

European Commission starts evaluation of the rules on environmental liability.

The Commission [launched](#) a call for evidence for an evaluation of the Environmental Liability Directive 2004/35 (ELD). The ELD establishes a framework to prevent and remedy environmental damage, based on the **“polluter pays” principle**. It deals with the “pure ecological damage” and it is based on the powers and duties of public authorities as distinct from a civil liability system for traditional damage. An operator that has caused damage within the scope of the ELD must bear the costs of necessary preventive or remedial measures. Both the ELD and the ECD aim at strengthening the protection of the environment. The first concerns address individual breaches of environmental law and the latter concerns remedial measures to be taken to restore environmental damage.

The ELD requires the Commission to carry out an evaluation by Q2 2023. The evaluation must be based on information from Member States, namely the cases of environmental damage under the ELD and any other relevant information on the experience. The evaluation is expected to take into account the recommendations given by the European Parliament in its resolution or by the European Court of Auditors to strengthen the ELD (see [Sustainability Outlook July 2021](#)), such as making polluters pay for contamination that happened long ago (“orphan pollution”) or the lack of sufficient financial security of some businesses.

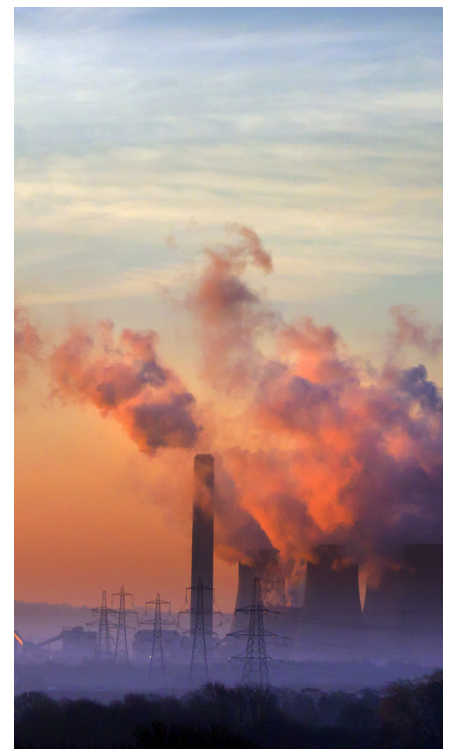
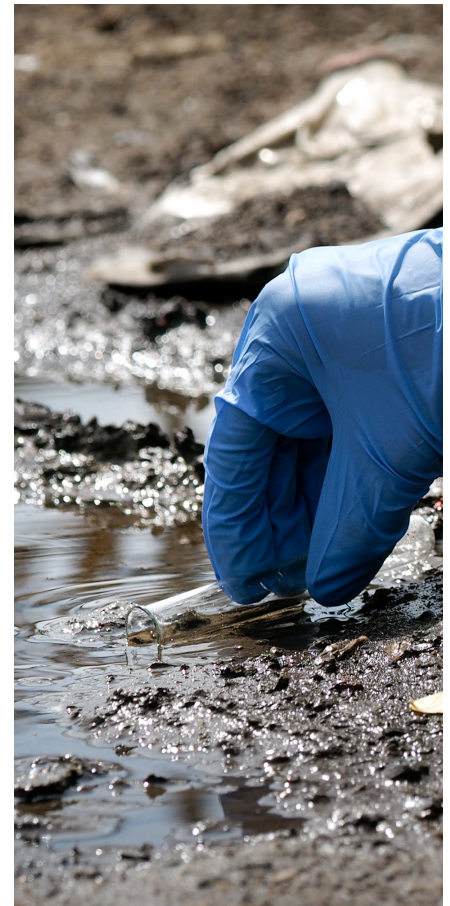
Earlier this year, the Commission adopted **guidelines** to clarify the scope of the term **“environmental damage”** and how Member States can better assess damage to water, land, protect species and natural habitats (see [frESH Law Horizons March 2021](#)).

A public consultation on the evaluation of the ELD is expected in Q2 2022.

European Commission updates recommendation on environmental footprint.

The Commission adopted a non-binding [recommendation](#) on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations (**PEF/OEF**), accompanied by two guides as Annexes. It updates a previous recommendation from 2013 to help companies calculate their environmental performance based on reliable, verifiable and comparable information. The fundamental principles of the Environmental Footprint methods are based on **Life Cycle Assessment (LCA)**. The PEF/OEF covers **16 environmental impacts**, including climate change, and impacts related to water, air, resources, land use and toxicity. Most of the **changes** introduced are of a **methodological** nature in the following three main areas: modelling requirements, data and data quality requirements and life cycle impact assessment. The recommendation states that Member States should **use** the PEF/OEF methods **in voluntary policies** involving the measurement and communication of the life cycle environmental performance of products or organisations, as well as provide assistance for SMEs to measure their products or organisations based on these methods. Also, it invites Member States to inform the Commission of the actions taken in this regard on a yearly basis.

As [stated](#) by the Commission, the use of the Environmental Footprint methods is already foreseen in legislation such as Taxonomy Regulation 2020/852 or the Sustainable Batteries Initiatives.





EU co-legislators agree on 8th Environmental Action Programme.

The Council and European Parliament reached a provisional agreement regarding the [decision](#) on “A General Union Environment Action Programme to 2030” (8th EAP). The Commission [welcomed](#) the agreement on its proposal. Under the decision, the Commission will carry out a **mid-term review** in 2024 of the progress achieved in the **priority objectives**: reduction of greenhouse gas emissions, adaptation to climate change, a growth model that gives back to the planet more than it takes, a zero-pollution ambition, protecting and restoring biodiversity and reducing key environmental and climate pressures related to production and consumption. Where appropriate, the Commission is tasked with presenting a legislative proposal to add an annex to the 8th EAP, for the period after 2025, containing a list of actions with a view to reaching such objectives, as well as the respective timeline of these actions. To achieve these priority objectives, the Council and European Parliament agreed on the introduction of EU 2030 **material and consumption reduction targets** in order to reduce the footprint and bring it to planetary boundaries, strengthening environmentally positive incentives, as well as **phasing out environmentally harmful subsidies**. To this end, the European Commission, the Member States, local and regional authorities and stakeholders, “as appropriate,” must establish a binding framework to monitor and report the progress of Member States towards phasing out fossil fuel subsidies, based on an agreed methodology, a deadline for the phasing out of fossil fuel subsidies and a methodology for identifying other environmentally harmful subsidies.

The Commission presented its proposal for the 8th EAP in October 2020. The Council adopted its position and the European Parliament amendments by a large majority in 2021 (see [Sustainability Outlook July 2021](#)). Both co-legislators will now formally adopt the decision, after which it will be published in the Official Journal of the EU and enter into force as a legally binding decision.

European Commission adopts guidelines on climate, environment and energy subsidies.

The College of Commissioners [endorsed](#) the new [guidelines](#) on State aid for climate, environmental protection and energy (**CEEAG**). The CEEAG set the conditions under which the Commission will consider State aid granted by Member States in this field compatible with the single market. The CEEAG are aligned with priorities set out in the [European Green Deal](#) and in the Fit for 55 Package (see [Sustainability Outlook July 2021](#)). They include a **broader range of categories of investments and technologies** that Member States may support, allowing for aid amounts up to **100%** of the funding gap. Under the CEEAG, a positive assessment on State aid for the most polluting fossil fuels is unlikely in light of their negative environmental effects.

The CEEAG apply generally to State aid granted to facilitate the development of economic activities in a manner that improves environmental protection, as well as certain activities in the energy sector. They cover State aid in a long list of areas, such as those for renewables, energy efficiency measures, clean mobility, infrastructure, circular economy, pollution reduction, protection and restoration of biodiversity, and measures to ensure the security of energy supply. They also addressed the specific criteria and requirements for each category of aid, such as the details of the scope, supported activities, the necessity and appropriateness of the aid. The following categories are not in the **scope** of the CEEAG: design and manufacture of environmentally friendly products; research, development and innovation; agriculture, forestry, fishery and aquaculture sector; and nuclear energy.

The Commission will formally adopt the new CEEAG and publish them in the Official Journal of the EU in the coming weeks, replacing the existing Energy and Environmental Aid Guidelines (EEAG). The Commission will apply the CEEAG from January 2022. Member States must amend their existing aid schemes to make them compatible with the guidelines before 2024.

Earlier in 2021, the Commission had mentioned the CEEAG in the broader context of a policy brief on how EU competition rules can complement environmental and climate policies more effectively (see [Sustainability Outlook September 2021](#)) and in the communication assessing the tools to make competition policy fit for the green transition (see [Sustainability Outlook November 2021](#)).

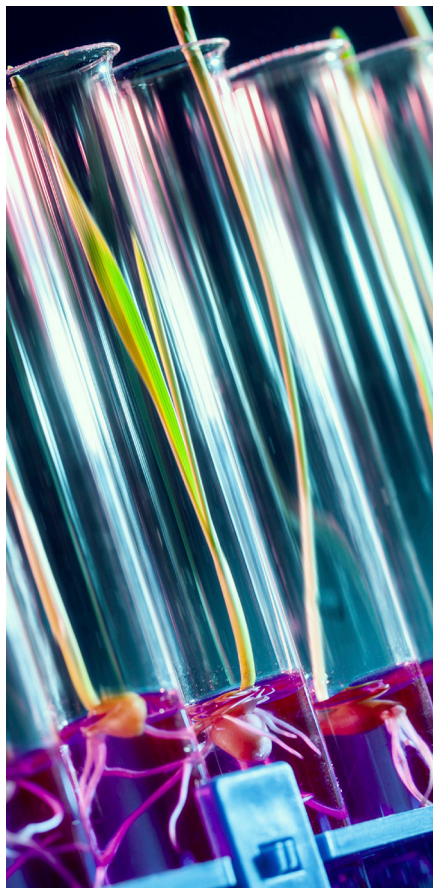
Chemical industry warns that upcoming EU chemical legislation puts industry at crucial crossroads.

Cefic, the European Chemical Industry Council, [released](#) a [phase-one report](#) (including [Q&A](#)) on the **impacts** of selected actions from the European Commission's [Chemicals Strategy for Sustainability](#) (CSS) on the European chemical industry.

The report commissioned by Cefic covers the addition of new **hazard classes and identification criteria** to the Classification, Labelling and Packaging Regulation 1272/2009 (CLP) for endocrine disruptors (EDs), PBT, vPvB, PMT, vPvM, immunotoxicants and neurotoxicants, and the extension of the **Generic Risk Approach** (GRA). The study concludes that the considered changes to the GRA and CLP are generally expected to restrict the manufacturing and use of products and increase the costs of their production. Once substances have been through the process of harmonised classification, substances, mixtures and possibly articles containing the CLP-classified substances would be affected by generic restrictions. According to the study, such changes will, in turn, have **significant and potentially negative impacts** on the evolution of the EU chemicals market and its competitiveness despite a robust mitigating response from the sector.

Phase 1 of the project will also include the introduction of a Mixture Assessment Factor (MAF), while phase 2 will address the PFAS ban, the export ban and extending REACH registration requirements to chemicals produced in low tonnage bands. The next report is expected to be published in Q2 2022.





High Level Roundtable issues report on enforcement and compliance.

At the end of November, the High Level Roundtable on the [Chemicals Strategy for Sustainability](#) issued a [report](#) on enforcement and compliance of and with chemicals legislation. It presents the outcomes of the Roundtable's discussions, which were gathered in particular through an online participatory workshop held in October 2021. Members then defined through a joint process a set of consensual recommendations to be further disseminated and discussed in relevant platforms and networks. Recommendations include **sanctions for non-compliant companies**, while non-compliant substances or products should be brought into compliance or recalled from the market. According to the experts, **authorities must follow up on identified non-compliances adequately**. Competent authorities should **make public transgressors** as well as enforcement actions and should share the details of non-compliant enterprises, products and chemicals with consumer organisations, who, in turn, could assist in alerting consumers via their communication channels. Another recommendation is for REACH and other relevant legislation to include an obligation to apply a **harmonised approach to enforcement** across Member States. New enforcement tools were needed to address **online sales and imports**, including clearly defining the responsibilities of online retailers.

The mission of the Roundtable is to realise the objectives of the CSS and to monitor its implementation in dialogue with the stakeholders concerned. As an expert group of the European Commission, its main task is to assist that EU institution regarding the implementation of existing EU legislation, programmes and policies, as well as the social and economic dimensions for the industrial transition pursued by the CSS. It is composed of representatives of 28 organisations from industry, academia and the civil society (NGOs). The Roundtable meets around two times per year. It adopts reports by consensus.

European Commission's consultant lays out action plan on essential uses of chemicals.

According to the [Chemicals Strategy for Sustainability](#) (CSS), the European Commission will "define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments." The CSS action plan indicates that the Commission will define the criteria in 2021-22.

In November, Wood, the consultant that supports the Commission regarding this task, [said in a presentation](#) that it will carry out eight case studies in key sectors, to test the concept and refine policy options. These case studies will in particular allow for an in-depth understanding of topics, displaying examples of non-essentiality, further testing criteria on practical cases, and further extracting operating elements necessary to implement the concept in legislation. The not-exhaustive and not yet final list of case studies includes:

- Perfluorooctane sulfonic acid (**PFOS**) and perfluorooctanoic acid (**PFOA**) in Persistent Organic Pollutants (POPs) Regulation 2019/1021
- **Nickel** in Toy Safety Directive 2009/48 (as example for carcinogenic, mutagenic or reprotoxic (CMR) substances)
- **Formaldehyde** in the Cosmetics Regulation 1223/2009 (as example for CMRs)
- **Triclosan** in the Biocidal Products Regulation 528/2012
- Bis(2-ethylhexyl) phthalate (**DEHP**) in REACH, Cosmetics Regulation 1223/2009, the Toy Safety Directive and the legislation on food contact materials (**FCMs**), in particular Regulation 1935/2004

The plan outlined by Wood foresees a one-day stakeholder workshop, an open public consultation and a targeted consultation, with a view to produce a final report at the end of June 2022.

European Commission opens consultation on simplification and digitalisation of chemicals labelling.

At the end of November, the Commission opened a [consultation](#) on **simplification and digitalisation of labelling requirements** regarding chemical substances contained in many products used daily, such as glues, laundry and dishwashing detergents, as well as fertilisers. The Commission's objective with the initiative is to improve the communication of essential information on chemicals. Two recent evaluations, the fitness check of the most relevant chemicals legislation (excluding REACH) and the evaluation of the Detergents Regulation 648/2004 had shown that label comprehension and consequently consumer protection could be further improved by avoiding that labels are overloaded with information.

The Commission formally started this initiative in July 2021 ([please see Sustainability Outlook July 2021](#)). It is linked to the broader [revision of initiative the CLP Regulation](#) ([please see frESH Law Horizons May 2021](#)).

The consultation will run until February 2022.

ECHA identifies need for regulatory risk management measures or further data regarding chemicals.

The European Chemicals Agency [announced](#) the results of the first assessments carried out on over 450 substances in 19 groups of chemicals. For 18 of these groups, ECHA concluded that **regulatory risk management measures or further data** are necessary. The aim of such assessments was to speed up regulatory action on chemicals of concern, protecting people and the environment, and avoiding regrettable substitution.

The first results include **four groups of phthalates** and phthalates-like substances that ECHA and Member States assessed as a group due to their potential reprotoxic, endocrine disrupting, or persistent, bioaccumulative and toxic (PBT) properties. For some of these phthalates, a restriction has been proposed to limit their potential releases from articles. In addition, the assessment highlights a need for harmonised classification and labelling, as well as identification as substances of very high concern (SVHCs) for some. For other substances in these groups, ECHA concluded that there is currently not enough information to confirm the potential hazard. A few did not require any new regulatory actions for the time being.

ECHA announces that its scientific committees support further restrictions of PFAS.

ECHA's Committees for Risk Assessment (**RAC**) and Socio-Economic Analysis (**SEAC**) **support Germany's proposal to restrict the use of undecafluorohexanoic acid (PFHxA) and related substances**. The potential restriction is expected to reduce further environmental and human exposure to these chemicals resulting mainly from uses in food contact materials (FCMs), textiles and fire-fighting foams. ECHA [will publish](#) the final text of the opinions. In the meantime, its [press release](#) highlights that RAC supported the proposed restriction in particular for uses **where it is not possible to minimise emissions** through other means. This was especially relevant for consumer uses in FCMs and textiles, as well as for fire-fighting foams used by municipal fire departments and at home. SEAC considered that a restriction of PFHxA is, in general, an appropriate measure to address the identified risks and to ensure a consistent level of protection for people and the environment across the EU. However, while SEAC concluded that a restriction of certain uses was likely to be proportionate (e.g. textiles in consumer apparel, paper and cardboard in food contact materials and cosmetic products), uncertainties in the available information prevented SEAC from concluding that the proposed restriction as a whole was the most appropriate means to address the identified risk.





ECHA launches call for evidence on possible restriction dossier for ortho-phthalates.

The European Chemicals Agency [launched](#) a call for evidence on restriction for ortho-phthalates, a group of chemicals commonly used as additives to produce plastics. The call for evidence concerns 10 phthalates, which represent three entries for which no applications for authorisations were submitted before their latest application date and seven entries in Annex XIV of the REACH Regulation 1907/2006 (the Authorisation List), whose sunset date has passed. The sunset date is the date from which the placing on the market and use of a substance is prohibited unless an authorisation is granted. As provided by REACH, ECHA must consider whether the use of Annex XIV substances in articles after the sunset date pose a risk to the human health or the environment that is not adequately controlled. If that is the case, ECHA must prepare an Annex XV restriction dossier. Following an assessment of the available evidence, **ECHA is currently of the view that there is no need to prepare such a restriction dossier.** Nevertheless, it is looking for information to support the potential future investigation of risks from ortho-phthalates with suspected similar concerns to human health and the environment. Risks from the use of these ten phthalates in articles will be considered as part of a larger investigation to address risks from ortho-phthalates. **This call for evidence does not aim to gather further information on DEHP, DBP, DIBP and BBP** as these phthalates are already restricted under REACH Annex XVIII. The deadline to [provide input](#) is 26 January 2022.

EFSA consults on a new tolerable daily intake of bisphenol A.

The European Food Safety Authority launched [a public consultation](#) on a draft scientific opinion of its expert Panel on Food Contact Materials, Enzymes and Processing Aids (CEP). It foresees to lower considerably the tolerable daily intake (TDI) of bisphenol A (BPA), a substance that is mainly used in combination with other chemicals to manufacture plastics and resins. It can be found in various food contact materials such as **tableware, microwave ovenware and cookware**. In particular, the draft opinion foresees to lower the TDI, i.e. estimate of the amount of a substance that can be ingested daily over a lifetime without appreciable risk, to **0.04 nanograms per kilogram of body weight per day**, compared to the temporary TDI of 4 micrograms per kilogram of body weight per day, set by EFSA in 2015. This is based on studies that have emerged in the literature between 2013 and 2018. The draft scientific opinion is open for public consultation until 8 February 2022.

In the framework of the REACH restriction process, **Germany proposed a restriction of a broader set of uses of BPA** ([please see Sustainability Outlook July 2021](#)).

ECHA reports on widespread non-compliance of articles sold online.

The [report](#) is the result of an enforcement project carried out during 2020 in 29 countries of the EEA and Switzerland (REF-8). Inspectors evaluated the compliance of online product offers with various requirements of the CLP and REACH Regulations. These included **information for the customer about the type of hazard** and the obligation to provide the most up-to-date version of the **safety data sheet** (SDS) for the hazardous substance or mixture for industrial/professional uses in an official language of the receiving country. Another aspect addressed is specific entries of **REACH Annex XVII for products or articles containing restricted substances** such as cadmium and nickel in jewellery, phthalates in childcare products and toys and CMRs. The inspections also focused on duties set forth by Biocidal Products Regulation 528/2012 (BPR).

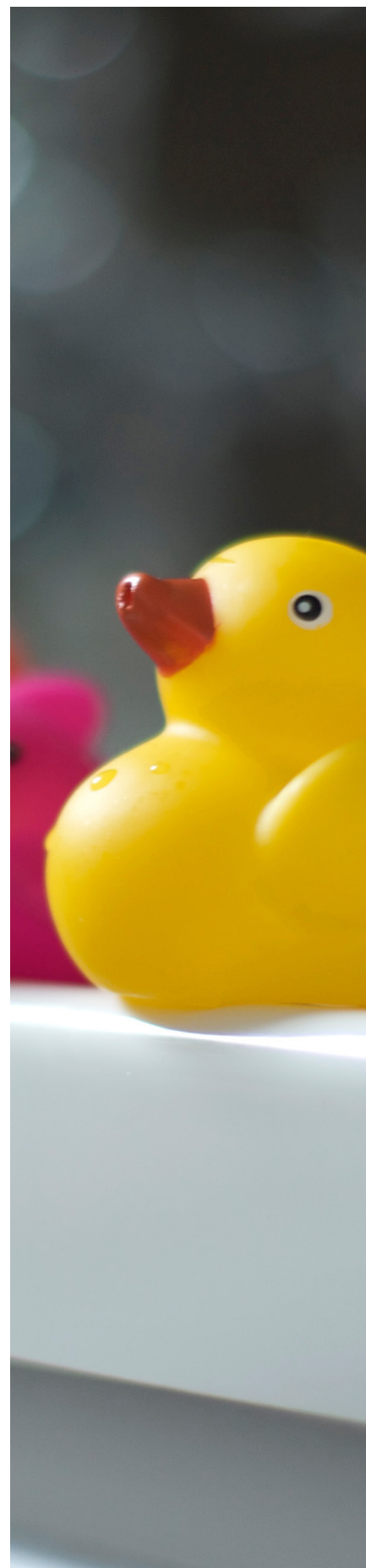
In many Member States, inspections targeted products and offers with high assumed risks (risk-based approach). This might have contributed to a higher-than-expected rate of non-compliance. The **non-compliance for restrictions regarding substances/mixtures was 95%** and **25% for restrictions regarding articles**. The lower rate for articles could be explained by the difficulty inspectors may have faced in determining non-compliance for articles by assessing information provided on the website, as chemical analyses often have to be done to detect non-compliance. CMR substances restricted under entries 28-30 of REACH Annex XVII had a high level of non-compliance (99%). These substances may only be sold to professional users, but they were found to have been offered to the general public.

The report makes some recommendations to the European Commission, which include **making online marketplaces “responsible and liable** for enforcement of illegal products/offers, especially from sellers outside the EU”, strengthening and harmonising the regulation of online commerce across the EY, as well as financing “targeting tools” for national enforcement authorities to “better scan online offers.”

European Parliament committee wants to strengthen rules on chemicals in toys.

The European Parliament’s committee on Internal Market and Consumer Protection (**IMCO**) voted unanimously for a non-binding report on a **more protective and strictly enforced Toy Safety Directive 2009/48**, in particular regarding exposure to chemicals. The report calls on the European Commission to consider consolidating all applicable limits for toys into one piece of legislation in order to streamline conformity assessment. It stresses that spreading out requirements across **several pieces of legislation**, and providing for **different limit values** can be burdensome and can, in some cases, make it necessary to duplicate measuring of substances, e.g. regarding migration and content limit values. The **derogation from the prohibition of chemicals** that are carcinogenic, mutagenic or toxic to reproduction (**CMRs**) set out in the Directive allowed for the presence of those chemicals in concentrations that are too high to ensure the protection of children. Therefore, the report calls on the Commission to **substantially reduce the generic limits for derogated CMRs**. The report also calls on the Commission to propose a **hazard identification procedure for endocrine disruptors**, based on the definition of the World Health Organization (WHO), and to apply it in a future revision of the Directive to ensure that they are banned in toys as soon as they are identified. In general, the report shows concern that the stricter provisions for chemicals in toys intended for children aged under 36 months do not take into account the fact that older children remain vulnerable to dangerous substances.

The European Commission will propose the revision of the Toy Safety Directive in the context of the [Chemicals Strategy for Sustainability](#) (CSS; [please see frESH Law Horizons May 2021](#)), expected in Q4 2022.





EU court dismisses another appeal on endocrine disrupting properties of bisphenol A.

The European Court of Justice (ECJ) **dismissed an appeal** brought by industry association PlasticsEurope (case [C-876/19](#)). In September 2017, PlasticsEurope brought an action for annulment in respect of ECHA's decision to identify **bisphenol A (BPA)** in the REACH Candidate List as a **substance with endocrine disrupting properties** that may have **serious effects on human health**. The General Court dismissed the action for annulment in September 2019 (case [T-636/17](#); [please see frESH Law Horizons September 2019](#)). PlasticsEurope appealed the judgement of the General Court in November 2019.

The appeal unsuccessfully alleged a misinterpretation of **Article 57(f)** of REACH (which allows for the identification of endocrine disruptors as substances of very high concern (SVHCs), a failure to state reasons, errors of law in the assessment of the evidence available to the General Court, an infringement of the principle of equal treatment and a misinterpretation of **Article 2(8)(b)** of REACH (which **exempts** onsite and transported **isolated intermediates** from the authorisation Title VII of REACH).

According to the ECJ, the General Court exhaustively addressed all the elements brought forward in the action for annulment and responded to the appellant's arguments concerning the application of the standard of proof referred to in Article 57(f) by ECHA. Among many other things, the appeal argued that the General Court erred in law in its assessment of the **equivalent level of concern** and should have determined whether ECHA had, in fact, reached the conclusion that BPA gives rise to an equivalent level of concern based on the evidence available to it. However, the Court of Justice found that the appeal did not specify what error of law the General Court allegedly had made or the part of its application that the General Court allegedly had not addressed.

The appeal also argued that the European Food Safety Authority (**EFSA**) had reached an opposite conclusion in a 2015 opinion to the one relied upon by the General Court, finding that it was not possible to conclude that BPA is an endocrine disruptor based on the World Health Organisation (WHO) criteria. However, the Court of Justice found that the General Court relied on the fact that EFSA's failure to reach a specific conclusion as to whether BPA is an endocrine disruptor is **based on a risk assessment linked to a particular use of BPA and not on an analysis of the hazards** arising from its intrinsic properties as carried out by ECHA. Therefore, the General Court did not manifestly err when finding that EFSA's opinion indirectly confirms ECHA's conclusion that BPA has an effect on the human endocrine system.

Regarding the alleged misinterpretation of Article 2(8)(b) of REACH, the Court of Justice recalled its case law. It establishes that the **exemption** is not applicable to the provisions of Title VII that govern substances in accordance with their intrinsic properties and that, therefore, that provision **does not preclude a substance from being identified as SVHC**.

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