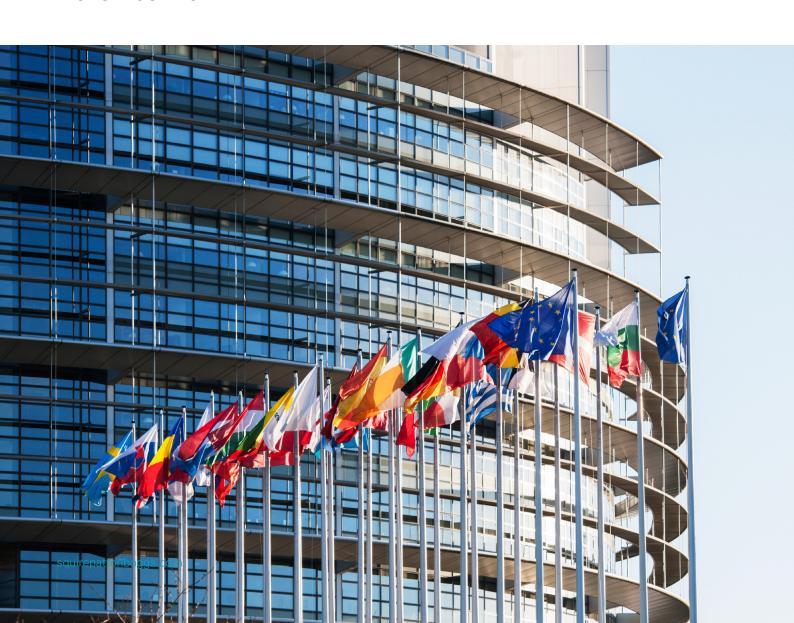


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Sustainability Outlook European Union

November 2021



Council discusses the progress of the "Fit for 55" package

The Council issued a report on the progress it made in negotiating the Fit for 55 package during the Slovenian presidency (please see Sustainability Outlook July 2021), which has made it a major priority. While negotiations on the proposals advanced at different paces, good progress at the technical level was achieved across the board. Work was most advanced on some of the **transport** proposals, and good progress was also made on the **energy** files, whereas the Environment and ECOFIN Councils need more time to fully assess the proposals in their remit. The Council observes that while some of the proposals represent new measures in the EU's toolbox, such as the Social Climate Fund and the Carbon Border Adjustment Mechanism, others, such as the ETS and LULUCF, contain several new elements.

Delegations continue to consider the Emissions Trading System (ETS) as the heart of the EU's climate policy. There have been some calls for further increasing the ambition of the ETS, but also questions regarding the possible impacts of certain parts of the proposals on both economic sectors and households, highlighting the need to take into account the different situations of Member States. In particular, the proposed introduction of emissions trading for buildings and road transport has prompted significant concerns with regard to its social impact on lower income households and the risk of increasing energy poverty.

Regarding the Renewable Energy Directive (**RED**), it appears that delegations support the aim of the proposal, as well as its overall level of ambition. However, they underline the importance of **flexibility for Member States to apply the most cost-efficient measures**, coherence with existing legislation, respecting the principles of subsidiarity and technology-neutrality.

On the carbon border adjustment mechanism (**CBAM**), the Committee of Permanent Representatives of the Council established an Ad Hoc Working Party (AHWP CBAM) to prepare further negotiations. Member States attach significant importance to it in the context of international trade, the competitiveness of EU industry and the effects on the economy, including on the labour market.

European Commission expected to set out a policy on sustainable carbon cycles

According to a leaked <u>draft communication</u>, the Commission will set out an action plan to achieve sustainable carbon cycles. The Commission plans to achieve this objective through three key actions: the **elimination** or **drastic reduction** of **reliance on carbon**, the **recycling of carbon from waste**, and **upscaling carbon removal solutions** that capture CO2 from the atmosphere and store it for the long term.

Recycling from waste streams, in particular, should be carried out from sustainable sources of biomass or directly from the atmosphere. Carbon thus recycled should then be used in place of fossil carbon in the sectors of the economy that will inevitably remain carbon dependent.

The Commission stresses the importance of the Innovation Fund. Carbon removal projects could increase their viability by combining the grants from the Innovation Fund with the revenues from the sale of **carbon removal credits**, while any **double funding** is to be **avoided**. The experience with carbon removal projects under the Innovation Fund would provide important feedback for the development of the **certification of industrial carbon removals**. The leaked document confirms that a **legislative proposal** on such **certifications** is planned for **2022**, with the purpose of scaling-up carbon farming and industrial solutions removing carbon from the atmosphere.

The Commission is expected to adopt the communication on 14 December 2021.





European Commission sets out how to "make competition policy fit for new challenges"

The Commission adopted a communication summarising the key elements of the review of its competition policy. The Commission has been assessing whether current policy tools and enforcement practices are fit for the twin green and digital transitions, as well as the creation of a more resilient Single Market. The communication portrays competition policy as a complementary tool to other measures in the European Green Deal, in order to support the green transition. As an example, the communication mentions the update of the Horizontal Block Exemption Regulations and Guidelines or the upcoming Climate, Environmental Protection and Energy Aid Guidelines (CEEAG). The Commission stated that the ongoing review of the **State aid guidelines** aims at ensuring consistency with regulatory principles relevant to the European Green Deal, such as the "polluter pays" principle and "Do No Significant Harm" principle. Under the draft CEEAG, State support for projects involving fossil fuels was unlikely to be compatible with State aid rules. In a broader context, the Commission might take into account negative externalities as part of the assessment of the negative effects of the aid on competition and trade.

Closely related to the content of the communication, the European Commission issued a policy brief on how EU competition rules can complement environmental and climate policies more effectively (please see <u>Sustainability Outlook September 2021</u>).

European Commission proposes new rules on waste shipments

The Commission adopted a <u>proposal</u> for a new regulation replacing EU Waste Shipment Regulation 1013/2006 and amending the regulation on electronic freight transport information. The Commission also published a <u>communication</u> on "waste shipments in a clean and more circular economy".

As stated by the Commission, the three main goals of the new rules are to (1) ensure that the EU does not **export** its **waste to third countries**; (2) make the transport of **waste for recycling and reuse within the EU** easier; and (3) better tackle **illegal waste shipments** both within the EU and between third countries and the EU.

First, the export of **waste to non-OECD countries** would not be authorised, except to those non-OECD countries that explicitly notify the EU of their willingness to receive EU waste exports of "green-listed" waste and can demonstrate their ability to treat this waste in an environmentally sustainable manner. The export of waste to OECD countries will be monitored, and the Commission will engage in dialogue with countries of destination where there are concerns about the environmental impact of such shipments. Companies exporting waste outside the EU will be required to ensure, by means of **independent audits**, that the facilities to which they ship waste operate in an environmentally sound manner. The Commission will adopt **criteria for specific wastes** (e.g. end-of-life vehicles (ELV), waste batteries and textiles) in order to **differentiate between waste and used goods**, and prevent the export of waste under the denomination of "used goods".

Within the EU, waste shipments for incineration or landfilling would be subject to stricter conditions and only authorised in limited and well-justified cases (e.g. the waste cannot be recovered in a technically feasible and economically viable manner and cannot be disposed of in the country where it was generated). An EU-wide electronic documents and information interchange system will be developed and both public and private actors will be able to submit and access information. The Commission will also support the use of fast-track procedures for shipments of waste destined to recovery, by allowing operators of recovery facilities to be pre-consented. Additionally, implementing powers will be conferred to the Commission to adopt measures to harmonise the classification of waste at the EU level (including the establishment of contamination thresholds for certain waste).

The Commission will be empowered to carry out investigative and coordinating actions in respect of **illegal shipments** and may entrust certain enforcement actions to the European Anti-Fraud Office (OLAF). The proposal includes non-exhaustive common **criteria** for determining the types and levels of **penalties** to be imposed for infringements.

The proposal will follow the ordinary legislative procedure. The Commission opened the usual feedback period, which will run until 17 January 2022.

European Commission publishes guidance on plastic waste shipments

In the consultation with the Correspondents (i.e. the national authorities that disseminate advice and information regarding waste shipments), the Commission adopted the so-called <u>Correspondents' Guidelines No 12</u>. It is not legally binding but provides guidance on the interpretation of certain terms in the entries on **plastic waste** in the EU Waste Shipment Regulation 1013/2006, and aims at providing legal clarity and certainty following the adoption of Commission Delegated Regulation 2020/2174. That regulation amended said entries regarding plastic waste in line with changes to the UN Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal.

The regulation and new guidelines aim at preventing low-quality plastic wastes from being classified under the entries B3011 (certain plastic waste imported from/exported to outside the EU) or EU3011 (certain plastic waste shipped within the EU), which allow for "easier" shipments. In order to be classified as **B3011**, the content of **contamination**, other types of wastes or non-halogenated polymers, cured resins or condensation products, or fluorinated polymers other than the one that makes the bulk of the plastic waste should not exceed a total of 2% of the weight of the consignment. The same rules apply for mixtures of plastic waste consisting of polyethylene (PE), polypropylene (PP) and/or polyethylene terephthalate (PET), provided that they are destined for separate recycling. In the latter case, PVC is included as another type of waste. Regarding intra-EU plastic waste shipments (EU3011), the content of **contamination**, other types of wastes or non-halogenated polymers, cured resins or condensation products, or fluorinated polymers other than the one that makes the bulk of the plastic waste is allowed up to a total of 6% of the weight of the consignment. However, Member States may decide to apply a maximum level of 2% after informing the Commission. Unlike B3011, EU3011 includes an indent on PVC shipments and the guidelines propose a maximum level of contamination or other types of waste of 6% of the weight of the consignment.

In addition, the new guidelines recall the precautionary approach in its recommendations and provide guidance on the classification of **hazardous waste**. They will apply from 3 December 2021.

EU court clarifies the rules on classification of waste for its transfrontier transport

The European Court of Justice (ECJ) decided on a preliminary reference brought by the highest administrative consultative body and court in Italy (Consiglio di Stato) on the interpretation of certain rules regarding waste shipments and the classification of waste for that purpose (Case C-315/20; not yet available in English). The Italian court had asked the ECJ whether a competent authority may oppose the shipment of mixed municipal waste destined for recovery. In the case at hand, the original **properties** of the waste had **not changed** substantially after a mechanical treatment for energy recovery, and it had been classified under the European Waste Catalogue (EWC) as "other wastes (including mixtures of materials) from mechanical treatment" (code 19 12 12). As provided in the Waste Shipment Regulation, competent authorities may oppose the shipment of mixed municipal waste (20 03 01) collected from private households, for both disposal and recovery. The ECJ concluded that the rules must be interpreted as allowing competent authorities of dispatch to oppose a shipment of municipal mixed waste that, (even) after a mechanical treatment for energy recovery, has not altered substantially the original properties of that waste, irrespective of the classification of waste given in the EWC. The ECJ followed Advocate General Rantos' opinion, which had recalled that the rules applicable to waste shipments depend on the substantial nature of the waste, and not on its formal classification in accordance with the EWC.









Member States back new rules on industrial emissions from large combustion plants

The European Commission submitted a <u>draft Implementing Decision</u> establishing the best available techniques (BAT) conclusions for large combustion plants (LCP) to a vote by its Committee on the **Industrial Emissions Directive** 2010/75 (IED). The committee gave a positive opinion.

BAT conclusions are the reference for setting **permit conditions** for installations covered by Chapter II of the IED. National competent authorities must set **emission limit values** that ensure that emissions do not exceed the emission levels associated with the BAT as laid down in the BAT conclusions under normal operating conditions. The LCP BAT conclusions cover (1) combustion of fuels in installations with a total rated thermal input of 50MW or more; (2) gasification of coal or other fuels in installations with a total rated thermal input of 20MW or more (only when this activity is directly associated with a combustion plant); and (3) disposal or recovery of waste in waste co-incineration plants for non-hazardous waste with a capacity exceeding 3 tonnes per hour or for hazardous waste with a capacity exceeding 10 tonnes per day.

Following the committee's favourable opinion, the Commission is expected to adopt the Implementing Decision in the upcoming months. It will then replace Commission Implementing Decision 2017/1442, which the **EU court annulled** on application by Poland, whose **energy** system still relies on **coal**, supported by Bulgaria and Hungary (Case T699/17; appeal pending, Case C-207/21). The court ruling required the Commission to adopt new LCP BAT conclusions before the end of January 2022. In the event that the Court of Justice reverses the judgment in Case T-699/17 so that Implementing Decision 2017/1442 remains valid, the decision to be adopted will cease to apply on 28 January 2022.

European Commission adopts a <u>proposal</u> for a regulation on deforestation-free products

The <u>proposed</u> regulation would establish **mandatory due diligence** requirements for companies placing specific commodities (**soy, beef, palm oil, wood, cocoa and coffee**) and some derived products (such as **leather and chocolate**) on the market. These commodities and products are associated with deforestation, forest degradation and illegal logging. Operators placing affected products on the market for the first time, whether as manufacturers or importers, will have to ensure that they have not been produced on land deforested or degraded after 31 December 2020; and that they have been produced in accordance with the laws of the country of production. Not meeting either of the two requirements will result in a **prohibition to place those products on the market**. Operators will need to have a due **diligence system** in place to assess and manage their risks.

European Commission proposes to set "new limits for some of the most harmful chemicals in waste"

The Commission presented its proposal to amend Regulation 2019/1021 on persistent organic pollutants (POPs; please see fresh Law Horizons June
2020). In particular, the proposal would update the concentration limits in Annexes IV and V, which determine how waste containing POPs must be treated, including whether it can be recycled or must be destroyed or irreversibly transformed. According to the POPs Regulation, the Commission must make legislative proposals to amend those Annexes in order to adapt the changes to the list of substances set out in the Annexes to the UN Stockholm Convention or Protocol, or to modify entries or provisions in these Annexes to the Regulation in order to adapt them to scientific and technical progress.

The Commission proposes to introduce stringent limits for three substances, or groups of substances, in waste: perfluorooctanoic acid (**PFOA**), its salts and compounds; **dicofol**; and pentachlorophenol (**PCP**), its salts and esters. According to the Commission, these substances are still present in some products such as textiles, fire-fighting foams and treated wood. In addition, the Commission is proposing to tighten the maximum limits in waste for other substances already regulated in these Annexes: polybrominated diphenyl ethers (**PBDEs**, cumulative threshold for five substances), short-chain chlorinated paraffins (**SCCPs**), hexabromocyclododecane (**HCBDD**), Polychlorinated dibenzo-pdioxins and dibenzofurans (**PCDD/PCDF**), and dioxin-like polychlorinated biphenyls (**dIPCBs**).

The proposal follows the ordinary legislative procedure, which involves amendments by, and legislative negotiations between, the European Parliament and Council before they adopt the final law.

European Commission prepares further changes to concentration limits for POPs

In parallel to the ordinary legislative procedure for the amendment of Annexes IV and V to the POPs Regulation (please see above), the Commission has been using the power delegated to it by that Regulation. For example, it opened for comment a draft Commission Delegated Regulation amending Annex I to the POPs Regulation as regards hexachlorobenzene. That substance is used in pesticides and is listed in Annex A to the UN Stockholm Convention (for elimination). Annex I to the POPs Regulation does not currently set a limit value for the presence of hexachlorobenzene as unintentional trace contaminant (UTC). Above that threshold, manufacturing, placing on the market (including import) and use of the substance (and articles containing it) is prohibited. The Commission discussed this amendment with its expert group for POPs in June. The comment period ends on 6 December 2021. After that, the Commission may adopt the delegated act; it would then enter into force after two months, unless the European Parliament or Council object.

European Commission publishes exemptions on phthalates in medical devices

The Commission published in the Official Journal three delegated directives (Commission Delegated Directives <u>2021/1979</u>, <u>2021/1980</u>, <u>2021/1978</u>) **exempting the use of phthalates** in medical devices and spare parts under EU Directive 2017/2102 on the Restriction of Hazardous Substances in electrical and electronic equipment (**RoHS**).

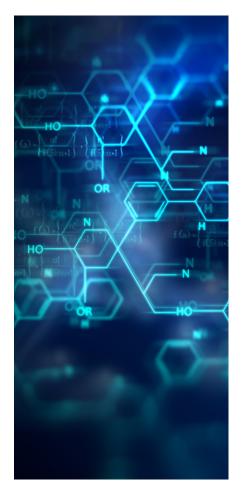
They add the following exemptions to Annex IV of RoHS: use of bis(2-ethylhexyl) phthalate (**DEHP**) in **plastic components** in magnetic resonance imaging (MRI) detector coils; use of **DEHP** (please see Sustainability Outlook October 2021 and frESH Law Horizons February 2021) in **ion-selective electrodes** for analysing human body fluids and/or in dialysate fluids; and use of **DEHP**, butyl benzyl phthalate (**BBP**), dibutyl phthalate (**DBP**) and diisobutyl phthalate (**DIBP**) in **spare parts** recovered from, and used for, the repair or refurbishment of medical devices. EU Member States are required to transpose the directives by 30 April 2022.

European Commission lifts exemptions for uses of DEHP in medicinal products

The European Commission adopted an <u>implementing regulation</u> amending Annex XIV of REACH, i.e. the so-called **Authorisation List** regarding **DEHP** (benzyl butyl phthalate, <u>please also see frESH Law Horizons February 2021</u> and <u>Sustainability Outlook October 2021</u>), **BBP** (Butyl benzyl phthalate), **DBP** (dibutyl phthalate) and **DIBP** (diisobutyl phthalate). The concentration limit applicable to the presence of these substances in mixtures for the purposes of an exemption from the authorisation requirement is set at 0.1%.

The Commission held that it would **not** be appropriate to use the option provided by REACH to establish exemptions based on specific (**other**) **EU legislation** imposing **minimum requirements** relating to the protection of human health or the environment ensuring proper control of the risks.

The European Commission exempted from the authorisation requirement the use of DEHP, BBP and DBP in the immediate packaging of medicinal products in Commission Regulation 143/2011. The Commission re-assessed the exemption set out in Annex XIV in light of the judgment of the Court of Justice in July 2017 in Case C-651/15 (VECCO), which clarified certain aspects of granting an exemption from the authorisation requirement. In particular, the court found that Regulation 726/2004 on authorisation and supervision of medicinal products, as well as Directives 2001/82 and 2001/83 on the Community code relating to veterinary medicinal products and relating to medicinal products for human use, do not impose such minimum requirements because they do not contain provisions that are specific to the substances at hand. Furthermore, the aforementioned EU laws lay down requirements related to the protection of **human health** only, while DEHP has intrinsic properties relating to hazards to the **environment**.









Council and European Commission hold workshops on REACH authorisations and restrictions

In an <u>information note</u>, the Council addressed a workshop on the reform of **REACH authorisation and restriction** in Brdo, Slovenia, at the start of November. 130 representatives of the Member States Competent Authorities considered several options for reforming the REACH authorisation and restriction regimes. The first option was **simplification** under the current authorisation and restriction system, the second was the merger of **authorisation and restriction**, and the third was the **complete or partial removal of the authorisation title** from REACH (<u>please see frESH Law</u> Horizons May 2021 and June 2021).

The participants expressed interest in merging authorisation and restrictions. With a view to **simplification**, there should be no need for the authorities to prove an **unacceptable risk** posed by uses of the most harmful substances (as is currently foreseen by REACH for restrictions). The **burden of proof** for authorisations and derogations from restrictions should remain on the industry. Member States also supported the continued use of the Candidate List of substances of very high concern (SVHCs) for prioritising further regulatory action. They considered favourably requiring additional use and exposure information upon the candidate listing.

One week later, the <u>Commission held a public workshop</u> on the same topic. According to a background document, challenges around the authorisation process include the so-called **upstream applications** covering several hundreds of downstream users. Where downstream users applied individually, this sometimes created a multitude of often-repetitive individual applications for similar uses of sometimes very small quantities of SVHCs. The **type and amount of required information** was a challenge for small and medium-sized companies (SMEs), which are often dependent on suppliers, the technological choices of their clients, etc.

Problematic aspects of the restriction process include the **burden of preparing restriction** proposals, as Member States do not always have necessary resources and access to key information, in particular in relation to uses and exposure, as well as technological choices and alternatives. It was also problematic to limit restrictions to "information-rich" substances, and restricting substance by substance, as that had led to **regrettable substitution** (with non-restricted substances that have similar properties), e.g. other PFAS following the restriction of PFOA. Although that problem had been partly addressed by broader restrictions (e.g. broad PFAS restriction under development), it remained an issue to be closely observed.

Among other and in addition to the aforementioned options, the workshop considered the introduction of the generic approach to risk management, the introduction of the essential use concept, strengthening the role of the ECHA Forum to assess the enforceability of restrictions and improving the feasibility of REACH restrictions for SMEs.

European Commission asks for more time to discuss endocrine disruptors and polymers

In $\underline{\mathsf{two}}$ documents submitted to the Competent Authorities for REACH and CLP (CARACAL) for the meeting of that body in November, the Commission asked to endorse the **extended mandates** of the two CARACAL subgroups on endocrine and disruptors polymers (CASG-polymers and CASG-ED), as additional time was needed to finalise their work. In particular, the CASG-ED may need additional meetings to discuss specific technical aspects of a future update of the REACH Annexes I and VII to X to include data requirements on endocrine disruptors (please see frESH Law Horizons June 2021 regarding recent changes to the data requirements). The Commission presented two initial draft proposals as a starting point for discussions at the CASG-ED meeting in October 2020. Following feedback received from the members of the CASG-ED, it revised the two proposals and presented them for discussion in March 2021. These revised proposals are used as policy options to be considered in a study aimed to gather further information in support of an impact assessment of potential options for the update of REACH Annexes. This study will feed into the impact assessment for the revision of REACH (please see frESH Law Horizons May 2021).

European Commission reports on progress with the Chemicals Strategy for Sustainability

Ahead of the second meeting of its **High Level Roundtable on the Chemicals Strategy for Sustainability** in November (<u>please see Sustainability Outlook October 2021</u>), the Commission <u>reported</u> on the status of the implementation of that <u>strategy</u>.

The adoption of the **Sustainable Products Initiative** is now planned for 2022. The Commission launched a study on **criteria for essential uses**, targeted consultations are ongoing, and the Commission has planned an open consultation in spring 2022, before presenting horizontal criteria by the end of 2022 and introducing the concept in its proposal for the **REACH revision**. Based on the concept of essential uses, the most harmful chemicals will only be allowed if their use is necessary for health, safety or the functioning of society, and if there are no acceptable alternatives. The Commission will also present three legal proposals: a horizontal proposal on the **reattribution of tasks to EU agencies** (2022), a proposal on **transparency and reuse of data** to allow EU and national authorities to commission testing (2023), and a proposal to improve the predictability and stability of **ECHA's funding** (2023). Furthermore, the "**one substance**, **one assessment**" approach also includes the development of a common open data portal on chemicals (2023) and of a repository of health-based limit values (2022).

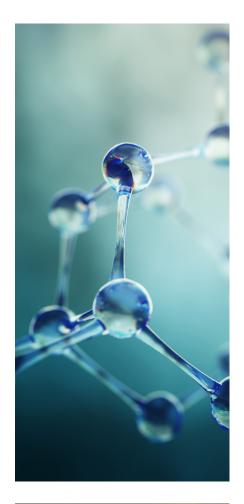
European Commission expected to adopt a restriction roadmap, considering measures on flame retardants

At the turn of the year, the Commission wants to adopt a **roadmap** to prioritise substances for REACH **restrictions**, after revising an earlier draft discussed since April 2021 in CARACAL. It presented a <u>new draft</u> to CARACAL in November. The roadmap will likely use the following categories: substances already on the registry of intention (Rol) for restrictions; substances under consideration by ECHA, Member States or the Commission for a restriction proposal; and potential restrictions where ECHA foresees a need for further regulatory action. While it primarily addresses hazard endpoints specified for the generic approach to risk management, the revised version of the roadmap indicates that restrictions may also address other endpoints, e.g. skin sensitisers to ensure a consistent use of regulatory resources.

According to the draft, and among many other things, ECHA, the Member States and the Commission are currently assessing the need for further regulatory measures regarding flame retardants in general. ECHA will prepare an overall strategy on flame retardants by 2022. This will support the Commission in deciding in 2023 to request that ECHA prepare a group restriction (or multiple restrictions) under REACH. Substances in scope are, in principle, all flame retardants, but there will be a particular focus on, and prioritisation of, brominated flame retardants.

ECHA finds effects of REACH authorisation regime

The European Chemicals Agency presented a report with two case studies that seek to quantify the causal effects that the **REACH authorisation regime** has had on the use of specific substances of very high concern (SVHCs). The study focuses on Sweden. It finds that Swedish firms have reduced their annual use of SVHCs by about 40% five years after their inclusion in XIV (the Authorisation List). This suggested that the inclusion of a substance in the Authorisation List has a sizeable substitution effect. The study found that adding substances to the REACH Candidate List may reduce their releases into wastewater. A very robust effect in that regard was found for 1,2-dichloroethane; its discharge had declined by about 66% over the period from 2011 to 2017. The report finds it at least plausible to attribute this to its inclusion in the Candidate List and its anticipated inclusion in the Authorisation List (which requires users to apply for authorisation). The results of two case studies indicated that both candidate and authorisation listing may have a sizeable effect on the use of SVHCs. It would be desirable to expand similar investigations to other EU Member States where data is available.







ECHA publishes a report on chemical recycling

The European Chemicals Agency stated that REACH requirements need to be considered in chemical recycling. The report drafted by consultant RPA for ECHA analyses the current knowledge regarding chemical recycling of polymeric materials such as plastics and rubber, and how different chemical recycling techniques can reduce the presence of substance of concern in recycled material. The report gives an overview of the different chemical recycling processes and the advantages and disadvantages of these techniques. Besides a literature review, the report includes the findings of a consultation, where stakeholders opined that chemical recycling could be treated as "supplementary" to mechanical recycling because it accepts waste that cannot be processed mechanically.

The report concludes that there is **not enough knowledge** about the abilities of chemical recycling processes to eliminate substances of concern and further research is necessary, in particular regarding gasification and chemolysis. The report recommends harmonising the terminology regarding chemical recycling, as there is no clarity of the term or its role in the circular economy. **Regulatory issues** (e.g. REACH registration), as well as the potential of chemical recycling, would need to be studied on a caseby-case basis, separately for each type of chemical recycling. As an example, the report provides that **pyrolysis** and **gasification** have the potential to serve efficient waste management technologies and substitute incineration and/or landfill despite some limitations regarding circularity. By contrast, for example, chemolysis was capable of contributing to the circularity of plastics, but its commercialisation was currently difficult. The paper stresses that some regulatory issues are particular to chemical recycling technologies, since mechanical recycling does not cause chemical changes to the processed substances. Finally, it recommends the use of digital technologies to improve the traceability of substances of concern in recycling.

ECHA launches a social media campaign to raise awareness regarding poison centres

The European Chemicals Agency launched an EU-wide <u>social media campaign</u> to increase awareness in particular of parents with small children about the **unique formula identifier** (UFI). European poison centres have asked callers for the **UFI** code since January 2021. It helps them to identify the product and its ingredients quickly so they can give accurate advice to the callers. The UFI can be found on the product labels of many everyday chemical products, such as cleaning agents, paints and adhesives. It should always be clearly visible on the product near its trade or brand name, or near the hazard information that includes, for example, pictograms and advice on how to use the product safety. The UFI is created from the company's VAT number (or company key) and a mixture-specific formulation number.

EFSA consults on phthalates in food contact materials

The European Food Safety Authority made available a <u>draft scientific opinion</u> on the identification and prioritisation for **risk assessment** of **plasticisers** used in food contact materials (FCMs) and a <u>draft protocol</u> for the **exposure assessment** of prioritised substances available for public consultation.

In particular, the draft scientific opinion presents an overview of **substances potentially used as plasticisers in** FCMs and categorises them into groups of high, medium and low priority for further risk assessment. EFSA will collect data on the migration of the prioritised substances from and their occurrence in FCM via dedicated calls in 2022, separately from the public consultation. The consultation on the draft protocol addresses the **exposure assessment** as part of the safety assessment of phthalates, structurally similar substances and replacement substances that are potentially used as plasticisers in FCM, in particular dietary exposure, contribution of FCMs to dietary exposure, and contribution of FCMs to overall (dietary and non-dietary) exposure. Comments may be submitted until 16 December 2021.

EU court upholds identification of PTBP as a substance of very high concern

The General Court <u>ruled</u> on the decision to identify the substance 4-tert-butylphenol (PTBP) as a substance meeting the criteria for inclusion in the REACH Candidate List for substances of very high concern (SVHC). It dismissed an action for annulment brought by Sasol, BASF and SI Group – Béthune.

In December 2016, ECHA's Member States Committee (MSC) gave its opinion on the REACH Annex XV dossier. While the majority of the MSC members took the view that PTBP had to be identified as a SVHC, the MSC was unable to reach a unanimous opinion. In July 2019, the European Commission adopted Implementing Decision 2019/1194 that identified PTBP as a SVHC pursuant to Article 57(f) of REACH due to its endocrine disrupting properties with probable serious effects to the environment. Following that decision, which the applications contested, **ECHA** included PTBP in the Candidate List.

Regarding the finding that the level of concern is equivalent to that of the substances listed in Article 57(a) to (e), the court found that the Commission did not simply analyse the hazards arising from the intrinsic properties of PTBP. On the contrary, it took into consideration the difficulties in adequately assessing the risks, while also noting that the effects were irreversible, that the effects may be relevant for wildlife populations and potency of PTBP, following the majority opinion of the MSC. The court also found that the **factors that the applicants contest** (i.e. degradability, bioaccumulation, potency and environmental exposure) **do not constitute information which must be regarded as relevant for the purposes of** such **identification**. Accordingly, the Commission was not obliged to consider them when identifying PTBP as SVHC. Furthermore, the court referred to the Commission Roadmap to 2020 on SVHC. According to the roadmap, endocrine disruptors may be identified as SVHC irrespective of the recommendations from the Risk Management Option Analysis (RMOA).

Particularly in the case of endocrine disruptors, a substance may be included in the Candidate List even if a restriction is foreseen, because formal identification as a substance of very high concern may avoid further discussion of hazardous properties during the restriction procedure. According to the court, the applicants rely on the **incorrect assumption that restriction is a less onerous measure** than the identification of a substance as SVHC, which essentially triggers information obligations, or even the eventual inclusion in the Authorisation List, which still allows for the authorisation of specific uses.

Italy expected to postpone the application of its plastic tax again

The Italian government announced the **postponement** of the national plastic **tax** of €0.45/kg on certain single-use plastic packaging (*manufatti in plastica con singolo impiego* (MACSIs)) **for the fourth time**. According to the <u>Budget Law</u> for 2022 that the government proposed, the tax will be postponed to 1 January 2023. The proposed Budget Law has been transmitted to Parliament for adoption.





UK consults on bans of single-use plastic products

The UK Department for Environment, Food and Rural Affairs (DEFRA) launched a <u>call for evidence</u> and <u>public consultation</u> on bans of certain single-use plastic products in England. DEFRA considers the prohibition of the supply of **plates**, **cutlery**, **balloon sticks** and **expanded and extruded polystyrene food** and **drink containers**, including cups, as of April 2023.

Unlike in the EU <u>Single Use Plastics Directive</u> 2019/904 (SUPD), this specific initiative focuses on bans of certain products and does not provide any other measures such as consumption reduction targets, labelling requirement or product requirements (i.e. minimum recycled content). Also, it does not include a ban of all products made from oxo-degradable plastic. However, it defines terms like "**single plastic product**" or "**plastic**" similarly to the SUPD. Therefore, plastic means a "material consisting of a polymer to which additives have been added or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified". The 2020 Environmental Protection Regulations, which ban the supply of plastic straws, drink stirrers and cotton buds, already used this definition (please see <u>Legal NewsBITE September 2020</u>). As in the SUPD, the intended prohibitions would include products made from all kinds of plastic, including **bio-based**, **biodegradable** and **compostable plastics**.

Under their devolved powers, **other parts of the UK**, in particular Scotland and Wales, have started other, similar, initiatives to prohibit single-use plastic products. Also, the UK has committed to transpose parts of the SUPD in Northern Ireland until January 2022, including restrictions on the placing on the market of certain single-use plastics products.

The call for evidence and the public consultation on the measures in England will be open until 12 February 2022.

If you are interested in UK as well as EU environment, safety and health law, procedure and policy, please take a look at our <u>frESH blog</u>.

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