

Sustainability Outlook European Union

August 2021



European Commission Discusses Implementation of the EU Single-use Plastics Directive With Member States

The Commission made available the summary record of the most recent meeting of its Waste Technical Adaption Committee in June. The Commission replied to multiple questions from the Member States' representatives in that comitology committee with regard to the implementation of the [Single-use Plastics Directive 2019/904 \(SUPD\)](#), the Commission's [guidelines on the scope of the SUPD](#) and Implementing Regulation 2020/2151 on **marking** specifications. The Commission also stated that it distributed the first draft on the implementing act on **reporting and quality check of post-consumer waste from tobacco filters** to the Member States for written comments. Regarding the calculation and reporting of the **consumption reduction target** for single-use plastic food containers and beverage cups, the Commission said that it would propose an approach based on the **weight of plastic** (including coatings) contained in those products in order to ensure consistency with the reporting under Packaging and Packaging Waste Directive 94/62 (PPWD). Reporting additionally on item count will be optional. This will likely motivate Member States to focus on reducing the weight of plastic in these products.

In addition, the Commission [made available](#) the draft of an explanatory document concerning the concept of "**placing on the market**" in the SUPD in view of its [Blue Guide on the implementation of EU product rules](#).

Member States Vote on Rules on Separate Collection of Single-use Plastic Beverage Bottles

The Member States representatives in the Commission Committee on Waste delivered a positive opinion on the draft [implementing act](#) laying down rules on the calculation, verification and reporting of data on the separate collection of waste single-use plastic beverage bottles. 26 Member States [voted](#) in favour and one against. The Commission implementing act under the SUPD is addressed to Member States to ensure the comparability of this data across the EU. The SUPD provides that Member States must collect 77% of single-use plastic beverage bottles by 2025 and 90% by 2029 and report data on this to the Commission each year. The draft the Committee voted on does not differ from the version on which the Commission [publically consulted](#). The implementing act provides, among other details, that the weight of waste single-use bottles must include the weight of their caps and lids, and may include the weight of labels and adhesives only if the Member State also includes their weight in the bottles placed on the market. This weight may be determined by counting the bottles and applying conversion factors to take into account the weight of each bottle size and polymer type. Waste bottles are considered as separately collected if they have been collected separately from any other waste for recycling, or if they have been collected together with other waste under certain conditions (such as not mixing with hazardous wastes and collection and designed and carried out to minimise contamination). Member States may adjust the weight of the single-use bottles placed on the market adjustment where there are significant imports, exports or other movements within the EU of such bottles by operators or by natural persons for their own personal use. The Annexes to the implementing act provide the calculation formulas, as well as the reporting and quality check formats. The Commission is expected to adopt the implementing act in the near future.





European Commission Registers Citizen Initiative on Plastic Bottle Deposit System

The European Citizen Initiative (ECI) "[ReturnthePlastics](#)" aims to implement an EU-wide deposit-return system (DRS) to recycle plastic bottles. According to its organisers, the system would be based on a €0.15 deposit for every plastic bottle purchased in the EU, which the consumer would receive back after returning the used plastic bottle to a reverse vending machine in a supermarket. In addition, they propose that plastic bottle manufacturers would bear the costs of putting this system in place.

Some Member States already have a DRS to collect beverage bottles (not only plastic bottles). The [Single-use Plastics Directive 2019/904](#) (SUPD) encourages this measure to achieve the collection of 77% of single-use plastic beverage bottles by 2025 and 90% by 2029. However, introducing DRS is not mandatory.

If the ECI receives at least 1 million signatures of citizens from at least seven Member States within 12 months from a date chosen by the organisers, which must be not later than six months from its registration, the organisers may present it at public hearing of the European Parliament and meet with the Commission, which must set out its legal and political conclusions on the ECI in a communication. However, the Commission is not obligated to take any further action. Since 2012, to promote participatory democracy at EU level, the Commission has found 82 of 107 requested ECIs admissible (i.e. in the EU areas of competence); only six reached the required threshold of signatures. The period for the collection of signatures of this ECI has not started yet.

European Commission Sets Up Plastic Expert Group on Packaging Waste Statistics

The Commission [Decision](#) on establishing an expert group for statistics on plastic packaging waste (SPPW) foresees that a representative of the **Eurostat**, the statistical office of the EU, will chair it. The expert group will be composed of Member States' authorities responsible for reporting the data under the [PPWD](#). Among other tasks, the group will advise the Commission on the comparability, reliability and exhaustiveness of the statistics on plastic waste generation and recycling and policy and legislative proposals on the **harmonisation of statistics** in this field. In addition, the group will be responsible for issuing annual opinions on the **appropriateness of the data** submitted by the Member States for the purposes of the own resource based on non-recycled plastic packaging waste ([Council Decision 2020/2053](#), the so-called "**EU plastic tax**"; please see [frESH Law Horizons July 2020](#)).

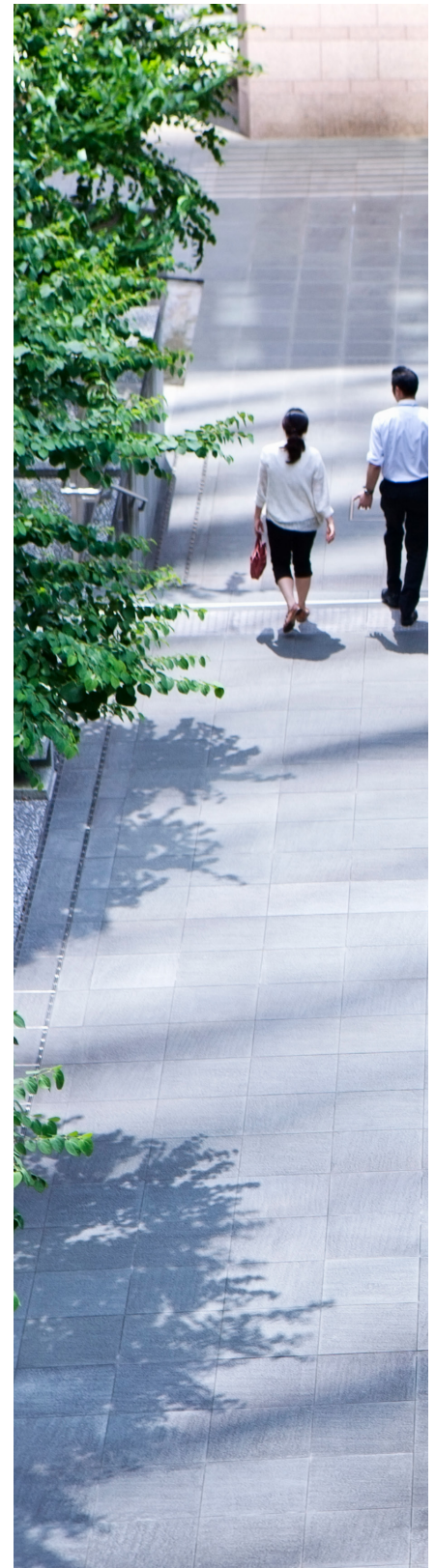
Commission expert groups can be set up by a (formal) Commission decision or (informally) by an individual Commission department that has obtained the agreement of the Commissioner and Vice-President responsible, and of the Secretariat-General. They can be composed of public and/or private sector members and provide advice and expertise to the Commission.

Commission Platform on Sustainable Finance Issues Draft Recommendations on Taxonomy Criteria

The [draft report](#) and its [Annex](#) present **technical screening criteria** for a first set of **priority economic activities** with regard to their **substantial contribution** to four environmental objectives: 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, as well as the criteria for “**do no significant harm**” (DNSH). They have been drafted by the Technical Working Group, a dedicated subgroup of the Platform on Sustainable Finance **requirements under the Taxonomy Regulation 2020/852**. The Technical Working Group has **prioritised** a wide array of economic **activities**, such as the manufacture of chemicals, chemical products, plastics, machinery and waste management systems. **Chemical recycling** is not as such addressed as an economic activity but as part of other activities. For example, the Technical Working Group considers it in the context of one criterion for the **manufacture of food products and beverages** to substantially contribute to the transition to a circular economy: 85% of its packaging (by weight) consists of, among other options, material fully manufactured by mechanical or chemical recycling of post-consumer material, with claims on recycled content made using a **batch level mass balance** method. For the **manufacture of plastic packaging goods**, the draft report includes as a criterion that the goods are 95% mechanically recycled, chemically recycled, biobased or carbon capture and utilisation (CCU) feedstock.

The draft criteria presented in the report are **working documents** of the Platform and not an official Commission document. They do not represent the final view of the Platform. It might eventually consider economic activities not included in the first-batch of priority activities. Stakeholders can submit their [feedback](#) until 24 September. The Platform plans to submit a final report to the Commission in November 2021, and the Commission wants to publish a delegated act with the technical screening criteria for these four non-climate environmental objectives in 2022.

The EU adopted the **Taxonomy Regulation** as an EU-wide classification system for sustainable economic activities to drive green investments supporting the objectives of the [European Green Deal](#). It entered into force in July 2021, but some of its provisions will be phased-in over the next few years. The EU Taxonomy system creates a list of **economic activities** with technical screening criteria determining which ones make a **substantial contribution** to one or more of the six **environmental objectives**: climate change mitigation; climate change adaptation; 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, and **do no significant harm** to any of the others. The Taxonomy Regulation tasks the European Commission with adopting delegated acts that establish technical screening criteria with which the activity has to comply. Earlier this year, the Commission [adopted](#) the delegated act on climate change mitigation and adaption. The European Parliament and the Council are examining that delegated act, which is supposed to apply from the start of 2022.





European Commission Consults on Pollutants in Surface and Ground Waters

The Commission has launched an [open public consultation](#) on its upcoming legislative proposal on the lists of pollutants affecting surface and ground waters and corresponding regulatory standards. In 2019, its [Fitness Check of EU Water Law](#) concluded that water legislation is generally fit for purpose, but there is room for improvement in many key areas, such as chemical pollution, where legislation did not sufficiently address pollutants of emerging concern, such as pharmaceuticals, (micro-) plastics and per- and polyfluoroalkyl substances (PFAS). In October 2020, the Commission issued an [inception impact assessment](#) (IIA), laying out the roadmap for a revision of various pieces of EU water legislation. The options that it presented include updating (1) the list of priority substances in surface waters (under the Water Framework Directive 2000/60), (2) the water environmental quality standards (under the Environmental Quality Standards Directive 2013/39), and (3) the lists of pollutants and standards in groundwater (under Groundwater Directive 2014/80) by adding, removing, or re-designating substances. Non-legislative options could include updating and developing guidelines on monitoring and on thresholds.

The public consultation will be open until 1 November. In parallel, an [expert questionnaire](#) will be available until 5 October. The Commission plans to issue its legislative proposal in Q3 2022. The EU co-legislators (Council and European Parliament) would then negotiate and adopt it following the ordinary legislative procedure.

European Commission Looks Into the Energy Use of Cryptocurrencies

On behalf of the institution, Internal Market Commissioner Thierry Bretton [replied](#) to a [parliamentary question](#). He stated that the EU Blockchain Observatory and Forum ([EUBOF](#)) would publish a report on the energy consumption and efficiency of **blockchain** technologies and **cryptocurrencies** by the end of August. EUBOF is a research hub created as a pilot project of the European Parliament and backed by the Commission. It monitors blockchain initiatives in Europe and makes recommendations on the role the EU could play in blockchain. The Commission had requested the report, which is [expected to cover](#) issues such as an overview and comparison of consensus protocols, analysis of the Bitcoin Energy Consumption Index and a comparison of blockchain performance and cryptocurrency mining infrastructure.

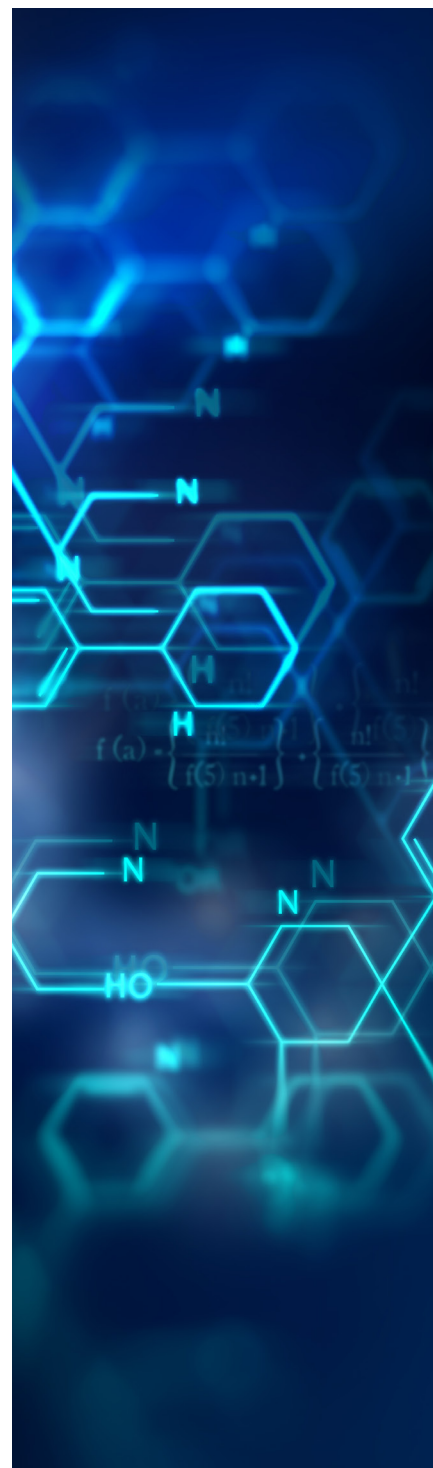
European Commission Grants Exemption for the Use of Phthalates in Medical Devices

The Commission adopted a delegated directive [allowing the use](#) of four phthalates (plasticisers) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, for the purposes of adapting to scientific and technical progress. The permitted substances are bis (2-ethylhexyl) phthalate (**DEHP**), butyl benzyl phthalate (**BBP**), dibutyl phthalate (**DBP**) and diisobutyl phthalate (**DIBP**). The Commission also granted exemptions for (1) the use of DEHP in ion selective electrodes for analysing human body fluids and/or dialysate fluids and (2) in plastic components in magnetic resonance imaging detector coils. The Commission explained that the total negative environmental and health impacts of substitution were likely to outweigh the total benefits.

In 2015, the European Commission [added](#) these phthalates to the list of restricted substances in the Annex of the **RoHS** Directive 2011/65 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, setting a maximum concentration value by weight in homogeneous materials of 0.1%. The restriction regarding these substances in medical devices and spare parts for their repair, reuse and updating of functionalities has applied since July 2021. The exemptions provided by the recently adopted delegated directives would apply retroactively from one day before these restrictions, and for seven years. The delegated directives are expected to enter into force after a period of scrutiny by the Council and European Parliament of, in principle, two months.

Commission Seeks Views on Endocrine Disruptors

The Commission launched a [targeted consultation](#) on **information requirements** on endocrine disrupting chemicals (EDCs). The input provided will be used by the Commission **to evaluate the potential impacts of two proposed options for introducing standard information requirements in REACH Annexes VII-X**. The Commission presented these options at the third meeting of CASG-ED, the Endocrine Disruptors Subgroup of CARACAL, the group of competent authorities for REACH and CLP in October 2020. In the consultation survey, the Commission recalls that it has been investigating the regulation of endocrine disruptors for a number of years, leading to the adoption of the [Community Strategy for Endocrine Disruptors](#) and to the [2020 Fitness Check on Endocrine Disruptors](#). The survey asks for views on the impact of endocrine disruptors, the measures to manage these, existing legislation and the appropriate ambition level, as well as the revision of the REACH Annexes. It also asks about alternative test methods that could reduce animal testing, as well as the impact on research, development and innovation, competitiveness and employment (in laboratories and the chemicals industry). Interested stakeholders can reply to the survey until 8 October 2021.





Commission Launches Consultation on the Revision of Classification and Labelling Rules for Chemicals

The [consultation](#) seeks views on the revision of the Classification, Labelling and Packaging of Chemicals (CLP) Regulation 1272/2008. The Commission had announced the revision of the [Chemicals Strategy for Sustainability \(CSS\)](#) in October 2020 (please also see [frESH Law Horizons March 2021](#)).

The survey asks about introducing **three new hazard classes** – endocrine disruptors (EDCs); persistent, bio-accumulative and toxic (PBT); and persistent, mobile and toxic chemicals (PMT). Questions cover using the World Health Organisation (WHO) **criteria for endocrine disruptors** as a basis for CLP criteria, either directly, or the EU criteria for plant protection products or for biocide products, which are based on the WHO definition and criteria. As foreseen in the inception impact assessment, the open public consultation addresses specific rules for **online sales**, the use of an only representative type-system for **poison centre notifications**, and changes to labelling rules. The survey also asks about the harmonisation of toxicological and ecotoxicological as part of the “One substance, one assessment” concept.

The survey will be open until 15 November 2021. The Commission plans to make the legislative proposal in Q2 2022. The EU co-legislators (Council and European Parliament) will then negotiate and adopt it.

The Commission is expected to run a public consultation on the options for a REACH revision in the first quarter of 2022, with the intention of putting forward a proposal in the fourth quarter of the same year (please see [frESH Law Horizons May 2021](#)).

ECHA Updates Guidance on REACH Registrations

The European Chemicals Agency (ECHA) published an [updated guidance on registration requirements under REACH](#). It aligns the Guidance with two **implementing regulations** that the Commission adopted recently on the registration and data sharing of phase-in substances after the final registration deadline and on updates of registration dossiers, respectively (please see [frESH Law Horizons October 2019](#) and [October 2020](#)). ECHA removed all the references to the now obsolete pre-registration process and guides companies on how to calculate the tonnage band in which they have to register. For each tonnage band, REACH defines the **minimum information** that the registrant must provide on the intrinsic properties of their substance. At the lowest tonnage level (1-10 tonnes per year), the standard information requirements are defined in Annex VII. When a new tonnage band level is reached, additional requirements must be fulfilled, which are described in Annex VIII, including **testing proposals** for studies addressed in Annexes IX and X. ECHA also provides guidance to companies on determining when they need to **update their REACH registrations**. Additionally, the updated document includes a section on **joint submission of data** that was previously in the guidance on data sharing. Information on data-sharing such as joint submission of data, joint submission obligation and conditions for opting out from the joint submission, has been added and updated.

European Commission Reports on Nanomaterials in Cosmetic Products

The [report](#) to the European Parliament and Council covers the use of nanomaterials in cosmetics in the context of a review of Cosmetics Regulation 1223/2009 as regards nanomaterials. The Cosmetics Regulation establishes that, if the Commission has concerns regarding the safety of a nanomaterial, it shall request its Scientific Committee on Consumer Safety (SCCS) to give an opinion on the safety of its use and on the foreseeable exposure conditions. The report found that **most of these SCCS opinions are inconclusive, due to a lack of or insufficient data**. Therefore, there is a need for the responsible **economic operators to provide information** as accurate as possible when making notifications to the Cosmetic Products Notification Portal (CPNP). However, the report addresses **shortcomings of the notification procedure**. For instance, whereas the safety assessment is carried out at ingredient level, notifications are made at product level. In general, the effectiveness of the current notification process via the CPNP merits specific attention, and the scientific safety assessment of nanomaterials could be strengthened, according to the Commission. It sees an urgent need for aligning the horizontal definition of nanomaterial throughout different pieces of EU legislation, as it announced for 2021 in its [CSS](#) (please also see [frESH Law Horizons March 2021](#)).

EFSA Guidance on Nanoparticles and Nanomaterial in Food Products

The European Food Safety Authority published two guidance documents, one on [technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles](#) and another on [risk assessment of nanomaterials to be applied in the food and feed chain for human and animal health](#).

In the first document, EFSA, following a mandate from the Commission, sets out **criteria for assessments, as well as information requirements** for applications in the regulated food and feed product areas (e.g. novel food, food/feed additives, food contact materials (**FCM**) and pesticides. The guidance outlines appraisal criteria that applicants may follow to confirm that a fraction of small particles is either not present or covered by the conventional risk assessment, or to assess whether conventional risk assessment should be complemented with nano-specific considerations. These considerations refer to three aspects: **(1)** solubility and dissolution rate as the main properties to assess whether consumers will be exposed to particles; **(2)** information requirements for assessing whether the conventional material contains a fraction or consists of small particles, and its characterisation; and **(3)** the information to be presented for existing safety studies to demonstrate that the fraction of small particles has been properly evaluated.

The second document updates a previous guidance and, together with the first one, elaborates on physico-chemical characterisation, as well as methods and techniques that can be used for the characterisation of nanomaterials and their determination in complex matrices.

EFSA Deems Silver Nanoparticles Used as FCM Additive Safe

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (**CEP**) issued an [assessment](#) on the safety of the silver nanoparticle additives used in plastics. These silver particles are in the size range of 1-100nm, with about 15nm mean diameter and 99% of the particles are smaller than 20nm. These additives are used as a surface biocide in **food contact plastic materials**, such as polyolefins, polyesters and styrenics. The experts panel considered information on theory, specific migration and abrasion tests. The data showed that, under the intended and tested conditions of use, **silver nanoparticles stay embedded in the polymer, do not migrate and resist release by abrasion. Thus, they do not give rise to exposure via food and to toxicological concern**. Therefore, they do not raise safety concern for the consumer if used as an additive at up to 0.025% w/w in polymers.



Renewal Procedure for Glyphosate as Active Substance for Pesticides Moves Forward

The [Assessment Group on Glyphosate](#) (AGG) submitted **updated versions of the Renewal Assessment Report (RAR) and the Harmonised Classification and Labelling (CLH)** report to EFSA and ECHA. The updated version of the documents will become available for consultation after the two agencies carry out some administrative formalities. The assessment procedure will continue and will include public consultations (originally expected in September 2021), and subsequent peer-review by experts from the Member States. The parallel consultations that were announced for the first week of September 2021 will be rescheduled.

Glyphosate is currently approved as an active substance for pesticides until December 2022. The Commission [appointed](#) four Member States (France, Hungary, the Netherlands and Sweden) acting jointly as “rapporteurs” for the next assessment of glyphosate in 2019, and known as AGG. It [concluded](#) in June that glyphosate meets the approval criteria for active substances set in Plant Protection Products Regulation (PPPR) 1107/2009 (please see [Sustainability Outlook June 2021](#)).

German Federal Institute for Risk Assessment (BfR) Publishes Overview on Europe Food Safety

The fifth edition of the [EU Food Safety Almanac](#) of the BfR, a scientifically independent institution within the portfolio of the German Federal Ministry of Food and Agriculture, provides an overview of the current legal frameworks for food and feed safety in 37 countries, by describing the work and responsibilities of the relevant institutions. It identifies 18 possible areas of responsibilities, which include contaminants, environmental risk assessment, FCM and packaging, food ingredients and nanotechnology. The book covers all EU Member States, as well as neighbouring countries (Albania, Bosnia and Herzegovina, Iceland, Kosovo, Montenegro, Norway, Republic of North Macedonia, Serbia, Switzerland and Turkey).



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