

IMEC

# EU Quarterly Report

Q4 2023

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# Glossary of EU terms

**Council of the European Union:** One of the two co-legislative bodies of the EU (together with the European Parliament), made of the 27 EU Member State governments (represented by Member State Ministers). It adopts laws by co-decision with the European Parliament.

**COREPER:** Preparatory body of the Council, made up of Member States' Permanent Representatives to the EU.

**EU Directive:** EU law which has to be transposed into national law for its implementation.

**EU Regulation:** EU law which applies directly upon its adoption, without the need for transposition into national law.

**European Commission:** Executive body of the EU, in charge of proposing laws.

**European Parliament:** One of the two co-legislative bodies of the EU (together with the Council of the EU), made of elected MEPs (Members of the European Parliament). It adopts laws by co-decision with the Council of the EU.

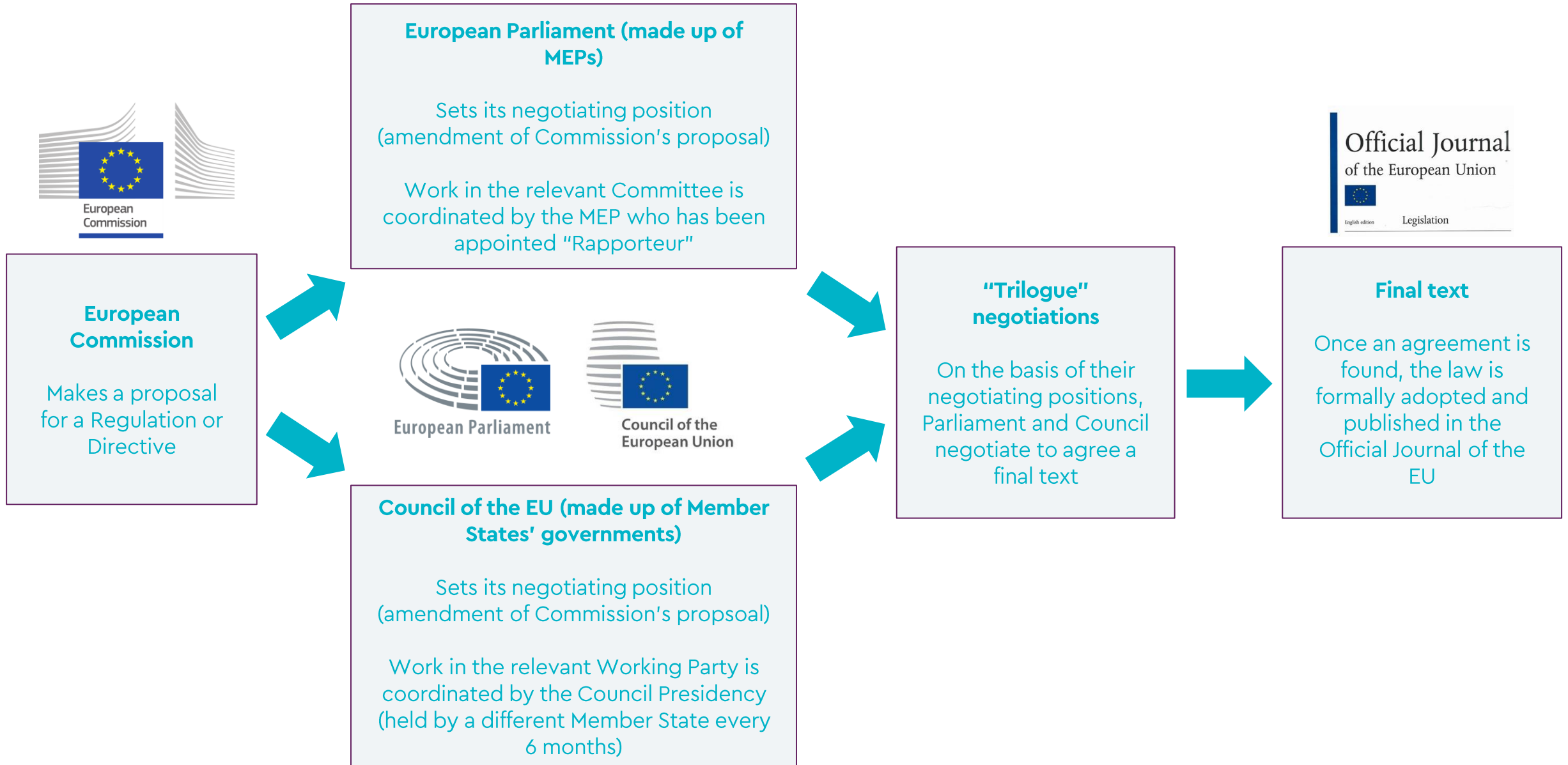
**European Parliament Committees:** Committees of MEPs, organised by policy area, which deal with specific proposals before they are adopted by the European Parliament plenary, e.g. ENVI Committee (Environment, Public Health and Food Safety), TRAN Committee (Transport and Tourism), IMCO Committee (Internal Market and Consumer Protection), ITRE Committee (Industry, Research and Energy).

**Rapporteur:** MEP in charge of coordinating the work for a specific proposal within a European Parliament Committee.

**Trilogue:** Negotiation between the European Parliament and the Council, also attended by the Commission, which aims at reaching an agreement on the final text of a proposal.

**Working Parties:** Preparatory bodies of the Council (below COREPER level) made up of Member State officials dealing with a specific policy area. There are over 100 Working Parties.

# Reminder on EU policy-making process



# 1. Cyber Resilience Act (CRA) proposal

## Background:

- The Commission released its [proposal](#) for a Regulation on horizontal cybersecurity requirements for products with digital elements (Cyber Resilience Act) on 15 September 2022:
  - The proposal introduces a legal framework to ensure the cybersecurity of digital products throughout their entire lifecycle. It applies to all products with digital elements whose intended or reasonably foreseeable use includes a direct or indirect logical or physical data connection to a device or network.
  - The Regulation sets out essential requirements for design, development and production, cybersecurity obligations, and rules on market surveillance and on the enforcement of requirements. Economic operators (manufacturers, importers and distributors) must meet the requirements before placing products with digital elements on the market.
  - Not in the scope:
    - Products for which the following acts apply: 2017/745 and 2017/746 (medical devices); 2019/2144 (vehicle general safety regulation); 2018/1139 (civil aviation).
    - Products developed for national security/military purposes or to process classified information.
    - Products covered by other EU laws laying down requirements that address all or some of the risks covered by the essential requirements of Annex I, if the sectoral rules achieve the same level of protection as the one provided by the CRA.
  - Annex I: Essential cybersecurity requirements.
    - 1. Security requirements relating to the properties of products with digital elements
    - 2. Vulnerability-handling requirements
  - Annex III: Critical products with digital elements – subject to specific conformity assessment procedures.

# 1. Cyber Resilience Act (CRA) proposal

## Latest developments:

- After three rounds of trilogues held 27 September, 8 November and 30 November, during which the European Parliament and the Council negotiated the text of the law, an agreement was found for a final text (not yet publicly available).
- As per the Commission proposal, the text will introduce cybersecurity requirements for the design, development, production and making available on the market of hardware and software products, ensuring that connected products are secure and resilient. Other aspects include:
  - Manufacturers' responsibility for compliance, including obligations like providing cybersecurity risk assessments, issuing declarations of conformity, and cooperating with competent authorities.
  - Vulnerability-handling processes for manufacturers.
  - Measures to improve transparency of and information on the security of hardware and software products for consumers and business users.
  - A market surveillance framework, to enforce the rules.
- The provisional agreement also includes various aspects that are different to those in the Commission proposal:
  - Changes to the scope, making it easier to identify which products are covered, and expanding the list of covered devices (to also include products such as biometric readers, smart home assistants and private security cameras).
  - Support period for digital products of at least five years, except for products with a shorter expected lifetime.
  - Competent national authorities would be the first recipients of the reporting of vulnerabilities and incidents. The role of ENISA (EU agency for cybersecurity) would also be strengthened.
  - Additional support measures for small and micro enterprises (e.g. awareness-raising and support for testing).
  - The rules will apply 3 years after entry into force, compared to the 2 years from the original proposal, to give manufacturers enough time to adapt.

# 1. Cyber Resilience Act (CRA) proposal

## Next steps:

- The text of the agreement will become available over the coming weeks.
- The Parliament's ITRE Committee is expected to vote on the agreement at the end of January 2024. Then the Parliament plenary will adopt the law, expectedly in April 2024. This will be followed by the Council's adoption of the law.
- The main requirements would kick in 3 years after entry into force. This would be around mid-2027.
- According to the Commission proposal, the new Regulation would apply 24 months after its entry into force (except Article 11 on the reporting obligations for manufacturers, which would apply 12 months after the entry into force). There are also a series of transitional provisions.

# 2. Ecodesign Regulation proposal

## Background (I):

- Ecodesign Directive ([2009/125](#)): establishes a framework for minimum eco-design requirements that goods which consume energy must meet before they can be used or sold (does not apply to transport).
- Proposal for an Ecodesign Regulation ([2022](#)) to replace the Directive:
  - Extension of scope: the Regulation will apply to all physical goods placed on the market
  - Ecodesign requirements:
    - General requirements:
      - Product durability, reliability, reusability and reparability
      - Energy use or energy efficiency
      - Resource use or resource efficiency
    - Specific requirements for specific products will be set through future Delegated Acts
  - Digital product passport
  - Working plan to set out priority criteria for products to be regulated by Delegated Acts
- Based on the [report](#) from the Joint Research Centre (JRC), the Commission published on 31 January 2023 the proposed [draft](#) list of priority products to be regulated through future Delegated Acts:
  - 12 end-use products: textiles and footwear, furniture, ceramic products, tyres, detergents, bed mattresses, lubricants, paints and varnishes, cosmetic products, toys, fishing nets and gears and absorbent hygiene products
  - 7 intermediary products: iron and steel, non-ferrous metals, aluminium, chemicals, plastic and polymers, paper, pulp paper and boards, glass
  - 3 horizontal measures: durability, recyclability and post-consumer recycled content



## 2. Ecodesign Regulation proposal

### Background (II):

- On 22 May 2023, the Council adopted its [position](#).
  - Excludes vehicles under the Type Approval Framework Regulation (2018/858), the Agricultural and Forestry Vehicles Type Approval Regulation (167/2013), and the Regulation on Motorcycle Type Approval (168/2013) from the scope
  - Agrees with the possibility for the Commission to adopt Delegated Acts establishing ecodesign requirements for specific products. However, the Council wants the Delegated Acts to apply 18 months after the entry into force
  - Extends the list of aspects of products to be improved by ecodesign requirements
  - Adds some exceptions to the information requirements on substances of concern based on the technical feasibility or relevance of tracking substances of concern, or the need to protect confidential business information
  - Adds that the Digital Product Passport should fully comply with the protection of information that constitutes trade secrets or intellectual property
- On 12 July 2023, the Parliament adopted its [position](#).
  - Agrees with the possibility for the Commission to adopt Delegated Acts establishing ecodesign requirements for specific products
  - Extends the definition of substances of concern to persistent organic pollutants (POPs) and substances restricted under REACH – Safety approach
  - States that the first working plan to set out the list of priority products to be prioritised must be adopted 3 months after the entry into force

# 2. Ecodesign Regulation proposal

## Latest developments:

- On 4 December 2023, the co-legislators reached a provisional agreement (final text not yet available) during the third trilogue. The agreed text includes the following provisions
  - Regarding the scope, the text adds practices leading to the malfunctioning of products due to product design features or unavailability of updates. Contrary, it excludes motor vehicles.
  - Extension of ecodesign requirements to include the presence of chemical substances that inhibit reuse and recycling of materials
  - Agreement with the possibility for the Commission to adopt Delegated Acts establishing ecodesign requirements for specific products. These will apply 18 months after the entry into force (earlier date of application under some circumstances)
  - Establishment of a public web portal accompanying the digital product passport. It would allow consumers to search and compare information included in the passports
  - Regarding the first working plan to set out priority criteria for products to be regulated by Delegated Acts
    - It must be adopted within 9 months of the entry into force of the Regulation
    - Inclusion of a list of priority products: textiles (notably garments and footwear), furniture, tyres, detergents, paints, lubricants, chemicals, iron, steel and aluminium, as well as energy-related products, ICT products and other electronics - plastics are not mentioned.
  - Harmonisation criteria for penalties. However, Member States will be responsible for determining which penalties should be imposed.

## 2. Ecodesign Regulation proposal

### Next steps:

- The European Parliament and the Council will now have to endorse the agreement during Q1 2024.
- Once adopted, it will enter into force on the 20th day following its publication in the Official Journal.
- After this happens, the first working plan under the Regulation will be adopted.

# 3. REACH Regulation

## Background:

- REACH Regulation ([1907/2006](#)):
  - Lays down provisions on the registration, evaluation, authorisation and restriction of chemicals produced, imported, sold and used in the EU.
  - Sets up the European Chemicals Agency (ECHA).
- The Commission's 2020 Chemicals Strategy for Sustainability announced the revision of the Regulation. The Commission is currently working on the revision proposal. A [public consultation](#) was open between 20 January and 15 April 2022.
- Key aspects of the revision include:
  - Increased information/registration requirements (e.g. info on hazardous substances, registration of polymers of concern, possible info on environmental footprint)
  - Better information along the supply chain (e.g. better eSDS)
  - Reform of authorisation and restriction processes (e.g. generic risk management approach for most harmful substances (ED, PBT, vPvB), "essential use" derogations)
  - Essential use concept for derogations from restriction:
    - Industries themselves would have to prove that the use of a substance is essential (i.e. necessary for health, safety or functioning of society, and no viable alternative). A Committee of Member States could evaluate the proof submitted by a company that a substance is essential – but final decision with the Commission. The concept will be developed in a specific non-legislative document.
  - Mixture assessment factor (MAF) to account for so-called "cocktail" effect of mixing substances
- According to the 2023 Commission Work Programme, the REACH revision proposal is scheduled for release in Q4 2023.

# 3. REACH Regulation

## Latest developments:

- On 25 September 2023, the Commission [adopted](#) a restriction on intentionally added microplastics under the REACH Regulation. It was [published](#) in the Official Journal on 27 September 2023 and entered into force on 17 October 2023.
- The restriction adopts a broad definition of microplastics to cover synthetic polymer particles below 5 mm that are organic, insoluble and resist degradation. Certain polymers are excluded from the definition.
- Products used at industrial sites are not in the scope of the restriction.
- The first measures (affecting loose glitter and microbeads) started applying on 17 October 2023, but for other products (which include cosmetic products, detergents, waxes, polishes, fertilising products not covered by the EU Fertilising Products Regulation, biocidal products, medical devices, and products for agricultural uses), measures will start applying between 2027 and 2035, depending on the product.

# 3. REACH Regulation

## Next steps:

- The microplastics restriction will apply on different dates to different products (see previous slide and text of restriction published in the Official Journal).
- Regarding the REACH Regulation revision, the Commission has yet to make a proposal for revision. It will likely go through the Ordinary Legislative Procedure under the next parliamentary term (after Q3 2024).

# 4. CLP Regulation proposal

## Background:

- Regulation on the Classification, Labelling and Packaging (CLP) of chemical substances ([1272/2008](#)):
  - Harmonises the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures.
  - Sets out obligations for manufacturers, importers and downstream users to classify substances and mixtures placed on the market, and obligations for suppliers to label and package substances and mixtures placed on the market, among other obligations.
- The Commission's 2020 Chemicals Strategy for Sustainability announced the revision of the Regulation. On 19 December 2022, the Commission released a revision [proposal](#), amending the CLP Regulation. Some of the changes include:
  - Art. 10: manufacturers, importers and downstream users are required to establish acute toxicity estimates for substances classified as acutely toxic for human health (except if these estimates already exist).
  - Art. 25: environmental properties must also be part of the label.
  - Art. 30: labels must be updated at the specified date of applicability or within 6 months after the decision to change a classification resulting in a new hazard class or a more severe classification.
  - Art. 34a and 34b: rules on digital labelling (which can be added on a voluntary basis).
  - Art. 36: new hazard classes – endocrine disruptors (ED), persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM).
  - Art. 37: gives the Commission the right to initiate the harmonised classification and labelling procedure.
- Together with the revision proposal, the Commission released a [draft Delegated Regulation](#) (and [Annex](#)) setting new hazard classes, classification criteria and labelling requirements for endocrine disruptors, PBT, vPvB, PMT and vPvM substances.

# 4. CLP Regulation proposal

## Latest developments:

- Following just one trilogue meeting between Parliament and Council on 5 December 2023, a final text was agreed between the co-legislators (not yet publicly available). The agreement includes the following measures:
  - Clearer labelling of hazardous chemicals (such as a minimum font size, and labels that are clear for people with impaired eyesight).
  - The possibility for businesses to use fold-out labels and voluntary digital labelling. Important safety information must remain visible on the package. For some products, the supplier can provide digital-only data but the consumer can request a physical copy of the product information.
  - For online sales of hazardous chemicals, websites will have to display the hazardous properties of products.
  - Regarding advertising, statements inconsistent with a product's classification would be banned (e.g. non-toxic, non-harmful, non-polluting, ecological, or other green claims).
  - The Commission will also have the right to develop classification proposals on potentially hazardous substances, not only Member States and industry. This will speed up the identification of hazardous substances.
  - Rules on refillable chemical products bought at refill stations, to prevent risks like overfilling, contamination, etc.. This will also help to reduce packaging waste.
  - Updated rules for classifying multi-constituent substances.



# 4. CLP Regulation proposal

## Next steps:

- The final text agreed between the Parliament and the Council will become available in the coming weeks.
- Council's COREPER and Parliament's ENVI Committee are expected to endorse the text in the coming weeks. After that, the Council and the Parliament will formally adopt the text, likely throughout Q1 2024.
- The law is likely to enter into force in mid-2024. The new provisions are expected to apply 18 months after entry into force.

# 5. Common Data Platform on Chemicals proposal

## Background:

- According to the [2020 Chemicals Strategy for Sustainability](#), as well as the Commission's [Work Programme for 2023](#), released in October 2022, a new legislative initiative was envisaged for Q4 2023, titled "Revision of the EU rules - improving access to and availability, sharing and re-use of chemical data for the purpose of chemical safety assessments".
- On 4 July 2023, at the 49<sup>th</sup> meeting of CARACAL (Competent Authorities for REACH and CLP), the Commission gave a [presentation](#) outlining the key objectives and structure of the upcoming legislative proposal.
  - The proposal will create a common data platform on chemicals, which will improve risk management, better assess environmental impacts of substances across their lifecycles, and better identify emerging risks.
  - The common platform would input data from stakeholders (researchers, industry, Member States and EU agencies) , and would include information gathered by stakeholders as part of their regulatory obligations as well as databases created specifically for the platform itself.
  - The platform would begin functioning three years after entry into force.
  - Authorities would have unrestricted access to the platform, while other stakeholders would have more limited access in order to comply with the confidentiality rules of each originating data provider.
  - In addition, reforms are being considered to ECHA's mandate, to allow it to commission scientific studies necessary for the performance of its mission.
  - The structure of the proposal would be the following: (I) Subject matter, scope and definitions; (II) Information systems and platforms; (III) Data formats and controlled vocabularies; (IV) Data use and confidentiality; (V) Monitoring and outlook framework for chemicals; (VI) Data generation mechanism; (VII) Notification of tests; (VIII) Delegated powers; (IX) Enforcement.

# 5. Common Data Platform on Chemicals proposal

## Latest developments (I):

- On 7 December 2023, the Commission published its [proposal](#) for a Regulation establishing a Common Data Platform on Chemicals and a staff working document ([SWD](#)) accompanying it.
- The Common Data Platform on Chemicals shall be set by ECHA. Its objectives are as follows:
  - Gather data and information on chemicals
  - Ensure that data and information are easily findable, accessible, interoperable and re-usable
  - Maintain records of studies commissioned or carried out by business operators to fulfil their obligations
  - Establish a wide scientific base for the implementation and development of EU legislation
  - Establish an early warning and action system for emerging chemical risks
- It would apply to the following chemicals data:
  - Generated or submitted under other EU legal acts (listed in Annex I) requiring chemical assessments - Carcinogens and Mutagens Directive (CMD), REACH, Marine Strategy Framework Directive, etc.
  - Generated as part of EU, national or international programmes or research activities in the sphere of chemicals and held by the ECHA, the EEA, the EFSA, the EU-OSHA or the Commission
  - Listed in Annex II and held by the EMA
- Chemicals-related data comprises:
  - Physico-chemical, hazard, use, exposure safety, risk, occurrence, emissions and manufacturing process-related data and information on chemical substances
  - Environmental sustainability related data and information

# 5. Common Data Platform on Chemicals proposal

## Latest developments (II):

- Information on legal obligations, academic studies and chemicals-related data not generated in an EU regulatory context but as part of EU, national or international programmes or research activities
- Data and information on reference values
- Data and information from study notifications
- Information related to regulatory processes under EU acts (listed in Annex III), data on applicable legal obligations under the EU legislation (Annex I); and data supporting the implementation of this Regulation
- The Common Data Platform on Chemicals shall be established 3 years after the entry into force.
- Note that this proposal does not create any new data requirements for economic operators, which will still be subjected to current information requirements under existing EU chemicals legislation.

# 5. Common Data Platform on Chemicals proposal

## Next steps:

- The proposal will go through Ordinary Legislative Procedure. It is now sent to the European Parliament and the Council for examination.

# 6. Restriction of Hazardous Substances (RoHS)

## Background:

- Directive [2011/65/EU](#) on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II Directive, replacing RoHS I Directive 2002/95/EC).
  - It lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE), to contribute to the protection of human health and the environment.
  - It does not apply to means of transport for persons or goods, together with a variety of other items outside the scope.
  - It sets maximum concentration value of 0.1% on the following substances in EEE: Lead, Mercury, Cadmium, Hexavalent chromium, Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP).
- The Directive was subject to an evaluation process launched in 2019 and finalised in 2021, which highlighted areas where the Directive could be improved. These included: the exemption mechanism process, alignment with circular economy recycling objectives, the frequent need for transposition of amendments, and the scope and alignment of the substance restriction mechanism and substance restriction with other EU legislation.
- In May 2023, the Commission released a [study](#) titled "Study to support the assessment of impacts associated with the general review of Directive 2011/65/EU (RoHS Directive) – Final report", prepared by consultants Ramboll and Öko-Institut e.V. The study supports the preparation of the Impact Assessment that will accompany the expected revision of the RoHS Directive.

# 6. Restriction of Hazardous Substances (RoHS)

## Latest developments:

- On 7 December 2023, the [Report](#) and the [Staff Working Document](#) presenting the outcome of the review of the RoHS Directive were made available.
- The evaluation considered the criteria of effectiveness, efficiency, coherence, EU added value, and relevance.
  - The RoHS Directive reduced restricted substances by two thirds between 2003 and 2016.
  - Several factors of the exemption process lack transparency and efficiency.
  - As regards consistency with other rules, the report found overlap between the substance restrictions under the RoHS Directive and those under the REACH Regulation. Furthermore, it found consistency with the Ecodesign Directive and the POPs Regulation to be problematic.
  - The study found the Directive to be able to continue to respond to the needs reflected in its objectives.
- The report suggested taking the following measures in a future revision of the RoHS Directive:
  - Updating the scope to include photovoltaic panels.
  - Updating the framework to bring it in line with scientific and technical progress.
  - Examining the added values of fees to the time-limited exemption system for applications using restricted hazardous substances.
  - Strengthening the circular economy for equipment.
  - Strengthening the interplay with other legislative instruments.

# 6. Restriction of Hazardous Substances (RoHS)

## Next steps:

- The Commission will continue working on the Impact Assessment and, once this gets approved internally, on the revision text itself, in order to release the revision proposal at some point during the second half 2024.



# 7. Machinery Regulation

## Background:

- Machinery Directive ([2006/42/EC](#)):
  - Sets essential health and safety requirements that machines must comply with before being placed on the market.
- In April 2021, the Commission released a [proposal](#) for a Machinery Regulation proposal to replace the Directive:
  - Provides more clarity in terms of scope and definitions.
  - Includes risks originating from emerging/digital technologies.
  - Addresses possible safety gaps from traditional technologies.
  - Allows manufacturers to provide online instructions with their products.
  - Addresses inconsistencies with other EU laws and inconsistencies in interpretation between Member States.
  - Allows the Commission to develop technical specifications.
- On 15 December 2022, the Council and the Parliament reached a [provisional agreement](#) on the proposed Machinery Regulation. The main differences between the Regulation and the Machinery Directive that is currently in force are the following:
  - Increased legal certainty because of the law being a Regulation (which entails uniform application) rather than a Directive.
  - Provisions on Artificial Intelligence, cyber safety, and autonomous and remote-controlled machinery.
  - Digitalisation of instructions and of the Declaration of Conformity.
  - Mandatory Notified Body conformity assessment for six higher-risk product categories (specified in Annex I, Part A).
  - Possibility for the Commission to adopt common specifications when suitable harmonised standards are not available.
  - Streamlined safeguard procedures.
- Following the publication of the new Machinery Regulation in the EU Official Journal as Regulation (EU) [2023/1230](#) on 29 June 2023, the Regulation entered into force on 19 July 2023.

# 7. Machinery Regulation

## Latest developments:

- On 9 November 2023, the Commission hosted a meeting of the Machinery Expert Group, following the previous meeting in March. The participants included representatives of Member States and of industry. During the meeting, the Commission gave various updates on the new Machinery Regulation and the status of harmonised standards.
- The new Machinery Regulation will apply from 20 January 2027. Declarations of Conformity for products can state that the product complies with the Machinery Directive until 19 January 2027 and with the Machinery Regulation from 20 January 2027.
- The Commission has prepared a standardisation request for CEN/CENELEC to draft new standards and revise existing standards, in order to bring harmonised standards in line with the new Regulation. The request will be sent to CEN/CENELEC at some point during the first half of 2024. From then on, the numerous Technical Committees of CEN/CENELEC will have to carry out a gap analysis of standardised harmonised under the Machinery Directive to assess whether they must be updated to bring them in line with the essential health and safety requirements of the new Regulation.
- The Commission will start working on the Application Guide of the new Regulation around summer 2024, carrying out a mapping exercise to see which sections of the Application Guide of the current Machinery Directive have become obsolete and which ones can be reused.
- As per a prior suggestion from industry, the Commission shared a proposal to update the Application Guide of the current Machinery Directive to make it clear that digital instructions and digital Declarations of Conformity are allowed under the Directive.

# 7. Machinery Regulation

## Next steps:

- The requirements of the new Machinery Regulation will apply from 20 January 2027.

## 8. European Parliament intergroups

European Parliament Intergroups are informal groups of MEPs from different political groups who wish to engage with particular topics in more detail and with the participation of civil society. Through Intergroup events, these MEPs have an informal exchange of views on particular subjects. These events serve to promote dialogue and involve stakeholders. The following events from the Intergroups, both from this past quarter as well as upcoming events, may be of interest to IMEC.

### ***SEArca (Seas, Rivers, Islands & Coastal Areas) Intergroup*** ([link](#))

- No events organised this quarter or scheduled for the future.

### ***Climate Change, Biodiversity and Sustainable Development Intergroup*** ([link](#))

- 24 January 2024: Hybrid Event: From changing Polar regions to policy responses – Strengthening EU and global climate preparedness.

### ***Sustainable, long-term investments and competitive European industry Intergroup*** ([link](#))

- 11 October 2023: Enabling industrial decarbonisation: The vital role of solar thermal and geothermal for the energy transition in industry.
- 7 November 2023: Next-Generation Infrastructure: Advancing the digitalisation of EU water and wastewater management

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