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PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

**Chemicals Strategy for Sustainability
Towards a toxic-free environment**

1. INTRODUCTION: BENEFITS AND RISKS OF CHEMICALS

Chemicals are present all around us, in both natural and industrial ecosystems¹. Man-made and found in nature, they **are fundamental for the wellbeing, high life standards and long life expectancy** and comfort of modern societies. They have widespread use across sectors, such as energy, mobility and housing. From medicines and vitamins to insulation materials, textiles and batteries, the vast majority of all manufactured goods rely on chemistry. Chemicals are the building blocks of low-carbon and energy-efficient technologies, as well as of materials and products, defining our capacity to reuse and recycle them and achieve the transition to a circular economy. The chemical manufacturing industry is the fourth largest in the EU², comprises around 30 000 companies, in particular SMEs, and directly employs around 1.2 million people.³

However, if not managed adequately **many chemicals can cause severe harm to human health and the environment**, resulting in major societal and economic costs to current and future generations. Certain exposure to certain hazardous chemicals affects the immune, respiratory, endocrine, reproductive and cardio-vascular systems, weakening humans' resilience and increasing their vulnerability to diseases.⁴ Human biomonitoring studies in the EU point to a growing number of different hazardous chemicals in human blood and body tissue including pesticides, biocides, pharmaceuticals, heavy metals, plasticisers and flame retardants.⁶ It is reported that combined prenatal exposure to several chemicals leads to reduced foetal growth and lower birth rates⁷.

Chemical pollution is also one of the key drivers that are putting the Earth at risk⁹, impacting and amplifying planetary crises like climate change, ecosystems' degradation and biodiversity loss¹⁰. Its regulatory framework makes the EU a frontrunner in the sound management of chemicals; nonetheless, the international community is failing to achieve its commitment for a sound management of chemicals by 2020, essential to Sustainable Development Goals¹¹. As chemical production is expected to double globally by 2030, **harm to people and the natural environment will exacerbate unless appropriate policy measures are earnestly taken on a global scale**¹². It has been defined by the UN as a human rights concern, with implications in particular for the rights of the child and vulnerable people¹³.

¹ A new industrial strategy for Europe (COM(2020) 102 final). An industrial ecosystem encompasses all players operating in a value chain: from the smallest start-ups to the largest companies, from academia to research, services providers to suppliers. So far, 14 industrial ecosystems have been identified, representing around 90% of the business value added in the EU.

² Behind automotive, food, and machinery and equipment. CEFIC, [Facts and Figures Report](#), 2020, p. 34.

³ Eurostat, [Structural Business Statistics](#), 2020.

⁴ Reference

⁶ European Commission, [Study for the Strategy for the Non-Toxic Environment](#), p. 123

⁷ *Ibid.*

⁹ Rockström, J.; et al. (2009). 'Planetary Boundaries: Exploring the Safe Operating Space for Humanity'. *Ecology and Society*.

¹⁰ Examples include negative effects on pollinators, insects, aquatic ecosystems and bird populations.

¹¹ United Nations Environment programme (UNEP), [Global Chemicals Outlook II](#), 2019. See notably target 12.4 of the Sustainable Development Goals.

¹² *Ibid.*

¹³ The UN has appointed a [special rapporteur](#) on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes.

The **EU already has the most ambitious regulatory framework for chemicals in the world** and is increasingly becoming a model for safety standards worldwide¹⁴. This framework includes legislation regulating the production, placing on the market and use of chemical substances¹⁵, the presence of chemicals in specific products, their management in recycling and waste, as well as legislation to protect workers¹⁶ and the environment^{17 18}. It has been undeniably successful in reducing the risks to humans and the environment from hazardous chemicals, for example from carcinogens in the workplace¹⁹ and from heavy metals²⁰, by making industry responsible to ensure safety and through additional regulatory measures.

Nevertheless, the current framework has not been sufficient enough to promote the substitution of hazardous chemicals and to induce a general shift to safe and sustainable production and use of chemicals. Indeed, the share of chemicals hazardous for human health and the environment has remained virtually unchanged since 2004, and substances of concern still represent **XX**²¹ of the total amount of chemicals produced in Europe²². **Alerts from scientists call on decision makers to take stronger and faster action.**

The COVID-19 pandemic has not only made the urgency to **protect human and planetary health increasingly evident** but also made us particularly aware of the essential role that chemicals play in our lives. This crisis illustrated the importance of a well-functioning internal market, open borders and robust and resilient production capacity and value chains. It showed that the EU is heavily reliant on imports from third countries as in the case of basic chemicals used to produce pharmaceuticals. The EU should strengthen its **open strategic autonomy** and production capacity for those chemicals that are critical for our health and for achieving a climate-neutral and circular economy. Given the enabling role of chemistry and the strong growth in the production of chemicals in other parts of world, it will also be paramount to reinforce the EU's industrial leadership by boosting the EU industry's competitiveness, innovativeness and capacity to produce and use chemicals in a safe and sustainable way. By fostering upstream and downstream innovation for safe and sustainable production and use of chemicals in materials and products, the strategy will support the **twinned green and digital transitions** and build a **more sustainable, resilient and fairer Europe**.

Almost 20 years after the first strategic approach to chemicals management in Europe²³, the time has come to boost the long-term vision for the EU's chemical policy. As defined in the European Green Deal, this strategy sets the path to Europe's **transition to a toxic-free environment**, where chemicals are designed, developed, produced and used in a way that maximises their contribution to society while avoiding harm to the planet and to current and future generations. It puts forward principles and actions to reach this aim, to mobilise

¹⁴ A. Bradford, *The Brussels effect*, 2020¹⁵ Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP).

¹⁵ Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP).

¹⁶ Chemical Agents Directive 98/24/EC; Carcinogens and Mutagens Directive 2004/37/EC

¹⁷ E.g. EU legislation on waste, water, marine, industrial emissions, ecodesign.

¹⁸ [COM \(2019\)264. final](#)

¹⁹ Estimated prevention of 1 million new cancer cases in the EU over the last 20 years; [SWD \(2019\)199 final/2](#).

²⁰ 66% emission reduction of mercury in the EU between 1990 and 2011; 64% emission reduction of cadmium in the EU between 1990 and 2011; 78% emission reduction of arsenic in the EU between 1990 and 2011; [SWD \(2019\)199 final/2](#).

²¹ **To be completed by ESTAT**

²² In 2018, the share of the tonnage of chemicals hazardous to health was 74%. Eurostat, [Chemical production and consumption statistics](#), 2020.

²³ White Paper on the Strategy for a future Chemicals Policy, [COM \(2001\)88](#)

investments to foster chemicals innovation and to further develop a competitive and sustainable EU chemicals production capacity for the benefit and with the involvement of citizens, authorities, industry and researchers, inside and outside the EU. This strategy will readily address substances of concern, in particular in consumer products or released in the environment, such as endocrine disruptors, persistent pollutants, combination effects of chemicals.²⁴ It will also apply a smart regulatory approach, promoting a simplified EU legal framework for chemicals, where procedures and outcomes are transparent, predictable and coherent across policy areas, and leading to science-based and effective regulatory action. It stresses implementation and compliance at the core of a well-functioning legal framework, as well as knowledge and data, which will be supported through an increased science-based approach. Strengthening the EU's position as a frontrunner in health and environment protection worldwide, the strategy furthermore promotes the highest standards for the sound management of chemicals globally, in international fora as well as with all its partners.

This Strategy represents the necessary first step to move towards Europe's **Zero Pollution ambition**, enabling to achieve the related targets defined in the Biodiversity and Farm to Fork Strategies, setting the foundations for the upcoming Zero Pollution Action Plan and ensuring the success of Europe's Beating Cancer Plan. By supporting industry's efforts of and responding to its needs for achieving the green, digital and resilient transition and recovery, this strategy is also complementary to the European Industrial Strategy²⁵ and the Recovery plan for Europe²⁶, and other European Green Deal strategies and initiatives such as the Pharmaceuticals Strategy, the Hydrogen Strategy, the Batteries Initiative where chemicals are inherent part of the EU industrial ecosystems.

2. THE VISION FOR 2030: TOWARDS A TOXIC-FREE ENVIRONMENT

The goal of EU's chemicals policy up to and beyond 2030 is to ensure a high level of **protection of health and the environment** from hazardous chemicals, while maintaining and further developing sustainable, innovative and competitive EU production capacity that serves **the EU's open strategic autonomy and contributes to the resilience of the industrial ecosystems and value chains**. It will exploit the potential of the EU's internal market and reap the benefits of new materials, technologies and digitalisation to enable the overall shift towards a zero pollution, circular and climate neutral economy. It will provide clear and easily implementable rules within a science-based, **transparent and predictable legal framework**, also through strong and **harmonised implementation and enforcement** across the EU and at its borders. It will strengthen its **science and knowledge base on chemicals** and support the **sound management of chemicals globally**.

A **toxic-free hierarchy, combined with a "smart regulatory approach"** will guide policy action towards this vision, to prioritise safe and sustainable chemicals, based on the EU principles of precaution, prevention, rectifying pollution at source, and polluter pays²⁷ as well as accountability and proportionality²⁸. This entails that substitution of substances of very high and potential action on other hazardous substances in consumer products will be

²⁴ Eurostat, [Special Eurobarometer 456](#), 2017.

²⁵ [COM/2020/102 final](#)

²⁶ Estimated prevention of 1 million new cancer cases in the EU over the last 20 years; [SWD \(2019\)199](#).

²⁶ Which has been reduced by an estimated 89% in the EU between 1990 and 2011, resulting in a significant reduction in levels of lead in blood; [SWD \(2019\)1](#)

²⁷ Art. 191 TFEU

²⁸ **Art 5 TEU**

systematically stepped up and accelerated. Through the application of those principles, elimination and remediation would in principle gradually be phased out.

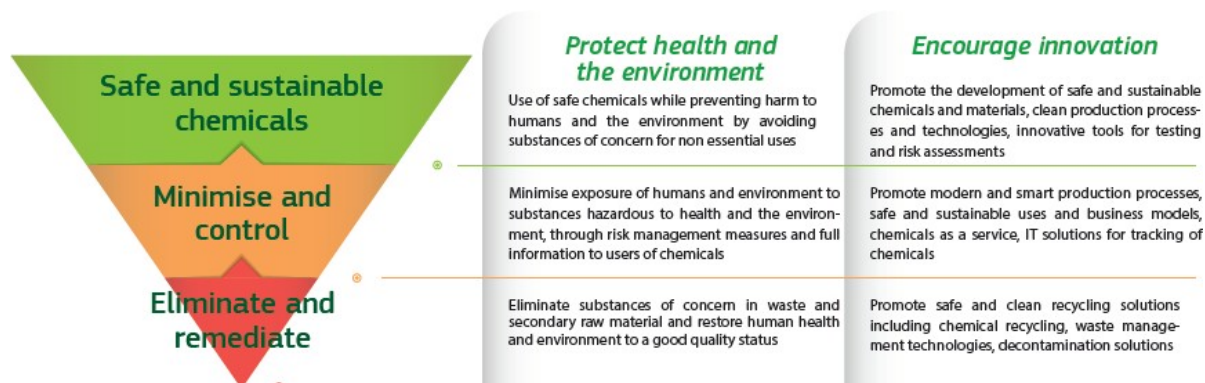


Figure: The toxic-free hierarchy – a new hierarchy in chemicals management

3. IMPLEMENTING THE VISION: FIVE PRIORITIES

3.1. Strengthen the EU legal framework to address pressing environmental and health concerns

The EU's approach to chemicals management has been effective in reducing human and environmental exposures to hazardous substances through a balanced mix of policy measures based on their intrinsic properties and on their risks³¹ as well as in shifting the responsibility to industry for the safety of chemicals throughout the life cycle. This includes some notable reductions in exposure to substances such as mercury, benzene, asbestos, polychlorinated biphenyls (PCBs), and to a range of other chemicals with severe hazard properties³².

However, on-going and emerging health and environmental concerns call for **urgent action and evolution of the legal framework to reflect scientific findings and respond to citizens' safety demands**. To strengthen the level of protection of health and the environment from chemical risks, **REACH and CLP should be reinforced as cornerstones for regulating chemicals**, and be complemented by **coherent approaches to assess and manage chemicals** in existing sectorial legislation.

3.1.1. Addressing endocrine disrupting chemicals

Exposure of humans and the environment to endocrine-disrupting chemicals requires specific attention. Those substances are linked to diseases of the hormonal system (e.g. disorders of the thyroid) and of the immune, digestive, cardiovascular, reproductive and metabolic systems³³. They also represent a serious risk to wildlife – in particular for insects and fish –. The Commission has already recognised the need to have a horizontal EU approach for the identification of those substances³⁵. The coherence of EU legislation in this area was recently evaluated, showing that the lack of a unified approach for the identification of endocrine disruptors can lead to different decisions for the same substances and to overall regulatory inefficiency. The evaluation also recommends that access to data generated under

³¹ [SWD/2019/199 final/2](#).

³² *Ibid.*

³³ World Health Organisation and UNEP, [State of the science of endocrine disrupting chemicals](#), 2012.

³⁵ [COM \(2018\) 734](#).

some pieces of legislation³⁶ is ensured to those policy areas that have provisions for achieving the safety of products placed on the EU market.³⁷

ENDOCRINE DISRUPTORS

The Commission will:

- **propose to establish the horizontal identification of endocrine disruptors (EDs) in the EU legislative framework**, based on the definition of the World Health Organization and building on the criteria developed for pesticides and biocides while **ensuring that it is fit for purpose for other relevant legislation**, particularly for REACH but also legislation on cosmetic products, toys and food contact materials. This will simplify and rationalise current parallel identification procedures,;
- **review and strengthen as necessary information requirements** on endocrine disruptors in the relevant legislation to improve the identification of EDs³⁶;
- explore options to strengthen the legislative framework in order to further minimise exposure to EDs, both for consumers and for exposure to the environment, and to manage the risks to humans and wildlife resulting from combined exposures to different endocrine disruptors regulated under different pieces of legislation.
- support the **development of methods for the screening and testing of endocrine disruptors** and accelerate the evaluation and use of new methodologies for their identification while reducing the reliance on animal testing.

3.1.2. Protecting people and the environment from the combination effects of chemicals

People and other living organisms in the natural environment are exposed throughout their lives to a variety of **chemicals originating from various sources**. Significant progress has been made in the past years to close some knowledge gaps on the impact of mixtures. However, current regulatory approaches to the assessment of chemicals are usually based on the evaluation of single substances or, in some cases, of intentional mixtures for particular uses without considering the combined exposure to multiple chemicals from different sources and over time³⁹. **For intentional mixtures there are still remaining challenges** related to their assessment and management, for example for additives used in the manufacture of tobacco and related products, where the Commission intends to step up efforts for their assessment⁴⁰.

To adequately address unintentional mixtures, scientific developments need to be integrated in the regulatory framework to ensure that risks from their exposure are adequately and systematically assessed and managed across the full range of chemicals-related policy areas. Explicit requirements for the assessment of unintentional mixtures only exist in the pesticides and biocides areas⁴¹, where the European Food Safety Authority has

³⁶ e.g. REACH, Biocides, Plant Protection Products

³⁷ accompanying SWD on EDs

³⁹ Accompanying SWD on mixtures

⁴⁰ Tobacco Products Directive, 2014/40/EU

⁴¹ The Regulation (EC) No 396/2005 on the maximum residue levels of pesticides (MRL, OJ L 70, 16.3.2005, p. 1) and Regulation (EC) No 1107/2009 on the Plant Protection Products (OJ L 309, 24.11.2009, p. 1–50) require that known cumulative and synergistic effects of active substances are taken into account in regulatory decision-making (in MRL setting and approval of active substances) once the methodology is available. As parts of the methodology is now partly available (two Cumulative Assessment Groups established), existing provisions must gradually start to be applied.

developed a methodology intended to implement the existing provisions which could be gradually extended to other areas.

Based on the experience gained in the area of pesticides and due to the complexity of assessing and regulating an infinite number of possible combinations of chemicals, realistic and workable regulatory approaches are needed. Accordingly, for mixtures that cannot be assessed and managed through more refined methodologies, **mixture toxicity needs to be integrated in risk assessment of substances** in a scientifically sound, simple and efficient manner, so that policy action moves forward on a sound basis. The Commission and EU agencies will also strengthen coordination to effectively address the combination effect of chemicals in risk assessment and risk management across legislation, including through **grouping of chemicals**.

CHEMICAL MIXTURES

The Commission will:

- accelerate the **development of methodologies for assessing risks from combined exposure from pesticides** and introduce their **use for risk assessment and risk management**, initially under the Maximum Residue Level Regulation and in a second phase under the Plant Protection Product Regulation and Biocidal Product Regulation;
- ensure the **further development of harmonised methodologies⁴² and their translation into practical tools** for the routine implementation of human health risk assessment to multiple chemicals in relevant legislation;
- launch work on how to integrate toxicity resulting from unintentional mixtures in chemicals legislation, starting with hazard and risk assessment methodologies applied to REACH and CLP; and taking into account the experience gained in other regulatory sectors, such as pesticides.
- assess how to introduce adequate legal provisions to take account of the **combination effects in other relevant legislation** in upcoming evaluations and revisions of relevant pieces of legislation.

3.1.3. Towards zero chemical pollution in the environment

The current **regulatory framework struggles to take into account long-term and large-scale environmental effects⁴³**, as the role of hazardous chemicals in the interaction with other environmental stressors and their actual impacts on the terrestrial and marine environment is very complex. Hazardous chemicals contribute to the reduction of ecosystem resilience, leading to rapid declines in animal populations and, ultimately, to extinctions⁴⁴. It is estimated that 2.8 million potentially contaminated sites exist in the EU, mainly from waste disposal and treatment, posing a significant environmental hazard for terrestrial and aquatic ecosystems and affecting the productivity of soils⁴⁵.

CHEMICALS IN THE ENVIRONMENT

⁴² Such as EFSA's 2019 Guidance, <https://www.efsa.europa.eu/en/efsajournal/pub/5634>⁴³ [COM \(2019\) 264 final](#).

⁴³ [COM \(2019\) 264 final](#).

⁴⁴ *Ibid.*

⁴⁵ European Commission, [Status of local soil contamination in Europe](#), 2018.

The Commission will:

- propose new hazard classes or criteria in GHS⁴⁶ to **fully address environmental toxicity, persistency, mobility and bioaccumulation**;
- tackle the concerns posed by **persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances** as categories of substances of very high concern under REACH.
- **Review whether current information requirements** allow comprehensive environmental risk assessments under REACH and other relevant legislation;
- **address the environmental aspects of pharmaceuticals** in the upcoming Pharmaceuticals strategy, in light of the Strategic Approach to Pharmaceuticals in the Environment⁴⁷ and taking account relevant policy evaluations⁴⁸;
- support through Horizon Europe the **research and development of remediation techniques** for terrestrial and aquatic environment.

Even when emerging chemical risks are identified – e.g. through research or monitoring⁴⁹ – regulatory action to prevent irreversible damage and socio-economic impacts still remains challenging, and the burden is often placed on the generations to come. The example of **per- and polyfluoroalkyl substances (PFAS)** is a case in point, considering the large number of contamination cases of soil and water - including drinking water⁵⁰ - in the EU and globally⁵¹, the number of people affected and the related societal and economic costs⁵². The Commission proposes a **comprehensive set of actions to address the use of and contamination with PFAS**, as a first step to tackle very persistent substances in Europe. In particular, those actions will ensure that the use of PFAS is minimised in the EU.

PFAS⁵³

The Commission will:

- request ECHA to **prepare a REACH restriction dossier for all PFAS in fire-fighting foams** and collaborate with the Member States authorities to restrict all other uses of PFAS, using the expertise of ECHA;
- step up initiatives to **address PFAS**, with a **group approach, under relevant legislation**, notably REACH, legislation on water, sustainable products, food, industrial emissions, and waste;
- use the expertise of Member States, the Zero Pollution Action Plan and the revision of the thematic strategy for soil protection to **address soil contamination** with PFAS;
- continue working internationally in the relevant fora (Stockholm, Rotterdam and Basel Conventions Convention and OECD) to **address PFAS concerns at a global**

⁴⁶ Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

⁴⁷ [COM\(2019\) 128 final](#)

⁴⁸ In particular the findings of the Fitness Check of the EU Water Legislation, [SWD\(2019\)439](#), and of the Urban Waste Water Treatment Directive, [SWD\(2019\)700](#).

⁴⁹ In particular, the EU funded Human Bio-Monitoring for the EU (HBM4EU).

⁵⁰ WHO, [Keeping our water clean: the case of water contamination in the Veneto Region](#), Italy, 2017.

⁵¹ Study funded by the Nordic Council of Ministers, [The Costs of Inaction. A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS](#), 2019.

⁵² Costs from exposure to PFAS in Europe have been estimated between EUR €52 and EUR €84 billion per year; *Ibid*.

⁵³ More details in the [accompanying PFAS SWD](#)

scale;

- establish an **EU-wide approach and adequate funding to identify and remediate cases of contamination** in the environment, as well as legacy presence in products and materials, to monitor the presence of PFAS in humans and the environment, and to guarantee safe disposal;
- provide **R&I funding for safe innovations to substitute PFAS** and to facilitate environmental remediation.

3.2. Accelerating the green, digital and resilient recovery from COVID-19 crisis in support of a competitive, innovative and sustainable EU chemicals production capacity

The crosscutting nature of chemicals and their enabling role across sectors and widespread use in products, the integration of the EU producers and users of chemicals within the internal market and their presence in global value chains means that investments in the green and digital transition and the resilience and **promoting** innovations for safe and sustainable-by-design chemicals, materials and products have the potential of bringing high societal added value across the EU. This strategy therefore **represents a crucial component of the EU's economic and social recovery**. Maintaining and further developing a competitive, innovative and sustainable EU chemicals production capacity **is key to achieve the ambition of the European Green Deal** in terms of a zero pollution, circular and climate-neutral economy, toxic-free environment and the EU's open strategic autonomy and resilience. By doing so, the EU will avoid exporting chemical risks and pollution only to import them through finished goods produced according to lower environmental and worker protection standards.

3.2.1. *Promoting innovations for safe and sustainable-by-design chemicals, materials and products*

Europe has the scientific and technical capacity to **lead the transition to a safe and sustainable-by-design approach to chemicals, materials and products**. Regulatory and market initiatives have been established⁵⁴, but frontrunners still encounter barriers that prevent them from gaining additional competitiveness. Moreover, while the REACH authorisation process has fostered substitution of the most hazardous chemicals along the supply chain, many economic actors still may encounter difficulties with finding alternatives to the most hazardous chemicals. Hazardous chemicals are often used because they fulfil a specific function. Possibilities to substitute hazardous substances depend first and foremost on the existence and availability of alternatives. Where alternatives do exist, additional challenges can result from the technical feasibility, cost effectiveness and complexity of the substitution process. Substitution may also require additional investments in infrastructure and equipment, re-training workforce and result in increased production costs.

The **transition to safe and sustainable-by-design**⁵⁶ is a societal urgency. It is for example the prerequisite to achieve the EU's commitment to reduce the use of more hazardous

⁵⁴ European Commission, [Chemicals innovation action agenda](#), 2019.

⁵⁶ Safe and sustainable-by-design (SSBD) can be defined as a pre-market approach to chemicals that focuses on providing a function (or service), while avoiding volumes and chemical properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile. Overall sustainability should be ensured by minimising the environmental footprint of chemicals in particular on climate change, resource use ecosystems and biodiversity from a lifecycle perspective.

pesticides by 50% by 2030⁵⁷, and it is relevant for all types of chemicals, including pharmaceuticals⁵⁸. Regarding in particular fostering substitution where risks cannot be managed otherwise, a **stronger policy and financial support**, as well as advice and assistance in particular for SMEs is needed, and requires a concerted effort from all: authorities, businesses, investors and researchers. Available tools under REACH⁵⁹ and other legislation – such as the Ecolabel Regulation and the Ecodesign and Industrial Emissions Directives – could be better used to **ensure and reward safer chemicals and effective substitution of substances of concern**. Furthermore **collaborations across supply chains and technology areas** are needed to facilitate development and market uptake of alternatives and incentivise the scaling up of green innovations and technologies is needed.-

SAFE AND SUSTAINABLE-BY-DESIGN

Together with the relevant actors, the Commission will:

- develop **EU safe and sustainable-by-design criteria**, in line with and complementing the EU Taxonomy Regulation⁶⁰ as well as ongoing international work by OECD and UNEP;
- **ensure financial support** – in particular to SMEs - for the development, commercialisation and uptake of safe and sustainable-by-design substances, materials, products and processes through Horizon Europe, cohesion policy, the LIFE Programme and other relevant EU funding and investment instruments as well as through public-private partnerships;
- initiate an **EU-wide safe and sustainable-by-design Support Network**, to promote cooperation – and sharing of information - on substitution, in particular of Substances of Very High Concern well as technical expertise and training on the evaluation and adoption of alternatives;
- **promote public-private partnerships** – together with the European Institute of Innovation and Technology (EIT) - to facilitate **development and market uptake** of safe and sustainable chemicals and alternative solutions and to **map skills mismatches and support the enhancing of adequate skills at all levels**.
- **Explore with academia how to promote and include environmental and health toxicity subjects in chemistry faculties.**

3.2.2. Achieving safe products and non-toxic material cycles

One of the pre-conditions for a successful transition towards a clean circular economy and non-toxic materials cycles, is the safety of both primary and secondary materials and products. This can play an important role for the market uptake of secondary raw materials and their capacity to compete with primary raw materials. Avoiding substances of concern in materials and products where risks cannot be managed otherwise is a necessary step to achieve non-toxic material cycles for secondary raw materials. The recently adopted Circular

⁵⁷ EU Biodiversity Strategy 2030, [COM \(2020\) 380 final](#), and Farm to Fork Strategy, [COM \(2020\) 381 final](#).

⁵⁸ In line with the Strategic Approach to Pharmaceuticals in the Environment, [COM \(2019\)128](#), and related policy evaluations, in particular the findings of the Fitness Check of the EU Water Legislation, [SWD \(2019\) 439](#), and of the Urban Waste Water Treatment Directive, [SWD \(2019\) 700](#).

⁵⁹ In line with Review of REACH, [COM \(2018\)0116, action 5](#)

⁶⁰ https://ec.europa.eu/info/publications/sustainable-finance-teg-taxonomy_en (to be updated with link to adopted text).

Economy Action Plan⁶¹ has shown that this requires a combination of actions upstream, to ensure that products are safe and sustainable-by-design; and downstream, to increase safety of and trust in recycled materials and products.

However, the transition to chemically safe primary and secondary materials and products is being slowed down by a number of issues⁶². For example, the **current lack of adequate information on the substances of concern contained in many products** is hampering the risk management activities of value chain actors and the protection of consumers, who cannot generally make purchase choices in full knowledge of the properties of products⁶³. This situation is particularly worrying for imports entering the European market, in particular via e-commerce⁶⁴.

In addition, when products become waste the presence of substances of concern can compromise the safety and quality of material flows.⁶⁵ This situation is an important concern in particular for plastics, where heavy metals, flame retardants and phthalates are often present. Many waste streams may be contaminated for many years to come. To move towards toxic-free material cycles and clean recycling, it is necessary to **ensure that substances of concern in products and recycled materials are minimised**. As a principle, the same limit value for hazardous substances should apply for virgin and recycled material. However, there may be exceptional circumstances where this principle may have to be derogated from, under the condition that the use of the recycled material is limited to clearly defined applications where there is no negative impact to consumers health and the environment, and the use of recycled material compared to virgin material is justified on the basis of a lifecycle assessment to be undertaken case by case.

Regulatory actions need to go hand-in-hand with increased **investments in innovative technologies to address the issue of legacy substances** which could in turn allow to recycle more waste⁶⁶. This is particularly important for certain plastics and textiles. The Commission will assess whether technologies such as chemical recycling could have a role in increasing the recyclability potential of otherwise non-recyclable waste. It would for example allow plastic and textile waste with legacy substances of concern to be chemically transformed into contaminant-free raw materials, in full consideration of the need to ensure an overall positive environmental performance of these technologies, from a full lifecycle perspective.

NON-TOXIC MATERIAL CYCLES

The Commission will:

- introduce, through the forthcoming legislative initiative on sustainable products⁶⁷, **minimum requirements to minimise the presence of substances of concern in products**, giving priority to those product categories affecting vulnerable populations

⁶¹ [COM \(2020\) 98](#).

⁶² As summarised in the Communication on options to address the interface between chemical, product and waste legislation, [COM \(2018\) 32](#).

⁶³ Some of the existing legal provisions under REACH on the presence of substances of very high concern in articles have not provided the expected results; [Accompanying SWD Art. 138](#).

⁶⁴ FORUM - [Substances in Articles. Pilot project report. Harmonised Enforcement Project](#); and Nordic Council of Ministers: [project on enforcement of internet trade](#).

⁶⁵ [COM \(2020\) 98](#).

⁶⁶ Currently restricted or banned substances are still present in products that were placed on the market when the use of the substance was still allowed. When the product becomes waste and is then recovered, those substance may still be contained in the recovered material. They are then called legacy substances. [COM \(2018\) 32](#).

⁶⁷ The Circular Economy Action Plan has announced that the sustainable product policy legislative initiative will address, inter alia, the presence of hazardous chemicals in products; [COM \(2020\) 98](#).

as well as those with the highest potential for circularity, such as textiles, packaging, including food packaging, furniture, electronics and ICT, construction and buildings;

- introduce, also through the forthcoming legislative initiative on sustainable products, **minimum information requirements on chemical content and safe use** using state-of-the-art technologies and including this information in material passports and product passports as announced in the new Circular Economy Action Plan;
- ensure that **authorisations and derogations from restrictions for recycled materials under REACH are exceptional and justified**;
- support **investments in innovative technologies** that can decontaminate waste streams, increase safe recycling and reduce the export of waste, in particular plastics and textiles, subject to the relevant state aid rules for example in the area of research and development or environmental protection;
- support investments in sustainable chemical recycling of otherwise non-recyclable waste, thus applying the principles and reaping the benefits of circular economy to the level of molecules;
- develop **chemical risk assessment methodologies that better take into account the whole life cycle of substances, materials and products**, including their reuse and recycling, building on the ongoing work on the product environmental footprint.

3.2.3. Strengthening the resilience and EU's open strategic autonomy for chemicals in critical applications

The COVID-19 crisis has highlighted that **excessive concentration of and overreliance on a limited number of sources of supply** of certain critical chemicals (e.g. chemical raw and starting materials, intermediates, active pharmaceutical ingredients), in particular in third countries **can put at risk the availability of medicines** to patients in Europe and the EU's capacity to provide an adequate and timely response to health crisis. A more resilient economy and public healthcare systems require sufficiently diversified sources of supply and a better management of risk of the disruption at all levels, strategic reserves and stockpiling, as well as mechanisms to ensure that supply chains can continue to operate unaffected in case of crises.

Ensuring that the EU is resilient to supply disruptions of chemicals used in essential applications for society is key not only for health applications, but also for **technologies needed to achieve the sustainability goals enshrined in the European Green Deal**. This means, in particular, exploring new methodologies and technologies, as well as new digital tools that can boost innovations needed for climate neutrality, for stepping up safe recycling and re-use of materials and for reducing the overall environmental footprint of products and EU production processes. Chemical innovations can make EU chemical industry the global leader in sustainable chemicals and bring sustainable solutions across sectors, notably for safer and more durable construction materials, more lasting and circular textiles, low-carbon mobility, batteries, wind turbines and renewable energies.

RESILIENCE AND EU'S OPEN STRATEGIC AUTONOMY

The Commission will:

- **identify chemicals that are strategic for key value chains and technologies** in particular to strengthen EU's resilience and open strategic autonomy, and setup a

Chemicals Platform to ensure a stable dialogue between the Commission and the industry producing and using chemicals and support evidence-based and future proof decision-making;

- promote **interregional collaboration along sustainable chemicals value chains**, through smart specialisation, to accelerate the development of joint investment projects;
- foster **inter-sectoral symbiosis and mobilise EU funding and investment mechanisms** - cohesion policy funds, Just Transition Mechanism, InvestEU, Strategic Investment Facility, ReactEU, Horizon Europe - to promote the resilience of supply and sustainability in Europe of **chemicals used in essential applications for society**. Those will support⁶⁸ in particular the production of **health applications** and of technologies critical to achieve **climate neutrality, clean and safe material circularity and zero pollution**.

3.2.4. Repair, recover and bounce fast-forward on the green and digital transition

The **consequences of the COVID-19 crisis on the EU industry producing and using chemicals vary** depending on their economic focus. Companies that are supplying food, healthcare, personal care products, plastic packaging, medical equipment, disinfectants and active pharmaceutical ingredients had to increase their production capacity to respond to the increase in demand. Other chemical companies – e.g. those supplying the construction sector - had to reduce or even stop their production because of the decrease in demand from manufacturing or retailers. The new recovery instruments together with the reinforced long-term EU budget represent a major opportunity not only to repair the damages suffered during the crisis but also to bounce fast-forward the industrial transition. The Commission invites the Member States and all the interested actors to seize the opportunities offered by those financial instruments to **help the recovery of the EU's economy and society while accelerating the green and smart transition** of the industry producing and using chemicals.

Chemical production is often considered as one of the most polluting, energy and resource intensive sectors,⁶⁹ although the environmental and carbon footprints of the EU chemicals industry have been reduced over time. For instance, its CO₂ equivalent emissions decreased from 325.1 million tonnes in 1990 to 126 million tonnes in 2016 (61.2% decrease).⁷⁰ In 2017, chemicals industry's CO₂ emissions only represented 2.3% of the total of air pollutants emitted.⁷¹ While the European chemicals industry has already invested heavily in new and improved manufacturing plants and processes⁷², the green and digital transition still requires significant investments for the sector. Moreover, as the consequence of the outbreak of COVID-19, companies are currently in a situation of great uncertainty.

⁶⁸ Subject to compliance with State aid rules when they apply.

⁶⁹ In 2017, the EU chemicals industry was the 2nd largest emitter of PM10 emissions. Chemical production was also responsible for the largest share of industrial releases to water (51%), EEA, [Industrial pollution in Europe](#).

⁷⁰ CEFIC Facts and Figures Report, CEFIC, 2018, p. 69

⁷¹ <https://www.eea.europa.eu/data-and-maps/indicators/industrial-pollution-in-europe-3/assessment>

⁷² The European chemical industry invests more than 15% of its value added in new and improved manufacturing plants and processes. In 2017, the chemicals sector invested about EUR 10 billion—about EUR 25 million a day—in research and development, including in finding ways to become more energy efficient and reduce our carbon footprint. Source: [Cefic](#)

This may delay the already planned investments and influence the necessary long-term investments negatively.

Energy efficiency must be prioritised in accordance with the ambition of the European Green Deal and for the sustainability of energy sources, fuels such as renewable hydrogen and sustainably produced biomethane could play a decisive role⁷³. The EU needs novel industrial processes and cleaner technologies not only to reduce the environmental footprint of the EU industry producing and using chemicals, but also to reduce costs, improve market readiness and create new markets. In addition, chemical innovations for advanced materials and technologies can bring sustainable solutions across sectors. Digital technologies - such as the internet of things, big data, artificial intelligence, smart sensors and robotics – also play an important role in greening manufacturing processes.

Beyond the role played by technology, **innovations in business models** can be an important driver for the green transition of the industry producing and using chemicals. Opportunities to **shift traditional chemical production and use of chemicals as a product to chemicals as a service**⁷⁴ should be explored and promoted. Those could optimise the use of expertise and ensure resource efficiency during the entire lifecycle, as well as encourage place-based innovation and the involvement of SMEs.

Beyond providing financial support and dealing with the most immediate impacts of the crisis, the recovery of companies producing and using chemicals must also be accompanied by an enabling legal framework, as that plays a big role in companies' investment decisions.

BOUNCING FAST-FORWARD ON THE GREEN AND DIGITAL RECOVERY AND TRANSITION

Through its financial and investment instruments – in particular the cohesion policy funds, the Just Transition Mechanism, InvestEU, Strategic Investment Facility, React-EU, Horizon Europe, and Digital Europe Programme – the Commission will:

- promote the **re-skilling and upskilling of the workforce** involved in the production and use of chemicals for it to acquire the digital skills and knowledge and skills necessary to design and use safe and sustainable chemicals;
- **facilitate access to risk finance and investments in R&D** in particular for SMEs and start-ups;
- promote the development of **green and smart technologies and innovative business models** – e.g. chemicals as a service – to enable the transition towards low-carbon and low environmental impact manufacturing processes of the chemical sector and its value chain, including by increasing its energy efficiency, the use and transport and storage capacity of renewable energy and CO₂, and by bringing sustainable solutions across sectors.

⁷³ The hydrogen strategy underlines the need for demand-side support measures, and for an uptake of renewable hydrogen in specific end-use sectors such as the chemical sector. Such quotas or minimum shares could also be considered for other renewable fuels such as biomethane. **Reference when adopted**

⁷⁴ 'Chemicals as a service' includes chemicals leasing (e.g. if the function of a chemical is to clean or protect a surface, a company will be paid depending on the number of pieces cleaned or the extent of area coated), but also the leasing of services such as logistics, development of specific chemical processes and application, and waste management.

3.3. Simplification for a coherent legal framework on chemicals

The **EU regulatory framework for hazard and risk assessment and management of chemicals is comprehensive and complex** at the same time. Overall various evaluations carried out in the recent past confirm that the EU chemicals legislation delivered results as intended and is fit-for-purpose. However, a number of important weaknesses were identified to be holding the EU chemicals legislation back from delivering its full potential.⁷⁵ If not rapidly addressed, the framework will struggle to timely and efficiently cope with the current and future production chemicals.

The complexity of the legal framework represents a specific challenge for authorities and stakeholders, and can lead to inconsistencies, slow procedures, inefficient use of resources and unnecessary burdens. A key ambition of this strategy is to **ensure greater transparency and predictability, combined with a simplification of this framework**, which will in turn result in burden reduction for all actors, more consistent and faster decision-making and greater predictability. Therefore, the Commission will initiate a process to **simplify the way chemical risk assessment and management is done across EU legislation**, and to gradually move away from assessing and regulating substance-by-substance into regulating them by groups. This will be complemented with stepped-up action to promote **full implementation, compliance and enforcement** of the EU rules on chemicals.

3.3.1. A smart regulatory process, including a 'à la carte' approach

The European Union needs to take up new regulatory challenges faster and in a more structured and transparent way so that we focus on the most relevant issues. At the same time regulatory procedures need to be streamlined, to ensure that we act in the most efficient and effective way.

Chemical safety assessments include assessments of hazards and environmental fate, of exposures from uses and of the resulting risks to human health and the environment. Such assessments are being **initiated under various pieces of legislation, by various actors and at different points in time** and they are performed by **various EU agencies⁷⁶, scientific committees⁷⁷, expert groups or Commission services**. Those assessments use **various methodologies and data**, which vary in terms availability, accessibility, quality and formats. In addition, **different transparency rules and practices** are applied to the way assessments are initiated and performed and to how data are used for the assessments. These variabilities may lead to situations where risks are not assessed for all relevant uses, to overlaps or to incoherent outcomes. Also, available resources and expertise are not fully optimised, and overall the general public and stakeholders struggle to keep track of those regulatory processes.

All actors – including citizens, industries and authorities at all levels - would strongly benefit from moving towards a process that increases the predictability, transparency, **efficiency, coherence and scientific quality of chemical safety assessments** across the various pieces of legislation and at the same time ensures timely, effective and consistent protection of

⁷⁵ [COM \(2019\) 264. final](#)

⁷⁶ The European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the European Medicines Agency (EMA) and the European Environment Agency (EEA).

⁷⁷ Scientific Committee on Health, Environmental and Emerging Risks ([SCHEER](#)), Scientific Committee on Consumer Safety ([SCCS](#))

consumers and the environment. The Commission will initiate a smart regulatory process, including a ‘one substance, one assessment’ approach, which will establish a step-wise approach to ensure that the initiation and priority setting of the **safety assessments is done in a coordinated** and transparent manner to the extent possible synchronised, that **responsibilities are clear**, that available **expertise and resources are optimally used** and that there is **good cooperation among all actors**. In addition, access to all available data will be ensured without technical or administrative obstacles and safety assessments should guarantee full transparency and be based on coherent and to the extent possible harmonised methodologies.

A SMART REGULATORY PROCESS, INCLUDING A ONE SUBSTANCE, ONE APPROACH

The Commission will:

- establish an **EU process for better coordination, prioritisation and increased transparency of decisions on regulatory actions thus creating EU level accountability and legitimacy** for the initiation of scientific assessments performed with EU budget and for regulatory action at EU level:
- - **Coordinated agenda setting and focus of efforts on the highest risks:** based on available input the Commission will organise early discussion on priorities and risks to be addressed through chemicals regulation. This will increase transparency on priority setting, improve planning and predictability for industry and engage stakeholders in discussions.
 - **Systematic analysis and discussion of regulatory options before deciding on the option to be pursued:** when there is a (new) concern for a substance, or a group of substances, the main available information shall be assessed and regulatory options discussed with all relevant stakeholders, including Member States and industry, social partners, NGOs, the Commission services and relevant agencies and/or scientific bodies. A public consultation shall also be organised on the regulatory action identified to pursue. Based on the discussions and the feedback from the public consultation, different regulatory options will be investigated, setting clear deadlines to ensure timely action. This will not cut the right of initiative of Member States but allow for joint decisions where appropriate and necessary. An EU level control mechanism will be introduced for cases where there is no consensus among Member States on whether to initiate regulatory action at EU level. The Commission will also get more rights to initiate regulatory action.
- **review the attribution of technical and scientific work on chemicals** performed under the relevant pieces of legislation to make the best use of expertise and resources in European Agencies and Scientific Committees;
- assess how to **strengthen the governance of the European Chemicals Agency**, in particular whether it will be appropriate to create a new Founding Regulation separate from REACH, and review the sustainability of its financing model;
- move from a substance-by-substance approach towards a **group assessment of chemicals with similar hazard, risk or function**, with the aim to simplify and

streamline the risk assessment process and gain efficiencies, accelerate the pace of regulatory processes and support the shift away from animal testing⁸²;

- propose **amendments to the CLP Regulation** to give the Commission a mandate to ask ECHA to develop harmonised classification dossiers, linked with the smart regulatory approach referred to **above** ;
- initiate the development of a **centralised and curated EU repository of human and environmental health-based limit values**, as part of the work on common open data platforms on chemicals, to strengthen the harmonisation and coherence of approaches to set ‘safe’ exposure level, including for the protection of vulnerable groups. These values, derived or validated by relevant risk assessment experts within the EU regulatory framework, should be available for reuse among EU risk assessors and managers unless there is an explicit scientific reason not to⁸³;
- establish a **working group of Commission Services, Agencies** (EFSA, ECHA, EMA and EEA) and Scientific committees to strengthen coordination across the different pieces of legislation and to oversee and promote the process towards ‘one substance, one assessment’, including work on methodologies and data as essential part of the approach.

3.3.2. *A simple and effective approach to manage risks*

Depending on the nature of the hazards and of the exposures, risk management measures in the EU are taken based on generic risk considerations or on specific risk assessments. In most cases, the EU chemicals legislation uses a combination of both of these approaches.⁸⁴ This balance is overall appropriate⁸⁵ but there is scope to increase efficiency by better prioritising and grouping action, earlier and more accountable and transparent discussion on regulatory options, and simplification of processes and procedures to lighten administrative burden and allow more swift regulatory action, in line with the smart regulatory approach.

Generic approaches to risk management⁸⁶ are currently applied in specific pieces of EU legislation to manage the risks from carcinogens, mutagens and reprotoxicants, in particular for consumer products and products that end up in the environment, although some incoherencies are still present across legislation. Those approaches have generally the advantage of being **simpler faster** and more appropriate to **ensure protection from**

⁸² [COM \(2019\)264](#).

⁸³ E.g. new evidence or not appropriate for use and exposed population.

⁸⁴ [SWD \(/2019/199 final/2](#)

⁸⁵ “Findings of this Fitness Check show that both the GRC and SRA have their role to play in the EU chemical legislative framework and that the current balance between the use of generic and specific risk management approaches works well, each under particular circumstances”. Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries, p. 57

⁸⁶ In the EU legislative framework for chemicals, generic approaches to risk management (sometimes also referred to as Generic Risk Assessment) is an automatic trigger of pre-determined risk management measures (e.g. packaging requirements, communication requirements, restrictions, bans, etc.) based on the hazardous properties of the chemical and generic considerations of their exposure (e.g. widespread uses, uses in products destined to children, difficult to control exposure). It is applied in a number of pieces of legislation on the basis of specific considerations (e.g. characteristics of the hazard, vulnerability of certain population groups, non-controllable or widespread exposure). Past evaluations concluded that generic and specific risk management approaches both have their role to play within the framework of EU chemicals legislation but the application of both approaches has room for improvement. [SWD \(/2019/199 final/2](#)

substances with critical hazard properties, in particular where consumers, vulnerable groups and the environment are at risk and risks cannot be effectively controlled⁸⁷. They **provide clear signals to all actors** (enforcement authorities, industry and downstream users) on the types of hazardous substances to be avoided and **ensure predictability of risk management processes**⁸⁸. They should therefore be extended where most appropriate, in particular to **ensure protection from substances with critical hazard properties** – e.g. those that have particularly undesirable consequences and where even low exposure is of concern – as well as **to protect vulnerable groups and** - such as children, pregnant women or elderly people⁸⁹ - who are particularly sensitive to chemicals with certain hazard properties and whose risk cannot be effectively controlled⁹⁰. Such an approach can help avoid legacy problems as they now exist for certain chemicals and better protect sensitive ecosystems and endangered species.

The **REACH Regulation** has put the EU at the forefront of regulatory action on chemical risks worldwide. Nevertheless, the authorisation and restriction procedures cause substantial administrative burden for authorities and for industry. Moreover, the current implementation of the REACH authorisation system, despite its success in triggering substitution to avoid later regulatory consequences, has led to delays in regulatory decisions which create uncertainties both for users of substances and alternative providers.

SIMPLIFIED AND FASTER RISK MANAGEMENT

The Commission will:

- simplify and strengthen the measures to prevent the risks associated with the use of substances with critical hazard properties across sectorial legislation. As a first step, extend the use of generic approaches to risk management across sectorial legislation to protect from carcinogenicity, mutagenicity, reprotoxicity, endocrine disruptors, PBTs⁹¹ and vPvBs⁹²; as a second step, gradually address immunotoxicity, neurotoxicity, specific target organ toxicity and respiratory sensitisers;
- Enhance the safety of childcare articles and other products for children (other than toys) against chemical hazards through the adoption of new safety requirements. The chemical properties of child care articles shall be in line with the state of the art knowledge, including the limits set in other relevant pieces of EU legislation.
- on the basis of the **definition of essential uses** in the Montreal Protocol, assess and consider if the concept could be used to manage risks and minimise exposure to certain chemicals;
- assess the need and possibility to **reform the REACH authorisation and restriction processes** based on key findings from its practical implementation, including to ensure equal conditions for EU and non-EU manufacturers for chemicals in articles placed on the EU market.⁹³

⁸⁷ [SWD\(2019\)199 final/2](#) ; Exposure to developmentally toxic chemicals during pregnancy can for example damage the development of the endocrine, immune or neurological systems, affecting brain development of the unborn foetus. C. Ganzleben, A. Kazmierczak, [Leaving no one behind – understanding environmental inequality in Europe](#), 2020.

⁸⁸ [SWD \(2019\)199. final/2](#)

⁹³ REACH review, [COM\(2018\)0116](#).

⁹³ REACH review, [COM\(2018\)0116](#).

⁹³ REACH review, [COM\(2018\)0116](#).

⁹³ REACH review, [COM\(2018\)0116](#).

⁹³ REACH review, [COM\(2018\)0116](#).

3.3.3. *A zero tolerance approach to non-compliance with chemicals legislation*

All chemicals, materials and products that are produced in the EU or placed on the European market must fully comply with the EU information, safety and environmental requirements. In spite of this, currently almost 30 % of the alerts on dangerous products on the market involve risks due to chemicals, and almost 90 % of those products come from outside the EU⁹⁴. Equally, only two thirds of the registration dossiers of the chemical substances registered by industry under REACH are compliant with the required information requirements.⁹⁵ Stepping up implementation and enforcement of chemicals legislation is urgently needed following a cradle-to-grave approach, exploiting and reinforcing instruments than can foster compliance for the production and placing on the market of chemicals as well for their release and disposal.

The level of **compliance of products** with existing requirements is a key concern, with **imported articles and online sales representing a particular challenge**. The implementation of the new Regulation on Market Surveillance and Compliance of Products⁹⁶ will be an important step to strengthen enforcement both within the single market and at the EU's external borders, as it will establish enhanced cooperation between market surveillance and customs authorities and a strengthened risk management framework. Moreover, the upcoming Communication on Customs is expected to announce measures to bring the EU Customs Union to the next level so that customs authorities are better equipped to protect EU citizens and the EU single market. Additional measures will also be put in place by the Commission to strengthen the **enforcement of REACH at the EU's borders**⁹⁷, as well as **cooperation with online platforms**⁹⁸. Complementary efforts need to be taken by Member States to reap the benefits from the EU's rapid information and alert tools, RAPEX and RASFF⁹⁹, and to enhance the identification of **chronic risks for human health and the environment from chemicals in products** placed on the EU market.

In addition, **enforcement of the chemicals legislation is not equally effective throughout the EU**, due to the different capacities and resources at national level. This can lead to an inconsistent application of the EU law, with ultimately negative consequences on the free movement of goods within the EU, jeopardizing the level playing field, and leading to different levels of protection of EU citizens¹⁰⁰. **Member States must increase their enforcement capacity** to levels where they can be effective, exploiting also **digital tools** for faster action and efficient allocation of resources. The European Chemicals Agency's Forum for exchange of information and enforcement¹⁰¹ has proven effective in advancing the

⁹⁴ Data extracted from the EU's [Safety Gate/Rapex](#), the rapid alert system for dangerous non-food products.

⁹⁵ The European Commission concluded in the REACH Review that the non-compliance of registration dossiers was a key issue hampering progress. In 2018, a study by the German Federal Institute for Risk Assessment and the German Environment Agency concluded that, out of a set of 3 800 dossiers of substances registered over 1000 tonnes per year, only one third met the information requirements, whereas one third likely did not. The situation for another third was unclear. ECHA and the Commission have in the meantime developed a [Joint Action Plan](#) to step up compliance checks on all registration dossiers.

⁹⁶ Regulation (EU) 2019/1020, which will enter into application in July 2021.

⁹⁷ A study is currently ongoing on how to integrate REACH requirements into customs processes.

⁹⁸ A number of online platforms have signed a [Safety Pledge](#) to remove from their online listings any product reported in Safety Gate/RAPEX.

⁹⁹ Which inform consumers and Member States authorities in case of products posing a risk; [Safety gate for consumers](#)

¹⁰⁰ [COM \(2019\)264](#).

¹⁰¹ The [Forum for Exchange of Information on Enforcement \(Forum\)](#) is a network of authorities responsible for the enforcement of the REACH, CLP, and PIC, POP and Biocidal Product regulations.

harmonisation of enforcement, in particular of REACH and CLP. The Forum will **extend its cooperation with existing enforcement networks**¹⁰², and the authorities involved in the enforcement of chemicals legislation¹⁰³ will **enhance cooperation to avoid duplication of actions** and increase effectiveness.

Ongoing activities are trying to improve compliance with environmental legislation relevant to chemicals¹⁰⁴. A good example is the **Environmental Compliance and Governance Forum**¹⁰⁵, which brings together Member States and environmental enforcement networks¹⁰⁶. The upcoming **Zero Pollution Action Plan** will initiate further specific actions to control chemical pollution by strengthening the implementation and enforcement of environmental legislation.

Actions to empower consumers will also be key, as their behaviour is a powerful driver to industrial change as well as to ensure compliance with legislation. Empowering consumers and consumer organisations will be pursued via the **implementation of relevant consumer protection rules**, such as the upcoming Directive on representative actions for the protection of the collective interests of consumers¹⁰⁷.

ZERO TOLERANCE TO NON-COMPLIANCE

The Commission will:

- further support a culture of compliance by economic operators, through proposals to **strengthen the principles of 'no data, no market' and 'polluter-pays' under REACH**, in particular by requiring **compliance of all registration dossiers** and allowing **market access only to those that are fully compliant** with registration requirements by revoking the registration number in case of non-compliance.
- introduce **the possibility for the Commission to carry out audits in Member States, where relevant, to examine all dimensions of compliance monitoring, promotion and enforcement of chemicals legislation**, in particular REACH. Those audits will aim at benchmarking the effectiveness of national enforcement systems and identifying challenges and potential solutions;
- propose **extending the coordination and investigation mandate of the European Anti-Fraud Office ('OLAF')**, to also include the circulation of illicit chemical products internally in the EU¹⁰⁸. Enabling complementary actions on chemicals, while ensuring a harmonised EU wide response and coordinated exchange of information

¹⁰² E.g. SLIC (occupational safety and health), PARCS (customs), IMPEL (waste and industrial emissions).

¹⁰³ I.e market surveillance authorities dealing with chemical legislation covering REACH, cosmetics, biocides, customs authorities, consumer protection authorities and agencies such as ECHA.

¹⁰⁴ For example, waste legislation and the Industrial Emissions Directive.

¹⁰⁵ European Commission, [Environmental Compliance and Governance Forum](#).

¹⁰⁶ IMPEL (inspectors), EnviCrimeNet (police), ENPE (prosecutors) and EUFJE (judges).

¹⁰⁷ Proposal for a Directive of the European Parliament and of the Council on representative actions for the protection of the collective interests of consumers, and repealing Directive 2009/22/EU, COM/2018/0184 final. The representative actions mechanism could be used to collectively enforce breaches of EU law instruments listed in the Annex I to the Directive, such as Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

¹⁰⁹ Regulation (EC) No 1367/2006.

based on all relevant Commission IT platforms;

- ensure **access to justice on behalf of environmental and consumer interests**, including through an amendment to the Aarhus Regulation¹⁰⁹.

3.4. Provide a comprehensive and transparent knowledge base on chemicals

The sound management of chemicals in Europe depends on the ability of the EU and its Member States to make their **decisions based on robust and relevant, up-to-date knowledge**. The EU has, over time, developed world-class knowledge on chemicals' properties and risks, also thanks to the work carried out by its scientific bodies, and this knowledge base has been widely used also in other parts of the world. Still, there is much knowledge to be acquired by authorities on the intrinsic properties of a vast majority of chemicals, including polymers and chemicals that are not manufactured in high volumes. Equally, knowledge on uses is fragmented, in particular as it relies on industry's willingness to provide accurate hazard and exposure information. The sheer number of chemicals on the market represents an immense knowledge challenge, and the expected future rise in chemical production and use risks further widening the 'unknown territory of chemical risks'.

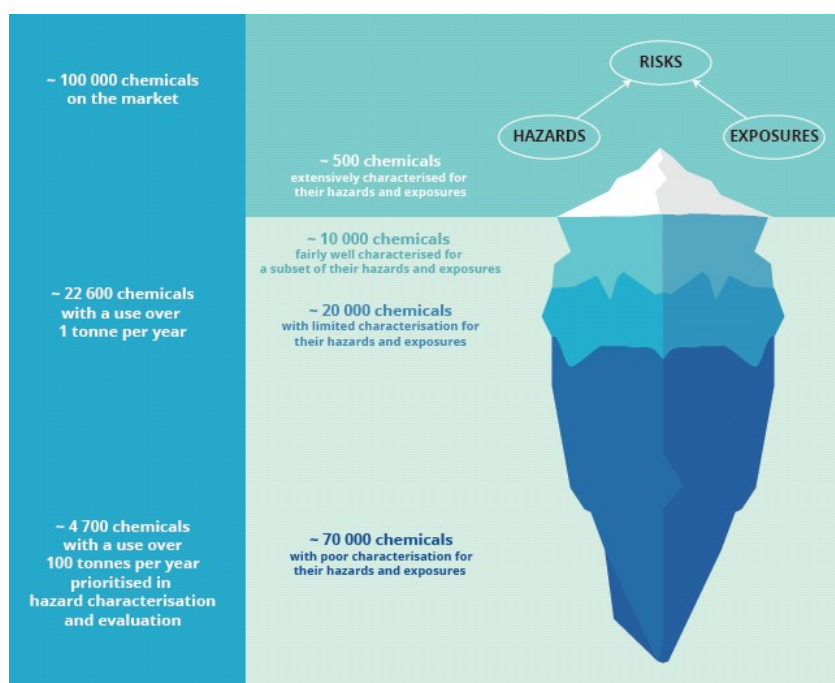


Figure: The unknown territory of chemical risks, EEA¹¹⁰

3.4.1. Improved access, availability and sharing of chemical data for citizens, authorities and industries

A comprehensive information base on all substances placed on the market is still missing in the EU, and this hinders the proper management of chemicals and products. In particular polymers, which are the fundamental building blocks of plastics, are not subject to

¹⁰⁹ Regulation (EC) No 1367/2006.

¹¹⁰ EEA, [The European Environment – State and outlook report](#), 2020, p. 239.

registration under REACH. As a general rule, only available information is required for substances in the lowest tonnages, while there are limited requirements to identify substances with critical hazard properties for the medium tonnage substances¹¹¹. Strengthening information requirements on the carcinogenicity of substances and on other critical hazards at all production levels plays a fundamental role to succeed in the fight against illnesses such as cancer, as it would allow **better and faster identification of substances that may cause them**¹¹². In addition, the efficiency and effectiveness of the evaluation procedures, implemented by ECHA, its Committees, the Member States and the Commission, need to be improved¹¹³.

DATA REQUIREMENTS

The Commission will:

- assess the impacts of and consider a proposal to **extend the duty of registration under REACH also to certain polymers** of concern;
- assess the impacts of and consider a proposal to amend REACH data requirements to enable an **effective identification of substances with critical hazard properties**, drawing from advancements in innovative tools, and being mindful of the aim to move away from dependency on animal data;
- assess the impacts of and assess possibilities to amend REACH **data requirements to allow for a better identification of carcinogenic substances manufactured or imported in the EU**;
- **step up measures to track harmful chemicals through the lifecycle of materials and products**¹¹⁴, including the waste phase, and to make this information available to value chain actors and, upon request, consumers. These tracking systems will build on current efforts¹¹⁵ and be developed in synergy with the future Digital Product Passports¹¹⁶, taking into account the ongoing work on supply chain communication for substances and mixtures¹¹⁷.

Past evaluation identified **shortcomings in interoperability, discoverability and accessibility of good-quality and reliable chemical data**. Interested parties are sometimes not aware of what information is available and where and how the existing data can be used and accessed, and re-use rights are sometimes too restrictive. Peer-reviewed studies are not easily available and discoverable and as a consequence they are not fully exploited in the regulatory work. There is a need to **better implement the EU Data Strategy principles for chemical data**, to ensure that data are created and reported once and used many times and that data and information are shared and re-used as widely as possible, also in line with the ‘one substance, one assessment’ process. Digital technologies offer the potential to improve the access and re-use for data, in particular for authorities and industry. Building on the

¹¹¹ Accompanying SWD on Art 138 of REACH.

¹¹² Review of REACH, [COM \(2018\) 0116](#)

¹¹³ *Ibid.*

¹¹⁴ In line with the Circular Economy Action Plan, [COM \(2020\) 98](#), and the REACH review, Action 4, [COM \(2018\)0116](#)

¹¹⁵ Notably, ECHA’s SCIP database.

¹¹⁶ [COM \(2020\)66](#).

¹¹⁷ Review of REACH review, [COM \(2018\)0116](#), Action 3.

important steps in terms of transparency put in place in the EU food safety sector¹¹⁸, it is also urgent to strengthen trust in the scientific underpinning of the overall EU decision-making process for chemicals risk management.

ACCESS AND SHARING OF DATA

The Commission will:

- as part of the European Green Deal Data Space¹¹⁹, develop a **common open data platform on chemicals** to facilitate sharing, access to and re-use of all information on chemicals coming from regulatory and non-regulatory sources, including from the private sector and civil society organisations.
- Assess the main barriers and examine options and impacts of a possible legislative proposal, where relevant and necessary, to **remove legislative obstacles for re-use of data** and to streamline the flow of chemical data among agencies, commission services and national authorities;
- develop a new tool for making **all relevant academic data easily and readily accessible** for the assessment and decision-making processes;
- consider establishing a new tool **to enable the Commission, EU agencies and national authorities to generate hazard and occurrence data** when further information is considered necessary, building on existing practices¹²⁰;
- evaluate the **transparency principles** from the EU food safety sector and consider a legislative proposal to **extend the principle of open data** to other pieces of chemical legislation.

Data will be progressively made available in appropriate formats to ensure interoperability. IUCLID¹²¹ and OECD Harmonised Templates will be promoted and progressively used as the principal format and tool to share chemical hazard and use data and classifications, while IPCHEM¹²² will be used for sharing chemical occurrence data.

Those efforts will feed and be complemented by a **comprehensive system of indicators** to monitor the drivers and impacts of chemical pollution as part of a wider Zero Pollution Monitoring and Outlook framework as well as to measure the effectiveness of chemicals legislation through the implementation of the upcoming 8th Environment Action Programme and the Environment Implementation Review¹²³.

3.4.2. A strengthened chemical science-policy interface

¹¹⁸ In particular in terms of mandatory notification of commissioned studies as well as in terms of the obligation to proactively make publically accessible all scientific data and information; on the transparency and sustainability of the EU risk assessment in the food chain.

¹¹⁹ Announced under the [EU data strategy](#)

¹²⁰ Such as the REACH substances evaluation, the watch lists under the water framework and the ground water directives, Land Use and Coverage Area frame Survey, HBM4EU, the European Partnership for Risk Assessment.

¹²¹ ECHA, [IUCLID](#).

¹²² European Commission, [IPCHEM](#).

¹²³ European Commission, [Environment Implementation Review](#).

Several efforts have been put in place to **improve the scientific understanding of the impacts of chemicals on health and the environment**. Monitoring the presence of chemicals in humans and ecosystems is particularly key to improve the understanding of their impact, and should be further promoted, including to understand the links between chemicals and gender¹²⁴. Building on acquired experience and knowledge, the Commission will continue to **support research to understand and prevent chemicals-related risks and drive innovation in chemical risk assessment to protect citizens and the environment** through its future framework programme for research and innovation and the newly established EU4Health programme.

Since 2013; the EU adopted a successful non-animal testing approach[1] for Cosmetic products. However, despite a strong EU policy for the **protection of animals used for scientific purposes**, adopted ten years ago, which makes full replacement of animal testing its ultimate goal, animals are still required to be used systematically in the field of chemicals.¹²⁵ In 2017, over 230.000 animal uses were carried out in the EU for satisfying requirements under chemicals legislation.¹²⁶ **Safety testing and chemical risk assessment need to innovate** in order to reduce dependency on animal testing, but also to be able to face persistent and emerging challenges and to overall improve the quality, efficiency and speed of chemical hazard and risk assessments on humans (with a focus on specific population groups), ecosystems and biodiversity.

KNOWLEDGE NEEDS

The Commission will:

- establish a **long term research and innovation agenda for chemicals** under Horizon Europe, with significant funding, driven by a EU-level Coordination Group *[placeholder to insert name for the Group, e.g. from a famous woman chemist]* that will involve EU and member states' representatives, and liaise with relevant stakeholders. The group will regularly identify and define how to address knowledge gaps jointly at EU-level and promote the regulatory uptake of research findings, including how best to foster new approaches to reduce animal testing;
- support multidisciplinary research as well as digital transformations in order to provide **advanced tools, methods and models, new data and data analysis capacities**¹²⁷ **to move away from animal testing**. Better science-policy interface and reinforced skills would also help to promote their regulatory recognition and uptake;
- support the development of **EU-wide human and environmental (bio)monitoring capacities** with harmonised governance, collection and storage (bio-banks), to feed and complement existing and future ecosystem monitoring initiatives¹²⁸ and their use to support early regulatory action in response to scientific evidence;
- develop a **EU Early Warning and Action System for chemicals**, building on and in connection with ongoing initiatives¹²⁹, to ensure that EU policies address emerging

¹²⁴ While policymakers begin to understand the role played by the sound management of chemicals in economic and social development, it is also important to recognize the significant linkages between gender and chemicals, but gender specific data on the exposure to and impact of chemicals is still largely missing. UNDP, [Chemicals and Gender](#), 2015.

¹²⁵ Directive 2010/63/EU

¹²⁶ [SWD/2020/10 final](#)

¹²⁷ E.g. predictive toxicology or virtual human platforms

¹²⁸ E.g. monitoring initiatives under EU environment legislation and monitoring schemes such as [LUCAS](#), EMBAL, the upcoming EU Soil Observatory and the [EU pollinator monitoring](#).

¹²⁹ Such as the RAPEX safety gate.

chemical risks as soon as they are identified through monitoring and research initiatives.

3.5. The EU setting the example and leading policies for the sound chemicals management globally

The Global Chemicals Outlook¹³⁰ has highlighted how **production, use and trade of chemicals are growing in all regions, driven by global megatrends**. The size of the global chemical industry exceeded 4 trillion euros in 2017 and is projected to double by 2030¹³¹. Chemical-intensive sectors (e.g. construction, agriculture, electronics) are growing, raising the demand for chemicals and creating both risks and opportunities. Chemical pollution has been identified as a significant and “almost certainly underestimated” contributor to the global burden of disease¹³², threatening the right to life and in particular the right to a life with dignity, notably for children¹³³. A UN report highlights that exposure to hazardous substances is the **single largest source of premature death in the world, causing and contributing to a silent pandemic of diseases and disabilities**¹³⁴, with strongest impacts happening in low and middle-income countries¹³⁵. The benefits of actions to minimise adverse impacts have been estimated in the high tens of billions euros annually¹³⁶.

The sound management of chemicals and waste has been recognised as an **essential crosscutting element to implement the 2030 Agenda and meet the Sustainable Development Goals (SDGs)**. Although much has been done at all levels and many international instruments are in place, it is widely acknowledged that the global commitment to reach the sound management of chemicals and waste by 2020¹³⁷ will not be met¹³⁸. **A real sense of urgency is needed**. Progress remains slow and insufficient and enhanced efforts at multilateral, regional and national levels are required to meet the 2020 goal without further delay. Governments, international and regional organisations, the industry, consumers and civil society, scientists and academia and all other relevant stakeholders need to significantly step up their efforts to ensure the sound management of chemicals throughout their lifecycle.

The European Union can and has to play a leading role globally, in particular to champion the strengthening of international standards, to promote the highest standards for chemicals management in the multilateral arena, and to cooperate with third countries by sharing knowledge, data and experience.

3.5.1. Strengthening international standards on chemicals management

A wide diversity of international, regional and national instruments and responses associated with the sound management of chemicals and waste are already in place. However, the **global**

¹³⁰ UNEP, [Global Chemicals Outlook II](#), 2019.

¹³¹ *Ibid.*

¹³² [The Lancet Commission on health and pollution](#), 2017

¹³³ Human Rights Committee, general comment No. 36 on the right to life, 2018.

¹³⁴ Report of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes, [A/74/480](#), 2019

¹³⁵ UNEP, [Global Chemicals Outlook II](#), 2019.

¹³⁶ *Ibid.*

¹³⁷ Target 12.4 of the Sustainable Development Goals, 2030 Agenda for Sustainable Development: ‘By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment’.

¹³⁸ UNEP, [Global Chemicals Outlook II](#), 2019.

governance remains extremely fragmented and standards and compliance vary widely across countries. This fragmentation has hampered the overall impact and effectiveness of existing organisations, programmes and initiatives. As of 2018, for example, more than 120 countries had not implemented the Globally Harmonized System of Classification and Labelling of Chemicals.¹³⁹

The EU will continue to lead efforts towards an ambitious international framework for the sound management of chemicals and waste, which addresses the current fragmentation by fostering coherent and complementary policies and action by all relevant international organisations and instruments¹⁴⁰, by governments and by all stakeholders, including industry. An essential element is to reach a multilateral agreement on a **renewed Strategic Approach to International Chemicals Management (SAICM) to fully address the sound management of chemicals throughout their lifecycle**, including chemicals in products and materials and their waste phase. In addition, the EU, together with its Member States, will advocate to mainstream the sound management of chemicals and waste throughout their lifecycle in the programmes of work of all relevant international organisations, in particular the participating organisations of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). Such mainstreaming will promote coherence of policies and actions under the 2030 Agenda for Sustainable Development.

INTERNATIONAL LEADERSHIP

The EU will:

- step up its international advocacy in various *fora* and through various instruments, to **meet the goals and targets of the 2030 Agenda regarding the sound management of chemicals throughout their lifecycle**, including the promotion of EU standards globally; **strive for the adoption of global Strategic Objectives and Targets for the sound management of chemicals and waste beyond 2020**, to reflect lifecycle approaches for chemicals, including with the post-2020 biodiversity targets. Those should be endorsed by and reflected in the programmes of all relevant international organisations to support the achievement of the respective goals and targets of the 2030 Agenda;
- promote the use of the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** as the means for identification of chemical hazards and communication to operators, workers and consumers;
- strengthen the UN GHS by submitting a **proposal to introduce new criteria or hazard classes** for PBTs/vPvBs, terrestrial toxicity, endocrine disruptors, persistency and mobility, and step up the protection from hazardous chemicals through **international instruments in the area of chemicals**, notably the Stockholm, Rotterdam and Minamata Conventions;
- promote the **development of common standards and innovative risk assessment tools internationally**, notably with the OECD, and promote their use under international frameworks to shift away from unnecessary animal testing, in particular by **adapting the UN GHS criteria to alternative methods**;
- track and **assess progress by the EU and its partners** in relation to implementation of chemicals-related Multilateral Environmental Agreements.

¹³⁹ UNEP, [Global Chemicals Outlook II](#), 2019.

¹⁴⁰ E.g. UNEP; WHO; ILO; UNIDO; World Bank; OECD; SAICM; MEAs; etc..

3.5.2. Promoting the highest safety and sustainability standards outside the EU

Global growth in chemicals sales will double by 2030 while the estimated global share of the EU chemical industry is expected to shrink to about 10.7%¹⁴¹. Much of the expected rise in chemical production will shift to developing countries and economies in transition, where manufacturing costs are lower and regulation for the production and management of chemicals and products is often less stringent.

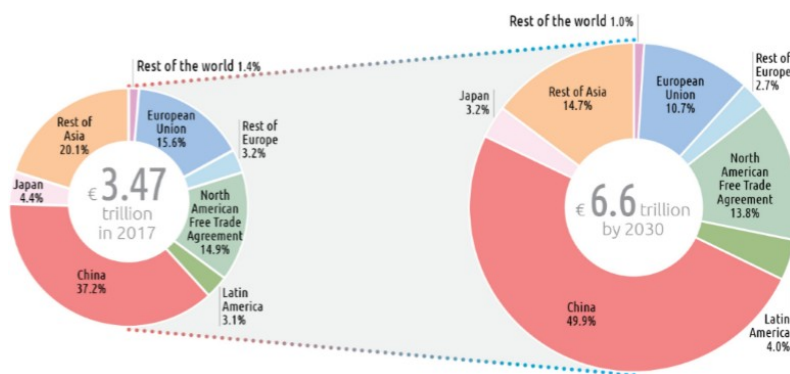


Figure: Projected growth in world chemical sales, 2017-2030. European Chemical Industry Council (2018)¹⁴²

The EU chemicals legislation has positioned the **EU as frontrunner in health and environmental protection** from hazardous chemicals and is expected to increasingly serve as a model for international and third countries' standards as awareness of the environmental and human health risks increases. The EU must also leverage its weight in the world to advocate for safe and sustainable-by-design approaches globally, in order to level the playing field and increase the market share for companies that produce and use safe and sustainable chemicals.

As chemical production and use is expected to grow in developing and neighbouring countries, increased cooperation, coordination and support to achieve sound management of chemicals is imperative. The EU is committed to **supporting partner countries' capacity to meet their international obligations and to adopt and enforce high environmental, health and social standards**. It will promote and mainstream the sound management of chemicals through their lifecycle and the transition to a toxic-free and circular economy as essential crosscutting elements for sustainable development, building on ongoing initiatives and taking into account policy coherence for development.

An essential element of the EU's international action on the sound management of chemicals is the **sharing of the EU's knowledge base and data, notably to support developing countries**, but also for the benefit of mutual acceptance of data amongst OECD and other relevant countries. This is key to avoid duplication of work, save resources and support international standards. Furthermore, the existing **knowledge base and experience of ECHA**, within its mandate, should be put to the benefit of EU international policies and leadership.

¹⁴¹ The EU contribution to world chemical sales already dropped from 26.5% in 2008 to 16.9% in 2018. CEFIC, [2020 facts and figures of the European Chemical industry](#).

¹⁴² CEFIC, [2018: Facts & Figures of the European Chemical Industry](#), p. 34

The EU will also continue to **support partner countries in the implementation of chemicals related international instruments**, including through the Special Programme for the sound management of chemicals and waste established under the UN Environment Assembly (UNEA). It will also ensure follow-up action to the resolutions on the sound management of chemicals and waste adopted by the UNEA, including in particular the work by UNEP.

COOPERATION WITH THIRD COUNTRIES

The EU will:

- promote the **sound management of chemicals through its international cooperation** with all its partners, in bilateral, regional and multilateral fora and through EU external financial and technical assistance instruments and programmes. This will include cooperation with Africa, in line with the **EU-Africa Strategy**, neighbours and other partners, taking into account distinct challenges in different parts of the world, to support third countries' capacity to assess and manage chemicals in a sound manner.
- promote **through EU's trade agreements the enforcement of MEAs and that partners increasingly respect high standards** of protection for the environment and human health;
- lead by example, and in line with international commitments, by **promoting a single approach to the exports and imports of hazardous chemicals**, notably by further restricting the export of chemicals and products banned in the European Union and by ensuring that products placed on the EU market respect the EU's legislative requirements;
- promote **due diligence for the production and use of chemicals** within the upcoming initiative on sustainable corporate governance;
- launch a **global pledging campaign** to progressively substitute the most hazardous chemicals.

4. CONCLUSIONS

This strategy is an opportunity to **reconcile the societal value of chemicals with human health and planetary boundaries**, while urgently addressing the legacy that chemical pollution resulting from current production and consumption patterns is bequeathing to future generations, in terms of climate change, biodiversity loss, IQ decline and chronic diseases. It is also the opportunity to respond to EU citizens' legitimate aspirations for a higher level of protection from hazardous chemicals and to promote the EU industry as global frontrunner in the production and use of safe and sustainable chemicals. The aim of this strategy is to provide a critical contribution to moving towards a Zero Pollution ambition for a toxic-free environment, for the good of people, the planet and society as a whole. This transition requires a shift of the industrial and societal mind-set: a joint effort of all actors, in particular public authorities, industry producing and using chemicals, researchers, non-governmental organisations and citizens.

The Commission invites the European Parliament and the Council to endorse this strategy and to contribute to its implementation. The Commission will reach out to citizens and stakeholders in a coordinated way to encourage them to actively participate.

The Commission will ensure that this strategy is implemented in close coherence with the other elements of the Green Deal – in particular the EU Biodiversity Strategy for 2030, the new Circular Economy Action Plan, the Climate Law, the Farm to Fork Strategy, and the Zero Pollution Action Plan - as well as with the Industrial Strategy, the Digital Agenda, the Pharmaceuticals Strategy and the Europe's Beating Cancer Plan. The measures presented in this strategy will all need to be taken forward in line with the better regulation principles, including evaluations and impact assessments as appropriate, and will need to live up to the green oath: 'do no harm'.