

2.2. Stronger EU legal framework to address pressing environmental and health concerns

Although the EU's approach to chemicals management has been effective in reducing human and environmental exposures to certain problematic substances, ongoing and emerging health and environmental concerns call for a **strengthening of the legal framework** to rapidly respond to scientific findings, making it more coherent, simple and predictable for all actors. In particular, the **REACH and CLP Regulations** should be reinforced as EU's **cornerstones for regulating chemicals**, and be complemented by **coherent approaches to assess and manage chemicals** in existing sectorial legislation, especially that regulating consumer products.

2.2.1. *Protect consumers, vulnerable groups and workers from the most harmful chemicals*

Consumers are widely exposed to chemicals present in products, from toys and childcare articles to food contact materials, cosmetics, furniture and textiles, to name a few, and millions of workers across the EU daily come into contact with chemical agents that can be harmful to them³⁸. Vulnerable population groups - such as children, pregnant women and elderly people - are particularly sensitive to chemicals with certain hazardous properties³⁹.

One of the biggest health benefits of the EU chemicals legislation in the past decades has been the reduction in the exposure of citizens to carcinogenic substances. This has been possible in particular thanks to a **preventive approach across legislation** - the '**generic approach to risk management**'⁴⁰ - which means that carcinogenic substances have been generally banned from most consumer products and for uses that expose vulnerable groups, while allowing limited exemptions under conditions clearly defined in law. Such preventive approach is **simpler, generally faster and provides clear signals to all actors** - enforcement authorities, industry and downstream users - on the types of chemical substances where **innovation** should be prioritised by the industry⁴¹.

However, the vast majority of chemicals in the EU is currently regulated on a case-by-case basis and for each specific use⁴². Ample evidence and citizens' worries justify that for the most harmful chemicals **the generic approach to risk management becomes the default**

³⁷ E.g. European structural and investment funds, the Just Transition Mechanism, European Strategic Investment Funds, ReactEU, Horizon Europe, subject to compliance with State aid rules when they apply.

³⁸ For chemicals where the workplace exposure is determined to be the dominating risk, the occupational safety and health directives are particularly relevant.

³⁹ SWD(2019) 199.

⁴⁰ In the EU legislative framework for chemicals, a 'generic approach to risk management' is an automatic trigger of pre-determined risk management measures (e.g. packaging 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). SWD(2019) 199.

⁴¹ SWD(2019) 199.

⁴² 'Specific risk assessments' consider the hazard, the use of the substances and related specific exposure scenarios for humans and the environment, and risk management measures are triggered based on their outcomes. SWD(2019) 199.

option, in particular as regards their use in consumer products. This will be done gradually. Firstly, the Commission will extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative. Secondly, the Commission will immediately launch a comprehensive impact assessment to define the modalities and timing for extending the same generic approach, with regard to consumer products, to further chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.

Extending the generic approach will ensure that consumers, vulnerable groups and the natural environment are more consistently protected, while still allowing for the use of these most harmful chemicals where proven **essential for society**. The criteria for essential uses of these chemicals will have to be properly defined to ensure coherent application across EU legislation, and will in particular take into consideration the needs for achieving the green and digital transition.

PROTECTION AGAINST MOST HARMFUL CHEMICALS

The Commission will:

- extend the generic approach to risk management to ensure that **consumer products** – including, among other things, food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textiles - do not contain chemicals that cause **cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative**. In addition, immediately launch a comprehensive impact assessment to define the modalities and timing for extending the same generic approach, with regard to consumer products, to further harmful chemicals, including those affecting the **immune, neurological or respiratory systems and chemicals toxic to a specific organ**;
- in the meantime, while the generic approach to risk management is not in place, **prioritise all the above-listed substances for restrictions** for all uses and through grouping, instead of regulating them one by one;
- ensure the safety of children⁴³ from hazardous chemicals in **childcare articles** and other products for children (other than toys) to provide the same level of protection as in toys, through the mandatory legal requirements of the General Product Safety Directive and restrictions in REACH;
- define **criteria for essential uses**⁴⁴ to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments;
- extend to **professional users** under REACH the level of protection granted to consumers;

⁴³ The right to health for children will also be addressed in the upcoming EU Strategy on the right of the child.

⁴⁴ Taking into account the definition of essential uses in the Montreal Protocol on Substances that Deplete the Ozone Layer, which was introduced to assess whether the use of certain chemicals is actually necessary, while acknowledging that the scope of chemicals covered by the EU chemicals regulatory framework is much broader than the specific scope of chemicals covered by the Montreal Protocol.

- **strengthen protection of workers** by defining, in the process of the upcoming Strategic Framework for Health and Safety at work, further priorities for addressing workers' exposure to hazardous substances, including by identifying most harmful substances for which the Commission will propose to set occupational limits following the established consultation process in the area of health and safety at work. Also, **strengthen protection of workers**, notably by proposing lowering existing occupational limit values for lead and asbestos and establishing a binding limit value for di-isocyanates.

The exposure of humans and the environment to **endocrine-disrupting chemicals** requires **specific attention**. These substances are increasingly linked to diseases acting via the hormonal system⁴⁵. Their use is on the rise, representing a serious risk to human health and wildlife as well as creating an economic cost for society. As hormones control brain development and growth, exposure to endocrine-disruptors during foetal development and puberty can lead to irreversible effects, some being detected only many years later⁴⁶. Although some pieces of legislation⁴⁷ are able to identify endocrine disruptors, the EU regulatory system is overall fragmented, limited and needs to be consolidated and simplified to ensure that endocrine disruptors are recognised in a timely manner and that exposure of humans and the environment is minimised. This requires the adoption of the preventive generic approach to risk management across legislation⁴⁸, especially to avoid the use of endocrine disruptors in consumer products.

ENDOCRINE DISRUPTORS

The Commission will:

- propose to establish **legally binding hazard identification** of endocrine disruptors, based on the definition of the WHO, building on criteria already developed for pesticides and biocides, and apply it across all legislation;
- ensure that **endocrine disruptors are banned in consumer products** as soon as they are identified, allowing their use only where it is proven to be essential for society;
- **strengthen workers' protection** by introducing endocrine disruptors as a category of substances of very high concern under REACH;
- ensure that sufficient and appropriate **information is made available to authorities** to allow the identification of endocrine disruptors by reviewing and strengthening information requirements across legislation;
- accelerate the development and uptake of **methods to generate information** on endocrine disruptors through screening and testing of substances.

2.2.2. *Protecting people and the environment from the combination effects of chemicals*

⁴⁵ Endocrine-related disorders impact in particular the functioning of the thyroid, the immune system, the reproduction system and the overall human metabolism. SWD(2020) 249.

⁴⁶ C. Ganzleben, A. Kazmierczak, *Leaving no one behind – understanding environmental inequality in Europe*, 2020.

⁴⁷ REACH Regulation; Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market; and Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

⁴⁸ SWD(2020) 249.

People and other living organisms are daily exposed to a **wide mix of chemicals originating from various sources**. Significant progress has been made in recent years to close some knowledge gaps on the impact of the combination effect of those chemicals. However, the safety of chemicals in the EU is usually assessed through the evaluation of single substances, or in some cases of mixtures intentionally added for particular uses, without considering the combined exposure to multiple chemicals from different sources and over time⁴⁹. For people, the combination effects of chemicals may intensify in closed environments. Some pieces of legislation⁵⁰ require to assess the cumulative exposure to the same chemical from different sources. Explicit requirements to take into account the impact of **unintentional mixtures** is generally lacking, currently existing for the protection of workers⁵¹. The pesticides and biocides legislation require to consider cumulative and synergistic effects⁵². For pesticides, progress has been made in developing a targeted methodology, and work will be accelerated so that existing provisions can be fully implemented⁵³.

To adequately address the combination effect of chemical mixtures, legal requirements need to be consistently in place to ensure that risks from simultaneous exposure to multiple chemicals are effectively and systematically taken into account across chemicals-related policy areas. As it is currently not realistic nor economically feasible to specifically assess and regulate an almost infinite number of possible combinations of chemicals, scientific consensus is emerging that the effect of chemical **mixtures needs to be taken into account and integrated more generally into chemical risk assessments**.⁵⁴ In parallel, targeted methodologies could be further developed and explored for specific policy areas.

CHEMICAL MIXTURES

The Commission will:

- assess how to best introduce in REACH (a) **mixture assessment factor(s)** for the chemical safety assessment of substances;
- introduce or reinforce provisions to take account of the **combination effects in other relevant legislation**, such as legislation on water, food additives, toys, food contact material, detergents and cosmetics;
- improve the assessments of the **mixtures used in the manufacture of tobacco and related products** by using where possible existing EU agencies⁵⁵.

⁴⁹ SWD(2020) 248.

⁵⁰ E.g. food contact materials and environmental legislation; SWD(2020) 248

⁵¹ Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (*OJ L 131, 5.5.1998*) foresees that the risk presented by a combination of chemical agents shall be assessed and managed.

⁵² SWD(2020) 248.

⁵³ This will be done initially under the Regulation (EC) No 396/2005 on maximum residue levels of pesticides and in a second phase under the Regulation on Plant Protection Products.

⁵⁴ SWD(2020) 248.

⁵⁵ Directive 2014/40/EU on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products. *OJ L 127, 29.4.2014*.

2.2.3. Towards zero chemical pollution in the environment

Hazardous chemicals and their complex interaction with other environmental stressors can have **long-term and large-scale environmental** impacts on the terrestrial and marine environment. They can contribute to the reduction of ecosystem resilience, leading to rapid declines in animal populations and, ultimately, to extinctions⁵⁶, as well as impacting human health and wellbeing, not least through the possible presence of contaminants in the food chain. 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 soils⁵⁷. The current regulatory and policy framework struggles to take this into account and needs to be strengthened.

CHEMICAL POLLUTION IN NATURAL ENVIRONMENT

The Commission will:

- propose new hazard classes and criteria in the CLP Regulation to fully address **environmental toxicity, persistency, mobility and bioaccumulation**;
- introduce **endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances** as categories of substances of very high concern;
- ensure that the information made available to authorities on substances allows comprehensive **environmental risk assessments** by strengthening requirements across legislation;
- address the **impact** on the environment of the production and use of **pharmaceuticals** in the upcoming pharmaceuticals strategy for Europe⁵⁸;
- support research and development for **decontamination solutions** in terrestrial and aquatic environments;
- reinforce the regulation of **chemical contaminants in food** to ensure a high level of human health protection.

Per- and polyfluoroalkyl substances (PFAS) require special attention, considering the large number of cases of contamination of soil and water - including drinking water⁵⁹ - in the EU and globally⁶⁰, the number of people affected with a full spectrum of illnesses and the related societal and economic costs⁶¹. That is why the Commission proposes a comprehensive set of actions to **address the use of and contamination with PFAS**. Those aim to ensure, in particular, that the use of PFAS is phased out in the EU, unless it is proven essential for society.

⁵⁶ COM(2019) 264.

⁵⁷ European Commission, *Status of local soil contamination in Europe*, 2018.

⁵⁸ And following up the Strategic Approach to Pharmaceuticals in the Environment, COM(2019) 128.

⁵⁹ WHO, *Keeping our water clean: the case of water contamination in the Veneto Region, Italy*, 2017.

⁶⁰ 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.

⁶¹ Costs from exposure to PFAS in Europe have been estimated between EUR 52 and EUR 84 billion per year; *Ibid.*

PFAS⁶²

The Commission will:

- ban **all PFAS** as a group in **fire-fighting foams** as well as in **other uses**, allowing their use only where they are essential for society;
- address PFAS with a **group approach**, under relevant legislation on water, sustainable products, food, industrial emissions, and waste;
- address PFAS **concerns on a global scale** through the relevant international fora⁶³ and in bilateral policy dialogues with third countries;
- establish an EU-wide approach and provide financial support under research and innovation programmes to identify and develop **innovative methodologies for remediating PFAS contamination** in the environment and in products;
- provide research and innovation funding for safe **innovations to substitute PFAS** under Horizon Europe.

2.3. Simplifying and consolidating the legal framework

The EU regulatory framework for hazard and risk assessment and management of chemicals is **comprehensive and complex**. Overall, EU chemicals legislation delivers results as intended and is fit-for-purpose. However, a number of significant weaknesses prevent the EU chemicals legislation from living up to its full potential⁶⁴. If not rapidly addressed, the framework will struggle to timely and efficiently cope with the current and future production and use of chemicals. A key ambition of this strategy is to ensure **simplification of this framework**, as well as the **consolidation and full implementation** of the EU rules on chemicals.

2.3.1. *One substance, one assessment*

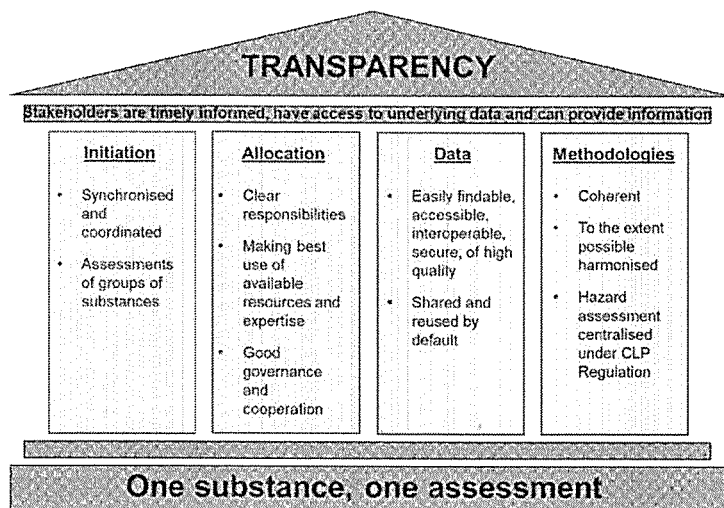
The complexity of assessment procedures represents a specific challenge for authorities and stakeholders. It can lead to inconsistencies, slow procedures, inefficient use of resources and unnecessary burdens.

The Commission will strive to make those assessment processes **simpler and more transparent**, in order to reduce the burden on all stakeholders and to make decision-making faster as well as more consistent and predictable. This process will also support the gradual move away from assessing and regulating chemicals substance-by-substance to regulating them by groups.

⁶² More details in SWD(2020) 247.

⁶³ Stockholm, Rotterdam and Basel Conventions and OECD.

⁶⁴ [COM\(2019\)264](#).



Chemical safety assessments are being initiated under various pieces of legislation, by various actors and at different points in time, and they are carried out by various EU agencies⁶⁵, scientific committees⁶⁶, expert groups or Commission departments. Stakeholders and the general public struggle to keep track of regulatory processes and resulting decisions. ‘One substance, one assessment’ will ensure that the **initiation and priority setting** of the safety assessments are done in a coordinated, transparent and to the extent possible synchronised manner taking into account the specificities of each sector. When an assessment is proposed under one piece of legislation, full account shall be taken of the planning under other pieces of legislation, so that coordinated action is ensured. This could be most efficiently done by building on the success of the ‘Public Activities Coordination Tool’, the existing mechanism in place under REACH and CLP⁶⁷. To avoid duplication of work, early agreement on the problem definition will be key, favouring the assessment by groups of substances with structural or functional similarities. The use of available resources and expertise shall be optimised, through a clear **allocation of responsibilities** as well as good cooperation among all actors.

COORDINATE AND SIMPLIFY ACTIONS ACROSS EU CHEMICAL LEGISLATION

The Commission will:

- use a single ‘Public Activities Coordination Tool’ to provide an up-to-date **overview of all planned and ongoing initiatives** on chemicals by authorities across legislation;
- establish an expert **working group of Member States, Commission services and EU Agencies**⁶⁸ to discuss initiatives on hazard/risk assessment on chemicals across chemical legislation, taking into account also the specificities of the sector

⁶⁵ The European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the European Medicines Agency (EMA) and the European Environment Agency (EEA).

⁶⁶ Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), Scientific Committee on Consumer Safety (SCCS).

⁶⁷ ECHA, Public Activities Coordination Tool.

⁶⁸ EFSA, ECHA, EMA and EEA.

concerned;

- establish a **coordination mechanism** within the Commission to agree and synchronise, to the extent possible, actions across chemical legislation as regards hazard identification/classification and risk assessment and oversee the process towards ‘one substance, one assessment’;
- rationalise the use of expertise and resources by proposing the **reattribution of technical and scientific work** on chemicals performed under the relevant pieces of legislation to European agencies, including work of the SCHEER and SCCS⁶⁹;
- make a proposal to strengthen the **governance of the European Chemicals Agency** and increase the sustainability of its financing model;
- reform the **REACH authorisation and restriction** processes based on key findings from its practical implementation⁷⁰.

In order to achieve consistency of regulatory outcomes, EU chemicals legislation need to use **coherent terminology**, in particular to define chemicals (e.g. nanomaterials). Policy evaluations also show that interested parties are not always aware of what information is available, and that re-use rights are sometimes too restrictive. They also highlight a number of shortcomings in the interoperability and accessibility of **chemical data**⁷¹. In addition, regulatory safety assessments use **various methodologies**, which may lead to incoherent outcomes, while **academic studies** are not sufficiently exploited. Different **transparency rules** are also applied to the initiation and performance of assessments and data use.

The ‘one substance, one assessment’ approach aims to ensure that methodologies are made more coherent and to the extent possible harmonised. It strives to free the data access of technical or administrative obstacles, according to the principles that data should be **easily findable, interoperable, secure, shared and reused by default**⁷². Data will be made available in appropriate formats and tools – i.e. IUCLID⁷³ and IPCHEM⁷⁴ - to ensure interoperability. ‘One substance, one assessment’ will also build greater trust in the scientific underpinning of the EU decision-making process for chemicals, building on the important steps taken regarding transparency in the EU food safety sector⁷⁵.

METHODOLOGIES AND DATA

The Commission will:

- ensure that the CLP Regulation is the **central piece for hazard classification** and allows the Commission to initiate harmonised classifications⁷⁶;

⁶⁹ Scientific Committee on Health, Environmental and Emerging Risks and Scientific Committee on Consumer Safety.

⁷⁰ REACH Review, COM(2018) 0116.

⁷¹ COM(2019) 264.

⁷² In line with the EU data strategy.

⁷³ ECHA, IUCLID.

⁷⁴ European Commission, IPCHEM.

⁷⁵ In particular in terms of mandatory notification of commissioned studies and accessibility of all scientific data and information, as defined for the transparency of the EU risk assessment in the food chain. See Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain *OJL 231, 6.9.2019*.

⁷⁶ In particular by adding endocrine disruptors, and PBTs/vPvBs, assessing the need for specific criteria for immunotoxicity and neurotoxicity, currently under the hazard endpoints ‘Specific target organ toxicity’ and ‘reproductive toxicity’, and amend them if necessary.

- review the **definition of nanomaterial**⁷⁷ and ensure its coherent application across legislation using legally binding mechanisms;
- develop a **common open data platform** on chemicals⁷⁸ to facilitate the sharing, access and re-use of information on chemicals coming from all sources;
- promote reuse and harmonisation of **human and environmental health-based limit values**⁷⁹ among EU risk assessors and managers through a centralised and curated EU repository;
- establish tools and practices to ensure that relevant **academic data** is easily and readily accessible for safety assessments and is suitable for regulatory purposes;
- enable EU and national authorities to commission **testing and monitoring of substances** as part of the regulatory framework when further information is considered necessary⁸⁰;
- remove **legislative obstacles for the re-use of data** and better streamline the flow of **chemical data** between EU and national authorities;
- extend the principle of **open data** and the relevant **transparency principles** from the EU food safety sector to other pieces of chemical legislation.

2.3.2. *A zero tolerance approach to non-compliance*

All chemicals, materials and products produced in the EU or placed on the European market must fully comply with 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, with almost 90% of those products coming from outside the EU⁸¹ and **imported articles** and **online sales** representing a particular challenge. Equally, only one third of the registration dossiers of the chemical substances registered by industry under REACH are fully compliant with the information requirements⁸². Stepping up implementation and enforcement of chemicals legislation is urgently needed to ensure compliance for the production and placing on the market of chemicals as well as for their release and disposal.

The implementation of the new market surveillance Regulation⁸³ as well as the forthcoming measures to reinforce the EU Customs Union will strengthen enforcement both within the single market and at the EU's external borders. The Commission is considering which

⁷⁷ As set in Recommendation 2011/696/EU on the definition of nanomaterial *OJ L 275, 20.10.2011*.

⁷⁸ As part of the European Green Deal data space announced under the [EU data strategy](#).

⁷⁹ E.g. PNECs, DNELs, health based occupational exposure limit values, water quality standards, maximum total daily intake, etc.

⁸⁰ Building on existing practices, 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, and the proposed European Partnership for Risk Assessment.

⁸¹ Data extracted from the EU's [Safety Gate/Rapex](#).

⁸² The European Commission concluded in the REACH Review that the non-compliance of registration dossiers was a key issue hampering progress. ECHA and the Commission have in the meantime developed a [Joint Action Plan](#) to step up compliance checks on all registration dossiers.

⁸³ Regulation (EU) 2019/1020 on market surveillance and compliance of products, which will enter into application in July 2021 *OJ L 169, 25.6.2019*.

additional measures could be put in place to strengthen the enforcement of REACH at the EU's borders⁸⁴, as well as to promote cooperation with online market platforms⁸⁵.

Furthermore, enforcement of EU chemicals legislation is not equally effective throughout the EU, due to the different capacities and resources at national level. Member States must increase their **enforcement capacity** to levels where they can be effective, allowing to reap the benefits from the EU's rapid information and alert tools⁸⁶, better exploit **digital tools** for faster action and optimise resources, including of market surveillance authorities. The European Chemicals Agency's Forum for exchange of information and enforcement⁸⁷ has proven effective in advancing the harmonisation of enforcement and will extend its cooperation with existing **enforcement networks**⁸⁸ and authorities⁸⁹ to avoid duplication of actions and increase effectiveness.

Ongoing activities aim at improving compliance with environmental legislation relevant to chemicals⁹⁰. A good example is the **Environmental Compliance and Governance Forum**⁹¹, which brings together Member States' chemicals authorities and environmental enforcement networks⁹². The upcoming **zero pollution action plan** will initiate further specific actions to control chemical pollution.

Actions to **empower consumers** and **consumer organisations** will also be key, as their behaviour is a powerful driver to industrial change and to ensuring compliance with legislation. This will be pursued by implementing **consumer protection rules**⁹³.

ZERO TOLERANCE FOR NON-COMPLIANCE

The Commission will:

- strengthen the principles of 'no data, no market' and the 'polluter-pays' under REACH, in particular by requiring **compliance of all registration dossiers** and revoking the registration numbers in case of non-compliance;
- propose to entrust the Commission with the duty to carry out **audits in Member States**, where relevant, to ensure compliance and enforcement of chemicals legislation, in particular REACH, and use infringement procedures as necessary;
- target known **areas of high risk of non-compliance**, in particular online sales,

⁸⁴ A study is currently ongoing on how to integrate REACH requirements into customs processes. This will be followed by an impact assessment to identify options forward.

⁸⁵ A number of online platforms have signed a Safety Pledge to remove from their online listings any product reported in Safety Gate/RAPEX.

⁸⁶ RAPEX and RASFF are tools which inform consumers and Member States authorities in case of products posing a risk; Safety gate for consumers.

⁸⁷ The Forum for Exchange of Information on Enforcement (Forum) is a network of authorities responsible for the enforcement of the REACH, CLP, PIC, POP and the biocidal products Regulations.

⁸⁸ E.g. SLIC (occupational safety and health), PARCS (customs), IMPEL (waste and industrial emissions).

⁸⁹ I.e. market surveillance authorities dealing with chemical legislation covering REACH, cosmetics, biocides, customs authorities, consumer protection authorities and agencies such as ECHA.

⁹⁰ For example, legislation on waste and industrial emissions.

⁹¹ European Commission, Environmental Compliance and Governance Forum.

⁹² IMPEL (inspectors), EnviCrimeNet (police), ENPE (prosecutors) and EUFJE (judges).

⁹³ The representative actions mechanism could be used to collectively enforce breaches of EU law instruments COM(2018) 0184 final.

- imported articles, classification and labelling and restrictions;
- extend the scope of action of the European Anti-Fraud Office for **coordination and investigation**, to tackle the circulation of illicit chemical products in the EU⁹⁴;
 - support Member States to prioritise **integrated enforcement** through multi-legislation checks;
 - ensure a **harmonised EU-wide response and coordinated exchange of information** on enforcement of chemical legislation, by strengthening the use of relevant Commission IT platforms;
 - explore the **use of digital tools** to support market surveillance and customs authorities as well as to improve the compliance of products containing chemicals sold online to European consumers;
 - encourage the Member States to use the Recovery and Resilience Facility to invest in the **reinforcement of market surveillance infrastructures** and digitalisation;
 - establish – under the Market Surveillance Regulation⁹⁵ – **uniform conditions and frequency of checks** for certain products where specific risks or serious breaches of applicable Union harmonisation legislation have been continuously identified.

2.4. A comprehensive 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 several decades, 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 and exposure is fragmented, in particular as it relies on industry to provide accurate 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'.

⁹⁴ Drawing inspiration from the rules on mutual administrative assistance in customs matters.

⁹⁵ Regulation (EU) 2019/1020 on market surveillance and compliance of products.

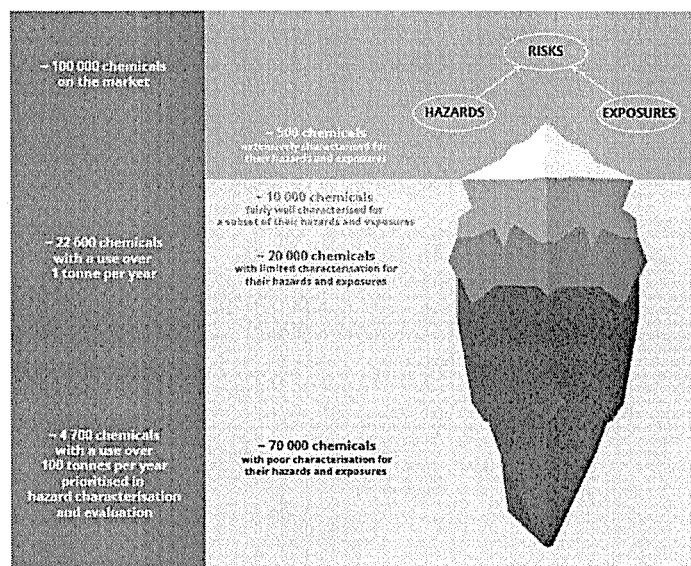


Figure: The unknown territory of chemical risks, EEA⁹⁶

2.4.1. Improved availability of chemical data

The EU is still **lacking a comprehensive information base on all substances** placed on the market and on their overall environmental footprint, including their impact on climate, and this hinders the proper management of chemicals and products and does not allow for a full sustainability assessment. In particular **polymers**, which are the fundamental building blocks of plastics, are not subject to registration under REACH. Furthermore, information required for substances in the **low and medium tonnages** under REACH does not fully allow to identify substances with critical hazard properties. Strengthening information requirements on the carcinogenicity of substances and on other critical hazards at all production levels plays a fundamental role in the successful fight against illnesses such as cancer⁹⁷. In addition, the efficiency and effectiveness of the REACH evaluation procedures need to be improved⁹⁸.

INFORMATION REQUIREMENTS

The Commission will:

- make a proposal to extend the duty of registration under REACH to certain **polymers** of concern;
- assess how to best introduce information requirements under REACH on the overall **environmental footprint** of chemicals, including on emissions of greenhouse gases;
- amend REACH information requirements to enable an effective **identification of substances with critical hazard properties**, including effects on the nervous and the immune systems;
- amend REACH information requirements to enable **identification of all carcinogenic substances** manufactured or imported in the EU, irrespective of the volume.

⁹⁶ EEA, *The European Environment – State and outlook report*, 2020.

⁹⁷ Review of REACH, [COM \(2018\) 0116](#)

⁹⁸ *Ibid.*

2.4.2. A strengthened chemical science-policy interface

Substantial efforts have been put in place to improve the **scientific understanding of the impacts of chemicals** on health and the environment⁹⁹. Monitoring the presence of chemicals in humans and ecosystems is key to improve the understanding of their impact, and should be further promoted, including to understand the links between chemicals and gender¹⁰⁰. In partnership with Member States, the Commission will **continue to foster research and (bio)monitoring** to understand and prevent chemicals-related risks and drive **innovation in chemical risk assessment and regulatory science** through its future framework programme for research and innovation.

Despite a strong EU policy for the **protection of animals used for scientific purposes**, adopted 10 years ago, which makes full replacement of animal testing its ultimate goal, animals are still required to be used systematically for testing in the field of chemicals¹⁰¹. **Safety testing and chemical risk assessment** need to innovate in order to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical hazard and risk assessments.

SCIENCE-POLICY INTERFACE

The Commission will:

- establish and update a **research and innovation agenda for chemicals**, driven by a EU-level Coordination Group, that would also promote the regulatory uptake of research findings;
- foster multidisciplinary research and digital innovations for **advanced tools, methods and models, and data analysis capacities**¹⁰² to also move away from animal testing;
- provide financial support for **EU-wide human and environmental (bio)monitoring capacities**, complementing ecosystem monitoring initiatives¹⁰³;
- develop an **EU early warning and action system for chemicals**¹⁰⁴ to ensure that EU policies address emerging chemical risks as soon as identified by monitoring and research;
- develop a **framework of indicators** to monitor the drivers and impacts of chemical pollution and to measure the effectiveness of chemicals legislation¹⁰⁵.

⁹⁹ The European Commission has since the year 2000 provided funding of over 800 million EUR to research projects dealing with chemical hazards and risks.

¹⁰⁰ While policymakers begin to understand the role played by the sound management of chemicals in economic and social development, significant linkages also exist between gender and chemicals, but gender specific data is still largely missing. UNDP, *Chemicals and Gender*, 2015.

¹⁰¹ Directive 2010/63/EU. In 2017, over 230 000 animal tests were carried out in the EU to satisfy requirements under chemicals legislation; [SWD \(2020\)10](#)

¹⁰² E.g. predictive toxicology or virtual human platforms

¹⁰³ 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.

¹⁰⁴ In connection with ongoing initiatives such as the RAPEX safety gate.

¹⁰⁵ Building on existing initiatives and indicators, this will be part of a wider zero pollution monitoring and outlook framework, in the context of the upcoming 8th Environment Action Programme and will also serve the [Environment Implementation Review](#).

2.5. Setting the example for a global sound management of chemicals

The **production, use and trade of chemicals** are growing in all regions of the world. World chemicals turnover was valued at €3,347 billion in 2018¹⁰⁶ and production is expected to double by 2030. Chemical-intensive sectors like construction, automotive and electronics are also growing, increasing the demand for chemicals and creating opportunities, but also risks¹⁰⁷. Although its contribution to the global burden of disease is still underestimated¹⁰⁸, chemical pollution is recognised to be a threat to the right to a life with dignity, notably for children¹⁰⁹ and in particular in low and middle-income countries¹¹⁰.

In 2015, the international community recommitted to achieve the target of a global sound management of chemicals by 2020¹¹¹, which is also an essential cross-cutting element to achieve most of the other **Sustainable Development Goals**. Although much has been done at all levels, progress remains slow and insufficient and this global commitment has not been met¹¹². **A real sense of urgency is needed**. The European Union can and must play a leading role to champion and promote high standards in the world.

2.5.1. Strengthening international standards

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 governance remains extremely fragmented**, and standards and compliance vary widely across countries. For example, as of 2018, over 120 countries had not implemented the Globally Harmonized System of Classification and Labelling of Chemicals¹¹³. This fragmentation has hampered the overall impact and effectiveness of existing organisations, programmes and initiatives.

Global strategic objectives and targets are needed for an **ambitious international framework** that addresses the current fragmentation and fosters coherent policies and action by all relevant international organisations¹¹⁴, governments and stakeholders, including industry. A renewed **Strategic Approach to International Chemicals Management** is the essential multilateral agreement that will allow to fully address the sound management of chemicals throughout their life cycle. While it is important to use relevant international standards, guides and methodologies when developing EU rules, unless they are ineffective or inappropriate, it is at the same time fundamental to **mainstream** the sound management of chemicals and waste in the work programmes of all relevant international organisations¹¹⁵. It will allow the EU to promote consistent policies and actions under the UN's 2030 Agenda, in line with EU's international commitments.

¹⁰⁶ CEFIC, *Facts and Figures Report*, 2020

¹⁰⁷ UNEP, *Global Chemicals Outlook II*, 2019.

¹⁰⁸ *The Lancet Commission on health and pollution*, 2017.

¹⁰⁹ Human Rights Committee, general comment No. 36 on the right to life, 2018.

¹¹⁰ UNEP, *Global Chemicals Outlook II*, 2019.

¹¹¹ Based on the 2006 SAICM objective, target 12.4 of the UN 2030 Agenda for Sustainable Development establishes that: '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'.

¹¹² UNEP, *Global Chemicals Outlook II*, 2019.

¹¹³ *Ibid.*

¹¹⁴ E.g. UNEP, WHO, ILO, UNIDO, World Bank, OECD, SAICM, MEAs.

¹¹⁵ In particular the participating organisations of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

INTERNATIONAL LEADERSHIP

The EU will:

- step up its **international advocacy** to meet the 2030 Agenda's goals and targets for the sound management of chemicals, in particular by having a leading role and promoting the implementation of **existing international instruments**¹¹⁶ as well as 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 life cycle approaches for chemicals, in line with the post-2020 global biodiversity targets;
- promote, together with industry, the implementation of the Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS) as the means for **identifying chemical hazards** and communicating them to operators, workers and consumers;
- propose to introduce, adapt or clarify **criteria/hazard classes** in UN GHS¹¹⁷;
- promote the development of **common standards and innovative risk assessment tools** internationally, notably with the OECD, and promote their use under international frameworks, inter alia to shift further away from animal testing.

2.5.2. Promoting safety and sustainability standards outside the EU

While **global chemicals production** is estimated to double by 2030, the estimated global share of the EU chemical industry is expected to shrink to about 10.7%¹¹⁸. Much of the expected rise in chemical production will shift to developing countries and economies in transition. EU chemicals legislation has positioned the **EU as a frontrunner** in health and environmental standards on chemicals management and this strategy aims to drive EU's leadership in producing and using sustainable chemicals. The EU must leverage its weight in the world to advocate safe and sustainable-by-design approaches globally, to level the playing field and to increase the market share for companies that produce and use safe and sustainable chemicals.

Closer international cooperation and coordination is also imperative. The Commission is committed to supporting the **capacity of EU partner countries** to meet their international obligations under the chemicals related international instruments and to adopt and enforce **high environmental, health and social standards**. The EU's external action will promote and mainstream the sound management of chemicals through their life cycle and the transition to a toxic-free and circular economy, as essential cross-cutting elements for sustainable development and taking into account policy coherence for development.

Finally, sharing the EU's **knowledge base** is important to support developing countries, but also for the benefit of mutual acceptance of data among OECD and other relevant countries.

¹¹⁶ Notably the Stockholm, Rotterdam and Minamata Conventions.

¹¹⁷ Introduce new criteria/hazard classes for PBTs/vPvBs, terrestrial toxicity, endocrine disruptors, persistency and mobility; adapt existing criteria based on scientific knowledge and progress, i.a. to take account of alternative methods, and clarify criteria for germ cell mutagenicity.

¹¹⁸ CEFIC, *Facts and Figures Report*, 2020.

This is key to avoid duplication of work, save resources and support international standards. The existing knowledge base and **experience of EU agencies**, within their mandate and resources, shall also be put to the benefit of EU international policies and leadership.

COOPERATION WITH THIRD COUNTRIES

The EU will:

- promote the sound management of chemicals through international cooperation and partnerships, in **bilateral, regional and multilateral fora**, including through cooperation with Africa¹¹⁹, as well as cooperation with neighbours and other partners to support their capacity to assess and manage chemicals in a sound manner;
- lead by example, and, in line with international commitments, ensure that **hazardous chemicals banned in the European Union are not produced for export**, including by amending relevant legislation if and as needed;
- promote **due diligence** for the production and use of chemicals within the upcoming initiative on sustainable corporate governance.

3. CONCLUSIONS

This strategy is an opportunity to **reconcile the societal value of chemicals** with human **health and planetary boundaries** as well as to **support industry** in producing safe and sustainable chemicals. It is also an opportunity to respond to the legitimate aspirations of EU citizens for a high level of protection from hazardous chemicals and to promote the EU industry as a global frontrunner in the production and use of safe and sustainable chemicals.

This strategy represents the necessary first step towards Europe's **zero pollution ambition** and the related targets defined in the biodiversity and farm to fork strategies, laying the foundations for the upcoming zero pollution action plan and contributing to the success of the Europe's beating cancer plan. The strategy is also complementary to the European industrial strategy¹²⁰, the recovery plan for Europe¹²¹, the circular economy action plan, and other European Green Deal strategies and initiatives such as the pharmaceuticals strategy, the hydrogen strategy and the batteries initiative.

New legislative initiatives announced in this strategy will be underpinned by the Commission's better regulation tools. Legal proposals, including a revision of the REACH Regulation in the most targeted way possible, limited to achieving the objectives of this Strategy, will be made on the basis of public consultations and subject to comprehensive impact assessments, including analyses of how small and medium size enterprises (SMEs) are affected and innovation is fostered or hindered.

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.

¹¹⁹ Towards a comprehensive Strategy with Africa, JOIN(2020)4 ‘.

¹²⁰ [COM/2020/102](#)

¹²¹ [COM/2020/456](#)



(https://ec.europa.eu/info/index_en)

Internal Market, Industry, Entrepreneurship and SMEs

Chemicals: The EU steps up action against hazardous chemicals in clothing, textiles and footwear

Published on: 30/10/2020

The Commission is taking another important step to protect EU consumers from hazardous substances in frequent contact with human skin, which are known to cause cancer and reproductive health problems.

On Sunday, 1 November, a restriction limiting consumers' exposure to 33 Carcinogenic, Mutagenic or Toxic for reproduction (CMR) chemicals will come into effect. It will ensure that everyday clothing, textiles and footwear bought by Europeans are safer, no matter which EU country they shop in and whether the products are EU-made or imported.

Commissioner

Thierry Breton, responsible for the Internal Market, said: *"The health and well-being of our citizens is of paramount importance, now more than ever. The Commission is continuously ensuring the safety of chemicals used in everyday products and is today restricting the use of 33 dangerous substances in textiles and footwear. The restriction is the result of good cooperation between the Commission, the European Chemicals Agency (ECHA), the chemical and textile industries, NGOs and medical specialists aiming to ensure the safety of these products for our citizens."*

The restriction specifies maximum concentration limits established for individual substances or groups of substances potentially present in these products, including for substances such as polycyclic aromatic hydrocarbons (PAHs), cadmium, chromium, lead

and its compounds and phthalates, among others. It also contributes to reducing the environmental emissions of these hazardous substances, which can occur for example during washing, and enhance the quality of recycled textile materials. The restriction is based on the EU's REACH Regulation (http://ec.europa.eu/growth/sectors/chemicals/reach_en), which provides the world's highest protection of human health and the environment.

See more information

(http://ec.europa.eu/growth/sectors/chemicals/reach/restrictions_en), including an explanatory guide aimed to support the implementation and enforcement by the Member States on the restriction.

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