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EUROPEAN CHEMICALS AGENCY

EU indicator framework for chemicals

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Executive summary

The chemicals strategy for sustainability towards a toxic-free environment (CSS) embraces two overarching goals of the chemicals legislation: preventing harm to people and the planet from hazardous chemicals and their toxic effects and supporting EU industry in the production of safe and sustainable chemicals.

As one of the CSS actions, the European Environment Agency (EEA), the European Chemicals Agency (ECHA) and the European Commission (EC) have developed an indicator framework on chemicals to support these goals. The aims of the framework are to monitor the drivers and impacts of chemical pollution and measure the effectiveness of chemicals legislation.

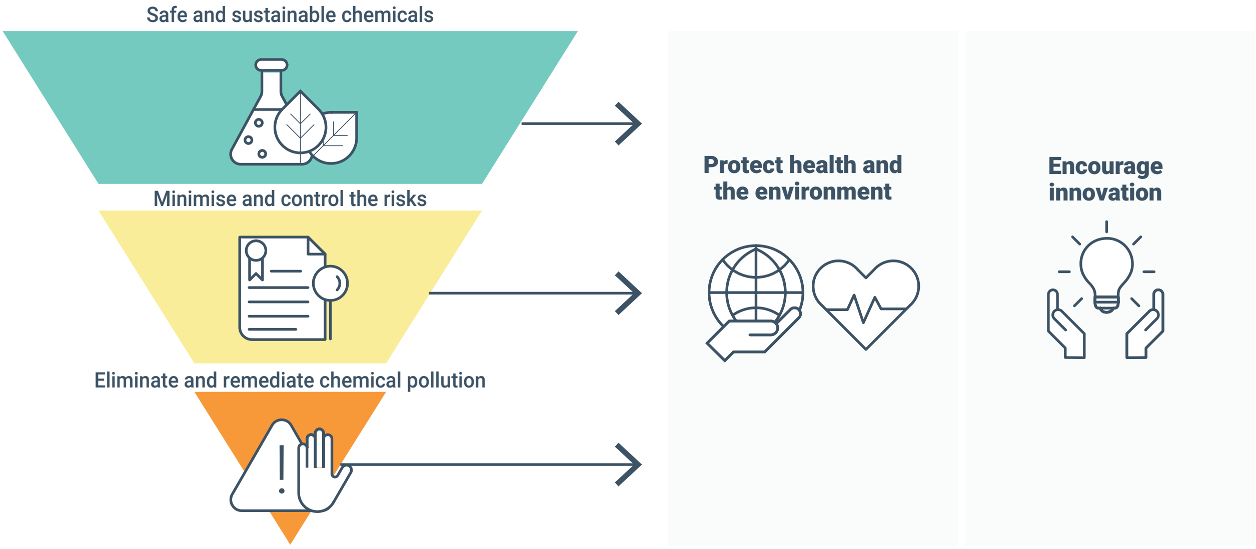
The framework has an online dashboard (available here: https://www.eea.europa.eu/en/european-zero-pollution-dashboards/chemicals-strategy-for-sustainability) and is accompanied by this synthesis report jointly drafted by the EEA and ECHA.

Existing data streams, indicators and other information were assessed for their potential effectiveness in monitoring trends in chemicals production, use, emission, and impact. The proposed framework consists of existing and newly developed indicators and signals. The latter are more limited in terms of spatial and time coverage. Some existing indicators are also part of other related monitoring frameworks such as the zero pollution action plan.

While individual indicators may not be able to measure progress on reducing the risks/unwanted impacts of chemicals directly, they should, as a whole, provide a fact-based picture to support the assessment of the effectiveness of the legislative framework for chemicals and the identification of the need for future action. However, since the impact of the current chemicals policy actions will only become apparent over time, the current dashboard and this report should be seen as a baseline.

The indicator framework is organised according to the elements of the toxic-free hierarchy as specified in the CSS (Figure ES.1).

Figure ES.1 Toxic-free hierarchy in the chemicals strategy for sustainability



Source: Adapted from EC (2020b).

Safe and sustainable chemicals

Transition towards safer and more sustainable chemicals is progressing in some areas while in others it is just getting started.

- The elements of the safe and sustainable by design (SSbD) strategy have only recently been established in an EC recommendation. A lot of interest has been expressed by industry and research and innovation projects are attracting public and private funding.

- Based on the currently available indicators it is difficult to directly measure substitution of the most harmful substances in the EU with safer and more sustainable alternatives. However, identification of substances for which there is clear scientific evidence of them being carcinogenic, mutagenic or toxic to reproduction (CMR category 1 in the Classification Labelling and Packaging (CLP) of substances and mixtures Regulation) suggests that overall, there is increasing pressure on industry to substitute the most harmful substances.

- The two available indicators on production/consumption and market growth of chemicals suggest that, for CMR category 1 substances, the volumes grew slower than the overall market over the last decade. However, there is no significant reduction in the overall use of CMR substances.

- In relation to consumption of resources, while the gross value added (GVA) of the chemical industry increased by 23% between 2012 and 2020, greenhouse gas emissions decreased by 11%. However, waste generation in the chemical industry (hazardous and non-hazardous) increased by 7%.

- Between 2015 and 2020, the total number of uses of experimental animals has remained stable. Nevertheless, during the same period, for specific tests where suitable alternative methods exist, the uses of experimental animals have significantly decreased, for example by 90% for eye irritation tests.

Minimise and control the risks

Action by authorities and industry has supported minimising and controlling the risks from several groups of hazardous chemicals. Efforts are ongoing to increase knowledge on chemical hazards and support risk management action where needed.

- The number of industrial chemicals that have come under scrutiny by EU authorities has substantially increased since 2010. EU authorities have currently much better knowledge about the hazardous properties of high-volume chemicals on the EU market. However, knowledge gaps remain for a number of substances registered under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation. Further effort is needed to close these gaps.

- Clarity on the hazardous properties of chemicals is the first step towards further (regulatory) risk management actions. Since entry into force of the CLP Regulation in 2009, 88 additional chemicals (used as industrial chemicals, biocides and/or pesticides) have been formally identified as carcinogens, mutagens or reproductive toxicants (CMR category 1). Harmonised classification as a CMR category 1 leads to additional risk management measures at the workplace, restricting their use in consumer mixtures and actions under various pieces of legislation (e.g. cosmetics, toys legislation).

- Specific evidence from regulating pesticides and substances subject to REACH authorisation indicates that regulatory action can effectively decrease the volume of the most harmful substances put on the market.

- The use of the grouping approach under REACH supports more consistent and coherent action on chemicals. It has the potential to accelerate both the assessment and regulatory measures taken on chemicals with structural or functional similarities. It also improves predictability of authorities' actions and helps to avoid regrettable substitution: innovation efforts could be directed towards chemicals that do not have the same or similar hazardous properties to the ones banned or to be phased out. Ongoing regulatory efforts regarding per- and polyfluoroalkyl substances (PFAS) and bisphenols are good examples of this.

- Controlling the risks from chemicals placed on the EU market requires regular and systematic enforcement to guarantee compliance with the requirements under the different pieces of legislation. The checks undertaken suggest that the level of compliance with REACH/CLP obligations has remained relatively high (above 70%) though there has been a slight decrease in compliance in relation to imported goods. However, results of enforcement provide only a limited overview of the overall fulfilment of obligations and control of the associated risks. Checks done by national authorities to ensure fulfilment of obligations by industry/duty holders are limited in number and targeted for instance to specific restrictions.

- Although some restrictions have been in force for many years, a high level of non-compliance is still reported in some cases (e.g. presence of phthalates in toys). For newer regulatory risk management measures, it takes time for industry to implement the measures. For example, in one targeted project on the compliance rate with REACH authorisation requirements, an overall non-compliance rate of 40% has been identified.

Eliminate and remediate chemical pollution

Available data suggest that there is little evidence of progress towards eliminating substances of concern from waste and secondary materials.

- Signals suggest that substances of concern continue to be present in waste and secondary raw materials such as treated wastewater, sewage sludge, and consumer goods made of recycled materials. These substances present a potential risk to human health and to the environment. This points to the need for concentrating preventive efforts upstream in the supply chain, at the design and production phases. Such substances need to be avoided as much as possible to foster a toxic-free circular economy.

- While waste recycling is improving, signals indicate that there are still some barriers to the recycling of specific wastes such as plastic. Furthermore, recycling processes and waste management solutions continue to pose challenges to human health and ecosystems in terms of e.g., human exposure during the treatment of electric and electronic equipment, and chemical emissions to the environment from landfilling.

- There are currently no data at the EU level on the development and implementation of soil and water decontamination techniques.

Emissions of certain chemicals to water and air have fallen following specific EU regulations (e.g. on industrial emissions) and international actions, but further measures are needed to reach concentration levels that are not harmful for human health and the environment.

- The use of and risk from chemical pesticides and more hazardous pesticides have decreased since the baseline period 2015-2017. However, this decrease has not yet resulted in improvement in environmental quality as shown, for example, by pesticide levels in surface waters and soils.

- The consumption of ozone-depleting substances (ODS) has been phased out since 2010 and the placement on the market of the hydrofluorocarbon greenhouse gases has been substantially reduced since 2015.

- Following the implementation of both EU and international policies, the emissions to water and air of a range of hazardous chemicals, such as persistent organic pollutants (POPs) and polycyclic aromatic hydrocarbons (PAHs), have fallen in the EU over the past 10 years.

- However, further actions are needed to reduce pollution to levels not posing a risk to human health and the environment. The level of certain groups of chemicals such as some pesticides and POPs were shown to exceed limit values in water (including the marine environment) and soil, thereby posing a risk to aquatic life and soil organisms.

- Regulatory measures have been taken to reduce the use and emissions of hazardous chemicals. However, the impact of these measures on chemical occurrence in the environment takes time as some hazardous chemicals persist in existing materials and products, and perpetuate human and ecosystem exposure.

Human biomonitoring offers the opportunity to understand human exposure to chemicals from multiple sources and thus health risks associated with chemical pollution.

- The bodies of EU citizens are contaminated by a range of chemicals. For some substances, such as bisphenol A and perfluorooctanesulfonic acid (PFOS), internal concentrations exceed safe levels, posing a potential risk to health.
- The monitoring of chemicals in the human body and in the environment remains key to maintaining visibility on pollution levels and impacts, identifying emerging risks and for tracking the effectiveness of policy interventions over time.
- Under the European partnership for the assessment of risks from chemicals (PARC), ongoing research projects will help provide further data on the occurrence of chemicals in the European population and associated risks.

Next steps

The indicator framework represents a knowledge base derived from the available data. This knowledge offers sufficient evidence to show that it is essential to keep transitioning towards safer and more sustainable chemicals. From the indicator framework, it is also apparent that there are certain data gaps (Box ES.1) and inherent uncertainties in the evidence currently available. Updates to the framework over time will allow new indicators to be added and data gaps to be addressed. This will support an assessment of progress in achieving chemicals policy objectives.

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Box ES.1

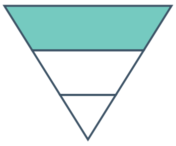
Examples of data gaps and ongoing developments

The indicator framework is designed to assess progress towards a number of policy objectives but limited data and information mean that it has not been possible to assess all policy objectives comprehensively. Data gaps should not be necessarily seen as a barrier to action, as the available evidence in many cases clearly identifies the risks posed by chemicals to human health and the environment. Additionally, knowledge to support the implementation of the CSS and ensure that chemicals legislation is effective will be strengthened as these gaps are addressed.

Data gaps and ongoing developments have been identified in the main report and a few examples are provided below:

- There are data gaps on the occurrence of substances of concern in articles on the EU market and on waste streams. A definition of substances of concern has been included in the Ecodesign for Sustainable Products Regulation proposal. The development of databases to track substances in waste and secondary raw materials is foreseen under the new circular economy action plan and especially for packaging in the revision of the legislation on packaging and packaging waste.
- Data gaps and limitations on the number of checks performed by Member States on articles placed on the EU internal market were identified. The newly adopted regulation on general product safety brings with it the potential for more harmonised checks.
- Currently monitored substances include a large share of so-called 'legacy substances' (i.e. chemicals no longer intentionally used such as polychlorinated biphenyls (PCBs)). However, there is less data on currently used substances. Ongoing research, such as in the PARC initiative, supports the development of new environmental monitoring frameworks using innovative techniques to focus on the most problematic substances in terms of risks and impacts.
- Knowledge is lacking on human exposure to and the impacts of many substances and materials, including how the combined exposure to many different substances can impact our health (the cocktail effect). This is also a key research area under PARC.
- Soil contamination and progress in decontamination techniques are difficult to assess because of a lack of data at the EU level. The recently proposed soil monitoring law includes the establishment of an EU soil monitoring framework, which will be crucial in informing on the current status and needs.
- The safe and sustainable by design (SSbD) framework is a new initiative and tools are still under development. Data on the uptake of the SSbD framework by the chemical industry for the (re-)design of chemicals and materials are not yet available.

Table ES.1 Overview of the EU indicator framework for chemicals: indicators and signals supporting the assessment of progress under the elements of the toxic-free hierarchy

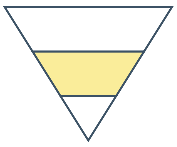


Safe and sustainable chemicals

11

- 7 indicators
- 4 signals

	Safe and sustainable chemicals
Indicators	Growth of the EU chemicals market for substances of different levels of concern
	Number of substances identified as carcinogenic, mutagenic or toxic for reproduction
	Production and consumption of chemicals by hazard class
	Total greenhouse gas emissions in the chemical industry
	Uses of animals by test type in regulatory testing of industrial chemicals
	Uses of animals in regulatory testing of industrial chemicals
	Waste generation in the chemical industry
Signals	Best available techniques (BAT) to cut the use and impact of hazardous chemicals
	Funding EU projects on safe and sustainable chemicals and materials
	Progress in regulating lead
	Safe and sustainable by design chemicals and materials



Minimise and control the risks

16

- 12 indicators
- 4 signals

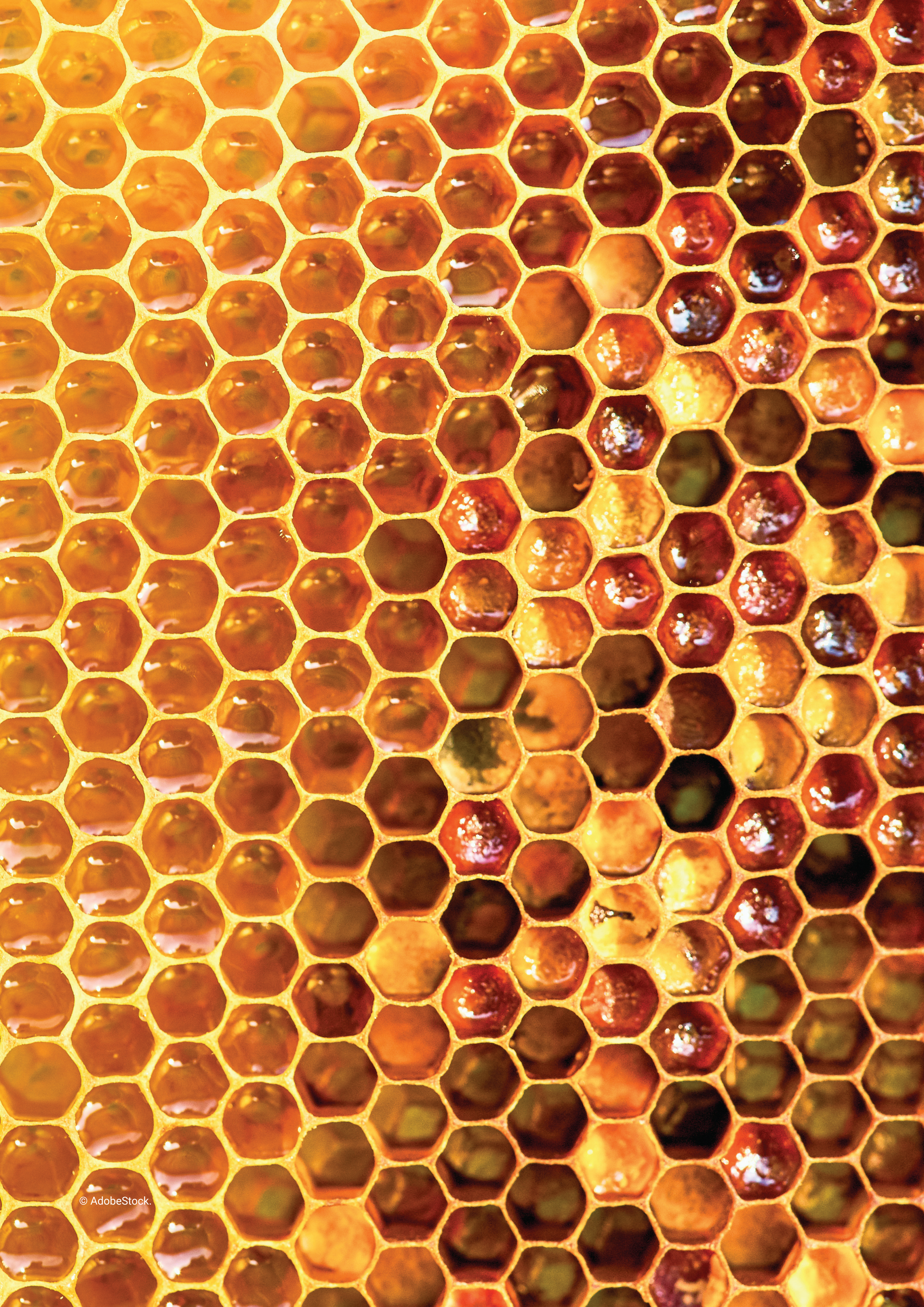
	Minimise and control the risks
Indicators	Alerts for products posing a risk to human health and the environment
	Antimicrobial consumption by food-producing animals in the EU
	CLP controls: percentage of compliant cases found in Member States
	Consumption of ozone-depleting substances
	EU trends in the use and risk of chemical pesticides
	EU trends in the use of more hazardous pesticides
	Human consumption of antibacterials for systemic use in the EU
	Hydrofluorocarbon phase-down in Europe
	Number of substances identified as carcinogenic, mutagenic or toxic for reproduction
	Percentage of REACH CLP-compliant cases found in imported goods
	Progress in regulating substances under REACH and CLP
	REACH controls: percentage of compliant cases found in Member States
Signals	Compliance with REACH restriction and authorisation measures
	Market volume changes of chemicals subject to REACH authorisation
	Progress in regulating lead
	Regulating groups of substances to speed up action and ensure a coherent approach

Eliminate and remediate chemical pollution

32

- **16 indicators**
- **16 signals**

	Eliminate and remediate chemical pollution
Indicators	Alerts for products posing a risk to human health and the environment
	Antimicrobial consumption by food-producing animals in the EU
	Consumption of ozone-depleting substances
	EU trends in the use and risk of chemical pesticides
	EU trends in the use of more hazardous pesticides
	Hazardous substances in marine organisms in European seas
	Human consumption of antibacterials for systemic use in the EU
	Hydrofluorocarbon phase-down in Europe
	Industrial chemical releases to air
	Industrial chemical releases to water
	Persistent organic pollutant emissions in Europe
	Pesticides in rivers, lakes and groundwater in Europe
	Population connected to at least secondary wastewater treatment
	Production and consumption of chemicals by hazard class
	Progress in the management of contaminated sites
	Waste generation in the chemical industry
Signals	Chemicals in European surface water and groundwater
	Ecological risk of pesticides in EU soils
	Leachate pollution from landfills
	How pesticides impact human health
	Human exposure to bisphenols
	Impacts of microplastics on health
	Long-term impacts of sludge spreading on agricultural land
	Occupational exposure in recycling facilities
	PFAS contamination and soil remediation
	PFAS in European seas
	Plastics recycling in Europe: obstacles and options
	Progress in regulating lead
	Recycling materials from green energy technologies
	Risks of chemical mixtures for human health in Europe
	Risks of PFAS for human health in Europe
	Treatment of drinking water to remove PFAS



1 Introduction

1.1 Context

Chemicals play a key role in the functioning of our society. They are integral to most human activities and production processes and provide specific functionalities to materials and products (such as phthalates and bisphenols used to provide softness and toughness, respectively, to plastic materials). The chemical industry supplies numerous downstream sectors such as plastics, agrichemicals (e.g. pesticides and fertilisers) and healthcare, in addition to consumer goods and specialty chemicals. In 2022, the total sales value of chemicals produced in the European Union (EU) (excluding pharmaceuticals) was EUR 760 billion, making the region the second largest chemical producer in the world after China (CEFIC, 2023).

Chemicals can have direct impacts on human health and the environment throughout their entire life-cycle since chemical emissions occur at all stages: during chemical manufacturing, chemical use in production, product use and waste treatment. There are further indirect impacts of chemicals due to energy consumption, greenhouse gas emissions and waste production. International and EU measures have regulated the production and use of chemicals for many years. In addition to driving the monitoring of chemical pollution, this has led to a stronger awareness of how ubiquitous chemicals are in the environment and the risks they pose to human and ecosystem health. In spite of this awareness, society's ability to assess and manage the associated risks is being challenged by the rapid increase in the volume, diversity and emissions of chemicals. New studies suggest that planetary boundaries for novel entities such as industrial chemicals are already being exceeded (Richardson et al., 2023; Persson et al., 2022). Alongside climate change and biodiversity loss, chemical pollution represents part of the triple planetary crisis (Almroth et al., 2022; UNFCCC, 2022).

1.2 EU chemicals policies

The EU has a comprehensive framework comprising approximately 40 legislative instruments to regulate chemicals ([1]). Most prominently this includes the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EU, 2006c) and the Regulation on the Classification, Labelling and Packaging of substances and mixtures (CLP) (EU, 2008c). Specific groups of chemicals such as biocides, pesticides, or specific types of products such as cosmetics and pharmaceuticals are covered by their own legislation (EU, 2009a, 2009d, 2009e, 2012). Similarly, specific product groups or situations where high exposure to chemicals is likely, in particular for vulnerable groups, are regulated separately. These include the safety of toys, food and carcinogens in the workplace (Figure 1.1).

A series of legislative instruments currently regulates emissions of chemical pollutants to the environment. These instruments also set the requirements for the quality and monitoring of air, water and soil. They include, among others: the Directive on National Emission reduction Commitment (NEC) for national emissions of pollutants to air (EU, 2016); the Industrial Emissions Directive (IED) and the European Pollutant Release and Transfer Register (E-PRTR) Regulation (EU, 2006b, 2010) or industrial emissions;

([1]) For a comprehensive policy overview, see the Fitness Check of the most relevant chemicals legislation (excluding REACH).

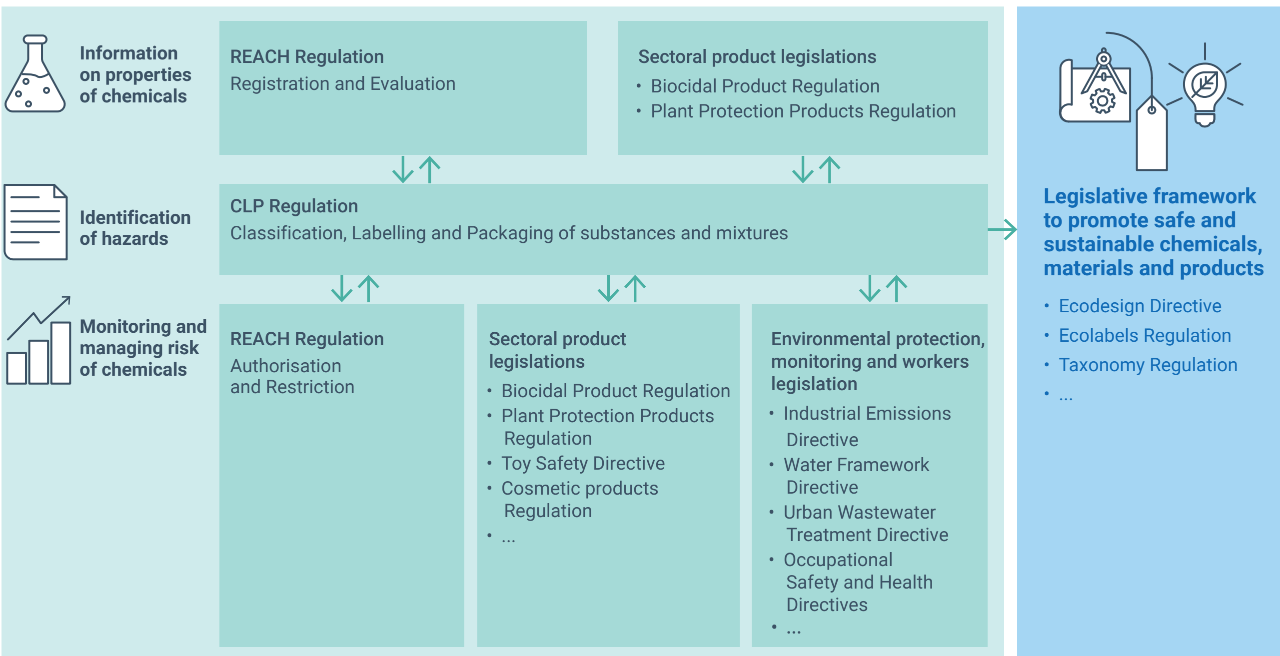
the Water Framework Directive (WFD) (EU, 2000) and associated goals to reach good chemical status for all EU waterbodies. Greenhouse gas emissions and waste production are monitored at the EU level under the Governance of the Energy Union and Climate Action Regulation (EU, 2018b) and Regulation on waste statistics (EU, 2002), respectively.

Different types of policies are also in place to address substances of concern in waste and secondary raw materials. This is to prevent emissions at later stages of a product's life-cycle. Some policies focus more on the substances in materials and products, while others relate to the handling of waste. In addition to the REACH and CLP regulations, these policies include: the Waste Framework Directive (EU, 2008b); the Ecodesign Directive (EU, 2009b); the Persistent Organic Pollutants (POPs) Regulation (EU, 2022e) covering manufacturing, use and waste; the Directive on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCBs/PCTs) (EU, 1996); the directive on urban wastewater treatment (EU, 1991); the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (EU, 2011).

The European Green Deal and the 8th Environment Action Programme have set out a pathway for strategically aligning chemicals-related policies. The Green Deal defines a series of interlinked policy goals to drive the transition to a sustainable economy and society. These goals include: climate neutrality, biodiversity protection, transition to circular economy and a zero pollution ambition for a toxic-free environment.

The zero pollution ambition is translated into action via the EU zero pollution action plan and, in the area of chemicals policy, via the chemicals strategy for sustainability towards a toxic-free environment (CSS). Other strategies and action plans, related to chemicals policy in various ways, are the circular economy action plan, the farm to fork strategy and the biodiversity strategy.

Figure 1.1 Legislative framework for chemicals in the EU



Note: REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. A proposal has been submitted for an Ecodesign for Sustainable Products Regulation (ESPR) (EC, 2022c).

Source: EEA.

1.3 The EU indicator framework for chemicals

1.3.1 Aim and content

Chemicals policies aim to tackle the challenge of producing and using chemicals to address societal needs while respecting planetary boundaries and avoiding harm to humans and the environment. The CSS sets out the ambition to ensure that all chemicals are used more safely and sustainably (EC, 2020b). The CSS emphasises two areas: minimising and substituting, as far as possible, chemicals that have chronic effects for human health or the environment (substances of concern) and phasing out the most harmful substances in uses that are not essential for society, in particular in consumer products. To achieve these objectives, the CSS calls for the regulatory framework on chemicals to be strengthened. The policy objectives of the CSS originate from the three main elements of the toxic-free hierarchy. In this hierarchy, prevention via safe and sustainable chemical production and use, is preferred over minimising and controlling the risks and over eliminating and remediating chemical pollution. The hierarchy and corresponding policy objectives that structure the report are outlined in Table 1.1.

Table 1.1 The toxic-free hierarchy and corresponding policy objectives for the CSS

Toxic-free hierarchy element	Objectives under the element: protect health and the environment	Objectives under the element: encourage innovation
Safe and sustainable chemicals	Use of safe chemicals while preventing harm to humans and the environment by avoiding substances of concern ([a]) for non-essential uses	Promote the development of safe and sustainable chemicals and materials, clean production processes and technologies
		Promote the development of innovative tools for testing and risk assessments
Minimise and control the risks	Minimise exposure of humans and the environment to substances hazardous to health and the environment, through risk management measures and full information to users of chemicals	Promote modern and smart production processes, safe and sustainable uses and business models, chemicals as a service ([b]), IT solutions for tracking chemicals
Eliminate and remediate chemical pollution	Eliminate as far as possible substances of concern from waste and secondary raw materials	Promote safe and clean recycling solutions including chemical recycling and waste management technologies
	Restore human health and the environment to a good quality status	Promote decontamination solutions

Note: ([a]) In the CSS, substances of concern are to be minimised and substituted as far as possible and the most harmful substances are to be phased out for non-essential societal use, in particular in consumer products (see Box 1.1).

([b]) As defined in the CSS: 'Chemicals as a service' includes chemicals leasing but also the leasing of services such as logistics, development of specific chemical processes and applications, and waste management (EC, 2020b).

Source: EC, 2020b.

One of the actions set out in the CSS is for the Commission, with the European Environment Agency (EEA) and the European Chemicals Agency (ECHA), to develop an indicator framework on chemicals to monitor the drivers and impacts of chemical pollution and measure the effectiveness of chemicals legislation. The indicator framework is published by the EEA in the form of an online dashboard (available here: https://www.eea.europa.eu/en/european-zero-pollution-dashboards/chemicals-strategy-for-sustainability) accompanied by this ECHA-EEA joint synthesis report. Both the online dashboard and synthesis report are structured in accordance with the three elements of the toxic-free hierarchy and objectives described in Table 1.1. The indicators (2) selected and developed under the framework (25 in total) have been mapped against one or several of the policy objectives, to support an assessment of the progress of the CSS. The framework also includes a series of signals (3) (22 in total), which complement the indicators. In this report, indicators and signals are referred to under their relevant policy objectives as presented in Table A1 in Annex 1. Indicators and signals are accessible on the online dashboard.

1.3.2 Scope and definitions

This report aims to offer insights and key messages, derived from current and historical data relevant to the policy objectives of the CSS, based on the framework's indicators and signals. However, since actions under the CSS have only recently been initiated, this report and associated dashboard should be regarded as a baseline and it should be assumed that the impact of the chemicals policy actions will only become apparent over time.

The drivers and impacts of chemical pollution can be identified at different stages of a chemical's life-cycle (i.e. from manufacture to waste) and relevant areas for each stage (e.g., research and innovation, associated processes and emissions). Mapping the indicators and signals that are included in the CSS framework against the different stages of the life-cycle allows us to understand which areas are covered by the framework. As shown in Figure 1.2, the framework partially covers the different stages, though there are currently data gaps for certain areas.

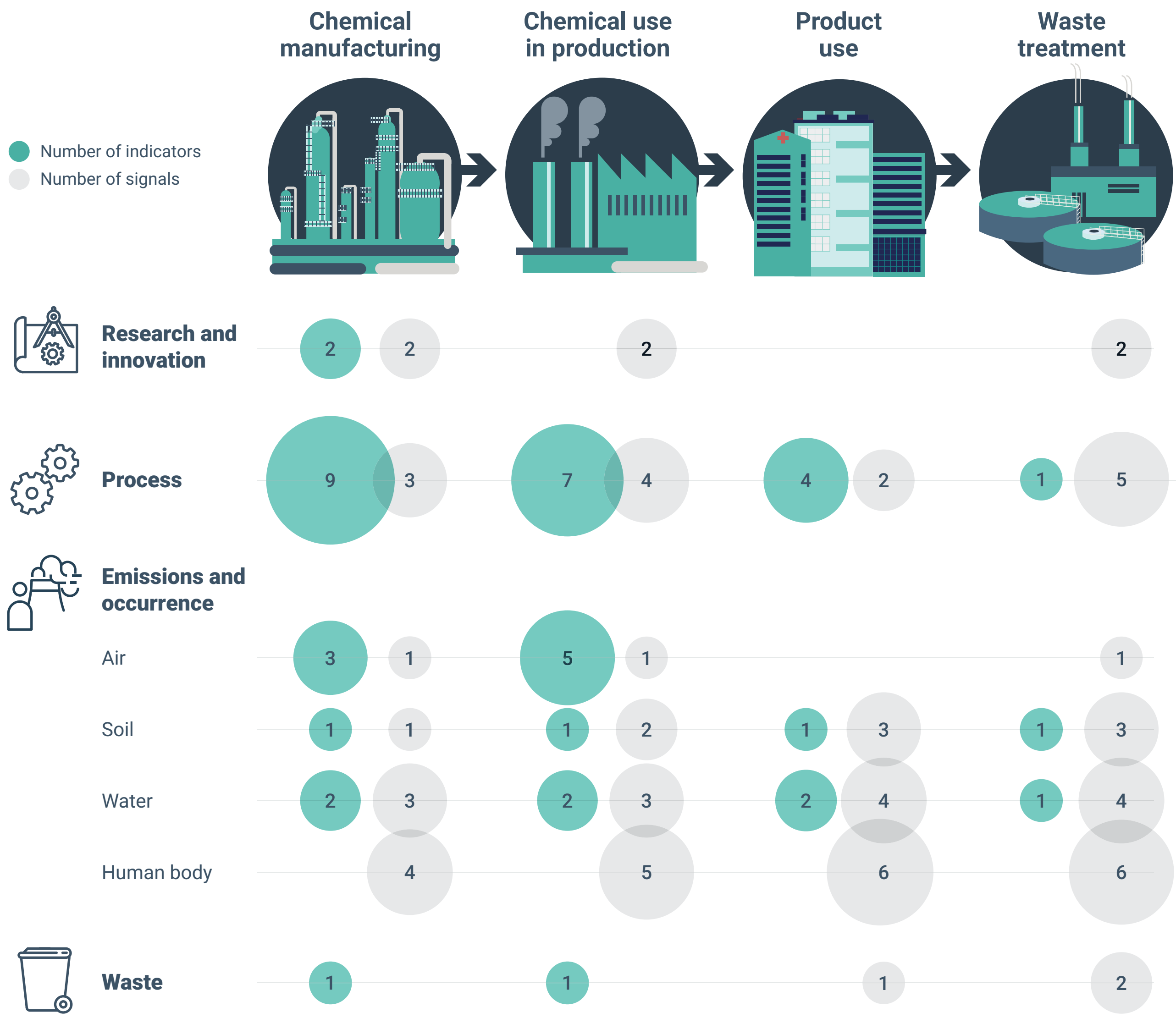
As such, the report is also useful for identifying data gaps encountered in the process of assessing specific objectives. The sections in the report relating to ongoing developments identify recently adopted legislations, current legislative proposals, and strategies with potential future impacts on the framework such as data provision to fill gaps or changes in chemicals production and use affecting the indicators' trends. Some of these ongoing developments may, however, be subject to changes in the near future. The indicator framework for chemicals assessed in this report is therefore a living product. The indicators and signals available on the online dashboard will be updated as new data and information become available, while this report is specific to one point in time.

The recently published European Commission (EC) proposal on chemicals data (EC, 2023c), aims, among other objectives, to maintain and further develop the framework.

(2) An indicator is a quantitative or qualitative variable showing the trend/status of a phenomenon over time and occurring at the EU level. In the context of the CSS, it is linked to a policy objective to monitor progress.

(3) A signal is a compilation of qualitative and/or quantitative data, which is limited in terms of geographical and time coverage but can still provide additional insights and/or indicate a trend for a specific phenomenon.

Figure 1.2 Mapping of the framework's indicators and signals against the four stages of a chemical's life-cycle and topic areas



Note: Topic areas correspond to research and innovation, processes involved in each stage, associated emissions to and occurrence of chemicals in environmental matrices and the human body, waste generation.

Source: EEA.

Throughout the report, the terms 'chemicals', 'hazardous substances', 'substances of concern (SoC)' and 'most harmful substances' are used. While 'chemicals' is a generic term that covers all types of substances and mixtures (including pesticides, biocides and antimicrobials), the terms hazardous substances, substances of concern, and most harmful substances are defined in Box 1.1.

In addition, the chemicals and groups of chemicals monitored across the report vary in terms of the scope of the indicators and signals. Under the two first overarching elements of the toxic-free hierarchy 'Safe and sustainable chemicals' and 'Minimise and control the risks', the indicators and signals are focused on the production and use of industrial chemicals (including waste generation and emissions from production processes), as well as chemicals in professional and consumer products placed on the EU market. However, in the third element of the toxic-free hierarchy 'Eliminate and remediate chemical pollution', the indicators and signals are focused on chemicals emitted into or present in the environment. This includes their emission into or presence in waste and secondary raw materials as well as environmental matrices — air, soil, water and biota — and human bodies. The scope covers areas including industrial chemicals, heavy metals and pharmaceuticals. The framework thus takes into account emissions across the entire chemical life-cycle. Moreover, the two first elements of the hierarchy relate to substances currently in use, while the third covers legacy substances in addition to those currently in use, due to the persistence of the former in the environment (Box 1.2).

Box 1.1

Meanings for the terms chemicals, substances of concern and most harmful substances in the report

Throughout this report, the term chemicals is used generically, to cover all substances, including special categories such as metals, polymers, nanomaterials and other categories (e.g. organic substances and pharmaceuticals), as specified in the strategic research and innovation plan (SRIP) for chemicals in the European Green Deal. Whenever text in the report refer to specific categories of chemicals, such as substances registered under the REACH Regulation, this is indicated in the text.

Hazardous substances are defined in the CLP Regulation and include all physical, health and environmental hazards. The CSS has introduced two sub-categories of hazardous substances: most harmful substances and substances of concern.

Most harmful substances are defined as substances requiring a generic approach to risk management as a default, in order to ensure that consumers, vulnerable groups, workers and the environment are better protected. Most harmful substances are substances that can cause cancers, gene mutations, affect the reproductive or the endocrine system or are persistent and bioaccumulative. They also include substances affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.

Substances of concern refers to a larger group of chemicals defined in the CSS as substances that have a chronic effect for human health or the environment. They also include those that hamper recycling for safe and high quality secondary raw materials. A substance of concern is further defined in the sustainable product regulation proposal as one that:

1. meets the criteria laid down in Article 57 and is identified in accordance with Article 59(1) of REACH Regulation (EC) No 1907/2006;

2. is classified in Part 3 of Annex VI to the CLP Regulation (EC) No 1272/2008 in one of the following hazard classes or hazard categories:

- carcinogenicity categories 1 and 2;
- germ cell mutagenicity categories 1 and 2;
- reproductive toxicity categories 1 and 2;
- [to be added in the course of the legislative procedure once Regulation (EC) No 1272/2008 contains these hazard classes: persistent, bioaccumulative, toxic (PBTs), very persistent very bioaccumulative (vPvBs), persistent, mobile and toxic (PMT), very persistent very mobile (vPvM), endocrine disruption];
- respiratory sensitisation category 1;
- skin sensitisation category 1;
- chronic hazard to the aquatic environment categories 1 to 4;
- hazardous to the ozone layer;
- specific target organ toxicity — repeated exposure categories 1 and 2;
- specific target organ toxicity — single exposure categories 1 and 2.

3. negatively affects the re-use and recycling of materials in the product in which it is present.

Substances of very high concern are defined in the REACH Regulation as substances that meet the criteria laid down in Article 57 and are identified in accordance with Article 59(1) of Regulation (EC) No 1907/2006:

- substances classified as carcinogenic category 1;
- mutagenic category 1 and toxic to reproduction category 1;
- PBTs, vPvBs or have an equivalent level of concern to substances which are carcinogenic, mutagenic or toxic to reproduction (CMR) and PBT/vPvB.

In addition, the CSS suggests adding all substances which are PMT, vPvM and endocrine disrupters.

In the report and in the indicator framework, any choices that have been made about the hazard classes being used are specifically indicated.

Box 1.2

Legacy and currently used substances

Legacy chemicals are those that are no longer intentionally used in production or specific settings (e.g. legacy pesticides) as their uses have been or are being phased out/banned. These legacy chemicals can still be present in environmental media and biota due to their historical use. As such, the risks associated with them can now largely only be dealt with via remediation actions, though some may become immobilised in sediments, for example, or break down into less harmful substances over time.

Currently used chemicals, in contrast, are those that are still being used intentionally in production and hence are continually entering society (e.g. in products). These can be subject to risk management measures throughout the chemical/product life-cycle (including remediation activities where relevant). These substances include emerging chemicals (e.g. from regrettable substitutions (Box 3.2)).

Thus, in terms of evaluating progress under the CSS (using chemical indicators), the progress achieved in terms of managing the risks from legacy chemicals falls primarily under the third element of the CSS toxic-free hierarchy 'eliminate and remediate'. In contrast, progress on managing the risks from currently used chemicals can fall under all of the overarching elements of the hierarchy: (1) safe and sustainable chemicals, (2) minimise and control and (3) eliminate and remediate. Chemical indicators that are dominated by legacy chemicals are not generally sensitive measures for progress under the first two elements of the hierarchy, as they are typically highly regulated and do not provide useful information on recent developments related to currently used substances.

2 Safe and sustainable chemicals

The first element of the toxic-free hierarchy focuses on safe and sustainable chemicals. It is underpinned by objectives presented in Table 1.1. These objectives aim for the 'use of safe chemicals while preventing harm to humans and the environment by avoiding substances of concern for non-essential uses', to 'promote the development of safe and sustainable chemicals and materials, clean production processes and technologies' and to 'promote the development of innovative tools for testing and risk assessments'.

2.1 Protect health and the environment

The 'use of safe chemicals while preventing harm to humans and the environment by avoiding substances of concern for non-essential uses' includes substituting substances of concern as far as possible in the EU to minimise human and environmental exposure to substances with chronic adverse effects. When possible substitutions are being considered, certain product categories should be prioritised — those that are likely to expose vulnerable populations (children, pregnant women and elderly people) to chemical risk as well as those with the highest potential for circularity, such as textiles, packaging including food packaging, furniture, electronics and information communications technology (ICT) and construction materials. If substitution is not feasible, the objective is to minimise the use of substances of concern and track their presence in articles and products.

In particular, the aim is to phase out the most harmful substances in consumer products and professional uses unless their uses are essential for society. The ultimate goal is to achieve non-toxic material cycles and a clean circular economy where the consumption of resources is also reduced.

2.1.1 Use of safe chemicals while preventing harm to humans and the environment by avoiding substances of concern for non-essential uses

The presence of the most harmful substances (see definitions in Box 1.1) in consumer products and in professional uses should be phased out unless their use is essential for society. These substances are high priority for action under the relevant regulations such as REACH, the Toys Directive (EU, 2009a), the Cosmetics Regulation (EU, 2009e) and the occupational safety and health (OSH) directives (EU, 1989). Most harmful substances include, for instance, substances classified as carcinogenic, mutagenic and toxic to reproduction (CMR) category 1. The CMR substances are used as a proxy group for most harmful substances in the rest of this section.

When the CLP Regulation was first introduced in 2009, approximately 1,100 CMR category 1 substances were transferred from the older legislative framework (the Dangerous Substance Directive, DSD) to Annex VI of the CLP. Since then 88 chemicals (used as industrial chemicals, biocides and/or pesticides) have been formally identified as CMR, as reported in the indicator Number of substances identified as carcinogenic, mutagenic or toxic for reproduction. The indicator measures progress based on the number of newly identified substances (or any changes to existing classification). The identification of a substance as CMR category 1, via harmonised classification, results in the implementation of new risk management measures in the workplace, restrictions on the use of the substance in consumer mixtures and actions under various pieces of legislation (e.g. in relation to cosmetics and toys). This can represent an important step towards substitution, in particular where the use of a substance is non-essential. It can also increase the incentives for industry to invest in the development of alternative chemicals and materials with less hazardous properties.

The indicator Production and consumption of chemicals by hazard class shows changes in the production of chemicals hazardous to human health and of chemicals not hazardous to human health relative to the changes in the total production of chemicals. The overall production and consumption of chemicals in the EU is increasing. However, while there has been an increase in the production of chemicals that are not hazardous to human health, data indicate a decrease in the production of chemicals that are hazardous to human health since 2004, relative to total production. The EU production of chemicals hazardous to human health (all five hazard classes together, see the indicator Production and consumption of chemicals by hazard class) reached a peak of 241 million tonnes in 2007 and was 22 million tonnes less in 2022 compared to 2021. However, there have been annual fluctuations and it is therefore difficult to extrapolate the data to future years. In particular, according to this indicator, the production of CMR category 1 chemicals has been relatively stable since 2004 with some minor fluctuations.

It is important to note that the indicator relies on statistics that track only very high tonnage bulk chemicals on the European market. The indicator also does not differentiate between the different uses of chemicals and includes the production and consumption of intermediates ([4]), some of which are only used under strictly controlled conditions involving limited or no exposure to workers and the environment.

The indicator Growth of the EU chemicals market for substances of different levels of concern provides an insight into the use of CMR category 1. While the volumes of chemicals in use overall have grown over the last decade, the indicator shows that the growth in CMR use over the same period has been 20% slower than that of less hazardous substances. The slower growth in CMR use was clearly more pronounced between 2014 and 2018. This seems to indicate that chemicals legislation has contributed to a reduction in the relative growth in the use of CMR substances.

The current indicators do not give clear direct measures of the trend in substitution of substances of concern in the EU with safe and sustainable alternatives. However, the data available do suggest that overall there is increasing pressure on industry to substitute the most harmful substances, thanks to the progress in the identification of new CMR substances. Data also suggest that the production and consumption of most harmful substances is not increasing at the same rate as the use of other substances. This, in turn, seems to suggest that measures are being taken to limit and progressively substitute most harmful substances.

([4]) Intermediates are chemicals used to produce other chemicals or products and which are completely consumed during the process.

2.2 Encourage innovation

The aim to 'promote the development of safe and sustainable chemicals and materials, clean production processes and technologies' is supportive of the development and uptake of chemicals and materials that are safe and sustainable by design (SSbD), whether within the chemical industry or downstream industries. The aim also supports the redesign of chemicals and production processes to minimise unwanted inherent properties (e.g. PBTs), carbon emissions as well as resource consumption.

The implementation of low-carbon and low environmental impact chemical and material production processes could also lower the material footprint of chemical production and reduce the consumption of resources depending on the type of chemical and resource being used. Improvements in this area represent another core element of this objective.

Finally, the objective aims to encourage 'the development of innovative tools for testing and risk assessments'; in particular, this refers to developing non-animal methods for testing chemicals.

Box 2.1

The safe and sustainable by design (SSbD) framework

SSbD is a framework applicable to chemicals and materials and established by the European Commission in the recent Commission Recommendation (EU) 2022/2510 (EU, 2022c). It aims to:

- steer the innovation process towards green and sustainable industrial transition;
- substitute or minimise the production and use of substances of concern, in line with and beyond existing and upcoming regulatory obligations;
- minimise the impact on health, climate and the environment during sourcing, production, use and end-of-life of chemicals, materials and products.

2.2.1 Promote the development of safe and sustainable chemicals and materials, clean production processes and technologies

Data available regarding greenhouse gas emissions from industrial facilities, the generation of total waste and the elimination of substances of concern from waste and secondary raw materials are used in assessing progress towards this objective.

The indicator Total greenhouse gas emissions in the chemical industry gives the emissions reported by EU-27 Member States for their chemical industry sectors; this includes, among others, ammonia production and fluorochemical production (see corresponding indicator). The indicator shows that between 2012 and 2021, greenhouse gas emissions from this sector decreased by 9%. However, since 2015 the total greenhouse gas emissions of the chemical industry have been levelling off, with fluctuations in emissions related to fuel combustion, industrial processes and product use. Additionally, since 2015, the gross value added (GVA) of the chemical industry, expressed in current prices (i.e. manufacture of chemical, pharmaceutical, rubber and plastic products), has increased by 9%.

The indicator Waste generation in the chemical industry shows that the total waste (both hazardous and non-hazardous) generated in the chemical industry increased by 7% between 2012 and 2020. Within that period, it decreased by 11% between 2018 and 2020, most likely temporarily due to the COVID-19 pandemic. The share of waste categorised as hazardous due to hazardous chemicals remained stable at about 50% of total waste, equating to 6 million tonnes during that period. Hazardous waste includes, among others, organic solvents from the manufacture of basic organic chemicals, waste oil from refining petroleum (also called used oil), spent chemical catalysts, waste from agrochemical products (e.g. pesticides), unused medicines and preservatives (Eurostat, 2010). During the 2012-2020 period, GVA and waste generation from the chemical industry appear to have been coupled, although the decrease in waste generation in 2020 shows a slight and presumably temporary decoupling.

With a transition towards the production of safe and sustainable chemicals, and as a larger share of chemicals and products are expected to be developed using the SSbD framework, reductions in the generation of emissions and waste should become apparent, while the value generated by chemical production — GVA — should remain stable or increase, resulting in a decoupling of the metrics.

The IED is the main piece of European legislation that targets all types of industrial processes and their emissions to air, water and land as well as waste generation. The signal Best available techniques (BAT) to cut the use and impact of hazardous chemicals shows that the implementation of BAT from the IED has led to reductions in emissions, though improvements are needed in terms of consistency of application and the use of derogations. The reporting itself has also had a positive effect in areas such as sharing information to the public, identifying cleaner production opportunities and monitoring programmes for cleaner production.

The signal Safe and sustainable by design chemicals and materials sheds light on the development of the SSbD framework (Box 2.1) and its operability, which will become a further important enabler of the transition towards safe and sustainable chemicals and materials, especially in terms of encouraging innovation. The signal shows that stakeholders — from for example the industry, academia, Member States and research and technology organisations — have participated very positively in the first reporting period for the SSbD framework. A total of 45 case studies on the application of the framework are currently being undertaken. These include studies on substances, mixtures, nanomaterials and other types of materials.

EU support for research and innovation is covered by the signal Funding EU projects on safe and sustainable chemicals and materials. During the period March 2021—September 2022, a total of 190 EU-funded active projects on safe and sustainable chemicals and materials were identified for Research and innovation (R&I), corresponding to over EUR 1 billion in EU funding. These projects come from four funding programmes, namely: Horizon Europe, ERASMUS+, the Innovation Fund and the LIFE programme. Most of the active projects are associated with R&I on safe and sustainable production processes and technologies and SSbD for chemicals and materials. However, the projects may also cover other activities such as education.

In addition, the cross-cutting signal Progress in regulating lead exemplifies how regulatory action, such as restrictions in the use of the most harmful substances, can result in environmental improvements (e.g. the recovery of a swan population) in addition to triggering the development of safer alternatives (e.g. for products currently containing lead such as ammunition and fishing gear).

Overall, the current data show that there has been some progress towards the production of safer and more sustainable chemicals. However, to date it is difficult to measure the progress because the SSbD framework was only recently developed. The signals indicate that more information on innovation in the chemical industry may be available in the near future to shed light on any progress that may have been made.

2.2.2 Promote the development of innovative tools for testing and risk assessments

Chemical risk assessment is a key tool in ensuring the safe use of chemicals; it is widely used by both industry and regulators. A risk assessment is based on two main components: chemical hazards (effect threshold) and exposure. Depending on the specific hazards linked to a chemical and the level of exposure, humans and other living organisms can be subjected to chemical risk. Concentrations of substances at which non- or observable adverse effects on health occur are often derived from toxicological studies. These studies commonly involve testing on laboratory species, especially non-human vertebrate animals (e.g. mice).

Due to animal welfare considerations and to better predict effects in humans (given that in some cases animal models may not be adequate proxies), R&I work has been ongoing over the last 20 years to develop non-animal testing methods. For some types of effects, it has been possible to completely replace animal methods. For other more complex types of effects, it has been more difficult to develop non-animal methods, which are adequately reliable and relevant. However, there have been recent developments in methodologies, such as defined approaches (DA), new approach methodologies (NAM) and new generation risk assessment (NGRA), which offer promising ways to reduce the use of experimental animals without compromising the protection of human health and the environment (Herzler et al., 2023).

The indicator Uses of animals in regulatory testing of industrial chemicals shows that, across all the EU-27 countries, the total number of uses of animals and the numbers by severity levels in the field of industrial chemicals remained stable between 2015 and 2020. This is mainly because adequate non-animal methods are not yet available to replace many of the tests currently required for safety assessments.

The indicator Uses of animals by test type in regulatory testing of industrial chemicals shows the trends in the use of animals for the most common toxicity tests (eight tests out of a total of 16). Where alternatives exist, the uses of animals substantially decreased between 2015 and 2020. In tests for skin sensitisation, skin irritation and eye irritation animal uses fell by 65%, 74% and 90%, respectively. This positive change can be attributed in part to amendments to the REACH Regulation that set non-animal methods for these tests as the default option.

Every three years, ECHA submits a report to the European Commission on the non-animal testing methods and testing strategies that are used to generate information about the intrinsic properties of substances and for risk assessment (Article 117(3) report). Under the REACH Regulation, testing on vertebrate animals (e.g. rats, other mammals or fish) can only be used as a last resort. In addition to providing an update on the use and implementation of non-animal testing methods and testing strategies used by companies, the more recent report also includes an overview of ECHA's activities to promote the development and use of alternatives and discusses the opportunities and challenges in moving away from animal testing as they apply to the risk assessment of chemicals in a regulatory context. Besides the clear decrease in animal testing for skin sensitisation, skin irritation and eye irritation, the report highlights that overall, adaptations to testing continue to be used by industry in the dossiers submitted to register their substances under REACH more than experimental studies; the technique of 'read-across' (i.e. predictions of intrinsic properties of one substance based on those of another substance from the same group), is the most frequent adaptation, followed by waivers ([5]), weight of evidence ([6]) and modelling

([5]) The option to omit the standard information, for instance, when testing is not technically possible or based on considerations relating to exposure.
([6]) Weight of evidence is a combination of information from several independent sources that allows for a conclusion on hazard and risk assessment, including classification and labelling, without further studies. The possible sources of information include: published literature, read-across from chemical analogues, QSAR predictions, data from existing studies, in vitro studies, epidemiological data/human experience.

(quantitative structure-activity relationship modelling, QSAR). Another finding is that the data on almost half (47%) of the available experimental studies in the REACH database are new; they have only been generated since the entry into force of REACH. This is mainly due to the fact that non-compliant information was submitted initially and REACH compliance checks required further testing to be undertaken.

2.3 Outlook

2.3.1 Robustness of current indicators and signals

The majority of indicators referred to in this chapter are proxies (e.g. CMR substances are a proxy for most harmful substances) and only certain aspects, for example those related to safer and more sustainable chemicals, are covered. This means that there are uncertainties in the established baseline in relation to areas like substituting substances of concern and promoting clean production processes and technologies. Data gaps that have been identified are presented in Table 2.1.

In addition, the underlying data used to provide statistics on the production and/or use volumes for chemicals are limited. For instance, as mentioned in Section 2.1.1, the information that supports the indicator Production and consumption of chemicals by hazard class relies on statistics that track, mostly, very high tonnage bulk chemicals on the European market and the data cannot differentiate between chemical uses. The indicator Growth of the EU chemicals market for substances of different levels of concern is based on the use volume recorded in REACH registration dossiers but industry is not obliged to update and/or report volume information for every calendar year. To overcome this, interpolation is needed and this introduces uncertainties.

In relation to the objective to develop innovative tools for testing and risk assessment, the data showing the number of animal uses in tests related to chemicals legislations are heavily influenced by the test requirements linked to the REACH registration deadlines for chemicals. The third and final registration deadline under REACH in 2018 and testing proposal evaluations and compliance checks performed by ECHA is likely to have resulted in an increase in the number of animal uses during the time period covered by the indicator (2015-2020). This affects the baseline and will need to be considered when interpreting any future trend.

A number of signals were also developed to complement the assessment under Section 2.2.1. These included an overview of measures that were already available on minimising the impact and reducing the use of hazardous chemicals by industry.

One signal provides specific insights on ongoing developments in the framework for SSbD chemicals and materials. A Commission Recommendation (2022/2510) establishing the framework and providing guidance on the design and evaluation of SSbD chemicals and materials was published recently (Box 2.1). Tools related to this are still under development. Thus, there are currently no data available at the EU level on the uptake of the framework in terms of R&I efforts and the (re-)design and production of SSbD chemicals and materials.

Despite the uncertainties related to the scope of the indicators and data gaps, the current evidence appears sufficient to highlight the need to persist in the transition towards safe and sustainable chemicals.

Table 2.1 Safe and sustainable chemicals — data gaps as they relate to policy objectives

Objective	Number of indicators supporting assessment	Main data gaps identified during the assessment
Protect health and the environment: Use of safe chemicals while preventing harm to humans and the environment by avoiding substances of concern for non-essential uses	3	Data on the occurrence of substances of concern in articles (products) on the EU market
Encourage innovation: Promote the development of safe and sustainable chemicals and materials, clean production processes and technologies	2	Data on the uptake of the SSbD framework by the EU chemical industry for the (re-design of chemicals and materials (including information gaps in cases of substitution to SSbD alternatives) Data on the use of resources by the EU chemical industry, including both feedstock for energy use (fossil fuels or renewable energy) and processes (raw materials and by-products of petrochemical processes)
Encourage innovation: Promote the development of innovative tools for testing and risk assessments	2	Data to assess the regulatory acceptance of non-animal test data

2.3.2 Ongoing developments

The European Commission recently published an action plan entitled the 'transition pathway for the chemical industry'; it was co-developed with EU countries, chemical industry stakeholders, non-governmental organisations and other interested parties (EC, 2023d). One of the actions to be implemented relates to the need for collaboration between the actors involved in the sector to support the transition, particularly in relation to innovation, clean energy supply and feedstock diversification. Certain initiatives are about to be implemented by the stakeholders and as these progress, the action plan can form an important source of information for assessing these changes.

With regard to the substitution of most harmful substances, there has been a move towards expanding the generic approach to risk management (GRA) to more hazard classes (beyond CMR category 1A/B) and to more consumer products; this progress is primarily linked to the introduction of new hazard classes for harmonised classification under CLP (see also Section 3.3.2). Furthermore the CSS mentions the need to extend to professional users under REACH the level of protection granted to consumers in particular when handling those most harmful substances.

Other actions have not yet been implemented and so the most harmful substances in consumer products and some professional uses are currently being phased out on a case-by-case basis via specific legislative frameworks like REACH or on a voluntary basis by the industry.

The Commission continues to work on testing the SSbD framework (Box 2.1), gathering feedback from the industry, academia, Member States and research and technology organisations and further supporting the development of SSbD approaches. As discussed above, the signal Safe and sustainable by design chemicals and materials indicates positive participation in the first reporting period for the SSbD framework with encouraging engagement from the different stakeholders and ongoing case studies.

R&I projects are also ongoing to support the transition to safe and sustainable chemicals. As part of the R&I funding programme Horizon Europe, the Commission has established an overarching strategic research and innovation plan (SRIP) for safe and sustainable chemicals and materials pointing at key R&I areas. The plan outlines the R&I needs for chemicals and materials across their lifecycle (EC, 2022e). In that context, a portfolio of 190 EU-funded projects was also identified in the period March 2021 to September 2022 for R&I on safe and sustainable chemicals and materials; corresponding to over EUR 1 billion in EU funding, as shown in the signal Funding EU projects on safe and sustainable chemicals and materials.

In the area of non-animal testing methods, scientific advances are still required in order to fully replace animal testing. These must be combined with policy and regulatory changes so that solutions can be developed to support a similar or better level of protection for human health and the environment at the same time as moving away from animal testing. It takes a long time for new test methods to be developed, validated and included in the regulations. The indicators show that while there are consistent developments in the area, much more effort is needed to fully replace animal testing. Currently, the European partnership for the assessment of risks from chemicals (PARC) aims to develop next-generation chemical risk assessment to protect human health and the environment and at the same time reduce or eliminate the need for animal testing. PARC was established in 2022 and will run for seven years. It supports the CSS and includes several relevant projects that are developing new animal-free methods. However, these are just starting and the first outcomes will only arrive in a few years.

3 Minimise and control the risks

The goal to minimise and control the risks associated with chemicals is the second element in the toxic-free hierarchy (Table 1.1). This aim includes an objective to 'minimise exposure of humans and the environment to substances hazardous to health and the environment, through risk management measures and full information to users of chemicals' in order to protect health and the environment. At the same time, it encourages innovation through the aim to 'promote modern and smart production processes, safe and sustainable uses and business models, chemicals as a service ([7]) (as well as) IT solutions for tracking chemicals'.

3.1 Protect health and the environment

3.3.1 Minimise exposure of humans and the environment to substances hazardous to health and the environment, through risk management measures and full information to users of chemicals

There is an obligation for industry to ensure the safe use of chemicals throughout their entire life-cycle (including in materials and products) by implementing risk management measures to 'minimise exposure of humans and the environment to substances hazardous to health and the environment'. The EU Member States, the European Commission and EU agencies are working together to minimise and control the risks posed by substances by continuously considering and implementing regulatory risk management measures at the EU level (see Section 1.2 above and Box 3.1).

([7]) As defined in the CSS: 'Chemicals as a service' includes chemicals leasing but also the leasing of services such as logistics, development of specific chemical processes and applications, and waste management (EC, 2020b).

Box 3.1

Industry and regulatory risk management measures

There is an obligation for industry (manufacturers/importers of chemicals and companies using the chemicals for various purposes down the supply chain) to ensure the safe use of chemicals throughout their entire life-cycle (including when present in materials and products). Safe use is achieved in a number of ways by implementing risk management measures on site (e.g. exhaust ventilation, operating an on-site wastewater treatment plant) but also by providing information on the safe handling of substances to all users down the supply chain.

Authorities may also initiate regulatory risk management actions at EU level to further minimise and control the risks posed by chemicals. These measures can be imposed on top of the existing measures taken by industry. Regulatory risk management refers to REACH (authorisation, restriction), CLP and sectoral legislations (e.g. on pesticides and biocides). Industry is obliged to comply with and implement the risk management measures agreed by the authorities.

Risk management measures under REACH

REACH registrations and CLP notifications offer information relevant to assessing progress towards the objective of minimising human and environmental exposure to hazardous substances through risk management measures. The indicator Progress in regulating substances under REACH and CLP draws on these data sources and tracks the progress in regulating chemicals on the European market (registered either in the 1-100 tonnes/year or above 100 tonnes/year) under REACH and CLP. It shows that the EU is making progress in assessing substances and identifying substances that need further risk management measures to be implemented. The number of substances under assessment has increased from circa 50 in 2010 to more than 2,000 in 2021. Understanding of hazardous properties and the potential for exposure from all REACH-registered substances on the EU market continues to improve within the EU and its Member States. The indicator also shows that additional hazard data are being generated. Currently, EU authorities have increasingly better knowledge about the hazardous properties of high-volume chemicals on the EU market. However, there are still knowledge gaps for a number of substances registered under REACH and more effort needs to be made to fill these gaps. There needs to be greater clarity on hazardous properties as a first step towards further (regulatory) risk management actions. Since the CLP entered into force in 2009, 88 chemicals (used as industrial chemicals, biocides and/or pesticides) have been formally identified as new category 1 CMR as reported in the indicator Number of substances identified as carcinogenic, mutagenic, or toxic for reproduction. As a consequence, new risk management measures have been introduced in the workplace along with restrictions on their use in consumer mixtures; additionally the new classifications have resulted in actions under various pieces of legislation (e.g. relating to cosmetics and toys).

Since 2010, there has been a moderate increase in the number of chemicals under REACH and CLP, which require risk management measures at EU level (e.g. harmonised classification, authorisation or restriction). Continued increases are expected in the future as more substances are assessed as reported under the indicator Progress in regulating substances under REACH and CLP. Authorisation is one of the regulatory risk management tools under REACH to support the replacement of substances of very high concern with less dangerous substances or technologies. To date, several analyses on the impact of authorisation on the EU chemicals market have been undertaken. The signal Market volume changes of chemicals subject to REACH authorisation offers some examples. From 2010-2021, the use volumes of registered substances subject to REACH authorisation is estimated to have decreased by 45%. In particular, the volume of phthalates (DEHP, DBP, BBP, DIBP and DIPP) placed on the market in this period decreased dramatically, by 90% (mainly due to reduction in the use of DEHP). By way of example, a study based on Swedish data suggests that regulatory action at EU level, on substances currently on the REACH authorisation list, has considerably reduced the annual use tonnages of these substances in Sweden.

More recently, on 25 September 2023, the Commission adopted a restriction on microplastics intentionally added to products (EU, 2023). This restriction will contribute to minimising human and environmental exposure to microplastics. The first measures, which include the ban on loose glitter and microbeads, entered into force in October 2023. Sales bans based on other measures will come into force after a longer period to give affected stakeholders the time to adjust their products and switch to alternatives. Lead is a further example of regulatory measures taken by authorities as described in the cross-cutting signal Progress in regulating lead.

REACH groups chemicals in a way that supports consistent and coherent action. This approach has the potential to accelerate both the assessment and regulatory measures related to chemicals with structural or functional similarities. More importantly it helps to avoid regrettable substitution (Box 3.2). The signal Regulating groups of substances to speed up action and ensure a coherent approach presents, for example, ongoing regulatory efforts relating to per- and polyfluoroalkyl substances (PFAS) and bisphenols. Other examples are also provided in the signal.

Box 3.2

Regrettable substitution

Regrettable substitution refers to cases where a banned chemical is substituted by another with similar or even unknown properties. Assessing chemical hazards of groups of substances with similar structures, rather than individual substances, is one approach that can prevent regrettable substitution.

See an example of regrettable substitution in the signal Human exposure to bisphenols.

Regulatory actions under other legislations

Phasing out hazardous chemicals has led, in some instances, to regrettable substitution, as in the case of ozone-depleting substances (ODS) and fluorinated gases. Additional regulation of the substitute is then required. The particular use of ODS in the refrigeration, air conditioning and heat pump (RACHP) sector has had a significant adverse effect on the ozone layer, thus impacting on human health and ecosystems. This led to a ban on ODS for a large range of applications in 2009 (EU, 2009c); there has been a drastic decline in consumption since then. Much of this decline was due to the substitution of ODS by fluorinated gases (F-gases), which are powerful greenhouse gases that contribute to climate change. These were themselves subsequently regulated (EU, 2014, 2024a). The indicator Consumption of ozone-depleting substances shows that ODS are being phased out in the EU. The consumption values between 2010 and 2022 are mostly negative; this means that more ODS are removed from the EU market than enter it. ODS production continues mainly for exempted uses, exports and destruction.

Emissions of F-gases increased between 1990 and 2014 (EEA, 2023a) mainly due to the substitution of ozone-depleting hydrochlorofluorocarbons (HCFCs) (i.e. ODS) with hydrofluorocarbons (HFCs) in the RACHP sector and the growth of this sector as a whole. The F-gas Regulation entered into force in 2015 to address the contribution of F-gases to climate change and phase down their consumption via a system of yearly quotas, which are reduced progressively. This has led to a decline in the quantity of HFCs placed on the market in the EU, as shown by the indicator Hydrofluorocarbon phase-down in Europe. The quantity of HFCs placed on the market was below the maximum set by the Regulation in 2015 and in each year since. Between 2020 and 2021, quotas for placing HFCs on the market were reduced by 38%.

Under the farm to fork and biodiversity strategies (see Section 1.2), the European Commission has established reduction targets for pesticides. There are two specific indicators to follow progress in this area. The aim is to reduce the use and risk of chemical pesticides by 50% and also reduce the use of more hazardous pesticides by 50% by 2030 compared to the baseline period 2015-2017. These targets are also set out under the zero pollution action plan. Since the baseline period of 2015-2017, EU trends in the use and risk of chemical pesticides shows that chemical pesticide use and risk has decreased by 33% and EU trends in the use of more hazardous pesticides shows a decrease in more hazardous pesticide use by 21% (in 2021). One of the key factors that can explain the downward trend in the overall risk is the categorisation of substances into defined groups; different groups carry different risk weighting factors in the indicator. The improvement in pesticide use and risk is driven by those substances that are in the 'candidates for substitution' and 'not approved' categories. It is important to note that these indicators do not consider actual pesticide use due to the lack of use data at the EU level. The indicators are based instead on sales. Also, pesticide categories used for weighting the risk in the indicator do not quantify the risk with scientifically-based evidence of harm. As a consequence, they do not inform on the effective reduction of pesticide occurrence in ecosystems and their related risks. Regulatory risk management measures undertaken by competent authorities (e.g. in relation to approval and use conditions) may have supported the overall decreasing trend in the indicator, especially in relation to decisions affecting the use conditions and quantities applied (sold). This suggests that regulatory risk management measures undertaken by competent authorities can help to reduce/avoid the use of hazardous chemical pesticides.

Another specific target under the farm to fork strategy is to reduce the sale of antimicrobials for farmed animals and in aquaculture by 50% by 2030 (compared to 2018 levels). This target has also been integrated into the zero pollution action plan. The aim is to ensure that antimicrobials are used only when necessary and to reduce the risk of antimicrobial resistance (AMR) developing and antimicrobial-resistant microorganisms being transferred through the food chain (EEA, 2022c). AMR is a term used to describe a situation where microorganisms, such as bacteria, become resistant to an antimicrobial to which they were previously susceptible. Inappropriate use of antimicrobials in human and veterinary pharmaceuticals is known to be a substantial driver of AMR. The indicator Antimicrobial consumption *by* food-producing animals in the EU shows that in 2022, the sales of antimicrobials for food-producing animals fell by 28% compared to 2018. This decrease represents over half of the reduction target for 2030 under the farm to fork strategy and the zero pollution action plan. Nevertheless, Member States will have to continue to take action in order to reduce sales of antimicrobials for farmed animals and aquaculture by another 22%. Human consumption of antibacterials (which is not in the scope of the zero pollution action plan's target), rose by 1% in 2022 compared to 2018, following a rebound after the COVID-19 pandemic (from 2021-2022), according to the indicator Human consumption of antibacterials for systemic use in the EU.

Compliance with regulatory risk management measures

When regulatory risk management measures are set up at the EU level, it is important to ensure that industry is actually abiding by those measures. Regular enforcement is needed to check that regulatory obligations under the different legislations are being followed. REACH and CLP are enforced by Member State authorities and enforcement activities vary across Europe in terms of effort and focus. Compliance with REACH and CLP measures is reflected in several indicators: REACH controls: percentage of compliant cases found in Member States, CLP controls: percentage of compliant cases found in Member States and Percentage of REACH CLP-compliant cases found in imported goods. These indicators show that compliance has remained relatively high, though there has been a slight decrease over the years in relation to imported goods under REACH and CLP.

However, the numbers of checks undertaken by national authorities to ensure obligations are fulfilled by duty holders are limited and only certain restrictions are monitored. As a consequence, it is hard to get a clear overview of how well obligations are fulfilled and associated risks are controlled for. The signal Compliance with REACH restriction and authorisation measures provides a summary of certain targeted enforcement projects that have been coordinated under the Forum for Exchange of Information on Enforcement ([8]). This signal indicates that even though some restrictions have been in force for many years, there is still a high level of non-compliance reported in a number of cases. On average 82% of the products checked complied with the inspected REACH restrictions. However, the two entries with the highest rates of non-compliance were phthalates in toys (19.7%) and cadmium in brazing fillers (14.1%). By way of example, another targeted enforcement project identified a high level of non-compliance with REACH authorisation requirements (up to 40%). This indicates that it usually takes time for industry to implement more recent regulatory risk management measures, such as authorisation requirements.

CLP controls: percentage of compliant cases found in Member States also suggests that most enforcement activity related to CLP requirements focuses on ensuring that the correct hazard information is communicated in the supply chain (including on packaging and labelling). Providing information to users of chemicals in the supply chain should ensure that the necessary risk management measures are put in place by the duty holders.

Alerts can currently be reported relating to products placed on the EU market that pose risks to human health and the environment. These are collected by national authorities under the EU Rapid Alert System for dangerous non-food products, established under the General Product Safety Regulation (EU, 2023b). The indicator Alerts for products posing a risk to human health and the environment provides an overview of the efforts made to identify and remove products on the EU market that pose chemical risks. On average, 870 alerts were reported each year between 2015 and 2023. Phthalates were the most reported group of chemicals regardless of the year and toys represented the most reported product category. However, EU and national initiatives that can have a certain focus on specific products and/or substances can influence the number of alerts; as such, the indicator does not allow any overall trend in the chemical risk posed by consumer products on the EU internal market to be discerned.

([8]) Forum for Exchange of Information on Enforcement

In summary, while the available data are mostly specific to industrial chemicals and pesticides, the indicators do show that the EU is making progress in terms of minimising and controlling the risks from chemicals. Risk management measures are continuously considered, established, implemented and enforced for an increasing number of chemicals. There is some indication that these activities are reducing risks and that information on hazards and necessary risk management measures are being provided to the users of chemicals. Efforts are ongoing to increase knowledge on chemical hazards and support risk management action where it is necessary. However, such activities can take time to have an impact on chemical occurrence in the environment. Hazardous chemicals, for example those present in recycled materials, long-lasting consumer products and wastes, can still find their way into ecosystems, in particular when they are persistent, bioaccumulative and toxic (see Chapter 4).

3.2 Encourage innovation

3.2.1 Promote modern and smart production processes, safe and sustainable uses and business models, chemicals as a service, IT solutions for tracking of chemicals

No specific indicator or signal is available for this objective. The aim to 'promote modern and smart production processes, safe and sustainable uses and business models' is meant to support more efficient use and production of chemicals and other resources and to minimise waste and emissions. It is also linked to the EU sustainable finance taxonomy. This taxonomy is a classification system that establishes and promotes a list of environmentally sustainable economic activities. It measures the degree of sustainability in a company's portfolio and helps companies to plan and report on their transformation by establishing disclosure obligations related to the proportion of investments and turnover that are compliant with the taxonomy. Due to the fact that neither indicators nor signals are available for this objective, it is not possible to assess progress towards it in any reliable way; however, its alignment with the EU taxonomy may generate relevant information as a basis for a potential signal in the future.

Similarly, there are no indicators available to assess progress towards the promotion of 'chemicals as a service' and this issue is not explored further in this report.

'IT solutions for tracking chemicals' are meant to guarantee the accessibility, transparency and availability of information on hazards and uses of chemicals throughout the entire life-cycle of materials and products; this includes tracking the presence of substances of concern. There are currently no indicators to assess the progress towards this objective. However, there is clearly some progress in Europe towards digital solutions that help consumers to acquire information regarding chemicals in products. The SCAN4CHEM mobile application is one such example. It was funded by the EU LIFE programme, the EU's funding instrument for the environment and climate action. The application helps consumers to request information from suppliers and retailers about the presence of substances of very high concern in products like clothing, sports equipment and toys. The tool is available in 19 countries. Suppliers are legally obliged to reply to such requests and the information received is added to a growing database of information. The database behind the application already contains information about 50,000 products from over 300 registered companies. Since its launch, over 10,000 users have scanned more than 220,000 barcodes and sent over 40,000 requests for information to suppliers across Europe. The German language application TOXFOX is also linked to the same database and has similar features as SCAN4CHEM.

3.3 Outlook

3.3.1 Robustness of current indicators and signals

All the available indicators have been developed to measure the progress in minimising human and environmental exposure to hazardous substances. They focus on regulatory actions taken by authorities under certain legislations, in particular REACH and CLP. The indicators provide indirect measure of progress since they measure actions taken by authorities, which are expected to reduce overall human and environmental exposure. They only cover the actions of authorities that lead to the implementation of risk management measures in industry. These indicators do not measure any other actions currently being taken, for example voluntary programmes put in place by industry to limit the use of certain chemicals or the implementation of specific dedicated risk management measures put in place to reduce the exposure of workers or environmental exposure.

With regard to the farm to fork strategy and pesticides, it is important to note that actual pesticide use is not measured in the indicators due to the lack of data at the EU level and the pesticide categories used for weighting the risk in the indicators do not quantify the risk with scientifically-based evidence of harm. As a consequence, they do not inform on the effective reduction of pesticide occurrence in ecosystems and their related risks.

Compliance indicators are a way to ensure that recommended risk management measures to minimise exposure are actually put in place. However (as already mentioned in Section 3.1.1) the number of checks undertaken is limited and the checks vary between different Member States. The indicator generated from data on product alerts reported by Member States to the EU rapid alert system is equally limited.

To complement the indicators, a number of signals were developed to provide examples of the potential impact on some substances of concern (e.g. in relation to authorisation and lead) of regulatory measures taken at the EU level.

No indicators are currently available for the promotion of modern and smart production processes, safe and sustainable uses and business models, chemicals as a service and IT solutions for tracking chemicals. However, there have been some initiatives in Europe developing digital solutions that help consumers in particular to acquire information about the chemicals that are present in products (see Section 3.2.1).

Table 3.1 Minimise and control the risks — data gaps as they relate to policy objectives

Objective 	Number of indicators supporting assessment	Main data gaps identified during the assessment
Protect health and the environment: Minimise exposure of humans and the environment to substances hazardous to health and the environment, through risk management measures and full information to users of chemicals	12	The indicators provide indirect measure of progress since they measure actions taken by authorities; data linking regulatory action directly to minimisation of exposure are absent
Encourage innovation: Promote modern and smart production processes, safe and sustainable uses and business models, chemicals as a service, IT solutions for tracking of chemicals	0	Lack of consistent data and tools at EU level even though some initiatives are ongoing

3.3.2 Ongoing developments

Under the revised CLP Regulation, the Commission recently adopted a Delegated Act (EU, 2022a) to introduce new hazard classes for endocrine disruptors (ED) and PBT, vPvB, PMT and vPvM substances (Box 1.1). These proposed hazard classes are useful for supporting better information and communication on hazards related to chemicals placed on the EU market, in particular the most hazardous chemicals.

Furthermore, the introduction of new hazard classes in the CLP will allow future reporting of ECHA indicators beyond CMR by also including those hazard classes. As a consequence, there will be more comprehensive follow up of the most harmful substances as CLP will cover more than CMR classes. Additionally, the CSS includes a proposal to extend the generic approach to risk management to ensure that consumer products do not contain chemicals with ED, PBT/vPvB or PMT/vPvM properties, in addition to the existing restriction on CMR in consumer products (mixtures). In light of this proposal, the identification of new hazard classes represents the first step towards greater protection against the most harmful chemicals.

The Commission is also proposing the 'one substance one assessment approach'; the aim of this is to improve the efficiency, effectiveness, coherence and transparency of issuing safety assessments for chemicals across different pieces of EU legislation (EC, 2023c). Under this proposal, a common data platform on chemicals would be established to bring together information on chemicals from different sources. The platform would ensure easy access to information, transparency and harmonisation across legislations. The development of an EU early warning and action system for chemicals is also included in this proposal, to shorten the time it takes to implement regulatory action when emerging chemicals are identified. All these elements should contribute to minimising human and environmental exposure and providing full information to users of chemicals.

Additionally, a new Ecodesign for Sustainable Products Regulation (ESPR) (EC, 2022d) is being considered to generate relevant information in the future. It aims to set out requirements for ecodesign for a wide range of products. Information requirements/tracking of substances of concern would be included to ensure transparency throughout the value chain. This is particularly important for recovery managers, recyclers and remanufacturers, who need to be informed on the substances used in their processes.

Decisions taken at the EU level on individual substances and groups of substances can also contribute to further data availability. For example, the restriction on microplastics intentionally added to products includes reporting requirements; this will contribute to more reliable EU-level data on microplastics. Additionally, a proposal has been made that microplastics in water should be measured under the Water Framework Directive.

4 Eliminate and remediate chemical pollution

The aim to eliminate and remediate chemical pollution is the last element of the toxic-free hierarchy under the CSS. It includes a series of objectives, listed in Table 1.1, to 'eliminate as far as possible substances of concern from waste and secondary raw materials', 'restore human health and the environment to a good quality status', 'promote safe and clean recycling solutions including chemical recycling and waste management technologies', as well as to 'promote decontamination solutions'.

This chapter reports on indicators that were used to estimate or measure the occurrence of chemicals in products, materials, waste and in the natural environment, to assess the level of exposure among humans and ecosystems. This will contribute to a better understanding of chemical pressures and risk in the broad sense. A wide range of chemicals is monitored in different environmental matrices (e.g. air and water) and in human bodies; they include industrial chemicals but also chemical pesticides, antibacterials, metals and microplastics.

4.1 Protect health and the environment

The objective to 'eliminate as far as possible substances of concern from waste and secondary raw materials' aims to ensure that recycled materials adhere to the same standards as virgin materials: substances of concern in products and recycled materials should be minimised; equally, secondary raw materials should respect the same safe limit values for hazardous substances in order for materials to be recycled. Minimising the use of substances of concern upstream by choosing safe and sustainable substitutes and preventing their occurrence downstream will support the generation of cleaner waste streams and safe secondary (raw) materials. In addition, reducing the production of virgin material may reduce the substantial environmental impacts that can occur during processing, including the emission of hazardous substances. In some very specific cases, there may be derogations on the consideration of safe limit values in secondary raw materials in order to promote recycling over virgin material production, while still ensuring safety.

The treatment of waste containing legacy substances (Box 1.2) that are restricted in the EU today is also an area of concern. These substances, e.g. polychlorinated biphenyl and terphenyls (PCBs/PCTs), can still be found in older materials (EC, 2023a) and also have the tendency to persist in the environment when released. This objective recognises the need to promote innovation to tackle this issue.

The objective to 'restore health and the environment to a good quality status' aims to tackle pollution from all sources in order to move towards a toxic-free environment where the chemical-carrying capacity of ecosystems is respected. This includes ensuring sustainable human and environmental (bio)monitoring capacities across the EU, complementing ecosystem monitoring initiatives. Good quality status refers to a safe level of chemical exposure that has no adverse effects on human health and the environment.

4.1.1 Eliminate as far as possible substances of concern from waste and secondary raw materials

As previously discussed in Chapter 2, the indicator Production and consumption of chemicals by hazard class shows that overall there has been relatively stable production of CMR (in tonnes) since 2004, although there have been fluctuations over the years. This implies that the volumes of contaminated waste and levels of substances of concern in secondary raw materials are unlikely to be decreasing, unless waste products containing hazardous substances are increasingly being kept out of waste streams through better waste collection and waste treatment. However, information about such processes is currently not available. It is also important to note that the indicator does not differentiate between the different uses of chemicals (e.g. in consumer or professional products and respective use settings); it also includes the production and consumption of intermediates in chemical production, which are used under strictly controlled conditions with a low level of exposure and release potential.

Production processes in the chemical industry include the generation of both hazardous and non-hazardous wastes. According to the indicator Waste generation in the chemical industry (see Chapter 2), the share of waste categorised as hazardous has remained stable at about 50% of total waste or 5.8 million tonnes since 2012.

Hazardous substances are not always eliminated during waste management and treatment; this leads to potential human and environmental exposure, for example from unintentional emissions from waste landfills (see Section 4.2.1). Additionally, contaminated materials, including older materials that contain banned substances, can be recycled with the risk that hazardous substances are channelled into secondary raw materials and ultimately into new products. The signal Plastics recycling in Europe: obstacles and options highlights how hazardous substances such as specific flame retardants, phthalates, and bisphenols form a significant obstacle to increased recycling.

In the industry, some waste streams could be used as a source of valuable materials; this could lead to cleaner wastes as well as greater recycling of key raw materials. The signal Recycling materials from green energy technologies indicates that there is a potential to recover valuable materials from items such as wind turbine blades and solar photovoltaic panels. However, technical challenges persist and existing waste processing facilities do not currently have the capacity to recycle these items effectively given the quantity of waste collected.

Large amounts of wastewater are also generated by human settlements. In urban areas, sewerage systems can carry wastewater from households, light industries and runoff from public areas (e.g. rain water) (EEA, 2022a). Urban wastewater treatment (UWWT) plants are key infrastructures in reducing loads of pathogens, organic matter and excess nutrients before water is released back to the environment. Wastewater can undergo progressive levels of treatment in UWWT plants, which are categorised as primary, secondary and tertiary under Eurostat reporting. The tertiary level of treatment is more tailored to specific cases and involves more intensive nutrient removal.

The indicator Population connected to at least secondary wastewater treatment shows that, in 2020, 81% of the EU population were connected to wastewater treatment which was at the secondary level at least. This was following a progressive increase in the percentage from 2000, as reported to Eurostat. Additionally, data reported under the UWWT Directive show that, in 2018, 82% of Europe's urban wastewaters were collected and treated in line with EU standards.

Wastewater that has been treated and meets certain quality requirements can be reused for agricultural irrigation according to the new EU Water Reuse Regulation (EU, 2020b). In some areas where climate change is leading to reduced rainfall, treated wastewater from UWWT plants plays an important role and contributes to a more circular economy (EEA, 2022a).

However, wastewater treatment does not eliminate all the hazardous substances that may be found in sewage. Mixtures of substances in treated effluents can end up being released to surface waters. This can happen, for example, when chemicals are used in the home as cleaning products, when they leach from consumer products and when pharmaceuticals are excreted. In this way, chemicals and in particular contaminants of emerging concern can be introduced into the environment when emitting treated wastewater or when re-using sewage sludge (EC, 2022b; Pastorino and Ginebreda, 2021). Additionally, the release of antimicrobial resistance genes into the environment via wastewaters (see Section 4.1.2) is of high concern.

UWWT plants produce sludge as residual waste; it is generated through sedimentation of organic material during the treatment process. Sewage sludge is a source of beneficial nutrients for plant growth and can reduce reliance on mineral fertilisers, thereby promoting more circularity. However, similarly to treated wastewater, the use of sewage sludge on agricultural land can result in contamination of soil, and food and feed grown on that land. In the signal Long-term impacts of sludge spreading on agricultural land, case studies show that applying sewage sludge on cropland can contaminate soils with a range of chemicals, including microplastics, though this does not necessarily pose a risk for human health and soil organisms. Yet, the case studies also highlight that contamination levels are variable, as the occurrence of chemicals depends on the consumption characteristics of the population and industry nearby and on national criteria on quality with regard to spreading sludge. In addition, uncertainties exist about which types of chemicals are being screened for and analytical methodologies applied for the screening of soil and sludge contamination.

Overall, the data currently available suggest that there is little evidence of progress towards eliminating substances of concern from waste and secondary materials.

Once material flows are contaminated with hazardous substances, it is challenging if not impossible to eliminate them when mechanical recycling takes place. This is particularly true for plastic waste (see Section 4.2.1). This highlights the need to shift towards the use of chemicals, materials and products that are safe and sustainable. This would ensure that chemicals are not channelled into recycled materials or contaminating consumer goods, food and the environment, while potentially posing a risk to workers in recycling facilities as well (see Section 4.2.1), and perpetuating human and environmental exposure as a circular economy is implemented.

4.1.2 Restore human health and the environment to a good quality status

The assessment below is structured around a number of sub-sections; these relate to pollution in environmental matrices, namely surface water and groundwater, the marine environment and soil, followed by emissions to air. Chemical risk to human health is discussed in another sub-section. Most of the indicators used to monitor this element of the toxic-free hierarchy were developed in earlier frameworks and are well established. As such, they inform on the effect of a number of environmental policies and inform on the need for further developments.

Surface water and groundwater pollution

According to the reported data, direct releases of a number of specific hazardous substances to surface waters by industry in the EU-27 have substantially decreased since 2010.This is shown by the indicator Industrial chemical releases to water. Releases of polycyclic aromatic hydrocarbons (PAHs) and nonylphenols (NP) and nonylphenol ethoxylates (NPEs) decreased by 9% and 89%, respectively. However, many substances are not systematically monitored in the environment, though ad hoc monitoring suggests that they occur ubiquitously (e.g. PFAS (Cousins et al., 2022) and microplastics (EEA, 2023c)).

Pollutants can also find their way into surface water bodies from diffuse sources as a result of effects such as atmospheric deposition and agricultural activities. One of the main pressures on surface waters from the agricultural sector, for example, is the widespread use of chemical pesticides in the EU (EEA, 2021).

The indicators on the EU trends in the use and risk of chemical pesticides and the EU trends in the use of more hazardous pesticides show a 33% and 21% decrease in the use and risk of pesticides, respectively, since the baseline period of 2015-2017, as previously discussed in Chapter 3. Yet, actual pesticide use is not considered for either of these indicators due to a lack of data at the EU level and pesticide risk categories are linked to regulatory criteria rather than scientific evidence of harm in the indicator on use and risk of chemical pesticides. Therefore, there are substantial uncertainties about whether the downward trends actually translate into reduced pesticide occurrence in ecosystems and decreased risks.

The indicator Pesticides in rivers, lakes and groundwater in Europe shows that, in 2021, pesticide levels exceeding EU environmental quality standards (EQSs) set out in the WFD were measured in 10% of all the reported surface water monitoring sites. The range of exceedance varied between 10 and 25% between 2013 and 2021. Similar analyses was done for groundwater; at between 4% and 11% of groundwater monitoring sites between 2013 and 2020, one or more pesticides exceeded the quality thresholds set out in the Groundwater Directive (EU, 2006a). This issue was mainly caused by the herbicide atrazine and its metabolites. Atrazine is no longer approved for use in the EU (EU, 2004).

As part of the WFD, chemicals other than pesticides are also monitored in surface waters and groundwaters in the EU. Good chemical status for surface water and groundwater is defined as water bodies achieving all the chemical quality standards established for a selected set of harmful chemicals, 'priority substances', at the European level. The definition is based on the 'one out, all out' principle, whereby failure to achieve good chemical status is often driven by a few non-compliant ubiquitous substances. Data reported by Member States in 2016 in the signal Chemicals in European surface water and groundwater show that only 33% of the surface water bodies being monitored were achieving good chemical status. This was primarily due to widespread non-compliance in relation to a small number of ubiquitous, persistent, bioaccumulative and toxic substances, mainly mercury. In contrast, around 23% by area of groundwater bodies in the EU-27 failed to achieve good chemical status.

Despite efforts to reduce emissions of chemicals to surface water and groundwater bodies, the substances monitored at the EU level continue to pose a potential risk to human health and the environment. In particular, this is due to so-called 'legacy substances' that were heavily used in the past (Box 1.2).

Many contaminants of emerging concern such as antibiotics and preservatives in pharmaceuticals and personal care products, though not persistent, have been found to be constantly present in aquatic systems in Europe due to their continuous release into the environment from UWWTPs (EEA, 2018a; Haman et al., 2015; Danner et al., 2019) (see Section 4.1.1). It is therefore essential to monitor currently used substances more closely, with a particular focus on those that pose a risk to human health and ecosystems. Innovative analytical methods such as effect-based methods and non-target analysis (NTA) are recommended. Such increased monitoring would also support early detection of new substances appearing in environmental and biotic media.

Marine pollution

Data are not currently available at the EU level for the quantities of direct and indirect (i.e. river basin discharge) pollutant emissions to the marine environment caused by human activities such as port and industrial activities, shipping and aquaculture. Nevertheless, the occurrence of hazardous substances in living organisms and the observation of large-scale sea contamination offer a direct indication of the level of marine pollution to which marine organisms are exposed.

For the indicator on Hazardous substances in marine organisms in European seas, nine hazardous substances were monitored between 2010 and 2019. The indicator shows that all of them exceeded safe limit values in some areas. This was especially the case for benzo[a]pyrene, lindane (HCHG) and PCB. Only the North-East Atlantic Ocean and the Baltic Sea had sufficient data from monitoring for trends to be discernible. Depending on the hazardous substances monitored, a stable or decreasing trend was observed in the North-East Atlantic Ocean. Despite time trends could be determined for the Baltic Sea, they were not significant. The substances being monitored are mainly heavy metals and synthetic substances that are no longer intentionally used, which fall into the 'legacy substances' category (Box 1.2).

Other substances also contaminate European seas. In particular, long-range transport of PFAS from land to sea leads to maritime pollution, as highlighted in the signal PFAS in European seas. The signal shows that substances such as PFOS and PFOA pose a risk to marine organisms and human health, especially through bioaccumulation in the food chain. Many other PFAS that are still in use are not currently being monitored.

Thus, persistent legacy substances continue to be present in the marine environment at a level posing a risk to marine organisms, despite regional cooperation to protect European seas under initiatives such as the Marine Strategy Framework Directive (EU, 2008a) and the Regional Seas Conventions. In addition, local data indicate that pollution of European seas by industrial PFAS is potentially widespread.

Soil pollution

The predominant sources of local soil contamination are historical contaminations, inadequate or unauthorised waste disposal, unsafe handling of dangerous chemicals within industrial or commercial processes and accidents. The large volume of waste production and the widespread use of chemicals during the past decades have resulted in local soil contamination at numerous sites. Yet, there are no complete inventories of contaminated sites at the EU level. The indicator Progress in the management of contaminated sites shows that, in 2016, 1.38 million potentially contaminated sites were registered based on data for 23 Member States; 69% of these sites have been confirmed by on-site investigations. The total number of potentially contaminated sites for the EU-27 was projected to be 2.8 million based on 2016 statistics. Contamination of these sites has generally been caused by substances such as hydrocarbons, mineral oil, polycyclic aromatic hydrocarbons, heavy metals and pesticides, some of which are 'legacy substances' (Box 1.2).

However, screening of currently used substances is crucial to understand the state and extent of soil pollution, including from substances like PFAS (see Section 4.2.2).

Due to the fact that agriculture covers a large area of land, it is a major source of diffuse pollution from pesticides, heavy metals (e.g. cadmium and zinc in fertilisers, copper in plant protection products and pig feed) and to a lesser extent other industrial substances present in organic fertilisers such as sewage sludge (see Section 4.1.1). The previously introduced indicators EU trends in the use and risk of chemical pesticides and the EU trends in the use of more hazardous pesticides show decreasing trends of use and risk since the 2015-2017 baseline period, although it is uncertain if there has been an effective reduction of pesticide occurrence and risk in soils (see Chapter 3). For the particular case of pesticides, the regulatory framework includes assessments of pesticide fate (e.g. in terms of a substance's persistence, metabolite formation and transport) as well as associated environmental risks. The framework makes use of both monitoring and modelling tools during the approval process and product authorisation phase at Member-State level. However, for many chemicals the pathways and mechanisms involved in the occurrence and long-term fate of substances in soil are not currently sufficiently monitored and understood. As such, significantly improved in-situ monitoring and further investigations are required in order to increase our understanding of exposure and risk.

As shown by the signal Ecological risk of pesticides in EU soils, it has not been possible to exclude the risk of adverse effects to soil organisms associated with pesticide mixtures in soil at 14% of the approximately 3,500 European sites monitored in 2018. The insecticides imidacloprid and chlorpyriphos and the fungicide epoxiconazole, currently not approved for use in the EU (EU, 2022a, 2018a, 2019), were the main drivers of toxicity at these sites. These results can be partially compared to data from the 2015 pilot study described in the signal; 73 of the sites monitored in this signal were common to those monitored in 2018. Although the number of comparable sites is limited, results from the two monitoring campaigns indicate that there is no sign of progress towards a risk reduction.

There is currently no systematic monitoring of soil pollutants and links to health impacts across Europe. Potential pathways for humans to be exposed to these pollutants include through skin contact, breathing in dust and consumption of contaminated food and water. While a European monitoring framework is needed across the EU to collect data on soil health and related risks, certain other actions also have the potential to decrease the chemical pressure on soil quality; these include increased waste collection and continued promotion of the sustainable use of plant protection products.

Emissions to air

Emissions of chemicals to air from human activities come from a wide range of both point and diffuse sources such as industrial and heating facilities and transport. These emissions can be transported over long distances from their point of release and thereby contaminate the wider environment, for example through atmospheric deposition.

The indicator Industrial chemical releases to air shows that point releases of PAHs to air from industry fell by 64% between 2010 and 2022. Meanwhile the indicator Persistent organic pollutant emissions in Europe shows that emissions of hexachlorobenzene (HCB), polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDDs and PCDFs), and PAHs declined considerably between 2005 and 2021 in the EU, from 15% to 53% depending on the substances. A particularly notable decline in POPs emissions was observed in industrial processes and product use, energy production and distribution and the waste sectors. Targeted EU legislation, such as the Community strategy for PCDDs/PCDFs and PCBs, the POPs Regulation and the

IED, has contributed to these substantial reductions. However, the industrial processes and product use sector remains a significant source of POPs, accounting for 51% of PCBs and almost 19% of PCDDs and PCDFs, as well as 13% of HCB emissions in 2021. Fuel combustion within this sector is not included in the reporting.

POPs are substances that are persistent, bioaccumulative and toxic to human health and the environment and prone to long-range transport in the environment. As such, once they are present in the environment they may pose risks to health and ecosystems for years even if there are considerable reductions in their use and emissions. This highlights the importance of designing substances that are SSbD and also ensuring clean production processes to avoid the production of substances of concern upstream and their introduction in products and to the environment.

As discussed in Chapter 3, ODS have been banned in the EU since 2009 for a large range of applications and there has been a drastic decline in consumption since then, mainly due to their substitution with fluorinated gases (e.g. HFCs), which are powerful greenhouse gases and therefore regulated (EU, 2024a). The indicator Consumption of ozone-depleting substances shows that ODS are being phased out in the EU. Mostly, the data show negative consumption values for ODS between 2010 and 2022; production is still ongoing for exempted uses but cancelled out by exports and destruction. Meanwhile, the indicator Hydrofluorocarbon phase-down in Europe shows that the quantity of HFCs placed on the EU market was below the maximum set by the Regulation in 2015 and in each year since.

The indicators thus show that targeted legislations on air pollutants, POP emissions as well as ODS and HFC gas consumption have led to a reduction in their emissions to air and in the use of chemicals that deplete the ozone layer and contribute to climate change. As such, the related risks posed to human and ecosystem health have also decreased.

However, occurrence and risks remain, especially due to the persistent properties of POPs in the environment. This is apparent in the levels of HCB, PCB and PAH substances exceeding safe limit values in marine organisms as shown in the indicator Hazardous substances in marine organisms in European seas.

Overall, emissions of certain chemicals to water and air have fallen following specific EU regulations (e.g. on industrial emissions) and international actions but further measures are needed to reach concentration levels that are not harmful for human health and the environment.

Chemical risk to human health

Exposure to chemical pollution can harm human health, and there is clear evidence that reducing pollution leads to improved health and wellbeing (EEA, 2020). Vulnerable people, including children and the elderly, are more sensitive to pollution; moreover, those in lower socio-economic groups tend to be exposed to higher levels of pollution (EEA, 2018b).

The indicator Alerts for products posing a risk to human health and the environment, introduced earlier, shows that a range of products on the EU internal market still pose chemical health risks for consumers due to the presence of hazardous substances. One example is the occurrence of banned phthalates in non-compliant toys that are frequently identified by enforcement authorities.

Certain endocrine disruptors such as phthalates and bisphenols are categorised as substances of very high concern (ECHA, 2024) due to their impacts on reproduction and development (Eales et al., 2022; Konieczna et al., 2015; Thoene et al., 2020). Phthalates and bisphenols are widely used in the manufacture of plastics to provide the materials with specific properties (e.g. softness and toughness, respectively). The signal Human exposure to bisphenols shows that the concentrations of bisphenol A (BPA) in human urine from nine European countries exceed the health-based guidance value established by the European Food Safety Authority (EFSA) in the period 2014-2020. Nevertheless, the data also show a trend towards decreasing BPA levels in urine during the monitoring period. This is likely to be a result of different regulatory measures that were implemented in the period. At the same time, two other bisphenols that may be used as alternatives to BPA were also monitored. There was a slight increasing trend in the use of bisphenol S (BPS) and a slight decreasing trend in the use of bisphenol F (BPF). Increasing BPS levels may be an indication of regrettable substitution, as BPS is known to have many of the same concerning properties as BPA (Box 3.2).

PFAS, also called 'forever chemicals', refers to a large group of chemical substances that do not break down in the environment; some of them are also known to be bioaccumulative. Exposure to such chemicals can result in increased accumulation in our bodies over time, which can lead to negative health impacts. The signal Risks of PFAS for human health in Europe, based on human biomonitoring surveys carried out between 2014 and 2021 across nine EU Member States (HBM4EU project), shows that it is not possible to exclude risk for adverse health effects from internal concentrations of four PFAS (PFOS, PFOA, perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS)) in European teenagers. In all the studies some participants had internal levels exceeding the guidance value, with exceedances varying between 1.3% and 23.8% with an average of 14.3%. Given the large number of PFAS and their widespread use, these results highlight the need for further upstream restrictions of these substances as a group, to limit human exposure to other PFAS not yet regulated.

Plastics do not degrade in the environment. Rather, they become fragmented into smaller pieces that can be categorised as macro-, micro- and nanoplastics. These small pieces of plastic can find their way into the human body through, for example, inhalation and ingestion. The signal Impacts of microplastics on health shows that, while there is evidence that microplastics are ubiquitous in the environment and that they may carry substances of concern, there are still many unknowns related to their effects on human health.

Other widespread chemicals that may have adverse effects on human health are pesticides. Exposure to pesticides and their metabolites occurs both through the environment and the consumption of food products and can often be found as mixtures of two or more substances. The signal How pesticides impact human health indicates that exposure to pesticides may be linked to increased risk of several chronic diseases. In addition, it highlights the human biomonitoring results from the HBM4EU project, which found that 84% of the samples taken from the bodies of children and adults across five European countries contained residues of two or more pesticides between 2014 and 2021. The levels of exposure measured for the pesticides pyrethroids and chlorpyrifos suggest a potential concern for adverse health effects, especially among highly exposed children.

AMR represents a significant threat to human and animal health. The indicator Antimicrobial consumption by food-producing animals in the EU (Chapter 3) shows that the sales of antimicrobials for food-producing animals fell by 28% in 2022 compared to 2018. Meanwhile, human consumption of antibacterials fell by 17% between 2018 and 2021, mainly due to the COVID-19 pandemic (ECDC, 2022, 2023); there was a rebound in 2022, however, resulting in a 1% increase compared to 2018, according to the indicator Human consumption of antibacterials for systemic use in the EU. Reduced antimicrobial consumption will help to decrease the risk of AMR in livestock and humans. It will also help to reduce instances of substances such as sulfamethoxazole, trimethoprim and miconazole being released; these are included in the surface water watch list under the WFD (Gomez Cortes et al., 2020; EU, 2022b). The watch list is designed to allow high-quality monitoring data to be acquired from across the EU on substances that may pose a significant risk to or via the aquatic environment at EU level. The substances included are toxic and widely used but monitoring data on them are currently insufficient to draw conclusions on the actual risk they pose.

It is also important to note that pharmaceuticals represent a specific group of chemicals within the 'eliminate and remediate' element that are dealt with differently to other substances. This is because their use is necessary to the health and wellbeing of both humans and animals. The goal for these substances is to ensure responsible use and eliminate the risk (rather than fully eliminating the substances) and ensure that the benefits of their use exceeds the risks. Environmental risk assessments are performed for pharmaceuticals before they are authorised for sale; these take into account both the environmental costs and health benefits of a given product.

The impacts of chemical pollution on health are likely to be underestimated. Despite the efforts outlined in Chapter 3, impacts are only known for a subset of pollutants and only in relation to a specific set of known health effects. In addition, chemicals are present as mixtures in the environment; where the risk of an isolated substance may appear low, the combined effects of co-occurring chemicals may lead to a higher risk for human health also called 'the cocktail effect'. This issue is supported by the signal Risks of chemical mixtures for human health in Europe, which covers the results from the European human biomonitoring project HBM4EU. The data indicate potential health risks from combined exposure to a mixture of 15 substances (or groups of substances), for the two periods 2007-2014 and 2014-2021. Of the 15 substances, the mixture risk was primarily driven by seven of them: bisphenol A, the perfluorinated chemicals PFOS and PFOA, arsenic, cadmium and two phthalates (monobutyl phthalate and monoisobutyl phthalate). Despite the uncertainties surrounding mixture risk calculations, it is worth noting that the results from the two periods point to a decrease in the overall human health risks from these 15 substances.

Human biomonitoring offers the opportunity to understand human exposure to chemicals from multiple sources and thus health risks associated with chemical pollution. Future human biomonitoring is essential to track long-term trends for previously and currently used chemicals and also detect cases of regrettable substitutions (Lobo Vicente et al., 2023) (Box 3.2).

4.2 Encourage innovation

The objective to 'promote safe and clean recycling solutions including chemical recycling and waste management technologies' integrates two aims: to increase waste collection and sorting to foster reuse and recycling and to prevent chemical emissions from waste management, from the collection to the treatment facilities. These aims cover the promotion of sustainable innovations — and their implementation — to decontaminate waste streams and increase safe recycling. They also include a move towards decreasing the export of waste, in particular plastics and textiles.

The objective to 'promote decontamination solutions' aims to support research, development and the implementation of solutions for soil and water remediation.

4.2.1 Promote safe and clean recycling solutions including chemical recycling and waste management technologies

Sewage sludge, a by-product of UWWT, is often used to fertilise agricultural land. As previously shown in the signal Long-term impacts of sludge spreading on agricultural land (see Section 4.1.1), there can be agronomic benefits to using sewage sludge on agricultural soil; it can provide essential nutrients for crop growth. However, it may also pose a risk to soil and human health. A very high percentage of the EU population is connected to at least secondary wastewater treatment (81% in 2021, see Section 4.1.1 for the indicator Population connected to at least secondary wastewater treatment), but secondary level treatment does not eliminate all the hazardous chemicals that may be present in wastewater and these can then concentrate in sewage sludge, thereby contaminating soils when sludge is used as fertiliser.

Waste generated from households, industry and other activities (e.g. agriculture and retail) includes a large variety of products and materials; these can be categorised (e.g. as packaging, waste electrical and electronic equipment and municipal waste). The overall recycling rate for waste (excluding major mineral wastes) is improving in the EU, although less than half of the total waste generated between 2010 and 2020 was recycled (EEA, 2024). In recent years, progress made in the recycling rate for electrical and electronic waste in particular has been more significant than the overall progress; however, the rate for this category of waste still remained at below 50% between 2010 and 2020 (EEA, 2024).

Some types of waste (e.g. electrical and electronic equipment) are categorised as hazardous because they may contain heavy metals and other substances of concern (ECHA, 2023). This can represent a barrier to recycling. This is particularly true for plastics, due to the presence of some hazardous substances, as indicated by the signal Plastics recycling in Europe: obstacles and options. Hazardous substances they may contain include: specific flame retardants, certain ultraviolet stabilisers, PFAS, phthalates and bisphenols. The signal also highlights other major barriers such as material blends and the costs of recycling technologies.

Waste landfill and incineration remain widely used routes for waste management in the EU, as shown by the stable amount of residual waste disposed of through landfill and incineration between 2010 and 2018. This was followed by a reduction in 2020, which was most likely temporary due to the COVID-19 pandemic (EEA, 2023c). These waste management routes are linked to negative environmental impacts, as highlighted by the signal Leachate pollution from landfills. The signal focuses on leaching from landfill, where diverse types of pollutants can be present, such as plasticisers and PFAS. It shows that, even though landfilling is strictly regulated, leachates remain a major management issue in terms of both collection and treatment.

The impact of a product on human health is a key element of sustainability in its life-cycle and negative impacts during waste treatment processes should be minimised. With a focus on waste electrical and electronic equipment, the signal Occupational exposure in recycling facilities highlights specific exposure routes for workers to a series of chemicals such as heavy metals and toxic flame retardants; this can be during collection, sorting, dismantling, shredding and/or grinding and further pre-processing and purification. However, there are not currently sufficient data on the general exposure level of workers in recycling facilities and the potential associated risks.

Overall, the indicators and signals point to the need to produce SSbD chemicals, materials and products to decrease hazardous waste generation, enable safe recycling and reduce the associated economic, environmental and social costs.

4.2.2 Promote decontamination solutions

Soil and water contamination from chemicals results from various types of human activities; these include inadequate or unauthorised waste disposal, handling of dangerous substances by private households (EEA, 2022a), use within industrial or commercial processes and accidents. Both diffuse and point sources of chemicals can contaminate waterways, making remediation challenging. Preventing such emissions at the local level is therefore an important element of the River Basin Management Plans (RBMPs) within the WFD; these are created for each river basin district in collaboration with regulators, the general public and other stakeholders such as private companies, conservation organisations, farmers and local government. As highlighted in Section 4.1.1, UWWT plants are key infrastructures in decreasing the levels of organic material and some chemicals in wastewater (Population connected to at least secondary wastewater treatment). However, as discussed earlier, the levels of treatment applied to wastewater do not necessarily allow all hazardous chemicals to be eliminated and some may concentrate in sewage sludge.

Areas around drinking water sources are particularly sensitive in terms of human activities and related emissions. In many Member States, groundwater is a source of drinking water (EEA, 2022b). However, transport of substances of concern through the soil down to groundwater reserves can threaten drinking water quality for public supply and may require dilution from other sources, specific treatments at high costs or closure of a well. The signal Treatment of drinking water to remove PFAS shows that new techniques are being developed for PFAS removal in drinking water. However, this remains challenging e.g. due to the wide range of PFAS with different physical-chemical properties that can be present. Additionally, while some techniques have been demonstrated successfully in the laboratory or at the pilot scale, a number of technical and economic challenges still exist and these need to be overcome before the techniques can be scaled up and more widely used to remove PFAS from drinking water.

For soils, the extent and level of contamination in Europe are not fully understood, as there are no complete inventories of contaminated sites at the EU level. There are estimates, however, about the number of 'potentially contaminated sites', where risks for soil and human health are suspected. As highlighted by the indicator Progress in the management of contaminated sites (see Section 4.1.2) a large number of contaminated sites have not yet been registered in Europe and only 8.3% of the sites registered at the national level by 23 Member States were remediated in 2016; more efforts are thus needed to identify contaminated sites, the type of contamination involved and to enable the development and implementation of subsequent remediation. For the specific case of lead, the ECHA (2021) showed that an estimated 20,000 shooting ranges in EU-27 were contaminated with lead. While past regulatory measures have been shown effective to reduce human and ecosystem exposure to lead, recently proposed restrictions on lead in ammunition and fishing gear will therefore be crucial to address remaining uses and avoid further contamination, as shown by the signal Progress in regulating lead. Recent evidence of widespread PFAS contamination in Europe also supports the need to develop decontamination techniques. The signal PFAS contamination and soil remediation identifies examples of hot-spot contamination across a series of Member States with associated findings related to health impacts. It also indicates that some techniques are already in use by industry but that there are related challenges, such as time and transport needed, energy demand, impact on the soil functioning but also generation of contaminated wastewater.

4.3 Outlook

4.3.1 Robustness of current indicators and signals

In this chapter, most of the indicators relate to emissions, consumption and sales as proxy for occurrence and exposure, and refer to the objective to 'restore health and the environment to a good quality status'. Progress under the other objectives (in relation to substances in waste and secondary raw materials, the promotion of safe and clean recycling and waste management solutions and promoting decontamination solutions) is mainly assessed based on signals. This results in uncertainties in the assessment. In particular, it highlights substantial data gaps that limit the assessment of the CSS policy objectives. The scope of existing indicators in terms of chemicals and groups of chemicals they monitor can also be seen as a limitation. While the current scope does show the impact of chemicals legislation, it overlooks certain hazardous substances currently in use that pose a potential risk for human health and the environment. Identified data gaps are summarised in Table 4.1. The signals used in the assessment address some key areas affected by these data gaps. With new data expected in the near future through European surveys and partnerships, some of these signals could become indicators.

Despite the gaps, the data and information available that are summarised in this chapter highlight difficulties in eliminating and remediating chemical pollution in the environment and thereby in reducing human and environmental exposure to substances of concern. This points to the need to concentrate on preventive efforts upstream, in the supply chain, to avoid the use of such substances as far as possible in the first place.

Table 4.1 Eliminate and remediate — data gaps as they relate to policy objectives

Objective 	Number of indicators supporting assessment	Main data gaps identified during the assessment
Protect health and the environment: Eliminate as far as possible substances of concern from waste and secondary raw materials	3	On substances of concern in waste streams: waste generation data are classified as hazardous or not hazardous only
Protect health and the environment: Restore health and the environment to a good quality status	13	On human exposure to chemicals and the associated risks and impacts (and the cocktail effect) On ecosystem exposure to chemicals and the associated risks and impacts (and the cocktail effect) On contaminated sites at the EU level and monitoring chemical pollution in soils On monitoring currently used substances as compared to legacy substances, to ensure linkages between used substances and their monitoring in the environment
Encourage innovation: Promote safe and clean recycling solutions including chemical recycling, waste management technologies and decontamination solutions	2	On the extent at the EU level of the recovery of treated wastewater and the impacts on human and ecosystem health On the extent of spreading sewage sludge on agricultural soils and associated impacts On the development and use of remediation techniques for hazardous substances in water (surface and drinking water) and soil

4.3.2 Ongoing developments

Several policy actions are currently under development to tackle environmental pollution and continue improving human and ecosystem health. The new proposals, actions and initiatives, described in the previous chapters, are cross-cutting in nature and have implications for the occurrence of and risk from chemicals in the environment. They include the proposal for a new Ecodesign for Sustainable Products Regulation (ESPR), the ongoing grouping approach for preventing regrettable substitution (Box 3.2) and the strategic research and innovation plan (SRIP) for safe and sustainable chemicals and materials. The ESPR proposal, in particular, identifies substances of concern that could negatively affect the reuse and recycling of materials and products in which they are present, thereby proposing restrictions for circularity reasons. A broad REACH restriction proposal was also submitted to the ECHA in 2023 by five national authorities to phase out the use of all persistent PFAS (around 10,000 substances) with time-limited derogations.

In addition, the PARC research initiative supports the development of new environmental monitoring frameworks using innovative techniques (e.g. effect-based methods and non-target analyses) to focus on the most problematic substances in terms of the risks and impacts for human health and ecosystems. It also includes human biomonitoring studies across European countries to maintain visibility on pollution levels and impacts. Additionally, the initiative involves projects to support the development of new methodologies to calculate the burden of disease from chemical pollution.

A set of other recently adopted legislations, current European strategies and proposals have the potential to improve the current trends in the emissions and occurrence of, exposure to, and risk from chemicals, while improving human and environmental (bio-)monitoring schemes. These developments are summarised below, structured around thematic sections, namely water pollution, soil pollution, ODS and fluorinated greenhouse gas consumption. Chemical risks to human health and hazardous chemicals in waste are addressed subsequently.

Water pollution

The current revision of the Urban Wastewater Directive (EC, 2022b) aims to tackle micropollutants and microplastics in the treatment of wastewater, by introducing new standards and monitoring requirements. The Commission's proposal also extends the obligation to treat water to smaller municipalities with 1,000 inhabitants (from 2,000 inhabitants currently) and the introduction of quaternary treatment to eliminate the broadest possible spectrum of micro-pollutants. If adopted, this would support wastewater monitoring for a larger part of the population and help reduce the occurrence of substances of concern in effluents from wastewater treatment plants, thereby enhancing freshwater quality in European surface water bodies.

Under the WFD, a proposal was submitted in 2022 to expand the list of priority substances for surface waters, among other actions, with the introduction of new substances such as a group of 24 PFAS and BPA (EC, 2022a). The proposal also suggests amendments to the Groundwater Directive to introduce additional EU standards for a series of pharmaceuticals, non-relevant metabolites of pesticides as well as a group of 24 PFAS. Microplastics are also covered but the development of a standardised monitoring methodology across Member States is required before progress can be made in this area. This proposal could help shed light on the occurrence and risk of substances that have not yet been monitored on a regular basis across all EU Member States.

For the particular case of pesticide, information on treated crops and pesticide application rates will start becoming available in 2028 following adoption of Regulation (EU) 2022/2379, which relates to statistics on agricultural input and output (EU, 2022d). This will help support closer monitoring of pesticide use and related risks in environmental media, especially in surface waters and soils. It will also complement existing indicators and signals.

Soil pollution

As part of the soil strategy for 2030 (EC, 2021), the Commission proposed a soil monitoring law (EC, 2023b) that would involve the establishment of an EU soil monitoring framework. If adopted, Member States will be required to systematically register potentially contaminated sites for all major polluting activities. This will increase the number of contaminated sites that are identified, risk-assessed and managed. Moreover, greater support for research and development relating to decontamination solutions under the soil strategy may foster soil remediation and reduce the threat hazardous chemicals pose to ecosystems and human health (e.g. via direct or indirect exposure in the food chain).

With regard to sewage sludge generated from wastewater treatment, the recent Commission Implementing Decision (EU, 2021) will help to provide an overview of the EU locations where sewage sludge is used in agriculture.

Ozone-depleting substances and fluorinated greenhouse gas consumption

To further support the phase-out of ODS, a new Regulation was recently adopted for more comprehensive monitoring of ODS including substances not yet controlled (EU, 2024b). Regarding F-gas emissions, a recently adopted revision of the F-gas Regulation (entering into force in 2025) aims to accelerate the phase-down of F-gases by further reducing quotas for placing HFCs on the market. It will also promote the use of sustainable alternatives, while further restricting or banning the use of F-gases (e.g. for additional applications in the RACHP sector, electrical equipment). The revision also calls for increasing control of their use and trade to ensure a more effective HFC phase-down (EU, 2024a). Many F-gases are also targeted by the aforementioned broad REACH restriction proposal submitted to the ECHA in January 2023 by five national authorities. Many F-gases are considered PFAS.

Chemical risk to human health

Recently, the Regulation on maximum levels for certain contaminants in food (EU, 2023a) and the Drinking Water Directive (EU, 2020a) have set additional limits (e.g. for four PFAS in a series of foodstuffs and for PFAS as a group of substances, respectively). Increased human biomonitoring would support measuring the impacts of such newly adopted legislation.

The veterinary medicines Regulation (EU, 2018c) introduced measures to restrict and optimise the use of antimicrobial medicines and to expand and make compulsory surveillance of antimicrobial use in animals. With regard to human consumption of antimicrobials, the review of the pharmaceutical legislation under the pharmaceutical strategy for Europe (EC, 2020c) plans to introduce measures to restrict and optimise the use of antimicrobial medicines. Together with the promotion of the prudent use of antibiotics among professionals and patients, these regulatory measures and the proposal, if adopted, will further support reductions in the consumption of antimicrobials and lower AMR risks.

As mentioned in Section 3.3.2, the Commission has developed a proposal for the 'one substance one assessment approach'. This proposal also includes the establishment of systematic collection of data based on human biomonitoring and generated across the EU, with the aim of informing policy makers about the levels of chemicals found in people (e.g. in blood or breast milk).

Hazardous chemicals in waste

Chemicals in waste streams act as a barrier to implementation of a circular economy in Europe. This issue calls for prevention over remediation to eliminate hazardous chemicals from material flows upstream to ensure these flows are clean and reuse is safe and to allow for recycling and, when necessary, disposal. More data on the presence of substances of concern in waste and secondary raw materials may be available in the near future with possible new legislation announced under the new circular economy action plan (CEAP). The CEAP specifically aims to develop methodologies to track and minimise the presence of substances of concern in recycled materials and products made with recycled materials (EC, 2020a). In the proposed revision of the EU legislation on packaging and packaging waste (EC, 2022d), the presence and concentration of substances of concern in packaging material is to be minimised; this would prevent them from being emitted during waste management and their occurrence in secondary raw materials. This is part of the overall objective to reduce the need for primary natural resources and create a well-functioning market for secondary raw materials, especially in terms of promoting the safe use of recycled plastics. The proposed revision foresees the establishment of databases, where not already available, to gather information on the toxicity or danger of packaging materials and components used for their manufacture (EC, 2022d). The proposal also aims to prevent the generation of packaging waste (e.g. by restricting unnecessary packaging and promoting reusable and refillable packaging solutions).

As part of revisions to annexes in the Regulation on POPs, the list of substances subject to waste management provisions was amended and certain substances including PFAS are now included.

The Regulation on minimum requirements for water reuse has recently come into force. It aims to regulate the use of treated water from municipal wastewater treatment plants for crop irrigation across the EU, to make the use of treated water safe for humans and the environment. It is foreseen that an overview of the results and impacts of this regulation will be reported as Member States implement the requirements.

List of abbreviations

Abbreviation	Name	Reference
AMR	antimicrobial resistance	
BAT	best available techniques	
BBP	Benzyl butyl phthalate	
BPA	bisphenol A	
BPF	bisphenol F	
BPS	bisphenol S	
CEAP	circular economy action plan	
CLP	Classification, Labelling and Packaging of substances and mixtures	
CMR	carcinogenic, mutagenic or toxic to reproduction	
CSS	Chemicals strategy for sustainability towards a toxic-free environment	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN
DA	defined approaches	
DBP	dibutyl phthalate	
DDT	dichlorodiphenyltrichloroethane	
DEHP	di(2-ethyhexyl)phthalate	
DIBP	diisobutyl phthlatate	
DIPP	Diisopentyl phthalate	
EC	European Commission	https://commission.europa.eu
ECDC	European Centre for Disease Prevention and Control	www.ecdc.europa.eu
ECHA	European Chemicals Agency	www.echa.europa.eu
ED	endocrine disrupter	
EEA	European Environment Agency	www.eea.europa.eu
EFSA	European Food Safety Authority	www.efsa.europa.eu
EMA	European Medicines Agency	www.ema.europa.eu
E-PRTR	European Pollutant Release and Transfer Register	
EQS	environmental quality standard	
ESPR	Ecodesign for Sustainable Products Regulation	
EU	European Union	
F-gases	fluorinated gases	
Forum	forum for exchange of information on enforcement	
GRA	generic approach to risk management	
GVA	gross value added	
HCB	hexachlorobenzene	
HCFCs	hydrochlorofluorocarbons	
HFCs	hydrofluorocarbons	
ICT	information and communication technology	

IED	Industrial Emissions Directive
NAM	new approach methodologies
NEC	National Emission reduction Commitments
NGRA	new generation risk assessment
NP	nonylphenols
NPEs	nonylphenol ethoxylates
NTA	non-target analysis
ODS	ozone-depleting substances
OSH	occupational safety and health
PAHs	polycyclic aromatic hydrocarbons
PARC	European partnership for the assessment of risks from chemicals
PBTs	persistent, bioaccumulative and toxic substances
PCB	polychlorinated biphenyls
PCDDs	polychlorinated dibenzo-p-dioxins
PCDFs	polychlorinated dibenzofurans
PCT	polychlorinated terphenyls
PFAS	per- and polyfluoroalkyl substances
PFHxS	perfluorohexane sulfonic acid
PFNA	perfluorononanoic acid
PFOA	perfluorooctanoic acid
PFOS	perfluorooctane sulfonic acid
PMT	persistent, mobile and toxic
POPs	persistent organic pollutants
QSAR	quantitative structure-activity relationship modelling
RACHP	refrigeration, air conditioning and heat pump
RBMPs	river basin management plans
R&I	research and innovation
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment
SoC	substances of concern
SRIP	strategic research and innovation plan
SSbD	safe and sustainable by design
UWWT	urban wastewater treatment
vPvBs	very persistent very bioaccumulative substances
vPvM	very persistent very mobile substances
WFD	Water Framework Directive

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Annex 1

Table A1 List of indicators and signals included in the indicator framework and listed by order of appearance in the report

Policy objective and Indicator/signal title	Report chapter
Use of safe chemicals while preventing harm to humans and the environment by avoiding substances of concern for non-essential uses 1. Number of substances identified as carcinogenic, mutagenic or toxic for reproduction 2. Production and consumption of chemicals by hazard class 3. Growth of the EU chemicals market for substances of different levels of concern	2. Safe and sustainable chemicals: Protect health and the environment
Promote the development of safe and sustainable chemicals and materials, clean production processes and technologies 1. Total greenhouse gas emissions in the chemical industry 2. Waste generation in the chemical industry 3. Best available techniques (BAT) to cut the use and impact of hazardous chemicals 4. Safe and sustainable by design chemicals and materials 5. Funding EU projects on safe and sustainable chemicals and materials 6. Progress in regulating lead **Promote the development of innovative tools for testing and risk assessments** 1. Uses of animals in regulatory testing of industrial chemicals 2. Uses of animals by test type in regulatory testing of industrial chemicals	2. Safe and sustainable chemicals: Encourage innovation
Minimise exposure of humans and the environment to substances hazardous to health and the environment, through risk management measures and full information to users of chemicals 1. Progress in regulating substances under REACH and CLP 2. Number of substances identified as carcinogenic, mutagenic, or toxic for reproduction 3. Market volume changes of chemicals subject to REACH authorisation over the period 2010-21 4. Progress in regulating lead 5. Regulating groups of substances to speed up action and ensure a coherent approach 6. Human exposure to bisphenols 7. Consumption of ozone-depleting substances 8. Hydrofluorocarbon phase-down in Europe 9. EU trends in the use and risk of chemical pesticides 10. EU trends in the use of more hazardous pesticides 11. Antimicrobial consumption by food-producing animals in the EU 12. Human consumption of antibacterials for systemic use in the EU 13. REACH controls: percentage of compliant cases found in Member States 14. CLP controls: percentage of compliant cases found in Member States 15. Percentage of REACH CLP-compliant cases found in imported goods 16. Compliance with REACH restriction and authorization measures 17. Alerts for products posing a risk to human health and the environment	3. Minimise and control: Protect health and the environment

Eliminate as far as possible substances of concern from waste and secondary raw materials 1. Production and consumption of chemicals by hazard class 2. Waste generation in the chemical industry 3. Plastics recycling in Europe: obstacles and options 4. Recycling materials from green energy technologies 5. Population connected to at least secondary wastewater treatment 6. Long-term impacts of sludge spreading on agricultural land **Restore human health and the environment to a good quality status** 1. Industrial chemical releases to water 2. EU trends in the use and risk of chemical pesticides 3. EU trends in the use of more hazardous pesticides 4. Pesticides in rivers, lakes and groundwater in Europe 5. Chemicals in European surface water and groundwater 6. Hazardous substances in marine organisms in European seas 7. PFAS in European seas 8. Progress in the management of contaminated sites 9. Ecological risk of pesticides in EU soils 10. Industrial chemical releases to air 11. Persistent organic pollutant emissions in Europe 12. Consumption of ozone-depleting substances 13. Hydrofluorocarbon phase-down in Europe 14. Alerts for products posing a risk to human health and the environment 15. Human exposure to bisphenols 16. Risks of PFAS for human health in Europe 17. Impacts of microplastics on health 18. How pesticides impact human health 19. Antimicrobial consumption by food-producing animals in the EU 20. Human consumption of antibacterials for systemic use in the EU 21. Risks of chemical mixtures for human health in Europe	4. Eliminate and remediate: Protect health and the environment
Promote safe and clean recycling solutions including chemical recycling and waste management technologies 1. Long-term impacts of sludge spreading on agricultural land 2. Population connected to at least secondary wastewater treatment 3. Plastics recycling in Europe: obstacles and options 4. Leachate pollution from landfills 5. Occupational exposure in recycling facilities **Promote decontamination solutions** 1. Population connected to at least secondary wastewater treatment 2. Treatment of drinking water to remove PFAS 3. Progress in the management of contaminated sites 4. Progress in regulating lead 5. PFAS contamination and soil remediation	4. Eliminate and remediate: Encourage innovation

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