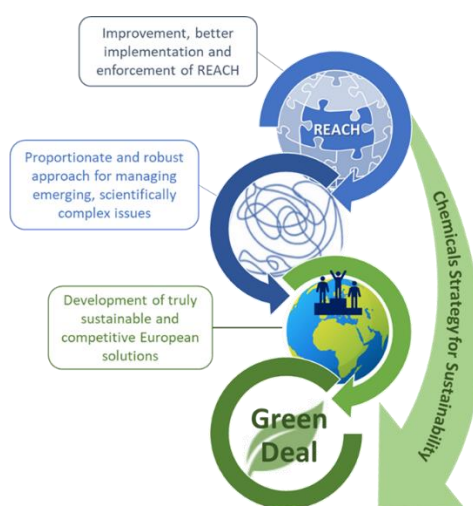


## Input Paper on the Chemicals Strategy for Sustainability

*This paper outlines the preliminary views and proposals of the European chemical industry, as represented by Cefic, on the future Chemicals Strategy for Sustainability proposed by the European Commission under the EU Green Deal. Its content may evolve at the light of future developments. It is organised in two parts: 1. an overview outlining the general approach and balance we are calling for. 2. In the second part, we offer specific policy proposals along the three principles we are advocating.*

**Executive summary:** Cefic calls for a Chemicals Strategy for Sustainability that recognises the essential role of chemicals to deliver climate ambitions and integrates multiple facets of chemicals management including safety, circularity, resource efficiency, environmental footprint, science and innovation. The key components of the strategy should be:

1. Consolidating and promoting the solid foundation Europe has already built, primarily REACH, via improvement and better implementation and enforcement
2. Adopting a proportionate and robust approach for managing emerging, scientifically complex issues
3. Enabling the development of truly sustainable and competitive European solutions to deliver the Green Deal.



## General approach

Cefic calls for a Chemicals Strategy for Sustainability that ensures a high level of protection of human health and the environment, and integrates in a holistic manner the multiple dimensions of the Green Deal - climate neutrality, materials circularity and resource efficiency - while boosting competitiveness and innovation to serve Europe's strategic interests, and thereby securing production in Europe.

As the 'industry of industries', we produce the building blocks and high-tech materials on which a modern, climate-neutral, resource-efficient society can be built. From medicines and vitamins to insulation materials and batteries, 96% of all manufactured goods rely on chemistry. Recently, the extraordinary COVID-19 events have shown that our products are essential to combat pandemics, with active pharmaceutical ingredients, hand and surface disinfectants, raw materials for personal protective equipment (masks, gloves, shields, gowns), life-saving equipment (medical devices), cleaning products, or water treatment chemicals, just to name a few. The Chemicals Strategy for Sustainability needs to reflect the multiple contributions of chemicals to a modern, healthy and thriving society.

The European Chemical industry is highly committed to implement REACH, the most complex and ambitious chemicals legislation in the world. Together with CLP for hazard assessment and communication, REACH constitutes a solid umbrella framework to regulate substances and mixtures. As a result of REACH, Europe has the most comprehensive knowledge database on chemical hazards and risks globally. With over 10 years of implementation, REACH has also been a significant asset in demonstrating safety of many existing chemicals. Various Reviews<sup>1</sup> and Fitness Checks<sup>2</sup> have concluded that **"EU chemicals legislation delivered results as intended and is fit-for-purpose"**. On the other hand, these exercises have also highlighted a number of areas for improvement, simplification and burden reduction.

Since the adoption of REACH, we have been dedicated to make REACH work and continue to invest significant efforts in improving its implementation, such as the recent major voluntary Action Plan for review/improvement of registration dossiers. In doing so, we want to cooperate and maintain a constant dialogue with stakeholders. **Therefore, the first priority of the future Chemicals Strategy for Sustainability should be to work on the improvement needs identified in these reviews and fitness checks:** streamlining where possible to achieve more consistency and eliminate duplication, solving some implementation issues to consolidate the existing regulatory foundation (REACH in particular) and stepping up enforcement, particularly on imports, alongside ensuring enforceability of regulatory measures.

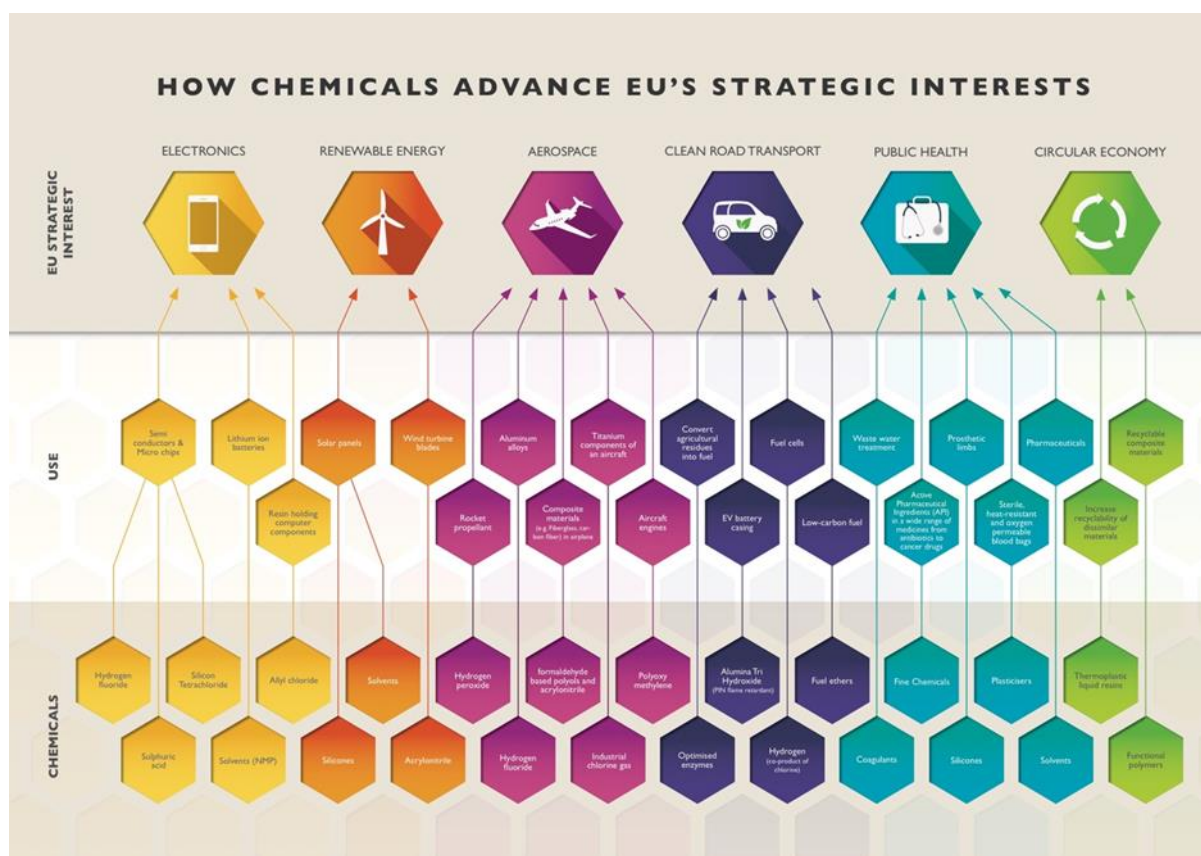
In addition, various stakeholders have repeatedly voiced concerns over emerging issues or areas requiring improvement (e.g. endocrine disruptors, combination effects of chemicals, chemicals that may build up in the environment). There is a genuine expectation that these concerns will be addressed by the new Chemicals Strategy for Sustainability. **Cefic calls for a proportionate and robust approach to manage these scientifically complex issues.** Science needs to remain at the heart of decision-making. Where there is scientific uncertainty, a stepwise regulatory approach should be taken: for instance, first step should be limited to a defined scope with a focus on main releases and risks and based on existing data. Alternatively, a tiered risk assessment approach could be implemented starting with a limited scope (focus on main releases / risks) based on existing data and reviewing it in a second stage when more science is available.

<sup>1</sup> Second REACH Review (March 2018), Interface between chemicals, products and waste legislation (2018).

<sup>2</sup> Fitness Check on EU Chemicals legislation excluding REACH (June 2019), Fitness Check on Endocrine Disruptors (on-going)

Finally, echoing one of the conclusions from the High-Level Conference on Chemicals Policy 2030<sup>3</sup>, we see an urgent need that the chemicals policy reconciles the following aspects, while enabling the transition to a climate-neutral Europe: circularity, resource-efficiency, reduction of environmental emissions under a 'zero-pollution' agenda, chemicals safety, societal concerns. Sustainability considerations should also reflect the contribution of chemicals to society as a whole, including economic and social conditions, as well as societal needs (food, energy and public health security) and aspirations.

This means for example, **exploring new methodologies and technologies<sup>4</sup>, as well as new digital tools, that can boost innovation towards safe and sustainable products that are needed for climate neutrality** (materials for wind turbines, solar panels, batteries, insulation of buildings, low carbon mobility), **enable product sustainability assessment (sustainable-by-design), step up safe recycling and re-use towards circular economy** and reduce overall environmental footprint. For that, we need a widely accepted framework and a reference methodology(ies) for product sustainability performance assessment, as well as tools to accelerate chemical safety testing while minimising animal testing. We also need to find practical solutions to address 'legacy substances' and enable the production of high-quality recycled materials.



<sup>3</sup> <https://euchemicalspolicy2030.teamwork.fr/en/home>

## Specific policy proposals

### ➡ CONSOLIDATE AND PROMOTE THE SOLID FOUNDATIONS EUROPE HAS ALREADY BUILT: implementation, improvement and enforcement

Let's make REACH fully effective. Considering the complexity of REACH and CLP, further complemented by a complex arrays of use and product-specific policies, the following areas should be handled as a matter of priority to make the most of REACH, in line with the Reviews and Fitness Checks findings:

- More positive communication from authorities, European and national, towards the general public regarding EU regulation of chemicals to educate and reassure citizens about risks of chemicals.
- **Improve data in registration dossiers, if and where needed**, to bring them in line with current demands and expectations. This is a collective effort that can be achieved via joint industry-authorities implementation of:
  - Cefic's REACH Dossier Improvement Action Plan in cooperation with ECHA (in place)
  - The Commission and ECHA "REACH Evaluation Joint Action Plan" (in place);
  - ECHA's Integrated Regulatory Strategy (in place);
  - Support from national authorities, e.g. via enforcement.
- **Clarify the most complex data requirements**. The availability of robust and up-to-date data is the cornerstone of a reliable chemicals policy. It will be important to
  - Further clarify some aspects related to data requirements between authorities and industry, including for the detection of endocrine disruptors. As a general principle, any test requirement must be scientifically justified, provide added value and minimise animal testing as much as possible;
  - Provide more clarity and certainty on the application of the data waiving provisions of REACH, particularly on how to establish robust justification for 'read-across' (both for positive and negative extrapolation) which is essential for grouping purposes, and on exposure-based waiving.
- **Ensure harmonised and effective communication of safe use information in supply chains** via clear and easy-to-use extended Safety Data Sheets. To overcome the lack of harmonisation, in line with the REACH Review conclusions and on-going CARACAL discussions, specific actions should include:
  - Standardise and harmonise tools and methodologies developed by the multi-stakeholder Exchange Network on Exposure Scenarios<sup>5</sup> for effective supply chain communication on safe use. This should lead to simplified and easy-to-understand documentation;
  - Digitalise as far as possible;
  - Establish minimum legal requirement for exposure scenarios.
- **Enhance Regulatory Management Options Analysis (RMOA)**. This tool clarifies whether regulatory action is necessary for a given substance and helps identify the most appropriate measures to address a concern for a given protection goal. We need:
  - A more harmonised, systematic, transparent and predictable RMOA process/tool that is followed by all Member States as a win-win for authorities and industry: it avoids regulatory duplication and inconsistencies. It also increases **predictability** of chemicals management;
  - Such a tool should be applied as early as possible, before a regulatory action is chosen;

- RMOA should give equal weighing of all options. It should also take socio-economic aspects into account;
- RMOA would also help clarify interactions between REACH and Occupational Health and Safety legislation;
- RMOA should identify before launching action whether REACH Restriction or Authorisation or another regulatory management option outside of REACH would be the best approach. A common understanding of whether SVHC identification should always be followed by authorisation (based on exposure) is needed.
- The RMOA tool could be useful to better integrate and ensure **linkage between different EU instruments**. For example, one of the options to handle microplastics may be an amendment to Sewage Sludge and Drinking Water Directives to end the re-use of wastewater sludges containing microplastics on agricultural fields. By stopping microplastics from re-entering the environment, where possible, this option could be more effective or complementary to a REACH restriction.
- **Optimise efficiency, without sacrificing robustness and specificity**
  - **Risk assessment** is a core principle of chemicals management that needs to be retained.
  - The **right balance between generic and specific risk management approaches** needs to be found, taking into account that suitable risk management might differ across substances as well as across uses of a substance. In general, where specific information is available, it should prevail.
  - Grouping of substances should be based on **already established grouping approaches**. Thoughtful use of grouping will contribute to **greater transparency** on the identification of priority chemicals **and avoid unnecessary animal testing**. Such approaches should
    - Be in line with the ECHA and OECD guidance on chemical categories and criteria for similarity;
    - Be applied in a manner that gives priority to actual data over predicted data on given substances;
    - Acknowledge that some structurally similar chemicals (even with the same or similar use profiles) may have different toxicological properties;
    - Ensure that relevant grouping criteria are used in a same way by all stakeholders through the various REACH stages/processes.
- **Step up enforcement because no substance or product should enter the EU internal market if it does not comply with EU rules**. We need a level-playing field for EU and non-EU producers. This requires:
  - EU-wide consistent and fairer enforcement measures;
  - Innovative market surveillance practices, including increased capacity at Member State level and intensified cooperation with customs authorities;
  - **Enforceability and monitorability** of measures: compliance tools and standardised methodologies, e.g. analytical methods to measure certain chemicals in products and complex articles, need to be available for each regulatory measure. **No restriction or ban should be adopted if the tools for 'on-shelf' compliance verification are not available**. Relying on paper statements (e.g. 'free of X' or 'does not contain X' statement) is not sufficient. SEAC and the Enforcement Forum should focus more on these points. An example of such a challenge is on the (pending) REACH restriction on intentionally used microplastics;
  - Special attention should be paid to **internet sales** of non-compliant products and **illegal imports**. Cefic's analysis of the RAPEX (rapid alert system for non-food products) database

shows that ~92% of the non-compliance of consumer products with REACH are from non-EU/EEA countries.

- Authorities should **communicate more positively towards the general public** to improve EU citizens' understanding and trust in European chemical legislation

## ➡ PROPORTIONATE, ROBUST AND COHERENT NEW POLICIES on scientifically complex issues

Several areas have recently emerged as requiring attention (combination effects / mixtures, protecting vulnerable populations, endocrine disruptors, microplastics in the marine environment, etc). They are all characterised by **scientific complexity** and are typically subject to ongoing research.

In all these areas, **EU agencies (ECHA, EFSA, EMA) and EU scientific bodies (SCHEER, SCCS) should cooperate together and with industry** to develop joint methodologies and processes, that would eventually be consistently applied across EU legislations and that would balance regulatory action vs scientific complexity. In all these complex cases, **impact assessments** need to be conducted to identify the most effective and most proportionate measure(s). We support the following:

- **Develop an agencies/scientific committees' coordinated approach on combination effects of chemicals** that reflects the latest scientific understanding, is applied consistently across legislation, uses the same terminology and differentiates between:
  - Aggregated exposure (same substance, multiple uses) covered under REACH;
  - Combined exposure to intentional mixtures that can be subject to modelling;
  - Potential exposure to unintentional mixtures, which is the most complex case due to the variety of potential combinations from multiple sources. A phased and proportionate approach to address risks from relevant combinations is needed. First step is to understand potential for co-exposure, i.e. risk scenarios, and whether existing measures are shown to be insufficient.

Combination effects are relevant to different areas of use of chemicals and across different pieces of EU legislation. Therefore, they should be addressed in a consistent way. Priority (groups) of chemicals need to be agreed, taking into account the scientific evaluations already performed by SCHER, the JRC and Horizon 2020 / Horizon Europe projects.

- A similar, cross-agency/scientific committee approach should be taken for the **identification, assessment and protection of vulnerable groups**.
- **Implement a horizontal definition and identification of endocrine disruptors (ED)** responding to stakeholders' calls and building on the conclusions of the (pending) Fitness Check. This should be done:
  - Under REACH;
  - In full alignment with the WHO definition for EDs;
  - By re-applying the criteria already adopted under the EU Plant Protection Products Regulation and the Biocidal Products Regulation for regulatory consistency;
  - Based on data/testing requirements that are tiered and proportionate, leveraging on existing data and weight of evidence.
- **Move towards 'one substance, one (hazard) assessment'** to avoid a situation where divergent regulatory opinions create uncertainty and undermine investments in safe and sustainable chemicals, as follows:
  - Start with hazard assessment. The same substance should be assessed by different EU regulatory bodies and different Member States in a coordinated manner and on the basis of the same data set, of the same methodologies to cover uncertainties, taking routes of exposure into account and leading to one hazard assessment outcome consistently applied



across agencies and legislation. So for example, if ECHA has done a comprehensive hazard assessment on a substance, that should clearly be used by other EU agencies/scientific committees and by Member States (who send their experts to ECHA);

- **Cross-agency/committees processes** need to be established.
- **Identify a targeted and meaningful approach for the assessment of polymers** under REACH to demonstrate the safety of polymers, as relevant, without creating unmanageable complexity and administration.
  - It should take into account the unique properties of polymers (that make them different from standard substances), as well as their uses;
  - Develop authorities' and other stakeholders' understanding of the unique properties of polymers;
  - Cooperation with industry is crucial in view of the complexity of polymer chemistry;
  - Registration should be organised around scientifically relevant groups of polymers;
  - Ensure availability of test methods as many test methods currently stipulated for other substances are not applicable to polymers.
- We need to come up with **refined and tiered methodologies for persistency (and mobility) assessment**. Chemicals that may persist days or months need to be differentiated from chemicals that may build up in the environment (in some media at least) over decades. In the lack of agreed methodology, uncertainty on future impacts leads to overly conservative regulatory management whereby any emission is considered as a potential risk. We have a shared objective of not creating a negative legacy towards future generations. At the same time, scientifically, there is no such thing as zero level of emission. The protection goals and priorities need to be based on clear evidence.
- For decision-making involving specific scientific complexity and emerging issues, ECHA Committee members should **leverage on external academic expertise** so that decisions reflect state-of-the-art science (e.g. on the model of the Scientific Advisory Mechanism).

### ➡ **ENABLE THE TRANSITION TO A SUSTAINABLE EUROPE: move from hazard-based substitution to sustainable-by-design assessment**

For the EU to be a front-runner with the Green Deal, and for its industry to be competitive, the Chemicals Strategy for Sustainability should enable the development of truly sustainable and competitive solutions. Beyond safety which is a 'must-have' starting point, sustainability considerations should reflect the contribution of chemicals to society as a whole, including economic and social conditions, as well as societal needs (e.g. food, energy and public health security). We support the call for safe and sustainable chemicals. The Chemicals Strategy should also encourage the development of innovative chemicals/materials that pose no unacceptable risk to health or the environment, including in recycled materials and articles made thereof, and thereby help realise the EU Green Deal.

Chemicals legislation needs to support and enable a move to circular economy and should reflect the different recycling pathways. To enable the production of high-quality recycled materials, solutions are needed to address concerns around hazardous substances that could be a barrier to mechanical recycling. Recyclers should have enough information for their workers to operate safely, a single market for waste needs to be fostered and different regulations need to support the fast scaling-up of secondary raw materials markets via chemical recycling. We call for the following specific measures:

- **Expand from a hazard-driven substitution to safe and sustainable-by-design**, i.e. a 'holistic substitution' that encompasses safety, different sustainability impacts and value chain drivers:
  - This approach requires a widely accepted framework **defining 'sustainable-by-design' principles and a reference product sustainability performance assessment methodology (or set of methodologies)** common to all substances, products and processes;

- It should build on existing initiatives particularly the one from the World Business Council for Sustainable Development on sustainable product portfolio assessment (<https://www.wbcsd.org/Projects/Chemicals/News/framework-to-assess-sustainability-of-company-product-portfolios>);
  - It should guide on how to define acceptable trade-offs for achieving an **overall improved health and environmental profile**, with safe production and use of chemicals as a minimum requirement;
  - The methodology could be complemented with product standards;
  - Both new materials as well as existing ones should be assessed for sustainability;
  - This should be a rigorous and inclusive exercise, involving a multi-stakeholder process (with European authorities, civil society, academia and industry including SMEs) led and funded by the European Commission to ensure its credibility and legitimacy;
  - This product sustainability assessment would become "the compass" for innovation and new solutions. If the development of alternatives integrates different dimensions of sustainability (e.g. prolongation of use phase, recyclability, resource efficiency, CO<sub>2</sub> emissions, water use, toxicological properties) in a life-cycle approach, substitution of individual or groups of substances is truly 'non-regrettable' (compared to substitution based on only one hazard consideration).
- **Both secondary raw materials and virgin materials need to be equally safe.** In line with the outcome of the public consultation on the interface between chemical, product and waste legislation, this implies that:
    - **A fit-for-purpose and transparent information system on chemicals in products** is needed to provide recyclers and users of secondary raw materials with sufficient information to enable safe use and recycling and to comply with all legal obligations;
    - We need to identify innovative, highly secure digital technologies to support **the effective and timely communication of such information (e.g. blockchain, 5G), while protecting confidential business information and intellectual property rights, and complying with anti-trust laws**;
    - Solutions need to be found to the issue of '**legacy**' substances. As more data are being generated and new regulatory assessments performed, there will always be legacy substances. Where they are unavoidable, and subject to further investigation, technologies such as chemical recycling could offer a solution to capture and separate, or destroy, some legacy substances that may be present in end-of-life plastic.
  - **Fast-track R&D to accelerate innovation**, ensure competitiveness, and safeguard Europe's strategic interests: Explore the potential of **new digital technologies and the power of big data to develop new tools that can analyse and predict chemical safety properties**<sup>6</sup>, for example:
    - In-silico prediction of (eco)toxicological properties of new chemicals (e.g. to build standard predictive toxicology tools) and thereby further avoid animal testing and optimise read-across;
    - Further development of alternatives to animal testing (in-vitro);
    - Identify exposure patterns; or
    - For early identification of emerging risks (e.g. monitoring data).

In this new era of digital transformation where 'data is the new oil', by applying scientific approaches we need to make the most of the data that have generated under REACH or collected via other programs.

<sup>6</sup> While recognising the importance of complying with anti-trust laws and the need to protect confidential business information and IP.



Such tools should support the clear demonstration of the safety of many existing chemicals as well as the development of innovative and safer chemicals. Cooperation with DG RTD / Horizon Europe is highly desirable.

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#### About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 16% of world chemicals production.