

# Contribution to the Commission consultation on the Chemical Strategy Roadmap

ClientEarth – contribution to the consultation on the Chemical Strategy

Detoxifying Europe's economy is as important to the health of people and the planet as decarbonising. EU action to transform how we make and use chemicals must be as ambitious as our climate agenda. Detoxification is indispensable to the Green Deal's health, biodiversity, farm-to-fork, and circular-economy objectives.

Actions to change the current trends and practices in the manufacture and consumption of chemicals are to the health, biodiversity, farm to fork and circular economy objectives of the Green Deal what the actions to reduce CO2 emissions are to the EU's climate objectives.

The chemical industry is a huge consumer of raw materials and energy<sup>1</sup>. It is the manufacturer of plastic, a material with high health and environmental impacts. Finally, over 70% of chemicals produced and consumed are dangerous to health<sup>2</sup> and find their way into our bodies or the

<sup>&</sup>lt;sup>1</sup> UNEP, Global chemicals outlook, 2019.

<sup>&</sup>lt;sup>2</sup> EEA, State of the European Environment, 2020 chapter on chemical pollution, p. 238.

environment via products or production processes<sup>3</sup>. The sector remains mostly quantity and cost driven, for harmful and non-harmful substances alike, rather than focused on providing services essential to the functioning of society.

Chemical manufacturers and users must engage in what needs to be the biggest revolution since the REACH Regulation to be allowed access to the EU market. It is essential for EU law to create the conditions for this revolution to deliver new systems of production and consumption that are non-toxic by design, to prevent damaging health or biodiversity and allow safe re-use, repair and recycling.

For EU law to lever the chemical industry into changing from a barrier to an enabler of the Green Deal, the Chemical Strategy needs to commit the EU institutions and States to:

- 1) Align Chemicals Strategy and laws with EU values
- 2) Reinforce business and governmental accountability with transparency
- 3) Ban all non-essential uses of endocrine disruptors and persistent chemicals
- 4) Accelerate the pace of the identification and restriction of harmful chemicals
- 5) Promote a change of mindset in chemical manufacturers and users
- 6) Expand and strengthen monitoring, control and enforcement

### 1. Align Chemicals Strategy and laws with EU values

President Van der Leyen made it clear that upholding European values is at the heart of her programme, focused on delivering on the Green Deal made with EU citizens<sup>4</sup>. EU values, as reflected in the Charter of Fundamental Rights, the Treaties and the commitments by President Van der Leyen, have two direct implications for chemical policy and laws, detailed below.

• Prioritise the protection of the most vulnerable population inside and outside the EU

Existing EU chemical and product regulations do not ignore populations that, because of physical or social circumstances, are especially vulnerable to chemical pollution. Signs of the need to provide extra protection may be found in existing toy or baby bottle regulations, in special protections for pregnant workers or in the limitations imposed on the sale of carcinogenic, mutagenic or reprotoxic substances or mixtures to the general public under REACH.

However, a coherent and horizontal approach is lacking to protect the most vulnerable people adequately, the EU institutions and States need to adopt a coherent and horizontal approach that would protect vulnerable populations by taking into account their specific situations.<sup>5</sup> That requires the **adoption of a definition of vulnerable sub-populations and adjusting the risk** 

<sup>&</sup>lt;sup>3</sup> See EEA, State of the European Environment, 2020, chapter on chemical pollution, Figure 10.1 p. 234.

<sup>&</sup>lt;sup>4</sup> See the President's political guidelines 'A Union that strives for more'.

<sup>&</sup>lt;sup>5</sup> See Milieu (on behalf of the European Commission), Study for the Strategy for a non-toxic environment of the 7<sup>th</sup> Environmental Action Plan, sub-study on vulnerable population.

assessment methodologies and risk management approaches accordingly. The EU has included definitions of "vulnerable persons" in Union legislation elsewhere<sup>6</sup> and needs to do so in relation to chemicals.

• Limit the production and use of harmful chemicals to what is essential for society

The determination of when the risk of using a chemical known or suspected to be harmful is worth taking is inherently a political decision that depends on the values and needs of a given society. Cousins et al.<sup>7</sup> refined the definition of 'essential uses' as a tool for public authorities to make this decision in an inclusive and transparent manner.

The concept does not exist explicitly in EU secondary law yet, but is reflected implicitly in, for example, the derogations to the cut off in the Pesticides or Medical Devices Regulations as well as the ban on animal testing in cosmetics. The EU institutions and States have also started using it under REACH (e.g., microplastic restriction and PFHxA restriction).

The EU institutions and States need to harness the potential of this concept by integrating it in the chemical management hierarchy and systematically using it under chemical and product regulations (see the hierarchy of chemical management in Annex I).

## 2. Create business and governmental accountability with transparency

Transparency creates accountability and provides people who are making decisions – any kind of decisions, from personal to professional – the information they need to understand the ramifications of what they decide. Transparency is also a core value of the EU, as reflected in the Treaties.<sup>8</sup> The EU Chemicals Strategy needs to harness the power of transparency, by applying existing rules – and adopting new ones where a gap exists – to:

• Ensure the transparency of decision-making processes

The decisions that identify harmful chemicals and set the conditions under which they may (or may not) be used are mostly taken at the EU level, in committees and expert groups composed of representatives of national governments. The final stages of decision making, involving the

<sup>&</sup>lt;sup>6</sup> Directive 2013/33, Article 21 (in the context of asylum seekers)

<sup>&</sup>lt;sup>7</sup> Ian T. Cousins, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Sharyle Patton, Martin Scheringer, Xenia Trier, Lena Vierke, Zhanyun Wang and Jamie C. DeWittl, The concept of essential use for determining when uses of PFASs can be phased out, *Environ. Sci.: Processes Impacts*, 2019, 21, 1803-1815. And Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Mark Miller, Carla A. Ng, Martin Scheringer, Lena Vierkej and Zhanyun Wang, Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health, *Environ. Sci.: Processes Impacts*, 2020, Advance Article.

<sup>&</sup>lt;sup>8</sup> As the Court put it: 'increasing the legitimacy of the Commission's decision-making process, transparency ensures the credibility of that institution's action in the minds of citizens and concerned organisations and thus specifically contributes to ensuring that that institution acts in a fully independent manner and exclusively in the general interest.' C-57/16, *ClientEarth v Commission*, para. 104.

Member States, still lack transparency – draft decisions and voting positions need to be **published** to ensure the legitimacy and participation required in a democratic system.<sup>9</sup>

• Ensure transparency on the use, presence and impact of chemicals

The recent reform of the General Food Law (GFL) considerably improved the rules on the transparency of safety studies for chemicals in food. However, the provisions governing the transparency for the safety studies of chemicals in product or manufacturing processes still lags behind. The GFL approach needs to be expanded to non-food sectors. In addition the EU must prepare the transition away from the current system of chemical assessment which relies on the companies that want to put the chemicals on the market providing safety data and instead move towards a system of chemical testing by independent laboratories under the supervision of public authorities paid by a fund fed by industry contributions.

The data gap on the presence of chemicals in products, materials, environmental compartments and human bodies is a massive obstacle to the identification and prioritisation of chemical issues. **Monitoring campaigns and an obligation to disclose chemical composition and ensure traceability would help considerably.** 

Finally, understanding the functions currently fulfilled by chemicals is key to starting a meaningful debate to identify those that are essential to the functioning of society. **The classification started under REACH needs to be refined and developed.** 

• Ensure that transparency serves the key decision-makers

Chemical and product regulations already contain some provisions that aim at collecting and disseminating the data needed by key decision-makers. But gaps remain that undermine their capacity to make informed decisions.

**EU law has not yet developed the tools that investors** need to assess the health and environmental performance – and hence the business risk – of the chemical manufacturers' and users' activities. **Companies in the value chain and other customers** are rarely bestowed the enforceable right to obtain the information they need from suppliers on the chemical composition and safety of materials and products. **EU agencies and States** do not share safety data because of technical limitations and excessively cautious interpretation of data protection rules. Finally the **public's** right to access environmental information is still interpreted restrictively by the EU institutions and States.

Address the barriers to access environmental information

EU law does not sufficiently address key barriers to accessing information at present. The remaining **legal barriers** – excessive interpretation of IPR and CBR – need to be taken down. The **technical barriers**, such as fragmentation between databases (public-public and private-public) need to be remediated by the creation of an EU chemical dataspace, facilitating system to system integration and easing data sharing, in line with the EU digital strategy. The **practical barriers** impairing the capacity to use the information by inadequate presentation, modalities of

<sup>&</sup>lt;sup>9</sup> The Court has left no room for doubt: access to environmental information aims at promoting 'more effective public participation in the decision-making process, thereby increasing, on the part of the competent bodies, the accountability of decision-making and contributing to public awareness and support for the decisions taken' C-57/16 P, ClientEarth v Commission, para. 98.

access, quality, nature or quantity of the data disseminated need to be addressed by a stronger focus on user-friendliness and accuracy, in line with the effort led by ECHA, for example, with the EUCLEF system.

## 3. Amend EU law to identify and minimize all exposure to endocrine disruptors and persistent chemicals

EU law has identified and restricted some EDCs and persistent substances, but without a set policy on how to address all sources of exposure consistently and effectively.

• Amend the identification systems set up in EU law

EU law created two systems to identify hazardous substances: the CLP Regulation and REACH candidate list. But the CLP Regulation does not include hazard categories that capture EDCs and persistent chemicals, and REACH creates the unnecessary hurdle of proving that these substances create an 'equivalent level of concern' to Article 57 (a) to (e) substances. The other identification systems, that consist of pre-marketing hazard or risk assessments are also currently unfit as they do not require the data/analysis that would enable the identification of these groups. **Both gaps need to be filled.** 

• Adopt a coherent and fit policy on how to restrict their uses

Humans and the environment are currently exposed to EDCs and persistent chemicals via industrial chemicals, agro-chemicals, chemical in products and materials, chemical products, waste, water, air and soil. EU law therefore needs to be amended across the board to minimize all sources of exposure and create transparency, in line with the hierarchy of chemical management (see Annex I), with a presumption that the substances of these groups are non-threshold.

• Act now to restrict the use of already known and suspected EDCs and very persistent chemicals

It will take a lot of time for the amendments proposed above to be adopted and then to deliver. The EU institutions and States cannot wait for this system to be in place before acting to identify and restrict the substances for which sufficient evidence exists to demonstrate that they are EDCs or persistent. For the substances that already made international<sup>10</sup>, EU<sup>11</sup>, national<sup>12</sup> or rigorous private lists<sup>13</sup> of harmful chemicals, immediate horizontal actions need to be taken under REACH.

### 4. Accelerate the pace of the identification and regulation of harmful chemicals

The implementation of EU law is leading to increasing harmful substances being identified and restricted. But the pace at which harmful substances are identified is too slow to address the 350 000 substances used worldwide.<sup>14</sup>

### • Make EU chemical and product regulations responsive to early warnings

EU law remains slow to react to early warnings, and sometimes even struggles to react to very old warnings.<sup>15</sup> The process public authorities follow to identify and regulate harmful chemicals needs to be as easy as possible to make EU law responsive to new and old risks. EU institutions and States **need to** 

<sup>&</sup>lt;sup>10</sup> See UNEP list of EDCs lists, 2016 and OECD list of PFAS, 2018.

<sup>&</sup>lt;sup>11</sup> See the Commission 2015 EDC screening list.

<sup>&</sup>lt;sup>12</sup> See for example the actions of the Nordic Council of Ministers on PFAS or the recent website listing EDCs fed by Denmark, France, Belgium, the Netherlands and Sweden.

<sup>&</sup>lt;sup>13</sup> Such as the SIN list or the TedX list.

<sup>&</sup>lt;sup>14</sup> Zhanyun Wang, Glen W. Walker, Derek C. G. Muir, and Kakuko Nagatani-Yoshida, Toward a Global Understanding of Chemical Pollution: A First Comprehensive Analysis of National and Regional Chemical Inventories, Environmental Science & Technology 2020 54 (5), 2575-2584, DOI: 10.1021/acs.est.9b06379

<sup>&</sup>lt;sup>15</sup> See EEA, Late lessons for early warnings reports.

## expand the use of existing legal tools that alleviate excessive burden, such as the precautionary principle and generic risk assessments.

### • Improve the EU's system of horizontal identification of harmful chemicals

The REACH review, non-REACH review and the non-toxic environment study all pointed to the need to improve the CLP and REACH SVHC lists in order to increase the scope and pace of hazard-based identification of harmful chemicals with horizontal effects (see Annex II for details).

### • Use effective and efficient regulatory tools

The regulation of chemicals is currently mainly done substance by substance using a specific risk assessment approach that requires detailed data on use and exposure even though this data can rarely be obtained. It is also often delayed or made heavier by formal or informal impact assessment such as the 'Regulatory Management Options Analysis' (RMOA). When EU institutions and States aim at protecting people and the environment from harmful chemicals, their work must be as effective and efficient as possible, for example by systematically using grouping and generic risk assessment. Ensuring predictability should never be a cause of undue delays that are costly for society at large.

### 5. Promote a change of mindset in chemical manufacturers and users

So far EU chemical and product regulations have done very little to promote a change in the business model of chemical manufacturers and users alike – a business model that today remains based on selling high quantities of chemicals, the vast majority of which are harmful to health and/or the environment. For such changes to happen the following actions are needed:

### • Protect the frontrunners

Far too often EU law forgets about providers of greener and healthier substances or technologies because chemical law is focused on the activities and needs of the brown industry. EU law must change its focus to allow greener and healthier substance producers to enjoy advantage in the EU and global markets, including by excluding laggards in the industry through broad restrictions and severely reduced or conditioned derogations.

• Define green chemistry

There is no common understanding of what 'sustainable' or 'green' chemistry is, even though several initiatives have developed criteria. An EU definition of the principles of **green chemistry**, **encompassing the health and environmental impact throughout the whole life-cycle**, would help send the right signal to investors and companies. Similarly, the principles of a "safe by design" product – within a new framework for products and materials – should be adopted and include the impact of chemicals.

### • Apply strict conditions to the obtention of public money support

The roadmap promises support to the socio-economic recovery of the European industry producing and using chemicals, and to promote the EU's strategic autonomy. However benefiting from public money

should systematically be conditioned to strict health and environmental conditions, as well as full compliance with existing EU laws.

### 6. Further harmonise compliance control and enforcement

The control of compliance with EU law and enforcement actions mostly happens at the national level for chemical and products regulations. There is very little harmonisation of the tools used to prove and control compliance, or the sanctions to enforce EU law when a violation is discovered.

This gap, as well as the lack of resources dedicated to compliance control and enforcement at the national level led to a significant compliance gap and to the absence of a real level playing field. The level of compliance and enforcement needs to be raised and harmonized across Member States.

• Harmonize the tools to prove and control compliance

The basic tools for companies to prove compliance (for example the exact content of compliance documents) are not always detailed by EU law, even though it would simplify the work of enforcement authorities. A collaborative development of common tools to prove and check compliance needs to be developed.

• Harmonize the sanctions for non-compliance

Reactions to violations of EU law, including applying sanctions, need to happen as quickly as possible in order to be a real deterrent and they need to apply with similar force throughout the EU. To achieve this result, further harmonisation of the sanctions is necessary, **by applying** sanctions **directly at EU level and by strengthening the harmonisation of the national enforcement systems.** 

## Annex 1 - Hierarchy in chemicals management

Adapted from Milieu (on behalf of the European Commission), Study for the Strategy for a non-toxic environment.



## Annex 2 – Detailed list of actions

1. Align Chemicals Strategy and laws with EU values

1.1 Prioritise the protection of the most vulnerable populations

Adopt a definition **of vulnerable populations** in legislation or a Commission Communication to enable a coherent integration of their needs across all sectors.

Adjust the risk assessment methodologies so that the benchmark for the evaluation of hazards and risks are tied to the needs of vulnerable populations (for example, children, the elderly, etc., rather than a healthy adult of 60 kg).

Adjust the risk management approaches to prioritise the protection of vulnerable populations, including by:

- Amending existing regulations and filling regulatory gaps by expanding the use of generic risk assessments leading to automatic bans of harmful chemicals in consumer products such as food contact materials, furniture and childcare equipment.

- Amending Article 68 (2) of REACH to expand the simplified restriction process to other substances of concern beyond CMRs.

- Ensuring that the impact of chemical manufacture and use is integrated into the future due diligence framework.

1.2 Limit the production and use of harmful chemicals to what is essential to the functioning of society

**Create a hierarchy of chemical management in the Chemicals Strategy** making use of the concept (see Annex I for a proposal).

**Systematically use the concept** when considering to allow (via authorisations or derogations to restrictions) the use of harmful chemicals, in particular for the most dangerous groups such as EDCs, very persistent or CMR chemicals - including by creating presumption of non-essential uses for certain sectors (e.g. toys, cosmetics).

### 2. Create business and governmental accountability with transparency

2.1 Ensure the transparency of decision-making processes

Systematically **publish work plans** and **draft decisions** before their adoption.

Systematically **take and publish detailed minutes**, **that include the voting positions** of the Member States in committees, comitology and Council<sup>16</sup>.

2.2 Ensure transparency on the use, presence and impact of chemicals

Transparency on **safety studies**:

- Expand the approach to transparency developed in the reformed General Food Law to all chemical regulations, including REACH.

- Progressively evolve towards a system where safety studies are done by independent laboratories managed by public authorities and paid by industries' contributions to avoid bias and IPR issues.

Transparency on the **function of substances**:

Create a system for consistent and precise classification of the function of chemicals under REACH.

Transparency on the **location of chemicals**:

- Provide adequate funding to ECHA to manage the SCIP database.

- Adopt requirements of full traceability of the chemical content of key materials and products (in particular plastic, textiles, construction products and electronics).

- Reform the information requirements on pesticides use to enable the creation of an EU map of pesticides use.

- Expand the obligations to collect information on emissions into the environment (under the E-PRTR database, Article 66 REACH)

- Organise EU and national campaigns of environmental monitoring (air, soil, water) and bio-monitoring.

2.3 Ensure that transparency serves the key decision-makers

Transparency for investors:

- Integrate the impact of harmful chemicals manufactured, used or present in products in the rating of the environmental performance of companies (in the application of the EU

<sup>&</sup>lt;sup>16</sup> As required by the Ombudsman in Case 1275/2018/THH.

taxonomy of sustainable activities, the future due diligence requirements and the future non-financial information regulation).

### Transparency for and among institutions:

- Expand the registry of regulatory studies created in the reformed General Food Law to other sectors and create heavy sanctions for dissimulation of information on harmful effects.

- Integrate the data handled by different EU agencies in an EU chemical dataspace to avoid inefficiencies and artificial blind spots.

Transparency along the value chain:

- Create an easily enforceable right to access information on the chemical composition of materials and products as well as conditions of safe use from the suppliers.

Transparency for the public:

- Proactively publish all information relating to emissions into the environment.

- Apply the exceptions to access on request in Regulation 1049/2001 and Regulation 1367/2006 restrictively, in compliance with the caselaw of the CJEU and the EU's international obligations in the Aarhus Convention.

2.4 Addressing the barriers to access

Facilitate **system to system integration** to ease the transfer of data from companies to public authorities.

Make the creation of an **EU chemical dataspace** a key component of the industrial and digital strategies.

Avoid 'data dump': fit the information to the audience for user-friendliness.

Do not support IPR or CBI protection undermining transparency.

3. Amend EU law to identify and minimise all exposure to endocrine disruptors and persistent chemicals

3.1 Amend the identification systems set up in EU laws

**Amend the CLP Regulation** to add hazard categories for the two groups, organised in 1A, 1B and 2 depending on the available scientific evidence.

**Amend REACH** so that EDCs and persistent, mobile and toxic substances have their own provisions under Article 57, rather than being submitted to the proof of 'equivalent level of concern' under Article 57 (f).

**Amend the data requirements** under the EU regulations requiring a pre-marketing hazard and/or risk assessment (cosmetics, FCM, pesticides, biocides, detergents, REACH) so that EDCs and high persistence may be identified.

**Define hazard categories for suspected EDCs and suspected PMT** in order to start addressing those hazards under REACH.

3.2 Adopt a coherent and fit policy to restrict the use of these groups

Amend Article 68 (2) of REACH to expand it to EDCs and very persistent substances.

**Apply a generic risk assessment approach** to the substances identified as EDCs or very persistent (under CLP, REACH or pre-marketing assessments) for EU and imported consumer products (cut off with no exposure-based derogations).

For essential uses, **keep emissions as low as can reasonably be achieved** following good practices during production and use.

**Ensure the traceability of products** containing the substances and reduction of emissions during their entire life-cycles.

Manage legacy substances by remediation and not allowing toxic recycling.

3.3. Act now to restrict the use of already known and suspected EDCs and very persistent chemicals

When adopting REACH restrictions, use REACH authorisations to grant potential derogations for essential uses only.

When the substances are already authorised/on a positive list, prioritise the review.

4. Accelerate the pace of the identification and regulation of harmful chemicals

4.1 Make EU chemical and product regulations responsive to early warnings

Make full use of the precautionary principle.

Create a system to identify early warnings, fed by independent research and monitoring.

Ensure that each regulation of chemical use and presence **contains a 'trigger' for the revision of chemical threshold and authorisation** i) connected to the EU early warnings mechanism; ii) that require a review in the case of new scientific developments; iii) require periodic reviews of chemical threshold and authorisations.

### 4.2 Improve the EU system of horizontal identification of harmful chemicals

#### Improve CLP

- Amend the Regulation to give the Commission and ECHA the power to initiate classification dossiers and to ECHA the power to control and coordinate the self-classifications; and

- Amend CLP to add hazard categories for EDCs, persistent chemicals, immunotoxics, neurotoxics, respiratory sensitisers and specific target organ toxicity.

### **Improve REACH**

- Amend REACH so that unanimity is not required for MSC to adopt a SVHC identification; and

- Amend the registration requirements so they cover polymer and low tonnage chemicals.

4.3 Use effective and efficient regulatory tools

Systematically use **grouping** to identify and restrict harmful chemicals to avoid regrettable substitution.

Expand the use of **generic risk assessment** to avoid resource consuming specific risk assessment.

Align actions between upstream and downstream (waste, water) regulations

Stop wasting time and resources by engaging in Regulatory Management Options Analysis, as the predictability and coherence required by the industry can be achieved in a lighter way by expanding the scope of PACT<sup>17</sup>.

5. Promote a change of mindset in chemical manufacturers and users

5.1 Protect the first-movers

Restrict the **import of products containing substances** not allowed for use in the EU.

Ban the export of substances banned for use in the EU.

Ensure that any derogation to a ban serves an **essential use** and is conditioned on the submission of a **substitution plan**.

**Amend the REACH authorisation provisions** so that: i) only chemical users (and not manufacturers/importers) may apply for authorisation; ii) a substitution plan is always

<sup>&</sup>lt;sup>17</sup> NGOs, consumer associations, trade union and one industry associations expressed in the context of the REACH review that RMOA hamper REACH substitution principle, undermine the precautionary principle and deny EU consumers their right to know. See Commission staff working document; SWD (218) 58 final p. 109.

prepared; iii) the fees paid to apply are used to fund a substitution center supporting the cooperative development of green alternatives in the sector concerned.

5.2 Define Green Chemistry

Adopt an **EU definition of sustainable chemistry**, taking into account the health and environmental footprint throughout the entire life-cycle.

Promote a **safe by design approach** by adopting a new framework for Products Regulation to address harmful chemicals in materials and products (following the recommendations of the Non-Toxic Environment study).

5.3 Apply strict condition to the grating of public funding

Public money (i.e., the recovery package, state aid, public procurements) may support chemical manufacturers and users only when strict **health, environmental and compliance conditions** are imposed and respected.

6. Further harmonise compliance control and enforcement

6.1 Harmonise the tools to prove and check compliance with EU law

Adopt detailed requirements for the content of compliance documents (for example FCM Regulation).

Create audits of the national enforcement systems.

Develop coordinated national enforcement campaigns.

6.2 Harmonise the sanctions for non-compliance

Grant to ECHA the power to **withdraw a registration number** in the case of noncompliance or non-updated registration dossiers.

Use transparency to create incentive to compliance (name and shine/shame).

Adopt harmonized requirements for national sanctions.

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