

## BRIEFING

# REACH reform: HEAL's key demands for health-protective upgrades of authorisation and restriction

March 2023

This briefing presents HEAL's demands regarding the upgrades of the authorisation and restriction chapters of the REACH regulation in the context of the current legislative reform <sup>1</sup>.

## Introduction

HEAL supports the speedy reform of REACH in line with promises made under the EU's [Chemical Strategy for Sustainability \(CSS\)](#). The reform should be driven by REACH's founding principles; namely no data, no market, burden of proof on industry, polluter pays, and transparency and accountability, and it should allow for the uptake of the latest scientific evidence as well as the implementation of the precautionary principle <sup>2</sup>.

Recent data and findings about the presence of harmful chemicals on the market and in the environment illustrate REACH's failure to deliver on the above principles, as well as the urgent need for its reform. Of the over 100,000 chemicals currently on the EU market, approximately 75% are considered hazardous to health and the environment <sup>3</sup>. Building on the mounting evidence, a recent cross-border investigation found that more than 17,000 sites around Europe are contaminated by per- and polyfluoroalkyl substances (PFAS) — also known as forever chemicals due to their intrinsic extreme persistence in the environment <sup>4</sup>.

The [Chemical Strategy for Sustainability](#) sets out a new toxic-free hierarchy in chemicals management, prioritising the use of safe chemicals and minimising exposure to harmful ones. Specific promises that are relevant to the authorisation and restriction processes include<sup>5</sup>:

- Develop safe and sustainable-by-design criteria for chemicals and implement safe substitution whenever safer alternatives exist for a substance of very high concern.
- Clearly define criteria for essential use\* of a chemical to be applied only if it is necessary for the health, safety, or functioning of society and there is no safe, sustainable alternative.
- Promote non-toxic, circular chemical lifecycles by prioritising products that impact vulnerable populations for stricter regulation in addition to those with the most potential for circularity.
- Apply a grouping approach for authorisation and restriction of chemical classes instead of regulating one chemical at a time.
- Develop criteria for more transparent, scientifically justified derogations.
- Extend the generic approach to risk management (GRA)\* to categories in the identification of substances of very high concern that include carcinogens, gene mutagens, reprotoxicants, endocrine disruptors, immunotoxicants, neurotoxicants, respiratory sensitisers, specific target organ toxicants (STOT), persistent, bioaccumulative, and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances. Before the GRA is phased in completely, prioritise these substances for restriction.

### For more information:

Natacha Cingotti

[natacha@env-health.org](mailto:natacha@env-health.org)

+32 (0)2 329 00 81 · [env-health.org](http://env-health.org)



The [Restriction Roadmap](#) is one of the deliverables of the Chemicals Strategy for Sustainability. It is essentially a priority list for restrictions of the most harmful chemicals (including groups of chemicals), to be used in the interim until the extension of the generic risk assessment approach\* is fully implemented in a reformed REACH. This list is comprised of many well-known hazardous chemicals and their uses such as PFAS in firefighting foam, lead in polyvinyl chloride (PVC), and polyaromatic hydrocarbons (PAHs), furans, dioxins, formaldehyde, and polychlorinated biphenyls (PCBs) used in disposable baby diapers, just to name a few. However, it is yet to be effectively implemented<sup>6</sup>.

**\*Essential Use:** Taking into account the [Montreal Protocol definition](#), the Chemical Strategy for Sustainability commits to:

Define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments<sup>7</sup>.

**\*Generic risk approach to risk management (GRA):** A hazard-based regulatory approach that only takes into account a chemical's intrinsic properties and aims to prevent risks associated with exposure to the well-characterised chemicals of concern. Use and exposure assessments are not part of the generic risk management approach. In the Chemicals Strategy for Sustainability, the European Commission committed to extend the GRA to the hazardous substances mentioned above in order to ensure that consumers and professional users are protected from them<sup>8</sup>.

**The authorisation and restriction processes are key risk-management components of REACH. Therefore, they need to be adequately amended to deliver the goals of the strategy.**

[The authorisation process](#) is supposed to be the main vehicle through which REACH promotes safe substitution. It aims to phase out substances of very high concern (SVHCs) and replace them with safer alternatives, unless there are no suitable substitutes and the socio-economic benefits are greater than the risks to human health and the environment. In principle, only in this case will chemicals be granted authorisation for specific, properly controlled uses throughout their lifecycle<sup>9</sup>.

**Unfortunately, the authorisation process is riddled with loopholes and procedural delays. This has created a scenario ripe for industry exploitation, which overburdens authorities already constrained by limited time and resources.**

- **Phase I: Candidate listing**

To begin the authorisation process, a member state or ECHA at the request of the EU Commission, submits a proposal for a chemical to be identified as SVHC and added to the [candidate list](#). In order to be added to the candidate list, the proposal requires unanimous backing from the ECHA member states Committee (MSC). However, a SVHC identification alone does not trigger automatic regulatory consequences, but only information requirements for companies<sup>10</sup>.

- **Phase II: authorisation listing**

Identified SVHCs can still remain on the market for a very long time. It can take a decade until ECHA is able to prioritise them and submit recommendations for their addition to the authorisation list (Annex XIV) to the EU Commission, who then makes the final decision <sup>11</sup>.

Only when substances are on the authorisation list, they can be prioritised for phase out. At the time of writing, out of the 233 SVHC currently on the candidate list, only 59 have been placed on the authorisation list.

- **Phase III: Applications for authorisation (AfA)**

Once a substance is on the authorisation list, ECHA prepares draft recommendations that include a sunset date and deadline for which companies must apply for authorisation to continue placing a chemical on the market, or using it after the sunset date<sup>12</sup>.

Unfortunately, a lack of comprehensive requirements for an AfA – namely no obligations for industry to provide comprehensive information on existing alternatives, or to annually update information on uses and exposures – also introduces regulatory pitfalls. To date, the EU Commission has only refused three AfAs, indicating the need for more health protective criteria<sup>13</sup>. Further, the EU Commission often grants unjustified derogations for continued use with long- or no time limitations for phase out, even when safer alternatives exist. The European Environmental Bureau has found that the duration of authorisation processes, from beginning to end, ranges between 6-13 years. This is a direct result of the EU Commission's often decade-long delays in decision making<sup>14</sup>.

The restriction process is another route for REACH to restrict or ban hazardous chemicals, which not only applies to substances produced and used in the EU, but also to imports.

- **Phase I: Submission and conformity check**

A member state or ECHA at the request of the EU Commission, initiates the restriction process, after which the risk assessment committee (RAC) and the socio-economic analysis committee (SEAC) conduct a conformity check.

- **Phase II: Consultations and RAC and SEAC's opinions**

Public consultations and committee discussions ensue, after which the two committees publish their opinions.

- **Phase III: Final decision**

Upon receipt of ECHA committees' consolidated opinion, the European Commission (theoretically within 3 months) makes a proposal on whether to support the restriction or not. This proposal is discussed and voted on by member states in a closed-door committee (the REACH Committee). If approved, the restriction proposal is submitted to the European Parliament, which can support or reject but not amend it<sup>15</sup>.

The European Environmental Bureau found that the restriction process has ranged between 3-11 years, with a median duration of approximately five years and seven months from the date of intention to enactment<sup>16</sup>.

- Under current REACH provisions, the burden of proof for authorities (especially member states), to propose restrictions is too high and the process is very resource- and time intensive. This allows for hazardous chemicals to remain on the market for longer periods of time or even indefinitely<sup>17</sup>.

- Further, the European Commission seldom respects the three-month deadline for acting on ECHA opinions, and the discussions on its proposals at the REACH committee drag on for a very long time without transparency about the positions of the member states<sup>18</sup>.
- The current stalemate on the restriction on microplastics intentionally added to products is a prime example of the delays and shortcomings of the restriction process as a whole. This process began in 2017 when the European Commission requested ECHA investigate the need for a restriction<sup>19</sup>. In 2019, ECHA submitted the restriction dossier and then in February of 2021, submitted its final opinion to the European Commission. Instead of issuing its proposal for follow-up action within three months (by the summer 2021), the Commission only did so in August 2022. Now more than six years into the process, the restriction is still sitting with the member state authorities, with a potential vote again postponed on 1 March 2023<sup>20</sup>.

Ultimately, these unjustified delays and derogations combined with breaches of existing procedural time limits allow well-known harmful chemicals to stay on the market for years.

## HEAL's demands for the European Commission

### 1. Streamline and expedite the authorisation and restriction processes

- **Shorten both processes, making them simpler, more transparent, and protective** by way of <sup>21 22 23 24</sup>:
  - Extending the generic approach to risk management beyond carcinogenic, mutagenic, and reprotoxic (CMR) substances to other critical hazard properties of concern including endocrine disruptors (ED), immunotoxins, neurotoxins, respiratory sensitisers, substances affecting specific organs (STOT), in addition to substances that are persistent, bioaccumulative, and toxic (PBT)/very persistent and bioaccumulative (vPvB), persistent, mobile, and toxic, (PMT) for the environment. These substances should be banned by default for consumer and professional uses on the basis of their sole hazards, unless their use is deemed essential as per the newly introduced criteria for the concept. The REACH reform proposal should provide a clear timeline for the phase-in of the different critical hazards under the GRA.
- **Develop clearly defined criteria for what constitute(s) essential use(s) of harmful chemicals in order to streamline how derogations are being granted.** Derogations need to be<sup>25 26</sup>:
  - Based on the same criteria for both restrictions and authorisations.
  - Limited in duration.
  - Tied to the requirements for applicants to provide:
    - Plans for safer substitution.
    - Extensive information to support the application request.

## 2. Simplify and integrate more health-protective updates to the authorisation process<sup>27 28</sup>

- Clarify the safe substitution aim of authorisation to ensure that authorisation is never granted when safer substitutes are available.
- Maintain the candidate list in the reformed REACH as an important driver of substitution and accelerate the process for adding chemicals to it.
- Introduce SVHC categories for endocrine disrupting chemicals, immunotoxic, and neurotoxic substances, persistent, mobile, and toxic (PMT) and very persistent and very mobile substances (vPvM) as per promises of the CSS.
- Apply an automatic SVHC identification for substances for which a harmonised CLP classification exists.
- Introduce a dynamic link between the candidate list and CLP for automatic updates of the hazard properties of classified substances.
- Introduce notifications and fees for SVHCs in the candidate list in order to incentivise and support substitution.
- Require industry to annually update information in a public database on uses, exposures, and safer alternatives.

## 3. Reduce burden on authorities and establish clear scientific guidance and deadlines to speed up the restriction process<sup>29 30</sup>

- Clarify the possibility for using the grouping approach for restrictions.
- Reduce burden on member states' authorities to bring forward restriction proposals when they have concerns for human health and the environment.
- Include legally binding deadlines for finalising ECHA opinion processes and follow-up decisions.

**HEAL's demands promote revisions of the authorisation and restriction processes of REACH, to offer stronger protection for people and the environment against the most hazardous substances, and incentivise safe substitution.**



Photo credit: [Victor](#), via Unsplash

## NOTES:

- <sup>1</sup> European Commission. [Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment](#). Cited 7 March 2023.
- <sup>2</sup> European Chemical Agency. [Understanding REACH](#). Cited 7 March 2023.
- <sup>3</sup> Eurostats. [Chemicals production and consumption statistics](#). (December 2022)
- <sup>4</sup> Forever Pollution Project: [The Forever Pollution Project – Journalists tracking PFAS across Europe](#). Cited 7 March 2023.
- <sup>5</sup> European Commission. [Chemical Strategy for Sustainability](#). (October 2020)
- <sup>6</sup> European Commission. [Restriction Roadmap](#). (April 2022).
- <sup>7</sup> European Commission. [Chemical Strategy for Sustainability](#). (October 2020)
- <sup>8</sup> Ibid
- <sup>9</sup> European Chemical Agency. [REACH Authorisation Process](#). Cited 7 March 2023.
- <sup>10</sup> Ibid
- <sup>11</sup> European Chemical Agency. [Authorisation list](#). Cited 2 March 2023.
- <sup>12</sup> European Chemical Agency. [REACH Authorisation Process](#). Cited 7 March 2023.
- <sup>13</sup> European Commission. [Authorisation Decision List](#). Cited 7 March 2023.
- <sup>14</sup> European Environmental Bureau. [Need for Speed](#). (July 2022)
- <sup>15</sup> European Chemical Agency. [REACH Restriction Process](#). Cited 7 March 2023.
- <sup>16</sup> European Environmental Bureau. [Need for Speed](#). (July 2022)
- <sup>17</sup> Ibid
- <sup>18</sup> Ibid
- <sup>19</sup> European Chemical Agency. [Microplastics](#). Cited 6 March 2023.
- <sup>20</sup> European Chemical Agency. [Registry of restriction intentions until outcome](#). Cited 7 March 2023.
- <sup>21</sup> HEAL comments on CARACAL 43 proposals for reform of REACH authorisation and restriction. (February 2022)
- <sup>22</sup> Joint comments from CHEM Trust, EEB and HEAL on considerations for extended REACH information requirements. (February 2022)
- <sup>23</sup> Comments following CARACAL 44 discussion on options to implement the extension of the generic approach to risk management in the REACH regulation. (March 2022)
- <sup>24</sup> Joint health and environmental NGOs' comments to the update of REACH annexes in relation to endocrine disruption properties as follow-up to the CASG-ED6 meeting. (February 2022)
- <sup>25</sup> HEAL comments on CARACAL 43 proposals for reform of REACH authorisation and restriction. (February 2022)
- <sup>26</sup> Joint comments from CHEM Trust, EEB and HEAL on considerations for extended REACH information requirements. (February 2022)
- <sup>27</sup> HEAL comments on CARACAL 43 proposals for reform of REACH authorisation and restriction. (February 2022)
- <sup>28</sup> Joint comments from CHEM Trust, EEB and HEAL on considerations for extended REACH information requirements. (February 2022)
- <sup>29</sup> HEAL comments on CARACAL 43 proposals for reform of REACH authorisation and restriction. (February 2022)
- <sup>30</sup> HEAL input on REACH revision roadmap consultation. (May 2021)

### Natacha Cingotti

Health and Chemicals Programme Lead  
Health and Environment Alliance (HEAL)  
E-mail: [natacha@env-health.org](mailto:natacha@env-health.org)  
Tel: +32 (0)2 329 00 81


### Hannah Donart

Senior Science Policy Officer  
Health and Environment Alliance (HEAL)  
E-mail: [hannah@env-health.org](mailto:hannah@env-health.org)  
Tel: +32 (0)2 329 00 80

### Health and Environment Alliance (HEAL)

Avenue des Arts 7/8  
1210 Brussels, Belgium  
Tel: +32 (0)2 329 00 80  
E-mail: [info@env-health.org](mailto:info@env-health.org)

 [@HealthandEnv](https://twitter.com/HealthandEnv)

 [@healthandenvironmentalliance](https://www.facebook.com/healthandenvironmentalliance)

 [Health and Environment Alliance \(HEAL\)](https://www.linkedin.com/company/Health-and-Environment-Alliance-HEAL/)



**The Health and Environment Alliance (HEAL)** is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

HEAL's over 90 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.



HEAL gratefully acknowledges the financial support of the European Union (EU), Global Greengrants and Adessium Foundation for the production of this publication. The responsibility for the content lies with the authors and the views expressed in this publication do not necessarily reflect the views of the EU institutions and funders. The European Climate, Infrastructure and Environment Executive Agency (CINEA) and the funders are not responsible for any use that may be made of the information contained in this publication.

HEAL's EU Transparency Register Number: 00723343929-96