

## BRIEFING

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

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This briefing presents HEAL's demands regarding the upgrades of the registration and evaluation 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>.

The '[Chemical Strategy for Sustainability Towards a Toxic-Free Environment](#)' aims to set out a new hierarchy in chemicals management, prioritising the use of safe chemicals and minimising exposure to harmful ones. Specific promises that are relevant to the REACH registration and evaluation processes include<sup>3</sup>:

- Zero tolerance approach to non-compliance and enforcement of the 'no data, no market' principle through stronger compliance oversight and enforcement of all registration dossiers and the ability for authorities to revoke registration numbers when industry does not meet legal obligations.
- Updated information requirements in REACH to include information on all carcinogenic substances irrespective of tonnage, in addition to information on endocrine disruption, respiratory sensitisation, immunotoxicity, neurotoxicity, other STOT (Specific Target Organ Toxicity), persistent, bioaccumulative and toxic (PBT), very persistent very bioaccumulative (vPvB), persistent, mobile, toxic (PMT) and very persistent and very mobile (vPvM).
- Extend registration requirements to certain polymers of concern.
- Account for combined exposures to multiple chemicals instead of singular ones, in order to assess real-life chemical hazards and risks.
- Grouping approach based on structural similarity for chemical assessment instead of one chemical at a time.

**REACH's registration process** is the gateway into the EU market for chemicals manufactured, imported, and used in industrial and consumer products. However, out of the approximately 100,000 chemicals currently on the EU market, only around 500 have enough data for authorities to comprehensively characterise their hazards and exposures. The European Environmental Agency has aptly dubbed this "[the unknown territory of chemical risk](#)"<sup>4</sup>. In fact, according to Eurostat's data approximately two-thirds of chemicals currently on the EU market are hazardous to health<sup>5</sup>.

### 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 Chemical Strategy for Sustainability** points out a history of industry non-compliance, with two-thirds of the registered chemicals currently lacking legally required safety data necessary to fulfil registration requirements <sup>6</sup>. Current [REACH information requirements](#) also do not cover all the relevant health and environmental properties of concern, such as endocrine disruption, neurotoxicity, and immunotoxicity. This means that industry does not have the legal responsibility to provide authorities with specific safety information to allow them to comprehensively assess these properties. Even for properties of concern for which information requirements exist (e.g. carcinogenicity), they are incomplete, particularly for low volume substances. This is also an issue for polymers, which are important building blocks of plastics, and yet are exempted of the duty of registration under current REACH provisions.

**The European Chemicals Agency** (ECHA), the body responsible for the administration of REACH in the EU, does not have real enforcement mechanisms. It lacks the ability to revoke registrations in the case of insufficient data and there are no sanctions in place when industry fails to comply with this legal obligation. Furthermore, with only three weeks to review registration dossiers, very limited resources allocated for compliance checks, and currently no legal ground to assess chemicals with similar hazards by groups, European and national authorities are unable to effectively check the sheer number of chemical registration dossiers submitted for compliance <sup>7</sup>. This has led to rampant industry non-compliance.

**Evaluation** is the next step in the regulatory process in which authorities review the data required for quality and safety. In contrast to registration, the evaluation process has been found to take authorities as long as a decade to determine the safety and hazards of a single chemical <sup>8</sup>. In essence, authorities are left with insufficient data, and thus are unable to evaluate chemical safety, while industry has very little incentive to cooperate and comply with data requirements because they suffer no financial consequences for the extra work created during the evaluation process - triggering long delays. In the end, these deficiencies and delays leave many hazardous chemicals on the market for years, polluting the environment and exposing people.

## HEAL's four demands for the European Commission

### 1. Update REACH standard information requirements to reflect real-life exposures and current science

- Updating the REACH annexes detailing industry's information requirements is urgent and must deliver the following <sup>9</sup>:
  - More complete information requirements for low-tonnage chemicals (substances produced or imported below 10 tonnes per year):
    - Low-tonnage substances currently have less information requirements, potentially leading to unidentified health hazards during the registration and evaluation process, even for those that are well characterised hazardous chemicals (i.e. known or suspected carcinogenic or mutagenic substances).
  - More complete information on uses, exposures, and critical hazard properties of concern for health and the environment:

- In particular, information must be required during registration on uses, exposures, and critical hazard properties of concern including endocrine disruption, respiratory sensitisation, immunotoxicity, neurotoxicity, other STOT (Specific Target Organ Toxicity), in addition to persistent, bioaccumulative and toxic (PBT), very persistent, very bioaccumulative (vPvB), persistent, mobile, toxic (PMT) and very persistent and very mobile (vPvM) for the environment.
  - For all properties of concern, the information requirements must be based on the most up-to-date scientific evidence:
    - A screening of all relevant literature, including independent peer-reviewed literature, should be requested for all volumes from annex VII onwards, through the requirement to follow a systematic data search approach.
    - The specific test requirements in all annexes must include the most recently validated relevant test methods available to investigate the different properties of concern.
    - The annexes need to leave room for expert judgement, so that authorities can have flexibility in requesting testing strategies that are fit for purpose depending on the level and quality of information available.
  - Accounting for combined exposures to cocktails of chemicals by integrating the [mixture assessment factor \(MAF\)](#) into the registration process <sup>10 11</sup>.
  - Introducing registration requirements for polymers, which are currently exempt from registration.



## 2. Strengthen authorities' ability to make zero tolerance for non-compliance a reality

- Introduce effective measures that shift the burden of proof back onto industry and give authorities the power to actively ensure compliance including <sup>12</sup>:
  - Strengthening legal provisions to force industry to maintain registration dossiers compliant at all times, introducing deadlines for expiry and obligations for annual updates.
  - Strengthening ECHA compliance checks to include comprehensive required information and necessary oversight before registration is granted.
  - Granting ECHA the right to revoke registration numbers upon non-compliance; make criteria for revocation clear.
  - Introducing industry fees to account for authorities' workload in dealing with compliance checks, or when information is missing during evaluation.

### 3. Streamline and optimise registration and evaluation

- Without adequate time for authorities to determine compliance, many hazardous chemicals are granted registration and entry onto the EU market, after which data bottlenecks and often decade-long evaluation processes ensue <sup>13</sup>. Recommendations for a more efficient, integrative approach include:
  - Better integration of registration compliance checks with dossier evaluations to speed up the evaluation process and give both ECHA and member states the mandate for this integrated approach <sup>14</sup>.
  - Speeding up the evaluation process by implementing compliance checks for groups of chemicals, shortening deadlines for data generation decisions, and introducing deadlines for risk-management follow-up on conclusions <sup>15</sup>.

### 4. Improve transparency

- In order to provide more transparency and incentivise industry compliance in providing required hazard data for registration and developing more safe, sustainable chemicals:
  - Introduce obligations for ECHA to hold a public list documenting the status of dossiers' compliance (i.e. compliant, not compliant, or in review) <sup>16</sup>.

**HEAL's four demands address current shortcomings in the REACH registration and evaluation processes and provide health-protective solutions that are closely aligned with the Chemical Strategy for Sustainability's commitments. These revisions also lay a solid foundation for a more effective and efficient implementation of the restriction and authorisation phases of REACH.**



NOTES:

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- <sup>1</sup> [Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment](#), European Commission (2023)
- <sup>2</sup> European Chemical Agency. [Understanding REACH](#). Cited on 24 January 2023
- <sup>3</sup> [Chemical Strategy for Sustainability Towards a Toxic-Free Environment](#), (2020)
- <sup>4</sup> European Environment Agency. [The unknown territory of chemical risk](#), (2020)
- <sup>5</sup> Eurostats. [Chemicals production and consumption statistics](#), (2019)
- <sup>6</sup> [Chemical Strategy for Sustainability Towards a Toxic-Free Environment](#), (2020)
- <sup>7</sup> The European Environmental Bureau. [Need for speed](#), (2022)
- <sup>8</sup> Ibid.
- <sup>9</sup> [Joint comments from CHEM Trust, European Environmental Bureau and Health and Environment Alliance on considerations for extended REACH information requirements](#), (2022)
- <sup>10</sup> [Comments on CA/MS/34/2020 'Towards a pragmatic procedure to regulate the risks of exposure to unintended combinations of chemicals in the EU'](#), (2020)
- <sup>11</sup> Chem Trust. [Chemical Cocktails](#), (2022)
- <sup>12</sup> The European Environmental Bureau (EEB) and Health and Environment Alliance (HEAL). [Joint comments from the EEB and HEAL on the proposal to reform the REACH registration and evaluation process](#), (2022)
- <sup>13</sup> The European Environmental Bureau. [Need for speed](#), (2022)
- <sup>14</sup> The European Environmental Bureau (EEB) and Health and Environment Alliance (HEAL). [Joint comments from the EEB and HEAL on the proposal to reform the REACH registration and evaluation process](#), (2022)
- <sup>15</sup> Cousins, I.T., DeWitt, J.C., Glüge, J., et al. [Strategies for grouping per- and polyfluoroalkyl substances \(PFAS\) to protect human and environmental health](#), (2020)
- <sup>16</sup> The European Environmental Bureau (EEB) and Health and Environment Alliance (HEAL). [Joint comments from the EEB and HEAL on the proposal to reform the REACH registration and evaluation process](#), (2022)

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### 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.



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