



REPORT EU-RAPPORTEURSHIP REACH

Members of Parliament Ines Kostić and Marieke Koekkoek

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Report on the EU REACH rapporteurship

Introduction

A proposal to revise the REACH Regulation on chemicals is expected to be published by the end of 2025 or the beginning of 2026. The Committee for Infrastructure and Water Management (hereafter: I&W committee) within the Dutch Parliament (House of Representatives) has appointed us as EU rapporteurs for this revision. In this memorandum we report on our activities in this role. We recommend that the I&W committee continue this rapporteurship after the upcoming general election, building on the insights gained thus far.

In the sections below, we discuss:

- the main findings from our discussions with stakeholders in the Netherlands and Brussels;
- the status of the REACH revision, as part of a broader package of measures for the chemical industry;
- basic information on REACH.

In the **annexes**, you will find:

- a comprehensive account of our discussions with stakeholders;
- an overview of the stakeholders we interviewed;
- a timeline of relevant documents, starting with the publication of the REACH Regulation in 2007 and ending in 2026.

1. Findings

1.1 Purpose and discussions

The purpose of our rapporteurship, as set out in the mandate (adopted on 1 July 2024), was threefold:

- to improve the I&W committee's information position;
- to make effective use of opportunities to influence EU decision-making and, where possible, promote the position of the Dutch parliament;
- to monitor the proposal after publication and make recommendations aimed at increasing knowledge and influence during negotiations. In view of the upcoming general election (and seeing as the proposal has not yet been published), this final stage has not yet been completed.

During the first phase of the rapporteurship, we held discussions with mainly Dutch stakeholders in order to achieve our first objective. We investigated how the current REACH Regulation works and took inventory of stakeholders' wishes. The outcomes of these discussions were recorded in an [interim report](#). Based on the findings from the first phase of our rapporteurship, the I&W committee, at our suggestion, sent a [letter](#) outlining a number of focus areas to the responsible European Commissioners (Roswall and Séjourné) to support a political dialogue.

In the second phase, Member of Parliament Kostić (also on behalf of Member of Parliament Koekkoek) met with stakeholders in Brussels. We also held joint online discussions with the European Chemicals Agency (ECHA) in Helsinki. Our findings from both phases were supplemented by a staff analysis of position papers from various parties and other literature.

1.2 Substantive findings

The figure below provides an overview of building blocks that, according to our discussion partners, could and should be considered during the REACH revision.

Accelerating and improving decision-making	Improving health and environmental protection	Phasing out animal testing	Improving enforcement and compliance	Streamlining communication within the supply chain
Shift from authorisations to restrictions	Clarify disclosure obligations upon registration	Process results from roadmap for phasing out animal testing	Products imported into the EU	Mandatory digital format for information exchanges in safety data sheets
Better compliance with European Commission deadlines	Extend registration requirement for low tonnages	Process results from EU strategy for test methods and validation	Keep registration files up to date	Simplify communication on substances in articles
Generic risk management approach (GRA): shortened procedure for restrictions in consumer products	Registration requirement for polymers	Extension of system for test proposals and adaptation of ECHA mandate	Revoke registration as a last resort	
Increase predictability for chemical industry	Mixture Assessment Factor (MAF) to account for combination effects	Framework for test methods and animal testing that can quickly incorporate new insights		

Combining goals amid shifting dynamics

The political dynamics within the Commission, the Council and the European Parliament have shifted in favour of simplification and strengthening competitiveness. In its letter to the Commission, the I&W committee advocated to combine multiple goals: strengthening competitiveness, simplifying regulations and improving health and environmental protection where possible. As this report will show, the parties involved see some possibilities in this regard.

Broader than REACH

In our interim report, we emphasised the necessity of broadening the scope beyond REACH alone (this was also noted in the letter to the Commission):

- Safety and health should be considered in the design of chemicals and products from the beginning (safe and sustainable by design). This requires innovation-oriented instruments.
- Broader strategies are needed to: (1) phase out animal testing and, in connection with this, (2) develop and, most importantly, validate test methods. The outcomes of the European projects around this subject should be properly reflected in the revised REACH Regulation.
- There are important areas of overlap with other regulations, for example on plant protection products and chemicals in toys and cosmetics. These connections should be taken into account, including in the regulation of harmful substances in consumer products.

Accelerating and improving decision-making on substances

Decision-making on substance restrictions (restrictions and authorisations) in REACH should be accelerated, as this will lead to a higher level of protection while also giving the industry faster clarity. In its current form, the decision-making process for these measures takes several years. Adaptation of procedures and better compliance with deadlines set by the European Commission are considered essential by most parties. The Commission envisages more frequent use of restrictions instead of authorisations, and a shortened procedure for restrictions on harmful substances in consumer products. There is no consensus yet on how to achieve this.

Improvements in health and environmental protection levels

In its letter to the European Commission, the I&W committee wrote that the information requirements in REACH are insufficient for identifying certain hazardous substance properties. As a result, the information provided by chemical companies when registering substances often does not provide clarity on these properties. To address this issue, the annexes to REACH need to be made less ambiguous. Other possible improvements include extensions of the registration requirement and taking into account the combination effects of substances by introducing a so-called Mixture Assessment Factor (MAF). Although the political dynamics are less favourable with regard to these elements, they are still likely to be mentioned in discussions about the REACH revision.

Phasing out animal testing and strategy for test methods

Our discussions revealed strong support for promoting alternatives to animal testing, as well as for phasing out animal testing altogether. At the same time, it remains

unclear what this means concretely for REACH. The European Commission is currently preparing a roadmap on phasing out animal testing in chemical safety assessments (broader than REACH). As this process has only recently started, it is unlikely that the resulting decisions and insights will be included in the REACH revision. It can, however, be agreed in this revision that this will be done at a later stage, for instance through a mandate to the Commission. Among other things, our discussion partners suggested expanding the system of test proposals in REACH. Another suggestion was to introduce a framework based on clearly defined information objectives rather than prescribed test methods, while maintaining the same level of protection and legal certainty.

In addition to the above roadmap, the EU is preparing a strategy for the development and adoption (validation) of test methods. The aim of this strategy is to ensure that newly developed or improved test methods can be applied more quickly for REACH (and other legislation). This could help phase out animal testing and boost industry competitiveness, as new advanced materials could be tested more quickly.

Improving enforcement and compliance

The need to improve REACH enforcement and compliance is widely recognised, especially for products imported into the EU. Moreover, the chemical industry needs to make a greater effort to ensure that registration dossiers are kept up to date. As a last resort, the European Chemicals Agency (ECHA) could revoke a registration when companies fail to meet their obligations. ECHA would like to have more instruments at its disposal to do so, as this would motivate companies to provide additional information more quickly and make it possible to verify registrations more quickly.

Streamlining communication within the supply chain

While there are significant opportunities to streamline communication between companies within the supply chain, these have so far received little attention. Companies that produce mixtures of various substances, such as manufacturers of paints and detergents, are calling for a mandatory digital format (in XML) for the exchange of information through safety data sheets. The digitisation of such exchanges would significantly reduce administrative burdens. The exchange of detailed information on substances in articles also places certain burdens on companies. Here too there are opportunities for simplification and/or digitisation.

2. Status of REACH revision: shifting objectives

2.1 Plans of the current Commission

In the [work programme for 2025](#), European Commission President Ursula von der Leyen announced a new package of measures for the chemical industry. [Jessika Roswall](#), the European Commissioner for Environment, Water Resilience and a Competitive Circular Economy, is responsible for this package, together with the Vice-President for Prosperity and Industrial Strategy, [Stéphane Séjourné](#).

The package aims to simplify regulations on chemicals, including REACH, and provide clarity on PFAS. The REACH proposal is expected by the end of 2025, and the intended restriction of PFAS under REACH is expected to be implemented in late 2026. Other components of the package include a chemical industry action plan and an omnibus package.

Communication on chemical industry action plan and omnibus package

On 8 July 2025, the Commission released a communication containing an action plan ([COM \(2025\) 530](#)), accompanied by an [omnibus package](#) for the chemical industry aimed at promoting the chemical sector's competitiveness and innovative capacity. The Commission also published a proposal to strengthen the governance and financial sustainability of the European Chemicals Agency (ECHA) ([COM \(2025\) 386](#)).

The [action plan](#) aims to:

- Create a 'Critical Chemicals Alliance' with the aim of identifying the risks of plant closures in the sector and addressing the underlying issues.
- Quickly present an Action Plan for Affordable Energy (as announced in the Clean Industrial Deal) to support businesses. The Commission will adjust the state aid rules in the Emissions Trading Scheme (ETS) to compensate energy-intensive sectors, such as the chemical industry, for high energy costs.
- Emphasise fiscal measures to encourage clean chemistry.

The Commission also intends to strengthen rules on chemicals in imported products, promote chemical recycling and facilitate carbon storage.

The [omnibus package](#) includes proposals to simplify chemical product regulations to reduce the associated financial burden on companies. These proposals focus on the labelling of hazardous substances and cosmetics – issues that fall within the remit of the Committee for Health, Welfare and Sport in the House of Representatives. The package will also simplify the registration of fertilisers by harmonising regulations, which falls within the remit of the Committee for Agriculture, Fisheries, Food Security and Nature.

In anticipation of the omnibus package, this issue was already discussed in the European Parliament on 7 July 2025. During this debate, parties on the right called for swift action to support the chemical industry, a stronger focus on jobs and less bureaucracy. Other parties criticised the potential price increases for consumers, as well as the reduction in public health and environmental protection levels. The focus on innovation was appreciated. The Commission noted that the announced ban on PFAS in consumer products must be implemented swiftly, but also explained that similar bans for defence applications, clean technology and the medical sector are more complicated. It did emphasise the importance of paying more attention to the risks posed by PFAS to humans and the environment.

REACH revision

The primary focus of the European Commission's revision is on improving the competitiveness of the chemical industry and simplifying the regulations. In official consultations with experts from the member states, the Commission shared more details on its plans for REACH.¹

The proposal for the REACH revision is likely to consist of a section to be discussed in the Council of Ministers and the European Parliament, and a more detailed section to be discussed in official committees. The latter section will include amendments to the annexes to REACH. While these annexes are mainly technical in nature, they could have equally substantial consequences. For this reason, it is also important to ask the Dutch government for insight into this process.

2.2 Objectives from the Chemicals Strategy for Sustainability (2020)

The previous European Commission had already announced a revision of REACH in its [Chemicals Strategy for Sustainability](#), published on 14 October 2020. This revision was later postponed. The previous Commission's strategy placed great emphasis on increasing the level of protection for humans and the environment as a goal of the REACH revision. In addition, the Commission wanted to streamline certain aspects of all chemicals legislation, including REACH. The 2020 strategy included many concrete objectives, partly based on the 2018 REACH review. In light of the current Commission's stronger focus on simplification and strengthening competitiveness, the role of certain elements of the strategy in the upcoming revision has become uncertain.

Overview of key policy documents

[Annex 3](#) provides a timeline for the main policy documents (and other relevant documents) mentioned above.

3. Basic information on REACH

What is REACH?

REACH is a European regulation governing the production, trade and use of chemicals. REACH stands for 'Registration, Evaluation, Authorisation and Restriction of Chemicals'. The [regulation](#) came into force in 2007, replacing 60 previous directives and regulations. The aims of REACH are:

- to achieve a high level of protection of human health and the environment;
- to promote alternative methods of assessing the hazards posed by substances (this objective has resulted in the principle of 'animal testing as a last resort');
- to ensure the free movement of substances within the internal market;
- to strengthen competitiveness and innovation.

Elements of REACH: registration, communication and restrictions

When REACH was introduced in 2007, the burden of proof for demonstrating the safety of chemicals shifted from the government to industry. This was achieved through the implementation of a [registration requirement](#), which meant that manufacturers and importers had to register substances before placing them on the market. In doing so,

¹ The Commission's presentations on [registration](#), [authorisation](#), [enforcement](#), [evaluation](#) and [restriction](#) can be found on Politico's website.

they must provide information on the hazardous properties of substances, in accordance with the 'no data, no market' principle. The amount of information required increases in proportion to the quantity of the substance placed on the market. The European Chemicals Agency (ECHA) only accepts complete registrations and conducts random spot checks to assess their accuracy (evaluation).

Based in part on the information in the registration files, authorities can take regulatory measures with regard to the production, placing on the market and use of substances.

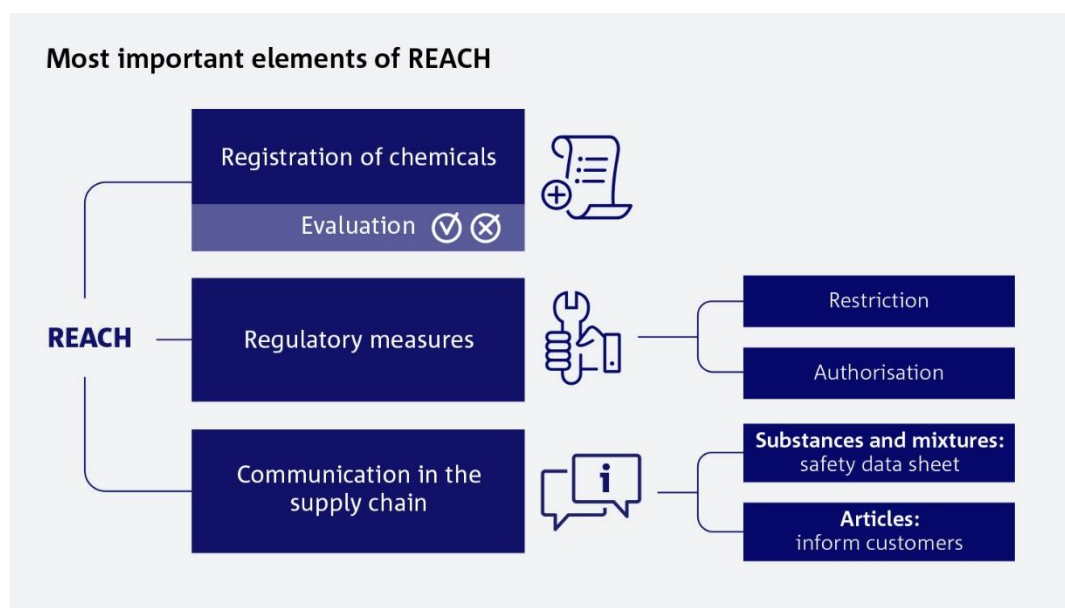
The primary regulatory instruments are:

- authorisation: a ban on the unauthorised use of a substance within the EU;
- restriction: restrictions on the production, import, marketing and/or use of substances.

Authorisation only applies to the use of substances within the EU, while restrictions can also apply to imported substances and to the use of substances in specific articles (e.g. lead in jewellery). Another difference is that with authorisation, the burden of proof for safe application lies with the company applying for the authorisation, whereas a restriction is only adopted once a government has demonstrated that this is necessary. This government can be the national government of an EU member state or the European Commission.

Substance information should also be communicated to companies that purchase chemicals (and mixtures of chemicals) to ensure safe handling. This is done through safety data sheets. There are also rules for substances in articles. When so-called substances of very high concern (SVHCs) are present in articles, suppliers of these articles must communicate this to their customers, or to consumers upon request.

The figure below provides an overview of the main elements of REACH.



Annex 1 – Outcomes of the discussions

1 Introduction

This annex provides more details on the outcomes of our discussions in the Netherlands and Brussels, which covered the following topics:

- guiding principles for the REACH revision (Section 2);
- regulatory measures in REACH (Section 3);
- registration of substances (Section 4);
- alternatives to animal testing and strategy for test methods (Section 5);
- communication within the supply chain (Section 6).

2. Guiding principles for the REACH revision

The first topic of discussion in our interviews was the set of guiding principles used for the REACH revision. These include the objectives of the revision and two broader topics: safety and sustainability by design, and the areas of overlap between REACH and other legislation.

2.1 Objectives of the revision according to the discussion partners

Our conversations revealed that our discussion partners had different objectives for the revision. VNCI (*Royal association of the Dutch chemical industry*) supported the focus on simplification and strengthening competitiveness, but also highlighted the objective of protecting people and the environment. The organisation noted that many chemical companies are facing difficulties and highlighted the significant challenges related to climate and the circular economy. It also argued that chemicals legislation in general has become exceedingly complicated, and called for greater predictability in decision-making on specific substances. Moreover, VNCI pointed out that significant progress has already been made through data collection under REACH.² Meanwhile, FME (*Federation for metal and technological industry*) found REACH's communication requirements for substances in articles too complex and impractical. The organisation called for simplification, especially for SMEs (see Section 6). Mengend Nederland (*Cooperation of trade associations for detergents, cleaning agents, maintenance products and disinfectants*) stressed the importance of proper impact assessments for all proposals.

WECF (*NGO Women Engage For a Common Future*) advocated simplifying REACH to make it easier for governments to regulate substances of concern, and offered suggestions for doing so (see Section 3). It did stress, however, that the level of ambition of the previous EU strategy on sustainable chemicals should not be compromised for the sake of simplification. This is consistent with the joint input from NGOs working in the areas of environmental protection and health.³ Gezondheid op 1 (Health at nr. 1) and other NGOs believe that the precautionary principle is insufficiently represented in REACH.

² See also [VNCI \(2022\), VNCI's response to the public consultation on the REACH revision](#).

³ See also European Environmental Bureau et al. (2022), Delivering a toxic-free environment under REACH: Eight key NGO demands to improve the REACH regulation.

2.2 Changing dynamics

Our discussion partners in Brussels, such as the European Environmental Bureau (EEB) and Cefic (the trade association for the European chemical industry), also had varying objectives. The EEB sees sustainability (including the 'detoxification' of the chemical industry) as a prerequisite for long-term competitiveness,⁴ and whereas Cefic was still willing to make concessions – on polymer registration, low tonnages and combination effects – just a few years ago, this is much less the case now.

As a result of geopolitical developments and the recent reports on strengthening the European single market and enhancing European competitiveness by Enrico Letta ('[Much more than a market](#)') and Mario Draghi ('[A competitiveness strategy for Europe](#)'), the dynamics in the Commission, the Council and the European Parliament have shifted towards a greater emphasis on competitiveness and simplifying regulations. Members of the European Parliament (MEPs) therefore stressed the importance of properly identifying how improvement proposals contribute to achieving these objectives. They also noted that health impacts (e.g. on fertility) should be clearly stated and taken into account.

In its current form, navigating the European Parliament is a constant balancing act, as there are multiple possible coalitions. In addition to the traditional centre coalition (S&D, Greens, Renew and EPP), the EPP can now also work with far-right parties, and regularly does so. This often leads to lower levels of protection and greater deregulation.

While it remains to be seen how the recent change in dynamics will affect the European Commission, it is notable that the Commission has lately been very attentive to the industry's concerns, and that it has been more willing to make concessions regarding protection levels.

Looking at the member states, Germany and France have adopted more moderate positions on REACH. France is also firmly committed to strengthening Europe's chemical industry. As before, Sweden has shown the greatest willingness to increase protection levels.

2.3 Looking beyond REACH: 'safe and sustainable by design'

In recent years, there has been a strong focus on designing substances and products that are inherently safe and sustainable, a concept known as 'safe and sustainable by design'. This was also a prominent topic in the European Chemicals Strategy for Sustainability (2020). In 2022, the Joint Research Centre (JRC), the scientific service of the European Commission, released a [framework](#) for safe and sustainable design. In July 2024, this was followed by a [manual](#) to help companies apply this concept in their research and development activities. The Netherlands is actively promoting safe and sustainable design.⁵ The European Commission is currently developing a plan to establish EU knowledge centres to promote substitution (i.e. the replacement of harmful substances). The ministry for Infrastructure and Water Management (the ministry of I&W) believes this provides opportunities to also promote safety and sustainability by design.

⁴ EEB (2025), [Chemicals industry action plan – EEB's 10 Key messages and demands](#).

⁵ See the collection of essays [Redesigning Chemical Innovation: Essays on Safe and Sustainable by Design](#), initiated by the Ministry of I&W in 2024.

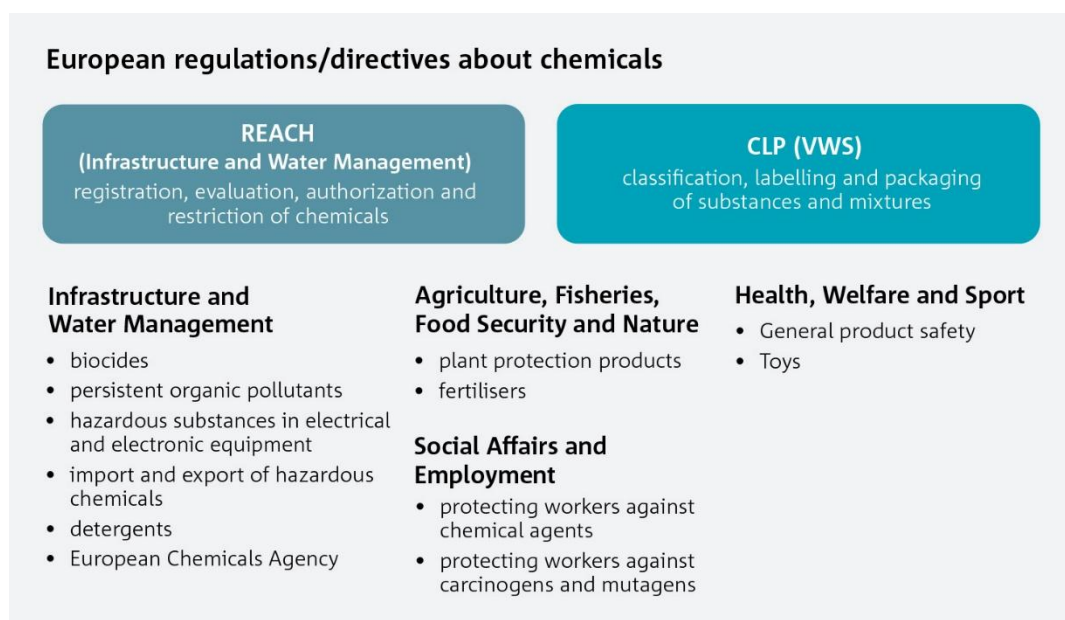
During our discussions in the Netherlands, other parties also appeared enthusiastic about this concept. However, they did not see the REACH revision as an appropriate vehicle for this. TNO, for instance, pointed out that REACH cannot keep up with the rate at which new chemicals are being developed. It further noted that voluntary instruments are needed, such as long-term collaborative research and development projects, preferably at EU level. Such projects – which TNO is involved in itself – could centre around semiconductors, medical applications, hydrogen production or specific types of fire-fighting foam. All of these involve the use of PFAS, and alternatives are difficult to find. In this context, WECF is calling for a European fund for substitution and green innovation. Meanwhile, VNCI would like to see practical guidance on safety and sustainability by design. It noted that the JRC manual mentioned above cannot be applied in practice yet, as it assumes an extensive and costly data collection process. FME believes that the circular transition will present opportunities for giving manufacturers more responsibility, and expects this to have an impact on the entire lifecycle, leading to improvements in safety. Safety and sustainability by design should also play an important role here, according to FME. Mengend Nederland emphasised the need for more advance information on alternatives for substances that will be banned or restricted. This could be provided by the proposed substitution knowledge centres in order to reduce the burden of the chemistry package.

This issue was briefly raised with MEPs, who appeared interested in the approach set out above.

2.4 Looking beyond REACH: better alignment with other regulations

Besides REACH, chemicals are also governed by various other EU laws, such as regulations and directives relating to biocides, plant protection products, toys, food contact materials and cosmetics. Waste legislation plays an important role as well, as does the [CLP Regulation](#), which governs the classification, labelling and packaging of substances and mixtures.

The figure below provides an overview of European legislation on chemical substances and the responsible House committees. REACH and the CLP Regulation feature



prominently, as they cover a large proportion of substances on the market and impact many other laws and regulations. The latter is particularly true of the CLP Regulation. There is a clear need for better alignment with other regulations with regard to:

- the concretisation of the 'one substance, one assessment' principle (Section 3.6);
- alternatives to animal testing and the development of test methods (Section 5);
- communication within the chain (Section 6).

FME believes that REACH regulates too many issues that should be governed by occupational health and safety or product regulations, such as the authorisation regime for chromium(VI) (occupational health and safety regulations) and communication obligations for substances in articles (product regulations). Some parties (Cefic, PETA, Eurogroup for Animals) stressed that ECHA should receive more funding to fulfil its obligations under REACH and other legislation.

3. Regulatory measures

The second topic we discussed were the regulatory measures within REACH. REACH can be used to impose restrictions on the production, placing on the market and use of substances, through the aforementioned authorisations and restrictions. Regarding the procedures for these regulatory measures, we discussed:

- the possibility of reducing lead times and, in conjunction with this:
- shifting from authorisation to restriction;
- a generic approach to risk management;
- the desirability of formal frameworks for initiating regulation;
- the concept of 'essential use';
- the application of the 'one substance, one assessment' principle;
- enforcement deficiencies.

These points are addressed below.

3.1 Bottlenecks: long lead times and onerous procedures

Experience shows that decision-making often takes years. It is not unusual for a period of ten years to elapse between the initial analysis and the implementation of a restriction or authorisation.⁶ In fact, the EEB has concluded (based on an analysis of data from ECHA) that, on average, the process of setting a restriction (including prior risk assessments) takes over 19 years, while the process of implementing an authorisation regime for a substance takes almost 23 years.⁷ In its 2018 review of REACH, the European Commission also insisted that 'restriction and authorisation procedures need to be implemented more efficiently, and decisions must be made more quickly'.⁸ Moreover, processing authorisation applications from companies places a significant burden on the Commission, ECHA's advisory committees and member states. Consequently, companies have to wait a long time to find out whether their application has been approved.

During our discussions in Brussels, the European Commission acknowledged that a significant amount of time could be saved by streamlining its own decision-making. Under Article 73 of REACH, the Commission must propose a restriction within three months of receiving an opinion from SEAC (the Committee for Socio-Economic

⁶ Analysis and Research Department (2020), [Regulating chemical substances: strengths and weaknesses in Dutch and European policy](#), p. 30.

⁷ EEB (2022), [The Need For Speed – Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections](#).

⁸ European Commission (2018), [Commission General Report on the operation of REACH and review of certain elements](#). COM (2018) 116 final, p. 7.

Analysis), but this deadline is never met. As this issue falls within the remit of both DG ENV and DG GROW,⁹ considerable coordination is required.

An official presentation also mentioned the possibility of shortening the statutory deadlines for RAC¹⁰ and SEAC. ECHA has reservations about this, as the issues these advisory committees are concerned with, have become more complex, partly due to the fact that they often involve multiple substances and applications. According to ECHA, ensuring an adequate level of protection (which is REACH's objective) requires robust advice from the committees. Some time could be gained by streamlining the consultation period, but this would only be a few months. ECHA believes that lowering the requirements for substantiating restriction proposals would mainly be a political choice. Moreover, this would be difficult to implement in practice, given that the European Commission asks additional questions as part of its decision-making process.

3.2 Shifting from authorisation to restriction

Different procedures apply to adding substances to either the authorisation list (REACH Annex 14) or the restriction list (REACH Annex 17).

Authorisations are established on the basis of the hazardous properties of substances, which must meet the 'substance of very high concern' (SVHC) criteria. The list of SVHCs is called the *candidate list*, because the substances on it are 'candidates' for the authorisation regime. At the time of writing (July 2025), it includes 250 (groups of) substances. Once a candidate substance is added to Annex 14, companies can apply for authorisation (permission) for an application. To be granted authorisation, companies must demonstrate that they use the substance safely or – in the case of substances with no toxicological threshold – that the socioeconomic benefits of authorisation outweigh the risks.

When setting a restriction, the relevant government must demonstrate both the hazardous properties of the substance and the risks involved in its practical application. This government can either be an EU member state or the European Commission. The Commission is considering improving consistency between the procedures for authorisation and restriction by:

- ensuring that all options are considered during the preparation phase, and that information on applications and risks is already available at this stage;
- making the candidate list for SVHCs a precursor not only to authorisation, but to regulation more broadly;
- introducing the possibility of excluding certain essential applications (for which insufficient alternatives are available) from the scope of authorisation. Currently, all uses of a substance fall under the authorisation regime by definition.¹¹

Our conversation with DG GROW made it clear that the Commission is mainly considering a shift from authorisations to restrictions. This would reduce workloads for companies, the European Commission and member states, since fewer authorisation applications would need to be processed. VNCI and FME are also in favour of regulating most substances through restrictions, as this would address imports to the EU as well. Moreover, these organisations would like restrictions and authorisations to be applied more selectively, targeted at specific applications and/or substances that pose actual risks. According to VNCI and Mengend Nederland, information from future product passports could potentially be used for this purpose.

⁹ The directorate-general for the internal market, industry, entrepreneurship and SMEs.

¹⁰ RAC is the Committee for Risk Assessment. RAC and SEAC are scientific committees that advise on the preparation of REACH restrictions, and on authorisation applications submitted by companies.

¹¹ [Official presentation](#) by the European Commission.

The EEB, on the other hand, is critical of the shift towards restrictions. It believes that the large number of authorisation applications is the result of an overly flexible interpretation of the instrument, which is inconsistent with its original intention. According to the EEB, authorisations should be refused more often (this does not happen in practice), and there should be less emphasis on helping companies navigate the authorisation process. It further asserted that a regulatory framework was already devised at the time of the Chemicals Strategy for Sustainability, and claimed that this has been set aside without substantiation.¹²

For restrictions, the so-called *group approach* is used more frequently than in the past.¹³ This involves the regulation of a group of similar substances (e.g. PFAS) rather than individual substances. The group approach prevents the introduction of new harmful substances (regrettable substitution), which, according to WECF and Gezondheid op 1, still occurs too often. These organisations therefore advocate using the group approach more frequently. The industry, on the other hand, has often argued against overly broad group definitions.

3.3 Generic risk management approach: discussion on scope

Many parties see the generic risk management approach (GRA) as an opportunity to expedite decision-making on restrictions for SVHCs in consumer products. In the Chemicals Strategy for Sustainability, the previous European Commission also expressed a desire to streamline this process. The intention was to start with carcinogenic, mutagenic, reprotoxic, endocrine-disrupting, and persistent and bioaccumulative substances, making it possible to ban substances more quickly if they were found to possess one of these hazardous properties. It would no longer be necessary to go through an extensive assessment and decision-making process for each individual substance and application. This approach would be applied not only to REACH, but also to product- and sector-specific legislation, such as regulations on toys, food contact materials and cosmetics.¹⁴ According to a [presentation](#), the current Commission intends to continue with this approach.

With regard to the GRA, our discussion partners in Brussels were primarily focused on the procedure set out in Article 68(2). While many parties view this as a good option, there is no consensus on what its scope should be. This procedure for restrictions on CMR substances¹⁵ (categories 1A and 1B) in products that can be used by consumers, has been shortened. No advice from RAC or SEAC is sought for these substances, since the presence of a risk can be assumed and does not need to be substantiated. So far, this route has mainly been used for mixtures, and only in two cases for articles (CMR substances in textiles and PAHs¹⁶ in rubber and plastics). In practice, this shortened procedure only led to time savings in the case of mixtures; for articles, the Commission still required scientific substantiation.

The Commission now seems to want to extend Article 68(2) to include endocrine-disrupting substances in consumer products. The EEB believes that other substances – such as persistent substances and those that disrupt the endocrine systems of animals

¹² See also [Chemicals industry action plan – EEB's 10 Key messages and demands](#), [Simplifying REACH for industry and authorities](#) and [Future-Proof EU Chemicals Policy](#).

¹³ ECHA (2021), [Report on the operation of REACH and CLP 2021](#).

¹⁴ See also European Commission (2022), [Workshop on the extended generic risk management approach under REACH](#).
¹⁵ Carcinogenic, mutagenic and reprotoxic substances. Categories 1A and 1B are the most harmful categories; 1A is based on evidence from human studies, 1B on evidence from animal studies.

¹⁶ PAHs are polycyclic aromatic hydrocarbons.

– should be included as well. It further believes that this procedure should also be available to member states, rather than just the European Commission. WECF, like other NGOs, favours a broad interpretation of the GRA.

Meanwhile, many industry stakeholders are cautious about the GRA, advocating a focus on the highest-risk applications instead. The industry fears that safe products will inadvertently disappear from the market.¹⁷

Cefic supports the shortened procedure for endocrine disruptors, provided that it is limited to consumer products; its scope should not be extended to professional and industrial applications. NGOs, on the other hand, are in favour of at least including professional applications used by workers with a similar level of exposure to consumers (e.g. painters).

Mengend Nederland has concerns about potential expansions if there is insufficient understanding of how these would affect businesses. Above all, companies want to have information about good alternatives, but this is difficult to find. One suggestion would be to already request this information during the public consultation on nominating a substance as an SVHC.

DG GROW pointed out that another overarching regulation, the General Product Regulation, already includes a procedure for rapid intervention in the event of acute risk. In the past, this has been used for harmful phthalates in plastic scoubidou threads.

3.4 Formal frameworks for preparing regulation?

Member states can propose the regulation of substances through a variety of legal frameworks, including REACH. Information on proposed regulations can be found on the ECHA website. According to ECHA, this has increased predictability for companies.¹⁸ However, Cefic stressed that companies still face substantial uncertainty, as member states may propose ‘poorly thought-through’ regulatory measures. A company’s reputation can be significantly damaged by the mere inclusion of a substance in one of the registries of intentions, which record intentions to file for SVHC status, restriction or harmonised classification. According to Cefic, the appropriate regulation of a substance should be given more careful consideration beforehand, and the preparatory phase should be more formal, allowing for industry input. The EEB, on the other hand, is wary of such formalisation, as this could further delay the preparation process and increase industry influence.

3.5 Formulating ‘essential use’ criteria remains challenging

In its Chemicals Strategy for Sustainability, the European Commission announced that it would set criteria for essential use: “the most harmful chemicals are only allowed if their use is necessary for health or 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”. The REACH revision may address these essential use criteria, which the Commission views as an opportunity to simplify procedures.¹⁹

Our discussion partners offered a variety of different perspectives on this issue. TNO highlighted the difficulty of identifying essential applications, pointing out that there is

¹⁷ Antea Group (2023), [Views on the REACH revision](#). Working document setting out the considerations, arguments and views of various Dutch parties, p. 22.

¹⁸ ECHA (2021), [Report on the operation of REACH and CLP 2021](#).

¹⁹ [Official presentation](#) by the European Commission.

a grey area. Moreover, the registration dossiers do not provide sufficient information on this. For some applications, such as pans and rain gear, there are good alternatives to PFAS. These are not as readily available for medical applications and semiconductors, as these products are not allowed to fail, which means that it takes much longer to find equally high-quality substitutes. TNO suggested that the government could work with the healthcare sector and the semiconductor industry, among others, to ensure safety and sustainability by design. The PFAS restriction proposal provides for a 13.5-year grace period for applications where PFAS are difficult to replace.

WECF warned that 'essential use' should not be an excuse for not addressing substitution. During our discussion, the organisation indicated that alternatives for substances such as PFAS are also available for medical applications. Meanwhile, VNCI expressed concerns about labelling entire applications or sectors as non-essential. It does, however, believe that the concept of essential use can play a role in decision-making on regulation. If certain applications of substances are 'safe' – and provided they are applied correctly – there is no need to discuss essential use.²⁰ This issue did not come up during our discussions in Brussels.

3.6 'One substance, one assessment' requires further concretisation

The Chemicals Strategy for Sustainability embraced the 'one substance, one assessment' principle. This is an alternative to the standard approach of evaluating the same substance under various EU regulations, which may result in undesirable discrepancies and inconsistencies.

In this context, the European Commission presented [three legislative proposals](#) in late 2023.^{21 22} Two of these proposals aim to redistribute scientific and technical tasks between the European chemical agencies (ECHA, EFSA, EEA and EMA), and to improve their cooperation.²³ They also aim to improve the efficiency, consistency, robustness and transparency of the delivery of chemical safety assessments between different legal frameworks. Ultimately, they should lead to a more harmonised approach to the assessment of chemicals across the EU and contribute to the principle of 'one substance, one assessment'. The third [proposal](#) is an amendment to the founding regulation for ECHA, as its tasks are currently set out in different [regulations](#). One of the guiding principles of this package was that ECHA should have the power to gather its own information.

After trilogues, the Council and European Parliament reached an [agreement](#) on the three proposals on 12 June 2025, and a plenary vote is scheduled for October 2025. The results are fairly consistent with the Dutch objectives set out in the BNC assessments.²⁴

VNCI pointed out that the 'one substance, one assessment' principle has not yet been widely adopted in practice. This may be due to the fact that the legislative alignment has only just been finalised, as described above. The [EEB](#) welcomes the 'one substance, one assessment' principle and its aim of reducing inefficiencies, streamlining procedures, and improving risk assessment and information provision. According to the ministry for Infrastructure and Water Management (the ministry of I&W), ECHA is to manage a database that will provide insight into the various pathways for (and

²⁰ [VNCI \(2022\), VNCI's response to the public consultation on the REACH revision.](#)

²¹ BNC assessments: Parliamentary papers 22 112, no. 3880 and 22 112, no. 3881.

²² [EP think tank analysis](#) 'at a glance'.

²³ The European Chemicals Agency, the European Food Safety Authority, the European Environment Agency and the European Medicines Agency.

²⁴ See footnote 21.

assessments of) specific substances. This is a step towards better alignment. The ministry also argues that the principle will be easier to implement if there is a strategy for the validation of test methods (see Section 5).

3.7 Enforcement deficiencies widely seen as bottleneck

In its review of REACH, the European Commission pointed out shortcomings in enforcement by member states. Many parties in the Netherlands and Brussels also view this as a bottleneck with regard to ensuring product safety and a level playing field in the EU and the global market. The main deficiencies identified relate to the regulation of products imported from outside the EU, including products purchased online. In the Netherlands, parties have called for increased funding and capacity for enforcement agencies.²⁵ An official presentation shows that the Commission is considering a package of enforcement measures:

- A European Audit Capacity. This instrument would make it possible to assess enforcement agencies through audits.
- Improved enforcement by customs authorities. This would include a requirement for importers to provide a safety data sheet to customs in certain situations, as well as mutual data exchanges between electronic customs systems, including for the enforcement of restrictions.
- Enhanced powers for the European Anti-Fraud Office (OLAF²⁶) to investigate serious infringements.
- A requirement that products can only be imported into the EU by a clear legal entity (economic operator) that can be held accountable for REACH obligations.
- Increased opportunities for natural and legal persons to raise substantiated concerns about non-compliance (including whistleblower protections).²⁷

4. Registration of substances within REACH

The third topic of discussion was the registration requirement in REACH. This included several related issues: supplementing information requirements, expanding the scope of registration obligations, compliance with registration obligations, and the combination effects of substances.

4.1 Supplementing information requirements for certain types of effects

The REACH annexes set out the health and ecosystem effects for which chemical companies must submit information during registration. For certain types of effects, these information requirements are not always sufficient to ensure the identification of harmful substances. This is especially true for:

- effects on the nervous and immune systems (neurotoxicity and immunotoxicity);
- carcinogenic substances;
- endocrine disruptors (for humans and animals).

The Netherlands has highlighted these shortcomings in recent years, and in 2022, in its input on the REACH revision, called for the information requirements for endocrine-disrupting substances to be updated as soon as possible. These should be made

²⁵ Antea Group (2023), [Views on the REACH revision](#). Working document setting out the considerations, arguments and views of various Dutch parties, pp. 24-26.

²⁶ This is an acronym of the agency's French name, Office Européen de la Lutte Antifraude.

²⁷ [Official presentation](#) by the European Commission.

consistent with the CLP Regulation, which now includes criteria for such substances.²⁸ For NGOs, addressing the above shortcomings is a key priority. The EEB noted that these deficiencies currently prevent the recent improvements to the CLP Regulation from being utilised. Although the recently revised CLP Regulation includes hazard classes for persistent and endocrine-disrupting substances, these are only useful if there is sufficient information to actually designate substances as such.

REACH allows for the identification of substances of very high concern (SVHC), independently of the information in the registration dossiers, based on records provided by member states (or ECHA). Often, this also requires information from companies, however. While it is possible to require companies to provide additional information as part of a so-called substance evaluation, ECHA has concluded that this is not an efficient process.²⁹ The Commission is considering adjustments to make it easier for ECHA to require companies to provide additional information.³⁰

In the Chemicals Strategy for Sustainability, the previous European Commission considered adding information requirements for the aforementioned effects. These were eventually implemented through two additional regulations, introduced in [2021](#) and [2022](#), which amended the REACH annexes.³¹ In the Netherlands' view, however, the concerns persist. The National Institute for Public Health and the Environment (RIVM), for example, emphasised that no methods have yet been added for detecting mechanisms leading to endocrine disruption, while there are several internationally aligned methods that can do so. According to the RIVM, effects on the nervous system and immunotoxicity are only indicated in certain cases, whereas a comprehensive approach is required. The regulatory changes also do not address the shortcomings identified for carcinogens.

Our discussions in Brussels revealed that the Commission is indeed considering clarifying information requirements, especially for endocrine disruptors. Given the current political dynamics, however, the outcome of this process is uncertain, as amending information requirements could be perceived as a (limited) burden increase.

4.2 Possible extension of the scope of registration obligations

The previous European Commission also considered some extensions to the scope of registration obligations. According to the ministry of I&W, there are signs that the current European Commission does not want to pursue this idea, or is less motivated to do so. The potential extensions are:

- An extension of the information requirements for substances placed on the market in relatively low tonnages (1-10 or 10-100 tonnes annually). The amount of information companies have to provide on these substances is currently relatively limited.
- A registration requirement for certain polymers (plastics) that have raised concerns. Polymers are exempt from the registration requirement under the current REACH regulation. In recent years, there have been discussions regarding a

²⁸ [Comments by the Netherlands on the European Commission's public consultation on the targeted revision of the REACH Regulation \(\(EC\) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals\)](#).

²⁹ ECHA (2021), [Report on the operation of REACH and CLP 2021](#).

³⁰ [Official presentation](#) by the European Commission.

³¹ Under Article 131 of REACH, the Commission has the power to independently amend the annexes. The procedure for this is set out in an [implementing decision](#).

potential registration requirement for substances with a low molecular weight that are placed on the market in large quantities.

- An extension of the current information requirements to include other aspects of the environmental footprint of chemicals, such as greenhouse gas emissions.

In our discussions, NGOs (such as WECF and Gezondheid op 1) proved to be in favour of the above clarifications and extensions, which would allow the 'no data, no market' principle and the precautionary principle to be implemented more effectively.³² VNCI pointed out that a proper assessment of proportionality and regulatory burdens should be carried out for low tonnages. It further noted that a problem analysis required to regulate polymers under REACH is lacking, and highlighted numerous potential issues regarding the demarcation of 'polymers of concern', alignment with other legislation and test methods. According to VNCI, environmental footprint aspects other than chemical safety should be covered by other legislation. Mengend Nederland asserted that the introduction of a registration requirement for polymers will mean that some of the companies in the formulating industry will also have to start registering substances. The organisation does not believe that this will lead to environmental improvements, since the more hazardous monomers (the building blocks of polymers) have already been registered. Professor Hartung³³ stressed that thoughtless expansion of the registration requirements for low tonnages and polymers could result in a sharp increase in animal testing (see Section 5).

The above lack of consensus was also evident in Brussels. Although Cefic opposes the registration of polymers due to the substantial additional administrative burden involved, it does support a light notification requirement. The EEB emphasised the need for a better understanding of the risks posed by polymers, such as harmful substances leaching into the environment during the degradation process. Chemical companies are already familiar with registration requirements for polymers in countries such as the US, Canada, Japan and South Korea. The EEB notes that a notification requirement could be a first step towards a registration requirement.

4.3 Compliance with registration obligations and updating of dossiers

The 2018 review of REACH found registrants' compliance with information requirements to be inadequate. Two main reasons were cited: (1) legal requirements to avoid animal testing may lead registrants to use alternative methods, even if this produces insufficient information and there is no justification for doing so; and (2) registrants and authorities' different perspectives on assessing hazards. According to ECHA's report, the quality of dossiers requires significant improvement.³⁴

Stakeholders in the Netherlands believe that malicious non-compliance should be dealt with more firmly. NGOs have suggested suspending or revoking registrations, and disclosing the substances, dossiers and companies involved in instances of non-compliance as possible measures. Manufacturers believe that malicious non-compliance is less common than suggested; they also noted that there are no easy solutions.³⁵ It

³² See also European Environmental Bureau et al. (2022), Delivering a toxic-free environment under REACH: Eight key NGO demands to improve the REACH regulation.

³³ Researcher affiliated with the Johns Hopkins Bloomberg School of Public Health in the US, and director of the Center for Alternatives to Animal Testing (CAAT).

³⁴ ECHA (2021), [Report on the operation of REACH and CLP 2021](#).

³⁵ Antea Group (2023), [Views on the REACH revision](#). Working document setting out the considerations, arguments and views of various Dutch parties, pp. 24-26.

appears that the Commission's proposal will include measures to make it easier for ECHA to revoke registrations.³⁶

The registration obligations stipulate that registration dossiers must be kept up to date. In practice, this almost never happens. According to the ministry of I&W, this could be remedied by requiring an update within one or two years.

Gezondheid op 1 offered the following suggestions for enforcement:

- risks across the lifecycle should be recorded in the dossiers. These include risks during the waste phase and effects on drinking water abstraction in the case of persistent substances;³⁷
- companies' sales should not exceed the registered tonnage bandwidth if the additional requirements for the higher tonnage bandwidth are not met.

Thus far, ECHA has reviewed 23% of all registration dossiers. For substances registered above 100 tonnes, ECHA has reviewed 34% of all registration dossiers (3,200 unique substances). A more general review, to check for completeness, has been conducted for all dossiers.³⁸ The EEB recommended combining this initial completeness check by ECHA with the subsequent compliance check. According to the EEB, the current process was appropriate for processing large volumes of registrations, but this is no longer necessary. Combining the two checks would prevent substances from entering the market without substantive assessment. ECHA, however, believes that the two checks cannot be merged, as they are fundamentally different. Moreover, ECHA does not see the use of further increasing the number of compliance checks. It noted that these checks are resource-intensive, and that building a new dossier takes a long time (two to five years). Furthermore, non-compliant companies face no consequences, even if their substances are found to be hazardous to humans or the environment. According to ECHA, a different approach could be developed to enforce compliance more effectively (it did not specify what this approach should be).

4.4 Combination effects of substances

The combination effects of chemicals have been a topic of discussion for some time, and will also be taken into account in the REACH revision. In chemicals legislation, risks are typically assessed for individual substances, even though people and ecosystems are exposed to multiple substances simultaneously and through different pathways. As early as 2012, the European Commission concluded that assessing individual substances and applications provided insufficient protection.³⁹

A pragmatic solution to this problem would be to use a Mixture Assessment Factor (MAF). This additional factor can be used to determine safe concentrations of substances in water or air when preparing registration dossiers. The introduction of a MAF could mean that companies would need to implement stricter measures to ensure that certain substances are handled safely. The Netherlands, which is in favour of introducing a MAF, has put the issue on the agenda in Europe through technical and policy discussions. An exploration of the feasibility of including a MAF in REACH was announced in the European Chemicals Strategy for Sustainability. Besides a generic factor for each substance, other variants are conceivable, such as a factor that focuses

³⁶ [Official presentation](#) by the European Commission. Currently, a registration can only be revoked if the company fails to pay the registration fee, or if it is not (or no longer) a legally registered entity.

³⁷ Information on the entire lifecycle should be part of the registration dossiers for substances placed on the market in quantities of 10 tonnes or more per year. See ECHA (2021), [Guidance on registration](#), p. 75.

³⁸ [ECHA news release, 26 February 2025](#).

³⁹ COM/2012/0252 final.

on the components of a mixture that contribute most to the risks. The latter does presuppose that this can be determined in advance, which is not always the case in practice.⁴⁰

Like Cefic, VNCI does not view REACH as a suitable vehicle for addressing combination effects. Instead, it believes that a site-specific approach that also focuses on the presence of plant protection products and medicine residues, would be more appropriate. According to VNCI, this should be implemented through other legislation, such as the Industrial Emissions Directive (IED), the Water Framework Directive (WFD) and occupational health and safety legislation. VNCI also believes that there is still insufficient scientific substantiation for establishing a MAF. A generic MAF would result in a substantial administrative burden, as all substances and mixtures would have to be recalculated. Moreover, the results of this assessment would need to be communicated to all stakeholders within the value chain. According to VNCI, the introduction of a generic safety margin could cause useful substances to disappear from the market unnecessarily.⁴¹ Mengend Nederland is also opposed to a generic MAF, although it has previously adopted more nuanced positions on MAFs for specific groups of substances, such as persistent substances.

Like other environmental and health NGOs, WECF and Gezondheid op 1 do support greater inclusion of combination effects through a generic MAF.⁴²

4.5 Disclosure of underlying studies

Gezondheid op 1 wants to increase the transparency of registration dossiers, for example by making the underlying studies publicly available. The organisation highlighted the risk that industry players may withhold studies with unfavourable outcomes.⁴³ In addition, Gezondheid op 1 believes that independent studies should carry at least as much weight as those conducted by the industry itself, even if they do not adhere to the Good Laboratory Practice (GLP) standards. Indeed, university studies often do not comply with these standards because doing so would be too costly. One possible solution could be to award peer-reviewed studies the same status as GLP studies.

5. Alternatives to animal testing and strategy for test methods

A significant majority of the House is in favour of phasing out animal testing, and this was a recurring topic of discussion throughout our conversations. In 2023, the House passed a [motion](#), submitted by Members De Groot and Wassenberg, which called on the government to advocate the use of New Approach Methodologies (NAMs) in the REACH revision. A previously adopted [motion](#), submitted by Members Beckerman and Wassenberg in 2022, requested (in more general terms) that the government create a timeline for ending the use of animal testing in safety tests, and that it submit this timeline to the House as soon as possible.⁴⁴

⁴⁰ [PARC explores the use of Mixture Assessment Factor \(MAF\) to enhance regulatory mixture risk assessment](#).

⁴¹ See also [VNCI \(2022\)](#), [VNCI's response to the public consultation on the REACH revision](#).

⁴² Antea Group (2023), [Views on the REACH revision](#). Working document setting out the considerations, arguments and views of various Dutch parties, pp. 13-14.

⁴³ ECHA [explains](#) that study results are, in principle, published on its website. However, registrants may request that ECHA keep certain data confidential. Such requests must be justified.

⁴⁴ See also other relevant motions, on [the Netherlands' status as a forerunner in the EU](#), [phasing out animal testing](#) and drawing up a [concrete timeline](#) for ending the use of animal testing in safety tests.

In addition to the issue of animal testing, the need for a broader strategy for test method development and validation was discussed as well. These two issues are being addressed through separate EU initiatives. It is important that the results of these initiatives are included in the annexes to REACH, as the Commission can only amend the annexes if there is a legal basis for doing so.

5.1 Animal testing regulations in REACH

Under REACH, animal testing may only be used as a last resort to test chemicals. Other ways of obtaining information about substances include using existing information, testing tissues, organs or cells (in vitro testing), using computer models to predict the properties of a substance, or deriving substance properties from the properties of similar substances (the read-across technique). These alternatives are sometimes referred to as New Approach Methods (NAMs). If animal testing is unavoidable, the least burdensome test must be performed. Under certain circumstances, animal testing requires prior approval from ECHA. The internationally accepted methods for animal testing are set out in REACH Annexes VII to X and the linked [regulation](#) on test methods. Most of these methods were developed by the Test Guidelines Programme of the Organisation for Economic Co-operation and Development (OECD). The OECD is considered the leading organisation when it comes to the alignment of test methods.

5.2 Discussion on the practical application of animal testing regulations

The discussion partners expressed differing views on whether ECHA applies the animal testing regulations correctly. According to Professor Hartung, ECHA's requirements for the use of the read-across technique and the EOGRT test for neurotoxicity and immunotoxicity are excessively strict.⁴⁵ Hartung believes that ECHA does not adequately consider the limitations and long lead times of animal testing. He also asserted that certain Artificial Intelligence tools are much more effective than animal testing.⁴⁶ According to the ministry of I&W and the RIVM, Hartung's claim about ECHA is not justified. In practice, it is often difficult to demonstrate the *absence* of harmful properties using in vitro tests, read-across and AI. I&W further noted that in vitro tests are only reliable under specific conditions. TNO also pointed out the limitations of in vitro tests, such as the fact that they focus on specific organs. The RIVM emphasised that it is impossible to make legally binding decisions based on AI tools whose information and training processes are not transparent. Furthermore, NAMs require separate methods to measure different effects, whereas animal tests allow several effects to be studied simultaneously. The RIVM also noted that NAMs are currently neither faster nor cheaper, since developing and validating individual methods is a costly and lengthy process.

VNCI agreed with Professor Hartung that NAMs should not be judged more strictly than animal tests, and believes that any decision to prohibit NAMs should be properly justified.

5.3 Launch of European roadmap for phasing out animal testing

⁴⁵ The OECD developed the EOGRT (Extended One-Generation Reproductive Toxicity) partly due to efforts by the Netherlands. The EOGRT is a set of guidelines for testing the effects of substances on human fertility and the development of unborn children. By following these guidelines, researchers can examine the effects on one generation of test animals more closely, eliminating the need to test a second generation. This reduces the use of laboratory animals by 40%. See also the [RIVM website](#). These guidelines are accepted within REACH.

⁴⁶ See also Hansell, L., J. Ritskes-Hoitinga, I.J. Visseren-Hamakers and T. Hartung (2024), Recommendations for the EU roadmap to accelerate the transition towards phasing out animal testing for chemical safety assessments. In: Frontiers (2024).

Ahead of the launch of its Roadmap towards Phasing out Animal Testing for Chemical Safety Assessments, the European Commission organised three conferences, in [December 2023](#), [October 2024](#) and [June 2025](#). This roadmap, scheduled for publication in early 2026, is partly a response to a 2023 [citizens' initiative](#) to end animal testing, which collected over 1.2 million signatures across the EU. Incidentally, the scope of the roadmap is much broader than REACH.

5.4 Strong support for phasing out animal testing, but the question is how

Many parties in Brussels, including the European Commission, the European Parliament, Cefic and various NGOs, want to reduce animal testing under REACH. The main issue is how this should be done. The Commission is open to the idea of including delegation provisions in REACH, as mentioned in the letter from the House, that would allow the outcomes of the above roadmap to be incorporated into REACH at a later date.

A revision of the Detergents Regulation, which included a ban on animal testing with strict exceptions, was recently adopted. Furthermore, on 2 July 2025 a life science strategy was published, which provides entry points for testing and validation in a broad sense. These will likely be useful for REACH as well ([COM \(2025\) 525](#)).

The animal protection NGOs PETA and Eurogroup for Animals raised several points:⁴⁷

- To ensure the effective implementation of the EU roadmap and align REACH with scientific insights, PETA advocates a framework based on clearly defined information objectives. This would replace the testing requirements set out in Annexes VII-X with broader information requirements, focusing on protection goals. Adopting such a framework would shift the focus to the type, scope and certainty of the required information, without compromising the level of protection, and ensure legal certainty by providing (non-binding) guidance on compliance. Certainty for companies should be safeguarded by clearly defining the information requirements and fleshing them out in ECHA guidance documents. This could be achieved by indicating which methods are accepted. According to PETA, these guidance documents should be updated regularly to reflect scientific advances. Eurogroup for Animals fears that the planned expansion of the information requirements in Annexes VII-X will lead to millions more animal tests. It believes that the promotion of alternatives should be a high priority in revising the annexes.
- To consistently enforce the principle of 'animal testing only as a last resort', both NGOs propose reforming the REACH test proposal system. Test proposals would be required for all in vivo studies and applied in all REACH processes. PETA also wants justifications for the use of animal testing to be structured and published in order to promote transparency. Moreover, the NGO believes that the deadlines for public consultations on test proposals should be extended. PETA argued that companies should be encouraged to engage in early dialogue with ECHA, and that ECHA and member states should be given the opportunity to propose evidence-based adjustments.
- Substances used in cosmetics are still tested on animals to assess risks to workers. According to the European Commission, the ban on animal testing for cosmetics does not cover risks to workers or the environment.⁴⁸ PETA feels that this

⁴⁷ PETA's views can also be found in this [memorandum](#) (the English version is available [here](#)).

⁴⁸ The European Commission confirmed this interpretation in its [response](#) to a 2023 citizens' initiative calling for the complete abolition of animal testing for cosmetics ingredients.

undermines the ban on animal testing. The organisation therefore suggested that data submitted for the Cosmetic Products Regulation should first be reviewed to assess any relevant health risks in relation to REACH. If additional information is required, it should be scientifically substantiated that there is a clear concern and that additional information will contribute to better risk management.

- According to PETA, an expert committee should be established to ensure the consistent and evidence-based implementation of 'animal testing as a last resort', and to accelerate regulatory approval of alternative methods. This could perhaps be achieved by making use of the existing working groups under the roadmap, or by setting up a committee focused on the overall strategy for test methods.
- Eurogroup for Animals does not want the introduction of a registration requirement for polymers to result in a large increase in animal testing. The organisation therefore supports the introduction of a notification requirement as a first step.

ECHA highlighted the need for more fundamental and conceptual thinking about the information required and the role of animal testing. The challenge here is that animal testing plays a major role in the global system of substance classification, which has developed over time. ECHA noted that this system has led to animal tests being unfairly designated⁴⁹ as the 'gold standard', despite the fact that the results of most animal tests do not directly apply to humans.

Nevertheless, there are currently insufficient alternatives for complex effects ('endpoints'), such as carcinogenicity, reproductive toxicity and effects on specific organs. If the sole purpose of testing is to demonstrate the presence of a mechanism (e.g. endocrine disruption), more options are available. It is therefore worth considering whether the effects can be described differently, and what the implications of this would be. In this context, it is important to ensure that ECHA decisions are legally tenable and enforceable for thousands of companies.

Besides this fundamental reorientation, ECHA noted that minor improvements are possible by amending a number of specific provisions in the regulation. It made the following recommendations:

- ECHA could be tasked with searching for possible alternatives when assessing test proposals for relatively simple effects. Allergic skin reactions, for instance, are relatively easy to model.
- ECHA could be mandated to determine when sufficient information is available to classify a substance and no further animal testing is necessary to reach a conclusion for that particular endpoint. This mandate should not cover substances that already have a harmonised classification.
- ECHA could be given more powers to act against under-dosing in animal testing, for example when assessing test proposals. While under-dosing can result in a lack of observable effects, in extreme cases studies may need to be repeated, including the required animal tests.

5.5 Developing a strategy for test methods

In addition to the above roadmap, the EU – at the initiative of the Netherlands – is preparing a strategy to accelerate the availability of accepted test methods. This strategy will focus on both the development of new methods and establishing the suitability of methods (validation). Acceleration is needed to reduce reliance on animal

⁴⁹ This is sometimes referred to as 'the animal methods bias', see also Proefdiervrij, [Een ingesloten voorkeur voor dierproeven remt proefdiervrije innovatie – óók in Nederland](#).

testing, but also to respond more effectively to the rapid development of new substances and materials. This desire to accelerate was also expressed in 2020, in the European Chemicals Strategy for Sustainability. The Netherlands has set out its position on this issue in a [discussion paper](#). In January 2025, it also organised an [international conference](#), which revealed strong support for developing an acceleration strategy. A taskforce may be established to examine the two main obstacles, namely the governance model and financing.

The governance model should lead to better coordination and cooperation between parties. According to the ministry of I&W, initiatives are currently not adequately aligned; for example, studies on test methods within the EU Horizon Europe programme often do not take into account regulatory requirements, rendering their results unusable. This is partly why there is insufficient validation of new and adapted test methods. Professor Hartung also mentioned the need for better coordination, and called for adequately funded, long-term cooperation between agencies such as ECHA, EFSA and EMA. This could be modelled after the long-standing cooperation between the three similar agencies in the US: the EPA, FDA and NIH.⁵⁰

The strategy will also have to include prioritisation in the development and validation of test methods. According to the ministry of I&W, gaps in knowledge about certain effects and new advanced materials could be a priority.

Professor Hartung believes that prioritisation is also needed with regard to the use of testing capacity. He feels that REACH places too much emphasis on extensive testing of substances that are placed on the market in high tonnages.

WECF called for a greater focus on the impact of substances on women, as the current focus is mainly on the effects on men.

VNCI suggested using more targeted data requirements to reduce the use of animal testing, and shifting the focus from the hazardous properties of substances to risks.

6. Streamlining communication within the supply chain

6.1 Current obligations under REACH and related waste legislation

The final topic we discussed regarding the REACH revision was communication within the supply chain. This issue came up across several of our conversations. In this context, a distinction can be made between substances and mixtures on the one hand, and articles on the other:

- Communication on substances and mixtures of substances takes place via safety data sheets (SDSs) and labels governed by the CLP Regulation. SDSs must be prepared for any substances or mixtures that are classified as hazardous. They are supplied to professional buyers of substances and mixtures (such as paints, detergents and lubricants) and contain information needed to comply with occupational health and safety and environmental regulations.
- For substances in articles, the obligations under Articles 33 and 7 of REACH are particularly relevant. Article 33(1) of REACH requires suppliers of articles containing an SVHC to provide buyers with information on the safe use of the articles, which must at least include the name of the substance. This obligation applies when the concentration of the substance in question exceeds 0.1% of the article's weight. Pursuant to Article 33(2), this information must also be provided free of charge and

⁵⁰ EPA: Environmental Protection Agency, FDA: Food and Drug Administration, NIH: National Institutes of Health.

within 45 days if requested by a consumer. In addition, manufacturers or importers of such articles must notify ECHA for quantities of more than 1 tonne per year (Article 7(2)).

Furthermore, companies supplying articles containing SVHCs (at concentrations of 0.1% or higher) must submit information to the SCIP database, which was introduced on 5 January 2021 under the Waste Framework Directive (and is thus not formally part of REACH).⁵¹ The aim of this database is to ensure that information on SVHCs remains available throughout the lifecycle of products and materials, including at the waste stage and during recycling and reuse.

6.2 Major burden reduction possible for safety data sheets

Research shows that preparing, distributing and applying SDSs results in the highest macro-level REACH-related costs for SMEs. This is due to the large number of SMEs that are required to use SDSs.⁵² Many parties agree that communication within the supply chain via SDSs is fraught with problems. A significant amount of information is lost, and the information in the SDSs does not align well with occupational health and safety regulations.⁵³ Moreover, formulators must manually extract information from substance SDSs in order to incorporate it into their own SDSs. As the SDSs are frequently updated, this is a labour-intensive process.⁵⁴

Many parties see opportunities to reduce the administrative burden imposed on companies by the SDS system through harmonised electronic data exchange (via XML). ECHA would have to take the lead in harmonising this information exchange.⁵⁵

Mengend Nederland also advocates a mandatory digital format, as this would greatly reduce the administrative burden. The organisation would prefer ECHA to use the open eSDScomXML standard, which was developed by the industry,⁵⁶ rather than the less user-friendly IUCLID.

The European paint and ink industry trade association CEPE lists the use of harmonised electronic data exchange as one of its 19 proposals for simplifying European rules. Other proposals include explicitly recognising QR codes on packaging as a means of disseminating the same information and, more generally, allowing SMEs to implement user-friendly digital tools.⁵⁷ It is worth noting here that a harmonised electronic format was frequently mentioned as a potential solution as early as 2015.⁵⁸ We discussed this issue with ECHA and were informed that it would be possible to use such a format. However, ECHA did note that this would require broad industry support. To demonstrate this support, the industry could consider submitting its own proposal for using a harmonised electronic format. ECHA could be tasked with making the data in registration dossiers available in this format, including for companies that need to prepare SDSs.

6.3 Communication on substances in articles

According to an official presentation, the European Commission is considering a greater role for digital product passports in the information exchange on substances in articles. Product passports are being phased in by product group under the European Ecodesign

⁵¹ SCIP stands for Substances of Concern In articles, as such or in complex objects (Products).

⁵² Ministry of Infrastructure and the Environment (2015), Final report on addressing REACH costs for SMEs.

⁵³ Antea Group (2023), [Views on the REACH revision](#). Working document setting out the considerations, arguments and views of various Dutch parties, pp. 15-17.

⁵⁴ [CEPE's proposals for simplification and digitalisation](#).

⁵⁵ Antea Group (2023), [Views on the REACH revision](#). Working document setting out the considerations, arguments and views of various Dutch parties, pp. 15-17.

⁵⁶ More information can be found on the [eSDScom website](#).

⁵⁷ [CEPE's proposals for simplification and digitalisation](#).

⁵⁸ Ministry of Infrastructure and the Environment (2015), Final report on addressing REACH costs for SMEs.

for Sustainable Products Regulation (ESPR). It is unclear whether the current REACH obligations would lapse as a result of this increased reliance on product passports. Companies and NGOs have different wishes when it comes to adjusting the rules that govern communication within the supply chain. According to FME, the current communication requirements for substances in articles are far too complex. It noted that compliance with these obligations is inadequate, partly because many companies are unable to ascertain from their suppliers (some of which are based outside the EU) whether their products contain SVHCs. Incidentally, this was confirmed by the REACH review.⁵⁹ FME does not believe that the communication obligation contributes to health and environmental protection, and argued that actual protection is achieved through authorisations and restrictions. Moreover, there are serious concerns among industry stakeholders and member states about the feasibility of the SCIP database given the granularity and volume of information. In accordance with a 2015 ruling by the CJEU, information must be provided separately for each component of an article; complex articles, such as cars and computers, can comprise thousands of components. As early as 2015, the then Ministry of Infrastructure and the Environment called on the EU to amend Article 33 in order to ensure a better balance between costs and benefits.⁶⁰ WECF stressed the need for more transparency about the presence of chemicals in products. It argued that people should have access to more understandable information to help them avoid hazardous substances. WECF also believes that harmful substances should be prevented from ending up in recycled materials.⁶¹

⁵⁹ European Commission (2018), [Commission General Report on the operation of REACH and review of certain elements](#). COM (2018) 116 final, p. 7.

⁶⁰ Ministry of Infrastructure and the Environment (2015), Final report on addressing REACH costs for SMEs.

⁶¹ See also European Environmental Bureau et al. (2022), Delivering a toxic-free environment under REACH: Eight key NGO demands to improve the REACH regulation.

Annex 2 – Discussion partners

Phase 1

During the first phase, interviews were conducted with:

- Ministry of I&W (REACH cluster coordinator);
- RIVM (head of REACH office);
- Royal Association of the Dutch Chemical Industry (VNCI);
- FME (trade association for the technology industry, which uses chemicals);
- Mengend Nederland (a partnership between the industry associations for disinfectants and cleaning agents (NVZ), cosmetics (NCV), aerosols (NAV), adhesives and sealants (VLK), and paints and printing ink (VVVF));
- Women Engage for a Common Future (WECF, an international NGO focused on women's health issues, such as exposure to endocrine disruptors);
- Gezondheid op 1 (an organisation representing people living near industrial plants);
- Netherlands Organisation for Applied Scientific Research (TNO);
- Professor Thomas Hartung, a researcher affiliated with the Johns Hopkins Bloomberg School of Public Health in the US, and director of the Center for Alternatives to Animal Testing (CAAT).

Phase 2

During the second phase, we conducted interviews with several key players in Brussels:

- representatives of the European Commission: DG GROW and the Cabinet of European Commissioner Jessika Roswall;
- MEPs Baljeu (VVD, Renew) and Van der Laak (CDA, EPP);
- representatives of the Permanent Representation of the Netherlands to the EU;
- the animal welfare organisations PETA (People for the Ethical Treatment of Animals) and Eurogroup for Animals;
- Cefic (trade association for the European chemical industry);
- European Environmental Bureau (EEB, a network of environmental organisations).
- In addition, online discussions were held with:
- European Chemicals Agency (ECHA).

Annex 3 – Timeline for the REACH revision and related dossiers

Date	Event
1 June 2007	REACH Regulation enters into force
2 July 2008	Letter on supporting businesses in preparing for REACH, launch of the European Chemicals Agency and the REACH Helpdesk annual report
20 January 2009	Classification, Labelling and Packaging Regulation enters into force
5 February 2013	First evaluation of the operation of REACH
19 January 2017	Letter regarding the Netherlands' contribution to the public consultation on the second REACH review
5 March 2018	Communication on the results of the second REACH review
14 May 2018	Letter setting out the Cabinet position on the REACH review
14 March 2019	Motion by Kröger and Laçin on an action plan for REACH dossiers
14 October 2020	European Chemicals Strategy for Sustainability
20 November 2020	BNC assessment Communication on the Chemicals Strategy for Sustainability
23 May 2022	Dutch response to the European Commission's consultation on amending REACH
16 May 2023	Motion by De Groot and Wassenberg on championing new techniques in the REACH revision
11 June 2025	Interim report by EU rapporteurs for the REACH revision
12 June 2025	Political agreement on revision of the CLP Regulation
18 June 2025	Letter from I&W committee to European Commissioners Roswall and Séjourné regarding the political dialogue on the REACH revision
30 June 2025	Request for government response to interim report by EU REACH rapporteurs
8 July 2025	Communication on chemical industry action plan
	Omnibus package for the chemical industry (simplification of CLP, cosmetics and fertiliser registration)
	Proposal to strengthen ECHA's governance and financial sustainability
20 August 2025	ECHA presents adapted proposal for PFAS restriction
Q4 2025	Expected proposal for REACH revision
Q1 2026	Roadmap towards Phasing out Animal Testing for Chemical Safety Assessments
Q4 2026	Proposal for PFAS restriction