EEB contribution to the Inception Impact Assessment on the revision of REACH Regulation to help achieve a toxic-free environment.

EEB proposals for objectives and policy options

Revision of the registration requirements

The EEB agrees with the Commission that there are still gaps in the knowledge of many substances and that a revision of the information requirements is needed. The revision of REACH should ensure that the registration dossiers include all information needed for the identification (and classification under CLP Regulation), hazard assessment and risk management of hazardous chemical substances. In addition to what is mentioned in the IIA, the revision of REACH needs to address the demands of the Chemicals Strategy for Sustainability (CSS), in particular information requirements for the identification of immuno- and neurotoxic chemicals, EDCs and information on carcinogenicity at all tonnage levels as well as clarification of the general rules to adaptation.

More specifically we propose to:

- Update the registration requirements that need to be considered for **crucial hazard endpoints**, including carcinogenicity, mutagenicity, reproductive toxicity, neurotoxicity, immunotoxicity and endocrine effects, as well as regarding the information needed for the PBT/vPvB and PMT/PM assessment. The general rules for adaptation, e.g. specific conditions for read-across should be clarified.
- Amend the REACH **information requirements to enable hazard identification**, in particular the identification of all carcinogens at all tonnage levels, in line with this priority action of the CSS.
- Require more precise information on use and exposure, especially on the description of actual uses, actual tonnages for each use, and better and transparent estimation of the exposure of consumers, workers and the environment. Further consideration should be given to existing monitoring data.
- **Oblige the registration of all polymers** with a stepwise process. Priority should be given to High Production Volume polymers and to those polymers to whom people and the environment are most exposed to due to their uses (plastics, paints, textiles, etc.) and/or their propensity to generate micro and nanoplastics. A notification process for all polymers to provide basic public information on identity, production volumes, uses and properties should be established in order to facilitate grouping and prioritize registration obligations [EEB&Chemsec, NGO position paper].
- **Require a chemical safety report for substances between 1 and 10 tpa**. Further analysis is needed of the information requirements for the chemical safety assessment of substances registered <10 tpa, despite it being an action of the CSS, it is not raised in the IIA.
- **Improve provisions for UVCBs**. The information provided in the registration dossiers of UVCBs does not allow a proper identification nor evaluation of the hazards and the implementation of regulatory measures by

authorities. The problem stems from poor identification and lack of justification of the groups identified by the registrants [BfR, page 7]. Different options to solve the issue, including introducing clarifications on the definition of UVCBs in the legal text should be considered.

- Consider a new REACH obligation for **downstream users to provide use information**.
- Create a process to **allow third party submission of hazard and exposure information** to registration dossiers that would support registrants in updating their dossiers and support authorities in evaluation.
- Require information to assess the sustainability of chemicals, to estimate their **environmental footprint**, including e.g. CO2 emissions.
- **Reject a quantitative risk assessment for non-threshold substances**. DMEL is not a legal concept under REACH. DMEL is not risk based, rather it expresses an acceptable damage based value. Non-threshold substances should be replaced by safer alternatives.

Introduction of a Mixtures Assessment Factor (MAF)

Combination effects are not taken into account in current chemical legislation and prevent adequate protection of people and the environment as recognised in the European Green Deal and the Chemicals Strategy for Sustainability. Chemical legislation typically tackles the risks of chemical exposure on the basis of single substance approaches. In real life, people and the environment are exposed to multiple substances at the same time and to different sources over time. The risks from such combined exposure are not adequately taken into account in the current REACH regulation and prevent adequate protection of human beings and the environment.

The EEB supports the **implementation of a generic Mixture Assessment Factor (MAF)** in every Chemical Safety Assessment of the registrant both for human health and for the environment to account for combination effects. The introduction of one generic MAF will reduce the total toxic pressure from chemicals on human health and the environment and is a practical and a feasible approach.

Simplifying communication in the supply chains

The EEB provides suggestions to **improve the duty to communicate information on substances in articles under REACH (Article 33). Making REACH work in the digital era** would require to:

- **Broaden the list of responsible actors in the supply chain**: To ensure a comprehensive application of the duty to communicate information, Article 33 of REACH should be revised and notably include online marketplaces and retailers. Consequently, related obligations, such as those determined under Article 9 of the Waste Framework Directive, should encompass retailers and be interpreted as having the intention to prove the broader range of information. To avoid losing information and be faithful to the spirit of Article 33 which includes all actors responsible.
- **Make the information readily available**. The 45 days deadline is not adapted for consumers and not suitable for an informed purchasing decision. Aligning Article 33.2 with Article 33.1 would oblige the supplier of the

article to provide the information to the recipient of the article, without request, regardless of its statute of consumer, downstream user, etc. Therefore, to avoid hampering the "right to know", the information should be readily available for consumers, before the purchase, notably thanks to labelling, and bar code systems. For instance, the SCIP database could be helpful to make information readily available.

- **Create an obligation to provide the information**: consumers submitting a request are currently facing uncertainties as to whether the information is simply absent; is there no SVHC present; or is the supplier unaware of its obligations? REACH should be revised to include an absolute obligation, that is to provide the information, and not to simply reply to the request, or avoid doing so. The information required under Article 33 should be expanded and encompass further information such as the concentration range and location of the SVHCs, the brand and model of the article containing the SVHC. This would be aligned with the spirit of REACH, placing the burden on the industry to prove that their chemicals can be safely used.
- **Consider whether SVHCs present below the 0,1% threshold should also be subject to the communication requirements**. The revision should be an opportunity to assess whether the 0.1% w/w threshold is sufficiently protective. A study could enquire whether that threshold should be lowered or removed.
- These modifications require parallel activities to **increase awareness** about these duties and obligations, including on their obligation to keep information according to Article 36.1.

Revision of the provisions for dossier and substance evaluation

Zero tolerance to non-compliance

The REACH regulation cannot comply with the EU Green Deal ambition "to protect citizens and the environment better against hazardous chemicals'' due to the consistently high levels of non-compliance with the legal safety information requirements. One of the objectives of the CSS is that ***"All chemicals, materials and products produced in the EU or placed on the European market must fully comply with EU information, safety and environmental requirements."*** In spite, only one third of registration dossiers under REACH are compliant with the legal information requirements. The 2nd REACH Review concluded that the non-compliance of registration dossiers was a key issue hampering progress under REACH. While the Commission expressed a strong ambition in the CSS on strengthening the "no data - no market" and the 'polluter - pays' principles under REACH, the proposals in the IIA are weak and will not sufficiently contribute to increasing compliance of registration dossiers.

A major cause for the slow implementation of REACH lies in the problems related to the adequacy and the quality of the data provided in the registration dossiers. The registration dossiers do not provide the data that authorities need for hazard assessment nor a clear substance identity, leading to evaluation procedures that delay the implementation of risk management measures by many years. Crucial information is missing in the registration dossiers as was already signalled in the 2nd REACH Review. The data are often not-up-to-date and the system lacks triggers for industry to update dossiers and improve the data quality. Instead, the system incentivises industry to wait for years before providing essential information, while problematic substances can remain on the market. The burden of proof did not shift to industry with the implementation of REACH.

The EEB agrees with the Commission that "The evaluation of registration dossiers and substances is too complex and insufficient" and supports the policy options proposed by the Commission in the Inception Impact Assessment, but considers that much more needs to be done to strengthen the 'no data - no market' principle, with the aim to speed-up the implementation of legislation and to improve protection of human health and the environment against hazardous substances. The EEB asks the Commission to consider the following proposals in the revision of REACH:

- **Revision of the provisions on the completeness check**. The revision of REACH should aim to strengthen the completeness check to adequately apply the 'no data - no market' principle. The completeness check should include as a minimum an assessment of the quality and adequacy of the information submitted on key hazard endpoints. This may also need to include a revision of the timelines currently stipulated for the completeness check. A registration number should not be granted in the first place if crucial hazard information is missing. Revision of the provisions of the completeness check is warranted now that all chemicals have been phased-in into REACH. The registration dossiers should include all information that is needed for hazard identification.
- **Revocation of registration numbers**. ECHA can grant registration numbers, but currently no mechanism exists to revoke registration numbers. With the revision of REACH, ECHA should be granted the possibility to revoke registration numbers. Effectiveness will be determined by the conditions, for instance by the granting of temporary registration numbers. On the contrary, the revocation of registration number only after follow-up evaluation of compliance check or even after failed enforcement action by a member state will not effectively speed-up regulatory control.
- **Introduce maximum validity of registration**. Once ECHA has assigned a registration number, the registration has an infinite validity, this is, open ended market access. As a consequence, registrants have little to no incentive to update the information of their dossiers.
- An option to consider for the revision of REACH is the assignment of a limited validity of the registration numbers, putting the obligation on the registrant to re-register e.g. every 5 years.
- An alternative policy option is to **require regular, mandatory dossier updates**. Although registrants are responsible for updating registration dossiers without undue delay with new information and deadlines for different kinds of information have now been specified, the majority of dossiers have never been updated since their first registration. An annual review on the need to update dossiers is already common practise for certain companies and should become part of the responsibilities of all registrants.
- **Review of fees and charges**. The registration fees and charges for services provided by ECHA should take account of the work to be carried out by the authorities. A review of the fees and charges is needed to correct for actual costs.
- **Introduction of an obligation for companies to bear the costs incurred by ECHA for reviewing non-compliant dossiers**. ECHA figures show that 80% of dossiers are compliant after the Agency has performed the compliance check, meaning that registrants wait for ECHA to do the job for them as, so far there has been no consequences to them for submitting non-compliant dossiers in the first place. Together with reviewing the provision for completeness check and strengthening ECHA's capacity to revoke registration numbers, companies should pay for the resources invested by ECHA to perform the compliance checks, when they are found non-compliant.

The evaluation of registration dossiers and substances is too complex and insufficient.

Evaluation under REACH consists of dossier evaluation by ECHA to check whether the registrations are compliant with the legal requirements, followed by substance evaluation by member states to clarify initial concerns for human health and the environment. The high level of non-compliance of the dossiers hinders REACH from achieving its objectives and requires a lot of resources from ECHA and the authorities for evaluation purposes. The EEB report on evaluation estimated that on average, evaluating the risks of chemicals under REACH, takes 7-9 years, during which exposure of people and the environment continues. Revision of the provisions of dossier evaluation and substance evaluation will be needed with the aim to accelerate the data generation and evaluation process. The various evaluation procedures that are performed one after the other, take too much time, resources to the authorities and lead to delays in decision making. Simplification, streamlining and integration of the evaluation processes is needed in order to get information faster and avoid unacceptable delays in the regulatory decision making. The EEB recommends the following options be considered in the revision of REACH:

- **Allowing authorities to commission tests to obtain hazard information**. The EEB supports the Commission proposal to allow EU and national authorities to commission testing and monitoring of substances. This could be a useful tool for group assessments. Registrants should pay the cost incurred by regulators.
- **Revise the scope of compliance checks and substance evaluation**. The data generation part of the substance evaluation could be integrated with the compliance check, shifting responsibility for all data generation requests to ECHA, while the substance evaluation (except the request for further information) and follow-up to substance evaluation remains the responsibility of the member state authorities.
- **Use of group assessments**. The principle of group assessments for dossier and substance evaluation should be formally enshrined in REACH. The group of chemicals should be treated as having the property of the most hazardous member, and the burden of proving that specific chemicals can be excluded from the group should be on industry.
- **Set legal deadlines for all steps in the procedure for adoption of decisions under evaluation**. Introduce the missing deadlines in the procedures for adoption of decisions under dossier evaluation (art 51.1) and under substance evaluation (art 52.2).
- **Formal recognition of the need to use weight of evidence approaches for regulating chemicals**. Allow the use of weight of evidence approaches by authorities in evaluation in case of non-compliance and in case safety is not sufficiently demonstrated in the registration dossiers. Apply the precautionary principle.
- **Accept MSC majority agreement for adoption of decisions under evaluation**. Qualified majority agreement on decisions by the member state committee should be accepted instead of unanimous agreement, in order to avoid delays due to the involvement of the Commission.
- **Introduce short deadlines in the Commission's procedure and decisions to avoid delays**.
- **Introduce general obligation for competent authorities to comply with their obligations** to protect people and the environment and timely act against harmful chemicals in the market if the substance evaluation concludes on the need for further risk management.

Reforming the Authorisation process

The REACH Authorisation is a unique process in the global regulatory framework and is considered as the main driver for substitution of hazardous chemicals. It puts the burden of proof on the industry to demonstrate that no safer alternatives are available and that the chemicals can be controlled. If non-negligible uncertainties remain, the applicant bears the risk of the rejection of its application. It is the best procedure to obtain information on how and where and for what the SVHC is used and the best procedure to accelerate and scrutinise substitution efforts by companies. Authorisation has contributed to the reduction of the emissions of SVHC, improved transparency and communication with authorities; it is a driver for innovation and helps to create a market for alternatives. It has resulted in relocation or closure of activities in only very few cases [UBA, EC].

The problems of the Authorisation procedure rely mainly on how the legal text has been interpreted and implemented [UBA, EEB, ClientEarth&Chemsec]. This has led to work for public authorities when the application should have been rejected from the outset, prolonged discussions, delays in the adoption of the final decision [ClientEarth] and several objections from the European Parliament as well as court cases. The ruling of the Court of Justice C-389/19 P on one of these cases mandates fundamental changes in the approach followed. The REACH revision offers an opportunity to clarify the legal text, streamline and reinforce the capacity of Authorisation to substitute SVHC and improve the protection of people and the environment.

We support reforming the Authorisation process to clarify the current provisions and improve the interface with the REACH Restriction process. Both should remain separate, complementary processes as they have distinct aims and merits. Restriction puts the burden of proof on the authorities to demonstrate risks, while Authorisation puts the burden on applicants to demonstrate safe use of an SVHC, where possible.

SVHC identification and inclusion in the Candidate List

SVHC identification is a fast (< 6 months) and straightforward process as it is based solely on intrinsic hazardous properties of chemicals. Formal recognition of SVHC properties triggers additional information throughout the supply chain and to consumers and is considered the main driver to substitution in Europe and beyond. However, only 220 chemicals have been candidate-listed so far, rather below the original expectations of the legislator (>1,400 chemicals). The process can be further strengthened and the EEB requests the Commission to consider the following proposals for the REACH Revision:

- **Including additional independent SVHC categories** under article 57 for EDCs, PMTs and vPvMs as proposed in the CSS action plan, but not mentioned in the IIA.
- **Establishing an automatic trigger between CLP classification and the Candidate List**, in both directions for CMR substances, and after revision of CLP also for PBTs, PMTs and EDCs.
- Alternatively: **Introducing a fast-track procedure (art. 59) for PBTs, vPvBs, PMTs, vPvMs and EDCs**, once classified under CLP similar to the current SVHC notification process for CMRs under REACH.

- **Increasing the use of grouping** for structurally related chemicals or chemicals with similar properties and establishing the burden of proof on Industry to justify the exclusion of specific chemicals from the group.
- **Establishing a qualified majority** instead of unanimous agreement **at the Member State Committee** to simplify the decision making and avoid delays.
- **Clarifying and providing guidance for the Assessment of Equivalent Level of Concern** - article 57f
- **Introducing short deadlines** in the Commission's procedure and decisions to avoid delays.

Inclusion of SVHC in the Authorisation List (Annex XIV)

Prioritisation of SVHCs to Annex XIV could also be a more automatic process based on SVHC category and basic information available in registration dossiers (use category and tonnage). Poor implementation has led to delays and only 55 chemicals have been included so far in the authorisation list. Annex XIV inclusion is limited by ECHA's capacity and remains under the discretion of the Commission. The procedure can be improved by:

- **Making it a regular, annual process** instead of recommendations provided "at least every second year" as currently required by Article 58.3.
- **Speed up and simplify the process** by including ECHA recommendations directly in Annex XIV once supported by the MSC, similar to the candidate listing process.
- **Introducing short deadlines** in the Commission's procedure and decisions to avoid delays.
- **Reducing the weight granted to ECHA's** "capacity to handle applications for authorisation in time" as currently allowed by Article 58.3. The prioritisation of substances for Annex XIV must necessarily be done by ECHA, which should allow for that prioritisation regardless of its capacity optimisation.
- **Prioritising** EDCs, PMTs and vPvMs and cumulation of properties, e.g. C+R+EDC.

Applications for authorisation (AfA) assessments

The Commission and ECHA have assumed that every application for authorisation (AfA) should be granted as companies would not apply if they could substitute. As a consequence, even highly deficient AfAs have been granted an authorisation, resulting in the protection of laggards instead of frontrunners, and hindrance of innovation towards safer chemicals, technologies and processes.

The procedures for the RAC and SEAC to develop opinions on applications for authorisations and for the Commission and member states to take decisions is lengthy (DEZA's DEHP AfA still waiting for a decision after 6 years), burdensome and controversial, and has resulted in objections from the European Parliament and Court cases against the Commission. This is due to:

- The acceptance of AfAs as being in conformity although the required information regarding uses, exposure and alternatives was poor or even lacking. This has been the case in particular for broadscope AfAs.

- The overfocus of the socio-economic assessment and the analysis of alternatives on applicants' perspective, lack of consideration of impacts on alternative providers and third parties.
- Vague legal text and inadequate socio-economic assessment guidance as well as lack of criteria and resources at SEAC to assess alternatives.
- Attempts by the Commission to «fix» applications that were not in conformity in the decision-making stage.

The Authorisation reform must consider:

Promoting substitution at an earlier stage by:

- Introducing an obligation for companies using SVHC to notify ECHA of their uses and prepare a substitution plan once the chemicals are placed on the candidate list.
- Introducing a fee to the use of SVHC that would provide resources to support substitution activities, including mapping of industrial use and end-uses, alternatives, and key performances; as well as also support company innovation and substitution efforts.

Simplifying the system by:

- Reducing the process to only one « route » where authorisation can only be granted if the applicant provides verifiable proof of adequate control or effective minimisation of risks and a precise substitution plan. The decisions to grant authorisations would be based on the assessments of the risks, the substitution plan including an analysis of alternatives.
- Stop over focusing on applicants and also include the perspective of downstream users (DU), consumers and alternative providers.
- Allow only individual or collective applications (co-downstream or upstream users) with similar uses (i.e. similar exposure scenario, operation conditions, function, etc.) to avoid the issues encountered with broad scope AfAs.
- Clarifying the definition of technical feasibility by linking it to:
    - the performance of the end use, rather than the SVHC's
    - the societal importance of the use, based on essential use concept (e.g. luxury, convenience or decorative uses have a lower importance than life saving and caring uses);
    - and the criticality of the SVHC performance in delivering the key function of the end use. A standard of acceptable performance loss should be established as well.
- Improving the transparency on companies authorised to continue using SVHC in ECHA's databases and including a CBI process under applications for Authorisation.

- Authorisations should be time limited.
- We firmly oppose the option for allowing national authorisation of SVHC. This would spur a race among member states to protect local businesses using SVHC, instead of enhancing substitution towards safer alternatives through common EU market rules.

Reforming the Restriction process

REACH Restriction is a straightforward process, largely accepted by stakeholders, that has the potential to highly reduce exposure to chemicals identified as hazardous through CLP, or candidate listing, or for which there is scientific evidence that they pose a risk to human health or the environment. However, its efficiency is hindered by how it is implemented as it:

- has suffered from the information on uses and exposure that is missing in registration dossiers;
- created considerable work and the burden of proof is too high (for the authorities) for limited result when restriction proposals have an excessively limited scope (e.g. BPA use in thermal paper);
- has been undermined by wide and non-time limited derogations and/or long transitional periods; excluding risks from the end-of-life phase; and the narrow approach when considering benefits to society;
- has been perverted since restriction has increasingly been used as a "disguised" route to keep toxic chemicals in use (e.g. asbestos, lead in PVC or to establish OEL).

The following options would improve the efficiency and speeding-up of the process:

- **Extending the generic approach to risk management** (article 68.2) as the default option to additional hazard categories as proposed by the CSS and included as a policy option in the IIA and also to extend to PMT/vPvM substances.
- **Introduction of**:
    - the **essential use concept** and consideration on the availability of alternatives as cut-off criteria for accepting derogations and establishing transitional periods.
    - **mandatory authorisation process** when not enough information is available to determine whether the use is still non-avoidable. This is to avoid continued use of the substance, without risk management.
    - **labelling, monitoring and reporting requirements** as well as mandatory risk management measures and fees for all derogated uses. Fees should be based on hazard properties and tonnage use.
- **Mandatory restriction follow-up** where the evaluation concludes on substantial risks, CLP notification of CMR or notifications of SVHC in articles, if not included in Annex XIV.
- **Support the use of the precautionary approach** in risk and socioeconomic assessments, notably by identifying the uncertainties, time needed to solve them and the impacts of inaction.

- **Promote the restriction of groups of substances** to speed up and enhance protection as well as avoid regrettable substitutions. The Commission should consider how to apply the precautionary approach more efficiently.
- **Strengthen obligations to restrict SVHC** in order to address imports and exports as not covered by authorisation or revise the authorisation procedure to include imports and exports of SVHC outside Europe.

Revision of provisions for transparency, control and enforcement

The lack of transparency of the comitology procedure hampers access to information and accountability of authorities taking decisions on chemicals regulations. The current reform of comitology procedure provides suggestions for improvements of the rules of procedure of the REACH Committee, which are suggested below; the REACH Revision is an opportunity to:

- **Publish member states' votes**
- **Oblige member states to motivate their vote**: give reasons for their vote, abstention or for any absence from the vote, and where particularly sensitive areas are concerned, relating to consumer protection, health and safety of humans, animals or plants, or the environment, which is the case for REACH matters
- **Share detailed minutes of the meetings**
- **Set strict deadlines for decisions to be adopted**

Effective control and enforcement is key to ensure health and environmental protection and fair competition since it ensures that all companies respect the law. Over the past years, the EEB raised concerns on:

- **Very high levels of non-compliance** under REACH that remained in time over the last decade (on average two thirds of the registration dossiers still not comply since more than a decade ago)
- **Too many unsafe products** on the EU market reported every year, including toys
- **Weak control and enforcement**, mainly due to:
    1. **General lack of resources** for enforcement. The lack of resources of authorities to control and enforce REACH is hampering the protection goals of the EU as well as the effective control of harmful chemicals. In our view, this is mainly due to an economically unsustainable system where the costs are externalised to the public, notably for control and enforcement of companies manufacturing and using toxic chemicals. Likewise, as well as for the costs of pollution.
    2. **Divergences of enforcement approaches**, regimes, measures and sanctions across the National Enforcement Authorities (NEAs)
    3. Despite REACH providing that ***"the penalties must be effective, proportionate and dissuasive"***, **priority is widely given to very soft measures**, mainly written and verbal advice. Almost no sanctions happen in the event of violations. An example: The Commission found

that for HPVCs, in most countries, the level of fine is lower than the costs of compliance. This is de facto an incentive for non-compliance.

4. **Lack of transparency** by the enforcement authorities notably on: what concrete measures are taken against non-compliant companies, the identity of these companies or of the non-compliant substances and products. This lack of transparency is hampering protection, incentivises non-compliance by companies and causes unfair treatment.

The EEB suggests that the Commission improves control and enforcement of chemicals manufacture, use and import/export by:

- **analysing and proposing economic instruments** that guarantee the economic sustainability of the control and enforcement system under REACH
- **harmonising enforcement** across member states by setting 'minimum' resources, inspections and sanctions/penalties to ensure consistency across NEAs and a level playing field across countries
- **providing transparency requirements** with regard to control and enforcement activities to ensure protection, information, scrutiny, fair competition and incentives for compliance.