Comments on the proposal to reform the REACH registration and evaluation process. (document CA/08/2022)

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Introduction

The EEB and HEAL welcome the opportunity to provide comments and recommendations on the European Commission's proposal with **potential options for amendments of the REACH Regulation in order to reform the REACH registration and evaluation processes (**Doc. CA/08/2022).

To end the problem of delayed action under REACH, the current revision needs to put the reform of the current registration and evaluation processes central stage. In this sense, **the proposed options for amendment of the registration and evaluation processes are urgently needed.**

We appreciate the opportunity to provide feedback to this text and we hope that our contributions will be considered in the revision of the REACH Regulation, geared towards achieving the Chemicals Strategy for Sustainability's (CSS) objectives, to increase the protection of humans and the environment.

The CSS aims to ban the most harmful chemicals fast and efficiently. This much needed ban can only be successfully achieved by requiring solid evidence at the early stage of substance registration, which means that the registration dossiers must contain all the information needed for hazard identification and risk management. At the same time, a zero tolerance approach is needed for substances with non-compliant registration dossiers currently on the market, because their safety is not yet proven.

The high level of non-compliance is a major bottleneck in the implementation of REACH and a serious cause for delays in implementing regulatory risk management measures. With the current practice, substances get stuck in the evaluation process for many years, causing delay in developing regulatory risk management measures that would ensure their safety. In the meantime, companies are allowed to market their (non-compliant) substances without evidence that they are safe, raising serious and legitimate concerns about their impact on people's health and the environment. As it stands now, the Commission's commitment to ban the most harmful substances fast and efficiently is in stark contradiction with the current practice of actively marketing potentially harmful substances which are still at the evaluation stage, moreover they are stuck in an (evaluation) process, which in some cases takes as long as a decade to complete.

In this context, four major changes for registration and evaluation are needed **to accomplish the CSS goals.**

1. **Apply the No data, No Market principle at the registration stage: make provisions for registration stronger.** Rigorously check that the new dossiers are complete on submission and that the already submitted ones fulfil the update requirements, allow ECHA to evaluate quality and adequacy of the registered data at registration, and give ECHA the power to revoke registration numbers when necessary.
2. **Update REACH information requirements:** Information requirements should include all data needed for hazard identification and risk management, including information on crucial hazard endpoints and on use(s) and exposure(s).[1]
3. **Revise provisions of dossier evaluation and substance evaluation:** Integrate compliance check and substance evaluation**.** The current process of consecutive compliance check - data generation followed by substance evaluation - data generation, results in unacceptable delays. Introduce flexibility and simplify both processes, also with the prospect of one substance - one assessment. In the new process, the mandate to perform the integrated compliance check and substance evaluation should be extended to MSCAs as well as ECHA.
4. **Reinforce accountability of registrants on their data:** Introduce fees for the costs associated with the resources spent by ECHA to handle non-compliant dossiers. Force registrants to provide adequate data at an early stage. To keep the licence to market, a deadline should be introduced within which a dossier needs to be compliant from the date of registration.

The REACH revision provides an excellent opportunity to improve and strengthen the future REACH registration and evaluation provisions. In 2027, 20 years after the entry into force of REACH, ECHA will have completed the screening of phase-in substances and will have issued compliance check decisions for all relevant dossiers according to the joint REACH Evaluation Action Plan of the Commission and ECHA. Therefore time has come for a revision of registration and evaluation to finally put an end to the problem of delayed action under REACH.

The Commissions' document with potential options for the reform of REACH registration and evaluation processes contains relevant proposals that are urgently needed to achieve the following CSS goals:

- strengthen the principles of 'no data, no market';
- have a zero tolerance approach to non-compliance;
- allow revocation of registration numbers;
- develop the 'one substance-one assessment' approach;
- approach substances by groups;
- make hazard identification and risk management fast and efficient;
- apply the polluters' pay principle.

Detailed comments and further reflections on the proposals are provided below.

[1] See our comments in the document [HEAL, EEB, and CHEM Trust comments on considerations for extended REACH information requirements (document CA/09/2022)]; 240222

Registration and Technical Completeness check (TCC)

Strengthen the completeness check at registration, clarifying that completeness check may include determination of compliance with information requirements

COM Proposal: Not meant as linking or merging TCC and CCH that remain separate mechanisms, but rather to address assessment of dossier before it is considered complete, likely also with modification of Article 20(2) on TCC, in particular last sentence "…shall not include quality or the adequacy of any data or justification provided".

Comments: Currently the REACH legal text does not allow ECHA to assess the adequacy and reliability of the data submitted at the time of registration (Article 20(2)). As a consequence, substances are *de facto* allowed on the EU market without proper safety data, resulting in a high level of non-compliance among REACH substances. The proposal to strengthen the completeness check at registration stage should ensure that the burden of proof shifts to registrants. Dossiers should contain all the information on crucial hazard endpoints and on use/exposure that is necessary for hazard identification and risk management. The benefits are large: chemicals with non-compliant dossiers of which safety is not demonstrated can be kept off market. This will speed-up the evaluation process as well as facilitate hazard identification and implementation of risk management measures. This revision needs to be linked to a change in the legal timeframe for ECHA to grant market access, as the current REACH text provides a very short deadline of 3 weeks only for granting market access. The bottom line is that chemicals can enter the market in 3 weeks, while it takes over a decade for authorities to take them off when known to be dangerous.

The REACH revision is an excellent opportunity to strengthen the provisions for the registration process for several reasons:

- ECHA's ongoing mapping of the chemical universe and assessments of regulatory needs for groups of substances contribute to an increased understanding of problematic substances;
- ECHA will have completed the compliance checks on phase-in substances by 2027.

It should be noted that any improvement to REACH will only be successful if the registration decisions (completeness checks) require comprehensive and adequate safety data before allowing chemicals on the market. The 'no data - no market' principle should be duly applied.

Maintain dossiers compliant; dossier 'expiration date'

COM Proposal: legal changes to strengthen the common expectation of dossiers compliant at all times. Data is expected to reflect, in a compliant manner, declared circumstances under which access to the market is granted, and is kept updated as required.

Comments: REACH puts the responsibility to keep data on registered chemicals up-to-date without undue delay on companies (Article 22). However, many dossiers have never been updated except when triggered by ECHA e.g. via an evaluation decision. 64% of the registration dossiers were never updated between 2010 - 2017. We support the proposal for legal changes to strengthen the dossier update requirements. Several options could be explored:

- **mandatory requirement for dossier review/update**, i.e. at least once a year or declaration that no changes occurred. In the present situation, many dossiers have never been updated by the dossier owners since initial registration, while other registrants have already

implemented the practice of annual dossier updates. Annual dossier updates could become the standard for all registrants, as a minimum requirement. A mandatory annual reporting requirement will stimulate companies to embed periodic review of dossiers in their regular business strategy and improve practicalities for companies (hiring consultants, annual reporting etc.).

- **implementation of a licence to market with expiration date**, after which the registration has to be renewed in order to keep market access. It should not be possible to renew market access if the dossier is still non-compliant at the expiration date.
- Fees should be coupled to both options.

Revocation of registration number

COM Proposal: grant ECHA the power to revoke registration number to be applied for persistent failure to comply.

Comments: The current legal text allows ECHA to grant registration numbers, but it does not allow the agency to revoke registration numbers for safety data reasons once granted. We support the proposal that ECHA should be granted the possibility to revoke the registration number when the dossier does not provide compliant safety data. However, the effectiveness of this measure will depend on the conditions under which it can be applied and on the legal definition of what constitutes a 'case of persistent failure'. The effect of this measure will be seriously flawed if ECHA can revoke a registration number only in cases whereby a company has remained in non-compliance following a long evaluation process. Evaluation can take many years[2] and can be further prolonged by registrants by filing complaints at the Board of Appeal. If a revocation can only take effect after that evaluation, the measure will be a free licence for industry to continue marketing non-compliant chemicals for years, while people and the environment will remain unnecessarily exposed to potentially hazardous chemicals. Under those conditions, the measure will not contribute to achieving the CSS commitment for zero tolerance to non-compliance. Therefore, **further discussion is needed on the implementation conditions of the revocation power of the Agency**.

Information requirements: application of waivers

COM Proposal: subject at least some specific waivers (e.g. exposure based) for validation/authorisation prior to their use.

Comments: Data is often waived on invalid grounds. This allows chemicals on the market without their safety being demonstrated. During the compliance check, registrants can submit completely new data, taking a lot of ECHA's resources. The burden of proof should truly shift to registrants. Therefore, ECHA should be allowed to validate waivers and other data before granting a registration number. Better selection of the substances allowed on the market will result in increased efficiency in the evaluation process later on. Triggers are needed for obtaining the necessary data rather than waivers for providing data.

Additional proposal:

- Introduce a tool that allows third parties to submit scientific and other information on specific substances.

[2] EEB report (2019) Report-Substance-Evaluation-under-REACH.pdf

Dossier evaluation

Testing proposals

COM Proposal: Restrict use or expand (for animal testing). Making changes to the legal provisions that determine when a testing proposal must be issued before proceeding with the testing, which may go in two directions:

- Raise expectation that (all) data is available when registering, also by generally reducing requirement to first prepare test proposals and subject them to examination, e.g. for higher tier in ecotox;
- Extend TP to effectively all animal/vertebrate testing to use the process to help ensure animal testing is only done where strictly necessary;
- Combination: limit TP to animal/vertebrate test

Comments: We agree with the Commission that further analysis and discussion are needed on the proposed options. Our initial view is that the legally required data should be provided at the time of registration, making testing proposals in most cases redundant. In either case, revision of articles 40 and 43 will be needed. If testing proposals are to stay in REACH, the following considerations should be taken into account:

- update of article 40 is needed to cover animal tests under Annex VII and VIII;
- testing proposals should be limited to vertebrate tests;
- update of article 43 is needed since the examination of test proposals related to phase-in substances should be completed by June 2022.

Compliance Check (CCH)

COM Proposal: Strategy after 2027 - percentage, prioritization; scope of compliance check and compliance check decisions (self-classification & DNEL; CSR/exposure and provisions for grouping and testing strategy); improving adaptations by registrants. Still an open question whether changes are really needed or can be left to ECHA to optimise.

Comments: The EEB and HEAL strongly support revisions of the legal text to include the Commissions' proposals for amendment of the compliance check provisions. By 2027, ECHA will have achieved the targets for compliance checks currently set in the REACH text. Therefore, a revision of the legal text will be needed and should include a strategy with updated targets and priorities for compliance checks beyond 2027. Determination is needed to achieve the CSS ambition of zero tolerance towards non compliance.

We also support revision of the REACH text to embed a legal frame to jointly check the compliance for all substances that are members of a group and to address data gaps with a testing strategy based on group considerations as a default approach. Compliance checks should happen by groups to speed up the process and avoid regrettable substitution while not increasing the time of the evaluation.

At present, the high levels of non-compliance overload the evaluation process, resulting in delays of hazard identification and risk management, and drain of ECHA's resources. In practice, there is no market consequence for non-compliance for registrants, and measures are needed in order to force registrants to provide adequate data at an early stage.

Additional proposals:

- **Integration of the compliance check and substance evaluation** should be considered. The current procedure with substance evaluation awaiting the outcome of the compliance check leads to unacceptable delays in hazard identification. Flexibility is needed.
- Both ECHA and MSCA should be allowed to perform the integrated compliance check and substance evaluation.
- **A deadline within which a dossier needs to be compliant from the date of registration should be introduced in order to keep market access.**
- The current time frame of 12 months for issuing draft compliance check decisions should be shortened, and a final decision for data generation should be adopted within one year from the start of the evaluation.
- Provisions should be included regarding the registrants' comments (scope, size).
- To increase transparency, the list of dossiers being checked for compliance should be published on the ECHA website, and so should ECHA decisions-linked to the registration dossiers, the names of the non compliant registrants and the follow-up conclusions of the completed compliance check.
- The possibility for ECHA to re-issue a decision as a follow-up should be eliminated.
- **ECHA should be allowed to revoke the registration decisions** when the information requested is not provided or is not in compliance; linked with revised provisions for registration.
- Fees should be introduced to reflect and account for the resources spent by the Agency for the handling of non-compliant dossiers.

Substance evaluation

COM Proposals: ECHA to be able to perform SEv; Extension of SEv requirements from risk-based concerns to hazard based concerns; Replace CoRAP with lightweight and dynamic registry; Role of SEv as data generation tool and safety assessment.

Comments: EEB and HEAL fully support the Commission proposals on substance evaluation and urge their inclusion in the revision of REACH. In particular we support extending the mandate to perform SEv from evaluating MSCA also to ECHA; extending SEv requirements from risk-based concerns to hazard-based concerns. Prioritisation for evaluation shall be primarily hazard based, and serving hazard identification, aligned with the CSS commitment for a generic approach to risk management.

In addition, we note that the current procedure whereby a substance evaluation is postponed until the data requested under compliance check is generated leads to unacceptable delays. The substance evaluation of the substances prioritised in the Community Rolling Action Plan (CoRAP) keeps being postponed year after year, because of awaiting data generation under ongoing compliance checks. These delays hamper the CSS commitment towards fast and efficient hazard identification. Integrating the processes of compliance check and substance evaluation is necessary to reduce these delays in the future. Several options could be considered:

- Full integration of the current provisions for compliance check and substance evaluation. ECHA and MSCA get the same mandate to perform the integrated compliance check/substance evaluation.
- Integration of the data generation provisions under compliance check and substance evaluation, under the mandate of ECHA. Under this option, the safety assessment dimension remains under the mandate of MSC.

Additional proposals:

- **Integrate compliance check and substance evaluation to reduce delays in risk management.**
- Introduce legal framework for evaluation of substances by groups and allow testing strategies based on grouping considerations. This will speed up the evaluation process and prevent regrettable substitution.
- **Deadlines for risk management follow-up of SEv conclusions should be introduced.** If substance evaluation conclusions confirm that the substance is of concern, the recommended follow-steps for hazard identification or risk management should start immediately and deliver within clear deadlines.

Changes to evaluation decision making procedures and conditions for registrants

COM Proposals: Specify conditions for and consequences of ceasing manufacture; Limit specific CCH process to assessment of the dossier and associated ECHA draft assessments; Removing & modifying procedural steps, provisions (e.g. Art 51 deadlines) involving registrants with commenting, authorities & ECHA, role of MSC.

Comments: We support a faster decision-making process. The current time frame of 12 months for issuing draft evaluation decisions should be shortened and a final decision for data generation should be adopted within one year from the start of the evaluation. The comments provided by registrants should be limited to a maximum text size. We note the efficiency gains over the last years in decision making avoiding repetitive discussions, and value the MSC involvement in the process. We do see a need to improve the transparency for stakeholder observers in the current process.

Testing by authorities

COM Proposal: New tool that should work in conjunction with other EU chemicals legislation (commitment under CSS), enabling authorities to do (or better: order using Contract Research Organisation) tests under specific circumstances. The tool shares data generation dimension with DEv and SEv but may not necessarily even be part of Evaluation. Different options to be assessed under IA:

- Link to DEv/SEv processes and to REACH reversal of burden of proof
- Who decides, orders and accepts results, data hosting, funding.

Comments: We support the consideration of introducing a new tool, but we would like guarantees that its use will not rely on financing by public budgets. Should public authorities request further testing, the costs should be borne by the industry, in line with the polluter pays principle and the tests should be commissioned and carried out independently.

Coupling fees

COM Proposal: Coupling fees to actions causing ECHA workload (e.g. dossier updates, comments on draft evaluation decisions, new adaptations, etc.). Under consideration/development within ECHA funding regulation discussion.

Comments: We strongly support the introduction of fees to actions that cause ECHA additional workload, for example a fee to cover costs associated with non-compliant dossiers.