Health and Environment Alliance (HEAL), European Environmental Bureau (EEB), and CHEM Trust comments on considerations for extended REACH information requirements (document CA/09/2022)

Comments sent by email to: GROW-CARACAL@ec.europa.eu ; ENV-CARACAL@ec.europa.eu ; GROW-ENV-REACH-REVISION@ec.europa.eu

24th February 2022

The Health and Environment Alliance (HEAL), the European Environmental Bureau (EEB), and CHEM Trust welcome the opportunity to provide written comments on current considerations regarding the extension of REACH information requirements. To start with, we would like to thank the Joint Research Centre (JRC) for the work carried out in preparation of the CARACAL 43 discussions as well as for the related supporting document and meeting presentation. However, the options presented raise a number of important questions and concerns, which we outline throughout this document.

The EU Chemical Strategy for Sustainability (CSS) commits to amending the REACH regulation to generate the necessary information on substances and toxicological endpoints to allow hazard identification and risk assessment generally and, in particular for '***critical hazards',*** i.e., CMR, PBT, vPvB, ED (human health and environment, respiratory sensitization, immunotoxicity, neurotoxicity, and other STOT (Specific Target Organ Toxicity). Further, the problem definition of the REACH inception impact assessment clearly states that **current information requirements do not allow a sufficiently thorough hazard assessment, including for carcinogenicity, neurotoxicity, immunotoxicity and endocrine disruption.** The lack of information occurs at all tonnage bands and is in particular significant for substances produced between 1-10 tpa and polymers.

We support the aim to update the REACH information requirements to serve the above-described purpose and allow REACH to better integrate the possibilities offered by New Approach Methodologies (NAMs) in the future.

Closing information gaps should be one of the most important priorities for the REACH revision as the information provides the basis for subsequent control measures and an improved protection for human health and the environment. However, we need to insist from the outset that for a future integration of the NAM to guarantee health and environment protection, it will be necessary to lower the level of evidence requested to identify chemicals' hazards compared to current requirements.

The important findings from the REACH review and the flaws that it has analysed in the current system should guide the considerations for adding new information requirements to the REACH Annexes. This is in particular relevant on those endpoints needed to clarify whether a substance has SVHC properties. As the Commission Staff working document on the REACH review[1] in 2018 stated:

> *"REACH has also promoted alternative methods for testing though the legislative requirements to only test on animals as a last resort has been implemented at the expense of hazard information relevant for the protection of human health and the environment."*

[1] https://eur-lex.europa.eu/resource.html?uri=cellar:2834985c-2083-11e8-ac73-01aa75ed71a1.0001.02/DOC_1&format=PDF

It will be important to link the new proposals for REACH data requirements very clearly to the CLP provisions and the new hazard classes so that sufficient data are available to make the hazard identification possible. Previous analysis from regulators found that *"REACH will hardly generate sufficient information for classification of substances as category 1B for mutagenicity and carcinogenicity. Therefore, indications of very severe hazards of substances are missed and health risks could occur."*[2]

The new REACH information requirements will remain a combination of in vitro, in vivo and non-test methods for the identification of the inherent properties for chemicals. In the future, more methods will become accessible to partly replace animal test methods. **Therefore, there is an urgent need to develop regulatory identification approaches based on in- vitro methods and other methods, like grouping and read-across. Still, it would not be acceptable to leave dangerous substance properties unidentified. In the future, the benefits of REACH for increased human health and environment protection will depend on the extent harmful substances are identified and regulated**.

1. General considerations to be taken into account in the general REACH IR update

Our organisations have long urged EU authorities to close the critical information gaps regarding hazards that the document refers to as 'critical', i.e., CMR, PBT, vPvB, ED (human health and environment), respiratory sensitisation, immunotoxicity, neurotoxicity, and other STOT (Specific Target Organ Toxicity) in order to serve better health and environment protection. **We believe that the Persistent, Mobile, Toxic (PMT) and very Persistent and very Mobile (vPvM) endpoints should also be considered in this list of 'critical' hazards.**

At present, **the document is not explicit on several points that are of utmost importance in the update of the general IR** and need to be clarified as the Commission progresses in the preparation of the impact assessment. Those points are the following:

- Whichever option is picked and further developed, **the IR update must guarantee that all relevant literature, including all relevant independent peer-reviewed literature, is being screened as a starting point** of any assessment, from annex VII onwards, e.g through requirements to follow a systematic data search approach.
- While considerations on the reduction of animal testing are welcome and necessary, the update of the annexes must ensure flexibility for the regulators to investigate any concerns they have in further details according to their expert judgement throughout the assessment. **For this reason, the logic of the buildup of the annexes should revolve around triggers rather than waivers.**
- Following from the precedent point, **considerations on the follow-up actions to NAM results must be approached with great caution if the objective of health and environment protection is to be strengthened through this update.** Based on expert judgement, a regulatory authority should always be able to request the test they deem most relevant in follow-up to a NAM result (e.g., a positive in vitro test result), whatever the endpoint is. Considering that NAMS are still in their early stage of development, expert judgement will be key to their improved uptake and integration.
- **We would welcome clarifications regarding the Commission's intentions to link the present discussion on the general REACH IR update and the specific one for the ED-IR part.** We

[2] Woutersen et al., Human and Ecological Risk Assessment 25(1):1-20, DOI: 10.1080/10807039.2018.1480351.

remind the Commission that we have provided specific comments for that latter part (in which we have supported option 2 to be used as a starting point to the update)[3]. As the Commission moves forward with the update of the REACH annexes, we would like to understand how the two processes will be integrated and how this will reflect in the options presented in the impact assessment. Inconsistencies between the updates of the general and the specific ED parts of the IR must be avoided at all costs. This is particularly important in a context when studies requested in the context of the assessment of endocrine disrupting properties might be informative for the investigation of other endpoints (e.g., reproductive toxicity) and vice-versa.

2. Preliminary comments based on the document put forward for consultation

We welcome the stated intention to update the information requirements in order to bring information on 1) Annex VII substances to provide a basis for chemical safety assessments; 2) information to identify, at all tonnage levels, carcinogenic substances and substances with 'critical' hazards, 3) information to serve chemical grouping and the use of read-across from registration stage to risk assessment. However, as explained below, we are not convinced that these intentions can be achieved with the options presented.

Regarding the common features shared by the 5 options presented, we have the following observations:

- **We are very surprised that option 1B is presented as an 'extreme', a point of view we do not share.** On the contrary, under the current objectives set by the Chemicals Strategy for Sustainability, option 1B appears as a very bare minimum to be fulfilled and is in the current form not even enough to guarantee the hazard classification of all substances.
- **We support the conduct of a chemical safety assessment at all tonnage levels.**
- **We need to further consider and reflect over the implications of the proposal to merge annexes VII and VIII** as a result of the lowering of certain requirements from annex VIII to VII.
- **We agree that no testing proposals should be needed for non-vertebrate studies.** In any case, registrants should provide legally required tests upon registration, and they should also provide authorities with the tests they request for safety assessment purposes later on.
- **We can consider the suggestion to include a potential revision of annex XI in the options of the future impact assessment**, because significant changes in the other annexes are likely to have implications for its specifications as well and in a view to further encourage the use of NAM-based adaptations of the Standard Information Requirements (SIRs). We, however, need more information to express a firm position. Furthermore, we note that 1) NAMs should ideally be validated under the OECD framework, although we are concerned about the slow processes and 2) as stated above, a proper uptake of NAMs in the REACH annexes will require lowering the level of evidence requested for hazard identification compared to present.

We still need to reflect carefully on the 5 options that are being considered to proceed with the extension of the REACH information requirements. As already stated above, based on the current regulatory reality, option 1B is the absolute minimum to use as a basis for the upgrade of the general REACH information requirements. We therefore do not understand why it is presented as an extreme.

[3] See: https://www.env-health.org/wp-content/uploads/2021/04/2021.04.26-HEAL_CHEMTrust_Comments_IR_April2021_draft-final.pdf and https://www.env-health.org/wp-content/uploads/2022/02/22.02.17.CASG_6_EDIR_Update_NGO_Comments.pdf

For health and environment civil society groups, the future REACH annexes need to provide the most comprehensive information to serve the hazard identification process in view of classification and labelling in addition to chemical safety assessment. This is because hazard identification is the foundation of a protective and efficient chemical regulatory system; in REACH as well as in other sectoral legislations. In moving forward, it will therefore be important to keep in mind that while certain options might come across as more expensive or resource-intensive than others at first sight, they might allow important efficiency gains throughout further regulatory steps that should not be overlooked.

3. Highlighted concerns based on the proposed options

At minimum, the information requirements should allow for hazard identification under CLP and a CSA at all tonnage levels. Unfortunately, we are not convinced that the proposed options meet this criterion for all hazard classes (including new hazard classes like EDCs).

We support inclusion of NAMs that have been validated within the OECD framework as standard information requirements. NAMs should only be used as information to support the hazard identification of substances, but not to overrule classification.

Furthermore, the **JRC proposes to replace long-term studies by NAMs in options 1C, 1D, 1E. We do not support the removal of these tests**, as long as these are needed to conclude on classification & labelling.

- **Regarding endocrine disruption**

Building upon considerations we have shared above (see 1.), **we struggle to understand the practical implications of the options 1B to 1E for future provisions allowing the investigation of the ED endpoint and the articulation between the different processes regarding the update of the REACH annexes (general and ED part)**.

- For instance, in the context of investigation endocrine disruption for human health, moving the request for TG422 to annex VII might bring some relevant information on a few reproductive and thyroid-modulated parameters earlier than is currently the case. However, based on the current wording of the options, it remains unclear to us what the guarantees are that a regulatory authority will be able to trigger a request for an EOGRTS/TG443, should the TG422 come out positive and concerns need clarifying. The wording needs to be unequivocal regarding regulators' flexibility to act based on expert judgement.
- Moreover, and of particular relevance to the investigation of ED concerns, the different options 1B-1E currently fail to reflect the fact that one study might be very informative on several endpoints. For instance, the request for a TG443 with DIT/DNT cohorts in the context of an ED assessment will be helpful for the investigation of other endpoints – reprotoxicity, immunotoxicity, neurotoxicity. Therefore, requesting such a study early in the assessment might in some cases be a very cost-efficient way to proceed instead of spending resources and animals to carry out lower levels' studies (e.g., TGs 422, 440, 441). We would once again welcome clarifications from the Commission on thoughts to safeguard the flexibility needed for regulatory authorities to exert their expert judgement when deciding on the appropriate testing strategy in order to best investigate the concerns at play while avoiding any waste in resources and animals.

4. Questions for feedback

4.1. Should a CSA be required for all REACH registered substances, or should there be derogations for substances of low concern (derogation criteria to be defined)?

A CSA should be required for all REACH registered substances. At present, we believe that the update of the REACH IR should serve the goal to urgently close data gaps on chemical substances, including for substances at low tonnage levels for which we have virtually no safety information. The introduction of derogation criteria appears challenging and will create additional burdens for the authorities instead of speeding up data gathering through registration. Furthermore, it is important for the reformed system to keep attuned to the development of scientific knowledge that might have implications on the judgement regarding the level of concern of a (group of) substance(s).

4.2. In relation to the protection and innovation goals of the CSS, are there any gaps or redundancies in the proposed SIRs?

We see major gaps in the proposed standard information requirements under options 1C, 1D, 1E. The proposed SIRs do not match the data needed for classification & labelling. For example, a 2nd PNDT and EOGRTS are still required under CLP by RAC. Further analysis is needed in this respect. This illustrates earlier concerns we have shared that reconciling the protection and innovation goals of the CSS in the context of the present REACH annex update exercise will only be successful if the level of evidence required to conclude on the hazardous properties of a substance is lowered. Reflecting on an improved uptake of NAMs in the REACH annexes is very welcome. However, considering that at present the data stemming from them cannot be used to conclude on adverse effects, fully integrating NAMS to conclude on hazards requires a change in the architecture of the regulatory system towards lower evidence requirements.

We also would like to emphasise the importance of the new hazard classes to be introduced in CLP for the identification of persistent chemicals, including persistent and bioaccumulative chemicals as well as persistent and mobile chemicals. To allow the hazard identification of such substances of very high concern the new CLP criteria require a biodegradation simulation test. In this respect we note a gap in options 1A and 1B where the biodegradation simulation test should be required at all tonnage levels to allow classification as PBT/vPvB or PMT/vPvM.

4.3. To what extent are trade-offs in the SIRs acceptable, given that it is not feasible to require a full set of information for all registered substances?

At this stage, we consider that it is not appropriate to approach the update of the REACH annexes based on the assumptions that trade-offs will be necessary to carry out the process.

Firstly, the Commission itself has acknowledged that the current lack of data on critical hazards at all tonnage levels is a major issue. Therefore, the update exercise must be approached from the perspective of the added-value that will be brought by requesting additional information, firstly for enhanced health and environment protection, and secondly for overall more efficient implementation of REACH from the registration stage all throughout regulatory steps stemming from it. In moving forward, it will therefore be important to keep in mind this

broad picture including where information requirements sit and the purpose that they serve. Based on a simplistic cost-impact approach, certain options will naturally come across as more expensive or resource-intensive than others, but it is important to remember that they might allow important efficiency gains throughout further regulatory steps on the long-term that should not be overlooked.

Secondly, as we have highlighted in response to the precedent question and further above, developing options for overhauling REACH information requirements that are protective for health and the environment, while promoting efficiency in the use of public authorities' resources and the use of animals, will require lowering the level of evidence that is considered necessary to identify the hazardous properties of chemical substances.

4.4. In the short term, what mechanism could be put into place to ensure the efficient recognition of acceptable NAMs? Possibilities may include an Agency List, Commission List, Test Methods Regulation.

The recognition of acceptable NAMs should be made through the validation under the OECD framework, similar to existing test method requirements. We fully support the rapid implementation of the use of validated NAMs to support the identification of hazardous properties. We are concerned about the slow pace of OECD processes in adopting NAMs, and therefore there is a real need to support and accelerate OECD processes.

As mentioned before, certain NAMs that have been validated under the OECD framework are already used today. Others will be used in the future once they have been accepted by the OECD. In any case, as long as the NAMs are not accepted for hazard classification under CLP, they cannot replace the current test requirements.

4.5. On a long-term perspective, should the level of information required continue to be based largely on tonnage, or should transition to a system based on levels of concern (generic measures of hazard and exposure)?

Over the long-term, a transition to a system based on levels of concern, including generic measures of hazard and exposure could serve the goals of increased health and environment protection. However, in order to deliver in such a protective way, such an approach requires significant changes to the REACH text and system and the prior introduction of the generic risk assessment approach for regulation (which is yet to be developed and included in the regulation). It also presupposes the readiness to lower the level of evidence required to classify substances and introduce restrictions thereof compared to what is necessary to do so today – especially if the future system aims at a better integration and reliance on NAMs for classification and regulation purposes. Finally, it raises important questions regarding the transparent development of criteria to define the three categories of low/medium/high concerns, which will have important implications for health, environment and society as a whole.