Health and Environment Alliance (HEAL), European Environmental Bureau (EEB) and CHEM Trust comments on the proposed amendments for REACH Annex XI (general rules for adaptation of the standard testing regime).

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Introduction

The standard information requirements for REACH registration dossiers are key to the identification of hazardous chemicals under the REACH and CLP regulation. Updating these requirements should enable an effective identification of critical hazards at all tonnage levels, including for the new CLP hazard classes regarding persistent chemicals and endocrine disruptors, as recognised in the CSS.

This document presents the joint NGO comments on the Commission proposals (CASG-IR-ED/10/2025) discussed at the REACH and CLP Competent Authorities subgroups meeting on 23 April 2025. It addresses the proposed amendments for REACH Annex XI (General rules for adaptation of the standard testing regime set out in Annexes VII to X). The update of Annex XI is necessary to address the high-level of non-compliant registration dossiers of chemicals on the EU market, which is often caused by the use of adaptations to the standard information requirements.

We welcome the opportunity to comment on the proposed legal text synopsis.

Comments

Reasoning for amendments of Annex XI

The introductory section ´Reasoning for amendments of Annex XI´ presents the Commissions' reasons for the proposed updates, namely a modernisation and clarification of the Annex regarding the aim of using adaptations, the use of new approach methodologies, the information required for compliance of an adaptation and introduction of the right for the European Chemicals Agency (ECHA) to request adaptations.

Within this description, we note a significant paradigm shift in the aim of using the general adaptations for standard test regimes. As stated in this section "The amendments aim to clarify also that adaptations can lead to the conclusion of both presence or absence of a hazard […]", The possibility to conclude also on the absence of hazard represents a departure from the current concept that the standard test regimes (and

not the adaptations) are usually needed to confirm negative results, e.g. of in vitro tests, owing to the more limited capabilities of tests in adaptions when compared to the standard tests defined in Annex VII-X.

We caution against portraying the general adaptation described in Annex XI as sufficient to conclude on the absence of hazards. All hazard identification and classification is based on available information on a substance. Therefore, the only viable conclusion can be that no hazards were identified or that the substance is not classifiable for the respective hazard class, based on the available/presented information. The experiences with many dossier evaluation decisions show that the information submitted by registrants as general adaptations to standard test regimes is often non-compliant with the legal provisions of REACH, i.e. incomplete or inadequate. Therefore, we fear further under-informed conclusions on the absence of hazards based on too little data, should the aim of Annex XI be modified according to the quoted Commissions descriptions in the introductory reasoning section.

General Rules for adaptation of the standard testing regimes set out in Annex VII to X

Commission proposal: The Commission proposes that ECHA may request adaptations of the standard testing regime in accordance with the general rules set out in Section 1 of this Annex in the preparation of dossier evaluation decisions.

NGO comments: We support the proposal in principle but have concerns about potential negative impacts of its implementation. While it may simplify and reduce burden in some cases, it may as well require repeated compliance checks in others, thereby increasing the burden for all stakeholders. Therefore, further consideration is needed on the implementation, and this proposal is only acceptable if the data requested by the adaptation is adequate for (self-)classification and risk management. Without such clarity, it risks delaying or weakening the identification of harmful chemicals and their risk management.

1. Testing according to standard information requirements is not scientifically necessary

Commission proposal: The Commission proposes to introduce a general text on the requirements for adaptations listed in sub-section 1.1 to 1.7. It also defines which information to include in an adaptation and proposes the development of a guidance document on the purposes to be met by a general adaptation, for each information requirement. The Commission proposes furthermore to delete throughout section 1 the requirement that data provided through adaptations should be "adequate for the purpose of classification and labelling and/or risk assessment."

NGO comments: We welcome the new introduction to section 1, outlining general requirements for adaptations to standard test requirements. However, as outlined above, we are critical of the proposal to include a provision on “the reasoned conclusion that a substance (..) has not a particular property.” We are generally opposed to allowing conclusions on the absence of hazards based on general adaptions of standard testing regimes. Information that is not sufficient to identify or classify a substance for a hazard,

should not automatically be regarded as sufficient to conclude on the absence of this hazard. The absence of evidence of effects is not evidence of absence of effects!

Furthermore, we do not agree with the introduction of the "margin of safety" as a new concept into REACH. For industrial chemicals significant uncertainties exist regarding uses and exposures, preventing the use of a "margin of safety" concept in REACH from our point of view. Additionally, we would like to highlight the Dutch comment during the meeting, pointing out that for certain hazard classes (e.g. genotoxicity) no margin of safety can be determined as there are no safe thresholds for these hazards. And for some ED mode of actions, a threshold for effects cannot be determined either. We agree with the Dutch proposal in the meeting to replace the "determination of a margin of safety" with "classification and risk assessment".

We **strongly oppose the deletion of the existing requirement that data generated through adaptations should be adequate for the purpose of classification & labelling or risk assessment throughout sections 1.1 - 1.7.** The adequacy for the purpose of classification and risk management is a key requirement, and therefore we ask the Commission to maintain this provision throughout the text or alternatively include it as an overarching requirement in a clear and legally robust way in the general introduction.

1.1. Use of existing data not generated according to test methods referred to in Article 13(3)

Commission proposal: The Commission proposes to add a reference to REACH Article 13(3), i.e. to the methods of the Test Methods Regulation, to the definition of "existing data". It also proposes to define what is expected for an "adequate and reliable documentation of the study".

NGO comments: We would like to ask the Commission for clarification of the consequences of adding the sentence on the tests not generated by the methods referred to in Article 13(3). During the meeting it was not clear to us whether, according to the Commissions' proposals, "existing data" should in the future continue to be limited to data generated before June 2008 or if all data generated by test methods outside of REACH Article 13(3) would be regarded as "existing data". We are also unsure how data generated before June 2008 but conducted according to a method corresponding to Article 13(3) would be considered under the newly proposed text. In our view only data generated before June 2008 can be considered "existing data" with regards to REACH, regardless of whether that data was generated according to a method corresponding to Article 13(3) or not. However, generally we support that data not generated according to methods corresponding to Article 13(3), for example academic data, is submitted in the registration dossier. REACH already stipulates that all available and relevant information should be used.

We support further clarification on what can be considered "adequate and reliable documentation of the study", but agree with France and the Netherlands that robust study summaries may not provide sufficient information to judge the adequacy and reliability of a study that was not conducted according to

standardised test guidelines. We support requiring robust study summaries, but in addition all relevant test information must be provided in these cases.

1.2. Weight of evidence

Commission proposal: The Commission proposes to highlight information from different methods that can be used in a weight of evidence assessment and clarify what must be included in the justification explaining why the sources of information together provide a conclusion on the information requirement.

NGO comments: We do not agree that two independent sources of information are enough to conclude on the absence of a hazard (see also comments above).

We support providing examples of methods that could be used to generate information that is incorporated into a weight of evidence assessment and agree with the Irish comment that this list should be denoted as "including but not limited to", to also allow for the ready inclusion of potential new methods in the future. Additionally, we agree with the Swedish proposal in the meeting, to include IATAs not in the legal text, but in an accompanying guidance document. To improve the coherence of the text and clarity on the requirements for the individual elements of the weight of evidence, we agree with the Dutch and French proposals from the meeting, to include references to sub-sections 1.3 and 1.4 to this sub-section and to change the order of subsections by moving section 1.2 to after section 1.6.

Finally, we propose to include further clarification on the documentation necessary for the data basis of weight of evidence adaptations, e.g. the documentation of a systematic literature search when scientific literature is included in the weight of evidence. This provision will improve the transparency on available (academic) data on a substance and thus reduce the burden of authorities in substance evaluations or the assessments of regulatory options.

1.3. Computational methods

Commission proposal: The Commission proposes to introduce a new sub-section on "other computational methods" i.e. computational methods apart from qualitative or quantitative structure-activity relationships (QSARs).

NGO comments: We agree with the use of relevant QSARs or other relevant, standardised, transparent and publicly freely available in silico (computational) methods as general adaptations to standard test regimes for hazard classification and risk assessment. We emphasize the importance of validation and full transparency for third parties. Without this level of openness, trust will remain limited, and it will continue to hinder regulatory uptake. Therefore, computational methods should be made fully accessible and documented accordingly.

1.4. In vitro methods (including cell-based and cell-free methods)

Commission proposal: The Commission proposes to delete the current text on in vitro methods and replace it with a new text, referring to OECD criteria for valid test methods and outlining aspects of an adequate

documentation of the test method and protocol. As part of this complete re-drafting of the section, they also propose to delete the current requirement to conduct the relevant standard requirement test in case of a negative (in vitro) result.

NGO comment: We have concerns for this section specifically because in vitro tests may have limitations for example with regards to metabolic capacity or transient periods of high susceptibility and vulnerability in the development of an organism. Therefore, we continue to support the identification of dangerous properties with in vitro tests, but we strongly oppose to draw a firm conclusion on the absence of such a property (see also our comments above e.g. section 1). Additionally, we would like to point out that currently the classification of hazards based solely on in vitro data is only possible for very specific hazard classes (e.g. genotoxicity). If Annex XI of REACH is updated according to the Commissions' proposal, enabling the conclusion on the "absence" of a hazard, based on in vitro tests, than a positive result in an in vitro test should always lead to classification, and would require also an update of the CLP classification criteria to equally enable the classification of hazards based on in vitro data alone.

We would also like to re-iterate our comments from the above section on in silico (computational) methods also for this section. A high transparency of the method needs to be ensured, so that its reliability and relevance can be assessed by the authorities and other interested parties. Dependency on untransparent and possibly insensitive methods needs to be avoided in the efforts to expand the use of in vitro methods as general adaptations to standard information regimes.

1.5. Grouping of substances and read-across approach

Commission proposal: The Commission proposes to clarify how the structural similarity and reliable prediction of similar properties must be demonstrated by registrants. Further clarification is proposed for the adequate and reliable documentation of the selected group and the resulting prediction.

NGO comment: We strongly support the Commissions' proposals for the clarification on group-selection, prediction and documentation of a read-across adaptation.

1.6. Available human information

Commission proposal: The Commission proposes to move this sub-section from the section on existing data (1.1) to a new sub-section 1.6.

NGO comment: We support the Commissions' proposals for the move of this sub-section to account for the fact that also relevant human information that was generated after June 2008 can be used as a general adaptation.

1.7. Defined Approaches

Commission proposal: The Commission proposes to introduce a new sub-section on defined approaches.

NGO comment: We would advise to reconsider this section, as we do not consider defined approaches that are merely described according to OECD Guidance No. 225 criteria to be sufficient to conclude on the

absence of a certain property. As outlined above, we would welcome further guidance on the use of IATAs and defined approaches in a guidance document but not (yet) in the legal text.

2. Testing is technically not possible

Commission proposal: The Commission proposes to include the obligation for the registrant to justify why testing is not technically possible.

NGO comment: We agree with this proposal by the Commission.

3. Substance-tailored exposure-driven testing *[no changes proposed]*

We understand that the Commission does not propose any changes to this section, however we would like to highlight that adaptations which are based on exposure considerations often possess shortcomings, due to the general poor information on the exposure and uses in the registration dossiers, not covering adequately all uses during the life cycle of the substance.

Conclusions and further recommendations

The standard information requirements for REACH registration dossiers are key to the identification of hazardous chemicals under the REACH and CLP regulation. Therefore, changes in the information requirements in REACH (incl. changes in Annex XI) need to be well calibrated to the classification criteria in the CLP regulation, to ensure the availability of data sufficient for classification purposes.

As implied by the name, the standard testing regimes described in Annex VII-X of REACH, should be the default methods for generating data and concluding on the properties of registered substances. When suitable, validated and standardised non-animal methods are available for the individual properties, these should be incorporated into the standard testing regimes, following due legislative procedures. Simultaneously, the harmonisation between the CLP classification criteria and REACH information requirements needs to be ensured at all times. This procedure would improve the clarity and legal certainty for registrants and authorities on the acceptability of new methods, compared to their advancement via Annex XI and general adaptations to standard test requirements.

We also note the need for an overall EU Test method and validation strategy to ensure prioritisation, development and validation of tests that provide relevant information for classification under the CLP regulation, and SVHC identification and restriction under the REACH regulation.