Action 9: Smoothen the registration process

The Issue?

Data requirements are too often treated as a tick-box exercise

REACH requires companies to register their chemicals with the European Chemicals Agency (ECHA) before placing them on the EU market. A standard information set is required to assess the chemicals, understanding their physical-chemical, toxicological and environmental properties. The dossier then goes through several steps of validation and checks with ECHA. Once a substance is registered, companies must ensure that the information is kept up to date, reflecting the latest amendments to REACH, dossier and substance evaluation decisions, emerging knowledge on the registered chemicals, etc.

Concerning the registration phase, when REACH was implemented, it was expected that the information requirements would be linked to exposure potential, promoting exposure-based testing. Depending on the likelihood of human and environmental exposure to such chemicals, the required tests would differ. For chemicals with low exposure, animal testing should not be required.

This was intended to be implemented in REACH through three key mechanisms:

- **Tonnage-based information requirements:** the more chemicals (in tons) placed on the market, the higher the assumed level of exposure, since tonnage is used as a proxy for exposure potential. This also implies more testing. However, a higher tonnage of chemicals on the market does not necessarily translate to a higher exposure; it depends on the chemical's uses.
- **Endpoint-specific adaptations in Column 2 (Annexes VII-X):** According to its Annexes, REACH allows companies to omit additional animal testing if sufficient data or studies are available (so called "adaptations"). This also applies to the most complex data required under REACH such as repeated dose, reproductive and developmental data. Despite this process, there have been cases where these adaptations were not accepted, leading to more animal testing.
- **Annex XI Section 3 exposure-driven adaptations:** REACH allows some or all information requirements to be adapted, i.e. by using information from other registration dossiers or "read-across", scientific literature and existing testing, etc. These adaptations can also include implementation of strictly-controlled conditions or risk-based exposure, if certain provisions are met. However, such adaptations are not often accepted, leading to additional resources and contradicting the legal obligation (REACH Art. 25) to perform animal testing only as "a last resort".

Updates are complicated by IT challenges

Keeping registration dossiers up to date is a complex, costly and time-consuming process for industry. ECHA uses a specialised IT software (IUCLID) to store and manage dossiers. Several inefficiencies have been observed:

- **Frequent, time-consuming updates:** To ensure the submitted information meets regulatory requirements, ECHA conducts a Technical Completeness Check (TCC). This step verifies that all necessary data is included in the dossier. Companies must manage and submit this information using IUCLID. However, IUCLID is updated twice per year to reflect changes in test methods, regulations, and software formats. Since companies have a legal obligation to update registration

dossiers[1], such obligation also applies to revising the dossier to align it with ECHA IT software updates. If this is not done, the dossier cannot pass the TCC and cannot proceed to the next validation step with ECHA. In addition, compatibility issues between ECHA's IT software and companies' IT systems further slowdown the process.

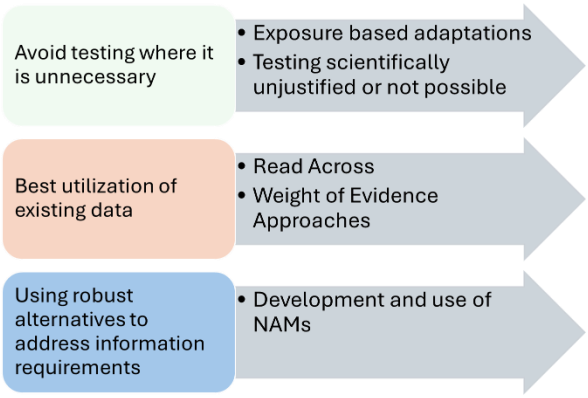
- **Complexity and timing of updates:** Dossiers are updated for various reasons, triggered at different times, leading to a fragmented and cumbersome process. For instance, updates are required due to regulatory changes (like updates in Annexes, new classifications or restrictions), voluntary updates, results from compliance checks (Article 41(4) REACH) and substance evaluations (Article 46(2) REACH).
- **Moving target to keep dossiers up to date:** maintaining dossiers up to date with current REACH requirements becomes a moving target due to continuous updates to the REACH regulation, implementing legislation/test guidelines and IUCLID software. This creates uncertainty and inefficiency, as companies must constantly adjust their dossiers to meet new information and formatting requirements; in many cases, the time and resources spent adhering to the formatting requirements exceed the time spent updating the data itself.

The Solution

Tailored data requirements

1. Improved exposure-based testing:

- To meet REACH's core goal of reducing animal testing, exposure considerations should be one of the pillars of testing. By using real-world exposure data, companies can better target their testing, and limit testing when it adds value to the risk assessment.



- In conjunction with read-across, weight-of-evidence approaches, and New Approach Methodologies (NAMs) (for the latter, see factsheet on Action 8), exposure-based considerations or "adaptations" can further reduce the need for unnecessary animal testing. These approaches should not be seen as undermining REACH risk assessment demands but as tools to effectively address information requirements.

[1] Article 22 REACH: *Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency (ECHA).* on 12 October 2020, the European Commission published an Implementing Regulation (EU) 2020/1435 in the Official Journal of the European Union, which clarifies the meaning of "*without undue delay*" related to registration updates under the REACH Regulation. The Implementing Regulation included deadlines for different scenarios, which triggered the need for the registrant to update their dossiers. Further clarification of timelines is provided in this Guidance: https://cefic.org/guidance/reach-implementation/deadlines-for-updating-reach-registration-dossiers/

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2. **Best utilisation of existing data:**

- Avoid unnecessary animal testing by using existing relevant and reliable data (*e.g.* using read-across, weight-of-evidence, in vitro/QSARs, etc.) and more efficient methods like NAMs to address information requirements.
- Exposure-based adaptations: These adaptations should be utilised more effectively. Where data will not add meaningful value to the risk assessment, these adaptations should be applied to prevent unnecessary testing.

3. **Revisions to Annex XI for Exposure-Based Adaptations:** The current text for Annex XI section 3.2 should be revised to make the process more flexible and aligned with actual risk. Specifically:

- Exposure assessments should consider all relevant uses throughout a substance's lifecycle and should not be limited to unrealistic expectations of "no exposure" under strictly controlled conditions.
- Allow studies that do not require animal testing and other existing studies to be used when exposure is controlled and low. This will prevent unnecessary requirements that do not add value to the risk assessment.
- Risk management considerations: It would be important to clarify the definition of "*exposure is well below*" in Annex XI Sec 3.2 (iii). When assessing risk, it should be sufficient for exposure to be within safe exposure limits as long as realistic and implementable risk management measures are used[2].

4. **Harmonisation of Column 2[3] Adaptations:**

- To improve the consistency and effectiveness of REACH, the Column 2 adaptations for repeated dose toxicity and reproductive toxicity should be harmonised and applied consistently across different data requirements. Concepts like low bioavailability and low toxicity should be better defined to enable more consistent and broader application. In general, a toxicity study should not be required if:
  - The substance is not significantly absorbed in the body through normal human exposure routes.
  - The substance has little to no toxic effects.
  - The substance does not build up in the body over time.
- Furthermore, we propose revisiting the environmental adaptations in Column 2 of Annexes VIII-X, especially for long-term aquatic toxicity and degradation testing. Under this revision, studies should not be required if:
  - The substance poses a low risk (shown by a Risk Characterisation Ratio (RCR) below 1), and it is not likely to build up in the environment or accumulate in living organisms.
  - The substance is already identified as a high concern due to certain hazards, Persistent, Bioaccumulative, or Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB), meaning that further testing is unnecessary.

[2] BoA-005-2014, notes that, due to existing risk management measures and the derived no-effect level (DNEL) for systemic liver toxicity, the risk of reproductive toxicity appears to be low or non-existent. The Board of Appeal found that the Agency had not provided sufficient evidence that a risk existed that needed clarification. Furthermore, it concluded that the requested information would not improve the risk management measures, as the current ones were deemed adequate to protect workers. The decision also mentions that a perceived data gap alone does not justify further information request.

[3] Column 2 of the REACH legal text allows for the adaptation of specific data requirements where some specific criteria are met. For the repeated dose, reproductive and developmental endpoints there are specific column 2 adaptations, and although they rely on the same overall approach whereby there should be low toxicity coupled with low exposure, there are some differences depending on the endpoint. It is proposed to revise the wording of these adaptations to improve how these can be used and to further refine the use of experimental animals in (eco)toxicity studies.

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- Additionally, we call for clearer rules for when companies can be exempted from bioaccumulation tests, using the knowledge and data gathered over the past 15 years[4]. Aligning this with existing EU rules would help prevent unnecessary testing, reduce costs, and ensure resources are focused on what truly matters for environmental protection.

Reduce unnecessary workload when updating registration dossiers

1. Provide a targeted update option for fast amendments of dossiers

- To reduce the extra workload of updating registration dossiers, we propose introducing a targeted update option. This would allow companies to amend specific data in IUCLID without triggering a rejection due to the Technical Completeness Check step (TCC). This approach would facilitate faster data submission, help companies meet deadlines, and provide authorities with earlier access to updated data, enabling more focused and timely regulatory action.

  This option could be particularly beneficial for the following scenarios:

  - Updates triggered by REACH Article 22 (e.g., new harmonised classifications, new identified uses, changes to the chemical safety report, including those resulting from new restrictions or authorisation requirements).
  - Updates during compliance check: companies have 30 days to comment and submit information after receiving a draft decision from ECHA. Moreover, the Agency asks registrants to provide such information by updating the IUCLID dossier.
  - Voluntary updates: allowing companies to submit useful data, e.g. to assist authorities with prioritisation or regulatory measures at short notice.
  - Updates following a dossier or substance evaluation decision with a limited scope.

2. Support pooling of updates

- REACH Annexes continuously evolve, with nearly 80 amendments enacted since its adoption. While deadlines are set for ECHA decisions, a more efficient approach is needed to streamline updates. So far, pooling is only foreseen for some specific update cases according to REACH Art. 22 (e.g. if a company needs to update its dossier due to a new classification requirement and also has to include new data, pooling would allow both updates to be submitted together rather than in separate submissions, see bullet point 7 in the background document). Pooling updates, where multiple amendments are grouped, would allow resources to be better allocated to more critical changes, making the process more efficient for both ECHA and the industry.
- The same approach should be applied to IUCLID software updates—less frequent, more substantial updates would increase resource efficiency and allow adequate time for testing and bug fixing. To support this, we propose the following:
- Longer transitional periods for updates of registrations due to technical adaptations in REACH or new implementing legislation. This would facilitate the pooling of updates required for the same dossier by companies, and ECHA's checks would be more efficient.
- Uniform transitional arrangements for all members of a joint submission, including new (potential) registrants.

[4] Gimeno et al. 2024 https://doi.org/10.1016/j.yrtph.2023.105556; Constantine et al. 2024 https://doi.org/10.1016/j.yrtph.2024.105651

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- More substantial and less frequent IUCLID updates: All software updates should be sufficiently tested with all bugs fixed before being released. During transitional periods, updated fields should trigger quality warnings but still allow dossiers to pass the TCC. This would reduce disruptions for ongoing updates.

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Annex

Background

- Animal testing: for the sake of simplicity, this factsheet and factsheet on Action 10 refer to "animal" testing, although this precisely refers to vertebrate testing. Vertebrates are animals that have a backbone or spinal cord (e.g. fish, reptiles, birds, mammals). Animals is a much broader terminology and also includes invertebrates – animals lacking a backbone or spinal cord, such as for instance, insects.
- In-vitro testing: these refer to experiments conducted outside living organisms, usually in a controlled environment such as a test tube or a Petri dish.
- Read-across: it is one of the most commonly used alternative approaches for filling data gaps in registration dossiers submitted under REACH. It allows (for companies) to use the same information already available for one set of substance(s) and apply it to another set of substance(s) that are similar (for instance, structurally). This method can reduce unnecessary animal testing. Registrants must justify the use of read-across and ensure that their approach falls within the conditions set out in Annex XI, section 1.5 of the REACH regulation.
- Weight-of-evidence: means using a combination of information from several independent sources to provide sufficient evidence in fulfilling a certain information requirement. The weight given to the available evidence depends on factors such as the quality of the data, consistency of results, nature and severity of effects and relevance of the information. This approach requires scientific judgment and adequate documentation to support the justification.
- QSAR: these are specific mathematical models that predict the properties of a substance based on its chemical structure. They help to reduce unnecessary animal testing.
- The ECETOC TR 137 report provides further information on what could be done to define and substantiate these points, and one can also consider how reliable and relevant NAMs could contribute in the future.
- For any update related to article 22 (1) points (a) to (f) and (i) of the REACH Regulation, whereby the registrant needs to modify GSU or CSR in endpoints 11 or 13.1 of the IUCLID dossier, an extended deadline to 12 months for submitting both updates apply after the registrant received the final test report needed to conduct the IUCLID dossier update. In the case where the registrant would need to undertake several combined updates linked to those identified in article 22 (1) points (a) to (i) of the REACH Regulation, they will be able to update the dossier using the longest of the deadlines as applicable on the respective updates. The deadline is to be counted from the date when the first need to update the registration has been identified.

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