How will the revision of REACH affect the Regulation's information requirements?

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Aleš Bartl, counsel in international law firm Keller and Heckman's Brussels office, looks at new elements, adaptations, impacts, cost sharing and the role of consortia in the proposal

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Based on the available information, the European Commission's work on a proposal to revise REACH – originally announced for the end of this year, but not likely to be published before spring 2023 – will substantially reinforce the Regulation's information requirements, in line with its chemicals strategy for sustainability (CSS).

This article will outline the main elements of the extended data requirements and the implications for data and cost sharing. We believe that neither the registrants – nor the Regulation itself – appear fully fit to address future data requirements and post-registration cost-sharing disputes. We will therefore provide some thoughts on how to improve REACH and give registrants advice on how to prepare and avoid falling short. We will also outline the impact that the availability of more data will have on further scrutiny of chemicals.

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New data requirements likely to be part of revised REACH

This discussion is mainly based on documents circulated by the Competent Authorities for REACH and CLP (Caracal). They do not constitute an official Commission proposal so may be subject to change.

Polymer registration

Only monomers in polymers are currently subject to REACH registration. When the Regulation was drafted, industry made a concession on monomers – that they would not benefit from reduced intermediate data requirements – as a trade-off for polymers not requiring registration. This is set to change.

The REACH revision will contain polymers requiring registration (PRRs). The latest proposal for PRR criteria can be found in a Caracal document from 1 April. PRRs will include:

- all fluorinated polymers;
- certain cationic polymers;
- polymers meeting specific molecular weight criterion;
- polymers with certain hazard classifications;
- certain polymers presenting surface activity; and
- polymers suspected to degrade into substances of concern.

Polyesters made from an EU-list of monomers – drawn up by the Commission – containing only 'low hazard' monomers will not be considered PRRs.

The extent of the data requirements for polymers is still unclear, in particular whether certain REACH endpoints can be waived considering the specific nature of their risks.

It is estimated that some 11,000 'unique polymers' will be subject to registration. That is why the Commission itself has conceded that grouping will be essential to reduce animal testing and manage the workload. An Echa proposal has suggested grouping according to the starting materials, where they have contributed at least 2% of the polymerised part of a polymer.

Importantly, developing and justifying the grouping strategy will require high levels of cooperation between registrants. This will probably entail the creation of new consortia for polymer groups to facilitate data exchange, read-across, and manage the grouping justification. Current monomer consortia may not work because of lack of overlap with the polymers.

New endpoints (endocrine disruption, immunotoxicants and neurotoxicants, PMT/vPvM)

The proposed REACH revision will consider requiring data on the following endpoints:

i. Endocrine disrupting chemicals (EDCs)

As far as animal testing is concerned, the Commission has proposed a tiered strategy involving a screening stage. Under this only a positive result in *in vitro* testing for Annex VII REACH will act as a trigger for *in vivo* studies.

In addition, on 20 September the Commission began a four-week public consultation on a draft delegated Regulation amending CLP. This includes adding endocrine disruption as a new hazard class (category 1A, 1B and 2), based mainly on a weight-of-evidence approach. This proposed new classification needs to be considered in conjunction with the proposed revision of the REACH requirements. The logic seems to be that the registrants will first generate endocrine disruption data under REACH. And this will then be used in the weight-of-evidence assessment for CLP purposes. This will inevitably lead to the classification of many substances as EDCs.

ii. Immunotoxicants and neurotoxicants

The Commission has announced its intention to extend the generic approach to restrictions to chemicals affecting the immune, neurological or respiratory systems, which could entail new hazard information requirements. While the content of these is still unknown, the Commission has mandated Echa to define them. In parallel, the EU executive has said that it will also assess the need for specific criteria for immunotoxicity and neurotoxicity under CLP, although these are not mentioned in the amendment of the Regulation.

iii. Persistent, mobile and toxic (PMT) very persistent and very mobile substances (vPvM)

The amendment of CLP is also going to introduce the new hazard classes of PMT and vPvM. Although data on the mobile element will probably not be required under REACH, registrants may have to generate some data anyway, to fulfil their CLP obligations.

Generic extension of data requirements for the 1-10 tonnes band

The Commission has also said that it intends to merge Annexes VII and VIII of REACH. Consequently, data requirements for the lowest tonnage band of 1-10 tonnes will be the same as for the 10-100 tonnes band. For substances that are only registered in the 1-10t band, this will involve:

- conducting additional costly vertebrate studies;
- providing further data on nanoforms; and
- carrying out a chemical safety assessment, including producing a chemical safety report (CSR).

Information on the environmental footprint of chemicals

The Commission has still not said whether this requirement will only include the manufacturing stage, or the entire lifecycle of chemicals (including in articles). It is also unclear whether this will be a REACH data requirement, or just a harmonised template that customers/consumers provide on request.

In our view, it will be difficult for the Commission to formulate this as a mandatory REACH requirement, because of the complexity of chemical supply chains and factors that the registrants cannot influence (energy sources, regional and natural aspects etc). All this makes it complicated to set out quantifiable, comparable and non-discriminatory data requirements. In addition, such data gathering would also require significant input from downstream users that may involve sensitive business information and competition law concerns.

Adaptations to testing

NAMs as a new adaptation

In order to make animal testing more efficient, the EU is also envisaging complementing the current adaptations to animal testing, in particular by introducing new approach methodologies (NAMs). NAMs will include various testing methods such as:

- *in silico* and *in chemico* approaches;
- new testing tools; and
- some 'conventional' methods that aim to improve understanding of toxic effects.

The Commission has presented five options for the REACH revision regarding NAMs. These differ mainly in terms of their role. They will either only be used as an additional Annex XI REACH adaptation to avoid animal testing (basically, as a screening tool), or they will serve as an additional data requirement to improve the existing data, or both. For example, under one of the options (Option 1B), presented as the most "extreme" by the Commission, NAMs would be a complement to existing sources of information instead of an adaptation: they would be used for ADME (absorption, distribution, metabolism and excretion) studies and critical hazards (including endocrine disruption, immune toxicity, respiratory sensitisation, neurotoxicity, bioaccumulation in aquatic species). They would additionally be used to support grouping. In our view, NAMs will probably serve both purposes.

Existing adaptations to animal testing

Based on publicly available documents, the Commission has not been discussing possible changes to the rather restrictive approach that Echa takes on existing adaptation techniques (Annex XI REACH), such as:

- read-across; or
- non-animal testing alternatives such as Qsar or *in vitro* and *in silico* methodologies.

However, this appears necessary given the expected scale of new animal testing, in particular with respect to polymer registration. In our view, the EU could consider establishing an *ad-hoc* working group (EU bodies/industry/independent experts/academia) to review the Echa read-across assessment framework (RAAF) to make read-across more workable where scientifically justified.

Cost sharing

The new requirements will generate significant costs. These should be shared equally by all registrants in the respective tonnage bands. However, it may be difficult to get an equal share from all registrants. Problems can be expected, for example, regarding some purchasers of letters of access that joined the registration later and some only representatives that represent non-EU manufacturers.

To put things into context: where a new registrant wants to join a registration, the lead registrant has important leverage power as prospective registrants need a registration token. This leverage does not exist where a registrant has already registered a substance, and this can be particularly difficult for lead registrants.

Are registrants ready?

To make things worse, based on our experience, purchasers of letters of access were often not required to sign respective cost- and data-sharing agreements which will make enforcement more difficult. In addition, many consortia and former substance information exchange fora (Siefs) have still not amended their data- and cost-sharing agreements to reflect Commission implementing Regulation (EU) 2016/9, in particular as regards cost sharing related to future data requirements. In fact, many of the existing consortia are 'dormant' and not ready for what many call 'second REACH'. Thus, as a first step, registrants should review their contractual framework to see if it is fit to enforce future data requirements. In addition, as stated above, future registrants of polymers should get together to discuss grouping and form new consortia if warranted.

Is REACH ready? How can it be improved?

REACH includes provisions on data-sharing disputes. However, its procedures are only applicable to new registrants joining the registration. It does not set out a framework for post-registration cost- and data-sharing

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disputes where new data needs to be generated. Based on Article 53(4) REACH, the only possibility is a lawsuit filed in the courts of the state of residence of the registrant (under the international procedural laws, the competent courts are those of the defendant). Alternatively, many Sief/consortia agreements include arbitration clauses that would apply (but only where a registrant has signed such an agreement). This may not be a viable option for many lead registrants.

Thus, as part of the revision of REACH, the Commission could consider introducing the framework for EU-bodies to manage post-registration data and handle cost-sharing disputes. This would be either for Echa or an *ad-hoc* EU body. The decisions would be directly enforceable in the member states so that national courts do not have to re-examine the case.

Given issues around workability and workload for this EU option, as a minimum, the Commission may want to introduce a harmonised framework for data- and cost-sharing disputes in member states. For example, requiring member states to set up REACH chambers within national courts, providing guidance documents and templates facilitating the filing of lawsuits in each EU jurisdiction and cross-border enforcement.

An additional useful tool to put pressure on the defaulting registrants would be to specifically empower Echa to revoke registration numbers in cases of a non-compliant dossier. This has been debated for years, with the Commission pushing back saying there is no basis in REACH for it. However, one of the CSS's goals is to introduce *'revoking the registration numbers in case of non-compliance'*. Thus, it is rather likely that it will be introduced in REACH. In our view, it could possibly be coupled with a tool for lead registrants to inform Echa of incomplete individual registrations.

What are the ways registrants can obstruct cost sharing?

Registrants may simply not pay when requested to do so, compelling a lead registrant to go to national courts or seek arbitration. Alternatively, registrants may attempt to opt out from a joint registration. However, this does not seem a viable approach.

Firstly, by the implementing Regulation (EU) 2016/9, the Commission made it clear that even if a registrant opts out, it is still part of the same registration and therefore subject to the same dossier and substance evaluation decisions as any other registrants. Thus opted-out registrants would have to have their own robust data (or solid waivers). This is not likely: if they have relevant animal tests available, they would be obliged to share them with other registrants (Article 30(1) REACH). If they have a viable waiver, this could typically be used by other registrants as well and testing would not be necessary at all. In this respect, it is worth noting that Echa should normally prioritise opted-out dossiers for compliance checks (see Article 41(5)(a) REACH).

Secondly, we are of the view that any attempts to opt out from the joint data requirements to escape cost sharing would breach Article 11(3) REACH laying down the reasons for which a registrant can opt out from a joint submission (data too costly, disagreement on data selection). This will typically not be invokable in case of future data requirements (unless, again a registrant has solid data available).

Importance of newly generated data in further scrutiny of chemicals

More data means a greater likelihood that substances will be classified in the critical hazard classes (and in particular in the new endpoints outlined above), which risks inclusion in the candidate list of substances of very high concern. This would be in line with the Commission's goal to have thousands of SVHCs on the list, rather than hundreds as is the case now. In addition, under the proposed revised REACH rules, one of the options is to consider all SVHCs for restrictions, with no derogations available other than for 'essential uses'.

Note on UK REACH

The UK government has still not taken a position on whether UK REACH will copy any revisions of the EU Regulation. However, it is quite likely, at least as far as data requirements are concerned. Otherwise, the UK version would provide a poorer dataset than the EU's. Also, most of the UK registrants do business in the EU so they will need to have access to the data anyway.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch

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FURTHER INFORMATION

8th Meeting: REACH and CLP competent authorities sub-group on polymers, 1 April 2022 →

Revised proposals for update of the REACH Annexes in relation to endocrine disruption properties, CASG-ED/2021/03 →

Draft Delegated Regulation →

Revision of EU legislation on REACH, Inception Impact Assessment, Ares(2021)2962933 - 04/05/2021 →

European Commission, Note for the attention of Mr Bjorn Hansen, grow.f.1(2021)2092268 →

Caracal CA/09/2022 →

Echa advice on using read-across for UVCB substances, May 2022 →

Chemicals Strategy for Sustainability, Echa →