

Note for the DCG / Sherpa's:

Pragmatic approach for access to data and to the joint submission for 2018 SME registrants

Purpose of the paper

SMEs experience substantial difficulties when facing the 2018 registration deadline for the registration of their substances. The data sharing obligation and related issues, namely the access to the joint submission and related costs, stand out as an important factor herein.

This paper describes a proposal for a pragmatic way forward to allow SMEs with limited resources that aim to register by the 2018 deadline to access data and the joint submission with minimum efforts.

Background

Cost sharing has been repeatedly identified as one of the main difficulties that SMEs experience when facing registration obligations. This has been recently confirmed by a study procured by ECHA: 'Segmentation of potential SME Market for ECHA Cloud Services for REACH Registration'. This study's preliminary conclusions include that SMEs face an important barrier to compliance when it comes to the cost of data in the context of the 2018 registration deadline for their substances.

In addition, feedback from individual companies and industry associations, as well as experience gained through the dispute process and other processes, have made ECHA aware of a number of specific problems that SMEs face with regard to data sharing and access to the joint submission:

- Costs of data / studies are too high: SMEs cannot afford the price of the LoA as it is disproportionate compared to the benefits of the manufacture/import of the substance. This puts in question the entire registration as the company may opt to cease activities regarding this substance,;
- Lacking experience in negotiation: cost sharing discussions can potentially re-adjust the LoA price, however, both in situations where only SMEs are involved, as well as when faced with larger companies, regulatory experience as well as experience with data sharing negotiations is low, and limited resources do not always allow to contract e.g. external consultants to conduct negotiations on their behalf;
- Finding it difficult to start a dispute with ECHA: while the dispute procedure has been set up as an easily-accessible process, awareness of this option remains rather low, and companies hesitate to make use of it without external support. In addition, the uncertain outcome and timeline of this procedure may further discourage companies from using it;
- Revision of ECHA's "OSOR"-implementation: Since 2016, the IT-implementation of the joint submission obligation prevents companies from submitting outside existing joint submissions. While the obligation to form a joint submission with their co-registrants is enshrined in the REACH-text, companies historically used ECHA's previous IT-implementation to submit individual registrations outside existing joint submissions. While this was in breach of the joint submission obligation, it allowed them to circumvent the dispute procedure in case of a standstill / disagreement in the negotiations on data sharing and access to the joint submission;

Available support from ECHA

ECHA has developed a lot of materials to support companies in data and cost sharing discussions, including many with a pragmatic “hands-on” approach especially targeted to SMEs. However, small companies remain unaware or seem only to make use of these materials when explicitly being informed. Further, ECHA’s role is limited to a supporting or advisory capacity, ultimately the negotiations and the way towards a data and cost sharing agreement are not ECHA’s competence. The ECHA SME Ambassador’s good offices can only offer active support in a limited number of cases.

Proposal for a pragmatic way forward

Industry and industry associations can help alleviate the difficulties for SMEs in two ways:

1. Reducing the burden of data sharing negotiations by making in certain cases data and access to the joint submission available for free to SMEs;
2. Playing an active role in the dissemination of information on data and cost sharing;

Ad 1.

A major contribution could be made by industry if the letter of access giving access to the data and the token to join the joint submission would be made available for SMEs for free in certain cases. This could be done in the situation where a registration already exists and data is submitted to ECHA. This approach would:

- Avoid any negotiation between parties, and hence save costs on both sides;
- Avoid the necessity to develop a full breakdown of the costs and proof of study costs (if not already available);
- Avoid the necessity to have a reimbursement mechanism in place;
- Reduce uncertainty on the decision to register for SMEs;
- Generate less revenues, but for already completed registrations these are sunk costs.

Making the data available for free could be done against a few conditions:

- The new registrant presents a self-declaration that it complies with the definition of an SME;
- The SME agrees with the classification in the lead dossier and the SDS, and therefore to implement and communicate the corresponding risk management measures;
- The SMEs agree to waive their right to request a detailed cost itemisation and a reimbursement scheme;
- The SME should be in a position to confirm that they have the same substance and that it does not possess any additional information relevant for the registration dossier.
- The access to free data only applies to existing data for the 2018 deadline, and is without prejudice to sharing costs for new data e.g. after substance evaluation.

Discussions can still be held on cost sharing for potential future updates.

Ad2.

It is important to ensure that SMEs have an easy access to all available support material and if necessary to the dispute mechanism. In order to achieve that, all parties should engage into as

many channels as possible to disseminate information on data and cost sharing. As SMEs get in contact with the existing registrants and their consortia /associations, these could play a role in informing the SME wanting access on the available information. This means to either proactively prepare easily understandable and easily accessible cost itemisations, which allow smaller companies to understand and assess the requested price; or, in line with the approach proposed in this paper, proactively approach potential SME registrants and inform them about the possibility to access the joint submission and the jointly submitted data for free.

For all measures to be effective, it is important that the requirements towards SMEs are as simple as possible and communicated to the SMEs upfront. ECHA, namely via its SME Ambassador and through the work in the DCG, can play an active role in promoting this as best-practice.

Proposal

It is proposed that the DCG endorses this proposal which is published as a DCG solution. All parties should then promote this voluntary approach (and spread existing information on negotiations and dispute procedure) among existing or future registrants that may be interacting or about to interact with SMEs in the context of their SIEFs.