Directors' Contact Group

DCG3/Recommendation/final/2017
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DCG Recommendation to help small volume and SME registrants in registering for the 2018 REACH registration deadline

The Directors' Contact Group (DCG) is concerned that the cost burden on SMEs for accessing data and for jointly submitting their registration dossiers is creating risks to the successful conduct of the REACH 2018 registration exercise to which all DCG members are strongly committed. For considerations of affordability, numerous SMEs are still undecided whether to register their substances. Fewer registrations of phase-in substances could ultimately lead to interruptions of crucial supply chains as well as to unintended market distortions. In many cases, small volume registrants will also be SMEs, which represent a majority of potential "new" (i.e., first-time) registrants for the 2018 deadline.

The DCG acknowledges that registrants and downstream users have already dedicated significant resources to their compliance with the REACH Regulation. Related investments into data, assessments and qualified personnel remain essential to the success of REACH and will continue to be necessary for phase-in substances also beyond the registration deadline of 31 May 2018. The DCG also recognises that awareness of the REACH Annex III criteria does not appear sufficiently widespread throughout all SIEFs.

In view of all challenges ahead, the DCG deems it to be in the best interest of all members of established SIEFs to reduce time and effort invested into SIEF-related negotiations, whilst nonetheless observing the principles of fair, transparent and non-discriminatory data sharing, as further clarified in the Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing[1].

In due consideration of these concerns and aspects, with less than six months still available until the third phase registration deadline of 31 May 2018, the DCG herewith issues the following

RECOMMENDATION

and invites Lead Registrants, SIEF managers as well as members of consortia and SIEFs to adopt them into their practices, to the largest extent feasible in their respective situations, as their contribution to the collective task of establishing the European Union chemical regulatory regime.

The DCG recommends the following actions which can be helpful to potential "new" small volume and SME registrants:

a) Reducing the costs for 1-10 tonne small volume registrants for acquiring data in joint submissions by thoroughly exploring data waiving arguments

Small volume (SME) registrants in the 1-10 tonnes per annum range should thoroughly check Article 12 (1) (a) and (b) of the REACH Regulation together with the criteria enumerated in its Annex III. If their substance is not likely to be i) carcinogenic, mutagenic or toxic to reproduction Category 1A / 1B nor likely to be ii) in wide dispersive use while already not likely to meet the

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&qid=1453380621080&from=EN

classification criteria for health or environmental hazards, then registrants are entitled to claim exemptions from complying with (eco)toxicological data requirements. Under those criteria, they only need to provide physicochemical data. Some further information is available on the ECHA webpage (https://echa.europa.eu/information-on-chemicals/annex-iii-inventory). Wherever data requirements can be waived on this basis, this can very usefully translate into reduced or exemption from data-sharing costs.

b) Addressing situations arising from late data-sharing negotiations or pending data-sharing disputes

Many SIEFs have already been in operation for around ten years and have been successful in submitting joint registrations in time for the previous two registration waves of 2010 and 2013, respectively. Their well-established management mechanisms and contractual arrangements will therefore be able to provide a stable framework for conducting and concluding most data-sharing discussions well ahead of the end of the phase-in registration period.

“New” registrants for the 2018 REACH registration deadline may find themselves in a situation in which they need to enter into data-sharing negotiations at a time already close to the deadline, or they may be party to a data-sharing dispute still pending with ECHA on the date of the deadline.

However, in those cases in which a conflict may still develop so that negotiations come to a standstill, the DCG recommends that respective parties file – as a last resort – a data-sharing dispute with ECHA. ECHA will assess the parties’ effort to come to an agreement, based on the evidence they provide. After filing a dispute, parties are nonetheless expected to continue negotiations and withdraw the dispute if an agreement is reached. Whilst these negotiations and/or the dispute settlement process are ongoing, companies are still able to submit a registration dossier, however their submission may be rejected subject to ECHA’s decision on the dispute and/or the completeness of the dossier.

The DCG notes that ECHA is further elaborating the details on how disputes pending at the deadline will be handled, which ECHA will publish on its webpage by the end of January 2018 (https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes).

c) Reducing the burden on SME registrants by agreeing on paying the costs of data instalments

In cases in which a potential “new” registrant convincingly claims that the one-time payment of the cost of a Letter of Access (LoA) imposes an unaffordable financial burden on the company, Lead Registrants and SIEF managers are recommended to consider granting the opportunity of staged payments (payments in instalments) to facilitate the acceding company’s registration.

To limit an increase in administrative effort, a single invoice may be issued for the full LoA with the agreed staged payments’ dates specified in the body of that invoice.

In case the company benefiting from such staged payment fails, upon notice, to pay any instalment by one of the agreed dates, the entire then outstanding amount should fall due. Lead registrants, data holders or SIEFs granting such instalments may in advance seek security through a bank guarantee provided by the beneficiary company.

d) Alternatively, reducing the burden on small-volume registrants in the 1-10 tonne range by charging a low-cost affordable lump sum payment

Various parties undertaking joint submissions are known to have adopted the practice charging a low-cost affordable lump sum payment on the occasion of the previous registration phases. By this the parties reduced the administrative burden (including setting up a reimbursement scheme) and reduced the risk of a data sharing dispute. This recommendation aims at making

this practice more widespread.

The DCG is conscious that this recommendation may not be feasible for very small SIEFs. Ultimately, each SIEF would need to consider to what extent its data-sharing agreement can be made compatible with this recommended approach. Offering a lump-sum payment would constitute a voluntary courtesy that joint submitters of existing registrations extend to late-coming registrants of small tonnages.

When determining the lump sum, administrative costs and costs for fulfilling information requirements should be considered.

Recommended circumstances for charging a lump sum

- The lump sum may be offered to registrants intending to register a substance in the 1-10 tonne band, wherever the existing registrants have already registered for the 2010 or 2013 deadline (i.e., at 100 tpa or above);
- To safeguard that all parties deem the lump-sum to provide a fair and non-discriminatory payment model to small-volume registrants joining the specific SIEF, unanimous explicit agreement of all members of the joint submission to any such arrangement should be sought and documented. Co-registrants joining the joint submission at a later stage would be expected to accept the low-tonnage lump-sum as an element of the existing data-sharing agreement. If a registrant has doubts about fairness, non-discrimination and/or transparency of the process, then he shall not waive his rights and insist on a detailed breakdown of costs based on the requirements of the Implementing Regulation.

Recommended conditions

- The low-volume registrant should be in a position to confirm to have the same substance;
- The low-volume registrant should agree with the classification in the lead dossier and the SDS, and therefore to implement and communicate the corresponding risk management measures;
- The low-volume registrant should undertake a commitment to participate in the outcome of the co-registrants' discussion on future costs, for instance for updates, to the extent they are justified by new requirements applicable to them under REACH provisions.

Annex

Motivation report

Rationale of the recommendation

SMEs are experiencing substantial difficulties in the face of the REACH 2018 registration deadline for registering their substances. The data sharing obligation and related challenges such as accessing the joint submission and bearing respective costs constitute an important factor in this regard.

This recommendation proscribes a pragmatic approach that should allow SMEs with limited resources, but obligations to register by the 2018 deadline, to achieve their access data and the joint submission with reasonable effort.

The recommendation solely concerns access to existing data for the purpose of registrations by the 2018 deadline. The DCG specifically states that it shall not apply to sharing the costs for establishing new data, such as for providing information in response to a substance evaluation process.

Background

Cost sharing has repeatedly been identified as one of the main difficulties that SMEs experience when facing their registration obligations. In its deliberations, the DCG took note of an ECHA-commissioned study[2] which, inter alia, drew the conclusion that SMEs meet an important barrier to compliance in the cost of data required for registering their substances within the 2018 deadline.

The study's findings are supported by feedback from individual companies and industry associations as well as ECHA's experience from the data-sharing dispute procedure and other processes. Consequently, the Directors' Contact Group (DCG) has concluded that it is necessary to address at least the first 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 because the cost is disproportionate compared to the benefits of the manufacture or import of the substance. Moreover, in the current practice the cost of LoA is typically charged upfront in one go, and therefore may constitute an unbridgeable barrier for SMEs, who do not have sufficient funds or access to financing to cover such one-off cost. This puts in question the entire registration as the company may opt to cease activities regarding this substance. In addition, in case of big disparities between the volumes produced/imported by the registrants (e.g., very high tonnages for some, very low for others), the registration cost per tonne may differ substantially to the disadvantage of registrants with the lowest volumes.

- **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.

[2] https://echa.europa.eu/-/smes-face-financial-challenges-registering-under-reach

- **Existing data sharing agreements are often complex** (e.g., cover several substances, involve consortia, etc.). Potential registrants have the right to receive a cost itemisation including proof and justification for all expenses and the approach taken, which poses an administrative and financial burden on the existing registrants. However, the recipients of this information, namely potential SME registrants with low regulatory capacities and limited resources, are struggling to assess the generated information, which makes creating an itemisation an additional burden on the existing registrants without improving the situation of SMEs in the data sharing negotiations.

- **Finding it difficult to start a dispute procedure with ECHA:** while the data-sharing 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 further discourages SME companies from using it.