

Directors' Contact Group

DCG3/Recommendation/1/2018
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DCG Recommendation to continue co-registrants' cooperation for phase-in substances after the 31 May 2018 deadline

The REACH Regulation stipulates that Substance Information Exchange Forums (SIEFs), designed for facilitating the data sharing as well as for agreeing on classification and labelling of the substance between the co-registrants, shall be operational until 1 June 2018. However the legal obligation to cooperate among the co-registrants continues for the joint registration and for data sharing related tasks. These obligations will continue even long after the initial submission of the registration dossiers by the co-registrants.

Regarding the joint part of their registration dossiers¹, companies have the joint obligation to keep them up-to-date by revising this part of the registration when they get new information on the substance's hazards, uses or other issues that affect risk management measures needed.²

Furthermore, authorities may approach registrants with regulatory requests, which call for a coordinated response from them. ECHA scrutinises the compliance of registration dossiers, and will contact registrants if information is deemed missing. Co-registrants need to coordinate their comments on ECHA's observations, decide how to generate the requested new information and share the costs, and agree on the conclusions resulting from the new information generated. Also, testing proposals in the registration dossiers may lead to regulatory requests.

In case of substance evaluation, ECHA may ask registrants to generate information even beyond the registration requirements, and similar coordination and decision making processes need to be in place among the co-registrants. Both dossier and substance evaluation may result in the need to update the joint registration dossier itself.

Finally, experience over the ten years of implementing the REACH Regulation has shown that the EU chemicals market is relatively dynamic, with companies continuously adjusting their portfolios of manufacture and import. Thus, the co-registrants need to be prepared to manage data and cost sharing requests of new registrants and reimburse the existing registrants accordingly. The Commission Implementing Regulation (EU) 2016/9 regarding joint submission and data sharing necessitates communication among members of a joint submission. It may also happen that co-registrants split or merge, resulting in a redistribution of registration costs, or in the need to change the lead registrant.

¹ Note: For the maintenance of their dossiers, apart from keeping the joint part up-to-date, registrants also need to individually revise such items as changes in their manufacture or import volumes or in their administrative information, such as contact details, as needed;

² Note: The "co-registrants page" in REACH-IT provides the contact details necessary for maintaining the joint part of the registration dossiers up-to-date.

If a form of cooperation is not maintained among the co-registrants, compliance with the above-mentioned legal obligations may become more complicated, and companies run the risk of not fulfilling their legal obligations.

In the light of the above, the Directors' Contact Group (DCG) recognises the need for co-registrants of phase-in substances to have a functional form of cooperation after 31 May 2018, and herewith issues the following

RECOMMENDATION

1. The DCG recommends that co-registrants of phase-in substances continue to cooperate after the last registration deadline for phase-in-substances of 31 May 2018.
2. This cooperation should cover, among other things, the process for managing update needs and updates of the registration dossiers as foreseen in Article 22 of REACH, coordinated responses to potential regulatory requests related to dossier and substance evaluation, and processes related to changes in the composition or status of co-registrants.
3. Co-registrants are free to agree on the form of their co-operation, and should put in place adequate, jointly agreed contractual measures for managing the work.
4. The cooperation contract should take into account the special nature of the work as 'cooperation among competitors', and ensure that only information that is necessary to complete the regulatory task is shared among the co-registrants. The cooperation contract should recognise also the administrative cost, and fair sharing of that cost, related to the co-registrants' cooperation. The involved parties shall make every effort to reach a mutual agreement. Thereby, the contractual framework as well as any decisions taken within such a cooperation between co-registrants shall aim to be fair, non-discriminatory and transparent to all involved actors.
5. The SIEF agreements should form a good basis for designing cooperation contracts among co-registrants.
6. As co-registrants of non-phase-in substances and of NONs (substances notified under Directive 67/548/EEC) also must create and maintain a joint submission and interact with newcomers, co-registrants of such substances may also consider establishing a form of cooperation as outlined for phase-in substances, above.