

# NEWSLETTER

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## CHANGES IN THE COURSE OF ACTION FOR REACH REGISTRATION FROM 2016 ONWARDS

Dear Subscribers,

On a short track we inform you about the following important issue concerning

### CHEMICALS / REACH



## Registration

### CHANGES IN THE COURSE OF ACTION FOR REACH REGISTRATION FROM 2016 ON- WARDS

The REACH Committee (under joint responsibility of DG ENV and DG Growth) has discussed a draft regulation for an "implementing act" on data sharing and costs incurred by data sharing under the REACH regulation at its recent meeting on 21-22 October 2015. As result of the discussion the Committee gave a favorable opinion by unanimity on the draft regulation.

The regulation will enter into force 20 days after its publication in the EU Official Journal. This is expected in Q1 2016 and will have an impact on upcoming SIEF agreement negotiations as well as on existing SIEF agreements.

In the last years an intensive discussion on data sharing was held between stakeholders, ECHA and member state competent authorities via different forums

(e.g. CARACAL meetings, ECHA REACH registration workshops). As outcome of the discussion one has concluded that especially the provisions of regulation (EC) No 1907/2006 on data-sharing and joint submission have not been used to their full potential. Their implementation is falling short of expectations.

The necessity was identified to specify duties and obligations for parties to agreements where data-sharing is required under REACH. The current draft regulation should therefore be established to reinforce the provisions of Title II (registration of substances) and III (data sharing and avoidance of unnecessary testing) of the REACH regulation.

The regulation covers four main issues: Transparency, One substance, one registration principle, Fairness and non-discrimination. Two main conditions are defined for existing SIEF agreements.

The Parties to a data-sharing agreement that already exists may, by unanimous agreement, waive some of the obligations implemented by this regulation (itemisation of costs, including a reimbursement mechanism). On the other side, a potential registrant of a substance shall not be bound by an existing waiver, unless he provides his signed consent to it to the previous registrants.

SCC comment: This is expected to have significant work load to the management of SIEFs and lead compounds

### Transparency (Article 2 of the regulation)

With this draft regulation the requirements on transparency in data sharing agreements are defined. The regulation implements the following aspects:

- SIEF participants shall make every effort to reach an agreement on data-sharing
- a data-sharing agreement shall be clear and comprehensible
- itemisation of the data to be shared including the cost of each data item
- a description indicating the information requirements in the REACH regulation to which each cost corresponds
- the itemisation of the administrative costs applicable for data-sharing agreement
- a cost-sharing model, which shall include a reimbursement mechanism
- yearly documentation of any further costs incurred in relation to the operation of data-sharing agreement.

Furthermore, registrants have the obligation to make every effort to provide itemisation of all relevant costs incurred before the entry into force of this regulation. The itemisation of costs shall be provided to the potential registrant without undue delay. The documentation of the cost will need to be kept for 12 years from the latest submission of a study and made available for free to any party within a reasonable time. This will probably cause significant administrative work for the management of existing SIEF agreements.

SCC comment: The impacts of Article 2 can increase the admin cost for SIEFs and consortia and consequently increase cost for all SIEF members. It will become more difficult to register substances in 2018 as often communication with lead registrants and work will

be delayed or not be done in time to the respective deadline when clear consent between all SEIF members is missing.

In practice this causes already today a lot of trouble as SIEF members often do not understand even the basics of REACH.

### One substance, one registration principle (OSOR principle) (Article 3 of the regulation)

Currently it is possible to file registrations outside an existing joint submission (*e.g.* Intermediate registration or as full opt-out). Certain industry sectors have claimed that this creates disadvantages for companies registering jointly as the SIEF has made significant collective investments in preparing a compliant dossier. Furthermore the registrations outside the joint submission have not involved the same level of financial investment. In this view, the possibility to breach the OSOR principle has a market impact. With this regulation ECHA is instructed to ensure that submissions for registrations for the same substance are part of an existing joint submission for that substance. This means, in all cases, potential registrants must become part of the joint registration, even if they choose to opt-out for all data requirements (*e.g.* intermediate registration).

In order to fulfill this obligation ECHA has announced to change the rules for REACH-IT. From 2016 onwards REACH-IT will block the submission of individual registrations outside an existing joint submission or an existing individual registration.

This will cause a higher administrative work for all registrations as communication and a written agreement with the LEAD registrant is necessary in any event.

If negotiations fail, the regulation on Data Sharing clarifies that potential registrants have the possibility to get access to the joint registration. ECHA will be enabled to provide this access as a possible outcome of the dispute. The aim of this measure is to create an additional incentive for existing and potential registrants to come to an agreement.

SCC comment: However, as data protection is infringed to this approach and to protect investments it is expected for such cases that clarification will be necessary and has to be clarified via data sharing disputes and board of appeal procedures.

## Fairness and non-discrimination (Article 4 of the regulation)

The following requirements, *inter alia*, are defined by this regulation:

- Joint submission members shall only be required to share costs for data they need to fulfil their REACH obligations. This condition applies also to administrative costs.
- The cost-sharing model shall include provisions for sharing any costs resulting from a potential Substance Evaluation decision to the extent that the studies required by that Substance Evaluation decision are relevant to this registration.
- Compiling information for the purposes of establishing substance sameness should not be the subject of any cost sharing between previous registrants and potential registrants.
- Reimbursement mechanisms shall be envisaged in every cost-sharing model and shall include a method of proportional redistribution to each participant
- Parties to a data-sharing agreement that already exists may, by unanimous agreement, waive their obligation to include a reimbursement mechanism in their cost-sharing model.
- A potential registrant who must participate in an existing data-sharing agreement shall not be bound by an existing waiver unless he provides his signed consent to it to the previous registrants moreover he shall have the right to obtain the inclusion of a reimbursement mechanism in the cost-sharing model in accordance with this regulation.
- Any registrant who has ceased his activities pursuant to Articles 50(2) or (3) of the REACH regulation may still be required to share costs resulting from a Substance Evaluation decision in accordance with Article 50(4) of that regulation.
- If parties cannot agree a cost-sharing model they will be required to pay an equal share of the costs, including a reimbursement mechanism.

SCC comment: Keeping in mind that a potential registrant of an existing joint registration cannot be forced to accept an existing SIEF agreement which is not compliant with this regulation, a revision of existing SIEF agreements and negotiations within the existing SIEF might be necessary. A lot of disputes about this can be expected, especially, as at the same time demands on documentation and communication in the SIEF was significantly increased. This will increase administrative costs for all SIEF members.

In conclusion, when this draft regulation enters into force at the beginning of 2016, it is expected to have a significant effect of the workload for a REACH registration. LEAD registrants of existing joint registrations should be prepared for challenging negotiations with potential new registrants and existing Joint submission members may question the existing Joint submission agreement. Companies which plan to start their REACH activities in 2017 (based on the low tonnage band) should reconsider their time schedule as negotiations might be more time consuming than expected and an individual submission outside the joint registration as "last resort" is no longer possible.

SCC has a lot of experience in negotiations of Joint Submission agreements and can support you during upcoming negotiations.



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Do you have any comments, questions or suggestions?  
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