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Home

News

Feature Articles

Industry Events

Magazine

Editorial Schedule

Circulation

Media Pack

Reprints

Subscriptions

Spec Chem Focus

Latest Issue

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Online Issue

Latest Online Issue

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## Unpleasant surprises on the home stretch

Tim Becker, chief REACH officer at REACHLaw, alerts co-registrants to risks of blank cheque SIEF agreements

Prohibitive, exorbitant, ridiculous - these are just some of the words you can hear more often these days in the REACH arena. They are coming from companies having signed up for a registration by 30 November 2010, who have received the latest cost estimates for the letter of access from their lead registrant.

All of a sudden the expected EU marketing approval in form of the registration number for some of their substances is put at risk by enormous joint registration fees. Other unpleasant surprises such as gaps in the joint registration dossier are becoming apparent for potential registrants only now, a few weeks before the November deadline.

This article brings the basic concepts of joint registration and data sharing conceived by the REACH legislator, the EU authorities and CEFIC face to face with the real life situation perceived by [REACHLaw](#) with its several hundred substances to be registered this year. An outlook is also given about the expected situation after the deadline.

One of the main objectives of REACH is to improve the knowledge about the hazardous properties of existing substances that were on the European market already by 1981, and to determine the conditions of their safe use. Responsibility for these tasks has been placed on industry, who should submit the data to the European Chemicals Agency (ECHA) in Helsinki by means of registration. Animal testing should be kept to a minimum and duplication of work should be avoided.



Becker - Non-lead registrants often face very poor set of choices

To this end, REACH mandates that manufacturers and importers of the same substance form a Substance Information Exchange Forum (SIEF), where they should share data and submit them jointly through a lead registrant by means of a joint registration dossier (lead dossier). However, REACH does not prescribe the working process of a SIEF, so it is up to the members to define it in each case via a SIEF agreement.

In addition, each co-registrant should submit its specific set of company, substance and use information via an individual dossier to the ECHA. The costs for the data submitted jointly should be shared amongst all registrants in a fair, transparent and non-discriminatory way. The collaboration should not infringe EU competition law.

Latest Issue



## How it works in theory

By 1 December 2008, manufacturers and importers made their pre-registrations specifying their substance's name, CAS and EINECS number in ECHA's REACH-IT system, which allows each pre-registrant to get in contact with all other pre-registrants of the same identifiers. One of them was supposed to take the initiative as the SIEF formation facilitator, which meant:

- Reaching an agreement with all other pre-registrants on the substance sameness in order to form a SIEF
- Sorting the pre-registrants according to their registration intentions and desired level of involvement in the joint registration process - in the CEFIC codes, leading, involved, passive or dormant
- Proposing operating rules for the SIEF and a lead registrant for joint registration

CEFIC published in June 2009 a model SIEF agreement to be concluded between the (candidate) lead registrant and the co-registrant(s) (non-lead member(s)), which is supposed to formalise these issues. Essentially, it obliges the lead registrant to prepare and submit the lead dossier in exchange for payment of compensation ('letter of access fee') by the non-lead member(s).

The parties were supposed to be free to negotiate the terms and conditions of the SIEF agreement. In addition, pre-registrants intending to register only in 2013 or 2018 were supposed to enter into the SIEF agreement already at this stage (Figure 1).



<sup>1</sup> From Cefic SIEF agreement explanatory note, 2 June 2009.

<sup>2</sup> From ECHA, Questions and answers on Data sharing and related disputes, 30 July 2010.

NB. Text in bold highlighted by the author

Figure 1 - Quotations from the ideal world of joint registration

SIEF agreements should be signed in good time before the registration deadline and before the start of registration work, so everyone knows what he has to do. The share of the costs would be fixed by the lead registrant based on general rules in the agreement, in principal by dividing the total costs of preparing the lead dossier by the number of signatories. The lead registrant would regularly update the signatories on the joint registration progress.

In the case that 'every effort' by the pre-registrants to reach an agreement on the data and cost sharing should fail, ECHA has set up a data sharing dispute procedure, which it published on its [website](#) at the end of July 2010. Pre-registrants were alerted to notify any such dispute to ECHA by 30 September 2010, in order for it to be resolved before the November deadline.

## How it is working in practice

The reality under REACH for a registrant who is not a member of a consortium and is required to register in 2010 has usually been fundamentally different. Timetables proposed by many consortia for granting access to joint registration have been persistently delayed and co-registrants not following up proactively with the leading companies might still be in the dark about the details.

Among the key issues is late SIEF agreements. Most are being offered by the leading company or consortium only upon finalisation of the lead dossier. Frequently, they have been sent out to co-registrants only during last summer, with short deadlines set to accept the agreement in order for the co-registrants to

participate in joint registration in 2010. For other substances with a 2010 deadline, the lead registrant had not even provided the SIEF agreement - at the end of September!

The diversity and complexity of the SIEF agreements poses a major challenge for companies, especially if legal resources to check the agreements are insufficient (Table 1). The CEFIC model has not been used in many cases or has been modified considerably. At the same time, negotiations of terms and conditions, which tend to be written in favour of lead registrant and consortium, are practically impossible for the co-registrants, considering the shortness of time and the dominant market position of the counterparts.

TABLE 1 - CHECK LIST FOR SIEF AGREEMENT

Issue	Implication
Parties to agreement	Rights and obligations limited to the parties - usually lead registrant and co-registrant - unless affiliates of the co-registrant are covered
Scope of agreement	Affects remaining workload of co-registrant; e.g. intermediate vs. full registration, CSR and/or guidance on safe use (not) shared
Cefic model used?	If CEFIC model is modified, this is often to the disadvantage of the co-registrant
Are costs defined?	Often costs are not fixed in the agreement, but cost sharing key is given (number of co-registrants) - blank cheque effect!
Lead registrant's right to require additional payments? (e.g. during dossier evaluation)	Common clause - blank cheque effect!
Refund clause?	If refunds based on future letter of access sales are excluded, cost sharing distorted and lead registrant may be able to make profits with REACH registrations
Study reference right granted?	If not granted, co-registrant may have to secure these by himself through negotiations with third party data holders
Limitation of lead registrant's liability	Common clause - co-registrant cannot claim damages from lead registrant for failure of registration, unless he can prove gross negligence or wilful misconduct
Duration of agreement (+surviving obligations)	The time during which rights and obligations persist; usually for the legal duration of the SIEF, i.e. until 1 June 2018, sometimes until 2022 or unlimited
Right to terminate?	Often excluded for the co-registrant already several months before the applicable registration deadline - financial liabilities and risks for many years

Against this background, the procedure ECHA finalised only on 30 July 2010, to resolve data sharing disputes and requiring 'every effort' to be made and documented by the co-registrants to come to an agreement, cannot be of much help for co-registrants struggling with these issues, as time is running short and the procedure is not tailored to the common problem case of the potential registrant without any data seeking access to the lead dossier from its holder. Nor is this situation covered by the five exceptional cases for which ECHA launched a support procedure for registrants on 27 September (Table 2).

ECHA'S EXCEPTIONAL CASES FOR 2010 REGISTRANTS SUPPORT

Case	Description
1) Missing data (1)	Difficulties to provide data required in Annexes VII and VIII in due time or difficulties for importers of mixtures to obtain compositional and analytical data of the substances in the mixture from their suppliers (Issue No. 10)
2) Legal entity change	Impossibility of transferring pre-registrations or submitting a late pre-registration due to legal entity changes (Issue No. 15)
3) Failing lead registrant	Failure by the lead registrant to submit a fully REACH compliant dossier (Issue No. 20)
4) No	Downstream users are obliged to become importers, as a substance is not

lead registrant	registered by any EU-based supplier (Issue No. 21)
5) Missing data (2)	Registrants need to accommodate new-updated guidance and hence have difficulties to provide data in Annexes VII and VIII in due time (Issue No. 10)

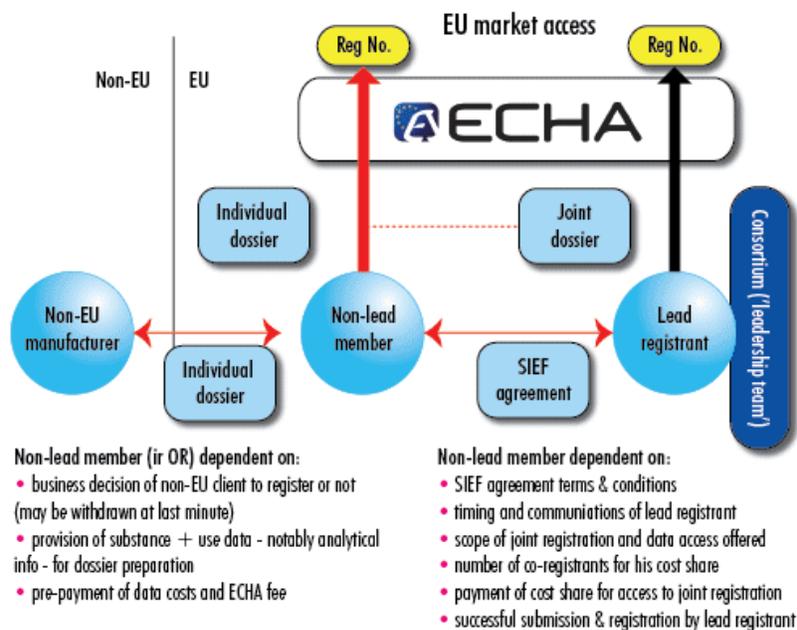
'Blank cheque' SIEF agreements that do not fix the joint registration compensation, but contain only general cost sharing rules based on the principle that the total cost for the development of the lead dossier is divided by the number of companies that have accepted the SIEF agreement are a particularly serious problem.

If the number of signatories is lower than estimated, the cost share per co-registrant may easily grow exponentially, whereas the co-registrant is no longer entitled to withdraw based on the SIEF agreement. If withdrawal is allowed, however, the cost share will grow further still for the remaining co-registrants.

The common fact that potential registrants for 2013 and 2018 remain passive and do not enter into such SIEF agreements at this point of time, as initially conceived by CEFIC, contributes to the cost increase for 2010 registrants. Obviously, the financial burden is disproportionately high for SME and companies from developing countries.

As another consequence of late SIEF agreements, the scope of the joint submission may remain unclear for some time. If optional parts of the joint registration which are complex to develop (chemical safety report (CSR), guidance on safe use), are not shared and the co-registrant realises this only now, it may already be too late to be still able to submit a complete dossier by 30 November.

Another layer of complexity is added for independent only representatives (ORs), who have to enter into the SIEF agreements as the registrants, whereas the business decision about registration is taken by their non-EU customers and is mainly driven by the final cost of the letter of access. Hence, without proper agreements set up with their non-EU clients, ORs may easily incur financial liabilities which they cannot pass on to their clients.



The 'straitjacket' of non-lead members

What will happen after 30 November?

By showing unequivocally the marketing approval to downstream users and distributors, the registration number is likely to become a valuable asset for their owners. On the other hand, EU manufacturers, EU importers and *de facto* non-EU manufacturers represented by an OR with a registration deadline in 2010 will no longer be allowed to market their substance in the EU.

Even a decrease of tonnage below the 2010 thresholds would not change this, because the highest tonnage manufactured or imported after 1 June 2007 is decisive. It is evident that this is going to strengthen the market position of registered companies and will make life more difficult for other players, even if they could still rely on pre-registration.

It can also be expected that enforcement authorities will verify the conditions to rely on pre-registration more carefully, whereas a registration number may easily appease their desire to detect non-compliance. Last but not least, companies who failed to register in time due to financial barriers or time constraints might call the EU competition authorities, lobbyists or claim a violation of WTO rules through REACH.

#### Conclusions

We saw a pre-registration rush in autumn 2008. Now we will witness the second showdown of REACH submissions of much higher complexity in the next few weeks, including a lot of hectic activity.

Legislators and the REACH community alike have clearly underestimated the magnitude of the challenges relating to joint registration until now and many companies without sufficient financial resources to pay the exploding costs will be off the market after 30 November. Even if not intended by the authors of REACH, this will affect SMEs in particular.

Companies intending to register should carefully check what they are signing up to in SIEF agreements. Admittedly, they will not normally be in a position to negotiate terms and conditions - the alternative is rather 'take it or leave it'. It will be interesting to see whether the authorities in EU will find a balanced approach between preserving the credibility of REACH and the protection of fair competition and SME enterprises in EU after the November deadline.

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