

SIEFs urgently need clarity on joint submissions

With just over nine months to go before the first REACH registration deadline, persisting difficulties for many substance information exchange fora (SIEFs) in preparing for joint submission remain a major concern. **Jean-Philippe Montfort** and **Giovanni Indirli** discuss a major obstacle.

REACH requires potential registrants in each SIEF to reach agreement on a lead registrant, which requires them not only to agree on the selection of a company but also on the terms and conditions of the joint submission.

In those SIEFs where a candidate lead registrant exists, in many cases they cannot obtain the necessary support from other members. This is because the lead registrant proposal often comes with a package that others find difficult to accept.

Often selected by and from members of consortia formed between major market players, candidate lead registrants then seek the agreement of other SIEF participants to act also on their behalf and then send them "SIEF agreements" or "joint submission agreements", setting out the proposed conditions to join their registration dossier.

Often presented on a "take it or leave it" basis, these draft SIEF agreements are sometimes very advantageous to lead members and have not been well received by other participants. Difficult elements include clauses allowing:

- * only lead members to obtain the right to use, or permission to refer, to studies for all of their affiliates while paying only one share,
- * study valuations that are often based on replacement costs,
- * important price-increasing factors, and
- * a lack of transparency regarding 'letter of access' costs.

Looking for alternatives

In a number of SIEFs a reluctance to accept such terms has prompted groups of potential registrants to consider alternative options, including preparing a separate dossier and selecting another potential lead registrant for joint submission.

This scenario might clash with the EU authorities' understanding of the joint



The REACH text may be interpreted to allow more than one joint submission per SIEF

submission obligation in REACH Articles 11 and 19. The practical effects of these Articles have not been fully clarified and the most important question that arises is whether the European Chemicals Agency (ECHA) will accept separate joint submissions from two or more lead registrants and, if so, what other consequences this may have.

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Article 11 provides that "when a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importer", part of the registration information "shall first be submitted by one registrant acting with the agreement of the other assenting

registrants (hereinafter referred to as the lead registrant)". Article 19 contains the same provision for intermediates. Registrants may nevertheless submit this information separately in three specific cases (the so-called "opt-out" conditions), provided that they submit appropriate justification to ECHA. Registrants that opt out are required to pay the full registration fee.

This wording lends itself to different interpretations and their application in practice is not straightforward.

The guidance document on data sharing indicates that "Only one lead registrant can be appointed per substance (... one SIEF = one substance = one joint submission = one lead registrant), even if several tonnage bands co-exist". More recently, ECHA confirmed on its website that "there can be only one lead registrant and one 'joint submission dossier' for a given substance" and that only potential registrants who "have officially been elected/appointed as lead registrant by **all** the members" of the relevant SIEF can qualify as lead registrant.

A question of agreement

However, Articles 11 and 19 state that the lead registrant should act with the agreement of the other assenting registrants

and the question is what if there is no “agreement” on the selection of the lead registrant among all SIEF members?

In our view, Articles 11 and 19 should not be interpreted to mean that a joint submission can be accepted only if all (potential) registrants agree to that joint submission. In practice, this would mean that a joint submission would not be possible in cases where even only one SIEF participant is unwilling to support the lead registrant, which would be disproportionate. Furthermore, this interpretation/approach could be impossible to implement. Indeed, ECHA is not in a position to verify whether the lead registrant actually acts on behalf of all registrants, unless and until another registration is submitted by another registrant, possibly years later.

First come, first served?

At the lead registrants workshop held in Brussels on 11 September 2009, ECHA officials seemed to concede that registrations by lead registrants acting with the agreement of several, but not all, potential registrants would be accepted as a joint submission. However, the question remains as to whether this means that only the first joint submission will be accepted or whether ECHA will accept several joint submissions.

In practice, accepting only one joint submission would mean that once a joint submission has been processed, no further joint submission will be accepted. To register the same substance, the other potential registrants (not covered by the initial joint submission) would have no other option but to agree *de facto* that the first lead registrant is the only lead registrant and opt out from that first joint submission. This also requires that they are able to justify their opt out and pay higher registration fees. As mentioned above, taking lead registrants on a “first come, first served” basis would not be in line with the text of Article 11, which requires “an agreement of the other *assenting* registrants”. As will be explained below, this would have discriminatory effects.

In our opinion, Articles 11 and 19 should rather be read as not preventing several joint submissions in the same SIEF if agreement among all participants cannot be reached. Indeed, this interpretation is in line with the wording of these Articles and is more respectful of the principles of proportionality and non-discrimination. When potential registrants cannot agree, they should still be able lawfully to register separately, and acceptance of their registration should not depend upon whether they are the first to

submit a registration dossier.

Which of the above interpretations is eventually accepted by the EU authorities will determine the contractual power of the negotiating SIEF participants and the outcome of the negotiations. Allowing only one joint submission on a first come, first served basis would considerably reinforce the contractual power of the participants who can register first. The other potential registrants, who could possibly prepare their own dossier at lower cost, would be forced to refer to the first lead registrant or pay higher registration fees to opt out. This might offset the lower dossier preparation costs and would mean that they are potentially prioritised by ECHA for dossier evaluation. On the other hand, if ECHA is willing to accept separate joint submissions, the otherwise increased power of the first entrant would be neutralised. As further explained below, we believe that there is no overriding public interest that justifies treating several groups of SIEF participants differently.

Checks and balances

Does that mean that potential registrants would have no incentive to seek an agreement to submit jointly? We do not think so.

Firstly, and even though several joint submissions would be accepted as valid registrations, it would be in the interest of all participants to seek an agreement and share the costs. Indeed, separate joint submissions are most likely to be more costly for each participant than an agreement between all SIEF members under fair conditions.

Secondly, assuming that this proves impossible, ECHA could still review at any time the fees payable for these registrations (Article 13 of the Regulation on fees and charges), ie. whether each joint submission is entitled to a reduced fee for joint submission or the normal fee for individual submissions, depending upon the circumstances of the case and the justifications that can be provided by the registrants.

Enforcement authorities of the Member States will also be able to judge, after the registrations are made, whether it was justifiable to submit separate submissions. Member State authorities could decide that these separate submissions, while valid, constitute a breach of Articles 11 or 19 and impose fines against the parties for that purpose. In our view, however, while registrants submitting separate joint submissions should be prepared to face some investigation, they should nevertheless be able to avoid being held responsible, or at least mitigate their responsibility, for a perceived breach of Articles 11 or 19 if they can show that they have made all reasonable efforts to come to an agreement on a single joint submission.

Time for clarity

Given the deadlock that some SIEFs are in at the moment, we believe it is time for the EU authorities to clarify their position on this issue. As explained above, whether Articles 11 and 19 are interpreted strictly or flexibly will have a direct impact upon the negotiating power of the parties and the preparation of the joint submission dossiers. In the absence of a clarification, however, the remaining uncertainties are unlikely to discourage dissenting registrants from pursuing alternative submissions, if faced with proposed conditions for joint submission that are unacceptable to them. If then their alternative joint submission is not accepted, the failed potential registrants will have no other choice but to challenge the ECHA decision before the Board of Appeal and, ultimately, the European Court of Justice, which would be in nobody's interest.

The above discussion should not, of course, prevent SIEF members from trying to reach an agreement on one joint submission and show due diligence in doing so. Whatever the interpretation eventually given by the EU authorities, being able to establish that all attempts were made to reach an agreement is likely to be key to ensuring compliance and/or avoid extra fees or even fines.

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