SIEFS AND DISPUTE RESOLUTION

I. INTRODUCTION

According to the European Chemicals Agency (ECHA), there have been more than 2,200,000 pre-registrations for more than 145,000 substances, which means as many pre-SIEFs. The number of participants varies from 1 to 9 (for 91,344 SIEFs) to more than 5,000 (for 2 SIEFs). Between these two extremes, there are around 20,000 pre-SIEFs with 25 to 1,000 participants.

The participants in a SIEF shall collaborate with a view to preparing the joint part of the registration dossier, in accordance with Article 11 of REACH. This part concerns in particular the following information:

- the classification and labelling of the substance (Article 10(a)(iv) REACH);
- study summaries of the information (Article 10(a)(vi) REACH);
- robust study summaries of the information (Article 10(a)(vii) REACH);
- proposals for testing (Article 10(a)(ix) REACH).

According to Article 29(2) of REACH, the aim of each SIEF is to:

- facilitate, for the purpose of registration, the exchange of information in order to avoid the duplication of studies; and
- agree on classification and labelling when there is a difference in classification and labelling of the substance between potential registrants.

The obligations of SIEF participants are described as follows in Section 4.3 of the Guidance on Data Sharing:

- [A]ll SIEF participants shall:
    - react to requests for information from other participants;
    - provide other participants with existing studies upon request.
- [P]otential registrants shall:
    - request missing information from other SIEF participants;
    - collectively identify needs for further studies to comply with registration requirements;
    - make arrangements to perform the identified studies;
    - agree on classification and labelling.

Even after a cleanup, and despite the availability of a variety of efficient and well-designed tools, including SIEFreach (www.siefreach.com), proposed to industry members by CEFIC (European Chemical Industry Council) and certain national chemical associations, as well as a number of tools proposed by service providers, the sheer number of participants will render the management of SIEFs, notably their internal conflicts, particularly difficult.

Indeed, the functioning of a SIEF will, in certain cases, generate both internal conflicts and external conflicts with regard to ECHA, certain of whose decisions could be contested, as well as vis-à-vis third parties. The purpose of this contribution is to examine in a synthetic manner the nature of these possible conflicts and potential means of resolving them.

II. CONFLICTS WITHIN SIEFS

1. NATURE OF POSSIBLE CONFLICTS

Discussions could arise amongst the various members of a SIEF concerning issues such as:

- data sharing;
- cost sharing (administrative costs, operating expenses, the cost of studies, etc.);
- the decision-making process relating to, amongst other things, the selection of relevant data and key studies, the generation of new information, the preparation of testing proposals, etc.;
- the admission and qualification of new members;
- confidentiality;
- liability;
- the application of competition law rules.

2. OBSTACLES TO BE OVERCOME

Given the extremely tight deadlines, at least insofar as certain pre-registrations are concerned, it is imperative to find a rapid solution in the event a conflict arises. Indeed, the deadlines for registration are as follows:[1]

- 1 December 2010: 22% of pre-registrations
- 1 June 2013: 47% of pre-registrations
- 1 June 2018: 31% of pre-registrations

In general, it is considered that the complete file, that is both the joint part and the individual parts, must be submitted six months before the deadline. For the first batch of registrations, the effective deadline will thus be 1 June 2010.

Moreover, given the size of many SIEFs, it is essential to come up with a flexible and informal solution.

[1] Art. 23 REACH

3. POSSIBLE MEANS OF DISPUTE RESOLUTION

3.1 ECHA

The participants in a SIEF are entirely responsible for its organisation, and ECHA will not be involved in the functioning of SIEFs in the absence of specific provisions to the contrary in the Regulation (see point 3.2 below). ECHA will in general not serve as an arbitrator between SIEF participants.

3.2 REACH Regulation

The REACH Regulation contains a certain number of provisions intended to help resolve disputes with regard to data sharing and cost sharing.

3.2.1 Data sharing

The general rule is laid down in Article 29(3) of REACH: *"SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies (…) and arrange for such studies to be carried out (…)."*

Article 30(1) of REACH further states: *"Before testing is carried out in order to meet the information requirements for the purpose of registration, a SIEF participant shall enquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving **testing on vertebrate animals** is available within the SIEF, a participant of that SIEF **shall request** that study. If a relevant study **not involving tests on vertebrate animals** is available with the SIEF, SIEF participants **may request** that study."*

According to Article 30(2), if a relevant study involving tests is not available within the SIEF, the SIEF participants must agree that one study per information requirement shall be conducted by one of its participants acting on behalf of the others. If they cannot reach an agreement, **ECHA shall specify which registrant or downstream user shall carry out the study** (see also Article 53(1) REACH, which contains a similar provision).

If the owner of a **study involving tests on vertebrate animals** refuses to provide either proof of the cost of the study or the study itself to another participant, the owner shall not be able to proceed with registration until he provides the information to the other participants. The other participants can proceed with registration without having to fulfil the relevant information requirement, explaining the reason for this in the registration dossier. If within twelve months following the date of registration the owner has not provided the requisite information, **ECHA may decide that the study should be repeated** by the registrants. If a registration containing this information has already been submitted, **ECHA shall give the other participants permission to refer to it**, provided they share the costs.

In the event the owner of a **study not involving testing on vertebrate animals** refuses to provide either proof of the costs of the study or the study itself, the other SIEF participants shall proceed with registration as if no relevant study is available within the SIEF (Article 30(4) REACH).

The owner of a study who refuses to provide either proof of the cost of the study or the study itself shall be sanctioned [2] by the competent Member State.

3.2.2 Cost sharing

The communication of existing studies is subject to cost sharing, which is to be determined in a *"fair, transparent and non-discriminatory way"* (Articles 27(3) and 30(1) REACH).

Furthermore, Article 11(3) of REACH allows participants to opt out of a joint submission if, for instance, it would be disproportionately costly for the participants to submit information jointly.

SIEF participants are free to agree on any model they deem to be fair, transparent and non-discriminatory. If no agreement is found, **REACH provides for the equal sharing of costs** (see e.g. Articles 26(7) and 30 REACH). It should be noted that, pursuant to Article 27(3), registrants are only required to share the costs of information they are required to submit to satisfy their registration requirements.

Article 53(4) of REACH provides that "the person performing and submitting the study shall have a claim against the others accordingly". This article indeed states that *"*[a]*ny person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed."* Such a claim shall be enforceable in national courts or can be submitted to an arbitration board.

3.4 SIEF agreements/consortia

Many issues can clearly be resolved at the outset by having all SIEF participants sign an agreement, which notably settles as precisely as possible thorny issues surrounding matters such as cost sharing and the decision-making process. Such an agreement is often referred to as a consortium agreement, while entering into such an agreement is commonly referred to as the collective route. The word 'consortium' does not appear in REACH and can describe various configurations. For example, some consortia comprise undertakings participating in various SIEFs, while others are made up exclusively of participants in the same SIEF. It is also possible to have different consortia in the same SIEF.

The ideal situation would be for all SIEF participants to join the same consortium, with the resulting consortium agreement covering all possible SIEF issues.

[2] Article 126 of REACH states that *"Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportioned and dissuasive."*

However, this will rarely be the case. Therefore, discussions will arise between consortia and SIEF participants regarding e.g. access to consortium data by non-consortium members and the compliance of membership restrictions with anti-trust rules.

3.5 Recourse to legal action

Considering the need to resolve disputes as rapidly as possible, on the one hand, and the number of participants, on the other hand, the duration of legal proceedings, especially when multiple parties are involved, renders this option untenable.

3.6 Arbitration

Firstly, arbitration assumes that the parties have agreed on this means of resolving their dispute, which implies that they have entered into an arbitration agreement. Moreover, arbitration is subject to a certain number of procedural rules, which render it not necessarily swifter than proceedings before the courts. Finally, the cost of arbitration can dissuade certain SIEF participants.

In light of the foregoing, this option does not appear ideal either.

3.7 Mediation/conciliation

Calling upon an independent mediator or conciliator, who is sufficiently familiar with the subject matter, to help the parties reach an amicable solution is undeniably an excellent means of dispute resolution. This method has the advantage of being swift, efficient and relatively low cost. Of course, success is not always guaranteed and depends in part on the good will and good faith of the participants.

Moreover, the number of participants can severely burden the process, especially if all or a significant majority of the participants wish to take part. It is thus recommended that each group defending a particular point of view appoint a single representative to represent them in the context of mediation and, if need be, conclude an agreement.

3.8 Neutral expert's opinion

An undeniably swift and efficient means of dispute resolution is to informally request a neutral third party to prepare an opinion on the dispute and the recommended solution.

This approach also requires a minimum consensus amongst the participants. This consensus should cover the participants' agreement to call upon a third party, cost sharing and the manner in which problems are to be submitted to the expert. Once more, this last issue can be resolved by designating a single representative per group, entrusted with preparing a note on the issue and possibly commenting on it orally.

The advantage of this method is that the rules of arbitration do not apply. One disadvantage is that the expert's opinion will not be binding. Nevertheless, if the parties have a modicum of common sense, they will weigh the need to respect the recommended solution against the risk of getting bogged down in unending litigation, thereby jeopardizing the registration of their substance.

4. EXCLUSION OF A PARTICIPANT

The basic rule contained in Article 11 of REACH is joint submission of data in the case of multiple registrants.

Article 29 of REACH is clear on this point: all potential registrants, downstream users and third parties who have submitted information to the Agency or whose information is held by the Agency for the same phase-in substance, or registrants who have submitted a registration for that phase-in substance before the deadline, shall participate in the SIEF.

There can be only one SIEF per substance (see Section 4.4.1 of the Guidance on Data Sharing). Participation of potential registrants is obligatory. Participation of data holders, including downstream users and third parties, will depend on their decision to share the information or data they hold. The formation of several SIEFs for the same substance violates data-sharing obligations and will be sanctioned.

The only possible grounds for exclusion of a SIEF participant therefore seem to be those provided for by REACH, namely:

- Article 30(3) of REACH:

  If the owner of a study which involves testing on vertebrate animals refuses to provide either proof of the costs of that study or the study itself to other participants, he shall not be able to proceed with registration until he provides the information in question to the other participants.

- Article 30(4) of REACH:

  If the owner of a study which does not involve testing on vertebrate animals refuses to provide either proof of the costs of that study or the study itself to other participants, the latter shall proceed with registration as if no relevant study were available within the SIEF.

- Article 30(6) of REACH:

  The owner of a study who has refused to provide either proof of the costs of the study or the study itself shall be penalised in accordance with Article 126 of REACH, which states that *"Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive"*. Whether such penalties or non payment of penalties could include exclusion from the SIEF will depend on national rules

In some circumstances, a participant can opt out of a joint submission. Pursuant to Article 11(3) of REACH, opting out is possible if one of the three following conditions is met:

- it would be disproportionately costly for the participant to submit information jointly;
- submitting the information jointly would lead to the disclosure of information which the participant considers commercially sensitive and likely to cause substantial commercial harm;
- the participant disagrees with the lead registrant on the selection of information.

Registrants that opt out shall submit, along with the dossier, proof that one or more of the above conditions are met.

However, as a SIEF participant, a party that opts out is still required to reply to requests regarding the sharing of data in its possession.

Consequently, it appears that, in light of the above rules, it is not possible for SIEF participants to exclude another participant, with the exception of those cases mentioned in Article 30.

On the other hand, opting out allows one or more participants to disassociate themselves from the others in the event of a serious disagreement. Of course, it's possible to imagine multiple participants opting out of a joint submission. In this case, the Regulation does not mention whether those participants that have opted out can submit a joint dossier.

III. CONFLICTS WITH ECHA

1. NATURE OF POSSIBLE CONFLICTS

Conflicts can arise with ECHA regarding the followings issues:

- exemption from the general obligation to register for product- and process-oriented research and development (Article 9 REACH);
- rejection of registrations (Article 20 REACH);
- sharing of existing data in the case of registered substances where the Agency has given the potential registrant permission to refer to the information provided by a previous registrant (Article 27 REACH);
- sharing of test data (Article 30(2) and (3) REACH);
- examination of testing proposals (Article 40 REACH);
- compliance check of registrations (Article 41 REACH);
- substance evaluation (Article 51 REACH).

According to Article 91 of REACH, the Agency's decisions taken pursuant to Articles 9, 20, 27(6), 30(2) and (3) and 51 can be appealed.

An appeal shall have suspensive effect. The appeal shall be brought before the Board of Appeal, an independent body within ECHA (see Article 90(2) REACH).

REACH lays down only basic rules regarding appellate procedures (Article 92 et seq.). Detailed rules on the organisation of the Board of Appeal and detailed rules of procedure for appealing to the Board are laid down in Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency.

In the event of appeal, a fee must be paid pursuant to Article 10 of Regulation (EC) No 340/2008.
The following basic rules should be kept in mind:

- any natural or legal person may appeal the decision addressed to that person or a decision which, although addressed to another, is of direct and individual concern to that natural or legal person (Article 92(1) REACH);
- the notice of appeal, together with an explanation of the grounds for appeal, shall be filed with the Agency within three months from notification of the decision on the person concerned or, in the absence thereof, of the date on which the decision became known to the latter, unless the Regulation provides otherwise (Article 92(2) REACH);
- Article 6 of Regulation No 771/2008 describes the information that should be contained in the notice of appeal;
- the Agency shall submit its defence within two months after service of the notice of appeal (Article 7 of Regulation No 771/2008);
- any person that can prove an interest in the outcome of the case may intervene in the proceedings (Article 8 of Regulation No 771/2008);
- the Board of Appeal shall hold a hearing if it considers this to be necessary or if a party so requests (Article 13 of Regulation No 771/2008);
- the language in which the notice of appeal is drafted shall be the language of the appellate proceedings (Article 14 of Regulation No 771/2008); however, if the decision on appeal was addressed to the appellant, the notice of appeal shall be drawn up in the language of the decision or in an official language of the Community appearing in the submission which gave rise to the decision;
- the Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action (Article 93(3) REACH).

According to Article 94 of REACH, an action may be brought before the Court of First Instance or the European Court of Justice, contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the Agency.

IV. EXTERNAL CONFLICTS

According to Article 10(a) of REACH, registrants shall be in legitimate possession of, or have permission to refer to, the full study report for the purpose of registration.

Legitimate possession or access must be agreed on with the owner of the full study report. The Guidance on Data Sharing clearly states that a mere copy of the full report, with no letter of access or right to use the data, is not sufficient for registration purposes, unless the full report is publicly available and not protected by any IP rights. Potential registrants should indeed bear in mind that reports are generally protected by copyright and may not be duplicated without the right owner's consent.

Furthermore, the use of a report or study for which the intellectual property rights are owned by a third party cannot only be refused by ECHA but also give rise to an action by the third-party right holders.

The right holders can take action before the competent courts in order to have any infringement of their IP rights sanctioned.

V. CONCLUSION

The implementation of REACH and the functioning of SIEFs will inevitably entail a risk of both internal and external conflicts.

Given the particular context and the applicable deadlines, it is essential that the parties put their imagination to work and show common sense in resolving these conflicts.

Philippe Péters
Partner
NautaDutilh Brussels
T + 32 2 566 80 00
Philippe.peters@nautadutilh.com
www.nautadutilh.com