Registration as a member of a joint submission

Introduction

When considering the need to register, attention generally focuses on the need for data review, new testing, deciding on classification and completing the full IUCLID 6 dossier. Even when considering the Chemical Safety Report (CSR) and Exposure Scenarios (ES), guidance is presented as if the reader needs to start from scratch. Most of the guidance is aimed at potential lead registrant or is at least taking an active role in the proceedings.

In reality, many registrants will have a minor role, especially in SIEFs run by larger organisations or consortia, or in cases where the substance is already registered and a letter of access is available for purchase. These (majority of) registrants will only need to conduct the minimal work to be part of a joint registration process, and of course pay data holders for access.

This short guide covers some of the main issues faced by those who are not active towards lead registration, but who will still need to do some work for their own registration.

Minimum requirements

As a minimum, all those planning to register (even if paid-up members of a consortium letting the consortium do the bulk of the work) will need to prepare their own personal dossiers in IUCLID 6 and submit with REACH IT. The submission will need to include supporting analysis (IUCLID Section 1.4) and descriptions of their own manufacture, tonnage, use and exposure (IUCLID Section 3.5, 3.7) together with a Chemical Safety Report and Exposure Scenarios where necessary.

Hopefully, members of a SIEF can work together to agree on suitable methods of analysis to help demonstrate substance ‘sameness’ and can support each other in the production of the Exposure Scenarios and CSR, but all registrants will need to provide their own personal reports in their own personal submission.

In many cases, especially within consortia, letters of access will also include some parts of Section 3 of IUCLID (e.g. uses), Section 11 (guidance for safe use) and a CSR.

Substance sameness

Establishing ‘sameness’ is in practice difficult. The basic position is that members of a SIEF wishing to share in a joint registration, or those buying into an existing registration, will need to demonstrate that the following conditions have been met with respect to ‘sameness’:

- ✓ The substance description in Section 1 of IUCLID 6 of all joint registrants is effectively the same in terms of the agreed substance identity for the substance; for example, the generic molecular weight spread, isomeric distribution, isotopic content etc. are comparable

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- ✓ The spectra, chromatograms and other analytical data and methods need to be supplied by each registrant in their own section 1 of IUCLID 6. This data must relate to their own substance; analysis performed by a consortium or the lead registrant is not sufficient, unless the joint registrant has provided samples.*
- ✓ The substance identified by each registrant that has been confirmed by personal analysis, corresponds to the substances used for evaluating hazards and physical properties

Note that 'sameness' or 'equivalence' is not the same as 'identical' and the system allows for flexibility. However, if for example the agreed substance specification is a range of molecular weights and a mix of isomers or isotopes, then all data used to support the registration must be valid for all samples within that specified range.

ECHA will have a final decision on sameness and even if a group or registrants claim sameness, review of the dossier by ECHA may lead to a Joint Submission being split; for example, if a definition of a UVCB is too wide, it may be decided that this should be considered as two or more substances. Likewise, if some members of a SIEF may try to exclude other registrants by claiming that their substance is not the same, ECHA will make a final decision. It is not necessary for members of a SIEF to share identity or purity details as that can be considered commercially confidential. Lead registrants or consortia cannot insist on seeing such information. If there is evidence of major suppliers using a 'dominant' position in the market to exclude others, they could be in breach of anti-competition laws.

It is recommended that the SIEF agrees ideal methods for analysis and that the lead registrant communicates these to other SIEF members to facilitate the sameness discussion. Even passive members need to be part of this process and if buying into an existing registration, it is recommended that the lead registrant is asked to advise on methods; review of dossiers by ECHA will look for substance sameness and if using comparable methods, it will be easier to demonstrate sameness.

** More details of analysis requirements can be provided on request*

Purity

It is in the collective interest of the SIEF to come to an agreement on purity, but it is apparent that the main justification to keep someone out of a joint registration process is that their 'impure' substance may impart hazardous properties not present in the agreed specification. Ultimately, this decision is one that ECHA will need to make and is why all registrants are asked to specify purity in their own personal part of the registration process (Section 1 of IUCLID 6). A compromise may be that if the known impurities a likely to cause a hazard, that registrant will classify their supply based on the impurity, but still enjoy access to the lead registration. Any known impurity found at levels of over 0.1% w/w may need identification on the Safety Data Sheet (SDS) and label of the supplier if a Substances of Very High Concern (SVHC) or sensitiser, or at over 1% w/w if otherwise hazardous.

If no compromise can be reached and the suppliers of low purity material cannot demonstrate that their substance is within the hazard assessment agreed by the SIEF, then it is possible they may need to register as two or more 'grades' (or consider the materials to be different substances with separate registrations). Any grade variation needs to be matched in Section 2 of IUCLID (Classification) and during supply of the substance, the SDS and label will need to reflect the grade.

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There is also the danger that exclusion of others from a SIEF could be considered as anti-competitive behaviour; this is deemed to take place when companies, or groups of companies, use their 'dominant market position' to make decisions that have a commercial impact on customers or competitors. In other words, if forced out of a SIEF without good reason, the company not given access to the SIEF discussion process or the lead registration may have legal grounds to insist upon it. There is little evidence that this happened in the first round of registrations in 2010.

Exposure Scenarios, Chemical Safety Report and Safety Data Sheet

In Section 3 of IUCLID 6, details of manufacture and use (including tonnage details) need to be entered and linked to Exposure Scenarios in the CSR. The CSR is required for substance registrations above 10 tpa and every registered use of ≥ 1 tpa needs to have a corresponding exposure scenario.

The first part of the CSR (Part A) is a summary of risk management measures (RMM) and declarations that these are being implemented by the registrant and a declaration that they are being communicated to customers. In cases where the CSR is being shared, by agreeing to share the CSR, the registrant also agrees to the declarations in Part A. Some consortia and SIEFs have provided only a generic CSR to joint registrants and asked each joint registrant to complete to their own 'standards' and complete their own Part A and submit with their own dossier. Other SIEFs have not prepared joint CSR.

Where joint CSR have been prepared, it is essential that those buying into the registration obtain a full copy of the CSR (preferably in a form that can be edited themselves at a later date if needed); the CSR is needed to prepare extended SDS. For this reason, joint registrants must be in agreement with the content of the CSR as it will impact on later supply conditions and uses.

A lot of the information in the SDS may be included in the lead registrant's dossier in Section 11 (Guidance on safe use) and this includes first aid, fire fighting, accidental release, handling, transport classification, stability and disposal. Some joint registrations do not include this section and even offered for sharing, joint registrants do not have to agree to this part.

More information on ES, CSR and SDS can be provided on request, including personalised in-house training.

Inclusivity in a SIEF or access to existing registrations

Non-active members of a SIEF may not find themselves included in all discussions taking place in the SIEF or be invited to meetings if being held; by being passive, the registrant has effectively surrendered their participation in the SIEF activities – the advantage to the registrant is that this means they are not spending significant time on SIEF work and can get on with other responsibilities in their employment. There is also the advantage to the active SIEF members that there are fewer potential registrants to consult and therefore the SIEF processes, hopefully, become more streamlined and efficient.

If buying into an existing registration, the joint registrant will find that work has already been done. Although by joining, the new registrant will find that they become collectively responsible for further requests for information by ECHA.

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However, being passive, or even dormant, does not mean that the registrant has no right to be involved and can ask for progress updates or even start taking a more active role if they wish. Late-comers to a joint registration have the same rights as all others in the joint submission and non-consortium members have the same status as those in consortia.

Note that there are web-based systems available that can help; however, there is no compulsion to join such systems, even if instructed to do so by lead registrants; likewise, registrants cannot be forced to join a consortium.

Costs in a SIEF

In 2016 the European Commission adopted an implementing regulation that defines more clearly what the terms “fair, transparent and non-discriminatory” mean in terms of data sharing within the SIEF. The implementing regulation defines rules to ensure that data-sharing agreements in SIEFs are clear and comprehensives. Those potential regulations who are looking to join a SIEF now have the right to ask for a breakdown of both the study and administrative costs that make up the final price for the joint registration. Most importantly, registrations are only required to share the costs of the information that they require for their registration, for example they do not need to pay for data that is required for higher tonnage bands. The regulation also requires that each SIEF set up a reimbursement mechanism as part of the cost sharing model which should consider potential future registrants and set out a method of reimbursement to each co-registrant.

Guidance on cost sharing is available on request.

Joint registration

Most registrations will be ‘joint’ in that one lead registrant will submit a complete dossier and others, the ‘secondary’ registrants, will only need to submit a reduced registration containing only personal information relating to their own substance identity and describing their proposed industry and process types. The technical information making up the bulk of the IUCLID 6 dossier on the substance that covers hazards, the derived no-effect levels (DNEL/DMEL), the predicted no-effect concentrations (PNEC) and proposals for classification will only be completed by the lead registrant.

This situation leads to the justified concern for many whether the lead registrant has got it right and the ‘master’ dossier is accepted; if taking a ‘passive’ role, the secondary registrant may not have had much input into this dossier and the counter argument is that if the passive member is that concerned, they should have taken a more active role. One risk is that the substance identity in the lead registration is incomplete and it is not possible to link the substance identity of the secondary registrants with that of the leader and this reinforces the importance of good analysis using comparable methods that allow sameness to be assessed.

The lead registrant will declare their intentions to ECHA through REACH IT and obtain a ‘token’ in the form of an electronic reference number to pass to other SIEF members. Joint registrants then declare their inclusion in a joint submission with this ‘token’ and when used, a message goes to the lead registrant. The token will expire over time and it may be necessary for the lead registrant to obtain new tokens; for this reason, some consortia are limiting registration ‘windows’ to certain time

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periods to reduce the time wasted constantly obtaining new tokens. Although lead registrants cannot withhold the token, joint registrants should be sensitive to these issues.

Support on the use of IUCLID and REACH-IT can be provided by REACHReady.

Conclusions to REACH in practice

Understanding the legal text and the official guidance will only give a framework in which to work. In practice, there are many examples of substances and articles that will not be covered in generic text and the methods for testing or how to register will need to be considered on a case-by-case basis.

Likewise, human nature will ensure that no two SIEFs will work the same way and what is considered appropriate, or fair, in one SIEF will be discounted in another.

Knowing the legal position and working to the spirit of REACH will help provide answers in more cases, but ultimately much of it is commons sense and good business and personal skills.

Finally, extreme caution is needed when entering any type of legal or financial agreement. Aiming for a win-win solution is essential, but there may be some who are seeking to take advantage of other's misfortune.

Need further help?

If you need help understanding the impact of REACH on your business, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.

If your customers or suppliers need help, get them to sign up to REACHReady's Gold service at http://www.reachready.co.uk/ and let us help them too!

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