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In the driving seat

Riku Rinta-Jouppi of **REACHLaw** looks at the issues in taking on REACH as a lead registrant

In REACH, the Lead Registrant (LR) 'holds the keys to the kingdom'. No registration is possible without one. And successful lead registration is ultimately the key to keeping substances available on the European market.

However, the LR takes on substantial legal and technical responsibilities by accepting the role. These span from the timely execution of a joint registration to managing compliance after registration when the authorities demand further data. A well-planned process and often the help of an external service provider can see LR through the critical path to registration and beyond.

As of 20 January 2010, only 2,261 lead registrants had informed the European Chemicals Agency (ECHA) of their nomination and substance information exchange forum (SIEFs) formation. SIEFs are the formal mechanism defined in the REACH regulation for information exchange on any given substance.

The ECHA had been expecting at least 9,000 joint submissions, notably those of High Production Volume (HPV) chemicals and those defined as carcinogenic, mutagenic or reprotoxic (CMR) for the 2010 deadline. The recommendation had been to submit joint registration dossiers to the ECHA by September 2010 at the latest for the individual registrants to be able to follow suit before the 30 November 2010 deadline.

Many companies are simply waiting for major manufacturers to take the lead in their pre-SIEF, a loose body which automatically includes any companies that have pre-registered a particular substance. However, these key players are often hesitating to do so, due to the financial and legal uncertainties as well as the organisational challenges associated with the LR role.

A pre-SIEF is simply a contact list of companies that have expressed interest in a substance by pre-registering it; it does nothing on its own. Moreover the ECHA has no mandate to interfere, even if it knows that a particular joint registration will

not be completed in time. Therefore, it is up to the company/ies with the greatest industrial interest in the substance to decide how best to organise and carry out the registration work.

In most cases, the first step is to nominate a LR to take responsibility for taking the process forward and take the legal responsibility for submitting the joint dossier. The co-operation between companies committed to registration should always be based on a written SIEF, a co-operation agreement, a consortium agreement or a combination of them to formalise the rules of co-operation.

After agreement on substance sameness, all the pre-registrants have become members of the same substance SIEF. Each SIEF must nominate a LR to submit the information. Once the LR dossier has been submitted, the other members of the joint submission may submit individual registrations according to their individual deadlines.

As described in Table 1 and Figures 1-4, the LR registration process as a whole requires a lot of legal and scientific expertise and an understanding of the underlying chemical business.

The Lead Registrant process

The first step in the LR process is to analyse the role and nomination of the LR for the same substance for each SIEF (Figure 1). At this stage, it might be necessary to consult a lawyer in order to ensure that the agreement and all joint registration activities are executed in a way to comply with EU competition law and to meet the standard of being fair, transparent and non-discriminatory.

The major activities in the lead registration process, are related to generation of the joint registration dossier which includes the data collection and evaluation, as well as hazard and exposure assessment and risk characterisation of the registration substance when needed according to the REACH regulation (Figure 2).

In the practical lead registration work, physicochemical, ecotoxicological and toxicological knowledge are essential to fulfill the REACH requirements. Therefore, it is usually more cost-effective and reasonable for companies acting as LR to use external assistance for the work instead of recruiting a separate project organisation for the task.

As described in Figure 3, the data gap evaluation requires an understanding of whether the study reports and literature are valid for registration purposes, and what information is missing. Expert judgment is also required if non-test methods (Figure 4) are used instead of laboratory testing.

REACH Technical Guidance Document Chapter R.6 states that: "The obligation to carry out vertebrate testing only as a last resort and to consider all other options before performing (or requiring) testing is laid down in REACH Article 25. This includes the need to gather all existing information on physicochemical, toxicological and ecotoxicological properties of a substance, including information generated by (Q)SARs and chemical grouping methods."

Influence of CLP

REACH is said to be arguably the most challenging piece of chemicals legislation worldwide. However, EU Regulation (EC) No. 1272/2008 on the Classification, Labelling & Packaging (CLP) of Substances & Mixtures, which implements the UN's

Table 1 - Practical tasks a Lead Registrant

LR Nomination
SIEF consultation on nomination as LR
SIEF operations
Agreement of substance ID
Agreement on SIEF rules via SIEF agreement
Liabilities & contractual arrangements
Decision on the scope of JS (e.g. CSR as part of the JS)
Definitions & timing for all actions
Centralisation of data sharing with data owners
Setting up a system for invoicing & payment
Establishment of data availability
Agreement on classification & labelling (C&L)
SIEF communication
Keeping SIEF members regularly informed
Keeping open communication with SIEF & the SIEF distribution list updated
Preparation of the Joint submission for Registration dossier
Creating a joint submission in REACH-IT
Ensuring that registration dossier passes the completeness check
Setting up internal systems in order to ensure that the registration fees are paid by the deadline defined by the ECHA
Post registration
Follow-up of the examination of testing proposal by the ECHA
Keeping the joint submission updated
Source - CEFIC

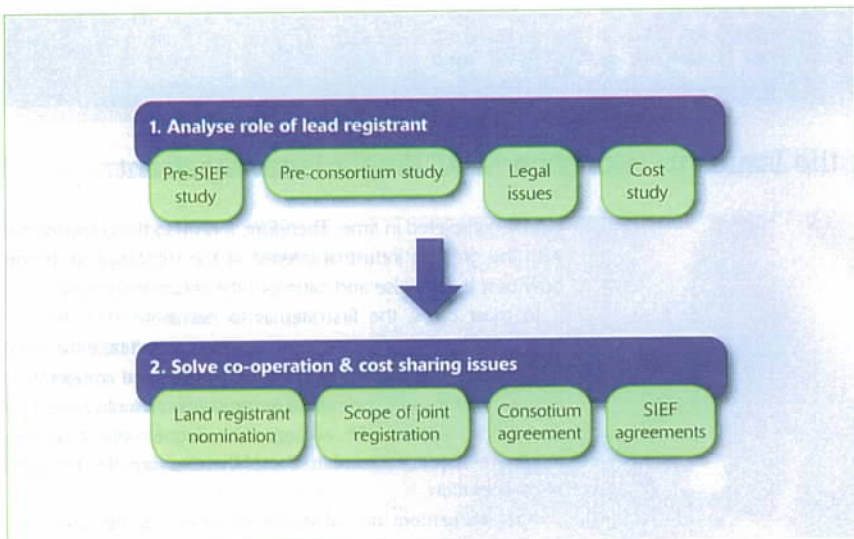


Figure 1 - (above) Administrative actions related to a LR registration process

Globally Harmonised System (GHS) of classification and labelling of chemicals (UN GHS), could well turn out to be one of the most underestimated EU laws.

The deadlines set by the CLP are 1 December 2010 for the classification, labelling and packaging of hazardous substances placed on the European Economic Area (EEA) market and 3 January 2011 for the notification of certain groups of substances to the classification and labelling inventory established and maintained by ECHA.

The LR in a SIEF will need to take into account CLP for his joint registration. CLP classification and labelling of the substance should already be included in 2010 registrations, after it has been agreed in the SIEF, otherwise a charged update of the registration dossier could be due immediately.

The CLP is also likely to push later registrants (those with deadlines in 2013 or 2018) to register in 2010, including CLP classification and labelling, in order to fulfill their individual CLP notification obligation.

Manufacturers and importers not participating in joint registration submissions 2010 have to notify the classification and labelling of substances subject to (later) REACH registration and hazardous substances regardless of tonnage they place on the market on or after 1 December 2010, either on their own or in a mixture above specified concentration limits.

To this end, they may approach the lead registrant for their substance to obtain classification and labelling information. The LR should consider this potentially increased workload. He may also have a role in organising joint notifications as a group for non-2010 registrants.

Joint registration agreements

The key to REACH joint registration is the one substance one registration (OSOR) requirement. OSOR stipulates that for each substance there is to be just one joint registration (joint dossier) submitted by one company - the LR - on behalf of all of the registrants.

When the joint dossier has been submitted, the other registrants can then register by submitting their company-specific information (individual dossiers) making reference to the joint dossier. Registration is not possible without referencing the joint dossier, although it is possible to choose to opt out of some parts.

In practical terms, therefore, the OSOR requirement forces manufacturers and importers of the same substance to select one among them as the LR. The LR then needs to proceed to co-operate with the other companies in sharing information and costs. The success or failure of the co-operation determines to a

great extent whether or not the individual registrants can continue to supply the substance to the European market after the registration deadline.

The purpose of joint registration agreements is to agree in writing how to execute the work needed for the joint registration of a substance. The scope of co-operation may vary, because potential registrants can choose to prepare certain parts of the registration either together or separately.

It is also good to keep in mind that in a typical pre-SIEF only about 10% of the companies are actually committed to registering the substance. For successful co-operation it is important to understand:

- The number of committed registrants out of all the pre-SIEF members
- The relative market position of the main committed registrants (though without breaching competition law)
- The concentration of ownership of existing data
- The common interests and willingness among the committed registrants to co-operate

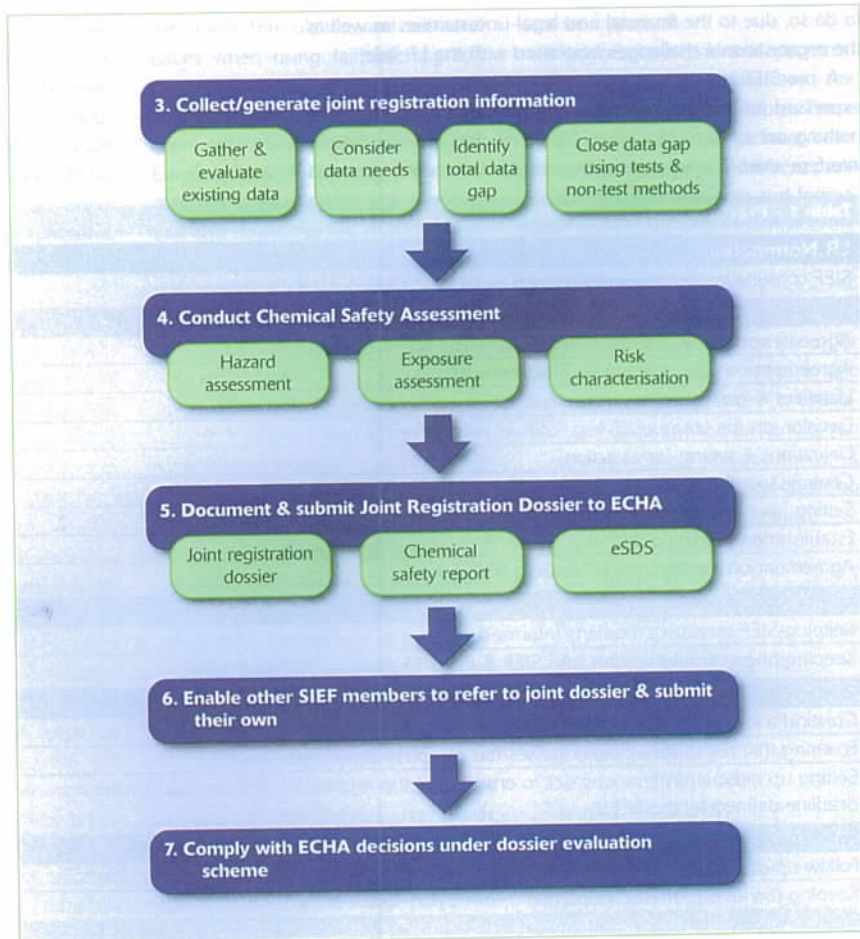
Considering these four factors together will give the prospective LR a good idea of the possible scope of co-operation and help in choosing the right instrument to fit the desired level.

Choosing the right instrument:

The lightest form of co-operation is a **SIEF agreement-based co-operation**. In practice this means that, if there is just one dominant manufacturer in possession of key studies and funds to start and prepare the joint dossier on its own, this company completes the registration work alone with the help of a project manager from a company like REACHLaw.

The SIEF agreement is offered to SIEF members to define the terms on which the other potential registrants can gain a licence to refer to the joint dossier without actual ownership of

Figure 2 - (below) Activities related to the more scientific part of the LR registrant process



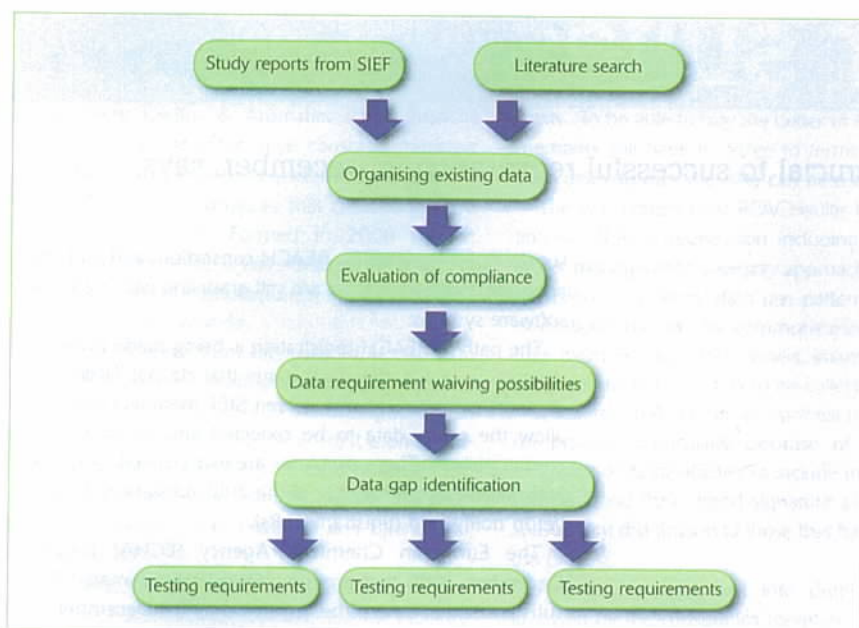


Figure 3 - Data gap identification in the LR registration process

data (a Letter of Access) by paying a fee to the lead registrant at the end of the project when they are about to register.

The major benefits of SIEF agreement-based co-operations are that the company with the greatest industrial interest and the best available resources can complete the technical work practically alone without spending resources on working in a group and consulting with other registrants. Of course, competition law needs to be taken into consideration and SIEF members need to be informed of the progress of the work periodically.

A **co-operation agreement** is often the simplest way of organising joint registration when there is a relatively small group of key registrants. These firms are invited to agree on the terms of co-operation and to share costs all the way from the beginning to the end of the project, under the leadership of the LR. Again, most of necessary work can be done with the help on an external project manager.

In this case, the co-operation can be managed quite flexibly on the basis of the co-operation agreement without the need to create the complex decision-making structures that are usually needed when the number of participants is high. The key characteristics for LR-driven co-operation are that:

- The co-operation covers only one or a few substances
- The lead registrant manufacturer takes most of the responsibility for the work
- The project team will be assembled by the LR
- There is only a very light project organisation

The major benefits of this kind of agreement are that the costs can be reduced, the LR can be sure that the costs will be shared on the basis of the co-operation agreement and there is a lower risk of disputes between the major manufacturers during the registration process.

A **consortium agreement for a large group of registrants**, by contrast, creates a formalised legal structure, within which a multitude of companies can participate in a joint registration. The consortium, which might be run by the REACHLaw secretariat, can undertake the technical and administrative tasks necessary to produce the joint registration dossier for the members.

It is always possible to expand the scope later if the members of the consortium find it necessary but the original scope should be just the bare essentials so as to minimise the time spent on negotiating the agreement. The consortium often uses a trustee to make it easier to manage confidential information which is needed for the registration.

The major benefit of this kind of consortium agreement is that the manufacturers are able to join forces to get the registration work done in an orderly fashion and share the costs between members within a large group of registrants.

Regardless of the type of joint registration agreement, the agreement and all joint registration activities must be executed in a way to comply with EU competition law and to meet the standard of being fair, transparent and non-discriminatory. The agreements are drafted to be as clear and concise and to the point as possible, covering the key points in a limited number of operative clauses to avoid protracted negotiations over contractual complexities.

Summary

Most commonly, a simple co-operation agreement is recommended if there is a relatively small group of committed registrants who are determined to form a leadership team to contribute actively to the work and to share costs from the beginning.

A relatively high number of registrants with a low level of input to the joint registration can be covered effectively by means of a SIEF agreement-based co-operation, if there is a single dominant manufacturer ready to take sole legal and financial responsibility for completing joint registration with the practical work being executed by an external service provider.

A formal consortium agreement is needed if the number of registrants wishing to participate actively in the process is high or if several substances are to be registered as a substance group. Time is of the essence, regardless of the choice of instrument. The first registration deadline for the submission of the joint dossier is now only months away.

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Figure 4 - Non-testing methods to consider before animal testing

