Sharing your suites

Using the right data sharing IT system is crucial to successful registration in December, says **Malcolm Pollard** of **Baytouch**

REACH places responsibilities on all European manufacturers and importers to identify and manage the risks that their substances may pose to human health. The formation of the Substance Information Exchange Forum (SIEF) is central to the REACH process, allowing SIEF members to share their toxicological data and prevent further animal testing.

The fact that shared studies have value and further research costs means that the exchange of contracts and the reconciliation of these costs occur when substance registration is due, the deadline being 1 December 2010. Effective IT systems are needed to manage this in order to reduce the significant administrative overhead.

Progressive consortia and SIEFs are now quickly moving towards successful REACH registration, thanks to new software developments, such as REACHsuite from Baytouch, a supplier of IT systems for REACH consortium and SIEF management. However, others are still grappling with inadequate software systems.

The path to REACH registration is being made even more difficult by overloaded IT systems that do not facilitate the essential communication between SIEF members that would allow the safety data to be collected and positions clearly communicated. These problems are exacerbated by the general malaise of the majority of the 2010 substances which are yet to notify lead registrants (LRs).

The European Chemicals Agency (ECHA) stated in December 2009 that around 75% of the estimated 9,000 substances that have to be registered by the December 2010 deadline had yet to nominate a LR. SIEFs can still form and begin operating immediately, but only by making use of the right software will they be able to facilitate SIEF operations quickly and collect safety data for the registration dossier on each chemical substance in time

Lack of communication between prospective SIEF members has proved to be the major stumbling block in the registration process. As well as inadequate software systems, companies have also struggled with the complexity of establishing, running and participating in a SIEF - which could logistically involve communication between hundreds, if not thousands, of members.

Part of the problem is that REACH software programmes have had to be revamped. The number of pre-registrations was hugely underestimated and IT systems designed for much smaller numbers were unable to cope when the preparations for drawing up registration dossiers started. Software has also struggled to keep pace with the rapidly evolving requirements of REACH.

Two significant barriers for SIEF members to start collaborating through online systems are the cost frequently involved in accessing the IT platform and the often protracted 'sign-up'. REACHsuite gets round these by barriers by adopting a different cost model. The consortium or LR picks up the cost of the IT platform, then redistributes this as a reasonable operational cost when the dossiers or the Letters of Access are made available to purchase.

In this way, there is no upfront cost for any SIEF member to access the system, so response rates are much higher than the industry average for communications and surveys - typically 10-20%, with one consortium regularly reporting a 25% response rate. REACHsuite also has no sign-up process for SIEF member access, making it much easier for members to get involved.

All that said, IT solutions are not the be-all-and-end-all of substance registration. No matter how good the IT platform, it will not support poorly designed business processes or cover for a lack of REACH knowledge and understanding. This is a major challenge at present, as there are too few experts around to help facilitate this process.

To address this, Baytouch has developed a network of service provider partners who can provide the support necessary to expedite registration and who use REACHsuite to support their processes and methodologies. This is being used in some major consortia where companies have established

Aluminium REACH consortium

The European Aluminium Association (EAA) is the European trade organisation for the aluminium industry, representing the complete production chain for aluminium in Europe. It has organised the Aluminium REACH Consortium, which comprises all of the major producers active on the European market (in effect, all of the world's major producers) and a number of smaller speciality producers.

As the representative of the major producers, the Aluminium REACH Consortium was determined to take the lead in the registration process. However, the process of SIEF formation and SIEF communication presented a major challenge.

After the pre-registration phase for REACH, according to Eric Nordheim, the association's EHS director, the EAA was faced with the situation of 5,200 pre-registrations for aluminium metal, 2,500 for aluminium oxide and 1,350 for aluminium hydroxide, a total of over 9,000 SIEF contacts. Many of these are not consortium members and many are only interested in the cheapest and most efficient way of being part of a registration process.

The consortium secretariat looked at different tools for organising the SIEF work and communication with all the SIEF members. It selected REACHsuite for this task, considering this to be an efficient tool and with the potential to develop additional functions as need, Nordheim says.

The consortium is now using the REACHsuite SIEF Management tool for all of its SIEF surveys and communication. It has
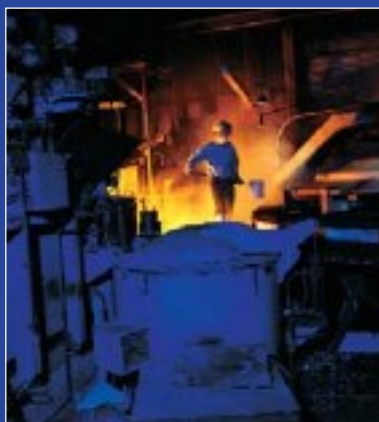
also worked with Baytouch to develop a web-based system for signing up to Letters of Access for companies who do not want to join the consortium but do want to be part of a joint registration.

The Letter of Access means that the company will be part of the joint registration from the LR, which will contain all the necessary data for the REACH registration and the GHS classification of aluminium metal, aluminium oxide and aluminium hydroxide. The company in this case only has to fill in its own details, substance information and the use information, and for the rest of the file refer to the LR file, which will also include a joint CSR.

The LR will issue a security token as soon as his registration file is submitted, and the other registrants will use this for their own registration submission. The intention is for the LR to submit the registration before end of September 2010.

Lower olefins and aromatics

The Lower Olefins & Aromatics (LOA) REACH Consortium is one of the larger consortia preparing for REACH and its plans to assist their membership to register those substances that are due in 2010 are well advanced. Formed in 2008 by the European producers, it has attracted almost all of the major world manufacturers, growing from a membership of 16 to 48.

The LOA consortium has used REACHsuite to manage the data, reporting and workflow requirements demanded by REACH. According to executive project manager Mike Penman, it is on schedule to enable its members to register for all 130 LOA substances in the summer, despite the enormous challenges, both technical and operational, posed by REACH.

Because the LOA consortium manages many of the basic building block substances in the industry, there is huge interest in its work and there are over 37,000 pre-registrants of these substances. These go to make up the SIEF members, so the amount of information to be managed is huge - and that is not only the case for the technical data.

The consortium intends to develop the common parts of the registration dossiers and make them available to non-members for a fee. This would cover the data rights to the information in the dossier, as well as the effort required to prepare

them. To be able to buy the Letter of Access, non-members will have to agree to terms and conditions defining how the data can be used.

The consortium uses REACHsuite for information on REACH registration including substances under management, category approached for data provision, proprietary data use patterns and data evaluations, but also for communication to the 48 SIEF members and data owners, enabling surveys to be conducted and data to be collected.

It regards REACHsuite as essential to the logistical process, particularly because of the recent extension of its capabilities to include the issuing of contracts and their digital signature and then the subsequent distribution to those that have paid into the process.

The data is organised into distinct modules accessed by the consortium members and service provider teams, grouped into task forces. The consortium or substance management part consists of:

- Substance Management, covering the substance details, registration plan, uses and exposure data, substance action plan, information requirements and costs
- Consortium Members & Service Providers, which lists all the consortium members and provides the basis for access to the substances, as not all members are interested in all substances

- Supporting Documents, a repository for all documents which can be shared across substances
- Proprietary Data, offering secure storage with access only by the data holder and the highest level administrator
- Action Tracking, giving common access throughout the entire system to store project plans and actions attributed to individuals monitored in real-time for delivery dates by the system

Figure 1 shows the functionality of the SIEF Management Module. This comprises SIEF Management, with downloaded details of SIEF members from REACH-IT, and SIEF Communications, where communications, both emails and customised forms, are managed by the consortium or the LR, along with responses.

Access for those SIEF members that are not the LR or consortium members is to their own information portal, the SIEF Report Pages. All the documents ever communicated by the consortium relating to the SIEF member are available here, including survey results, position papers, classification and labelling information, contracts for signing and so on - everything that a SIEF member should have access to in order for the consortium workings to be seen to be fair, transparent and non-discriminatory.
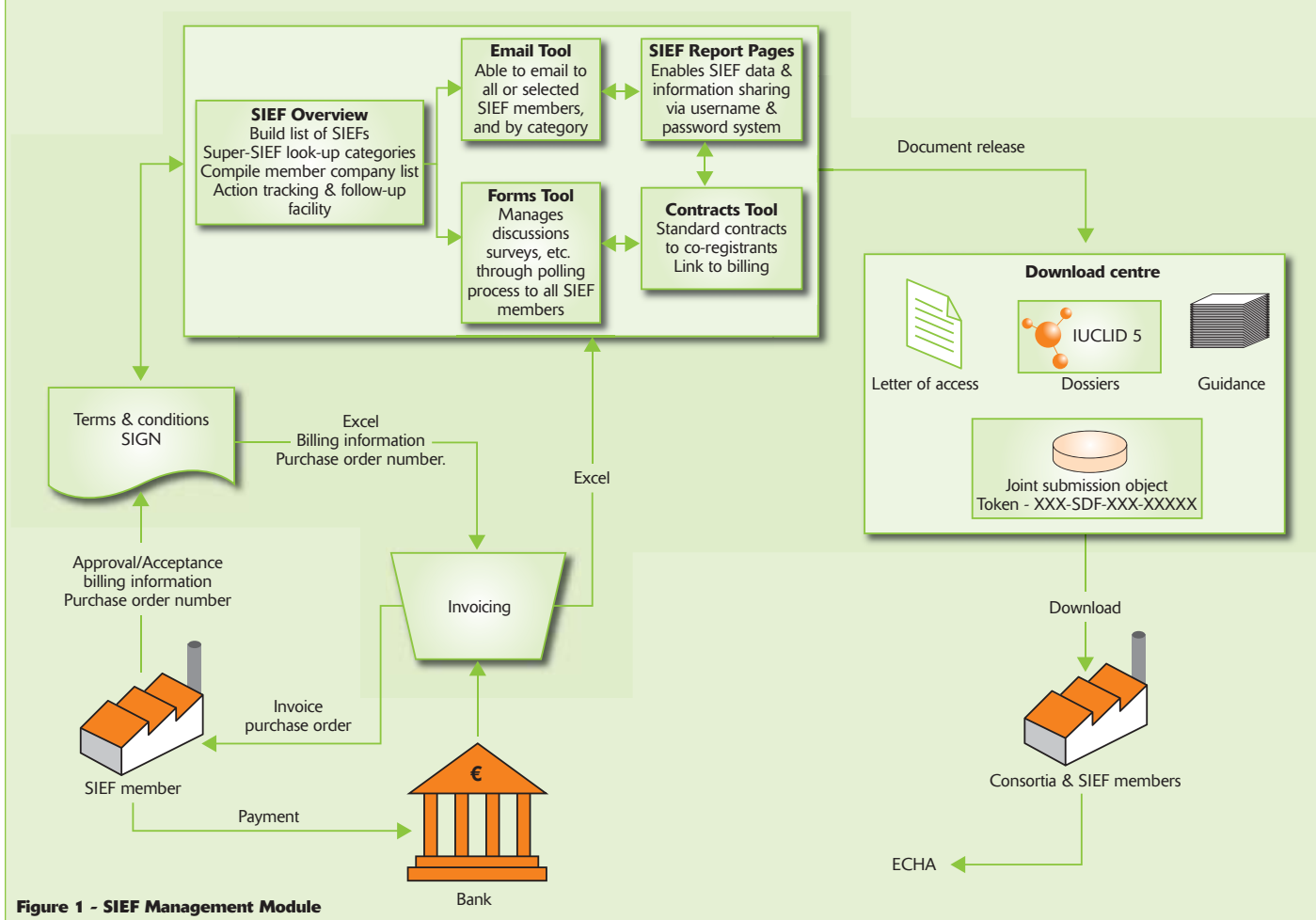

Figure 1 - SIEF Management Module

leadership roles in SIEFs and are bearing the major part of the workload towards registration.

One customer has been Stephanie Barrett, project manager for ICF International Environmental Services in Brussels. She has used REACHsuite for a sizeable REACH consortium managing 126 substances, 19 service providers, 37 consortium members and 1,100 SIEF contacts.

For a small number of substances, however, buying REACHsuite outright may not be the most cost-effective option, particularly if those managing the SIEF lack the time to administer it and feed in data. For example, Graham Robb of Penman Managed Services (PMS) has used it selectively in the management of SIEFs, in SIEF communications, work planning and cost sharing management.

The usual model, according to Robb, is such that PMS is contracted by the lead registrant, but the costs will later be shared between all active participants. This works much better than trying to get all SIEF members to contribute up-front. Someone, he adds, needs to bite the bullet but the overall result is that all can see a plan towards registration and a means to get there.

Recently Baytouch showcased new technology that meets legal guidelines enabling contract development, billing and document and dossier distribution to be done online, which will allow thousands of SIEF members to sign online and download all the documents required for their registrations without the need for lengthy paper-based processes. Other recent enhancements have included improved taskforce management facilities extending support for securely managing multiple substances within consortia, IUCLID integration and the secure handling of proprietary data.

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Another REACHsuite customer has been Mike Neal, of Petkonsept Polymer Consulting, who uses it to manage two consortia: Epoxy Resins and Polyester Monomers. He says that he has found it quick, easy and the best way to generate responses from within SIEF. By contrast, working via email has proved to be very costly from a time point of view and is also logistically difficult to manage.

At the moment there are only about 9,000 substances going for a 2010 registration. For the 2013 deadline, that figure could be over 50,000, perhaps with less data available to assist the registration process. I believe that people will look at those substances that make it through to 2010 and, hopefully, reflect on the organisation, the service providers and the software platform used when evaluating the success factors and these will guide them with their 2013 choice of partners and IT platforms.

There is no doubt that REACH has had an impact far beyond the EU and is now influencing the thinking and approach to chemical safety in many other emerging international regulations, notably the US, where the Obama administration is signalling its review of chemical safety legislation. Baytouch already has US-based partners acting as Only Representatives for US companies importing into the EU who want experience with REACHsuite to be ready for when the call comes for similar services and tools.

We are now at an early stage of discussions with partners about how to repackage our expertise for the Chinese market. There is a growing awareness of REACH in China and one day a similar regulation may come into being there. There is no doubt at all that demand for services like this will continue to grow across the globe.