

Lower olefins consortium on track for 2010 REACH deadline

While there is concern about the lack of progress in many REACH Substance Information Exchange Fora (SIEFs), the Lower Olefins and Aromatics (LOA) consortium appears to be forging ahead. Emma Chynoweth describes the group's approach.

The LOA consortium is unique in a number of ways. It was one of the first multi-substance consortia, officially established a year ago to provide a platform for the joint development of REACH registration dossiers. Its executive project manager, Mike Penman, says the consortium is on schedule to produce lead registration dossiers for some 128 substances by May 2010. "The work plan is on track and we see no problem in delivering."

Last month it held a webinar to provide a progress report to companies belonging to SIEFs for the substances the consortium plans to cover. It was also an opportunity for SIEF members to ask questions. The information included a tentative pricing structure for letters of access to data that companies will require to complete their REACH registration dossiers. The figures have now been agreed by the consortium's general assembly and it plans to consult 20,000 SIEF members this month.

Cost sharing

According to Jonathan Forbes-Lane, chair of the LOA general assembly, the figure for most substances will be in the range €5,000 to €20,000 per substance, per legal entity, depending on anticipated costs and the number of SIEF members interested in purchasing the letters of access. In some cases, where few companies are involved or the data requirements are uncertain, cost sharing still has to be assigned. He adds that the consortium is aiming to be cost neutral and "balance fairly the interests of our member companies and those that prefer to stay outside the consortium."

Companies have two options: they can join the consortium – costs incurred so far are approximately €120,000 per member – but the joining fee will not cover data access rights or the costs of additional studies; or



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The LOA consortium is striving for a fair cost sharing balance for members and others

they can buy letters of access depending on substance and number of legal entities. The consortium regards the base cost of €5,000 per substance per legal entity as highly competitive.

The consortium stresses that the price is per substance, even if the substance is

similar to another. Its cost basis takes into account the fact that it will be producing joint dossiers for categories – 90 of the substances under its remit are grouped within 12 categories. Costs will be spread for studies used for more than one substance. The consortium is aiming to source appropriate data from companies and trade associations, including those outside the SIEF system, setting up agreements that will enable it, in as many cases as possible, to pass on data rights for REACH purposes.

Lead registrants

As well as making progress on costs, lead registrants have now been agreed by consortium members for over 90% of LOA substances, in some cases potentially by-passing the role of the SIEF formation facilitator. For the 128 LOA substances there are almost 37,000 SIEF members. The

Price of letters of access to data from €5,000 to €20,000 per substance, per legal entity depending on costs and numbers interested

consortium has identified the proposed lead registrants on its website. No negative feedback has been received from either SIEF members or the European Chemicals Agency. Mr Forbes-Lane says the consortium is interpreting this as a sign the SIEF members are happy with the consortium's choice of lead registrant.

Free access

Mr Penman points out that communication with the consortium is free for SIEF members in order to make the process open and fair. The consortium has set up SIEF-specific pages on the LOA website with specific sections, for example, on substance sameness, proprietary data, classification and labelling and uses and exposures.

LOA is also developing use information and exposure scenarios. "REACH is just as much about understanding use and exposure as toxicology," says Mr Penman. In as many cases as possible it will use generic exposure scenarios.

And where specific uses are not covered by the wider interests of the consortium members, or companies want to maintain confidentiality, LOA will provide data for companies to prepare their own risk or environmental assessments.

Mr Penman says the potential success of the consortium is based on its structure as well as the management systems specifically

developed to deliver the information that companies will need for REACH and the hard work of its members.

The consortium itself comprises a general assembly, within which each member can vote on decisions relating to the consortium's agreement, budget and

prepares draft dossiers and use information. A technical steering committee of around 20 people who, according to Mr Penman, have a "deep experience of LOA substances, EU regulatory aspects and REACH specifics", reviews outputs and provides oversight.

At present the consortium has 28 members. Four companies are in the process of joining, and there have been expressions of interest from a further 70 firms.

The management system relies heavily on its IT platform – REACHsuite (see box) – which is described as a filing cabinet containing all the relevant information, such as companies, substances, UIDs, substance categories, proprietary data, data evaluations, and so on. The IT system also provides a link to the SIEF members for each substance covered. It also enables surveys to be conducted and data to be collected.

May 2010 goal

The consortium has identified over 130 actions that need to be undertaken for each substance, such as data gathering and review, data entry, classification and labelling, use, exposure and risk characterisation. These actions have been scheduled into a complex work plan to ensure that all technical activities are completed by May 2010 in order that lead

Over 130 technical actions per substance will need to be completed by May 2010 in order to enable lead registrants to submit joint dossiers by June 2010

financial statements, approval of the core registration data and membership status.

An executive committee oversees the day-to-day running of LOA. A service team – including lawyers, financial controllers, IT experts, technicians and scientists –



registrants can submit dossiers in June 2010. This should then allow plenty of time for lead registrants to be awarded their registration number by ECHA and distribute it to co-registrants.

Every registrant will be responsible for compiling company data, including substance identification, classification, manufacturing, use and exposures and Part A of the Chemical Safety Report.

Call for proprietary data

The consortium will provide data for the lead registration, including physicochemical properties, environmental fate, ecotoxicology and toxicology and guidance on safe use.

It will also provide the common assessment report for the CSR, if needed, agreed classification and labelling positions, and develop the common elements of the extended Safety Data Sheet, including exposure scenarios.

The group will shortly be putting out a call for proprietary data from vertebrate testing using the SIEF management system and asking for SIEF comments on draft classification and labelling dossiers as the positions are developed in the consortium.

The IT system will be extended to include contracts for the letters of access to the dossiers and invoicing.

The benefits of the LOA consortium include its competence for registration; convenience and financial flexibility.

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But Mr Penman warns: “I would not want to underplay the size of the technical challenges. For each substance there is a

large amount of detailed technical work to be done that has to be checked and agreed with a large number of people.

At the same time it has to fit with ECHA guidelines and pass the completeness check that will be applied. As yet we do not have the final tool to do this work, so some aspects of what we are doing now will have to be revisited.”

Major challenge next year

The amount of information to be managed overall is huge and that is not only for the technical data. Communication has to take place with SIEF members and data owners, followed by negotiations on valuations: “Next year will be a major accountancy and logistical challenge,” Mr Penman predicts.

He advises any company waiting for a SIEF to be proactive. “If a substance is important for your business then you will have to make the first move.

“Waiting for someone else to do something is likely to mean that meeting the 2010 deadline with all the difficult tasks it involves, with a decreasing pool of competent resource, will become almost impossible.”

Meeting the IT challenges of large, multi-substance REACH consortia

There is currently no single IT solution that encompasses all data management, reporting, and workflow requirements driven by REACH and this situation is unlikely to change in the near future, says Malcolm Pollard CEO, and co-owner with Mike Penman, of Baytouch, which sells the REACHsuite IT communications platform.

REACH requires multiple reporting of the same data to different audiences with different systems.

Of these, REACHsuite meets three core needs:

- * Integrated IT for substance, use and cost management
- * Supply chain communications
- * Consortia management with Substance Information Exchange Fora

(SIEF) communications

The system is designed to handle information on substances, products, mixtures, polymers and article portfolios; and covers uses, including in-house and supplier, and customer intentions. Supply chain communications is done with web-based forms.

Managing super-SIEFs

“REACHsuite is specialised in dealing with large consortia, where we have a number of key benefits, such as being able to cater for categories – the so called super-SIEFs,” says Mr Pollard, “and the system has proved up to the task of managing and reporting for some of the largest consortia and SIEFs within REACH.”

The system contains process tools for complex project management and

includes use and registration intentions. It develops action plans for each substance or category being managed by a consortium and captures information requirements and proprietary data costs so that consortia members have a clear picture of on-going costs.

A specific characteristic of the system is that the central consortium or in the case of a SIEF, the leading members, picks up the IT costs, which are then transparently passed on to non-consortium members as operational costs.

“There is no IT cost for the non-consortium SIEF members to interact with the system at the outset. This aids fairness, transparency and non-discrimination,” Mr Pollard adds.

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