



# REACH: petroleum industry support to registration and compliance

.....  
**If you thought that  
the REACH registration  
process ended in  
December 2010,  
think again!**  
.....

The petroleum industry successfully met the first REACH<sup>1</sup> deadline in December 2010 with the registration of all petroleum substances and sulphur. (See CONCAWE *Review* Vol. 19, No. 1 for details.)

Under the REACH legislation, all registrants of chemical substances are obligated to collaborate with each other through Substance Information Exchange Fora or SIEFs. However, no legal structure or communication mechanism for managing these SIEFs was provided by the REACH legislation or by the Technical Guidance Documents issued by the European Chemicals Agency (ECHA). The only service that ECHA provided was to inform pre-registrants of other pre-registrants for the same substance, then leave it to the participants to organise themselves into SIEFs. This included working out the complicated contractual relationships that must exist between competing businesses under EU competition law.

ECHA's guidance did introduce the concept of a SIEF Formation Facilitator (SFF), a legal entity for facilitating the pre-registration of chemical substances by all registrants. CONCAWE volunteered to act as the SFF for all petroleum substances and sulphur, and expects to continue in this role until 2018, the date of the final registration deadline. CONCAWE's SFF role has already proved its value to member companies by substantially simplifying their involvement in the SIEFs.

As the SFF for petroleum substances, CONCAWE's main responsibilities have been to:

- maintain the integrity of CONCAWE's Risk Assessment reports, including the Chemical Safety Reports;
- protect the intellectual property contained in CONCAWE's REACH registration dossiers that were developed and funded by CONCAWE member companies over many years;
- ensure that access rights are in place for all studies referred to in the registration dossiers;
- ensure communication among all SIEF participants who may be CONCAWE member companies or non-members;
- facilitate submission of the REACH Registration Dossiers to ECHA by SIEF participants;

- streamline the REACH process for all SIEF participants by merging related SIEFs and by forming 'Super SIEFs' covering specific categories of petroleum substances; and
- help all SIEF participants fulfil their legal obligation under the REACH legislation to share relevant data in a fair, objective, transparent and non-discriminatory way.

## SIEF activities supervised by the SMCG

Since 2009, CONCAWE's REACH activities have been coordinated by a SIEF Management Coordination Group (SMCG). This group provides oversight for the REACH activities of CONCAWE member companies and the ongoing relationship with non-member companies who are also obligated to register petroleum products. These non-members can include importers and traders who are not eligible for CONCAWE membership under the Association's statutes.

CONCAWE's Secretariat ensures that the SIEFs run smoothly and manages the process of providing SIEF members with access to information under a licensing agreement. This agreement, signed by all SIEF members, includes:

- Licence agreements, essentially a legal framework for the SIEF collaboration, that cover criteria for accessing information and principles for a fair and non-discriminatory sharing of costs. These costs include developing the REACH registration dossiers, updating dossiers, and managing the SIEFs in full compliance with the REACH legislation and with EU competition law.
- A web-based communication platform, called the 'SIEF Communication Tool', that provides SIEF members with timely and relevant information about the substances, the dossiers and their registration under REACH.
- Organisation of the complex but mandatory joint submission of the common parts of the REACH registration dossiers and the continuous update of the dossiers. In 2010, this included the appointment of more than 200 Lead Registrants in charge of submitting common data to ECHA on behalf of all other SIEF registrants.

<sup>1</sup> REACH: Registration, Evaluation, Authorisation and restriction of Chemicals



- A budget for the SIEF management activities covering legal, administrative, information technology, and communication services. These costs were initially fully funded by CONCAWE's member companies and a portion of these costs are being recovered from non-members through the SIEF membership fees.
- A cost model for tracking expenses that were incurred in the preparation and updates of the REACH registration dossiers and for managing the SIEF activities. Importantly, the cost recovery principles needed to be compatible with CONCAWE's non-profit status.

### The first REACH registration deadline

More than 4,000 registrations were filed for petroleum substances before the first REACH registration deadline in 2010. This represented almost 18% of all of the registrations that were submitted to ECHA before the first deadline.

These registrations were successfully completed using the registration process set up by CONCAWE in its capacity as SFF. CONCAWE sold licences for more than 1,000 non-member registrations, and provided access to the common parts of the registration dossiers that were prepared by CONCAWE members for 21 different categories of petroleum substances.

According to the REACH principle of 'One Substance, One Registration', all registrants of the same substance should submit their registration dossier jointly through a single 'Lead Registrant'. The Lead Registrant is then responsible for submitting the common parts of the registration dossier on behalf of the other co-registrants and remains the single point of contact with ECHA during the subsequent evaluation of the dossier.

To support the joint submission of these registrations, CONCAWE—in its SFF role—identified more than 200 Lead Registrants, mostly from CONCAWE member companies, who signed Lead Registrant Agreements (LRAs) that defined their unique roles and responsibilities.

Using an on-line approval process, co-registrants were then asked to read and accept the terms of the LRA for

each substance that they intended to register. Accepting the LRA enabled them to receive the ECHA 'token' that was required to take part in the joint submission process.

### SIEF activities during 2011

Support to CONCAWE member and non-member registrants continued throughout 2011. This included about 120 new licences sold, and another 60 for late registrations and for registrants entering the market after the 2010 registration deadline.

Non-member registrants have also been encouraged to renew their subscriptions to the SIEF Collaboration Service (SCS), coordinated by CONCAWE. This SCS ensures that registrants continue to be informed of REACH and SIEF activities and receive feedback from ECHA about their evaluation of the submitted registration dossiers. This is important because all REACH registrants have a legal obligation to update their dossiers with any new information about the registered substances or their own activities that occurred after the initial registration in 2010.

About 96% of 2010 registrants renewed their subscription for 2011 and a similar number is expected to do so in 2012. A key part of an SCS subscription is access to the CONCAWE SIEF Communication Tool, re-launched in 2011 as *SIEF.space*. This tool was revamped in response to SIEF members' feedback about functionalities and access to information. *SIEF.space* now provides a more streamlined and user-friendly interface for access to dossiers and tokens, as well as valuable CONCAWE guidance and other information on dossier preparation and submission.

### Preparation for the next registration deadline in May 2013

Although some may have thought that REACH was finished after the first registration deadline in 2010, this is far from the case. Lower tonnage substances, those between 100 and 1000 tonnes per year, must be registered next by 30 May 2013. Although the REACH data requirements are less extensive for these substances compared to the 2010 registrations, CONCAWE will



continue to provide all SIEF members with complete registration dossiers containing all the information related to these lower tonnage petroleum substances. Fortunately, the number of substances to be registered in 2013 is expected to be much smaller, only about 10% of the 4,000 petroleum product registrations completed in 2010.

All pre-registrants have now been contacted and asked to communicate their intentions regarding the REACH deadlines in 2013 and 2018. Only about 10% of these pre-registrants have responded so far. The remainder are urged to do so, so that CONCAWE can better define the level of SIEF support that will be required in the coming years.

CONCAWE members can download the registration dossiers for 2013 registrations directly from *SIEF.space*. Accepting the terms of the licensing agreement also provides them with the special token that enables them to take part in joint submissions with other registrants.

Non-members will receive links to a special web page where they will be able to purchase licences. The licence fee will remain at the same level as in 2010, except where the underlying dossier has been updated since then. As was the case in 2010, 2013 dossier licences are being sold solely to achieve a fair recovery of the costs already incurred by CONCAWE for preparing the registration dossiers based on research completed previously.

Registrants will also receive extensive information and guidance via *SIEF.space*, and the SIEF team will continue to provide assistance and answer questions about licensing, registration, joint submissions, cost sharing and, of course, ECHA's evaluation of the registration dossiers already submitted.

### Evaluation of registration dossiers and updates

REACH requires registrants who have already submitted a dossier to update their registration without undue delay with any new information about the substance or registrant. CONCAWE has developed a dossier update programme which ensures that dossiers revised with

new information in the common parts of the dossier remain compliant with any new guidance published by ECHA since 2010. This also ensures compliance with any updates to ECHA's software system.

This programme will also address updates to the dossiers that may be required in response to evaluation feedback that is expected after ECHA has completed the first dossier reviews. Registrants were encouraged, in ECHA's 2011 report on dossier evaluations, to update already submitted dossiers before ECHA starts their evaluation so that the dossiers are in line with any new recommendations. CONCAWE intends to ensure compliance of its registration dossiers by grouping updates into several releases throughout 2012.

The first major update of CONCAWE's dossiers took place in February 2012, covering three substance categories. All co-registrants have been informed of the content of these updates as well as the implication of any changes and the importance of extending their co-registrant licences to ensure continued access to the updated dossiers. Lead Registrants have also been asked to update their registrations and confirm their successful submission to CONCAWE. Information is always shared on *SIEF.space*, the central information repository for Petroleum Substances SIEFs.

### More questions?

Current or future registrants can contact CONCAWE's SIEF Team at one of the contact e-mails below depending on the nature of their question:

- [Licence@super-sief.eu](mailto:Licence@super-sief.eu) for questions related to licence agreements.
- [LR@super-sief.eu](mailto:LR@super-sief.eu) for questions related to the joint submission of their registration.
- [Info@super-sief.eu](mailto:Info@super-sief.eu) for questions related to the technical content of the dossier prepared by CONCAWE or the category approach.
- [Admin@super-sief.eu](mailto:Admin@super-sief.eu) for questions on the licences ordering process and payment of licence fees.
- [Siefspace@super-sief.eu](mailto:Siefspace@super-sief.eu) for questions regarding the SIEF Communication Tool.