

CONCAWE'S role in REACH¹ registration

The 'end of the beginning' of the REACH registration process

CONCAWE's role within the REACH registration process is significantly more extensive than that of most other industry associations. Several years ago, CONCAWE's member companies agreed that the Association should act as the key focal point for many of the activities that will be needed for the successful registration of petroleum substances and sulphur by both manufacturers (refineries) and importers. These activities include:

- producing the common parts of the registration dossiers for use by CONCAWE members;
- licensing these dossiers to non-member companies (importers);
- providing advice and guidance on the practicalities of the preparation and submission of dossiers to both members and non-member licensees;
- acting as a SIEF (Substance Information Exchange Forum) Formation Facilitator for all petroleum products (except gases) and sulphur; and
- working with the European Chemicals Agency (ECHA) to clarify guidance and support the registration process.

REACH dossiers

Registration under REACH will require each registrant to submit a comprehensive dossier via the REACH on-line system, which has been set up by the ECHA. Each substance to be registered will require a substance dossier which is assembled in IUCLID². The dossier comprises both registrant-specific information and the common part of the technical dossier.

CONCAWE is nearing completion of the common parts of the registration dossiers to cover almost 600 individual petroleum substances. A full inventory of these substances can be found on the *REACH Implementation* page of the CONCAWE website.

An extensive database of the properties, hazards, classification/labelling and safe use of petroleum products has been assembled with the significant help of CONCAWE's member companies and other organisations, such as the American Petroleum Institute (API). In this way, the number of new studies needed to complete the REACH dossiers has been reduced and, most importantly, the need for additional testing has been limited.

The common parts of the dossiers will be completed and made available to registrants during the summer of this year, which will be in time for the first registration deadline of 30 November 2010.

Licences for non-member companies

CONCAWE member companies have agreed that the common parts of these registration dossiers should also be made available to non-member companies who need to register. Because almost all European manufacturers are CONCAWE members, non-members are usually those companies that import and sell or use these products in Europe. The dossiers that CONCAWE is preparing are being made available to non-member companies through licence agreements with CONCAWE.

As CONCAWE is a not-for-profit association, the cost of each non-member licence has been set to cover an appropriate share of the cost of the work that has been undertaken to create the dossiers. This fee was initially set at €7000 per substance per legal entity, and was increased to €10,000 from 1 April 2010 after it became clear that the number of non-member registrations would be lower than the estimate upon which the fee was originally based.

In fact, more than 50,000 pre-registrations were made with ECHA for petroleum substances alone. During the

¹ REACH: *Registration, Evaluation, Authorisation and restriction of Chemicals*

² IUCLID: *International Uniform Chemical Information Database*

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past year, CONCAWE has written several times to all of these pre-registrants to enquire whether they intend to register those substances for which they have already pre-registered. Because pre-registration was an easy and free process, it is perhaps not too surprising that the majority of pre-registrants have not indicated that they intend to complete the registration process. The replies that CONCAWE has received suggest that only a few hundred importers of large volumes of petroleum substances and a few importers of CMR substances will actually register this year!

Registration fees

The European Commission has set out the fees to be paid to ECHA for each registration, as shown in Table 1.

All of CONCAWE's members and all non-member licensees should be able to benefit from a Joint Submission, through the SIEFs that CONCAWE is also organising. In this way, the registration fee will be at the lower fee level, compared with an individual submission.

SIEFs

The REACH Regulation calls for the formation of so-called Substance Information Exchange Fora, or SIEFs, through which any company that has data for a specific substance is obliged to cooperate with others to pool certain information and studies required for registration. This mandatory collaboration can voluntarily be expanded to include all information in IUCLID Sections 2 and 4–13.

To facilitate this, CONCAWE is also acting as the SIEF Formation Facilitator, or SFF, for petroleum substances and sulphur. This SFF role can be established by any entity to contact and communicate with all active SIEF participants in order to ensure that all relevant data are collected and shared. In addition, the SFF can organise the identification of a Lead Registrant (the entity that will register the common parts of the dossiers on behalf of all other registrants participating in the joint submission) and arrange the co-registration process for all other registrants of the same substance.

Table 1 Fees for registrations submitted under Articles 6, 7 or 11 of Regulation (EC) No. 1907/2006

Standard fees (EUR)	Individual submission	Joint submission
Fee for substances in the range of 1 to 10 tonnes	1,600	1,200
Fee for substances in the range 10 to 100 tonnes	4,300	3,225
Fee for substances in the range 100 to 1000 tonnes	11,500	8,625
Fee for substances above 1000 tonnes	31,000	23,500

Source: European Commission Regulation (EC) No. 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No. 1907/2006.

The REACH Regulation contains detailed requirements for registration but is almost silent on the legal framework for the operation of SIEFs. In other words, it is up to each SIEF to establish its own legal basis for cooperation.

CONCAWE has established such a legal framework for petroleum products, that will be used by both member companies and non-member licensees.

Contractual framework

REACH registration rules require the establishment of contractual relationships between the different actors, i.e. the owners of substance data, the lead registrants, co-registrants and SFFs. In particular, contracts are needed to establish:

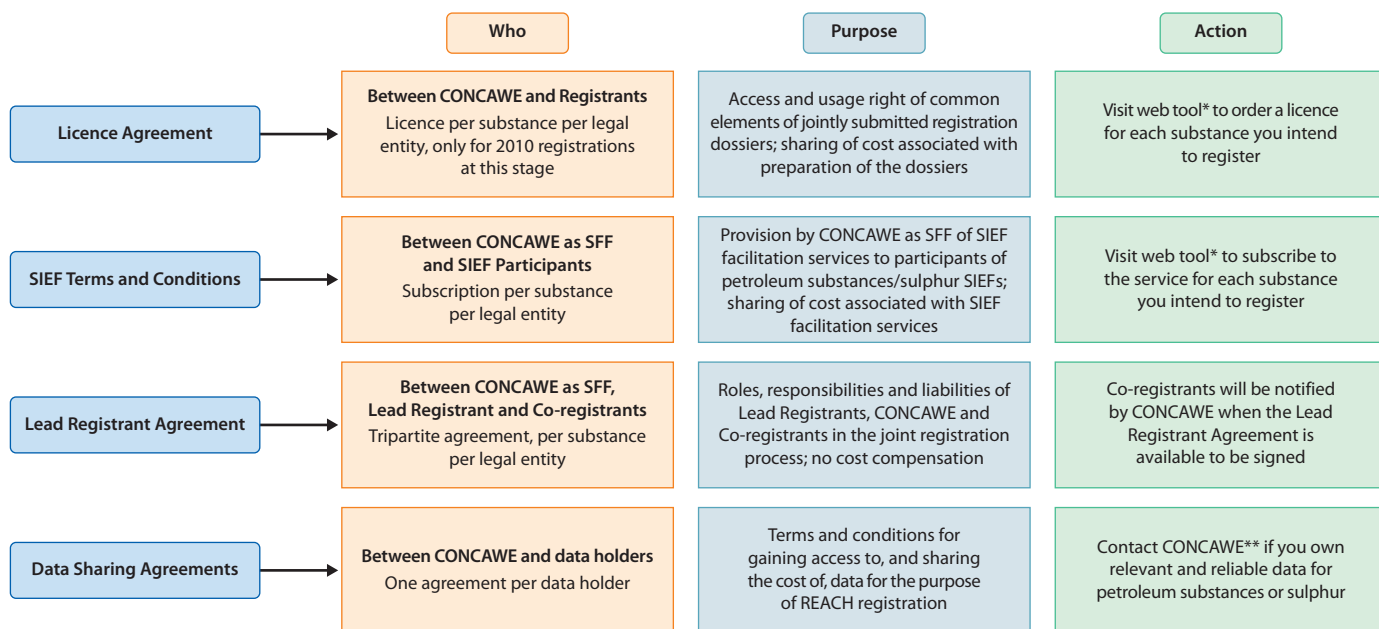
1. What access registrants will have to substance data and how much that access will cost: this is set out in CONCAWE's **Licence Agreement**.
2. Who administers/coordinates the whole process and provides a communication platform so that the various parties can interact: this is set out in CONCAWE's **SIEF Terms and Conditions**.
3. Who the lead registrant is, and what their responsibilities and liabilities are: this is set out in the **Lead Registrant Agreement**.
4. How substance data can be assembled by one entity to facilitate its dissemination to all other registrants: this is set out in CONCAWE's **Data Sharing Agreements**.

These agreements are outlined in this overview (see Figure 1), which was also shared with active SIEF members in CONCAWE's January 2010 Newsletter.

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Figure 1 The contractual framework for the preparation and submission of joint registration dossiers within REACH



* Individualised invitation and link to web tool sent by e-mail ** Contact: info@super-sief.eu

Status of CONCAWE's preparations for REACH registration

The technical dossiers are now in the final stages of preparation. They will be extensively reviewed by CONCAWE's technical experts and finalised during the period from June until mid-August this year.

In parallel, the licensing of dossiers to non-members has been under way since December 2009. This task will continue almost until the 30 November 2010 registration deadline for those who have not yet purchased access to the dossiers. However, we strongly encourage companies to order their licences as soon as possible in order to give themselves sufficient time to complete the registration process. Moreover, ECHA has recently reminded registrants of the disadvantages of last minute registration.

CONCAWE has also set up a web-based SIEF Communication Tool that is the main vehicle for communicating with all active SIEF members and registrants.

The appointment of Lead Registrants (most of whom will be CONCAWE members) is being finalised and CONCAWE began executing Lead Registrant Agreements (LRAs) in early June.

As soon as each LRA has been signed by the Lead Registrant and by CONCAWE, co-registrants for the same substance will be able to execute the same agreement using an electronic acceptance tool. This tool will greatly reduce the time and complexity associated with these multi-party agreements.

As soon as the common parts of each substance dossier are finished, they will be made available to the Lead Registrant who will then register with ECHA. It is expected that the first registrations will begin in August/September 2010.

Soon thereafter, or possibly in parallel, depending on the final system being designed by ECHA, the dossiers will be made available to all co-registrants so that they can also register.

In conclusion

We are nearing the end of a major milestone in the REACH journey that will continue until at least 2018, and we remain confident that we will succeed in helping our members and non-member licensees to register their petroleum products this year.