

Substance Information Exchange Fora (SIEFs) for petroleum substances

Collaboration amongst REACH registrants has commenced

Introduction

Like all other chemical substances that are manufactured in, or imported into, the European Economic Area (EEA), either as such or in preparations or, under certain circumstances, in articles, petroleum substances will have to be registered with the European Chemical Agency (ECHA) under the REACH Regulation¹. While registration is an obligation for each *individual* legal entity that manufactures or imports a substance in or into the EEA, REACH makes *collaboration mandatory* between all registrants during the preparation of registration dossiers as well as during registration.

The legislation foresees that this mandatory collaboration will be initiated through Substance Information Exchange Fora (SIEFs). Guidance issued by the European Chemical Agency (ECHA) suggests that one of the pre-registrants volunteers as SIEF Formation Facilitator (SFF) during pre-registration.

CONCAWE acting as SIEF Formation Facilitator

CONCAWE has volunteered to act as the SIEF Formation Facilitator for practically all petroleum products and for sulphur, and this has been formally recorded in the ECHA's REACH-IT system. This concerns a total of 572 substances. CONCAWE, however, has developed a category approach that will allow 571 substances to be consolidated into 20 categories of petroleum products with similar characteristics. Sulphur will be dealt with as a single substance.

¹ Corrigendum to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006), OJ L 136, volume 50, 29 May 2007.

The number of pre-registrations has exceeded all expectations

Both pre-registration itself and the subsequent downloading of SIEF information suffered from performance problems with the REACH-IT system that ECHA had put in place. ECHA explained that the difficulties were due to the unexpectedly large number of pre-registrations and pre-registered substances (Table 1).

Table 1 Numbers of pre-registrations

	Expected	Actual
Pre-registered substances	30,000	>100,000
Pre-registrations	150,000	>2.7 million

By the end of January 2009 CONCAWE had downloaded the information from the REACH-IT system and established the identity of the SIEF participants for all petroleum substances and sulphur. The basic statistics are shown in Table 2.

Table 2 Composition of the SIEFs for all petroleum substances and sulphur (REACH-IT data)

	CONCAWE members	Non-members	Total
Pre-registered substances	320	572 (i.e. all)	572 (i.e. all)
Active pre-registrations	8,502	48,471	56,973
Legal entities	223	7,982	8,205
E-mail contacts for one or more pre-registrants	40	5,196	

It should be noted that these figures are not final. Pre-registrants may decide to deactivate or even withdraw pre-registrations, thus reducing the numbers. On the other hand, there is also a possibility for manufacturers and importers to carry out a 'late pre-registration', thus increasing the numbers.

CONCAWE's SIEF facilitation team will have to download the information for all 571 petroleum substances and for

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sulphur at regular intervals to ensure that the list of SIEF participants is kept up to date and that all SIEF participants are being contacted. This will represent a significant workload.

Initial communication to pre-registrants

In March 2009 the SIEF facilitation team issued an initial communication to all participants in petroleum substances SIEFs. This communication had the following main messages:

1. CONCAWE will combine the SIEFs for substances belonging to the same substance category (using a common 'template' data set) into so-called Super-SIEFs.
2. In addition to the legal obligations as SIEF Formation Facilitator, CONCAWE will offer registration dossiers to all SIEF participants, not just its own member companies, under licence agreements. These registration dossiers will have to be complemented by a minimum of legal entity/registrant-specific information.
3. The number of non-member pre-registrations exceeds CONCAWE's expectation by a factor of 10.

There are indications that many pre-registrations have been made 'to be on the safe side' or because, according to guidance from the ECHA, in certain circumstances a pre-registration was required without any need to subsequently register the pre-registered substance. More than 1,000 pre-registrations have been made with the additional comment that the pre-registrant has no intention to register.

The ECHA and industry associations, for example Cefic, have commented that as many as 80 to 90% of the pre-registrations will not be followed up by a registration.

CONCAWE has therefore asked pre-registrants to advise whether they intend to register the substances they had pre-registered, and if so, in

which volume band².

4. SIEF participants who have confirmed their intention to pre-register will receive, together with a SIEF collaboration agreement, an invoice for EUR 200 as their share of the SIEF facilitation costs. In turn they will be provided with access to a web-based SIEF communication tool.

CONCAWE performs its role as SIEF Formation Facilitator as a non-commercial activity and has no intention to make any profit from this activity, but simply to cover the additional costs that it generates. The cost of SIEF facilitation will be shared equally among both members and non-members.

Responses from pre-registrants

Because the rate of response to the initial communication was low, the SIEF facilitation team sent a reminder at the end of April 2009. The current picture for petroleum substances (excluding sulphur), which already includes the effect of the reminder, is shown in Table 3.

Unfortunately almost 50% of the initial responses had no, or only partial, information regarding the volume band. Such respondents have also received the reminder.

Table 3 Current level of responses for petroleum substances (excluding sulphur)

	Number of responses
Pre-registrations covered	12,492
Responses from focal points	1,025
<i>Intention to register confirmed by volume band:</i>	
≥1000 t/a	1,605
<1000 t/a to ≥100 t/a	412
<100 t/a to ≥1 t/a	1,674
Intention not to register confirmed	4,851

² The volume bands are: 1000 t/a, <1000 t/a to ≥ 100 t/a, <100 t/a to ≥ 1 t/a

The volume bands determine the registration deadline and the information requirements in the registration dossiers. 30 November 2010 is the registration deadline for substances in the volume band ≥1000 t/a plus substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, which are manufactured or imported in quantities of ≥1 t/a, plus substances classified as very toxic to aquatic organisms, which may cause long-term adverse effects in the aquatic environment (R50/53) and which are manufactured or imported in quantities of ≥100t/a.

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In line with the opinion of the ECHA, the SIEF facilitation team will regard pre-registrants who have neither responded to the initial communication nor to the reminder as 'dormant', i.e. currently without the intention to follow up their pre-registrations with registrations.

This will also apply to those pre-registrants who wish to keep their options open until shortly before their respective registration deadlines.

However, strictly speaking each pre-registrant remains a SIEF participant until the respective registration deadline for his volume band has passed. Hence the SIEF activities will have to make allowance for pre-registrants changing their mind at a later stage.

Knowing who will register and when is not only essential information for CONCAWE in its role as the SIEF Formation Facilitator, but this information is also needed in order to determine the licence fee for registrants.

SIEF facilitation

It cannot be over-emphasised that, initially, the SIEFs have no formal legal structure, no communication system and no leadership. On 1 January 2009, the SIEF was just a set of legal entities with a common interest in manufacturing or importing a particular substance in or into the EEA. The SIEF Formation Facilitator is expected to initiate the creation of an operating structure and the provision of an intra-SIEF communication tool.

As mentioned above, CONCAWE intends to enter into a 'SIEF collaboration agreement' with all pre-registrants who have confirmed now (or will confirm later) their intention to register. This SIEF collaboration agreement will be separate from the licence agreement for the registration dossier, the scope of which is described above.

Licence fee for the registration dossiers

Before the end of June 2009, CONCAWE will communicate to pre-registrants of petroleum products the cost of a licence per substance. This cost will be based on an assumption of the final number of registrations.

Gases, petroleum coke and sulphur—special cases

There are a number of substances in which other industries also have an interest. Discussions have been initiated with their respective associations and, where appropriate, specific arrangements are being made. Whatever form these arrangements finally take, CONCAWE will continue the preparation of the REACH registration dossiers for petroleum substances and sulphur, pending further clarification. Some specific cases are described below.

For petroleum gases, the registration dossier will be prepared by the contractor of the Lower Olefins/Aromatics consortium (LOA) on behalf of both CONCAWE and LOA, and for a category that includes both gases from refinery operations and from steam-cracker operations (except the pure steamcracker gases ethylene, propylene and butadiene). LOA will take over the SIEF Formation Facilitator role for petroleum gases, but CONCAWE will represent all of its members in these SIEFs, so that CONCAWE members will not need to join this SIEF individually.

There is still the possibility that one or more of the three types of petroleum coke will be exempt from registration under Annex V of REACH. However, clarity will only be provided by the ECHA at a later date, perhaps as late as the end of this year. In the meantime CONCAWE continues preparing the registration dossier. CONCAWE's SIEF facilitation team has informed pre-registrants of petroleum coke that they will not be charged a share of SIEF facilitation costs until the ECHA has clarified the status of petroleum coke under REACH. Should all three types eventually be exempt, then the Super-SIEF for this category and the three SIEFs will be disbanded.

Unlike for petroleum substances, most existing substance data for sulphur that is not in the public domain is held by companies which are not CONCAWE members. Moreover, sulphur is not produced exclusively in refineries, but also by desulphurisation of natural gas, as a by-product of making coke from coal and by mining. Although committed to its role as SIEF

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Formation Facilitator, CONCAWE was prepared to leave the management of the preparation of a joint registration dossier for sulphur to a non-member company, provided this company held substance data. However, the companies holding data for sulphur have turned down this offer. CONCAWE will therefore prepare the joint registration dossier for sulphur and share it with all registrants under a licence agreement.

Path forward

Since 2002 CONCAWE has worked voluntarily on an ambitious and comprehensive risk assessment programme for all petroleum substances. This programme has become the basis for the preparation of REACH-compliant registration dossiers for the benefit of its member companies.

CONCAWE is working on registration dossiers, which it intends to offer to all non-member company registrants under a licence agreement. In addition, CONCAWE has volunteered to facilitate all SIEFs for petroleum substances. This task has turned out to be more complex than expected, but it is hoped that it will become simpler once contact has been established with those companies that intend to register and when communication among these SIEF participants becomes routine. Nonetheless, there is considerable work ahead. CONCAWE's main focus, however, remains the preparation of the dossiers for petroleum products in time for the registration deadline of 30 November 2010.