

Mandatory collaboration of all registrants under REACH

CONCAWE has established early contacts with potential SIEF members

Introduction

Under the new REACH Regulation¹ all chemical substances will have to be registered with the European Chemical Agency (ECHA). This includes petroleum substances that are manufactured in, or imported into, the European Economic Area (EEA), either as such or in preparations or—depending on certain criteria—in articles. Registration is an obligation for each individual legal entity that manufactures or imports a substance.

In addition, the REACH legislation foresees mandatory collaboration between all registrants, both during the preparation of registration dossiers and during registration itself. There are two objectives behind this requirement for collaboration:

1. To reduce the need for animal testing by mandatory sharing of animal test data; and
2. To harmonise substance information and consequently the hazard classification and labelling of chemical substances.

Collaboration between registrants requires information and communication:

- Registrants need to know who the other registrants of the same substance are; and
- There has to be an effective system of communication between the registrants of the same substance.

The ECHA plans to set up a REACH IT system that will allow pre-registrants to establish contact with each other before the deadline for pre-registration (see

timeline in Box 1). However, such contacts would be voluntary. Definitive information about all pre-registrants will only be available when the ECHA informs all co-registrants on 1 January 2009 of the identity of, and contact names in, all other legal entities that had pre-registered the same substance. Through their pre-registration, the legal entities will have automatically become members of a so-called Substance Information Exchange Forum (SIEF).

REACH does not foresee any legal structure, communication system or leadership for the SIEFs. On 1 January 2009, the SIEF will just be a set of legal entities with the same level of knowledge of who the other registrants are and whether a legal entity had indicated in its pre-registration submission that it volunteers as a SIEF Facilitator (see Box 1). It is obvious that the voluntary early contacts between co-registrants through the ECHA REACH IT system ('pre-SIEF formation') will facilitate the process.

In line with the first of the two objectives of collaboration among SIEF participants, REACH allows parties that hold relevant substance information, but that have no

Box 1: Timelines for pre-registration and the SIEF process

- 1 June 2008: Pre-registration starts; voluntary pre-SIEF formation possible
- 1 December 2008: Pre-registration ends
- 1 January 2009: ECHA informs pre-registrants of:
 - Identity and contact details of all other pre-registrants of the substance
 - Identity and contact details of data holders who are not pre-registrants
- 30 November 2010: Registration period ends for phase-in substances $\geq 1,000$ t/a, for CMRs cat 1/2, substances harmful to the environment

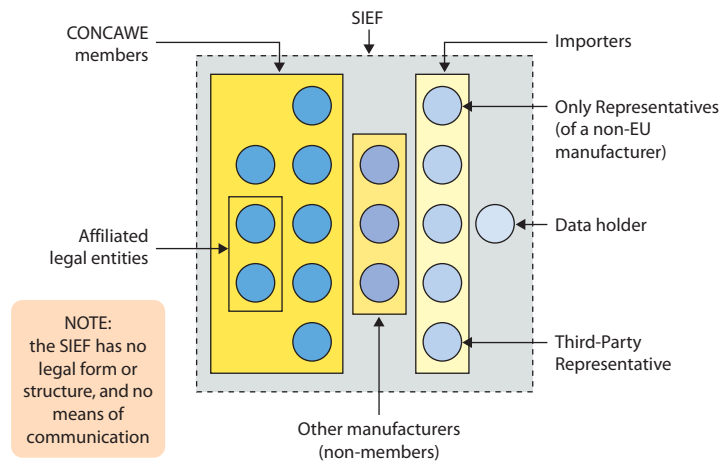
NOTE:
No further involvement of ECHA in the process!

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 L136, volume 50, 29 May 2007.*

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Figure 1 Composition of a typical Substance Information Exchange Forum



Box 2: Actors in the pre-registration process

- Manufacturers: as future registrants
- Importers: as future registrants
- Data holders: can offer data to future registrants
- Only Representative: as future registrant; represents a non-EU manufacturer
- Third-Party Representative: represents and acts on behalf of a future registrant

Option also available to CONCAWE for its members

Option also available to CONCAWE members

obligation to register the substance, to join SIEFs as data holders. Such data holders could be downstream users, trade associations, universities, governmental or independent research organisations or non-governmental organisations (NGOs). The rights of data holders in the SIEF are limited to selling access rights to the substance information they hold. Nevertheless, they add an extra dimension to the complexity of collaboration within SIEFs (see Figure 1 and Box 2).

In addition to the legal obligation to collaborate among SIEF participants (see Box 3), REACH provides the option for registrants to collaborate beyond the legally required scope. CONCAWE's preparation for the registration of petroleum substances under REACH aims to maximise the amount of information that members will be able to submit jointly during the registration process. However, even in this case, there are still certain parts of the regis-

tration dossier that each legal entity of CONCAWE Member Companies will have to submit to the ECHA separately and individually (see Box 4).

Moreover, the registrants, i.e. the legal entities that wish to register a substance, will have to submit the registration dossier themselves. Whereas during pre-registration and during the phase of collaboration in a SIEF, a legal entity can choose to be represented by a third party—and consequently hide its identity from the other SIEF participants—this is not possible during the registration as such. The only exception is where a non-EEA manufacturer chooses to appoint a so-called 'only representative', e.g. an importer who registers all import volumes including those that are imported directly by other legal entities. These other importing legal entities have no obligation to register. In the terminology of REACH, they become downstream users.

Box 3: SIEF scope—the legal minimum

- Share animal testing data (and agree cost sharing mechanism)
- Agree substance data (study summaries)
- Agree testing proposal (if required)
- Agree classification and labelling
- Agree on Lead Registrant
- Collaboration initiated by a 'SIEF Formation Facilitator'
 - Identity and contact details of all other pre-registrants of the substance

Box 4: Registrant specific information

- Identity of the registrant
- Identity of the substance (linked to the category)
- Manufactured and/or imported volume
- Type of substance (intermediate or not)
- Manufacturing process (reference to generic CSR)
- Manufacturing or other relevant sites (reference to coded information in the generic CSR)
- Uses and relevant Exposure Scenario(s) (reference to the generic CSR)
- Any additional uses and associated Exposure Scenarios

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How CONCAWE has structured collaboration among its members

Collaboration between CONCAWE members started in 2001 when the CONCAWE Board decided to embark on a comprehensive programme for risk assessments of petroleum substances. These risk assessments were conducted according to the Technical Guidance Document (TGD) of the Council Regulation (EEC) 793/93, the Existing Substances Regulation or ESR. Under the ESR, Member State Competent Authorities (MSCAs) carried out risk assessments for priority substances, none of which were petroleum substances. Companies manufacturing or importing these priority substances were obligated to make substance data available to the so-called rapporteur, i.e. a MSCA that carried out the risk assessment of a particular substance. It has to be noted that, in reality, it was the trade associations, for example Cefic sector groups, that collected data from their members and submitted them to the rapporteur. Unfortunately, the authorities did not involve all market participants including importers. Within the trade associations it was common practice to share substance

information among all member companies without financial compensation.

REACH has forced a dramatic change, by putting a sudden end to the common practice of sharing substance information between manufacturers in legal or voluntary programmes without compensation for the cost of the underlying studies. Since the registration is now a prerequisite for the licence to operate in the market and since substance information is needed to prepare a registration dossier, substance information has a commercial value and becomes a marketable good.

When the requirements for registration dossiers under REACH were eventually fixed² CONCAWE had voluntarily completed risk assessments for three groups of petroleum substances as 'ESR risk assessments'. These covered naphtha/gasoline, gasoil/diesel and kerosine.

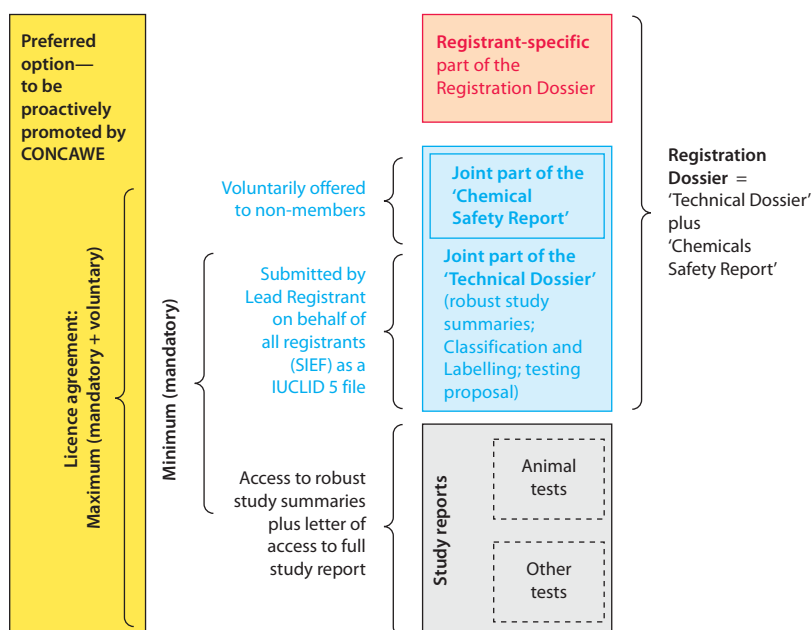
Meanwhile CONCAWE has instructed its contractors to apply the approaches and methodologies of REACH to their work on the risk assessment programme and to provide the results in a REACH-compliant format for all remaining groups of petroleum substances.

Questions of ownership of substance information, sharing such information among CONCAWE member companies and access for CONCAWE member companies to the output from the risk assessment were addressed in a licence agreement between CONCAWE and its member companies. The licence agreement also reflects the structure of the registration dossiers and the maximum scope of collaboration among registrants (see Figure 2).

How CONCAWE intends to structure collaboration with non-members

There are several factors that are unique to petroleum substances—and possibly to other substances of unknown or variable composition (UVCBs)—that will determine the collaboration between CONCAWE

Figure 2 Scope of the CONCAWE REACH licence agreements



² It should be noted that at this stage the final details are still not certain because Annex I of REACH that describes the details of the Chemicals Safety Report (CSR) is under review by the Commission. Full certainty will be lacking until October 2008, i.e. after approval of the final version of Annex I by the legislator.

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members and non-members in the SIEFs. The main factors are:

1. The minimum information that needs to be shared among SIEF participants will not enable a legal entity to register a petroleum substance in those cases where a Chemicals Safety Report including a risk characterisation is required.
2. CONCAWE has developed a strategy to support the registration of individual substances by the use of categories of substances having the same physico-chemical, toxicological and eco-toxicological properties.
3. CONCAWE has developed new methodologies for the risk assessment of petroleum substances. The methodologies have been presented to the MSCAs in the context of the risk assessments for the ESR and extended to all groups of petroleum substances.

Non-members are obviously free to develop their own methodologies for performing chemical safety assessments. However, in view of the complexity involved and the short time that remains before registration is required, CONCAWE intends to offer to non-members the legally possible option of jointly submitted information. One vehicle for sharing this jointly submitted information could be an external licence agreement.

Whereas the licence agreement between CONCAWE and its members covers all groups of petroleum substances, there would be several licence agreements with non-members, each covering a specific group of petroleum substances, for example naphthas/gasoline or gasoils/diesel. This takes into account the fact that most of the non-members can be expected to be independent importers, trading only in a few substances.

It was mentioned earlier that initially SIEFs will have no legal structure and no established means of communication. The REACH guidance published by ECHA foresees that SIEF participants will form consortia. Cefic has embarked on a project to develop a communication tool for SIEF participants. There is consensus in industry that creating and managing consortia will be complex and enormously time consuming. This is based on experience from the implementation of the ESR and from

voluntary industry initiatives like the 'HPV Initiative' of the International Council of Chemical Associations (ICCA) or the 'HERA project' of the detergent raw material producers and the detergent formulators.

A licence agreement would drastically simplify the relationship between SIEF participants and minimise the need for extensive communication within the SIEF.

It is therefore in CONCAWE's interest to promote this way of working as early as possible at the beginning of the pre-registration period. It is inconceivable that CONCAWE will be able to contact all potential SIEF participants before the pre-registration period is over and the exact composition of the SIEFs is known (1 January 2009). Contacts should therefore be established through 'multipliers' such as trade associations.

A 'REACH conference for petroleum substances' was the most efficient vehicle for CONCAWE to not only promote the system of licence agreements as a tool of simplifying the collaboration in the SIEFs, but also to:

- promote common interpretations of REACH requirements (e.g. the definition of the importer under REACH).
- express its intention to volunteer to act as the SIEF formation facilitator, a role that has to be offered during pre-registration; and
- address the issue of CAS registry numbers (CAS RNs) for traded imported substances.

It was mainly the latter that determined the timing for the conference. To avoid confusion a common understanding of traded CAS RNs needs to be established before the pre-registration process starts. The conference was held on 23 May 2008 in Brussels.

Besides representatives of its member companies, CONCAWE invited delegates from relevant trade associations, for example the Cefic sector groups for lower olefins and aromatics, associations of importing industries (mainly industries that import fuel for their own consumption), associations of importing traders and associations of tank farm operators. The outcome of this conference will be separately advised.