International Titanium Association
General Annual Meeting
24 September 2008

The Impact of REACH on Your Business
by
Elena Kostadinova

1. INTRODUCTION

Jennifer Simpson has invited me to present to you the new EU legislation called REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) which is expected to have a significant impact on trade in chemicals, including metals, not only in the EU but also worldwide. Currently, REACH applies in all countries that form part of the European Economic Area (EEA).2

Hopefully, by now those of you with significant business activities in the EEA are aware of REACH and have already pre-registered. For those of you familiar with REACH, and more importantly perhaps, those with little or no knowledge of REACH, my presentation aims to explain the objectives, principles and practical implications of REACH for companies based outside the EEA who do business in the EEA. In particular, I will focus on practical issues such as which metals fall under REACH, what is a registration, who should register, and why registration is crucial. You will also obtain useful information on pre-registration and a comprehensive overview of the basic principles of REACH, including joint submission of a registration dossier, data sharing and SIEF (Substance Information Exchange Forum) participation. Last but not least we will discuss the purpose and importance of concluding a Consortium Agreement.

2. WHAT IS REACH?

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is the new EU Regulation on chemical substances which entered into force on 1 June 2007. It is a complete and radical review of policy on chemical substances. Most chemical substances currently placed on the EEA market (about 30,000) will be subject to registration with the European Chemicals Agency (ECHA) by their manufacturers and/or importers. REACH requires registration for each chemical substance produced in and/or imported into the EEA in quantities of one tonne or more per year with few exceptions. REACH is a regulation, which means that it is directly applicable in all EEA Member States. However, pursuant to REACH the Member States are responsible for its effective enforcement, including by imposing sanctions for non-compliance. National laws are expected to enter into force by 1 December 2008.

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1 Elena Kostadinova is the Assistant to the Hearing Officer at the Trade Policy Department of the European Commission. Previously, Elena Kostadinova worked at the international law firm McDermott Will & Emery/Stanbrook LLP exclusively on interpretation and implementation of REACH. This article represents her personal views and is not an official position of the Commission.

2 The EEA includes the 27 EEA Member States and Norway, Iceland and Lichtenstein.
3. **Why Will REACH Affect Titanium Companies?**

The members of the International Titanium Association that produce in and/or import into the EEA titanium or titanium compounds in quantities of one or more tonnes per year will not be able to continue their business legally if they do not pre-register and later register their substances. Only registered substances can be placed on the EEA market, and only registrants can manufacture and/or import them.

EEA Member States are required to adopt proportionate, effective and dissuasive sanctions for non-compliance. Depending on the EEA Member States the sanctions vary from fines of up to EUR 60,000 to imprisonment, depending on the nature of the violation.

4. **Which Substances are Covered by REACH?**

REACH applies to all chemical substances if they are produced in and/or imported into the EEA in quantities of one tonne or more per year. A substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process or synthesis. Substances which form part of a preparation (e.g. an alloy) must also be registered. Alloys are considered special preparations. Therefore, if you import into the EEA an alloy incorporating titanium and another substance such as iron, aluminium, vanadium and molybdenum, you have to ensure that you have a registration for titanium and any of the other metal substances mentioned above which is intentionally part of the alloy (impurities do not have to be registered separately).

For the purposes of registration, REACH distinguishes between existing (phase-in) substances and new substances. The existing (phase-in) substances are those listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). Phase-in substances are also those that were produced in the EEA but never placed on the market and those which were subject to the reduced registration requirements for new chemical substances under the old regime.

Titanium has an EINECS number and is a phase-in substance. Therefore, the registration of titanium will be subject to the rules for registration of phase-in substances. Titanium dioxide, titanium trichloride, titanium carbide and titanium nitride are also substances listed in EINECS and should normally be registered. You can find EINECS database using the following link: [http://ecb.jrc.it/esis/](http://ecb.jrc.it/esis/) and look for your other substances (titanium compounds).

There are certain exemptions from REACH as a whole and from registration only. REACH does not apply to certain substances which are covered by other EEA legislation. Examples are radioactive substances, substances under customs supervision, non-isolated intermediates, and waste. The registration process under REACH does not apply to certain substances used in medicinal products, food or feeding stuffs, re-imported and recovered substances and substances included in Annex IV and V to the Regulation. Annex IV refers to the substances for which there is sufficient information and they are considered to cause minimum risk for the human health and the environment. Unfortunately, the list does not include titanium or any of its compounds. Annex V includes the substances for which the registration is considered inappropriate or unnecessary. Such substances are those which “occur in nature”, are not chemically
modified and are not (i) dangerous, or (ii) persistent, bio-accumulative and toxic. Among them are ores and ore concentrates. Finally, REACH provides for a special “light” registration of on-site and transported isolated intermediates. It should be noted that most of these exemptions have raised a number of legal and practical questions and should be considered carefully under the particular circumstances.

5. **WHAT IS A REGISTRATION?**

Registration under REACH is the submission of a registration dossier to ECHA. The registration dossier consists of two parts: (i) a technical dossier, and (ii) a chemical safety report.

The technical dossier must contain details of the registrant, the chemical substance, the manufacture and use of the substance, its classification and labelling, and its intrinsic properties. The volume of each chemical substance produced in and/or imported into the EEA will determine the level of information required. The data requirements increase for quantities exceeding 100 tonnes or 1,000 tonnes per year. This increasing burden reflects the potentially greater safety risk associated with larger volumes of chemical substances.

A chemical safety report (CSR), including a chemical safety assessment and details of risk management measures is required for registration of substances produced and/or imported in quantities of 10 or more tonnes per year by a manufacturer and/or importer.

All data is submitted electronically through a system known as IUCLID 5.

Each registrant has to bear its own costs for the preparation of the registration dossier (including laboratory costs, administrative costs, etc.). Other metals industries have calculated that the preparation of a registration dossier of a substance in the lowest tonnage band would require about EUR 30,000 whereas the preparation of a registration dossier of a substance in the highest tonnage band may cost up to EUR 2 million, and possibly more if the substance is deemed a dangerous substance. Synergies may be achieved if you register a number of titanium compounds because you may be able to use the studies on for example titanium tetrachloride for your analysis of another titanium compound.

In addition, the registration of each substance triggers the payment of a registration fee to ECHA. Thus, if you want to register titanium metal, titanium carbide and titanium nitride, you have to make a separate registration for each of the substances and pay three fees. The amount of the fee will depend on the tonnage that is registered, if the hazard data is submitted jointly or separately, or if the company is a small or medium size company (SME). SMEs benefit from reduced registration fees. On 17 April 2008, the Commission published Regulation 340/2008 which determines the fees payable to ECHA. The registration fees may vary from EUR 1,200 for the lowest tonnage band to EUR 23,250 for the highest tonnage band.3

Once you register you have to ensure that you update your registration dossier whenever necessary. The registration is not time-limited.

If you are required to register and do not pre-register (please see below), you have to register your substances immediately in order to be able to place them on the EEA market.

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If you do not pre-register but continue placing your substances on the EEA market from 1 June 2008 until the date of your registration, you will be placing your substances on the EEA market illegally and may be subject to sanctions.

6. **WHO CAN REGISTER A SUBSTANCE?**

Only individuals and companies established in the EEA can register. These are (i) manufacturers of substances, (ii) importers of substances and (iii) “Only Representatives” of non-EEA manufacturers.

Companies that have no legal entity in the EEA cannot (pre-) register. If you are a non-EEA company, you have to first check your corporate structure and see whether you have a legal entity (legal person) in the EEA. A “legal person” is a concept, applied in many legal systems to refer to companies who have legal personality and therefore are capable of carrying rights and obligations, independently of the people or other companies behind them. A subsidiary of a company has a legal personality but a branch of such company does not have a legal personality of its own. Currently, REACH does not appear to allow registration by a branch (except the UK). Therefore, if you do not have a company with a legal personality established in the EEA, you may either (i) establish such a company in the EEA, or (ii) appoint an Only Representative.

You may register as an EEA manufacturer if you manufacture in the EEA or as an importer if you have a company in the EEA that does the importing for you. The concept of import under REACH is different from import under the customs legislation. Import under REACH means the physical introduction into the customs territory of the Community. A customs agent is not an importer. The definition of an importer has raised a number of legal and practical concerns. It may in fact be possible for a company to be the importer for a corporate group even where the company does not take title or possession of the substance or preparation, but this must be assessed on a case-by-case basis.

You may also register through an Only Representative. The Only Representative is a natural or legal person established in an EEA Member State who has sufficient background in the practical handling of chemical substances and the information related to them. The role of the Only Representative is to register the substances imported into the EEA by a non-EEA manufacturer. This Only Representative may register all quantities of a substance imported into the EEA by the non-EEA manufacturer and may register more than one substance sold by the non-EEA manufacturer in the EEA.

The Only Representative may be a subsidiary or affiliate of a non-EEA manufacturer based in the EEA. An Only Representative can also be any natural or legal person who satisfies REACH requirements and agrees to represent the non-EEA manufacturer on a contractual basis. In principle, REACH does not prevent two or more non-EEA manufacturers from appointing the same Only Representative. In such a case the parties should ensure that competition law is observed since the Only Representative will be informed about all quantity of imports and sales to customers in the EEA.

Currently, there are an increasing number of companies (start-ups) who offer to act as Only Representatives. Many can be found on the Internet. Non-EEA companies should, however, be careful when selecting this type of start-up company as their Only
Representative. This is because the Only Representative should be a legal or natural person who has sufficient background in the practical handling of chemical substances and the information related to them. Many of these start-ups do not have the required expertise. Furthermore, the Only Representative must hold data on the imported quantities of the registered substances and the customers. Such access to market knowledge gives a significant advantage to companies acting as an Only Representative for several non-EEA manufacturers of the same substances. Therefore the choice of an Only Representative should be done very carefully and after consultation with a lawyer. Indeed, in many cases, non-EEA manufacturers may want to consider establishing a subsidiary in the EEA to fulfill the Only Representative function.

7. PRE-REGISTRATION

Pursuant to REACH all existing (phase-in) substances had to be registered on 1 June 2008, unless the existing (phase-in) substances are pre-registered. The pre-registration extends the deadlines for registration of a substance with ECHA as follows:

a. 30 November 2010 for tonnage band $\geq$ 1,000; CMRs; and R50/53 $\geq$ 100 t/y
b. 30 May 2013 for tonnage band 100 $\geq$ 1000
c. 31 May 2018 for tonnage band 1 $\geq$ 100

Pre-Registration is an administrative procedure for existing (phase-in) substances. Pre-registration is a very simple procedure which is free of charge.

Pre-registration can be made from 1 June 2008 to 1 December 2008 with no obligation to pursue registration of the pre-registered substance. Companies that do not pre-register may be prohibited from manufacturing in and/or importing into the EEA until they submit a complete registration dossier.

Pre-registration can be made only by the persons that can register, i.e. (i) EEA manufacturers, (ii) EEA importers and (iii) EEA based Only Representatives of non-EEA manufacturers.

Pre-registration is made electronically to ECHA by providing the following information: (i) company and contact information; (ii) substance information (EINECS number); (iii) likely tonnage band and deadline for registration (best estimate of annual quantity taking into account future market developments or company reorganisation); (iv) name(s) of other substance(s) for which the available information is relevant for performing adaptations to the testing requirements (i.e. read-across approach).

You can either make an online pre-registration using the following website https://reach-it.echa.europa.eu or by using IUCLID 5 (a computer file format required by REACH) to prepare and submit a “bulk” pre-registration to the REACH-IT website. A bulk pre-registration allows pre-registrants to submit one (or more) files with pre-registration information for multiple substances.

8. SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF)

All potential registrants of existing (phase-in) substances that pre-register the “same” substance will be automatically included in a SIEF. For example, all registrants of titanium trichloride with EINECS number 231-728-9 will become members of the same
SIEF. The SIEF is an IT platform which aims to facilitate the identification of the companies that register the “same” substance and the exchange of data and tests. The first company that pre-registers will trigger the creation of a web page of the pre-registered substance. The second company that pre-registers a substance with the same EINECS (CAS) number will be automatically directed to this web page. The first company will be informed by an e-mail that another company has joined the SIEF. The second company itself will be able to see the contact details of the first company. The procedure will be the same for any following company. In addition to their SIEF, the participants of one SIEF will be able to “see” the participants in any other SIEF which they have indicated for “read-across” purposes in their pre-registration. The SIEF participants will be able to exchange e-mails and also to post comments in a free field.

At pre-registration, any company may tick the “facilitator” box. This means that this company would like to take responsibility for the communication within the SIEF.

ECHA must publish the list of pre-registered substances by 1 January 2009 together with the first registration deadline. At that moment data-holders may request ECHA to be included in a SIEF. A data-holder may be anybody who can offer a study or test to SIEF participants – a downstream user, a manufacturer and/or importer of the substance in quantities below one tonne per year, a research centre, university laboratory, etc. Data holders cannot request data from the SIEF participants. However, if they are requested to provide data, they must provide this data and may request a compensation for it if used to support the registration.

Each SIEF remains operational until 1 June 2018, the date by which all existing phase-in substances should be registered.

9. **Joint Submission**

Each company must register its substances individually. However, if there are several registrants for the same substance, they must make a joint submission of certain parts of the technical dossier, except in certain limited circumstances. The parts of the technical dossier that must be submitted jointly are: (i) classification and labelling of the substance; (ii) study summaries; (iii) robust study summaries; and (iv) proposals for testing. The requirement to make a joint submission requires that the registrants work together on the preparation of the technical dossier and there will be one technical dossier for each substance. Therefore, the registrants have to designate a lead registrant who will submit, on all registrants’ behalf, the joint part of the technical dossier. The lead registrant may be the SIEF facilitator (see point 8 above).

Refusal to sign up to a joint submission is only possible if: (i) it is disproportionately costly for the specific registrant; (ii) the registrant needs to prevent disclosure of commercially sensitive information; or (iii) the registrant disagrees with the lead registrant on the selection of the information. Companies that wish to opt out from joint submission must bear in mind that their registration dossier will be examined by ECHA with priority and they will have to pay higher registration fees. In addition, such companies will not be exempt from the obligation for data-sharing, as explained below.

The joint submission does not exempt the other registrants from the obligation to register. Each registrant must submit individually all other information which forms part of the
technical dossier, including its identity, the identity of the substance and information on manufacture and use.

The guidance on safe use and the chemical safety report may be submitted individually or jointly by the lead registrant, if the registrants opt for a joint submission.

The obligation for joint submission guarantees that SMEs will not be excluded from the compilation of the registration dossier by big companies and will be able to split their costs for the technical dossier together with the big companies. In most cases, SMEs produce or import substances in quantities of less than 10 tonnes per year and therefore they have to provide limited information only.

10. DATA SHARING

In addition to the joint submission, REACH contains a data sharing obligation. Registrants that have to submit a registration dossier must collect a significant amount of information and in certain cases will have to perform a number of complicated tests. In order to limit the number of tests and avoid unnecessary testing, REACH introduces the obligation to share data.

REACH differentiates between two types of tests: tests on vertebrate animals; and other tests. If a registrant needs to perform an animal test, it must first ask ECHA whether previous or other registrants have performed such a test. If so, the registrant must refer to that test result in its registration dossier. The owner of the test results must permit the registrant to refer to its test result, subject to payment of an appropriate license or access fee. For non-animal testing, a manufacturer and/or importer may, but is not obliged to, request the other registrants to share information. If requested, they are obliged to provide the information but are entitled to compensation. Compensation is always required where a substance has been registered in the last 12 years. If the test was submitted to ECHA more than 12 years ago, the registrants can use its results without paying compensation. The same rules on data sharing as described above apply to all SIEF participants.

11. REACH CONSORTIUM AGREEMENT

REACH obligations for joint submission and data sharing lead to the conclusion that REACH compliance is not possible without co-operation among manufacturers and/or importers of the same substance. REACH, however, does not provide detailed rules for such co-operation. Indeed, REACH provides for the creation of a SIEF, but the SIEF only facilitates the co-operation, it does not provide for the rules of such co-operation.

A consortium structure can remedy this by creating a secure and flexible basis for REACH compliance for one or more substances. A consortium is an association of two or more individuals, companies and/or organizations with the objective of pooling their resources for achieving a common goal. The consortium agreement is not a mandatory requirement of REACH and does not replace the SIEF, it complements it.

A consortium agreement can have a number of positive effects, such as clear membership rules, control over costs, reduced labor intensity and also provide a means of choosing best quality studies, whilst protecting confidential information. The consortium members may also determine the degree of flexibility they will enjoy when preparing the registration dossier for the selected substances. The consortium agreement is therefore a
convenient tool to organize compliance with REACH obligations and at the same time safeguard the essential business interests of the participating companies.

A number of consortia have already been formed for a number of substances. For examples, there are consortia for the registration of substances with which titanium forms alloys such as aluminium, vanadium, iron and molybdenum. You may obtain more information on these consortia through the REACH portal of the European Association of the Metals Industry Eurometaux http://www.reach-metals.eu.

12. WHAT SHOULD YOU DO TO COMPLY WITH REACH?

If you want to continue your business in the EEA, you must comply with REACH requirements.

The first step is to analyse which substances you produce in and/or import into the EEA in quantities of one tonne or more per year. You can make an inventory of these substances. If you are a non-EEA company, you should analyse your distribution system. In particular, you must find out which company imports into the EEA for you. Based on this information, you may consider appointing this company as your importer or Only Representative. You may also consider establishing a company in the EEA, or sign an agreement with an Only Representative that does not belong to your group.

In any case, you must pre-register before 1 December 2008. If you do not pre-register, on 1 June 2008 you should have stopped placing your substance on the EEA market until you complete your registration. Before or after pre-registration, you may wish to check whether there is an existing consortium for the registration of your substance. An unofficial website where you may find information on existing consortia is http://chemicalwatch.com/consortia.

If there is no consortium for the registration of your substances you may consider forming such a consortium. The consortium may be formed either through ITA or by individual companies alone. Any consortium would require additional human and financial resources. Each company that intends to submit registrations to ECHA must review its budget for the following years and ensure that it has enough means to support such a registration.

13. CONTACT

You may contact Elena Kostadinova at Elena.Kostadinova@ec.europa.eu, Tel. + 32 2 296 54 32, Fax: + 32 2 297 21 85, Avenue des Nerviens 105, office 06/91, Brussels 1040, Belgium http://ec.europa.eu/trade/issues/respectrules/hq/index_en.htm
The Impact of REACH on Your Business

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DG Trade, European Commission
REACH

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals
Why Register Titanium and Titanium Compounds?

No Registration = No Market in the EEA

Member States will apply dissuasive sanctions
Which Chemicals Fall under REACH?

- All existing and new chemical Substances
- Produced and/or imported in quantity of one or more tonnes per year
- Existing Substances ("phase-in") are *inter alia* those that have an EINECS (CAS) number
- Titanium has EC No 231-142-3, titanium dioxide – EC No 236-675-5, titanium carbide – EC No 235-120-4
- Exemptions from **REACH** (Substances covered by other EU law, e.g. waste)
- Exemptions from **Registration** (e.g. ores and ore concentrates and Substances used in medicinal products)
What is Registration? (1)

Submission of
(i) a technical dossier and
(ii) a chemical safety report
to the European Chemicals Agency (ECHA)

You pay a fee for each registration with ECHA depending mainly on the tonnage band of the produced/imported Substance

The costs for the preparation of the technical dossier and the chemical safety report are born by the registrants of the “same” substance
What is Registration? (2)

(i) The technical dossier includes:

- Information about the Substance and the registrant
- Classification and labelling of the Substance
- Manufacture and use(s) of the Substance
- Guidance on safe use
- Information on the physicochemical properties of the Substance, toxicological and eco-toxicological information ((robust) study summaries)
- Test proposals

The scope of the technical dossier depends on the tonnage band of the produced/imported Substance.
What is Registration? (3)

(ii) The Chemical Safety Report (CSR) includes:
- Human health hazard assessment
- Human health hazard assessment of physicochemical properties
- Environmental hazard assessment
- Persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment
- Exposure assessment
- Risk characterisation

CSR is prepared for a Substance produced/imported in 10 or more tonnes per year.
Who Can Register a Substance?

The following natural or legal persons can register a Substance:

- Manufacturers of Substances established in the EEA
- Importers of Substances established in the EEA (responsible for the physical introduction into EEA territory)
- EEA based “Only Representatives” of non-EEA manufacturers (Only Representative = Importer for the purposes of REACH)
Pre-Registration (1)

The pre-Registration ensures that you can sell your product in the EEA from 1 June 2008 until the date of your Registration.

The pre-Registration extends the deadline for your Registration from the 1 June 2008 to

- 1 December 2010 - for 1000 or more tonnes per year; CMR category 1 and 2; and R50/53 very toxic to aquatic organisms ≥ 100 t/y)
- 1 June 2013 (100 ≥ 1000 tonnes per year)
- 1 June 2018 (1 ≥ 100 tonnes per year)

If you do not pre-register, you should have stopped selling in the EEA on 1 June 2008 until your Registration is complete!!!
Pre-Registration (2)

Pre-registration is simple and free

From 1 June 2008 to 1 December 2008 you have to submit to ECHA:

- The name of the Substance (EINECS and CAS)
- Your name and address and the contact details of your contact person
- Date of Registration and tonnage band (1 to 100, 100 to 1000 and above 1000 tonnes per year)
- The name of the Substance(s) (EINECS and CAS) for read-across
Welcome to REACH-IT

REACH-IT provides an online platform to submit data and dossiers (pre-registration, registration, C&L notification...) on chemicals. It also allows the Agency and Member States authorities to review the dossiers. The Agency will also use REACH-IT to make non-confidential information on chemicals accessible to public on its website.

What can you do?

To login to REACH-IT you first need to sign-up and provide information on your identity and set-up an account for a user who will have administrator privileges to manage your account. You can sign-up either as a company or as a third party.

- If you already have an account, you may login to the system.

If you have not created an account yet, you can do it here below.

- Sign up as a company
- Sign up as a third party representative

Need help with REACH-IT or with this site?

- REACH Frequently Asked Questions (FAQ)
- The REACH legal text
- Contact information
Pre-registration (4)

More information on pre-Registration at:

http://reach.jrc.it/pre_reg_en.htm

http://echa.europa.eu/pre-registration_en.asp

https://reach-it.echa.europa.eu (online pre-Registration)

http://www.reach-metals.eu (REACH Metals Gateway)
SIEF

- SIEF = Substance Information Exchange Forum (Electronic Platform)
- SIEF is created for existing phase-in Substances
- Each manufacturer or importer that pre-registers a Substance with the same CAS No becomes automatically a member of a SIEF
- One Substance – one SIEF – one Joint Submission

- Voluntary participation in a SIEF – anybody who can offer a study or test (downstream user, manufacturer/importer below 1 t/y, research centre)
Joint Submission (1)

- You have to register jointly with other Registrants on the principle “one Substance = one Registration”
- REACH imposes the Joint Submission of a part of the technical dossier. Some information is submitted individually
- The Joint Submission will be made on behalf of all Registrants by a Lead Registrant elected by the other Registrants of a same Substance
- In exceptional circumstances you can opt-out from Joint Submission. Consequence – higher Registration fees and evaluation of your dossier by ECHA with priority
## Joint Submission (2)

<table>
<thead>
<tr>
<th>Joint Submission</th>
<th>Separate submission</th>
<th>Joint or separate submission: free decision</th>
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<tbody>
<tr>
<td>Classification and Labelling</td>
<td>Identify of manufacturer or importer of the Substance</td>
<td>Guidance of safe use</td>
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<tr>
<td>Study summaries</td>
<td>Identity of Substance</td>
<td>Chemical Safety Report</td>
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<tr>
<td>Robust study summaries</td>
<td>Information on the manufacture and use(s) of the Substance</td>
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<tr>
<td>Proposals for testing</td>
<td>Exposure information (1 to 10 tonnes per year)</td>
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<td>Optional: Review by an assessor</td>
<td>Optional: Review by an assessor</td>
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Data Sharing

Data sharing includes

- Obligation to request a study/data involving tests on vertebrate animals
- Right to request a study/data not involving tests on vertebrate animals
- Obligation to provide a study/data if requested whether involving tests on vertebrate animals or not

Any potential registrant registering the “same” Substance or a “read-across” Substance can/must request a study/data

The potential registrant who requests a study/data must pay for it
REACH Consortium Agreement

The Consortium Agreement is not a legal requirement and does not replace the SIEF

Why participate in a REACH Consortium?
- Preparation of the Registration Dossier
- Clear organisation rules – who does what
- Rules on Joint Submission and data sharing
- IP rights and data protection and non-disclosure agreements
- Control over costs

**SIEF/Consortium**

<table>
<thead>
<tr>
<th>SIEF</th>
<th>CONSORTIUM</th>
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<tbody>
<tr>
<td>SIEF is a virtual room, no structure, <strong>starting in January 2009</strong></td>
<td>Consortium could be formed, according to your views on structure etc, NOW</td>
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<tr>
<td>SIEF is created for data exchange only</td>
<td>Consortium has a larger scope</td>
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<td>SIEF is mandatory</td>
<td>Consortium is voluntary</td>
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<td>No clarity on who will appoint the lead registrants if no agreement can be reached</td>
<td>Select a lead registrant independently</td>
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<td>No influence, no flexibility regarding membership</td>
<td>Trust (known members)</td>
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<td>One SIEF per Substance</td>
<td>Consortium can cover more Substances and facilitate the read-across</td>
</tr>
<tr>
<td>Data sharing and compensation are imposed</td>
<td>Protection of IP rights, confidentiality and fair compensation can be guaranteed</td>
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<tr>
<td>No guarantees for quality of third party’s data</td>
<td>Ability to choose best study and control testing proposals</td>
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REACH Authorities

- European Chemicals Agency (ECHA)
  - Manages registration and dossier evaluations
  - Makes decisions on animal testing
  - Provides opinions on authorisation and restriction
  - Provides technical guidance and exchanges information with national authorities

- European Commission
  - Adopts implementation regulations (e.g. on fees)
  - Reviews the REACH Regulation, including Annexes
  - Grants authorisations and decides on inclusion on the list of restricted Substances

- Member States
  - Propose substances for evaluation, authorisation, restriction
  - Enforce REACH, including sanctions for non-compliance
What to Do?

You want to continue your business in the EEA:

- Make an inventory of your Substances for Registration, including produced/imported tonnages per year
- Select your legal entity established in the EEA that will (pre-) register your Substances - changes in supply chain cannot be excluded
- Pre-register before 30 November 2008
- Contact the consortia registering your Substances - [http://chemicalwatch.com/consortia](http://chemicalwatch.com/consortia) (unofficial)
- Consider the creation of your own Consortium
- Review your budget – a Registration Dossier in EUR per Substance may cost from about 30k for the lowest tonnage band to about 2 million for the highest
## Key REACH Dates

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<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>1 June 2007</td>
<td>Entry into force</td>
</tr>
<tr>
<td>1 June 2008</td>
<td>Entry into force of Titles: Registration, Data-Sharing, Downstream users, Evaluation, Authorisation, Fees and charges and Information</td>
</tr>
<tr>
<td>1 June 2008 – 1 December 2008</td>
<td>Pre-Registration of phase-in Substances</td>
</tr>
<tr>
<td>1 January 2009</td>
<td>Publication of phase-in Substances on Agency’s website</td>
</tr>
<tr>
<td>1 June 2009</td>
<td>Entry into force of Title VIII on restrictions on production, placing on the market and use of certain dangerous Substances and preparations</td>
</tr>
<tr>
<td>1 December 2010</td>
<td>Deadline Registration of phase-in Substances (i) of 1000 or more tonnes per year; (ii) classified as carcinogenic, mutagenic or toxic to reproduction; and (iii) classified as very toxic to aquatic organisms</td>
</tr>
<tr>
<td>1 December 2012</td>
<td>Decisions on test proposals submitted by 1 December 2010 by registrants of phase-in Substances</td>
</tr>
<tr>
<td>1 June 2013</td>
<td>Deadline Registration of phase-in Substances of 100 or more tonnes per year</td>
</tr>
<tr>
<td>1 June 2016</td>
<td>Decisions on test proposals submitted by 1 June 2013 by registrants of phase-in Substances</td>
</tr>
<tr>
<td>1 June 2018</td>
<td>Deadline Registration of phase-in Substances of 1 or more tonnes per year</td>
</tr>
<tr>
<td>1 June 2018</td>
<td>SIEF ceases to exist</td>
</tr>
<tr>
<td>1 June 2022</td>
<td>Decisions on test proposals submitted by 1 June 2018 by registrants of phase-in Substances</td>
</tr>
</tbody>
</table>
The Impact of REACH on Your Business

THANK YOU!

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