REACH

REGISTRATION, EVALUATION, AUTHORIZATION (AND RESTRICTION) OF CHEMICALS

A GUIDE FOR API MEMBERS

MARCH 13, 2008

energy API®

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REACH—A Guide for API Members

What is REACH?

REACH[1] is the new European Union (EU) legislation concerning the Registration, Evaluation, Authorization (and Restriction) of Chemicals, which came into force on June 1, 2007. The regulation sets out new requirements for chemicals and substances manufactured within or imported into the EU to ensure that substances (including refinery streams and substances used to produce them in the EU) can continue to be used. Each substance, along with every identified use, will need to be registered with the newly formed European Chemicals Agency (ECHA). If a use is not registered, then the substance cannot be employed in that application within the EU unless the user takes the responsibility for conducting a risk assessment and ensuring safe use.

Registration

Evaluation

Authorization of CHemicals

The introduction of the legislation has a phased approach, starting this year (2008), through to final submission in 2018. For those in commerce with substances in the higher tonnage bands, the effective first major deadline is 2010.

REACH is the most comprehensive chemicals legislation in the world, and is also likely to become one of the most complicated to comply with—at all levels from the technical to managerial and business challenges. It will also have global implications. Even those not immediately involved in the EU market are in the supply chain of others who are, and will be asked for information and support by those formulators who do, or whose customers decide not to, support substances that are currently exported to the EU.

The newly formed European Chemicals Agency (ECHA) will administer REACH. Because the legislation is so complex, the EU Commission, through ECHA, has issued, or will be issuing, guidance in various aspects of the legislation and its implementation. A list of this guidance and a link to the source is given in Appendix 1.

This guide does not seek to replace the official EU guidance, but rather to provide an overview and to highlight the main issues and places to go to for help.

[1] *Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation and Authorization of Chemicals.*

Is our Business Affected by REACH?

We export catalysts to the EU through a series of business partners and distributors. We have no EU presence ourselves—it has always been handled by our distributors.

You will be affected.

Under REACH it is the responsibility of your importers to comply and register your substances.

However, if they do not comply, you will not be able to distribute directly into the EU. By leaving this activity to importers you have diminished control of your future business activities as the importers will have the registration.

Consider working though an "only representative" or a company with whom you have a firm long lasting partnership agreement.

There will inevitably be a cost associated with all the work that is required

We sell product to a formulator who then imports final product into the EU—sometimes the product goes through other regions first.

You will be affected.

Unless someone does a registration of your substance and its use within the EU then it cannot be supplied.

It is likely that the formulator will want an assurance from you that you will support the registration-information, costs, and time. However, you may not want to give the confidential information that this may require.

The rules on how to register in this case are complex and still being formally adopted. You may need to obtain specialist advice on the best way for you to proceed, in order to protect your business activities.

We do not sell to the EU, but we do buy critical substances for our manufacturing process and product line.

You could be affected.

Registration will have a cost implication for any company manufacturing in the EU.

It is possible that because of these costs the EU manufacturer decides not to continue a substance that is critical to your business continuation.

You may want to contact your supplier to ensure that the substances you buy will be supported by your supply chain.

REACH Timeline

June 1 2007	REACH Came into Force
2008 1st June to 1st December 2008	Pre-registration >1 tonne
3.5 Years 30th November	Registration 1,000 tonnes/yr + CMRs[1] (Category 1 & 2) ≥ 1 tonne/yr + very toxic[2] ≥100 tonnes/yr
6 Years 31st May	Registration 100 – <1,000 tonnes/yr
11 Years 30th November	Registration 1 – <10 tonnes/yr 10 – <100 tonnes/yr

[1]CMRs—Carcinogens Mutagens Reprotoxins following current EU classification scheme

[2]EU Environmental classification

What Does REACH Try to Do?

The stated goals of REACH are to improve scientific knowledge about environmental and health impacts of substances and to encourage their safe use. REACH was specifically designed to place the responsibility with the industry to demonstrate safe use and show why hazardous substances should continue to be used. Through the provisions of authorization and restrictions, REACH will also allow regulators to act to limit the use of hazardous substances. There has been some criticism of the regulation because it is all-encompassing, ambitious and complex.

However, despite many attempts to change the legislation, it is now on the European statute and its progress is firmly under way.

The Business Impact of REACH

Because REACH may cause the withdrawal of a substance from the EU market, it has immediately gained the attention of management within companies. But, this is not the only threat that makes REACH a major business process issue requiring management attention. REACH easily translates into "No registration—no global market" in today's economy, where materials are supplied on a worldwide basis, rather than a regional one.

There is also the potential for the loss of production of certain chemicals if a supplier does not register for reasons of cost or complexity.

Notwithstanding the potential loss of chemistry or uses through restriction, authorization, or costs, the registration process will also have significant resource and organizational implications—both technical and managerial—in almost all areas of the business.

Potential sources of costs implementing REACH

Internal resources:

- Management time—relationships with suppliers and downstream users
- Technical expertise
- Systems changes for business practices and IT
- Representation in SIEFs: one per substance—engage and brief representatives
- Production facilities—inventories and data collection

External resources

- Supplement internal teams?
- Data write-up for the registration dossier (>20K€)
- Toxicology testing >2M+ € per substance
- Registration fees up to 30K€ per substance per Legal Entity

** Worst case—for a substance >1000 tpa with no pre-existing data, costs not shared in a SIEF and a cancer bioassay required.*

While the list at left covers potential costs that will be generated by REACH, it should also be noted that companies who have already performed the necessary studies for registration will be able to recoup some of the costs through the SIEF, from those who have not previously invested in these studies.

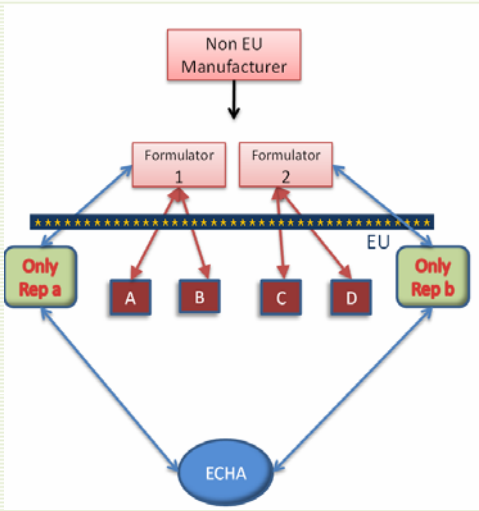
Specifics for U.S. Exporters

Manufacturers who export into the EU will need to ensure that their substances on their own, components in preparations, and substances in articles under certain conditions are registered. However, it is not possible for them to do so directly. It is the obligation of the Legal Entity who imports the substance into the EU to register. That importer must be a Legal Entity established in the territory of the EU (EEA). Consequently, if the substance is imported by a number of different legal entities, each one should make a separate registration detailing both the tonnage imported and also the uses of the material. To provide a legal representative for a company in the EU where one does not currently exist, the construction of the "Only Representative" can be employed.

Only Representative

Many U.S. businesses—whether in the chemicals sector or in industries that use chemicals in the production of finished articles—will either have affiliates, distributors or customers in the EU. Shipping chemicals or finished products to either may impose potentially burdensome registration obligations. An importer for REACH purposes is the EU Legal Entity that pays import duty on a given consignment and completes the customs formalities. This may not be the member of the U.S. exporter's company group, or its customer's group, that is best placed, in terms of administrative or technical capabilities, to deal with the resulting requirements. Moreover, if the importer does not pre-register between 1 June and 1 December 2008, it may have to stop importing shortly thereafter.

The Only Representative (OR)



Article 8 of REACH offers one solution to the U.S. exporter in these circumstances: the appointment by the "Non-community Manufacturer" of an "Only Representative" within the EU, who will then assume the actual importers' duties under the regime. Such a representative must have sufficient background knowledge in the practical handling of chemicals and information relating to them.

Another solution might be for the U.S. exporter to re-route and channel its distribution via a trusted, EU-based affiliate or importer, which would satisfy registration obligations, before selling to other European customers.

However, the effects of REACH will not be limited to EU suppliers. Although REACH is not intended to have extraterritorial effects, non-EU companies must still be mindful of its impact. For example, the American Chamber of Commerce has raised concerns over the potential "black list" effect of the Annex XIV list of substances subject to authorization, the need to register monomers present in imported polymers and the consumer information provisions of REACH as they relate to consumer products. (Amcham EU. *Position Paper on Areas of Concern and Priority Issues*. April 10th 2006.)

REACH may lead to distortions in the international market for chemicals by encouraging EU-based companies to source their chemicals, preparations and articles from other EU-based companies, rather than risk facing registration requirements as an importer by sourcing them from outside the EU.

Basic Overview of REACH Provisions

The legislation marks a move away from a regulatory-led environment, where authorities had to prove there was a hazard or risk for a specific chemical before taking action, to one where the onus is on the manufacturers and importers of chemicals to demonstrate the safety in all intended uses of that chemical. If they do not do so, the substance cannot continue to be supplied to the market or used in European facilities.

The Scope of REACH—What Is Covered and What Is Not

REACH requires registration and evaluation of substances on their own; substances in preparations; and substances in articles that are intended to be released during normal or reasonably foreseeable conditions of use.

However, there is no need to register certain substances, for example the following are exempt from registration, but could be brought into authorization:

- *Polymers* (but their monomers and other bound substances must be registered)
- *Substances/groups named in Annex IV*, certain low risk substances such as sugar and oxygen
- *Substances falling within Annex V exemptions*, e.g. unrefined natural substances, included in this list are natural gas and crude oil, and by-products (unless these are placed on the market)
- Substances to the extent used in food or pharmaceuticals
- Other substances are totally exempt from REACH:
- Radioactive substances and substances under customs supervision
- Non-isolated intermediates
- Waste

Consult the Scoping provisions of Article 2 and the Annexes for the full listing

Registration

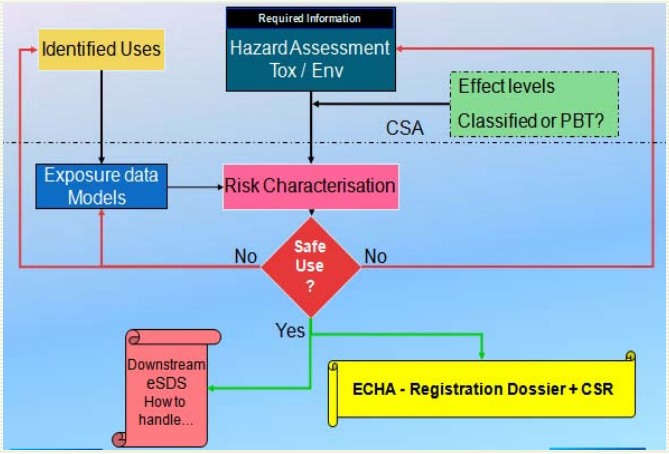
REACH requires any EU-based company (Legal Entity) that manufactures or imports a substance into the EU in amounts of one tonne or more per year to submit hazard and safe use information to the new European Chemicals Agency (*ECHA*). If a chemical, sold as such or in a preparation, or in an article where it is intended to be released during use, is not registered where REACH so requires, it cannot be placed on the EU market. If the substance is known in the EU as a phase-in substance, then it can benefit from the delayed implementation timetable shown in the REACH timeline box.

The registration consists of an extensive electronic dossier of information. The prescribed information requirement is dependent upon the tonnage (*see Appendix 2),* produced or imported into the EU. It encompasses physico-chemical, toxicology, health and environmental properties. If the information is not available, then it either has to be generated (for simple tests), or for some vertebrate toxicology, a testing proposal developed. The proposal has to be made in the registration dossier, for subsequent approval by ECHA after the registration has been submitted. There are lesser requirements for some on site and transported intermediates.

The registration dossier also requires the inclusion of details on the substance, impurities, additives, and use. The properties data is used to determine whether the substance is hazardous, either for man or for the environment and if so, further work is required to assess the risk of the defined uses—in what is known as Exposure Scenarios. If it can be demonstrated that the substance is not hazardous, or that there is no risk to man or the environment from the use of the substance in the way it is handled—as described in an Exposure Scenario—then the substance can be registered.

Before the registration of a substance at the 10-tonne level, any hazards and any Exposure Scenario (and the so called Risk Management Measures that it details) and other information necessary to ensure safe use must be communicated down the supply chain in a new-style, extended Safety Data Sheet (eSDS).

The Basic REACH Process—Per Substance



A suitable responsible officer of the Legal Entity making the registration needs to declare that these actions have been taken in a Chemical Safety Report (CSR). This report details the hazards and the risk characterization and the risk management measures to ensure safe use of substances that are classified as hazardous by the Chemical Safety Assessment process.

A standard fee is payable to ECHA when the registration is made.

Dossier Evaluation

Once a dossier has been submitted to the ECHA, it will be checked to make sure that it is completed correctly. This electronic completeness check may be followed by an evaluation of the dossier by a staff officer of the ECHA or by an EU Member State Competent Authority. They can then ask questions of the registrant on technical and other aspects of the dossier.

Standard Registration Fees[1]

Substance Tonnage Range	Individual Submission €	Joint Submission €
1 to 10 tonnes	1,600	1,200
10 to 100 tonnes	4,300	3,225
100 to 1 000 tonnes	11,500	8,625
above 1 000 tonnes	31,000	23,250

Extract of draft regulation[1] final values will be published in the Official Journal of the European Communities.

Restriction

Restriction is the so called "safety net" for REACH. Depending upon the data contained within the dossier and its interpretation, ECHA may propose restrictions on substances for its use in any condition, or prohibition of the manufacture, use or placement on the market. There is a formal process that any such restriction has to go through before it is mandatory, including discussion at a formal committee hearing and publication of the associated risk assessment.

Authorization

The REACH text also contains a provision for a list known as Annex XIV. This will be a listing of Substances of Very High Concern (SVHC). Many of these will be substances that are already known and classified as Category one or two Carcinogens, Mutagens or Reprotoxins (CMRs) and also substances that are Bioaccumulative (B) and Persistent (P) and Toxic (T) (called a PBT) or very B and very P but not necessarily T within the environment. Annex XIV will also include other substances that are of "equal concern," for which there is some uncertainty. For these, authorization must be sought for their continued use, with a technical dossier, a socio-economic case and proof that there is no suitable alternative for the application to be provided. An Annex XIV substance cannot be manufactured, used or placed on the market unless authorized, and the Authorization, if granted, will be subject to time limits and conditions. Polymers, although exempt from registration, are not exempt from authorization. The application fee authorization will cost 50,000€ per substance with an additional 10,000€ per use.

There are also a number of exemptions from authorization—this includes "(c) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of October 13, 1998 relating to the quality of petrol and diesel fuels." [2]

The First Step—Pre-registration in 2008

To qualify for the "benefits" of a phase-in substance it is necessary to pre-register any substance with the ECHA by December 2008. The process and actions needed for pre-registration are relatively straight-forward once a manufacturer or importer a) knows which substances they want to register and b) have resolved who will do the registration for them if they do not have a legal representative in Europe.

After the end of the pre-registration phase, the ECHA will inform companies who have pre-registered a specific substance of the results of this process. Companies producing this specific substance will be put into a Substance Information Exchange Forum (SIEF) in order to facilitate data sharing for the purpose of organizing the mandatory joint submission of data, and to allow the members of the SIEF to agree on the classification and labeling of the substances. Other possible purposes of the SIEF include exchanging the data needed to conduct the Chemical Safety Assessment and drafting the Chemical Safety Report (below). There is no fee and no obligation to register even though a pre-registration has been made. However, by pre-registering, a company undertakes to participate and reply to correspondence within the SIEF—a process that might be burdensome in its own right.

The EU Guidance Document on Data Sharing should be consulted in detail for information and advice on: The Pre-registration Process; the formation of SIEFs; data sharing within SIEFs; data sharing for non phase-in substances; and joint submission of data and opt out. It also contains practical recommendations to help companies meet their obligations and achieve their objectives, covering: cost-sharing mechanisms; the protection of Confidential Business Information (CBI); competition law; and forms of co-operation, including consortia.

[2] Article 56, Paragraph 4, Section (c)

Compulsory Sharing of Data

After pre-registration closes, there is a period before the SIEFs become operational (called pre-SIEF discussions) to ensure that pre-registrants of a substance have in fact pre-registered the "same substance" for data sharing purposes. Once the sameness of the substance is established, the SIEF becomes operational. Each pre-registrant within a SIEF is given the contact details of the other pre-registrants to allow the parties to come together to share data and come to a common decision on what the data means in terms of hazard and possibly risk. There will be rules to compensate companies for studies already done and for effort expended in the past. There will be a significant managerial and technical challenge to ensure that the SIEF works efficiently. Company representation will require a considerable resource that is knowledgeable both about the process and the technical content under discussion, who has management backing to make decisions on the company's behalf. Companies may appoint a third-party representative onto the SIEF.

On January 1, 2009, ECHA will publish a list of pre-registered substances to allow data holders to join the SIEF. This will also allow users to check whether substances of interest to them have been pre-registered at least by one Legal Entity.

Even if working in a SIEF is cumbersome and expensive, most companies will use the pre-registration phase because by pre-registering, the substance becomes a "phase-in" substance and gains the benefit of a delayed registration deadline.

Information Requirements

The information requirements for REACH are given in Appendix 2.

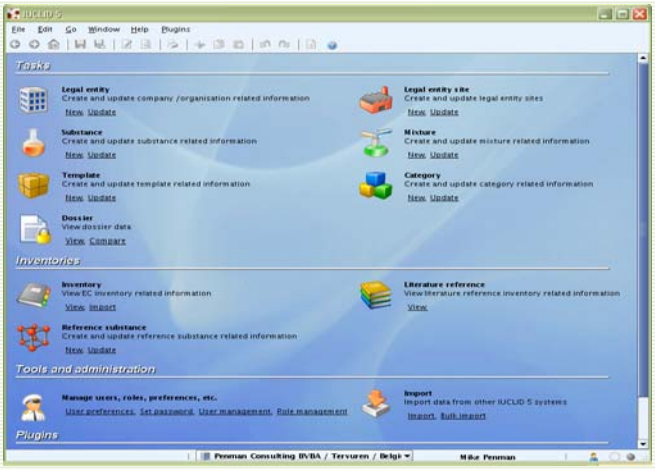
There is extensive guidance on the integrated testing strategies that should be used to meet these requirements. Wherever possible, animal testing should be avoided and alternative techniques employed. The alternative techniques include: QSAR; read across (categories); in vitro data; weight of evidence; exposure-based waiving; and substance-specific testing strategies. However, in practice this will not always be possible in a large number of cases, and if there is a data requirement, either a test is done (Annex VII and Annex VIII) or a testing proposal is made to the ECHA (Annex IX and Annex X). Only after agreement with ECHA are such tests done.

Chemical Safety Assessment

The purpose of all this data is to drive the process of hazard evaluation and, if necessary, risk characterization as shown in the Figure at right.

All of these data are entered into a software tool, IUCLID 5, available free from ECHA. This database system, developed for use by REACH and other regulatory programs, has extensive fields for adding all the toxicological, environmental and physico chemical data. It also has extensive fields for data summary and evaluation.

IUCLID



Classification and Labeling

As REACH is being implemented, the EU will also adopt its variation in the new Global Harmonized System (GHS) for classification and labeling. In this new scheme, each substance will be required to undergo checking for its classification. Under REACH legislation, this process will be documented and presented within the registration dossier, based on tonnage. Each registration must contain the rationale explaining why a substance is, or is not, classified for the endpoints where there are information requirements. It is likely that both the existing EU scheme and the new EU scheme will need to be reported in the registration dossier.

DNELs and PNECs

For both human health and environmental aspects, the levels at which no effect can be anticipated is calculated. For human health, these are referred to as Derived No Effect Level (DNEL), and for the environment as Predicted No Effect Concentrations (PNEC). They are based upon the level at which no effect is seen in the experimental data and divided by a set of predefined assessment, or safety, factors to give a level which will assure no effect in man or the environment, respectively. For substances that have biological effects that are agreed to be non-threshold, i.e. there is not a level at which you theoretically do not see an effect, there are other values calculated—such as Derived Minimal Effect Levels (DMEL). This is another complex process and will be driven by the procedures given in the EU's guidance documentation. The guidance is not yet published, but is expected before June 2008.

Environmental Assessment

An assessment of whether the substance is Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) must also be made and documented. This is another technical assessment—and it is important as both PBT and vPvB substances may be subject to the complex and costly Authorization phase. Many see this environmental assessment as one of the major changes that REACH brings, as this concept was not included in previous EU legislation. As for DNELS and PNECs, the guidance on this crucial step is expected by June 2008.

The Consequences of the Chemical Safety Assessment: The Chemical Safety Report

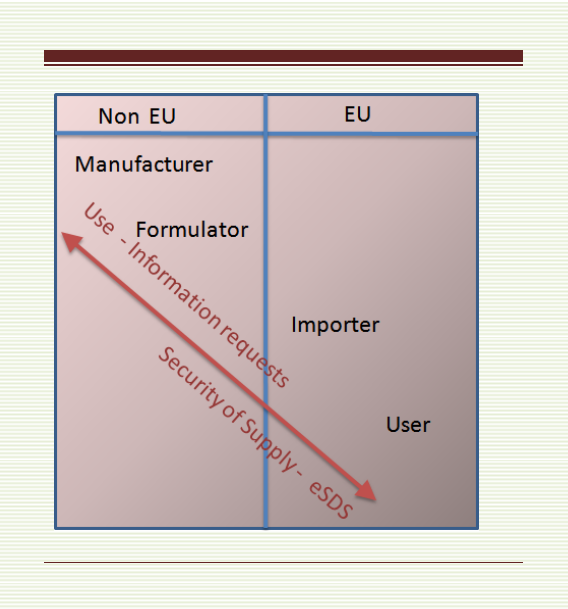
If a substance meets the criteria for classification as dangerous under the DSD or is deemed to be a PBT or a vPvB, there is a requirement to provide further information including a risk characterization on exposures from the intended uses. The use of a substance is evaluated and an "Exposure Scenario" is developed to describe how the substance is used, including any risk reduction measures. From this Exposure Scenario an assessment of exposure is made (directly, or by models) and compared to the levels which are considered not to have an effect on man or the environment—the risk characterization. All of this information is detailed in a specific report format known as the Chemicals Safety Report (CSR).

As well as providing the scientific data in Part B of a CSR, a manufacturer or importer must declare, in Part A, that they have implemented the appropriate risk management measures to cover their use of the chemical and have communicated the Exposure Scenarios to users using the new style SDS. This requirement means that it will not be possible to register without first supplying the extended Safety Data Sheet to customers.

Supply Chain Interactions

One of the main features of REACH is that the use of the substance needs to be considered and included in the registration. If the substance is hazardous, there are requirements to collect or model exposure data to man (occupational or consumer) and to the environment. For this reason, a manufacturer or importer needs to maintain a dialogue with the downstream user in order to determine all uses of the substance that may need registering.

When the downstream user wishes to keep a use confidential, they may register this use themselves—doing the risk characterization, if required, for a hazardous substance, using that given to him by his supplier and the same as that registered with the ECHA.



In addition, there is a requirement to pass a greater degree of information down the supply chain using extended Safety Data Sheets (eSDS), than has previously been the case. The eSDS gives a greater degree of information on toxicology and environmental aspects so that the downstream user can make specific assessments. The eSDS also contains the Exposure Scenarios that the manufacturer, or importer, supports.

This aspect of covering uses in Exposure Scenarios and communicating information up and down the supply chain will lead to a great deal more traffic between suppliers and users of substances.

Because gathering information in the supply chain has become such an important issue, a number of standardized questionnaires have been, or will be, produced by trade associations.

Many of these questionnaires may need revision when the final guidance on the documentation on use and Exposure Scenarios is finally published—this is expected before June 2008.

The Extended Safety Data Sheet

The extended Safety Data Sheet (eSDS) will be the way that hazard is communicated down the supply chain. The details of the new requirements are shown in the panel at right. Those sections in bold have an increased data requirement compared to that currently demanded. It is likely that the eSDS will be considerably longer than the data sheets used today. The inclusion of Exposure Scenarios (ES) of uses that are supported by the manufacturer or importer will further complicate the authoring of the sheet and will be problematic for complex preparations.

Activities by European Trade Associations—CONCAWE Activity and Plans

CONCAWE, the European refining trade association, has a highly developed plan to help their membership cope with the requirements of REACH.

The basis for the CONCAWE activities is their risk assessment program on refining streams and the category approaches built up over many years for the Existing Substances regulation and EU classification and labeling.

The Extended Safety Data Sheet

Prescribed format for all hazardous substances

Increased requirements and additional detail compared to the current the EU standard

Sections

1. ***Identification of the substance/preparation and of the company/undertaking***
2. ***Hazards identification***
3. ***Composition/information on ingredients***
4. *First-aid measures*
5. *Fire-fighting measures*
6. *Accidental release measures*
7. *Handling and storage*
8. ***Exposure controls/personal protection***
9. *Physical and chemical properties*
10. *Stability and reactivity*
11. ***Toxicological information***
12. ***Ecological information***
13. *Disposal considerations*
14. *Transport information*
15. ***Regulatory information***
16. *Other information*

ANNEX—Exposure scenarios of uses supported by the manufacturer/importer

CONCAWE will …

- complete risk assessments for petroleum substances
- prepare, on that basis, common parts of joint registration dossiers (both mandatory and optional), including classification
- manage the consortia process arising from SIEFs on behalf of its membership
- offer the common parts of the dossier to non-members by way of a licensing agreement
- provide guidance and templates for non-common parts of dossiers for Member Companies

CONCAWE will not be able to prepare complete registration dossiers. Additionally, some registrant specific elements will have to be prepared by the registrants themselves for each Legal Entity.

Cefic, the European Chemistry Industry Council, has a number of REACH related activities which are described in their general pages.

Specific sector groups within Cefic which have related chemistries to the refining industry—for example the Cefic Aromatic Producers Associations and Cefic Lower Olefins Sector Group—are starting programs to manage REACH issues. Links to these groups are available via the Cefic website.

The European Metals industry has set up a REACH metals Gateway —to assist those manufacturers and importers who have specific interest in metal chemistries.

Practical Aspects—A Way Forward

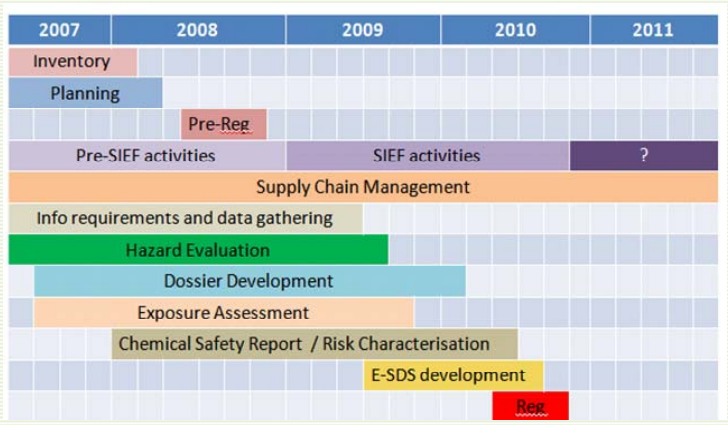
Company Planning Basics—To Registration

1. Inventory Development
2. Understanding Requirements, Decisions and Planning
3. Pre-registration
4. SIEFs and Consortia Formation—Representation and Management of Activities
5. Management of the Supply Chain—Use and Exposure
6. Information Requirements and Data Gathering
7. Hazard Evaluation—Human Health, Environmental and Physiochemical
8. Development of the Registration Dossier—Information/Test Plans
9. Development of Exposure Scenarios
10. Chemical Safety Report/Risk Characterization
11. Extended Safety Data Sheet Development
12. Registration

Many activities in parallel—timelines dependent upon registration type

Potential joint activity in Consortia or SIEF

Relationships between illustrative actions



The panels at right show basic steps that can be taken to implement and manage REACH. While they are a useful guide of basic steps, it should be emphasized that many of these are very high-level views of the activities that are required. Experience has shown that no two business or business units are ever quite alike. Specific and detailed planning is required to be able to drill down to the many specific substance actions that are required for registration purposes.

It should also be noted that these indicative steps are not sequential. They are interrelated and need to progress concurrently. The complexity in the planning is aggravated by the need to consider how to work with co-manufacturers and importers in consortia and SIEFs, and designate roles and responsibilities. Even the steps required to enable the necessary agreements to allow such work to go on can be very time consuming.

Further Information

The reference section provides a number of links to the official EU sources of information as well as to contact points within the various trade associations.

Within Europe there is a series of helpdesks run by both the ECHA and EU Member State Competent Authorities. A list of these National help desks is available on the ECHA website—link.

API Contacts

Derek Swick, Policy Advisor, 1220 L Street, NW, Washington, D.C., 20009.
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Email: whiter@api.org; Phone Number: 202-682-8344.

This project was completed under the direction of API's Health and Product Stewardship Program Group. The lead technical consultant involved in compilation of this guidance document was Mike Penman of Penman Consulting BVBA.

Reference Section

Web Links

CEFIC
CONCAWE
EC Directorate general for Environment, Nuclear Safety and Civil protection
ECHA website—REACH Guidance
ECHA overview of REACH
Eurometaux
European Chemicals Bureau
European Commission—REACH
The European Chemicals Agency (ECHA)
UK Health and Safety Executive

Main Definitions—Article 3

Distributor: any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.

Exposure Scenario: the set of conditions, including operational conditions and risk management measures, that describes how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

Full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed.

Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.

Importer: any natural or legal person established within the Community who is responsible for import.

Monomer: a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

Non-isolated intermediate: an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.

Notified substance: a so-called ELINCS substance, for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/CEE. These substances have a “notification number.”

Phase-in substance: a substance which meets at least one of the following criteria:

1. It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

2. It was manufactured in the Community, or in the countries acceding to the European Union on January 1, 1995 or on May 1, 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this.

3. It was placed on the market in the Community, or in the countries acceding to the European Union on January 1, 1995 or on May 1, 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/CEE, but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this.

Major Definitions—Article 3(2)

Polymer: a substance consisting of molecules characterized by the sequence of one or more types of monomer units (reacted form of a monomer substance in a polymer) and distributed over a range of molecular weights.

Preparation: a mixture or solution composed of two or more substances. A paint or resin made up of several substances is a preparation. Composite materials, alloys, lubricants, paints, varnishes, adhesives, etc. are preparations.

Producer of an article: any natural or legal person established within the Community who makes or assembles an article within the Community.

Registrant: the EU manufacturer or the importer of a substance or the EU producer or importer of an article submitting a registration for a substance.

Registrant's own use: means an industrial or professional use by the registrant.

Robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report.

Study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study.

Substance: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Supplier of a substance or a preparation: any EU manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation.

Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization.

Glossary

Cefic: The European Chemical Industry Council

CONCAWE: CONservation of Clean Air and Water in Europe. The Oil Companies' European association for health, safety and environment in refining and distribution.

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DNEL: Derived No Effect Level. The point below which the hazardous substance is considered not to harm health.

ECHA: European CHemicals Agency, managing the implementation of REACH legislation.

European Union: in this document, this term refers to all the EU member States and some other countries that will be implementing REACH and will be considered to be "inside the EU"—namely Iceland and Norway. Note that Switzerland is outside the EU for the purposes of REACH.

GHS: Globally Harmonised System for the classification and labelling of dangerous substances and preparations.

IUCLID: International Uniform ChemicaL Information Database

Only Representative: The legal entity registered in the EU, who is representing a non-EU company, thereby allowing them to comply with REACH in their own right.

OSOR: One Substance One Registration

PBT: Persistent, Bioaccumulative and Toxic

PNEC: Predicted No Effect Concentration: The predicted level below which the substance is expected to have no effect.

RIP: REACH Implementation Projects. The European Chemicals Bureau (ECB) is responsible for developing the technical guidelines and IT tools required for putting REACH in place and for its satisfactory operation. These activities are carried out in cooperation with the member States, industry and the non-governmental organisations in the form of RIPs.

SDS: Safety Data Sheet

SIEF: Substance Information Exchange Forums

SVHC: Substance of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Appendix 1—EU REACH Guidance Documents

Each aspect of REACH compliance is, or will shortly be made available from the ECHA. Many of these documents are highly technical in nature and will require expert assistance to understand the guidance. They are also comprehensive and therefore very lengthy—the guidance to industry and authorities exceed 10,000 pages. Not all of these documents are yet published, and although the links are provided they may return a response indicating that the guidance will be posted shortly. It is anticipated that all the industry guidance will be available by June 2008.

Guidance on Registration. When and how to register a substance under REACH. It consists of two parts: one on Registration tasks and obligations and the other on the preparation of the Registration Dossier.

Guidance on Pre-registration. How to identify the substances that can be pre-registered as well as when and how to pre-register them.

Guidance on Data Sharing. Data sharing mechanisms for phase-in and non phase-in substances under REACH. It includes the communication within the SIEF and the cost sharing guidance. The document also describes the Confidential Business Information and Competition Law issues in the context of data sharing.

Guidance for Intermediates. When and how the specific provisions for the registration of intermediates under REACH can be used.

Guidance for Monomers and Polymers. Specific provisions for polymers and monomers under REACH.

Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD). Specific provisions for substances manufactured, imported or used in scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD).

Guidance on Classification and Labeling Notification. When and how to notify a classification and labeling for a substance under REACH.

Guidance on Requirements for Substances in Articles. Assists producers and importers of articles in identifying whether they have obligations under REACH; in particular in relation to registration and notification according to Article 7, and in relation to article supply chain communication according to Article 33.

Guidance for Downstream Users. The roles and obligations of downstream users, and advises them on how to prepare for the implementation of REACH.

Guidance on the Preparation of an Application for Authorization. This document describes how to prepare an application for authorization and provides guidance on analysis of the alternatives and substitution plan. It also describes how third parties may prepare and submit information on alternatives.

Appendix 2—Information Requirements

Data Requirement Annex VI & Annex XI +

	<1	1 – 10 tpa*	10 – 100	100 – 1000	>1000
Substance	—	Annex VII	+ Annex VIII	+ Annex IX	+ Annex X
Non Isolated Intermediate	—	—	—	—	—
On-site Isolated Intermediate under strict control	—	1	1	1	1
Transported Isolated Intermediate under strict control	—	1	1	1	Annex VII
Monomer	—	Annex VII	+ Annex VIII	+ Annex IX	+ Annex X
Polymer	—	—	—	—	—

[1] *Registration to include the following: Identity of manufacturer and intermediate, classification, any available phys-chem, health or environmental data. Brief description of use, details of risk management measures.*

Annex VII

State of the substance at 20°C and 101.3 kPa
Melting/freezing point
Boiling point
Relative density
Vapour pressure
Surface tension
Water solubility
Partition coefficient n-octanol/water, flask shake method
Flash-point
Flammability, liquids
Explosive properties
Self-ignition temperature for liquids and gases
Oxidising properties
Granulometry (particle size distribution)

Short-term toxicity testing on Daphnia
Growth inhibition study on algae
Ready biodegradability - Modified Sturm test
Ready biodegradability - Closed bottle test

Skin irritation (indicate if in vitro)
Eye irritation (indicate if in vitro)
Skin sensitisation
In vitro gene mutation study in bacteria
Acute toxicity, oral route (OECD 420, 423 or 425)

Annex IX

- Fish early-life stage (FELS) toxicity test
- Fish short-term toxicity test on embryo and sac-fry stages
- Fish, juvenile growth test
- Simulation testing on ultimate degradation in surface water
- Soil simulation testing (for substances adsorbing to soil)
- Soil simulation testing (for substances adsorbing to sediment)
- Identification of degradation products
- Bioconcentration in (one) aquatic species, preferably fish
- Further studies on adsorption/desorption
- Short-term toxicity to invertebrates
- Effects on soil micro-organisms
- Short-term toxicity to plants
- Long-term toxicity testing on Daphnia, 21 days

- Sub-chronic toxicity study (90-day) in rats, oral/dermal/inhalation
- Development toxicity study, rats
- Development toxicity study, rabbits (depends on 1st result)
- One-generation reproduction study (enhanced)
- Two-generation reproduction toxicity study

Annex VIII

- Short-term toxicity testing on fish
- Activated sludge respiration inhibition testing
- Hydrolysis as a function of pH and identification of degradation products
- Adsorption/desorption screening study (HPLC method)

- In vitro cytogenicity in mammalian cells
- In vitro gene mutation study in mammalian cells
- Other in vivo mutagenicity test: micronucleus test (OECD 474) or UDS assay (OECD 486)
- Acute toxicity, inhalation
- Acute toxicity, dermal route
- Short-term repeated dose toxicity in rats (28 days), oral/dermal/inhalation
- Screening for reproduction/development toxicity, rats
- Assesssment of toxicokinetic behaviour (based on required studies)

Annex X

- Stability in organic solvents and identity of relevant degradation products
- Dissociation constant
- Viscosity

- Further environmental fate and behavioural studies
- Long-term toxicity testing on invertebrates (unless in Annex IX)
- Long-term toxicity testing on higher plants (unless in Annex IX)
- Long-term toxicity to sediment organisms
- Long-term or reproductive toxicity to birds

- Chronic toxicity (12 months or longer), rats (exposure/use driven)
- Carcinogenicity study/combined chronic toxicity, rats (exposure/use driven)
- Other studies (to be listed below)

- Confirmatory testing on biodegradation rates (aerobic and/or anaerobic)
- Long-term toxicity testing on soil invertebrates other than earthworms
- Emissions to water
- Emissions to land
- Emissions to air
- Occupational exposure in manufacture
- Occupational exposure in use
- Consumer exposure
- End of life
- Analytical methods (may be requested or lack of availability justified)

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