



## Four Ways U.S. Companies Can Prepare for REACH Now<sup>1</sup>

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Andrew Fasey is one of the (very few) authors of the REACH proposal from his time working for Directorate General Enterprise (DG ENTR) of the European Commission. He also had responsibility for taking the proposal through the complex EU regulatory system (i.e. the European Parliament and the Council of Member State Governments) and for international aspects of the proposal. He was also a member of the IOMC group that drafted the GHS (the Globally Harmonised System for the classification and labelling of chemicals). He has recently established a consultancy to advise stakeholders on international regulatory chemicals issues; Protection Through Knowledge Ltd ([www.ptkltd.com](http://www.ptkltd.com))

### Who is Affected by the proposed EU Regulation<sup>2</sup> REACH<sup>3</sup>?

REACH imposes duties on users, manufacturers and importers of chemicals as well as on EU Member State (MS) authorities and a new European Chemicals Agency. The duties include the registration of substances (on their own, in preparations or in articles) that are manufactured in, or imported into, the EU, the authorisation of individual uses of substances

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<sup>1</sup> This note is based on the REACH proposal of 29 October 2003 as amended by the political agreement of the European Council of Ministers on 13 December 2005. The explanatory parts of the text are intended to be as objective as possible. However, it should be appreciated that the REACH legislation runs to many hundreds of pages of legal text; not every nuance can possibly be covered below. It is therefore essential that you seek detailed expert and legal advice before taking action. The views expressed are those of the author alone and do not constitute a legal interpretation. A definitive legal interpretation of the text can only be made by Courts in the EU once the REACH legislation comes into force.

<sup>2</sup> A Regulation has direct effect in all EU Member States and does not have to be transposed into national legislation. In contrast, a Directive has to be transposed into national legislation.

<sup>3</sup> Whilst REACH will be further amended during the co-decision process (i.e. during the 'second reading') it is the author's view that these amendments are highly unlikely to change its fundamentals and that REACH or something very close to it will be implemented in the near future (probably by the end of 2006 or early in 2007).

of very high concern (SVHC), the evaluation of testing proposals and substances potentially posing a risk, and restrictions on the marketing and use of chemicals. These duties will start to apply shortly after REACH comes into force, expected to be early 2007. Registration will largely be phased according to tonnage with the first deadline (1000 tonnes or more per year per manufacturer or importer) being three years after REACH enters into force.

REACH will potentially have a direct impact on all businesses that manufacture in, or import into, the European Union (EU) chemical substances on their own, in preparations or in articles. In addition, REACH may have an indirect impact on businesses whose supply chains (either up or down) involve chemical substances that are subject to REACH (e.g. a substance manufactured in the EU that is present in a preparation that is used in the US; an article containing a substance that is manufactured in the US and exported into the EU). This note is aimed at giving US-based companies an insight into how REACH may impact on their business.

**Companies are making decisions now that may affect your business on the assumption that REACH will happen. Waiting for the final Regulation to arrive before looking at your supply chain or evaluating the materials you use puts your company at risk of being too slow, or unable, to react when decisions and actions need taking. Four steps are given below that should help prepare your company.** The text sets out some of the many questions that may need to be considered. Of course the questions that apply will depend on, and need to be applied with due consideration of, the circumstances surrounding each individual company and their particular business.

The note assumes a good knowledge of REACH; it does not attempt to explain the elements of REACH. The REACH text and other explanatory material can be found on the website of the [European Commission](#) and in other parts of this website.

## **Four Ways to Get Started Now:**

### 1) Understand Your Supply Chain

It is important to understand the supply chain because REACH may have a number of affects including:

- Removal of substances from the market. This may be because an EU manufacturer decides that the additional costs make the continued manufacture uneconomic. This could require alternative sources, substances or methods of production being required.
- Increased costs for EU-based importers. EU-based importers may need to meet requirements under REACH. For example, substances manufactured in the US and imported into the EU may need to be registered. This will incur costs and information is likely to be requested from the US manufacturer.
- Increased costs to purchasers. This may need to be factored into business decisions and could necessitate looking for alternative sources, substances or methods of production.

- Uses not being supported in the EU. Registration under REACH requires appropriate risk management measures (RMM) to be developed for 'identified uses'. Appropriate RMM need to be developed for EU-based uses of substances that are subject to Registration. The use of a substance of very high concern (SVHC) may not be authorised in the EU either because an authorisation was not sought or was not granted.

The key to effective and efficient implementation of REACH is therefore to work with and understand the supply chain for all substances - on their own, in preparations and in articles - in your 'portfolio'. The depth of analysis will reflect the nature of each business but should start with an initial 'risk assessment' (in terms of impact on, importance, and potential threat to your business). This is a key first step in the business level assessment of REACH.

### Case Study 1

A US-based company exports 500 tonnes of substance x into Europe (assume that the substance is listed on EINECS (i.e. is an 'existing' substance) and is not otherwise exempt). What are their duties under REACH?

1. The US-based company has no duties under REACH. The duties will be placed on the EU-based importer. N.B. EU-based importers may decide to only import the substance if they are given appropriate support from the exporter such as information required for registration.
2. The importer may be responsible for the imports they deal with only (i.e. into one EU Member State) or may be appointed by a US-based manufacturer as the 'only representative' covering the import of that substance into all EU Member States.
3. The importer will have to provide a safety data sheet (SDS) on first supply to all its customers. N.B. the SDS will have to be updated as and when new information comes to light (e.g. as a result of registration) and when exposure scenarios are produced for 'identified' uses. Most EU-based importers will depend on the non-EU manufacturer for such information and keeping it updated.
4. The importer will have to pre-register the substance 18 months after REACH comes into force. Again they are likely to be depend to a large extent on the manufacturer for help with this.
5. The importer will have to cooperate with other EU manufacturers and EU-based importers of the same substance to produce a common data-set for registration; 'one substance one registration' (OSOR). Much of this work will be highly technical and may also have confidentiality implications; the non-EU manufacturer is likely to need and/or want to support the importer in this activity.
6. The importer will need to make a registration within 6 years of REACH entering into force. N.B. the importer will need hazard and exposure data which it may get from the US-based exporter. The registration should cover uses identified by EU-based downstream users; i.e. the chemical safety assessment needs to address the uses for

which the substance is supplied. Again this is a highly technical and scientific exercise which is likely to require the support of the non-EU manufacturer.

7. The importer will have to supply classification and labelling information on the substance within three years for the Classification and Labelling Inventory.
8. The importer will have to comply with any restrictions imposed on the substance and its uses.
9. If the substance is a 'substance of very high concern' (SVHC) the importer will have to apply for an authorisation of each use as and when the substance is listed in Annex XIII (List of Substances Subject to Authorisation). N.B. only a limited number of substances will be brought forward for authorisation every year. Also see Case Study 2.

The above is a non-exhaustive list. Each case should be considered separately and detailed and legal advice sought. However, it is clear that if a non-EU manufacturer is to maintain an interest in the EU market they will need to provide considerable support to the EU-based importer.

## 2) Map Your Supply Chain:

- Map the flow of substances, preparations and substances in articles both inward and outward.
- Map **each** supply chain (SC) both up and down N.B. the same substance may be in several supply chains.
- Identify whether the supply chain may be affected by REACH (i.e. part of the supply chain is EU-based). For example,
  - How much is imported into the EU or EU-made?
  - Who is the supplier?
  - Is the substance in or outside scope of REACH?
  - Your duties, if any, under REACH (may be different for the same substance in different SCs). N.B. duties will apply to EU-based companies only such as importers.
- Identify 'linked' substances e.g. other ingredients that may be affected by REACH and having an impact on your supply chain.
- Evaluate the preparedness of customers and suppliers. If others in the supply chain are not prepared it could mean that the impact of REACH will be unexpected and steps will not have been taken to, for example, ensure continued supply of an essential substance.
- Determine the intentions of customers and suppliers. Some suppliers are taking decisions now on which substances they will continue to manufacture in the EU and which uses they will 'support'.
- Identify, as necessary, possible alternatives suppliers, substances, processes.

## Case Study 2

A US company producing a substance that is exported to the EU for the treatment of fabric used in the manufacture of chairs are concerned that the substance may be affected by the authorisation process.

1. Only SVHC are affected by the authorisation process. Is the substance included on the list of SVHC published on the new European Chemicals Agency website? If yes it is potentially subject to authorisation.
2. Is the substance listed on Annex XIII? If yes an authorisation application is needed for the use in question by the deadline given. If a substance is listed on Annex XIII and the deadline for applications has passed only authorised uses are allowed and even then only as long as you are in the same supply chain as the company granted the authorisation. If the deadline has passed a new application may be made but the use is not allowed in this case until the use has been authorised.
3. If the substance is a SVHC (i.e. on the Agency list) but is not yet on Annex XIII you should check the Annex regularly.
4. The EU-based importer of the substance would be responsible for submitting any authorisation required. N.B. they are likely to require considerable support from the US-based exporter otherwise they may stop importation or go to another supplier who can give them the support they need. The authorisation application would need to include the use of the substance in fabric treatment in order for the chairs to continue to be exported from the US into the EU.
5. If you suspect that the substance is a SVHC but has not been included on the Agency list you should check the list regularly to see if it has been added. N.B. the importer has a duty to provide information on the properties of the substance and to use this information to classify the substance.

The above is a non-exhaustive list. Each case should be considered separately and detailed and legal advice sought.

### 3) Identify Vulnerable Products

A good understanding of your supply chain will help you to make an assessment of which products (substances, preparations, and articles) may be vulnerable under REACH. Key factors to consider include:

- **Low margin substances** are more vulnerable because of the additional costs of complying with REACH
- **Low volume supply** means that the additional costs may be disproportionate to the value of the product
- **Importance to supplier**

- The more important your business is to the supplier the more likely they are to continue supply
  - The more important a substance is to your supplier the more likely supply is to continue
- **Direct costs** of registration will vary considerably depending on available data, uses, and the complexity of the risk assessment(s) that will be required. The higher the direct costs the greater the potential that supply of a substance will be under threat.
  - **Substances of Very High Concern (SVHC)** will at some point require Authorisation. This adds costs and uncertainty, meaning that supply may be discontinued as a result. All authorisations will be time limited i.e. indefinite supply of the substance for a particular use cannot be assumed. If suitable safer alternatives are available authorisation may not be given or time limited to a short period only.
  - Where **less hazardous alternatives** exist substances may be increasingly vulnerable. For example, they may be targeted for evaluation, restrictions and/or authorisation. This may lead a supplier to withdraw supply before such processes have an effect or as a result of them.
  - Customers may be affected by other suppliers having a **'knock-on' effect**. Whilst your supply may not be problematic a customer may depend on the supply of other substances or formulations from other suppliers. If these are affected as a result of REACH it may mean that your supply is no longer needed.

The output of the work on mapping the supply chain will be the start of an inventory of your 'portfolio' of substances. This information will feed into the commercial and other considerations across different business functions.

### Case Study 3

A US company export a red paint to Europe. What are their duties?

1. REACH applies equally whether a substance on its own or in a preparation is imported into the EU.
2. The duties are therefore as for Case Study 1.
3. The registration deadline per substance will depend on the amount of each substance in the preparation. N.B. the EU-based importer will have to add together the amounts of each substance in all the preparations they import.
4. If a substance is not on EINECS (i.e. is a 'new' substance) it will have to be registered as a 'non-phase in' substance i.e. registered immediately and before starting supply. If this is the case the EU-based importer will require immediate support from the US company to meet the registration requirements immediately.

The above is a non-exhaustive list. Each case should be considered separately and detailed and legal advice sought.

#### 4) Create a Substance Portfolio/Inventory:

Depending on the outcome of the supply chain mapping, it may be necessary to produce a more detailed inventory. For example, if the EU-based importers from US companies are going to need to register a substance it is likely that the US companies will have to identify most of the information below to help support the preparation of a registration dossier. If your concern is further down the supply chain much of the following information will be unnecessary; your interest will be in communicating along the supply chain to help ensure that your interests are being covered e.g. continued supply, supported use.

#### **Possible Elements of a Substance Portfolio/Inventory**

- **Inventory of substances manufactured, imported, used and supplied**
    - CAS
    - EINECS (existing) / ELINCS (new)
    - Quantities (most relevant to substances potentially subject to registration)
    - Status. For example:
      - Phase-in (existing)/ non-phase-in (new)
      - Tonnage band – if manufactured in, or imported into, the EU
      - Exemptions
    - Data available (hazard and exposure)
  - **Status of company under REACH (per substance)**
    - Downstream User (DU)
    - Manufacturer (M)
    - Importer (I)
    - Only representative of non-EU manufacturer (OR)
  - **Registration strategy**
    - Importer (I)
      - Per I in each MS or
      - I on behalf of all EU imports or
    - Only representative of non-EU manufacturer (OR)
  - **Implications on your business**
    - Uses i.e. yours and customers (M/I, 'in-house', identified by DUs)
    - Confidentiality concerns (e.g. uses, data)
    - Alternatives
      - Process
      - Substance
      - Suppliers
    - Suppliers
      - Understand REACH?
      - How meeting obligations?
      - Identified uses (i.e. yours & DUs)
      - Information needs
- => Threat of substance withdrawal?

- **Customers / Downstream Users**
  - Identified uses
  - Implications on their business
  - Available data (i.e. hazard, exposure)
  - Support needed
  - Suitability of risk management measures (RMM) identified
  - System of communication
- **Other REACH effects**
  - Authorisation
  - Restrictions
  - Priority for evaluation
  - Substance Information Exchange Fora (SIEFs)/ data sharing / pre-registration
  - 'Product & Process Orientated R&D' (PPORD)

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