REACH, if you are a downstream user.

Defining what we mean by ‘use’ of a substance

One of the concepts that underpins much of the way in which REACH will affect Downstream Users, is the concept of the ‘use’ of a substance.

In the REACH regulation, the definition of ‘use’ is as follows

“*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 utilisation*;”

When we refer to the use of an article, we think about it being used in service – it generally refers to a single life cycle step.

That is not the way in which ‘use’ of a substance is considered in REACH.

The first use of a substance is when it is first extracted from the ground or synthesized, and its last use is when it is now defined as waste under the waste directives / regulations, and therefore REACH no longer applies. The use refers to EVERYTHING that can happen to the substance throughout the supply chain, including transportation, storage, decanting, sampling, testing… Therefore ‘use’ of a substance is a very broad term and refers to any activity occurring at any point in the entire substance life cycle.

How the substance use affects the REGISTRATION process

The ways in which a substance is used will determine:

- The exposure pathways of the substance into the body
- The exposure pathways of the substance into the environment
- The population exposed, and the scale of environmental effect, which in turn help determine how dispersed the substance will become

This information in turn will help define the EXPOSURE SCENARIOs that are the start-point for deciding which END POINT TESTS the registrant will need, in order to assess the hazard posed by the substance in each use.

The end point tests are the experiments that need to be performed either in vitro or via invertebrate and vertebrate testing, to assess the risk to people and to the environment. The guidance from ECHA gives a list of many possible end point tests, and the registrant will only want to conduct those that are relevant to his customer base (or contribute to the cost of those relevant –

the testing will only be done once for each Substance Information Exchange Forum (SIEF)).

Therefore during the registration process, it is important for the registrant to identify the uses that his customers (all the way down the supply chain) have for the substance.

Of course, some uses will be mainstream, and others will be niche uses. Where uses are mainstream, it will be in the commercial interest of the registrant to include the use in the registration dossier.

Where it is a niche use, it is likely that the registrant will not know about the use, and therefore will not be likely to register it. However it is quite possible that all the relevant end-point tests for the niche use will be conducted anyway. So it is in the interests of the downstream user to provide information on niche uses to the registrant, so that they can be added into the registration dossier.

WHY should downstream users provide information to registrants on the uses they have for the substance?

Unless the use of a substance is listed on the material safety data sheet for the substance or for the preparation, then the use is illegal once the registration process is completed. Inclusion in the MSDS can only occur if the use was known and assessed as part of the registration process carried out by the registrant in your upstream supply chain.

Therefore, there is a risk that the current uses your business has for substances or preparations could disappear. It is important to assess how likely this is, and then act accordingly.

If you do not wish to inform your supplier about your use of a substance, or if the supplier does not intend to register your use of the substance (which the supplier can choose to do on either commercial or safety grounds), it is possible to create your own ‘Downstream Users Chemical Safety Report’, in order to continue to use the substance legally.

These DUCSRs will take resource and time to produce, and consequently should be avoided if the supplier can be encouraged to include your use as part of the registration process at the outset.

Downstream users may use a pure substance, but in this case the registrant is also very likely to know all about the use, and no action is necessary.

It is far more likely that a downstream user will use a preparation which contains the substance – such as a paint, adhesive, NDT developer, a resin or a lubricant.

The downstream user may not know exactly which substances are contained within the preparation: his own supplier is likely to be a formulator rather than

the original manufacturer of the substance, and the upstream supplier of the preparations used to make the formulation may not have identified all the substances on the MSDS (particularly if they are not known to be hazardous in any way).

In this instance the downstream user needs to inform his immediate supplier of the use of the preparation, **if the use is in any way other than that envisaged by the supplier.** For example, a company may use a floor cleaner for cleaning walls. A dip cleaning solution may be used in a sprayer with a cloth. Washing up liquid may be used to deal with aphid infestations in the garden. A dye for brush application may be spray applied to fabric.

If a company uses an etchant for etching, an adhesive for gluing, and a spray can of paint for spray painting, then it is the manufacturer of the adhesive, spray can, or etchant that needs to contact their supplier to inform them of the use of the constituent substances for those applications. As a consumer of these etchants, adhesives or spray cans, the obvious use will be presumed, and you do not need to take any action.

However, if your company routinely has novel uses of substances or preparations, it is important to ensure that your use is going to be covered by the registration.

WHEN should downstream users provide information to registrants on the uses they have for the substance?

The REACH downstream users guidance presumes downstream users will wait until they receive a materials safety data sheet which defines specific uses following registration, before contacting suppliers.

REACH Downstream User Guide:
http://reach.jrc.it/docs/guidance_document/du_en.pdf

The REACH Downstream User Guide explains that downstream users have to compare their own conditions of use with the information in the safety data sheet and relevant exposure scenario (if provided).

If the downstream user uses the substance or the preparation differently than described in the exposure scenario, and the total amount used is one tonne/year or more, the downstream user has to notify the Chemicals Agency of the difference and implement measures to ensure safe use. However, if the amount used is 1 tonne/year or more, the downstream user has the following options:

- To contact the supplier with the aim of getting an exposure scenario that covers his use
- To make his own downstream user chemical safety report
- To implement the conditions of use in the exposure scenario

- To substitute the substance/preparation.

However, waiting until the MSDS has been revised following registration, as is suggested by this route, means that the testing required for your use may not occur during the rest of the testing.

It is far better to take the initiative and contact suppliers at the beginning of the registration process, to ensure that your use is included from the outset. This will

- improve the probability of a continuity of supply via your existing supply chain,
- provide more warning of the need to take action (such as to create a downstream users chemical safety report) if the route of supply could be jeopardised,
- give you opportunity to change supplier if the existing supply chain will not support your use,
- give you opportunity to improve your risk management measures, including the purchase of any capital equipment, in a timely manner to be able to change your use to be in line with the uses being registered.

HOW should downstream users inform registrants about their uses?

The registrant needs to have information about use in the format of the use descriptor system, as this gives a classification that can be related easily to exposure scenarios by the registrant.

REACH Use Descriptor System:
http://reach.jrc.it/docs/guidance_document/information_requirements_r12_en.pdf

There is a relationship between the process/activity being carried out by the downstream user and the exposure scenario ('common features relevant for exposure') that can then determine end-point tests. This is illustrated in the table below.

Table R.12-1: Examples for assigning process categories to the use of a substance

Examples for process/activity	Process category from Append ix R.12-3	Common features relevant for exposure
Spraying of paints, cleaners or air care products	Air dispersive techniques, like e.g. Spraying (PROC 7 and 11)	Substances can be inhaled as aerosols. The energy of the aerosol particles may require particular exposure controls: in case of coating, overspray may lead to waste water and waste.

The use descriptor system categorises the use of a substance into several groupings: Sector, Product category, Process category, and Article.

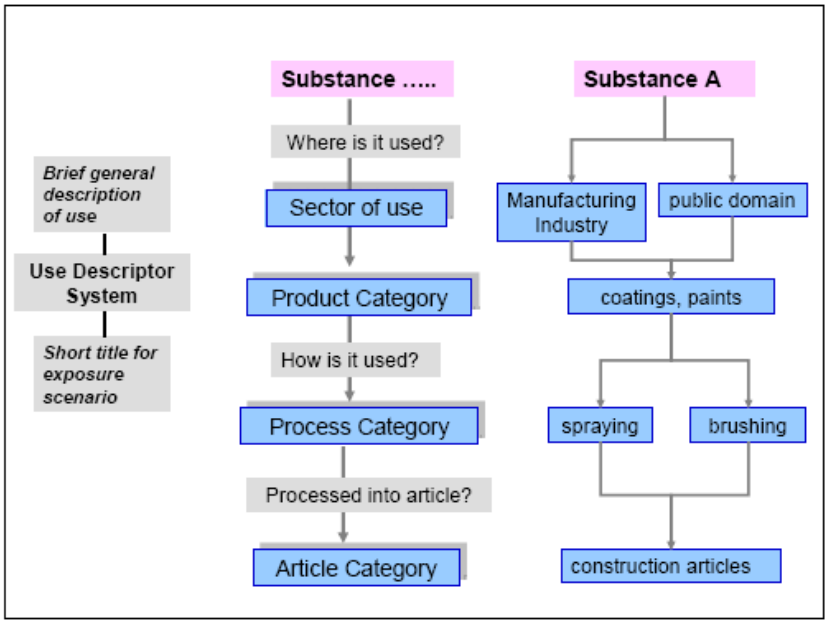

Figure R.12-1: Descriptor system for short titles and a brief general description of use

For preparations, uses will relate to all the substances within the preparation. It is not necessary to know what all of the substances are, provided that you inform the supplier of the preparation of your use of the substance, and inform them of the need to pass the information on up the supply chain to their suppliers of each individual substance and preparation that they have used.

Sector of use code

The sector of use relates to the type of industry that the substance is being used in, but all downstream uses need to be considered. The sector of use code is given on page 13 of the use descriptor system.

If you cannot find a code that is relevant to your business, you can use the NACE code instead. NACE is a classification system widely used to identify different types of sector, for all kinds of analysis. There are very, very many codes for each type of sector, so you should be able to find a classification that reflects you. NACE codes can be found at http://ec.europa.eu/comm/competition/mergers/cases/index/nace_all.html

For substances and preparations used within your facility, it is very likely that they will all have the same use code.

Product category code: Descriptor for types of preparations

By product, the use descriptor system means the preparation or substance as sold – not the article that the substance may be incorporated into later. Therefore it would relate to the alloy cast stick and not to the casting, or the

phenolic resin but not the composite component made from the resin, or the adhesive not the final assembly being glued.

The product category table is given on page 14 of the use descriptor system document, and an extract is shown below.

Types of preparations [PC = Product Category][7]		
PC1	Adhesives, Sealants	2
PC2	Adsorbens	
PC3	Air care products	
PC4	Anti-Freeze and De-icing products	
PC5	Artists Supply and Hobby preparations	2
PC6	Automotive Care Products***	2
PC7	Base metals and alloys	
PC8	Biocidal Products (e.g. Disinfectants, pest control)	1
PC9	Coatings and Paints, Fillers, Putties, Thinners	1,2
PC39	Cosmetics	1
PC10	Building and construction preparations not covered elsewhere	1
PC11	Explosives	
PC40	Extraction agents	
PC12	Fertilizers	

The general classifications given above will cover the majority of applications for preparations that you are likely to come across. However in some parts of Europe, notably in Denmark and Norway, there are more detailed classification systems for product category already in existence. Where companies prefer to use these more detailed classifications, that is fine, but you will need to identify which classification system you have used if it is not the PC code.

The more detailed categorizations are embedded within the ConsExpo exposure estimation tool or in the TRA exposure estimation tool, and classifications are also available on the Substances in Preparations in Nordic Countries (SPIN) website.
http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp
http://195.215.251.229/fmi/xsl/spin/SPIN/guide/menuguide.xsl?-db=spinguide&-lay=overview&-view

Process category code

The process category defines different types of application of a preparation or substance, detailing whether the process is industrial or non industrial, an open or closed system, and how the preparation is used or applied (such as used under pressure, used for dipping or pouring, hot work operations etc.

The process category codes are given on pages 16 to 18 of the use descriptor system.

Covering your own and your customer's uses

It is important to consider not just your own uses, but also those of your customers. For example, if you manufacture gearboxes, you could classify your own sector of use as general manufacturing. However your customers may use the substance within the automotive transportation sector and 'other transportation' sector as defined in the sector table. As your customers are likely to be consumers of your gearbox, they will not be expected to contact you and inform you of their use, for you to pass the information up the supply chain. You will need to do this on their behalf.

To help you map out the use categories you have for products within your own facilities, a spreadsheet has been prepared giving an example layout (with dropdown menus for the different information sets) of information you would benefit from compiling.

Glossary:

Downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.

Therefore a company that uses a substance on its own or in a preparation to make articles, or to formulate other preparations, is a downstream user.

SIEF: The group of companies (Registrants) who have pre-registered a substance and now will be registering. The SIEF will pay for one set of end point tests, to be determined by the exposure scenarios identified through uses.

End Point Test: Tests which will identify the effect of a substance on the body such as vertebrate tests, relevant to the exposure scenario (inhalation tests, ingestion tests etc) and similar tests for the environment relating to water, soil and air.

Exposure Scenario: The identified way in which the use of a substance can result in an exposure to man or the environment, which results in the need for an end point test to find out how big the effect of the exposure could be.

ECHA: The European Chemicals Agency, based in Helsinki. See http://reach.jrc.it/guidance_en.htm