

REACH APRIL 2008

REACH
THE NEW
LEGISLATION
AND YOU
DOWNSTREAM
USE OF
SUBSTANCES



REACH REFERS TO THE REGISTRATION, EVALUATION AND AUTHORISATION OF CHEMICALS FOR MANUFACTURE, IMPORT OR USE IN THE EU.

REACH APRIL 2008

REACH OBLIGATIONS

REACH requires that each legal entity manufacturing or importing 1tpa or more of a qualifying substance to register that material with the European Chemicals Agency (ECHA). The information required concerns the hazards of the substance and an assessment as to whether they could pose a risk to human health or the environment when being used.

Under REACH, downstream users must not use or place on the market any material that has not been appropriately registered. In future it will be against the law to use a substance outside of the conditions within your suppliers registration dossier. A downstream user (ie. not a manufacturer or importer) will receive more information on the hazards and safe use of substances than is currently available. This information may include guidance from the supplier on appropriate risk management measures to ensure safe use of the substance. The downstream user is obliged to implement these controls and to communicate the information onwards down the supply chain.

This booklet provides an introduction to the requirements of REACH on downstream users of substances. Comprehensive information is available in the European Chemicals Agency guide 'Guidance for Downstream Users', available from their website.

PREPARING FOR REACH

The key deadlines for the first registration phase are reviewed below alongside the activities recommended to prepare for those deadlines.

REACH TIMELINE	INDUSTRY PREPARATION
1 June 2007 REACH Entered into Force	<ul style="list-style-type: none"> • Compile inventory of individual chemicals and substances in preparations. • Determine which are manufactured or imported, which remain in preparations and which are used in manufacturing. • Check exemptions for substances from REACH. • For those manufactured or imported determine: your annual volume, CAS number and EINECS or ELINCS number, availability of toxicology data, customer details, available usage data. • For those remaining in preparations compile: customer details, available usage data, list of suppliers, level of support from suppliers. • For those used in manufacturing compile: list of suppliers, own use scenario, level of support from suppliers, communication routes.
1 June 2008 Pre-registration begins	<ul style="list-style-type: none"> • Suppliers should pre-register all substances, including components of mixtures, manufactured or imported in quantities ≥ 1 tpa. • Confirm if exposure scenarios are required for the substance and, if so, collate information on customer's downstream uses. • Determine which downstream uses will also need support from suppliers of raw materials and establish communication links in supply chain.
1 December 2008 Pre-registration ends	
1 December 2010 1st Registration deadline ≥ 1 tpa cat 1 or 2 CMRs ≥ 100 tpa dangerous to environment (r50/53) ≥ 1000 tpa per registrant	By this time suppliers of substances subject to the first registration should have compiled a dossier assessing all the downstream exposure scenarios and developed a GHS compliant eSDS that allows downstream users to confirm the risk management measures required for their use.
1 June 2013	Registration deadline for tonnage ≥ 100 tpa but < 1000 tpa.
1 June 2018	Registration deadline for tonnage ≥ 1 tpa but < 100 tpa.

Note: Volume bands are based on annual tonnage averaged over previous 3 years.

REACH ROLES AND OBLIGATIONS

Under REACH it is the responsibility of the manufacturer or importer of the substance to conduct the registration. The focus of this guide is on the role of the downstream user. A downstream user is someone established within the EU other than a manufacturer or importer who uses a substance, either on its own or in a preparation, in the course of his professional activities.

The following roles are examples of downstream users under REACH.

	ACTIVITY	EXAMPLE
Formulator	Mixing substances and/or preparations to place preparations on the market.	Paint or resin manufacturer
End-user	Using substances and/or preparations in an industrial or professional activity but not supplying the substance to another actor in the supply chain.	Professional painter
Industrial-user	End-user using substances and/or preparations, which do not remain in the final product.	Using substances in processes
Article producer	End-user incorporating substances and/or preparations into articles so that they become an integral part of the article.	Acrylic sheet, sink/bath/spa manufacturer
Re-filler	Transferring substances and/or preparations from one container to another.	Drum filler
Importer (where supplier has an Only Representative)	Using substances and/or preparations supplied from outside the EU where supplier nominates an Only Representative to complete the registration and undertake obligations under REACH on your behalf.	
Re-importer	Importing substances and/or preparations originally manufactured in the EU and proven to be registered in the supply chain.	

Other roles that have obligations under REACH but not officially described as downstream users are those of **distributors** and **retailers**.

OBLIGATIONS OF DOWNSTREAM USERS

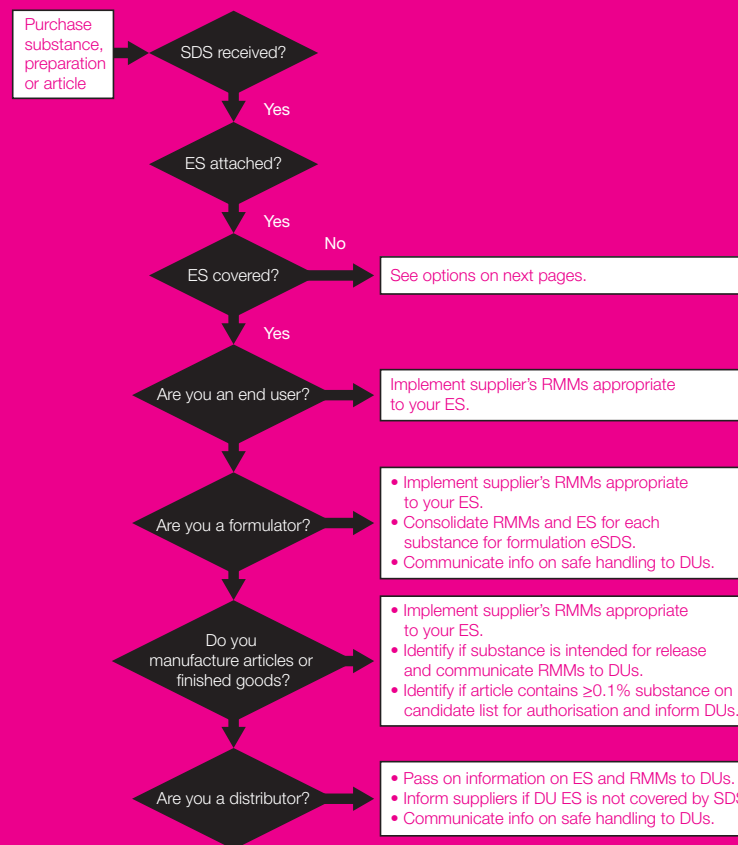
The main obligations for downstream users are:

1. To follow the instructions given in the revised safety datasheet pertinent to your use and exposure scenario (this includes taking action if your use and exposure scenario is not covered).
2. Follow up with your supplier if your use and exposure scenario are not covered by those included on the extended safety datasheet. An outline of the options is given later in this booklet.
3. Inform your supplier if you have any new or additional information on the hazards of the material or if you believe that the risk management measures specified are inappropriate.
4. Collate and pass on information on hazards, safe use and risk management measures of substances or preparations supplied to customers.
5. Identify and inform customers if an article you supply contains more than 0.1% of a substance of highest concern that may be a candidate for authorisation.

These are considered in more detail in the following pages.

ACTIONS TO TAKE WHEN RECEIVING INFORMATION

REACH will increase the amount of information on substances received from suppliers. This starts with the REACH registration number, but may include much more detailed information on the hazards of the substance according to how it is used and what measures are required to ensure safe use. The following workflow is developed from the RIP guidance:



OPTIONS IF YOUR USE SCENARIO IS NOT COVERED

If your use or conditions of use for the substance are not covered by the exposure scenarios assessed by your supplier then you may be obliged to carry out your own downstream users' chemical safety report. This may be time and resource consuming and there are some alternative solutions:

1. Confirm if a chemical safety report is required for that substance.
 - If your supplier is not obliged to provide a safety datasheet then a chemical safety report is not required.
 - If your supplier is not obliged to provide a chemical safety report (possibly due to volume) then you do not need to conduct one for your own or downstream uses.
 - Confirm if your use scenario is exempt from inclusion within the chemical safety report (eg. for Product or Process Orientated Research and Development).
 - If the concentration of the substance within the preparation is below that listed in article 14(2) of REACH then a chemical safety report is not required and use and exposure scenarios of the low concentration do not need to be reviewed.
2. If a chemical safety report is required but the declared exposure scenarios do not cover your use then you can:
 - Make your use known to the supplier with the aim of having it included in an updated chemical safety report.
 - Alter your conditions of use to comply with those of the exposure scenario.
 - Find an alternative supplier with an exposure scenario that covers your conditions of use.
 - Substitute the substance for an alternative substance with exposure scenarios that cover your conditions of use.
 - Conduct your own chemical safety assessment and submit it to the European Chemicals Agency.

If your use scenario is not covered by your supplier's registration, is not authorised, or is restricted then you may need to look for an alternative that is supported through REACH. This may mean modifying your use or identifying an alternative supplier or substance.

IMPLEMENTATION OF RISK MANAGEMENT MEASURES

REACH requires the downstream user of a substance to apply the risk management measures (RMMs) specified by the manufacturer or importer. These may come in two forms.

A manufacturer or importer of a substance in a quantity over 10tpa is required to conduct a chemical safety assessment. This means identifying how the substance is used and assessing if the associated exposure levels are safe or specifying suitable RMMs. The RMMs are to be communicated alongside the exposure scenario in the extended safety datasheet.

However, it is also possible for suppliers to communicate RMMs through Section 8 of the safety datasheet. This is for information on measures for all identified uses and will be more generic in nature. There is a duty to apply these RMMs or inform your supplier if you believe they are inappropriate.

When your supplier receives information regarding the RMMs he should then re-assess his recommendations. He may then either change his recommendations according to the new information or decide that the original measures are still appropriate and leave the safety datasheet unchanged.

AUTHORISATION AND RESTRICTION

Authorisation aims to ensure substances of very high concern are properly controlled. The process is firstly for those substances of highest concern to be identified and placed on a 'candidate list' to be gradually included in Annex XIV of REACH, the list of substances subject to authorisation. Once included in Annex XIV, substances will be given a 'sunset date' after which it cannot be placed on the market or used unless the company is granted an authorisation for that use. The first recommendation for substances to be included in Annex XIV is due to be made by the Agency by 1 June 2009. This will be a rolling list incorporating other substances from the candidate list at a later date.

Authorisations can be applied for either individually or together with the substance manufacturer, importer or other downstream users. However, if you use a substance under the authorisation of another actor in the supply chain you must report this to the European Chemicals Agency.

How to apply for an authorisation is detailed in the 'Guidance on Authorisation Application' available from the Agency website. This includes details of the specific uses of substances, such as Product or Process Orientated Research and Development (PPORD), that are exempt from authorisation.

The counter to authorisation is the restriction process. In this case, specific uses of a substance may be limited. The list of restrictions is included in Annex XVII of REACH and is available on the Chemicals Agency website. The supplier of a substance subject to restrictions is obliged to include these details on the safety datasheet to inform downstream users.

MANUFACTURING OF PREPARATIONS / MIXTURES

Formulators of preparations are required to gather and communicate information on the preparations they supply down the supply chain. The main obligations are as follows:

1. Provision of safety datasheets.
2. To communicate information on safe use and handling.
3. To inform downstream users of presence of a substance subject to authorisation or restriction.

Compiling a safety datasheet for a number of substances within a preparation requires several steps, which are outlined overleaf.

COMPILATION OF A SAFETY DATASHEET FOR PREPARATIONS

A safety datasheet is required if the preparation meets the criteria for classification as dangerous or may need to be provided on request.

When compiling a safety datasheet a formulator needs to include the relevant exposure scenarios and data from the safety datasheets supplied to him. This may require consolidation of exposure scenarios covering a number of substances and suppliers into exposure scenarios specific to the preparation. The steps in assessing the requirements are as follows:

1. Collect data on substances used in the manufacture of the preparation.
2. List and determine the concentration of dangerous substances.
3. Carry out the classification of the preparation (to determine if a safety datasheet is required).
4. Confirm concentrations of any Annex XIII or Annex XIV substances (Annex XIII – PBTs, vPvBs).
5. Confirm suppliers have registered and included relevant exposure scenarios.
6. Check if each substance's required exposure scenarios are included (determined by concentration limits in Article 14.2).
7. Select the relevant exposure scenarios for the preparation.
8. Sort and consolidate the exposure scenarios.
9. Check compliance with the exposure scenarios – own use and downstream in the supply chain.
10. Consolidate risk management measures for substances and exposure scenarios.
11. Compile safety datasheet.

OBLIGATIONS FOR DISTRIBUTORS

Distributors are required to pass information on substances through the supply chain. Primarily this is through safety datasheets, although there are circumstances where a safety datasheet is not required (eg. for an article) but information on safe handling is required by another actor in the supply chain. In order to ensure that exposure scenarios and risk management measures are suitable to customer use scenarios, this may require information to be passed to both suppliers and customers. The type of information could include:

- Information required to identify use scenarios – either manufacturers confirming that those identified are appropriate, or customers looking to ensure their scenarios will be included in the manufacturer's registration.
- Specific information on the hazards of the substances required by downstream users who wish to keep their use confidential but are obliged to carry out their own chemical safety report.
- Safety datasheets - some will include exposure scenarios.
- Details of substances of high concern contained in articles – either requests for information from customers or declarations of substances from suppliers.
- Details on authorisations or restrictions.

FREQUENTLY ASKED QUESTIONS ABOUT REACH

- When do you need to generate an exposure scenario?
Exposure scenarios are required for the registration phase for substances manufactured or imported in a quantity ≥ 10 tpa (Article 10, 14.1) and classified as dangerous according to Directive 67/548/EEC or Directive 199/45/EC or is assessed to be a PBT or vPvB (Annex I (0.6)).
- What happens if my supplier has not included my use in his registration?
A downstream user may make a request in writing for a use to be included. For phase-in substances this request must be made 12 months before the registration is due (Article 37.3). For registered substances, the supplier must complete the exposure assessment the later of prior to next supply (if the request was made at least 1 month before supply) or within 1 month (Article 37.3). A downstream user may prepare their own chemical safety report for any use outside the conditions described in an exposure scenario and this must be done within 12 months of receiving the registration number from the supplier (Article 37.4, 39.1).
- What happens if my supplier fails to pre-register?
If a substance does not appear on the list of those pre-registered and published by the Agency by 1 January 2009 (ie. no-one pre-registers) then a downstream user may notify the Agency of his interest and details of his current supplier. The Agency shall publish the name of this substance on its website in the event that there may be a potential registrant (Article 28.5). Otherwise, it would be possible to look for an alternative supplier who has pre-registered, or to consider manufacturing or importing the substance. In the latter case, it is possible to submit a late pre-registration for that substance if completed within 6 months of first manufacture or import (Article 28.6) as long as it is more than 12 months before you would be due to fully register your volume. This option would allow import for 6 months whilst an alternative was sought.
- What happens if I want to introduce a new use for a registered substance?
A downstream user may make a use known to the supplier and, if an exposure assessment is required, the supplier must provide that information before next supply or within 1 month of the request (Article 37.3). If a downstream user decides to register the new use directly to the Agency (potentially for reasons of confidentiality) then that assessment is required within 6 months (Article 38, 39.2).
- What happens if I want to start manufacturing or importing a substance after pre-registration has ended?
See Q3.
- How do I pre-register a substance?
IT tools are available from the ECB website which links from the ECHA website (see further info section for link). The system to be used for collating the data required for registration is IUCLID5 and is available as a free download from the website. Systems are being developed to allow this data to be submitted for pre-registration.

DEFINITION OF SOME COMMON REACH ACRONYMS

C&L	Classification and Labelling	IUCLID	International Uniform Chemical Information Database
CA	Competent Authority	LEO	Legal Entity Organisation
CAS	Chemical Abstracts Service Number	M/I	Manufacturer/Importer
CMR	Carcinogen, Mutagen or Reproductive Toxin	MS	Member State
CSA	Chemical Safety Assessment	MSDS	Material Safety Datasheet
CSR	Chemical Safety Report	NLP	No Longer Polymers
DNEL	Derived No Effect Level	OECD	Organisation for Economic Co-operation and Development
DU	Downstream User	OSOR	One Substance One Registration
DUNS	D&B Unique Numbering System	PBT	Persistent, Bioaccumulative and Toxic
EBW	Exposure Based Waiving	PNEC	Predicted No Effect Concentration
EC	European Commission	PPORD	Product and Process Orientated Research and Development
ECHA	European Chemicals Agency	QSAR	Qualitative Structure Activity Relationship
EC No	EINECS or ELINCS Number	REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
EIF	Entry into Force	RIP	REACH Implementation Project
EINECS	European Inventory of Existing Chemical Substances	RMM	Risk Management Measure
ELINCS	European List of Notified Chemical Substances	RSS	Robust Study Summary
EP	European Parliament	SEA	Socio Economic Analysis
ES	Exposure Scenario	SIEF	Substance Information Exchange Forum
eSDS	Extended Safety Datasheet	SME	Small/Medium Sized Enterprise
EU	European Union	SPORT	Strategic Partnership on REACH Testing
GHS	Global Harmonised System	SVHC	Substances of Very High Concern
GLP	Good Laboratory Practice	TGD	Technical Guidance Document
HPV	High Production Volume	vPvB	Very Persistent and Very Bioaccumulative

FURTHER SUPPORT FOR REACH

This guidance document has been developed with the support of REACHReady. Contact details for REACHReady and additional sources of support to help you understand your obligations under REACH are listed below:



UK Chemical Industries Association REACH Service:

www.reachready.co.uk

UK National Competent Authority:

www.hse.gov.uk/reach

CEFIC REACH Service:

www.reachcentrum.eu

European Chemicals Agency:

www.echa.europa.eu

For more information on preparations for REACH within Lucite International:

www.reach-and-you.info

For more information about Lucite International:

www.luciteinternational.co.uk

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