

WATER INDUSTRY

REACH is the European Union Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals, which entered into force on 1 June 2007. REACH places greater responsibility on industry to manage the risks that chemicals may pose to human health and the environment. This WCA Sector Guide to REACH provides a summary of the REACH Registration process and, in particular, the role of Downstream Users. It is designed to help UK Water Companies in understanding their REACH obligations. It includes information on:

Registration

- Who has to Register
- What to Register
- When to Register
- How to Register
- Other obligations
- What happens next

Downstream users

- What are Downstream Users and how does REACH affect them?
- What do Downstream Users need to do?
- Summary of Downstream User obligations

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Glossary

Article	An object with a specific shape, surface or design which determines its function to a greater degree than does its chemical composition (e.g. furniture) [See "How to Deal with Articles" in the WCA Guides to REACH Series].
CSA/CSR	Chemical Safety Assessment/Chemical Safety Report
Directive 1999/45/EC	Dangerous Preparations Directive
Directive 67/548/EEC	Dangerous Substances Directive
Distributor	An actor who stores and places on the market substances, preparations and articles exclusively inside the EU and makes them available to third parties without further processing.
Downstream user	A person or company established within the European Community, other than the manufacturer or importer, who in any way uses a substance on its own or in a preparation.
ECHA	European Chemicals Agency. Their website is at http://ec.europa.eu/echa/reach_en.html
EINECS	European Inventory of Existing Commercial Chemical Substances.
End-user	An operator using substances or preparations in an industrial or professional activity.
Exposure scenarios	Sets of conditions that describe how substances are manufactured or used during their lifecycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.
Formulator	An operator who produces preparations by mixing substances or preparations in which no chemical reaction takes place.
Health and Safety Executive (HSE)	The Competent Authority for REACH in the UK. The HSE's REACH website can be found at http://www.hse.gov.uk/reach/index.htm and their REACH helpdesk can be contacted by calling 0845 408 9575 or via email at ukreachca@hse.qsi.gov.uk
Importer	A person or company established within the European Community who imports (i.e. physically introduces) a substance on its own, or in a preparation or article, into the European Community.
Inquiry process	Mechanism for sharing certain data between registrants for the same non phase-in substance.
Isolated intermediate	An intermediate that during synthesis is intentionally removed from the equipment in which the synthesis takes place.
IUCLID 5	International Uniform Chemical Information Database, version 5.
Manufacturer	A person or company established within the European Community who manufactures (i.e. produces or extracts) a substance within the community.
Non phase-in substance	A substance not fulfilling any of the criteria for a phase-in substance, and registered after submission of an inquiry dossier to the ECHA to determine whether data sharing mechanisms apply. A non phase-in substance cannot be manufactured in or imported into the EU before registration.
Non-isolated intermediate	An intermediate that during synthesis is not intentionally removed from the equipment in which the synthesis takes place (except for sampling purposes).
Only representative	A person or company appointed by a manufacturer, formulator or article producer outside the EU (i.e. an importer not based in the EU) to fulfil the registration obligations of an importer. The only representative can represent one or several importers.
PBT	A substance that is Persistent, Bioaccumulative and Toxic.
Phase-in substance	A substance already being manufactured or placed on the market before 1 st June 2007, listed on EINECS (http://ecb.jrc.it/esis), not notified previously under Directive 67/548/EEC, and pre-registered with the ECHA between 1 st June 2008 and 1 st December 2008.
PPORD (Product and Process Oriented Research & Development)	Any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plants or production trials are used to develop the production process and/or to test the fields of application of the substance.
Preparation	A mixture or solution composed of two or more substances.
Pre-registration	Period from 1 st June 2008 to 1 st December 2008 during which phase-in substances can be pre-registered with the ECHA. A pre-registered phase-in substance can continue to be manufactured in or imported into the EU between pre-registration and registration.
Producer	A person or company established within the European Community who produces articles containing substances within the EC.
Re-filler	An actor who transfers substances or preparations from one container to another
Re-importer	An actor who imports substances or preparations which have originally been produced in the EU.
SDS	Safety Data Sheet
Substance	A chemical element and its compounds [See "How to Identify Substances" in the WCA Guides to REACH Series].
Substance Information Exchange Forum (SIEF)	Mechanism for sharing certain data between registrants for the same phase-in substance after pre-registration.
vPvB	A substance that is very Persistent and very Bioaccumulative.
Waste	Any substance or object which the holder discards, or intends or is required to discard.

Who has to Register?

You **must** Register under REACH if you are an:

- EU **manufacturer** or **importer** of **substances** on their own or in **preparations** when the substance is manufactured or imported in quantities of one tonne or more per year.
- EU **producer** or **importer** of **articles** meeting certain criteria (See "How to Deal with Articles" in the WCA Guides to REACH Series).
- EU-based **only representative** appointed to fulfil the role of importer by a manufacturer, formulator or article producer from outside the EU. This is because registration can only be performed by a company or person legally established in the EU.

You **do not** have to Register under REACH if you are:

- A **downstream user** using a substance that you do not manufacture or import (although downstream users need to ensure that the substances they use are registered by a manufacturer or importer).
- An **importer** of a substance, preparation or article for which an only representative has been appointed by a non-EU company.
- A manufacturer or importer of a substance **exempted** from REACH. This includes:
 - **Radioactive** substances.
 - Substances under **customs supervision**.
 - Substances being **transported**.
 - **Non-isolated intermediates**
 - **Waste** (although recycled or recovered substances do fall under REACH – see below)
 - **Recycled** or **recovered** substances as long as each substance has previously been registered, and the recoverer has information on the registered substance (e.g., a safety data sheet).
 - Human and veterinary **medicines** (including excipients).
 - **Pesticides** listed in Annex I of Directive 91/414 (Directive on Plant Protection Products); or in Regulations (EEC) No. 3600/92, (EC) No. 703/2001, or (EC) No. 1490/2002; or in Decision 2003/565/EC.
 - **Biocides** listed in Annexes I, IA or IB of Directive 98/8/EC (Biocidal Products Directive), or in Regulation (EC) No 2032/2003 (active biocidal substances on the market before 14 May 2000).
 - **Notified substances under Directive 67/548/EEC** and appearing on the European List of Notified Chemical Substances (ELINCS): <http://ecb.jrc.it/elincs/>. But note that only the notifier is regarded as being registered; all other parties must still register.
 - **Polymers** (although not the monomers in them if present at $\geq 2\%$ and ≥ 1 tonne pa; see "How to Deal with Polymers" in the WCA Guides to REACH Series).
 - Substances used for process and product oriented R&D (**PPORD**), although this use needs to be notified to the ECHA, and the exemption is

initially for five years. [See “How to Deal with Process & Product Oriented Research (PPORD)” in the WCA Guides to REACH Series].

- **Food or feeding stuffs** (including additives and flavourings).
- **Minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components, crude oil, coal and coke.**
- **Natural substances** if they are not chemically modified and are not classified as dangerous under Directive 67/548/EEC (e.g., water).
- Elements for which the hazards are already well known: **hydrogen, oxygen, argon, helium, neon, xenon and nitrogen.**
- Substances resulting from a chemical reaction:
 - after exposure of another substance or article to **environmental factors** (e.g., air, moisture, microbes or sunlight);
 - after **storage** of another substance, preparation or article;
 - upon **end use** of other substances, preparations or articles, but which are not themselves manufactured, imported or placed on the market;
 - as a result of the **intended use** of substances such as stabilisers, solvents, coagulants, etc.
- **By-products** (unless imported or placed on the market)
- **Hydrates** of a substance, as long as the substance itself has been registered using this exemption.
- **Re-imported** substance, as long as it is the same substance and batch, was registered before export from the EU, and the re-importer has information on the imported substance (e.g., a safety data sheet).

See “How to Use the REACH navigator” in the WCA Guides to REACH Series to find out how to check whether a substance is exempt.

WHAT DO WATER COMPANIES NEED TO DO?

- Review the chemical substances they use (e.g., by compiling information from site managers, purchase records, the DWI list of approved substances, etc.) and develop an inventory (see later).
- Determine whether they manufacture or import any substances that they use, either alone, in preparations, or in articles; or whether they are only downstream users. This should be done for substances used in both water and waste treatment processes.
- Determine whether any substances they manufacture, import or use are exempted under REACH.

What to Register

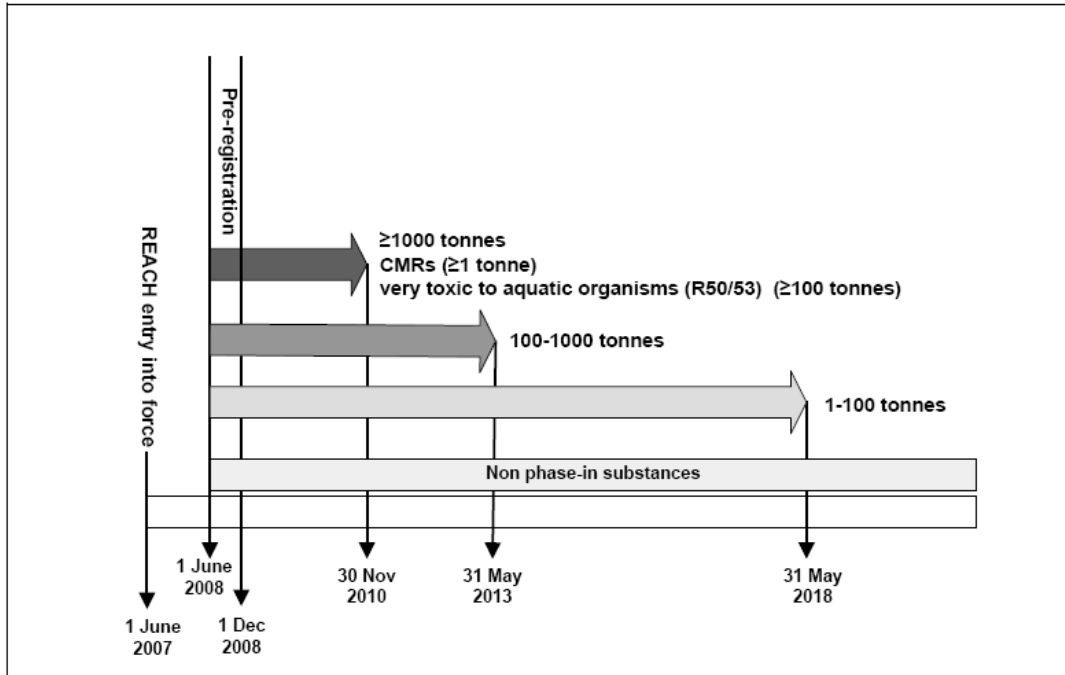
- All non-exempted substances manufactured or imported at **>1 tonne per annum per manufacturer**.
- Amounts are calculated as follows:
 - **Phase-in substances:** the average annual amount manufactured or imported over the previous three years (or the current calendar year if manufacture or import is for <3 years).
 - **Non phase-in substances:** the amount expected to be manufactured or imported in the calendar year of registration.
- Amounts of a substance are **summed for each manufacturer or importer** across:
 - the substance alone;
 - preparations containing the substance (using the maximum amount); and
 - articles (if the substance is intended to be released from articles).
- **Exempted uses** of the substance (e.g. biocidal uses) are not included when calculating amounts for placing a substance in a tonnage band.

WHAT DO WATER COMPANIES NEED TO DO?

- For any substances that they manufacture or import, sum the total non-exempted tonnage manufactured or imported to determine whether it exceeds 1 tonne per company per year. This summation must be performed across use of the substance alone, in preparations and in articles from which it is intended to be released.

When to Register

Deadlines for registration depend on whether a substance is a pre-registered phase-in substance within different tonnage and hazard categories, or is a non phase-in substance:



Notes: CMR = Carcinogenic, Mutagenic or Reproductive toxicant; R50/53 = risk classification of very toxic to aquatic organisms.

There are significant advantages to manufacturers and importers who pre-register substances alone, in preparations or in articles that are already on the market, as their access to market is very unlikely to be interrupted by REACH before their phase-in registration deadline.

WHAT DO WATER COMPANIES NEED TO DO?

- Pre-register between 1st June and 1st December 2008 any substances that they manufacture or import.
- Determine the registration deadline for the volume of substance that they manufacture or import.
- Ensure that suppliers pre-register phase-in substances.

How to Register

- The four basic Registration steps identified in the REACH Regulations are:
 - **Step 1 – Gather and share existing information**
 - **Step 2 – Consider information needs**
 - **Step 3 – Identify information gaps**
 - **Step 4 – Generate new data/propose testing strategy**
- Each manufacturer, importer or only representative is **individually** obliged to submit a **separate** registration for **each** of his substances.
 - However, registrants for the same substance must **jointly submit** information on its hazardous properties, classification and labelling, future testing proposals, and safe uses via a **lead registrant** who is selected through discussion amongst all registrants.
 - A **third party representative** can be appointed by a manufacturer, importer or downstream user during joint submission discussions with other companies, particularly if they wish their identity to remain unknown to other companies.
 - However, the substance must still be registered with the ECHA by the manufacturer or importer **themselves**.
 - A manufacturer or importer can only **opt out** of joint submission if they can demonstrate to the ECHA that:
 - Joint submission is disproportionately costly, or
 - It would lead to disclosure of confidential business information, or
 - There is a disagreement with the lead registrant about the information submitted in the lead registration.
- The **Substance Information Exchange Forum (SIEF)** is the main mechanism for sharing data for phase-in substances after pre-registration. The **inquiry process** is the mechanism used for non phase-in substances. [See "How to Share Data" in the WCA Guides to REACH Series].
- Manufacturers or importers of substances above 1 tonne per year must submit a **technical dossier** electronically to the ECHA. Submission must be via **IUCLID 5** software [see "How to Use IUCLID 5" in the WCA Guides to REACH Series] and must contain information on
 - Manufacturer/importer identity
 - Substance identity, manufacture and use
 - Substance classification and labelling
 - Safe use guidance
 - Substance intrinsic properties in the form of **robust summaries**
 - Whether the above information has been reviewed by an assessor
 - Proposals for further testing, if relevant
 - Main use categories, type of uses and significant routes of exposure (for substances registered in quantities of 1 to 10 tonnes per year)
- Manufacturers or importers of substances above 10 tonnes per year must submit a **chemical safety report (CSR)** to the ECHA, which documents a **chemical safety assessment (CSA)** for the substance [See "How to Prepare a Chemical Safety Report" in the WCA Guides to REACH Series]. If the substance is classified as dangerous, **PBT** or **vPvB**, an exposure assessment needs to be performed, using **exposure scenarios**.

- See “What are the information requirements under REACH” in the WCA Guides to REACH Series for a detailed summary of the information required for a substance to be registered in each tonnage band. The Table below provides a concise overall summary:

1-10 tonnes/year*	10-100 tonnes/year	100-1000 tonnes/year	> 1000 tonnes/year
<p>REACH Annex VI information General information on the Registrant (e.g. name, address, contact person, production sites, etc.) Substance identity (e.g. name, EINECS/CAS #, formula, impurities, etc.) Manufacture & use (e.g. overall manufacture, form supplied to downstream users, waste quantities, unsafe uses, etc.) Classification & labelling (e.g. hazard classification, specific concentration limits, etc.) Guidance on safe use (e.g. Safety Data Sheet information) Exposure (use category, use specification, significant routes of human & environmental exposure, exposure pattern)</p>			
<p>REACH Annex VII information Physicochemical properties (e.g. melting & boiling point, solubility, octanol-water partitioning, explosivity, etc.) Toxicology (skin & eye irritation, skin sensitisation, mutagenicity, acute toxicity) Ecotoxicology (acute toxicity to invertebrates, algal growth inhibition, ready biodegradability)</p>			
<p>REACH Annex VIII information Toxicology (repeated dose toxicity, reproductive toxicity, toxicokinetics) Ecotoxicology (acute fish toxicity, sludge respiration, hydrolysis, sorption)</p>			
<p>REACH Annex IX information Physicochemical properties (stability in organic solvents, dissociation constant, viscosity) Toxicology (further repeated dose & reproductive toxicity tests) Ecotoxicology (long term invertebrate & fish tests; degradation in water, soil & sediment; fish bioaccumulation; tests with terrestrial invertebrates, plants & microbes)</p>			
<p>REACH Annex X information Toxicology (further reproduction studies, carcinogenicity study) Ecotoxicology (further degradation, fate & behaviour studies; long term toxicity to terrestrial invertebrates & plants, & to aquatic sediment organisms; long term toxicity to birds)</p>			

* REACH Annex III on identifying CMRs and dangerous substances also applies to substances in this tonnage range

- With **expert argument**, it is possible to adapt or avoid the tests identified in the Table above if,
 - Testing does not appear **scientifically necessary** (e.g., use of alternative non-testing approaches, or weight of evidence from existing studies), or
 - Testing is not **technically possible**, or
 - **Exposure assessment** for the specific substances suggests that particular tests for a hazard are not required.
- **Confidential data** supplied by a registrant about precise uses, tonnages and supply chains for a substance will not be published by the ECHA or shared with other manufacturers and importers, unless urgent action is essential to protect human health, safety of the environment.

What else must manufacturers and importers do?

- Registrants must provide a **Safety Data Sheet (SDS)** to their downstream users and distributors (but not necessarily to the general public) with information on classification, occupational exposure and biological limit values, and exposure scenarios. These SDS must be provided after **1st June 2007** if a substance is:
 - Classified as **dangerous** under Directive 67/548/EEC or is a preparation containing the dangerous substance under Directive 1999/45/EC, or
 - **Persistent, bioaccumulative and toxic (PBT)** or **very persistent and very bioaccumulative (vPvB)**, or
 - Included on the candidate list of substances for **authorisation** under REACH, or
 - If an SDS is requested by a downstream user or distributor for a **preparation** containing
 - $\geq 1\%$ (by weight) for a non-gaseous preparation or $\geq 0.2\%$ (by volume) for a gaseous preparation, of a substance posing human health or environmental **hazard**, or
 - $\geq 0.1\%$ (by weight) for a non-gaseous preparation of a **PBT** or **vPvB** substance, or
 - A substance for which there is **EC workplace exposure limits**.
- Registrants must notify the ECHA electronically by **1st December 2010** about **classification and labelling** of a substance alone or in a preparation that is placed on the market and for which a registration has not already been submitted. This must be done if the substance meets criteria for classification as **dangerous in Directive 67/548/EEC** or exceeds **concentration limits in Directive 1999/45/EC** if present in a preparation. The ECHA will collate all information received into a classification and labelling inventory which will identify whether registrants and notifiers differ in their labelling or classification for the same substance. If this occurs, the registrants and notifiers are required to make every effort to come to an agreed classification. [See "How to Notify Classification and Labelling" in the WCA Guides to REACH Series].

WHAT DO WATER COMPANIES NEED TO DO?

- For any pre-registered substances that they manufacture or import in volumes ≥ 1 tonne per year, gather all available data on hazards and exposure.
- Prepare SDS for those substances, preparations and articles for which they are required.
- Prepare for SIEF involvement by
 - Identifying any confidential data.
 - Considering whether appointment of a third party representative is in their commercial interests.
 - Allocating sufficient resource for effective SIEF and consortium involvement and for likely testing requirements for each substance.

What happens after submission of a Registration dossier?

- When a registrant submits a registration dossier the ECHA performs the following actions:
 - Assigns a **submission number**.
 - Checks the dossier for **technical completeness** within 3 weeks of submission – have all the different elements for a particular tonnage range been included?
 - Checks that the registrant has paid the appropriate fees by the due date. **If payment is not made after a second date has been set, the registration will be rejected and the manufacturer or importer will not have market access in the EU for the rejected substance.**
 - Within 30 days informs the **Competent Authority**, or Authorities, in the Member State(s) in which manufacture or import takes place that the registration dossier has been submitted. The **Health and Safety Executive (HSE)** is the Competent Authority in the UK.
 - If a new registrant provides additional information, the ECHA will inform all other registrants for the substance and relevant Competent Authorities that this has happened.
- A registrant can **appeal** in writing against an ECHA decision on registration dossiers within 3 months of the decision.

WHAT DO WATER COMPANIES NEED TO DO?

- Ensure that if they need to register a substance that the registration dossier is technically complete and the fee is paid promptly.
- Ensure that they have the technical resources in place to respond within 3 months to an ECHA decision about the registration of a substance with which they disagree.

What are Downstream Users and how does REACH affect them?

- A **downstream user** of a substance is a person or company established within the European Community, other than the manufacturer or importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.
- REACH affects downstream users in the following ways:
 - **Substances which are not registered will no longer be available in the EU.**
 - They will receive updated and extended **Safety Data Sheets (SDS)** from the manufacturer or importer from **1st June 2007** if they use dangerous substances or preparations. These SDS may contain **exposure scenarios** which describe how a substance or preparation can be used safely, and the **risk management** measures necessary to control risks to human health and the environment.
 - The **classification and labelling** of some substances may change, so downstream **formulators** may need to change their SDS.
- In most cases downstream users do not need to register the substances that they use. However, it should be noted that many companies may be both manufacturers/importers of some substances and downstream users of other substances. It is therefore important for each person or company involved in the use of chemical substances to identify whether they are a manufacturer, importer or downstream user. For example, if a substance is purchased from outside the EU and the supplier does not have an **only representative** to register the substance, the downstream user may in fact have legal responsibility as an importer to register.
- **Important dates for downstream users:**
 - **1st June 2008:** Non phase-in substances manufactured or imported at ≥ 1 tonne per manufacturer/importer per year must be registered before they can be placed on the EU market.
 - **1st June to 1st December 2008:** Manufacturers and importers pre-register phase-in substances, so that these substances can remain on the market prior to registration between 2010 and 2018.
 - **1st January 2009**
 - ECHA **publishes** a list of pre-registered substances on its website.
 - Potential registrants who have pre-registered become part of a **Substance Information Exchange Forum (SIEF)** (downstream users can participate, but this is not essential; see "How to Share Data" in the WCA Guides to REACH Series).
 - **1st June 2009:** ECHA makes first recommendations for substances to be considered for **Authorisation**.
 - Registration deadlines are:
 - **30th November 2010:** Substances in volumes ≥ 1000 tonnes per year; known CMRs (category 1&2) in volumes ≥ 1 tonne per year; and substances classified as R50/53 (Very toxic to aquatic organisms, may cause long term adverse effects in aquatic environment) in volumes of ≥ 100 tonnes per year.

- **31st May 2013:** All other substances in volumes ≥ 100 tonnes per year.
- **31st May 2018:** All other substances in volumes ≥ 1 tonne per year.

WHAT DO WATER COMPANIES NEED TO DO?

- Water Companies are downstream users of far more substances than they manufacture or import. It is therefore likely that most Company resource available for REACH will need to be allocated to fulfilling downstream user obligations, and this should be planned for.
- Substances imported from a supplier outside the EU may lead to registration responsibilities for Water Companies. Inventories of substances (see below) need to identify such cases promptly so that Water Companies can take appropriate action either to fulfil registration responsibilities or substitute suppliers or substances.

What do Downstream Users need to do?

- Downstream users need to **understand** the chemical substances they use, how they are used, what they are used for, and where they are sourced from. They should compile an **inventory** of chemicals that are used anywhere in their business in the form of substances, preparations, or articles from which a substance is intended to be released. This might take the form of Table 1.

Table 1. Potential format for a downstream user substance inventory

Substance name	CAS/ EINECS #	Properties	Supplier	Use
		Classification according to Dangerous Substances Directive (67/548/EEC) CMR category 1 or 2, PBT, vPvB?	Name EU/non EU?	Tonnes per year Function/purpose Qualification/approval required as raw material or in finished product? Customer use (if known/relevant)

- Once an inventory has been prepared by a downstream user a **priority for communication with suppliers** can be developed:
 - High priority** for communication:
 - CMR, PBT, and vPvB substances for which there are no viable alternatives (as these may become subject to Authorisation).
 - Substances classified as dangerous under the Dangerous Substances Directive for which there are no viable alternatives (as these may also become subject to Authorisation).
 - Substances supplied to a downstream user in only small amounts (as these are less likely to be included by a supplier in his registration because they are of low value to him).
 - Uses that a supplier may not know about.
 - Uses in a raw material or product that might require approval, e.g. by a government agency (because changing such a substance may require a long lead-in time).
 - Lower priority** for communication:
 - Substances not classified as dangerous, CMR, PBT or vPvB, or viable alternatives are available.
 - Substances supplied to a downstream user in large amounts, for uses known to the supplier, and which do not need to pass through an approval process.
- Downstream users should contact all current **suppliers** to ask whether substances that are used by them are phase-in substances which the supplier will pre-register. This should be checked on again before the deadline for pre-registration of **1st December 2008**.
- Downstream users should check the ECHA website on **1st January 2009** to ensure that the substances they use have indeed been pre-registered. If a substance does not appear on the list, a downstream user should inform the ECHA immediately of their interest. The ECHA will then publish the name of the

substance on the website and provide any potential registrants with contact details for the downstream user. Under some circumstances it may then make commercial sense for the downstream user to fulfil the role of manufacturer or importer if a business-critical substance has not been pre-registered. This is because a person or company who manufactures or imports a phase-in substance for the first time may benefit from extended registration deadlines **even if they did not pre-register the substance before 1st December 2008**. To do this they must submit a registration to the ECHA within 6 months of first manufacture/import of the substance, and no later than 12 months after the relevant registration deadline for particular tonnage bands. This process ensures at least short-term continuity of supply of a substance that has not been pre-registered.

- If a substance is subject to **Authorisation**, it can only be used by a downstream user subject to the conditions of that authorisation (as indicated by the supplier in their SDS). If a use is not covered by an authorisation, the downstream user will need to apply for one for their own use and for that of their customers. The ECHA will publish its first recommendations on what substances will require Authorisation on **1st June 2009** (with a candidate list likely to appear in the last half of 2008). Downstream users should check this list to determine whether they use any of these substances, and liaise with suppliers if they do.
- Downstream users should ensure that **suppliers** are aware of all uses of a substance in sufficient time for the supplier to prepare their registration dossier and include all downstream uses. Early contact with suppliers should help ensure that unnecessarily expensive risk management measures are not specified by a supplier through ignorance of particular downstream uses. The deadlines for registration are:
 - Before **30th November 2010** for substances in volumes ≥ 1000 tonnes per year; known CMRs (category 1&2) in volumes ≥ 1 tonne per year; and substances classified as R50/53 (Very toxic to aquatic organisms, may cause long term adverse effects in aquatic environment) in volumes of ≥ 100 tonnes per year.
 - Before **31st May 2013** for other substances in volumes ≥ 100 tonnes per year.
 - Before **31st May 2018** for all other substances in volumes ≥ 1 tonne per year.
- **Customers** of downstream users should be contacted and asked to identify their uses of a substance, so that this can be included in the registration dossier. If this is not done, customers have only a 12 month period after registration in which to comply with exposure scenarios attached to an SDS. This might include potentially onerous yet inappropriate conditions for their particular use, and could even require process changes or substance substitution.
- A substance subject to **Restrictions** on use must be used by a downstream user in accordance with those restrictions.
- Some downstream users may be **producers** or **importers of articles**, and may have to register substances that are intended to be released from those articles.
 - This is unnecessary if the substance is already covered by another registration.

- The ECHA may need to be notified, and customers informed of safe use, if an article contains $\geq 0.1\%$ (w/w) of certain dangerous substances.
- Downstream users should check **Safety Data Sheets** provided by a manufacturer or importer to ensure that their own use of a substance is covered by an **appropriate exposure scenario**. If this is not the case they should do one of the following:
 - Make their own use known to their supplier so that the supplier can prepare an appropriate exposure scenario.
 - Change their conditions of use so that they comply with the supplier's exposure scenario.
 - Find another supplier who provides an exposure scenario covering their conditions of use.
 - Prepare their own Chemical Safety Report. [See "How to Prepare a Chemical Safety Report" in the WCA Guides to REACH Series]. However, note that a downstream user chemical safety report is not required for uses of <1 tonne per year, even if the use is outside the exposure scenario.
 - Find an alternative substance, preparation or process and stop using the substance or preparation in question.
- **Formulators** who place dangerous substances on the market need to provide **Safety Data Sheets** to their customers. They may also need to provide exposure scenarios for uses of substances in preparations further down the **supply chain**.
- Downstream users need to **communicate to suppliers** any new information on hazards or possible inadequacies in risk management measures. This may also need to be communicated upstream to suppliers from a downstream user's own customers, or vice versa.

WHAT DO WATER COMPANIES NEED TO DO?

- Compile a formal inventory of all substances used in their business.
- Prioritise substances for communications with suppliers about Registration.
- Check with suppliers on pre-registration status.
- Ensure that suppliers are aware of uses and exposure scenarios relevant to Water Companies and their customers, and that these are reflected in Safety Data Sheets and Registration dossiers.
- Appoint an individual to keep a watching brief on substances used in the company that may be subject to Authorisation or Restriction, and prepare plans for substituting these substances for others, if possible.
- Ensure that a mechanism exists for promptly communicating any new information on hazards or risks to suppliers.

Summary of Downstream User obligations

Downstream user type	Obligations
All downstream users (including distributors, retailers & storage providers)	<ul style="list-style-type: none"> Identify roles and obligations. Inform suppliers of any new information on hazards, including classification and labelling. Communicate information that might call into question the appropriateness of the risk management measures in any exposure scenario received. Distributors shall pass on relevant exposure scenarios and use the relevant information in the safety data sheet (SDS) received when compiling own SDS. Furthermore a distributor shall provide customers with the information that is supplied to him in accordance with Article 32 of REACH regulation. Downstream users that supply substances or preparations have additional obligations, as described below.
Formulators, refillers & end-users only	<ul style="list-style-type: none"> Identify and apply appropriate measures to control the risks communicated in safety data sheet or other information supplied with non-dangerous substances or preparations Check compliance with an exposure scenario, if you receive one from your supplier, and take further action in case of non-compliance For substances subject to authorization, comply with the conditions of the authorization covering your use. You may need to apply for an authorization if your use is not covered by an authorization granted to a supplier and you want to continue this use. Check compliance with any restrictions on the substance
Formulators and refillers only	<ul style="list-style-type: none"> Provide information to your customers and to retailers / consumers to enable safe use of substances or preparations. Downstream users that supply substances or preparations shall recommend appropriate measures to control risks, identified in SDS, the information that is supplied to him in accordance with Article 32 of REACH regulation, or in own chemical safety report.
Article producers only	<ul style="list-style-type: none"> Provide information to enable safe use of articles you produce or supply containing substances of very high concern in concentrations above 0.1 % w/w and, if requested, to consumers (Article 33).
Distributors only	<ul style="list-style-type: none"> Forward requests to make a use an identified use to the next actor or distributor up the supply chain.
Re-importers only	<ul style="list-style-type: none"> Document substance(s) are identical to those registered in the EU by you or someone in your supply chain. Have documentation according to Article 31 (safety data sheet and exposure scenario where applicable) or Article 32 available

WHAT DO WATER COMPANIES NEED TO DO? EXAMPLES

On-site generation of sodium hypochlorite

A Water Company generating sodium hypochlorite on-site is manufacturing a substance. However, sodium hypochlorite is a biocide listed in Regulation (EC) No 2032/2003 (active biocidal substances on the market before 14 May 2000). It should therefore be exempted from REACH as long as its use is only for biocidal purposes [*but note that there are ongoing discussions on this subject with the Health & Safety Executive*]

Fluoridation of drinking water

Water Companies will usually be Downstream Users of sodium fluoride. However, they need to check that they are not legally classed as importers if their supplier is outside the EU and has not appointed an only representative. As Downstream Users they should ensure that their suppliers have pre-registered sodium fluoride so that they can continue to be supplied with this substance, and that their supplier fully understands its uses and potential exposure scenarios in the water industry.

Production of fertiliser from sludge

Fertiliser products made from sludge involve recovery of nutrients from wastes by Water Companies. An argument can be made that these nutrients will previously have been registered when first manufactured or imported into the EU, mainly in the form of inorganic fertilisers. The recovered nutrients are therefore exempted from REACH, although Water Companies should ensure that they have information on the registered substances within the fertilisers (e.g., safety data sheets).



Watts & Crane Associates supplies the chemicals, water, retail and regulatory sectors with independent, high quality, and objective scientific advice on the environmental sources and pathways of chemicals, and their effects on human and ecological receptors. We are a partner of the REACH Centre (www.thereachcentre.com) and a REACHReady approved supplier.

This series of Guides to REACH includes:

Guides mainly for Industry use

- How to register
- How to pre-register
- How to share data
- How to deal with intermediates
- How to deal with monomers and polymers
- How to deal with Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)
- How to notify classification and labelling
- How to deal with articles
- What should downstream users do?
- How to apply for authorisation

Guides on what Authorities will do with information from Industry

- How will dossiers and substances be evaluated?
- How will Annex XV dossiers on harmonised classification and labelling be prepared?
- How will Annex XV dossiers on the identification of substances of very high concern be prepared?
- How will substances in Annex XIV (substances subject to Authorisation) be identified?
- How will Annex XV dossiers for restrictions be prepared?
- How will priorities for evaluation be set?

Guides on different methods under REACH

- How to identify and name substances in REACH
- How to comply with the Regulation on Classification, Packaging and Labelling of substances and mixtures
- How to prepare a Chemical Safety Report
- What are the information requirements under REACH?
- How to perform a socioeconomic analysis
- How to use IUCLID 5

For more information on Watts & Crane Associates or on this series of Guides to REACH please contact us at solutions@wca-environment.com

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