Registration, Evaluation, Authorisation and Restriction of Chemicals Regulations (REACH)

Five Steps to REACH

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Introduction

From June 2007, REACH will affect all industrial and business sectors in Ireland. The REACH regulations are a new European wide set of regulations aimed at controlling and organising the manufacturing and distribution of harmful substances. Each member state may have its regulations looking at the classification and supply of substances and REACH aims to bring these and all of other the applicable regulations under the one banner.

The main duties of REACH fall on those employers who may already be involved in the manufacturing and supply of substances, however there will be a lot of employers who are indirectly involved in these roles and might not have been subjected to previous regulations, but will come under the scope of REACH. As well as this, REACH takes a cradle to grave approach and so for the first time those employers who simply just use substances in the workplace also have duties under the new regulations.

One further aspect of REACH is that it also includes the manufacturing of articles. Previously the focus has been on substances, however, now most manufacturers

will find that they too have specific duties under REACH. This will mean there will have to be consideration of everything from the manufacturing of the components included in a mobile phone to a car.

This guidance aimed is primarily at, though not limited to, employers who will be new to any form of classification, packaging and labelling of substances and articles and will take employers systematically through the first 12 months of REACH from June 2007 to June 2008. This period of time is set aside for the establishing the European Chemical Agency, but to also give employers time to gather information on the substances they generate or import ready for pre registration.

Downstream users will have some duties under REACH. Although these duties mainly relate to passing information back up the supply chain, downstream users should be particularly aware that where substances are not registered in the specified periods, then those substances cannot be placed on the market. This could mean that downstream users could have difficultly sourcing substances vital to their operations if their suppliers have not registered them. However, where the employer is a downstream user of a substance, they do not have to use this guidance.

The first action for employers is to consider the ready reckoner contained in this guidance along with the definitions contained in the glossary of terms. From this, employers will know whether this guidance is relevant to them.

Contents

REACH Ready Reckoner

REACH Ready Reckoner

Introduction

REACH will affect all Irish employers to some extent, however, the main duties and roles may only on specific work practices and those employers who would already be involved in the classification, packaging and labelling of chemicals. Though there has been an expansion of the scope of these employers, the majority of employers will fall into the "downstream user" role. This ready reckoner will identify whether or not an employer will have to register substances. If the answer is "no" to all of these questions and the employer's only involvement with substances using them, then the employer is a downstream user and should refer to IBEC's specific guide for downstream users.

Where an employer has answered "yes" to any of the questions, or where the employer does not have enough information to answer some of the questions, then this guidance will help steer them through the process of gathering the requisite information to register their substances.

Ready Reckoner

Provision:			
		Yes	**No**
1	Do you manufacture "substances or preparations?" in quantities of over 1 tonne per calendar year?		
2	Do you manufacture "articles" in quantities of over 1 tonne per calendar year?		
3	Do you import substances, preparations or articles from outside the EU in quantities of over a tonne per calendar year?		
4	Do you manufacture substances, preparations or articles that contain carcinogens, mutagens or toxic to reproduction in quantities greater than 1 tonne per calendar year?		
5	Do you manufacture substances, preparations or articles that contain carcinogens, mutagens or toxic to reproduction in quantities greater than 1 tonne per calendar year?		
6	Do you import substances, preparations or articles from outside the EU that contain carcinogens, mutagens or toxic to reproduction in quantities greater than 1 tonne per calendar year?		

Glossary of Terms

Glossary of Terms

REACH contains a large section of specific definitions. These are important to employers as they define the roles within the regulations and help identify what substances and articles are part of the scope of REACH and those that are exempt.

The key definitions relevant to this guide can generally be broken down into the topics: what is being used, who does it and what is being done.

Definitions – What is being used

It is possibly easier to give details on what is exempt under REACH than to detail all that the regulations actually cover. Naturally, with a piece of legislation with as broad a scope as this, there may be room for confusion over what exactly REACH covers.

The Steps in this guide will help employers to identify what they use and which acts they perform and then evaluate which of these definitions applies to them:

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

- **Preparation:** means a mixture or solution composed of two or more substances;

  There is a clear distinction between a “substance” and a “preparation” in the regulations. Although in general health and safety, there is a tendency to use these terms interchangeably, the focus of REACH is on the substance rather than the preparation. When looking at a data sheet for something used in the workplace, employers will see that this contains a list of ingredients. These ingredients are the “substances” and they are combined to make the “preparation”. Using domestic bleach as an example, the bleach itself is the preparation as it is a mixing of several ingredients. The substances in bleach would be Sodium hypochlorite, Sodium carbonate anhydrous and water.

  Therefore, employers need to identify what substances make up the preparations that they use. REACH requires the registration of the substance not the preparation.

- **Article:** means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

  An article is more difficult to explain. The easiest examples would be electronic devices, even something as simple as a remote control, or a digital clock display for an oven are articles. However, this definition is so encompassing, that everything from a microchips to textiles are “articles”.

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

- **Polymer:** means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

  (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

  (b) less than a simple weight majority of molecules of the same molecular weight.

  In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer

  Although not particular to the majority of workplaces, these definitions relate to certain plastics. A polymer is the plastic as a whole and it refers to the composition and make-up of the plastic (i.e. long chains of molecules). Examples would be any material used that begins with the term “poly” such as polystyrene, polyester, polyvinyl chloride (PVC) etc. The monomer would be the individual molecule, so: in PVC, the polymer is the PVC material and the monomer is the individual vinyl chloride molecule. As a simple example, the polymer is the wall and the monomers are the individual bricks.

  The reason for separately defining these is because of their different chemical compositions and in many cases the different toxicity of the two. The monomers can be very hazardous materials, such as vinyl chloride,

which is a carcinogen, but there can be a dramatic reduction in toxicity when combined to make the PVC polymer, which is much less toxic.

- **Carcinogens (Category I & II)**
  Substances deemed to cause or suspected of causing cancer are categorised based upon the information available. Generally, category I carcinogens are known to cause cancer in humans, in category II there is evidence of some cancers amongst humans and has been shown to cause cancer in animal studies. Category III (not included in REACH) are suspected of causing cancer in humans.

  Information supplied with the substance will state if the classification of a substance is either a category I or II carcinogen. In addition, knowing the CAT number of the substance will also help in identifying the harm it could cause. The symbol for Category I & II carcinogens is the toxic sign (skull and crossbones pictogram) and the risk phrase R45: May cause cancer or R49: May cause cancer by inhalation. Category III carcinogens have the symbol for harmful (a black cross pictogram) and R40: Some evidence of cancer.

- **Mutagens (Category I & II)**
  Mutagens have a specific property that causes hereditary (i.e. the defect is passed on to future generations) changes to human DNA. As with carcinogens, there are different categories depending on current knowledge of the substance's effects. The first identified mutagen was dichlorodiethyl sulfide, more commonly known as mustard gas.

- **Toxic for reproduction (Category I & II)**
  This is any substance that can affect the process of human reproduction in both men and women. For example, the fungicide Cycloheximide has an affect on both male and female reproductive systems. The most common example of substances that are toxic for reproduction is "teratogens". These are substances that affect the unborn foetus or interfere with the development of the foetus and the most well known teratogen is thalidomide, the morning sickness drug that caused malformations in the developing foetus.

- **Bioaccumulative substances**

  Some substances can accumulate in both the body and the environment and have a “bio half-life”. This is the time taken for the substance in the body to reduce by half and this can be over a period of days or years. Naturally, where the substances takes a long period to leave the body, there is a risk of accumulation from repeated exposure to even relatively small amounts, which can eventually reach harmful levels. Examples of this are prolonged exposure to lead, mercury and dioxins. The body stores these and they are not completely metabolised or excreted, so that when there is further exposure, there is then an accumulation of the substance in the body. Substances can also accumulate in the food chain, so that even a small concentration in contaminated water can be concentrated up the food chain.

Definitions: What is being done with the substance?

There are several critical actions within REACH and these lead to prescribed roles and obligations within the regulations. Where substances or articles exist in the workplace, employers need to establish what happens to them and where did they come from.

- **Manufacturing:** means production or extraction of substances in the natural state

  This process refers to those who manufacture substances. Obvious examples relate to the chemical industry, however, where there is mixing of two substances as part of a process or task, then technically this is the creation of a new substance (where they react together to create a substance) and the employer becomes involved in manufacturing substances. If there is no reaction, then this would be manufacturing of a “preparation” and this is part of the scope of REACH.

- **Import:** means the physical introduction into the customs territory of the Community;

  The act of importing is a common one seen in many European wide regulations such as packaging waste. Where a substance or an article is brought in from outside of the EU, then this is “importing”. It does not relate to substances or articles purchased in the EU. Therefore, one employer uses digital display clocks in a microwave oven from China and the other from Germany. Only the clocks coming from China would be “imported”.

- **Placing on the market:** means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

  Although covered in other areas under roles of the various parties, the main issue with this definition is the “free of charge” statement. It has been the case that redundant substances and articles have been given or donated to schools, colleges and even between employers. They are still considered to be “placed on the market” under this definition.

- **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;

  A self-explanatory definition covering every possible scenario under which a substance or article is considered to be in use.

Definition: Who is doing what?

The roles that are contained within REACH are vital components of the regulations and one that employers must establish early on. These will prescribe the duties, actions and ultimately costs associated with REACH.

- **Manufacturer:** means any natural or legal person established within the Community who manufactures a substance within the Community;

  Using the above example of “manufacturing”, the employer described is a manufacturer of a substance.

- **Importer:** means any natural or legal person established within the Community who is responsible for import;

  As discussed above, when an employer imports the article or substance from outside the EU, they take on the role of “importer”.

- **Producer of an article:** means any natural or legal person who makes or assembles an article within the Community;

  This may seem self-explanatory, but the definition contains a very specific term: ‘assembles’. This therefore also includes the manufacturing of electronic equipment or other articles, but more significantly, it also means that where there is the assembly of pre-made, imported components, the employer is a “producer of an article”.

- **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. A re-importer exempted pursuant to Article 2(7) (c) shall be regarded as a downstream user;

  This will be the duty that will apply to all enterprises irrespective of size or operations. Hardly a business exists that does not use chemicals in the workplace. If there is a can of air freshener in the office, then the employer is a “downstream user”. Note, there is no role for users of “articles”, only those who make or import articles.

- **Actors in the supply chain:** means all manufacturers and/or importers and/or downstream users in a supply chain.

  A generic term used when describing all parties having duties.

- **Supplier of a substance or a preparation**: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;

- **Supplier of an article:** means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;

  Any person involved in the sale or distribution (remember “place on market” also includes giving it away free of charge) of article or substances, becomes the supplier and will have a role under these regulations.

Abbreviations:

- **CAS number** - the Chemicals Abstracts Service number for a chemical and is unique to that substance. Only the substance is assigned a CAS number and not the preparation.
- **EINECS** - the European Inventory of Existing Commercial Chemical Substances and is a list of all chemical substances on the EU market up to 1981
- **ELINICS** - the European List of Notified Chemical Substances and is a list of substances which have been notified in the EU in accordance with Directive 67/548/EEC
- **CMR** - Carcinogens, Mutagens, Toxic to Reproduction

- **PBT** -Persistent, Bioaccumlative and Toxic
- **VPVB** - very persistent and very bioaccumulative (vPvBs)
- **SvHC** - substances of very high concern

Overview of Regulations

Overview of the regulations

Introduction

The aim of the REACH regulations is to replace the current regulatory system for the supply of hazardous substances with a single, coherent legislative system for new and existing chemicals.

The basic elements of the Regulation are:

- industry must register all existing & future new substances of quantities of 1 tonne or more per year, with a new European Chemicals Agency
- pre registration of existing substances
- existing substances have to be registered within the first 11 years (the phase in period)
- these substances are prioritised based on volume produced or imported into the EU on an annual basis

Registration

The first phase of REACH will be to compile a register of all substances currently in the supply chain in the EU. This will be completed in stages with the volume manufactured or imported being one of the criteria along with the hazardous nature of the substance. The greater the volume or potential harm to health, then the sooner the deadline is for registration and a need for a greater amount of technical information.

The timescales for registration are as follows:

1. **June 2007-2008**
   Set-up of European Chemical Agency

2. **June 2008-November 2008**
   Pre-registration

3. **June 2008-November 2010**
   Registration of chemicals in volumes greater than
   - 1000 tonnes
   - 100 tonnes of chemicals with risk phrases R50-R53 (refers to chemicals with significant environmental affects to water courses)
   - 1 tonne of carcinogens, mutagens and toxic to reproduction chemicals

4. **November 2010 – June 2013**
   All other substances in volumes of between 100 and 1000 tonnes

5. **June 2013-June 2018**
   All other substances in volumes of between 10 and 100 tonnes and substances in volumes between 1 and 10 tonnes.

For those who manufacture and/or import substances, in addition to registration, they are also required to produce documentation on the substance. This will be composed of a **technical dossier** and in some cases a **chemical safety report**.

The technical dossier will require the employer to provide information on the properties of the substance and the harm it can cause. This information will be similar to that already seen in Safety Data Sheets, but will mean that testing an research will have to be carried out on the substances to evaluate and establish this information.

Where there is manufacturing or importing of substances in volumes greater than 10 tonnes, then the employer must also produce a chemical safety report. This will be more extensive as it is a requirement that the report has details of all the uses of the substance and then provides detailed risk control measures associated with these exposures and uses.

Although these standards relate to the manufacturers and importers of substance, downstream users will be obliged to provide their suppliers with information on their use of the substance, quantities, exposures, risk control etc and then comply with the control measures specified in the chemical safety report. Where the downstream user does not or cannot use the control measures specified in this report then they will need to have their method evaluated by the European Chemical Agency.

Documentation in REACH

REACH requires the production of several documents several documents through the registration process.

- **Technical Dossier**
  For registered substances manufacturers and importers will have to gather physicochemical, toxicological and ecotoxicological properties and produce a **Technical Dossier**. For larger quantities of substances some animal testing may be required, however at this stage the registrant will only need to have written proposals of

these tests. The information required for the technical dossier is outlined in Annex II of this document.

- **Chemical Safety Report (CSR)**
  If a substance is manufactured or imported in volumes of more than 10 tonnes/year then a Chemical Safety Report (CSR) is required. A CSR provides information on all the identified uses of the substance.
- **Chemical Safety Assessment (CSA)**
  The CSA will assess the risks to human health and the environment associated with those uses and what control measures should be put in place. The CSA is contained in the CSR
- **Safety Data Sheets (SDS)**
  Employers will be familiar with the layout and content of SDSs. There is no threshold limit on the production of these and it is for the employer who places the substance on the market to produce the SDS.

Evaluation

This process checks and evaluates the information submitted in the registration. It will identify where there is a need for obtaining further information. It will also include the examination of the harmful effects of a registered substance.

Authorisation

One of the main issues referred to in any discussion on REACH, is that there will be a prohibition of some substances. This will be through the authorisation process and rather than just prohibition of substances. Employers who manufacture or import these substances will have to seek authorisation to use them. This will be for substances that are of very high concern because of the potential harm they could cause.

Restriction

Ultimately, the authorisation process may result in the banning of certain substances from manufacture and use if there are no reasonable justifications for the use of that substance.

Exemptions:

REACH does not apply to all substances or all process and the regulations list some of the exemptions to the regulations. However, there is some word of caution about some of these exemptions. Firstly, the reason for most of these being exempt is not that they are harmless and safe, it is simply that they

already have detailed, specific legislation covering them that highlights the nature and potential harm of those materials.

Secondly, most of the exemptions tend only relate to the finished products. For example, there is a part exemption for cosmetics, but only the finished product. Therefore, whereas selling the lipstick to consumers is exempt from certain parts of REACH, the raw materials that went into the manufacturing of the lipstick are not and the manufacturer will still have to comply with REACH for the individual components.

Current complete exemptions are for the following substances:

- radioactive substances
- substances subject to customs supervision
- naturally occurring products (as long as they remain in natural state)
- non-isolated intermediates
- carriage of dangerous goods (though the use of these is covered)
- waste products
- certain medicinal products
- certain veterinary products
- certain food or feedstuffs

With medicinal products, veterinary products and food/feedstuffs, the regulations refer back to specific definitions under European directives. Employers who are involved in the manufacturing or supply of these materials must check to see what the scope is of these definitions, as it may not apply to all products, only certain ones.

Also within REACH there are partial exemptions, either relating to the state of the product (i.e. only exempt if it is a finished product) or exemptions from certain parts of the regulations, but not all parts.

The following finished products, although covered by REACH, are exempt from the requirement to provide information in the supply chain (Title IV):

- certain medicinal and veterinary products
- cosmetics
- medical devices
- certain food or feedstuffs

Step One:

Identification of substances and articles

Step One – Identification of substances and articles

1.0 Introduction

The purpose of this inventory is to identify all the uses and manufacturing of substances and what they are, but also the production or importing of any articles. By listing all these items employers will have a record of everything the regulations will affect. Completing a detailed inventory is vital to ensuring compliance and ensuring the identification of all substances and articles.

This stage takes a task-based assessment approach to activities and the "inputs" and "outputs" of those processes or tasks. In many cases, this will be a relatively simple process. The use of chemicals may be for cleaning or preparation of a task and here it is simply a matter of identifying those chemicals. However, where manufacturing is involved, then it may need a more detailed analysis as the output could be an article or the generation of a new substance

For the purposes of this stage, "inputs" will be the use of substances as part of a process or task. A simple example would be the cleaning of an office. In this example, the inputs will be the use of substances on their own or in preparations to clean the office and there will be no "outputs" as there are new substances or articles resulting from the process. Remember, waste products are not included as part of REACH unless they are being sold as a specific product.

"Outputs" are therefore anything that comes out of a process. As these may be new substances unique to that employer's operations, identifying these is important to establish the full range of duties under REACH. They could be products that are not exempt, articles or mixtures of substances.

1.1 Rationale for Stage One

For the majority of employers their only involvement in REACH is as a downstream user. Even though this may seem the simplest of duties within the regulations, there are still specific requirements placed on downstream users. It is in the employer's interest to ensure that for each substance they use that they provide the supplier with as much information as possible on the current use and quantities as is possible, including current safety controls. This can then be included in the risk control measures of a Chemical Safety Report. But it is also essential that the employer checks whether the substances are registered. If they are not, then the employer will not be able to buy that substance or preparation

With the Chemical Safety Report and the identified risk control measures, there is a legal obligation for downstream users to follow these measures, even if the measures are not reasonably practicable to that employer's usage.

Therefore, employers who are downstream users can pass on the information gained at this stage to suppliers and the downstream user's specific use of that substance is considered and appropriate controls are part of the safety report.

Regular review of this information will also help identify any changes in the use of substances, through either elimination, substitution or where use has increased over the calendar year.

1.2 Who needs to complete this Stage?

All parties

1.3 Break down the task

For general health and safety purposes, employers may already have an analysis of the tasks and activities that occur as part of their operations and these will help form a basis for this part. The steps involved are:

- pick a task and break it down into the key stages.
- for each of those stages look at what substances are used(at this stage just identify the chemical).

Once completed, employers should now a have a list of all the substances in a process. Where there are outputs from the process, similarly employers need to establish what they are and if they are a substance or an article.

Form 1.1 (Task Analysis) can be used to record the task analysis. Use a separate form for each task.

Example Task Analysis – Screen Printing

Key Steps	**Inputs (Substances used in task or added to the process)**	**Quantities**
1. Cleaning screen pre printing. Solvent applied with cloth and screen	Isopropyl Alcohol	10 ml

Key Steps	Inputs (Substances used in task or added to the process)	Quantities
cleaned by hand.		
2. Applying inks Inks poured onto screen in requisite quantities. Screen is printed and the further applications as required.	Solvent based inks: Red Blue Black Green	 2 ml 1 ml 4 ml 2 ml
3. Fine finishing using brush applications When finer detailing is required for some printing, use of fine brushes and application by hand.	Solvent based inks: Red Blue Black Green	 0.01 ml 0.01 ml 0.01 ml 0.01 ml
4. Cleaning Screen post printing As in step 1.	Isopropyl Alcohol	10 ml

The quantities here relate to the specific use in the single occurrence of this task. The employer must then establish what quantity of the substance they use over a calendar year as well as where they buy the substance from. If it is greater than 1 tonne and imported by them from outside the EU, then the employer will have to register this substance. This is part of step two.

Activity	Record No:
Person Completing Task Analysis	
Date	Signature:

Key Steps	Inputs (Substances used in task or added to the process)	Quantities	Outputs (Substances or articles generated by the task or process)	Quantities
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10				

Form 1.1 (Task Analysis)

Step Two:

REACH Substance Evaluation – Supplier information

Step Two – REACH Evaluation – Supplier information

2.0 Introduction

For the substances that have been identified as inputs in Step One, employers need to establish who the supplier of these substances are and where the substances come from.

2.1 Rationale for Step Two

There are many aspects to REACH that mean it is important for employers to know who they get their substances from. Firstly, employers may need to contact the supplier in the event of missing product information, such as lack of or out-of-date data sheets. Secondly, the duties are far more significant for an employer who imports the substances they use from outside the EU. Therefore, where some substances or articles are imported, then the employer must know exactly which ones, where they come from and the quantities brought in on an annual basis.

In addition, with the broad definitions already discussed, it might be the case that the employer is the manufacturer of a substance or article. Again, knowing the specific details and quantities of these materials is vital

2.2 Who should complete Step Two?

All parties.

2.3 Identify suppliers

Existing records for chemicals will help in this stage. Any safety data sheet that accompanied the substances will identify the supplier and their address/location.

Where, in the case of outputs and even some inputs, it is the employer who produces and uses these materials, the employer is the “supplier”.

Using Form 2.1 (Supplier record), list all identified substances, the supplier of the substance, their location and whether they have supplied a safety data sheet for the product.

Example Supplier Information – Screen Printing

	Substance	Supplier	Location	Total Annual Tonnage	MSDS	
					Y	N
1	Isopropyl Alcohol	World Chemicals	USA	2 tonnes	X	
2	Red Ink (PR1000)	Dublin Inks	Tallaght Dublin 24	0.5 tonnes	X	
3	Blue Ink (PR1001)	Dublin Inks	Tallaght Dublin 24	0.5 tonnes	X	
4	Green Ink (PR1002)	Dublin Inks	Tallaght Dublin 24	0.5 tonnes	X	
5	Black Ink (Ink992)	WVK Chemicals	Germany	0.5 tonnes		X

In the above example, four of the substances used in the silk screening process are from inside the EU. Therefore, irrespective of quantities used, in the case of these substances the employer's role is of a "Downstream User". However, in one case, (the black ink); they will need to contact the supplier to ensure they have an up-to-date safety data sheet before progressing with Step Three.

The first substance, however, originates from the USA. In this case, the employer is now an "importer". How big a role they will have, will depend on the quantities they import per calendar year and the safety information that is available on this product.

	Substance	Supplier	Location	Total Annual Tonnage	MSDS	
					Y	N

Form 2.1 (Supplier Record)

Step Three:

REACH Substance Evaluation – Hazard and Use Assessment

Step Three – REACH Substance Evaluation – Hazard and Use Assessment

3.0 Introduction

This stage looks to identify the individual hazards and risks associated with the substances used. Most of this information is contained in the data sheets that should be available for the substances used.

3.1 Rationale for Step Three

This information will give employers a greater understanding of what the hazards associated with those substances is. This will be valuable information in the case of registration and it will alert employers to some of the key substance groups that are likely to be subject to restriction. In addition, downstream users will have a summary of the substance and its use, which they can the give to their suppliers to the ensure inclusion of their usage is in the Chemical Safety Report.

3.2 Who Should Complete Step Three?

All parties.

3.3 Record

From all the information gathered regarding the use and the substance itself, complete Form 3.1 (REACH Substance Record) for each substance used as part of operations.

This step will combine all the information gathered so far so that the employer has one record sheet for each substance. The critical points for this exercise are that the employer can:

- identify and trace all substances used by its CAS number
- identify those substances for which no CAS number exists
- identify the quantity of the substance used per calendar year
- identify if it is manufactured or imported

In the case of the downstream user for substances, this record will still need to be completed. However, if there is no manufacturing or importing of a substance, then the downstream user does not have to complete any more information beyond this step.

Silk Screen Example: Isopropyl Alcohol

Substance Used	**Hazard Classification**	**Maximum Exposure Limit/ Occupational Exposure Standard**
Isopropyl Alcohol Synonyms: ▪ isopropanol, ▪ IPA ▪ propan-2-ol ▪ rubbing alcohol	R11 Highly flammable R36 Irritating to eyes R37 Irritating to respiratory system	980 mg/m3 (UK OEL)

CAS Number	67-63-0

Manufacturer/ Supplier Details	Klondike Kemicals Boston USA

Supplied from EU	Yes	**No**

Quantities Used per calendar year	**Data Sheet Available**	**Is it a CMR or of special concern?**
2 Tonnes	Yes	No

Is the substance used		
As supplied	**Diluted**	**Mixed***
Yes	No	No

Description of Work

Applied to cloth and then used to clean screen. Used in well-ventilated area and exposure below OEL. Employees use disposable gloves and safety glasses. Waste clothes put into fire proof bin for disposal by incineration.

*complete form 3.2 (REACH Substance Record – Mixing)

Silk Screen Example: Red Ink

Substance Used	**Hazard Classification**	**Maximum Exposure Limit/ Occupational Exposure Standard**
Red Ink ▪ Petroleum blend ▪ Naphtha ▪ Aluminium Dust	Flammable Harmful Irritant	▪ TWA 50ppm ▪ TWA 25ppm ▪

CAS Number	8052-41-3 64742-95-6 7429-90-5
Manufacturer/ Supplier Details	Dublin Inks Tallaght Dublin 24

Supplied from EU	**Yes**	No

Quantities Used per calendar year	**Data Sheet Available**	**Is it a CMR or of special concern?**
0.5 Tonnes	Yes	No

Is the substance used		
As supplied	**Diluted**	**Mixed***
Yes	No	No

Description of Work

Applied to screen using applicator. Stored in small 5 litre containers in fireproof press. Used in well-ventilated area, employees wear disposable gloves and eye protection.

Waste containers disposed of in fireproof bin and disposed of as flammable waste.

*complete form 3.2 (REACH Substance Record – Mixing)

Substance Used	**Hazard Classification**	**Maximum Exposure Limit/ Occupational Exposure Standard**

CAS Number	
Manufacturer/ Supplier Details	

Supplied from EU	Yes	No

Quantities Used per calendar year	**Data Sheet Available**	**Is it a CMR or of special concern?**

Is the substance used		
As supplied	**Diluted**	**Mixed***

Description of Work

*complete form 3.2 (REACH Substance Record – Mixing)

Form 3.1 (REACH Substance Record)

3.4 Manufacturing record

In some cases, there maybe a mixing of a substance with another and this is the used in a process or sold as a product.

Where the employer identifies this, they will need to detail as much information as they can gather regarding the individual substances and the mixture.

Form 3.2 (REACH Substance Record – Mixing) can be used as a record of this.

Part One: General Information

Mixture Name	
Mixture Use	

Part Two: Mixture Break Down

Substance	CAS Number	Volume in Mixture	Proportion (%by wt)

Part Three: Detailed Analysis of Mixture

CAS Number of Final Mixture	
Hazard Classification of Final Mixture	
Total Quantity of Mixture produced per year	

Form 3.2 (REACH Substance Record – Mixing)

Step Four:

REACH Article Evaluation – Article Analysis

Step Four: REACH Article Evaluation – Article Analysis

4.1 Introduction

Where the employer is a producer or importer of an article, an evaluation must take place as to whether it is likely that in normal use (including circumstances such as foreseeable misuse), there could be the release of any substance from the article. This will also include any potential release from repair or maintenance, including any release of the substance when it is disposed of.

As stated already, the requirements regarding articles relate only to producers/importers and not the downstream users. Therefore, only those who make or bring in an article from outside the EU need to list and analyse these.

4.2 Rationale for Stage Four

The focus of all the debate about REACH has been on chemicals and those manufacturing the chemicals. Perhaps one of the more significant aspects of REACH is that it also relates to articles as well as substances. The duties imposed for articles are the same as for substances in that registration may be required and in some cases possible restriction of the substances contained in the article.

Many manufacturing processes will be producing articles as defined by these regulations and it is very important that employers understand and evaluate the nature of these products. Additionally, it is likely that many employers will be importing articles sourced from outside the EU. This is more likely where there is branding or the addition of small electronic goods to a finished product. In this case, the employer will have a lot of work to complete to analyse the components of these devices.

4.4 Who Should Complete Step Four?

Producers and importers of articles only.

4.3 What are they?

Where articles have been identified as part of the task analysis in Step One, employers next need to establish if they are the producers of the article or importers and if so how much do they produce or import.

4.4 What is its use?

The design of articles will be for a specific use. Producers and importers of the articles will have to consider this use and look at any potential release under normal conditions.

As part of this step, look at any maintenance, recharging or wear and tear that are likely to occur through the lifetime of the article. The use of the article will be relatively simple, for example, the digital clocks already discussed, although they will contain some potentially harmful substances for the display, it is highly unlikely that in normal use that these substances will be released. The only time there is likely to be a release is when the product is disposed of and are therefore covered by existing environmental and waste regulations. An example of an article that could release chemicals could be a lead/acid battery used in forklift trucks. Even if used as described, there is still a chance that the battery could leak during normal usage. In addition, the user of the battery may have need to top up the battery with water or acid as part of normal use and therefore again increasing the likelihood that the substances in the article could be released.

Employers can use Form 4.2 (Article Analysis Record) to record all articles, their use, and any expected circumstances under which there could be the release of substances and what those substances are likely to be.

Example: Office Supplies Company
An office supply company imports photocopying toner from Turkey and sells them in Ireland.

Part One – Supply Record

Article and contents	Produced	Imported	Total Weight/ year
Photocopier Toner ▪ Styrene-Acrylate copolymer ▪ Carbon black ▪ Organic ammonium salt ▪ Polypropylene ▪ Iron Oxide		Supplied from Turkey	2 tonnes

As different toners will contain different ingredients, the employer in this case would need to look at each toner and the safety information that comes with them.

The employer will next have to consider what the normal use is of the toner and if there is any likelihood of release of the substances.

Normal Use description	Release of substance when used		Details and quantities of substances released
	Y	N	
Storage		X	
Removal of packaging	X		Toner powder Trace amounts
Installation of toner	X		Toner powder Trace amounts
Access to photocopier for repairs or clearing jams.	X		Toner powder Trace amounts
Removal of spent toner cartridge	X		Toner powder Trace amounts

The analysis here shows that there are several scenarios where it is likely that the exposure of the user to the substance could occur.

4.5 Individual Substance Analysis

As in Step Three, producers and importers of articles will need to establish what the hazards are associated with the individual substances that make up the article and the quantities that are present.

This is to establish whether the article meets the criteria for registration under REACH. The regulations separate this on two grounds, the first is the volume of a substance contained in the articles and the other criterion is where the article contains CMRs.

Form 4.2 (Article Analysis – Substances) will provide employers with a record of this. Complete this for each substance contained in an article or where it is a CMR.

Example: Office Supplies Company

Substance	CAS Number	Hazard Classification	CMR?	
			Yes	No
Styrene-Acrylate copolymer		None		**X**
Paraffine wax		None		**X**
Polypropylene		None		**X**
Iron Oxide	1309-38-2	None		**X**

Substance	Volume in article (kilograms)	Proportion (%by wt)
Styrene-Acrylate copolymer	0.235	47
Paraffine wax	0.02	4
Polypropylene	0.02	4
Iron Oxide	0.225	45

	Article and contents	Produced	Imported	Total Weight/ year	Normal Use description	Release of substance when used		Details and quantities of substances released
						Y	N	

Form 4.1 (Article Analysis Record)

Article Name	

Substance	CAS Number	Hazard Classification	CMR?		Volume in Article	Proportion (%by wt)
			Yes	No		

Form 4.2 (Article Analysis – Substances)

Step Five:

REACH Evaluation - Registration

Step Five: REACH Evaluation - Registration

5.1 Introduction

The first stage of the introduction of REACH into European law will be to register substances and articles. The conditions for registration are varied. They will affect far more employers than simply chemical manufacturers.

The various stages of this guide will have identified the specifics associate with the use and nature of substances and articles in the workplace. This information will now play an important role in establishing if employers have to be part of the registration process or if, as downstream users; they only need to compile information.

5.2 Rationale for Stage Five

With the global market for all kinds of materials and substances used as part of work, it is likely that some employers will fall between a variety of roles and not just downstream user. Where this is the case and based on other conditions, then the employer must register the substance and/or the article.

5.3 Results from examples used in guidance

Throughout the guidance, there were several examples used to demonstrate the different steps to working with REACH. Each example had a different outcome concerning what role the employer has under REACH. Therefore, before considering registration, what were the outcomes for those employers?

5.3.1 Example One – Silk Screening

In steps one-three, the example looked at an employer using substances and preparations as part of a simple silk screening process. It was identified from this that the variety of inks used by the company were all sourced from within the EU and so for all these products the employer is considered a “downstream user”. Therefore, in this case the employer will use the specific information from Step Three to inform their supplier of their specific uses and exposures to those inks. Once the registration process is complete, the supplier will provide the employer with the chemical safety information and risk control measures for that specific use of the inks.

However, the employer also imported Isopropyl Alcohol from America. The total quantity imported within a year was just over a tonne. The employer now must

look at the registration of these substances. They could change their supplier to a European based supplier, or they could follow the steps through registration.

The safety information supplied with the alcohol show no specific concerns (that is CMRs or specific environmental effects) and so under the REACH timescales, the employer would have 11 years to register the substance.

5.3.2 Example Two – Office Equipment Supplier

Step four looked at the example of an office equipment supplier importing photocopier toner from outside the EU and sold this to employers. In this example, although the toner (the article) did not contain any specific substances of concern, the volume imported was 2 tonnes and even though the majority of that weight was the casing for the toner, the total volume of the toner was over 0.1% and the total weight imported was over 1 tonne. In addition, there is a potential for release of the toner under normal usage and this therefore means that the employer must register the photocopier toner.

5.4 Requirements for Registration

There are different requirements for a substance and an article. The duty to register falls on specific roles within the chain of supply and use. Where the employer:

- Manufactures, supplies or imports substances
- produce or import articles

Then they may have to register these with the European Chemical Agency. Employers will need to have gathered the information so that they know the following about the substances and articles:

- where they come from (inside or outside EU)
- what they are (CAS numbers of substances if known and the component substances of articles)
- quantities produced or imported

5.4.1 Registration of Substances

There are two parties with a duty to register substances: the manufacturer and the importer.

1. Any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency."

And

2. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

(a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

The Agency in this case is the European Chemical Agency who will be the body to register substances to and not the Health and Safety Authority (who will be the enforcers of the regulations).

In the first case, employers will be aware from step one of the substances where they will be classed as the manufacturer or where it has been identified that they import substances. Here, for each substance/preparation the employer needs to note the total tonnage produced. If this is greater than 1 tonne in a calendar year, then they will need to register those substances with the agency.

Referring back to the glossary of terms, if an employer produces such items as polystyrene (as an ingredient rather than a finished packaging product) then if the product contains 2% or more (weight by weight) of the monomer and the total quantity of the monomer is more than 1 tonne in a year, then this too has to be registered. Both these conditions have to exist before registration is required. For example, if the final product is PVC, this is the polymer. The monomer is the Vinyl Chloride. For this to be registered, the Vinyl Chloride must make up 2% or more of the PVC and the employer must be using more than 1 tonne of Vinyl Chloride in a year.

5.4.2. Registration of Articles

Registration of articles requires more consideration than the substances. This is because of the fact that there could be a wide variety of substances in the article (think of all the components that would make up a simple circuit board) and the need to establish exactly what those substances are and what their nature is.

As such, the basis for registration is on two areas, one the tonnage used and secondly where the articles contain CMRs.

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

    (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
    (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Completion of step four will have provided the relevant information to determine whether the article meets this requirement. Again, this is not just a matter of weight and the amount either produced or imported. The article also has to meet the requirement where there could be release of the substance under normal use. Therefore, if during the lifetime of the article there will not be a release of the substances when used normally, even if the employer manufactures or imports over a tonne a year, there is no need to register this. However, if the article contains something that is a CMR (carcinogen, mutagen etc) then other criteria apply:

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:
    (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;

    (b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w)

The reference to Articles 57 and 59 relates to the specification of certain substances that are of particular concern because of the harm they can cause. The term “Article” is used within European regulations and directives in the same way as regulations refers to “regulation 12” or and Act “section 8”. Therefore, Article 57 and 59 are within the REACH regulations themselves.

The specific substances referenced are ones that are:

- Carcinogens (Category I & II)
- Mutagens (Category I & II)
- Toxic for reproduction (Category I & II)
- Various bioaccumulative substances

Therefore, if an article contains a substance with any of the above classifications it does not matter if there is no likely release under normal use. The employer must register this if it is in a concentration of greater than 0.1% and the total quantity of the substance (not the article) produced or imported in the year is greater than 1 tonne.

For example, the importing a digital clock used in a microwave oven from China. It is found that the clock contains a substance that is classified as a category I carcinogen. To need registration the substance must constitute more than 0.1% of the article. Therefore, if the digital clock weighs 60 grams and the total quantity of the carcinogen is 0.06 grams or greater, then this may need to be registered as long as the other criteria is met. To do this, there also has to be over 1 tonne of the substance present. One metric tonne contains 1000,000 grams. Therefore, the employer would need to produce or import nearly 17,000 digital clocks before this needed registering.

5.5 Options for Registration

The regulations provide for several options relating to how a substance is registered. Depending on a variety of factors, an employer with substances and articles that need to be registered could use one or a variety of these.

5.5.1 Solo Registration

The employer can directly register its substances or articles with the Agency. This will mean the employer will incur the full cost of registration, examination and for any technical information that will follow.

Employers may have to use this route where they are the sole producer or importer of a substance or article. However, where there may be an issue of business sensitive information, again employers may chose to register directly with the agency.

5.5.2 Pre-registered

Commonly used substances or articles may already be registered. Employers should check to see whether there is already a registration for the identified substances or articles.

The main benefits of pre-registration are that employers will then have 11 years to complete the full registration process as the pre-registered substances become “phase-in” substances. If existing employers do not pre-register, then the

substance will be a “non phase-in” substance and the full registration process within a period of 6 months.

Pre-registration also enables employers, with identical substances to share the cost and burden of the registration process so that there is only one registration for each substances. This way the costs of testing and developing the various documents can be spread through the group.

5.5.3 Group registration

Employers from a similar industry belonging to business federations or groups that produce or import the same substances or articles can provide a group submission for these common materials and therefore share the costs of registration.

5.5.4 Speaking to suppliers of imported materials

The duty for imported materials is on the employer who first receives the materials in the EU. However, the advent of REACH will mean that many employers may be unwilling to import materials knowing that the economics of registering these may negate any savings made from importation. It is therefore likely that many of the larger suppliers will register their products to ensure they retain the business.

Where there is a large volume of employers importing the same materials, speaking to the supplier regarding the REACH regulations may encourage them to register the product rather than the employer.

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