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# REACH Guidelines for the Ministry of Defence

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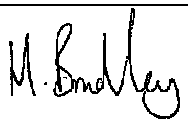
| | **Name** | **Signature** | **Position** | **Date** |
|---|---|---|---|---|
| **Author** | Dr Nik Robinson |  | Principal Consultant | 22/01/08 |
| **Reviewed by** | Megan Bradley |  | Principal Consultant | 22/01/08 |

**BMT Cordah Limited,**
Scotstown Road,
Bridge of Don, Aberdeen,
UK, AB23 8HG.

Tel: +44(0)1224 414200
Fax: +44(0)1224 414250
Email: enquiries@bmtcordah.com
Website: www.bmtcordah.com

# Document log

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## CONTENTS

# Ministry of Defence Guideline Document on REACH for consideration of the Enactment of the Defence Exemption

## 1 INTRODUCTION

The purpose of this guidance document is to:

- Provide a comprehensive overview of requirements under the new REACH legislation regarding the Registration, Evaluation, Authorisation and Restriction of Chemical Substances in the European Union.
- Promote awareness amongst MoD staff of the exemptions that can be sought, for substances used in the interest of defence.
- Act as a useful guidance document when deciding what will be required to enact the defence exemption within REACH, for substances used by the MoD.

It is the MoD's intention that any defence exemption process would involve processes and standards that are at least as good as those in the REACH Regulations themselves.

This will require an internal system to be set-up to ensure that where the exemption is enacted, all the human and environmental health requirements are still met, as set out in REACH regulations.

## 2 SUMMARY OF EU REACH REGULATIONS

### 2.1 Background

The recent introduction of legislation regarding the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) No 1907/2006, requires all chemical substances, new and existing, that are manufactured or imported in the European Union in a quantity of ≥1 tonne per year to undergo registration. One of the main differences in the new legislation is that substances need to be assessed at the component level, requiring comprehensive communication up and down the supply chain to ensure that all uses of a substance are covered during registration. This legislation therefore applies to substances on their own, contained in preparations or contained in articles.

REACH legislation requires all substances currently in use to be "pre-registered" between 1st June and 1st December 2008, for the manufacturer/importer to take advantage of the phase-in period. Depending on the classification of the substance and the quantity being manufactured, full registration must occur before the deadlines set out in the REACH phase-in guidelines.

## 2.2 REACH Processes

Registration of substances under the REACH regulations will take place in a number of steps as outlined below. However, not all manufacturers or importers will have to complete all steps for all substances:

1. Pre-registration
2. Registration
    a. Gathering and evaluation of existing physical, chemical, human health and environmental data
    b. Further data generation when data gaps are identified
    c. Preparation of Technical Dossiers (TD) and Chemical Safety Reports (CSR)
    d. Submission of registration dossier to the European Chemical Agency (ECHA)
3. Evaluation, of dossiers and substances
4. Authorisation
5. Restriction

Steps 3-5 will not be completed for all registrations. The evaluation of the submitted dossiers will only be completed for a small percentage of submissions, whilst substance evaluation, authorisation and restriction will only be completed for the more toxic substances and those of concern.

**WHAT MUST BE REGISTERED**

- **All substances** manufactured in, or imported into the EU in quantities **greater than one tonne** per year per legal entity **must be registered**
- There is **no minimum** volume for substances subject to **authorisation**

### 2.2.1 Pre-registration (Article 28)

Pre-registration is the process whereby manufacturers, producers/importers of articles with an intended release and importers of 'phase-in substances' have to submit a brief set of information to ECHA in order to qualify for the extended registration deadlines. The extended deadline for registration is dependant on the tonnage of a substance and the classification of the substance (e.g. Carcinogenic, Mutagenic or Toxic to reproduction or R50-53, very toxic to aquatic organisms). All substances on the European List of Notified Chemical Substances (ELINCS) are deemed as already registered.

**PRE-REGISTERATION**

- **Pre-registered substances may continue to be marketed** during the phase in registration period
- **Substances on the ELINCS list** are "notified substances" and classed as **already registered**

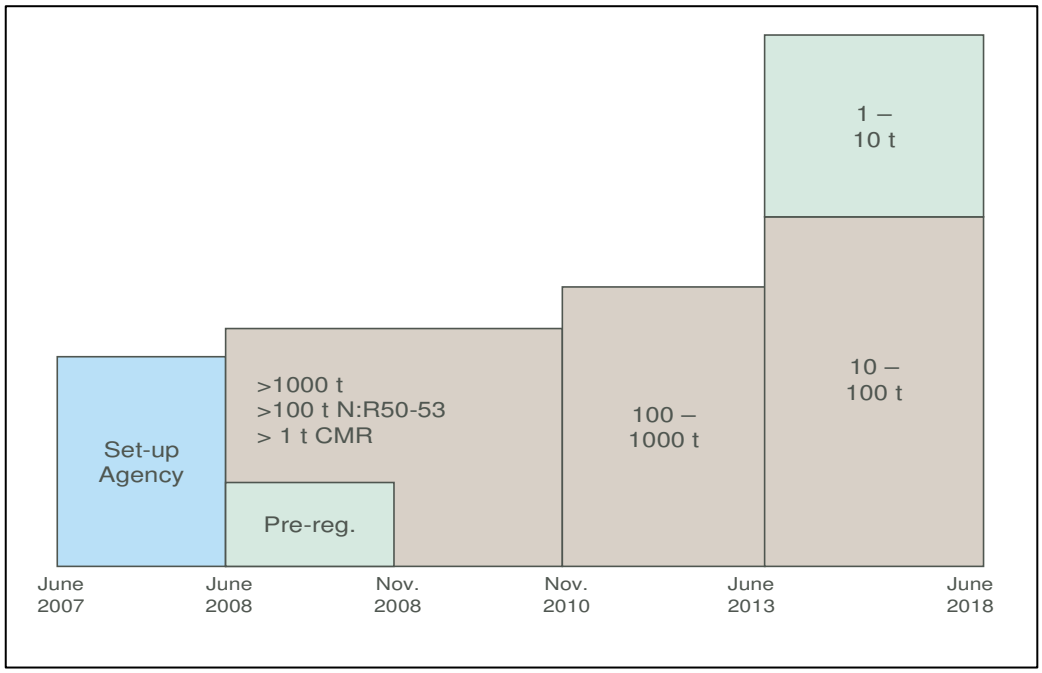
Pre-registration is free and must be completed in the period from 1st June 2008 to 1st December 2008. Pre-registration is not mandatory, but failure to pre-register before the deadline will result in it being illegal to market the substance until full registration has been completed. The REACH timeline is shown in Figure 1 below.

Pre-registration can be carried out by:

- Manufacturers or importers of substances on their own or in preparations, in quantities of 1 tonne or more per year.
- Producers and importers of articles containing substances in quantities of 1 tonne or more per year.
- Only Representatives of non-EU manufacturers where the substances are imported into the EU in quantities of 1 tonne or more per year.
- Pre-registration only requires basic information to be supplied based on the identity of the substance, the name and contact details of the registrant, and the tonnage band in which the substance is being marketed in.

Further details on the pre-registration stage are given in Section 4.1.

**Figure 1 - REACH Regulation Pre-registration Timeline**




### 2.2.2 Registration

Whether the substance has been pre-registered or not, manufacturers and importers must compile a registration dossier for each substance. If the substance has been pre-registered, then the substance can remain on the market until the agreed phase-in deadline, based on substance volume; if the substance was not pre-registered, it cannot be marketed until registration has been completed.

**What to Register (Article 2)**

Generally all substances on their own or in preparations (mixtures) require registration. In addition substances contained in "articles" require registration under certain circumstances, and there are provisions for polymers and intermediates as well. There are also a number of exemptions that apply.

**WHAT TO REGISTER**

- **Substances**
- **Preparations**
- **Articles**
- **Polymers**
- **Intermediates**

- **Substances**
  Chemical elements and their compounds in their natural state or formed by any manufacturing process, e.g. argon, aluminium oxide, acetone.

- **Preparations**
  A mixture of two or more substances without the formation of a new substances e.g. paint, lubricants

- **Articles**
  An object for which the shape, surface or design determines its function more than its chemical composition, e.g. a bearing, fragrant soap,

- **Polymers**
  A substances comprising of molecules formed from one or more types of monomer units with a range of molecular weights, e.g. plastic mouldings

- **Intermediates**
  A substance that is manufactured for and consumed in or used in a chemical process in order to be transformed into another substances, e.g. dimethyl-hexadiene in the production of pyrethrin

- **Exemptions**
  Various exemptions are possible for radioactive substances, non-isolated intermediates, wastes, nano-materials and for the interest of national defence.

Manufacturers and importers must compile a registration Technical Dossier (TD) for their substances, the dossier will include physico-chemical, ecotoxicological and toxicological data, the quantity of which is dependent on the tonnage threshold the substance is marketed in and it toxic properties. The substance must be registered for identified uses and these must be evaluated.

All substances require a registration TD, substances marketed in volumes over 10 tonnes per annum require a more detailed Chemical Safety Assessment (CSA) which is presented in a Chemical Safety Report (CSR).

### 2.2.3 Evaluation

**EVALUATION**

- **Dossier Evaluation –** small number of submitted registration documents will be checked by ECHA
- **Substance Evaluation –** some substances will be prioritised for consideration for Authorisation and Restriction

There are two types of evaluation as part of the REACH process, with two different and distinct aims:

**Dossier evaluation - T**he ECHA will do a quality check of the registration TD, the intention is that at least 5% of dossiers will be checked. Any testing proposals will also be evaluated to prevent unnecessary animal testing.

**Substance evaluation -** The ECHA in co-operation with the Member States will develop guidance on the prioritisation of substances for further evaluation. This will be published in the form of a rolling action plan for Member State to carry out the evaluation of the priority substances. Substance Evaluation may lead to the restrictions or authorisation procedures being enacted.

### 2.2.4 Authorisation (Title VII)

The purpose of authorisation is to ensure that the risks associated with use of a substance of very high concern are properly controlled throughout their life cycle, and to ensure that these substances are progressively replaced by other substances or by the implementation of new technologies when they are economically and technically available and viable.

**AUTHORISATION**

- To continue to market a **substance of very high concern**, an authorisation will need to be sought if alternative substances/technologies are not available.
- The process requires the socio-economic advantages to be presented and a programme for replacing substances / technologies to be presented.

The ECHA may require substances in the following categories to be included in Annex XIV, the list of substances subject to Authorisation:

- Carcinogenic, Mutagenic or (toxic to) Reproduction (CMR) category 1 or 2 in accordance with Directive 67/548/EEC
- Persistent, Bioaccumulative and Toxic (PBT)
- Very Persistent and very Bioaccumulative (vPvB)
- Substances (such as those having endocrine disrupting properties or those having PBT and vPvB properties, which do not requirements of the above catergories) for which there is scientific evidence of probable serious effects to human health or the environment (Article 59).

### 2.2.5 Restriction (Title VIII)

A restriction to the use of a chemical may be imposed by ECHA when there is an unacceptable risk to human health or the environment.

The Commission or a member state may submit a restriction proposal relative to the manufacture, placing on the market, or use of a chemical substance.

The restriction system is referred to as the REACH "safety net" for controlling the risks that have not been taken into account elsewhere in REACH.

## 3 MoD ENACTMENT OF THE REACH DEFENCE EXEMPTION CLAUSE

These mechanisms are subject to further investigation and subject to change.

**PROPOSAL FOR MOD EXEMPTION**

- The MoD will introduce internal standards at least as good as those in the regulations where reasonably practicable.
- Applications for exemption will be handled by DE&S.
- Exemptions will be reviewed every two years.
- An annual report of exemptions in place will be submitted to the UK CA and SoS.

The Ministry of Defence (MoD) will comply with the REACH Regulations. However, where it is necessary in the interests of defence, the Secretary of State (SoS) may exempt the

MoD or anyone involved in defence related business from the requirements of specific articles of the REACH regulations. These exemptions will be conferred by written certificates, the content of which will conform to UK legislative requirements.

SoS's Policy Statement on Safety, Health and Environmental Protection stipulates that where the Ministry of Defence has been granted specific exemptions, disapplications or derogations from legislation, international treaties or protocols, the MoD undertakes to introduce internal standards and management arrangements that are, so far as reasonably practicable, at least as good as those required by the legislation.

In accordance with this policy, the MoD will utilise a management system to mirror the principal functions of the REACH regime. This system will be administered on behalf of the MoD by Defence Equipment and Support (DE&S) and applications for an exemption will be scrutinised by a senior board within DE&S, that will make recommendations to the SoS for the granting of a certificate on a case-by-case basis. Certificates will be time limited, depending on the use and reviewed every two years. An annual report will be provided to the SoS and the UK competent authorities. The exemption certificates will be linked to the appropriate safety information containing the same level of detail that would be covered under the normal REACH arrangements.

Where the SoS has granted an exemption, the use of any substance, preparation or article will be subject to normal legislative controls. DE&S will manage all substances, preparations and articles with defence sensitive uses within MoD (including Defence Partners) and all those imported from outside of the EU. DE&S will also act as the main focal point for all MoD related REACH issues.

## 3.1 Scope of Exemption Authority

The MoD managed exemption will be extended to:

- Defence Industry Partners that supply the MoD with items that come under the remit of REACH and have national security implications.
- UK based Defence Industry Partners that supply the EU defence community with items that come under the remit of REACH and have national security implications.
- Visiting forces in the UK.
- Permanent British bases overseas.

The MoD, with assistance from Department for Environment, Food and Rural Affairs (DEFRA) and the Health and Safety Executive (HSE), will ensure that the attention of the relevant authorities is drawn to REACH obligations and compliance requirements. In

principle US bases would be covered by the same exemptions and MoD administrative arrangements as UK facilities.

Principally, the MoD will be classed as a Downstream User (DU), however, we do have some importer duties.

## 3.2 Co-operation with HSE and DEFRA [freedom of limited information]

The exemption process will be subject to scrutiny from the HSE as the REACH Competent Authority (CA) in the UK, and will be given assurance that the process will only apply in specific cases for certain substances where it is necessary in the interests of defence. In all other circumstances the requirements of the REACH regulations will apply. The scheme cannot be used to 'hide' substances that are not covered by other obligations, e.g. the Chemical Weapons Convention. The exemption will not cover defence exports that include substances that the UK military would not use, items that were also commercially available in the UK, or be used by defence industry companies to avoid their own compliance obligations.

The MoD will share sanitised information about exemptions, such as the numbers of certificates issued. The MoD will be able to share the model of the defence exemption, including mandatory reports to the Commission on the enforcement arrangements and later on implementation and operation of REACH in the UK with all interested parties.

The MoD will establish appropriate links with HSE (as the CA), to provide copies of exemption certificates, lists of generic substances, with the CA in turn acting as a focal point for the other UK enforcement bodies, as well as the European Chemicals Agency and Commission, in respect of the defence exemption.

## 3.3 Timing

The SoS's power to grant exemption is not time limited. The certificates of exemption granted by the SoS will take effect immediately upon the coming into force and will be valid for 2 years, after that point a review will be undertaken. SoS may vary or revoke the certificates of exemption at any time by a certificate in writing.

## 3.4 Exemption Process

The defence exemption will be served through an administrative system of certification, issued by the SoS, for generic categories of substance (rather than listing specific substance names, for confidentiality). The enforcement Statutory Instrument will provide the means for legal exemption, linking it to the Secretary of State's certificate.

The MoD will identify the Articles within REACH regulations that they wish the defence exemption to cover. Included in that would be substances that would be subject to authorisation (Article 56) or restriction (Article 67). Certificates of exemption will be issued by the Secretary of State for Defence.

The certificates will show:

a. The identity of the individual or organisation benefiting from the exemption;

b. The substance, preparation or article to which the exemption applied; and

c. Those parts of REACH from which (a) was exempt in respect of (b).

The duration of certificates will be for 2 years and will be backed up with technical data in an annex, explaining in more detail the uses for and descriptions of the substance, preparation or article. The exemption certificate number will be used as a tracker device to ensure the validity of an exemption up and down the supply chain.

Chemicals that are likely to fall within the restrictions under Title VIII of REACH (subject to 76/769 EC controls on Dangerous Substances) will be subject to a certificate, but supported by a business case for continued use. MoD will also include substances that require authorisation in the exemption. Exemptions for substances already subject to existing Marketing and Use restrictions will be granted on a case-by-case basis and will be time limited to ensure that the potential for substitution is undertaken.

MoD will keep certificates internal to MoD/HSE, but will make publicly available some statistical information on an annual basis (e.g. number of certificates issued).

The HSE will in the normal course of duty monitor observance of the REACH Regulations and will expect to find demonstrable evidence of compliance with all appropriate legislation, including the conditions detailed in the SoS's certificates of exemption. SoS's exemption does not impede the HSE's powers to enforce the Regulation and/or action for non compliance with the Regulation.

The MoD will act to initiate "mini-SIEFs (Substance Information Exchange Fora)" within the defence industry and are committed to reducing animal testing. The sharing of animal test data (as required by REACH) will be considered on a case-by-case basis, and complied with where national security is not an issue.

# 4 FURTHER DETAILED INFORMATION

## 4.1 Pre-registration

The following is a more detailed breakdown of the information to be submitted to the ECHA as part of the pre-registration process:

- The name(s) of the substance (as specified in Section 2 of Annex VI,).
    - The names in the International Union of Pure Applied Chemistry (IUPAC) nomenclature or other international chemical name(s);
    - Other names (usual name, abbreviation and trade name);
    - European Inventory of Existing Commercial Chemical Substances (EINECS) number (if available and appropriate);
    - Chemical Abstract Services (CAS) name and number (if available);
    - Other identity code (if available);
- The name and address of the pre-registrant and the name of the contact person and, where appropriate, the name and address of a Third Party Representative whom the pre-registrant has selected to represent him for all the proceedings involving discussions with other Manufacturers, Importers and Downstream Users;
- The envisaged tonnage band and the subsequent full registration deadline;
- The name(s) of other substances for which there is available information for performing adaptations to the testing requirements, i.e. the use of results from (Q)SAR models and the read-across approach;

There is an option for the pre-registrant to act as “facilitator” to kick start Substance Information and Exchange Forum activities.

## 4.2 Registration

### 4.2.1 Data Gathering, Evaluation and Sharing (Title III)

After pre-registration, REACH regulations provide for the formation of Substance Information and Exchange Fora (SIEFs) to share data among manufacturers and importers of pre-registered substances, phase-in substances registered without pre-registration as well as allowing Downstream Users and other stakeholders (termed “Data Holders”) who have information on the substance they are willing to share in exchange for financial recompense.

SIEFs will be formed for each pre-registered substance and will begin after the ECHA publish a list of all potential registrants for each substance, which is due on the 1st January 2009. All potential registrants are mandatory members of the SIEF, whereas data holders are not mandatory members of a SIEF but are encouraged to share any data or information they hold.

The main aims of the SIEF are:

- To facilitate data sharing for the purposes of registration, thereby avoiding the duplication of data generating studies, and
- To agree on the classification and labelling of substances
- A SIEF is not a legal entity or a consortium, but a forum to share data and information on a substance and SIEF participants are free to organise themselves as they see fit to fulfil their obligations under REACH.

### 4.2.2 Obligations of SIEF Participants

SIEF participants share the following obligations:

All SIEF participants shall react to requests for information from other participants and provide other participants with existing studies upon request.

Potential registrants shall request missing information from other SIEF participants, collectively identify needs for further studies to comply with registration requirements, make arrangements to perform the identified studies (further testing proposals) and agree on classification and labelling of substances.

Data holders, if members of the SIEF, must respond to any query from potential registrants if they hold data relating to this enquiry.

### 4.2.3 Consortia

There are several possible forms of co-operation that companies can choose to organise their co-operation under REACH. The SIEF model, although mandatory for all potential registrants, is a fairly loose form of co-operation (e.g. using IT tools to communicate between all SIEF members). Other members of a SIEF may wish to use a more structured and binding model, such as a Consortium.

A consortium, in this instance, is referred to as a more organised and formal method of co-operation between parties, which may include either a signed agreement, the adoption of operating rules or reference to an agreed set of general rules.

It is important to realise that a consortium is a separate entity to the SIEF, but shares the same obligations as all potential registrants that are mandatory members of the SIEF.

Formation of consortia may prove very useful for the smooth running of the data sharing, cost sharing and preparation of further testing proposals processes that are essential to completing registration.

For example, the potential registrants of the same substance may have different data requirements, due to the tonnage thresholds of members differing. In this case, multiple consortia may be formed outside the SIEF for each tonnage threshold. This setup will still facilitate data sharing between consortia, but each consortium within the SIEF can focus more on their specific requirements for registration, as the data needed for each tonnage threshold differ significantly.

Another scenario may see a major consortium created by several companies that cover a family of substances that all members are interested in registering, that participate in several different SIEFs.

Elements of co-operation that may be included in a consortium are as follows:

- Conduct or document the identity check
- Designation in a SIEF of the facilitator or the Lead Registrant (in cases where the consortium groups all SIEF members)
- Organisation of the co-operation and thus the consortium
- Consideration of the data (existing data, missing data, new data to be generated)
- Defining the data to be shared
- Facilitating data sharing and co-ordination
- Data valuation, data evaluation (including identification, data access and collection)
- Facilitating cross-reading between SIEFs
- Organisation to preserve the confidentiality of business information and data
- Cost sharing
- Data ownership
- Preparation of letter of access to data for non-consortium parties

- Liability
- Classification and labelling

The consortium may also co-ordinate joint submission of data, joint registration, and the life of the consortium may continue after the joint registration by jointly following up the registration file and interacting with ECHA until final registration/evaluation.

### 4.2.4 Further Data Generation

Once all available data and information on a substance have been gathered, the SIEFs and consortia must then identify "data gaps", where the data required for registration under REACH is not available.

Depending on the nature of missing data, a testing proposal may have to be prepared and submitted to ECHA for approval. Potential registrants within the SIEF and consortia have to agree on one of the members to perform the study on behalf of the others.

All participants who require the missing information are required to contribute financially for the generation of new information by a share corresponding to the number of potential registrants interested in the missing data. Once the new data has been generated, each SIEF has the right to receive a copy of the full study report within three weeks of payment.

### 4.2.5 Preparation of a Registration Dossier (Title II)

The Technical Dossier (TD) and Chemical Safety Report (CSR) are the components that will make up the Registration Dossier for submission to ECHA.

For substances manufactured or imported into the EU in quantities of ≥ 1 tonne but ≤ 10 tonnes per annum, the registrant need only submit a TD. If, however the substance is manufactured or imported in quantities in excess of 10 tonnes per annum, then the registration dossier must consist of both the TD and CSR.

The requirements for the TD and CSR require expert knowledge, when for example writing robust study summaries or conducting hazard assessments. BMT have a dedicated REACH team with skills and experience in all aspects of preparing Registration Dossiers.

### 4.2.6 Technical Dossier (Articles 10 and 12)

A Technical Dossier is always required for substances, whether in the ≥ 1 tonne but < 10 tonne threshold or in the > 10 tonne threshold.

The technical dossier contains a variety of information about the intrinsic properties of a substance and includes the following:

- The identity of the manufacturer/importer
- The identity of the substance and information on its manufacture and use
- Classification and labelling
- Guidance for safe use
- Robust study summaries of the information on the intrinsic properties of the substance
- An indication as to whether any of the information on the intrinsic properties of the substance has been reviewed by an assessor
- Further testing proposals, if relevant
- If the substance falls in the ≥ 1 tonne but < 10 tonne threshold, the Technical Dossier shall also contain exposure related information for the substance
- The "end product" technical dossier must be in International Uniform Chemical Information Database (IUCLID) format.

### 4.2.7 Chemical Safety Report (Article 14)

The Chemical Safety Report is the documentation of the registrants Chemical Safety Assessment for his substance(s). The Chemical Safety Report will contain a detailed summary of information on the environmental and human health hazard properties of the substance, together with an assessment of exposure and risk where such an assessment is required.

The Chemical Safety Assessment will consist of two main components, the human health hazard assessment and the environmental hazard assessment, with both components will be carried out as follows:

1. Gathering and sharing of existing information
2. Consider information needs under REACH
3. Identify information gaps
4. Generate new data/propose testing strategy

### 4.2.8 Human Health Hazard Assessment

The human health hazard assessment will consider the following groups of potential effects:

- Toxicokinetics, metabolism and distribution
- Acute effects (acute toxicity, irritation and corrosivity)
- Sensitisation
- Repeated dose toxicity, and
- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction)
- Based on all the available information, other effects shall be considered when necessary
- The hazard assessment shall comprise the following four steps:
- Evaluation of non-human data
- Evaluation of human data
- Classification and labelling
- Derivation of the Derived No-Effect Levels (DNELs)
- Development of exposure scenarios
- Occupational exposure risk assessment
- Consumer exposure assessment
- Risk management measures
- Risk characterisation

### 4.2.9 Environmental Hazard Assessment

The environmental hazard assessment will comprise the following three steps, each of which make up a significant component of the Chemical Safety Report:

- Evaluation of data
- Classification and Labelling
- Hazard Assessment for all environmental compartments
- Derivation of the Predicted No-Effect Concentration (PNEC)
- Environmental Exposure Assessment

- Risk characterisation

Once the Chemical Safety Report is complete, updated and extended Safety Data Sheets then need to be prepared where necessary.

### 4.2.10 Registering a Substance (Articles 10-14)

After completion of the Technical Dossier and the Chemical Safety Report, all in IUCLID format, the Registration Dossier then needs to be submitted to ECHA (the Agency) via REACH-IT prior to the relevant full registration deadline.

Once submitted, the Agency will send the registrant a submission number unique to that Registration Dossier.

The agency will then carry out the completeness check for the registration. The completeness check consists of two components:

- The technical completeness check, and
- The financial completeness check

The main purpose of the technical completeness check is to ensure that depending on the tonnage threshold of the substance, all elements of the registration dossier that are required are present. The financial completeness check will monitor and confirm the clearing of all payments required for that specific registration

Once registration is complete, ECHA assigns a registration number to the registrant that should be used in all correspondence associated with registration, this number should also be displayed on all Safety Data Sheets for any supply after receipt of registration confirmation.

Within 30 days of the submission date, ECHA will notify the competent authority of the member state within which manufacture takes place or the importer is established (for example, the Health and Safety Executive in the UK), that the registration has been submitted and that all the relevant information relating to the registration is available on the ECHA website.

Once complete, a registration is valid until the need for a registration update, for example if a new registrant submits additional information on a substance already registered.

## 4.3 Authorisation

Authorisation is the process by which substances that are of concern will be controlled under REACH.

A substance subject to authorisation will not be "authorised" but specific uses at specific quantities will be "authorised". Authorisation is necessary for any use and is independent of the quantity of the substance used. Authorisation is granted on a case by case basis and for a limited time period.

There are two ways to apply for an authorisation:

1. By demonstrating that the risk from the use of this substance is properly controlled throughout its life cycle (Article 60 (2)).

2. By demonstrating that the socio-economic advantages provide a greater benefit than the risks from the use of the substance for human health or the environment and that no appropriate replacement substances/technologies (Article 60 (4) and 60 (5)) are available.

Authorisation may be applied for by manufacturers, importers or DUs.

## 4.4 Toxicity Criteria

The PBT and vPvB assessment is required as part of the Chemical Safety Assessment and the results must be documented in the Chemical Safety Report. The objective of the PBT/vPvB assessment is to determine if the substance fulfils the criteria given in Annex XIII, and if so, to characterise the potential emissions of the substance.

Relevant Information regarding the persistence, bioaccumulative properties and toxicity should already be available in the CSR under Section 4 for Persistence and Sections 5 and 7 for Toxicity.

After the assessment, if the substance is considered to be PBT/vPvB, an emission characterisation shall be performed and reported in the CSR as well.

### 4.4.1 PBT

A substance fulfils the Persistence criterion when:

- The half-life in marine water is > 60 days, or
- The half-life in fresh- or estuarine water in > 40 days, or

- The half-life in marine sediment is > 180 days, or
- The half-life in fresh- or estuarine water sediment is > 120 days, or
- The half-life in soil is > 120 days

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which must be described by the registrant.

A substance fulfils the bioaccumulation criterion when:

- The bioconcentration factor (BCF) is > 200

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

A substance fulfils the toxicity criterion when:

- The long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 ng/L, or
- The substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2) or toxic for reproduction (category 1, 2, or 3), or
- There is other evidence of chronic toxicity, as identified by Directive 67/548/EEC.

### 4.4.2 vPvB

A substance that fulfils the criteria below are considered vPvB.

A substance fulfuls the very Persistent criterion when:

- The half-life in marine, fresh- or estuarine water is > 60 days, or
- he half-life in marine, fresh- or estuarine water sediment is > 180 days, or
- the half-life in soil is > 180 days

A substance fulfils the very Bioaccumulative criterion when:

- The Bioconcentration Factor (BCF) is > 5000

### 4.4.3 CMR

Substances may be classified as Carcinogenic, Mutagenic or Toxic to Reproduction (CMR) by the following criteria.

**Carcinogens:**

Category 1 – For substances and preparations that are known to be carcinogenic to humans.

Category 2 – Substances and preparations for which there is a strong presumption that human exposure to such substances and preparations can lead to cancer or increase their frequency.

Category 3 – Substances and preparations concern to humans because of possible carcinogenic effects, but for which available information is insufficient to classify these substances and preparations in Category 2.

**Mutagens:**

Category 1 – substances and preparations that are known to be mutagenic to humans.

Category 2 – Substances and preparations for which there is a strong presumption that human exposure to such substances and preparations can produce heritable genetic damage or increase the frequency.

Category 3 – Substances and preparations concern to humans because of possible mutagenic effects, but for which available information is insufficient to classify these substances and preparations in category 2.

**Substances Toxic to Reproduction:**

Category 1 – For substances and preparations that are known to be toxic to reproduction man.

Category 2 – Substances and preparations for which there is a strong presumption that human exposure to such substances and preparations can produce or increase the frequency of adverse effects in the non-hereditary offspring or adversely affect the function or reproductive capacities .

Category 3 – Substances and preparations concern to humans because of possible toxic effects to reproduction but for which available information is insufficient to classify these substances and preparations in category 2.

## 4.5 Substance Safety Data Sheets (SDS) (Title IV)

The key tool for communicating information down the supply chain is the SDS. The SDS is used to transmit the appropriate safety information for a substance or preparation to DUs. The goal of the SDS is to allow employers to determine whether dangerous chemical agents are present in the workplace and evaluate any risk for the Health and Safety of workers resulting from their use.

Suppliers of a substance or preparation must provide the user of the substance or preparation with an SDS under the following circumstances:

- When classified as a dangerous substance or preparation
- When the substance is PBT or vPvB
- When the substance is included in the list of substances that are candidates for Authorisation

The information in the SDS must correspond to the information contained in the substances chemical safety assessment. The SDS must contain exposure scenarios pertaining to all uses of the substance or preparation. Timely and thorough communication up and down the supply chain prior to registration is essential in order to ensure all downstream uses are covered in the CSA. The exposure scenario describes the operating conditions, hazard management measures and the substance use recommendations. The substances complete life cycle must be taken into account.

For substances and preparations where an SDS is not required, suppliers must nevertheless provide a certain amount of information to the user by the time of first delivery. This information should contain:

- The registration number(s) (when available)
- A “declaration” stating whether the substance is subject to authorisation
- Details regarding any authorisation granted or refused in the supply chain concerned
- Details on any restriction that may have been imposed.

# 5 REACH GLOSSARY OF TERMS

| Abbreviation | Definition |
|---|---|
| CSA | Chemical Safety Assessment |
| CMR | Carcinogenic, Mutagenic or Toxic to Reproduction |
| CSR | Chemical Safety Report |
| DNEL | Derived No-Effect Level |
| DU | Downstream User |
| ECHA | European Chemical Agency |
| EINECS | European Inventory of Existing Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EU | European Union |
| IUCLID 5 | REACH IT system for submission of Registration Dossier |
| OR | Only Representative |
| PBT | Persistent, Bioaccumulative or Toxic to Reproduction |
| PNEC | Predicted No-Effect Concentration |
| REACH | EU legislation for Registration, Evaluation, Authorisation and Restriction of chemical substances |
| RMM | Risk Management Measures |
| SDS | Safety Data Sheet |
| SIEF | Substance Information Exchange Forum |
| TD | Technical Dossier |
| VAT | Value Added Tax |
| vPvB | Very Persistent and Very Bioaccumulative |

# 6 REFERENCES

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