Defence Equipment & Support

THE REACH REGULATION

A GUIDE TO REACH PROCESS AND EXEMPTION IN THE MINISTRY OF DEFENCE

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1 INTRODUCTION AND BACKGROUND

The purpose of this Guidance Document is to:

- Provide a comprehensive overview of EC Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH);
- Define the Defence exemption criteria and identify the conditions where it may be enacted;
- Promote awareness amongst Ministry of Defence (MOD) staff of the exemptions that can be sought for substances used in the interest of Defence;
- Assist Directors (or equivalent), Project Teams (PTs) and Defence Industry Partners in identifying the processes and timelines associated with REACH Registration and exemptions in the interest of Defence;
- Provide clear guidance on the processes involved in Registering chemicals under REACH and complying with the United Kingdom (UK) MOD policy concerning exemptions from REACH in the interests of Defence:
    - If no Defence exemption is sought or granted by the Secretary of State, the substance(s) must be REACH Registered and;
    - If on Annex XIV the substance use must be Authorised and all necessary information must be provided to the European Chemicals Agency (ECHA) as stipulated in the Regulation, within the timescales required;
    - If on Annex XVI the substance use must be compliant with the Restriction as stipulated in the Regulation and within the timescales required;
    - Non-disclosure of either the **substance** or its **use** under REACH, should be managed internally, where reasonably practicable, whilst all aspects of REACH compliance are met.

This document will serve as a general reference document for the MOD supporting the registration of chemicals under REACH and compliance with the Secretary of State's policy for exemptions in the interest of Defence, which states:

> *"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".*

The MOD REACH process mirrors the REACH Actor obligations, but within the limited environment of MOD use.

1.1 Background

Regulation (EC) No 1907/2006, commonly known as REACH, is an ambitious piece of legislation that aims to improve the level of protection of human health and the environment from chemicals that are placed on the market in the European Union (EU). REACH applies to individual chemical substances (not products), both new and existing, that are manufactured in, or imported into, the EU in a quantity of greater than or equal to 1 tonne per year. The 1 tonne per year trigger volume applies to each individual EU legal entity.

The REACH Regulation will also control substances that are identified as "substances of very high concern" and listed for inclusion in REACH Annex XIV (substances subject to Authorisation), and substances considered dangerous and included in REACH Annex XVII (Restriction on the manufacture, placing on the market, and use of certain dangerous substances, preparations and articles).

The basic principle of REACH is for industry to collate or generate substance-specific data regarding human and environmental health risks and submit the information to ECHA for "registration". The amount of data and complexity of assessment for REACH takes a tiered approach, with higher tonnage chemicals requiring more data and more in-depth investigation of hazards and risks than lower tonnage chemicals. The data and information submitted in the registration will be evaluated by ECHA to ensure that all potential risks posed by a substance and its uses have been thoroughly assessed and are acceptable.

This is a step away from the previous regulatory system which focussed on preparations and mixtures, as opposed to REACH which breaks it down to the constituent level. By taking this approach REACH encourages more open relationships within the supply chain to facilitate the communication of the classification and safe use of the substances.

REACH also requires assessment of certain substances contained within articles (a product such as a component, assembly or system). This is applicable to substances that are manufactured or imported in quantities exceeding one tonne per year, and that are intended to be released at any point during their identified use.

REACH thus regulates substances on their own or in preparations, and substances in articles, resulting in a broad legislative scope with onerous implications for manufacturers or importers.

1.2 Overview of the REACH Registration process

The following steps from 1 to 5 must be followed by legal entities wishing to register existing substances (also called "phase-in substances") to comply with the REACH Regulation.

1. Pre-registration

All existing manufacturers or importers of phase-in substances should have submitted a pre-registration before 1 December 2008. Late pre-registrations may be submitted by new manufacturers or new importers of phase-in substances at any time until 1 year prior to the relevant full registration deadline.

Basic data on the legal entity wishing to pre-register, substance identity and the tonnage band the substance will be in is required for pre-registration. See Section 4.1 for further information.

2. Registration

The following steps describe each major stage of the REACH registration process:

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 ECHA.

See Sections 4.2 to 4.7 for further information.

Pre-registration and registration, as outlined in steps 1 and 2, will follow the timetable in Figure 1, with registration deadlines dependant on the tonnage band and for certain chemicals the classification of the substance.

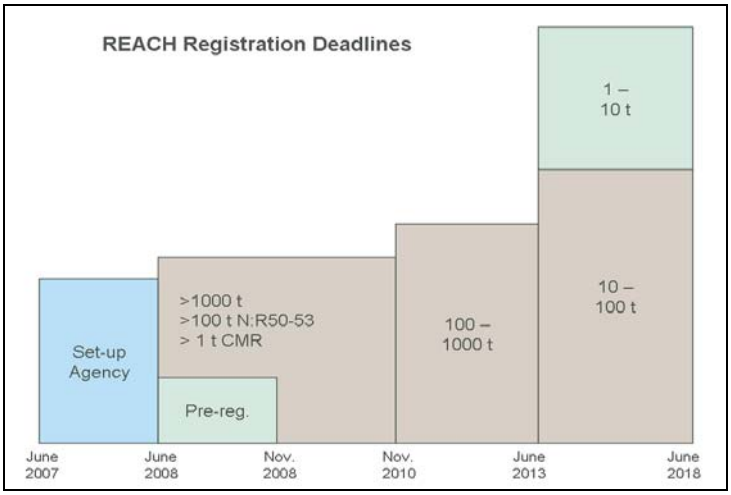

Figure 1 - REACH Regulation registration timeline for each tonnage band.

3. Evaluation

Although ECHA will conduct a “completeness” check on every dossier submitted under REACH, only a small percentage of dossiers will actually undergo a full evaluation by the Agency.

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

See Section 4.8 for further information.

4. Authorisation

As part of the substance evaluation process in Step 3, certain substances will be identified as being of very high concern, and may then be listed on REACH Annex XIV, the list of substances subject to Authorisation.

To continue to manufacture, import or use substances subject to Authorisation, an Authorisation application must be submitted to ECHA.

See Section 4.9 for further information.

5. Restriction

Any substance on its own, in a preparation or in an article, for which REACH Annex XVII of REACH contains a Restriction, shall not be manufactured, placed on the market, or used unless it complies with the conditions of that Restriction. See Section 4.10 for further information.

Aside from these main steps in REACH, other "information supply" requirements apply where ECHA has to be notified of activities in certain circumstances:

- When product and process oriented research and development (PPORD) is taking place for a new use of an existing substance (not covered in an existing registration) or PPORD is being done on a new substance;

- When a substance subject to Authorisation (REACH Annex XIV of REACH Regulation) within an article at >0.1% w/w, and the total amount of the substance of very high concern is sold across all of the product range of a company, in quantities totalling more than 1 tonne (Article 7(2)). Suppliers of articles containing a substance subject to Authorisation at >0.1% w/w must also provide information on the safe use of the article to customers and further downstream consumers (Article 33).

2 INTRODUCTION TO THE DEFENCE EXEMPTION

The UK MOD is committed to complying with the REACH Regulation, but where it is necessary in the interests of defence, the Secretary of State (SofS) 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.

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 Defence Equipment and Support (DE&S).
- Exemptions will be reviewed after a pre-determined period of time.
- An annual report of exemptions in place will be submitted to the UK Competent Authority (CA) for REACH and SofS.

SofS's Policy Statement on Safety, Health and Environmental Protection stipulates that where the MOD has been granted specific exemptions, disapplications or derogations from legislation, international treaties or protocols, the MOD will undertake 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 use a management system to mirror the principal functions of the REACH regime. This system will be administered on behalf of the MOD by DE&S. Applications for an exemption will be scrutinised by a senior board within DE&S that will make recommendations to the SofS for the granting of a certificate on a case-by-case basis.

Certificates will be time-limited, depending on the substance and/or use, and reviewed regularly. An annual report will be provided to the SofS and the UK REACH CA (the Health and Safety Executive, HSE). The exemption certificates will be linked to the appropriate safety and environmental information containing the same level of detail that would be covered under the normal REACH arrangements.

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

2.1 Identifying REACH Registration or Exemption Obligations

As the MOD is considered one legal entity under REACH, all quantities of manufactured or imported chemical substances must be cumulatively reported and used when the MOD is

identifying its REACH obligations. Therefore the MOD must obtain information from all PTs in order to keep accurate records of internal manufacturing and importing activities. This will help determine the appropriate tonnage threshold for the MOD for registration and help to ensure no substance meeting the 1 tonne per year threshold, across the MOD as a whole, will be missed, see Section 3.

PTs should use the following prompts when deciding if they need to report information pertaining to REACH or exemptions from REACH for defence[1]:

a. **If you MANUFACTURE any substance(s) in quantities greater than or equal to 5 kg per year, please report to DE&S;**

b. **If you IMPORT any substance(s) in quantities greater than or equal to 5 kg per year, please report to DE&S;**

c. **If you IMPORT an article from outside the EU, please report any chemical substances contained in this article, that are imported in quantities greater than or equal to 5 kg per year, and that meet the requirements for registering substances within articles detailed in Section 8 of this document.**

This reporting of manufacture and importing activities must be conducted on an annual basis, using the standard format spreadsheet to be circulated to PTs prior to the deadline. **The deadline for all PTs to submit their reports is 31st October of every year.** Please contact destech-qsep-REACH@MOD.uk for further information.

Where any of the above situations apply, this document details the internal processes required to achieve the REACH requirements.

It is essential that PTs seek assurance from their suppliers to ensure continued supply of products after REACH pre-registration and full registration. Guidance on this issue is presented in Section 8.

2.2 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 are obtained in the interests of defence;
- UK based Defence Industry Partners that supply the EU defence community with items that come under the remit of REACH and are supplied in the interests of defence;
- Visiting forces in the UK;
- Permanent British bases overseas.

The MOD, with assistance from Department for Environment, Food and Rural Affairs (DEFRA) and the HSE, will ensure that the attention of the relevant authorities is drawn to REACH obligations and compliance requirements. In principle United States (US) military bases in the UK would be covered by the same exemptions and MOD administrative arrangements as UK facilities.

[1] Defence Industry Partners shall adhere to the 1 tonne per year trigger volume per legal entity, as stipulated in the REACH Regulation.

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

The exemption process will be subject to scrutiny from the HSE as the REACH CA in the UK. 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 Regulation will apply. The scheme cannot be used to 'hide' substances that should be covered under other legislative controls, 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 are also commercially available in the UK, and the exemption may not be used by defence industry companies to avoid their own compliance obligations.

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

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

2.4 Timing

The SofS's power to grant an exemption is not time limited. However, the certificates of exemption granted by the SofS will take effect immediately upon signing. The certificates will be valid for a pre-determined period of time; a review will be undertaken when the certificate expires. The SofS may vary or revoke the certificates of exemption at any time by a certificate in writing.

2.5 Exemption Criteria

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

An exemption certificate is the internal MOD equivalent of a REACH Registration number, and, if granted, the process detailed in Section 5 will need to be followed. This certificate will have an expiry date of 2 years, and will be reviewed at the end of each validity period. The completed chemical assessment for the MOD internal equivalent of REACH registration (see Section 5) must be submitted to the management board by the REACH phase-in deadline equivalent to the MOD tonnage band (see Figure 1).

The MOD has identified the articles within the REACH Regulation that the defence exemption will cover (see Section 9). Substances that would be subject to Authorisation (Article 56) or Restriction (Article 67) would be included in that list.

A substance will be considered eligible for an exemption certificate if the substance and/or its use are classified as "Official-Sensitive" or above. (MOD Classification Policy is described in Joint Service Procedure (JSP) 440, Part 4, Section 1). However, a substance that is contained in a "Official-Sensitive" process or system may not be enough to warrant exemption, so a short business case detailing the reason for the need for exemption must also be included. Substances subject to Authorisation under Title VII of REACH (a current list of authorised chemicals is presented in REACH Annex XIV) and substances whose uses are restricted under REACH, such as asbestos, under Title VIII of REACH (a current list of

restricted chemicals is presented in REACH Annex XVII), may also be eligible for exemption. Details on the exemption application processes are available in Sections 4.9 and 4.10 respectively.

2.5.1 Applying for an exemption

For substances supplied by Defence Industry Partners, an application for exemption should be completed by Defence Industry Partners and submitted to PTs. PTs will screen all applications prepared by industry prior to submission to the REACH team in DE&S.

In addition, PTs must submit their own exemption applications for substances that they manufacture or import. PTs must also include accurate information on the tonnage of each substance manufactured or imported so a cumulative quantity for the MOD can be determined.

Applications for exemption certificates for existing chemicals should have been made by PTs (where the PT manufactures or imports), or Defence Industry Partners, in conjunction with PTs, prior to the end of the REACH pre-registration phase. Any new applications for a defence exemption or for amendments to existing exemptions should be made using the process described below.

Information to be included in the exemption application:

- The identity of the applicant(s) (PTs and Defence Industry Partners where applicable);
- The identity of the substance (a pseudonym is acceptable where it is necessary to protect the security classification provided it can be linked to the original identity through an accompanying reference document of higher security classification);
- The UK Protective Marking Classification (JSP 440, Part 4, Section 1);
- The annual tonnage of manufacture or import of the substance;
- A business case for exemption, including the articles of the REACH Regulations from which exemption is sought.

The exemption application form and guidance notes are available from the MOD internet site, internally via the REACH (DE&S) intranet site or by contacting destech-qsep-REACH@MOD.uk.

Should the exemption application for the chemical substance be unsuccessful, it will then be necessary to move forward with registration of the substance under REACH. If the chemical is a “new substance” under REACH, the chemical may not be manufactured or imported until full registration is complete. If the chemical is a “phase-in” substance, the MOD may opt to submit a late pre-registration and enter the phase-in period. This is only possible if the chemical substance has not been manufactured or imported by the MOD in a quantity greater than or equal to 1 tonne per year on or after June 2007. This late pre-registration allows manufacture or import of the substance to continue. If the chemical has been manufactured or imported by the MOD on or after June 2007, the MOD must cease all manufacture or import activities until a full registration has been completed.

All exemption application forms should be completed and submitted by PTs via the MOD REACH helpdesk (destech-qsep-REACH@MOD.uk).

2.5.2 The Exemption Certificate

The certificates will show:

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

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

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

The exemption certificate will be backed up with technical data in an REACH 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 throughout the supply chain.

Chemicals that are subject to Authorisation and Restrictions will also require a certificate if an exemption is applied for and granted.

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

The HSE will, in the normal course of duty, monitor implementation of the REACH Regulation, and will expect to find demonstrable evidence of compliance with all appropriate legislation, including the conditions detailed in the SofS's certificates of exemption. SofS's exemption does not impede the HSE's powers to enforce the Regulation and/or action for non compliance with the Regulation. All recipients of exemption certificates must provide a sanitised copy to the CA upon request, to ensure that security classification is not compromised. PTs should be careful to ensure only appropriate information is disclosed to the HSE during any active enforcement action on your PT.

For assistance with external enforcement action, please contact destech-qsep-REACH@MOD.uk.

Defence Industry Partners should refer the HSE, or relevant body, to the MOD/PT if they are subject to enforcement action and manufacture or import exempt substances. Exemption certificates are Official-Sensitive and will not generally be available to Defence Industry Partners.

Where applicable, the MOD will act to initiate "mini-SIEFs" (Substance Information Exchange Forums) within the defence industry and are committed to upholding the principles of REACH by obtaining substance data with minimal animal testing. The sharing of animal test data with external stakeholders (as required by REACH) will be considered on a case-by-case basis, and complied with where national security is not an issue.

If exemption is not granted, the process required for registration under REACH will apply as described in Section 4.

3 HOW TO BE REACH COMPLIANT WITHIN THE MOD

PTs should first consider whether the substances manufactured or imported by the MOD or Defence Industry Partners are eligible for exemption from REACH; if not the normal REACH process will be followed.

If there are no valid grounds for exemption (i.e. exemption is not sought or the application for exemption is rejected) then the MOD and/or Defence Industry Partners must participate in REACH activities, working towards registration according to the existing REACH timetable. If the chemical is a "new substance" under REACH, the chemical may not be manufactured or imported until full registration is complete.

For substances on the candidate list for Authorisation, their manufacture or import in any quantity or their presence in articles will have to be notified to ECHA if they are used in the articles at greater than 1 tonne per year and the substance composes more than 0.1 % (w/w) of the article. In addition, substances also listed in REACH Annex XVII will have their use restricted. Exemptions for defence by PTs for authorised or restricted chemicals will follow a similar format to general REACH exemptions, using the same application forms. Refer to Sections 4.9 (Authorisation) and 4.10 (Restriction) for further information on these processes.

Figure 2 presents a flow diagram of the decisions that should be made when applying for an exemption from REACH and acts as a reference for directing the reader to the appropriate process flowchart.

Figures in Sections 4 to 6 present subsequent process flow charts that are designed to act as guidance for Directors and PTs to conduct the correct processes for REACH compliance. The flow charts are intended for PTs working towards exemption or registration under the REACH Regulation.

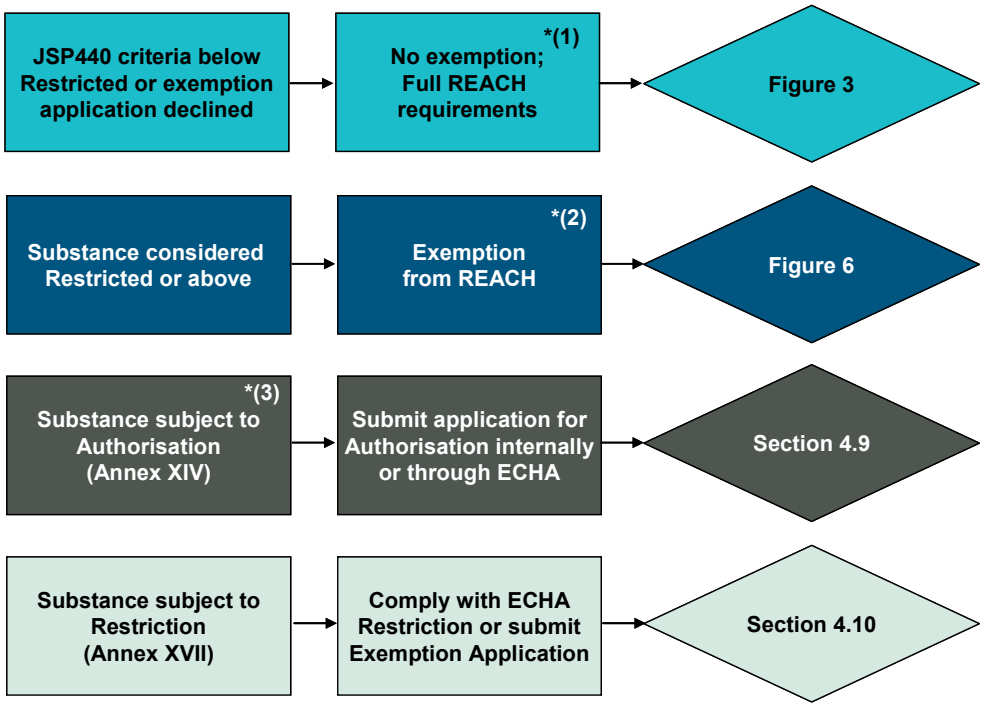

Figure 2 - Guidance on determining which MOD REACH process will be required for exemption or Authorisation.

Notes for Figure 2:

1. Where there is no issue of sensitivity associated with the substance, or where previous applications for exemption were unsuccessful, the substance will require REACH registration.

2. Where a substance is considered Defence Sensitive (and is Official-Sensitive or above – see JSP 440, Part 4, Section 1), the Director (or equivalent), PT and Defence Industry Partner may decide to apply for full exemption from REACH (i.e. exemption from disclosing both the substance and its use), for all parts of the REACH regulation, as applicable to the substance.

3. ECHA published a candidate list for substances that may be subject to Authorisation (and potentially restricted use) in October 2008 followed by a prioritisation process by the authorities and a public consultation. Once a substance is subject to Authorisation, the application for Authorisation will have to be submitted to ECHA, or internally to DE&S if the substance is considered defence sensitive and an exemption from REACH is sought. See Section 4.9 for further details on Authorisation.

4 COMPLIANCE PROCESS 1: REGISTRATION

Registration of a substance with ECHA is an administrative procedure which involves the compilation of a TD/ CSR, the content of which will depend on the tonnage band and hazardous nature of the substance. There are several methods available for the collection of information and these are outlined below.

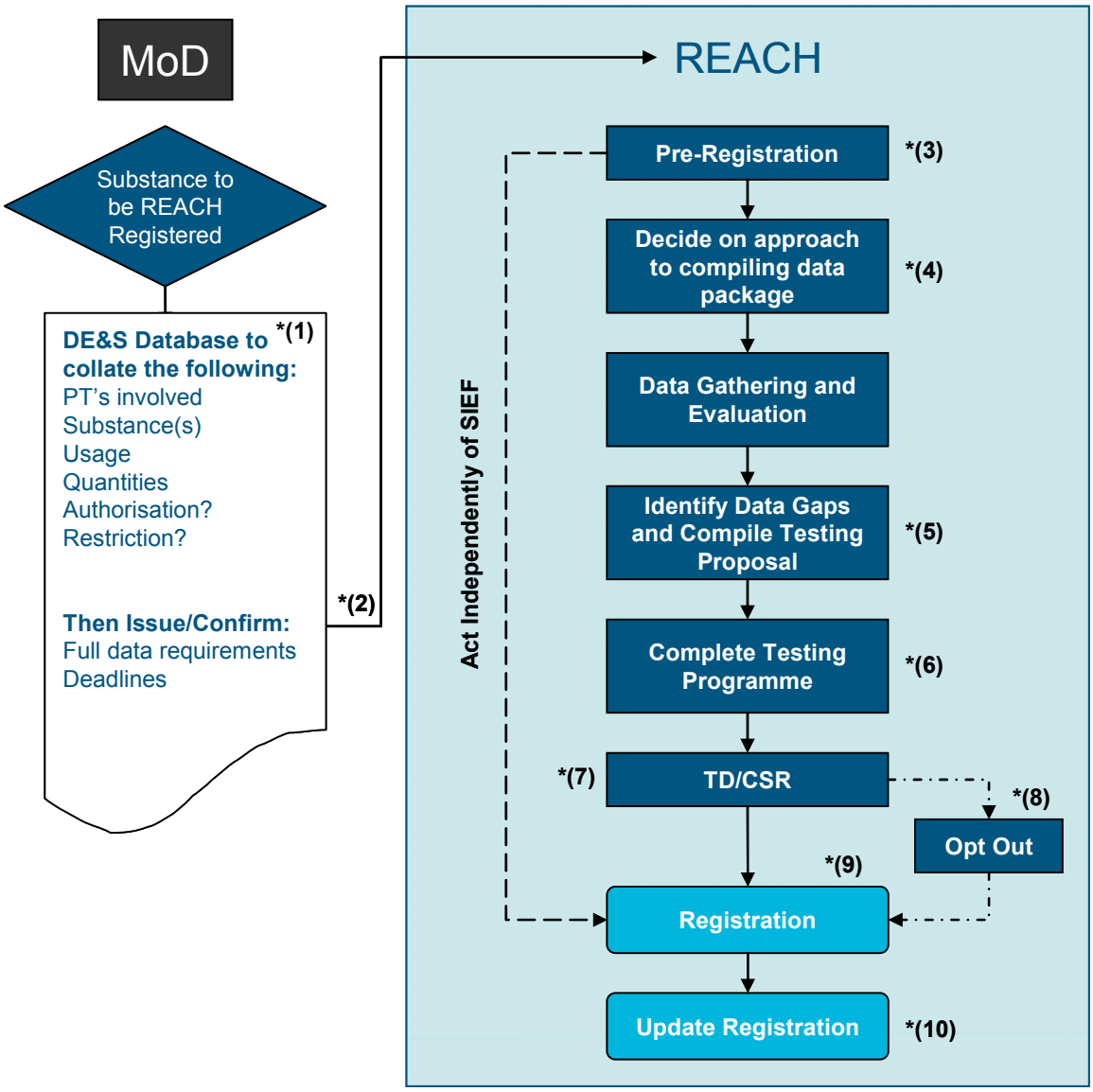

Figure 3 - Processes required for achieving REACH compliance when registering a substance under the REACH Regulation.

Notes for Figure 3

1. PTs or Defence Industry Partners that manufacture/import the same substances will be informed via the DE&S database advising them on their requirements under REACH. For PTs, the cumulative annual tonnage of a substance throughout the MOD and subsequent data requirements will also be confirmed.

2. The MOD may appoint a representative to carry out REACH registration duties.

3. The pre-registration dossier for an existing substance(s) should have been submitted to ECHA before the 1 December 2008 deadline. For substances that were manufactured or imported for the first time after this deadline, a late pre-registration may be submitted. See Section 4.1 for further information.

4. The MOD will decide on the most efficient approach to gather information on the substance. This is described in further detail in Section 4.2.

5. Where data gaps are identified after all avenues of data sharing/acquisition have been exhausted, a proposal for further testing will be prepared by the SIEF members for submission to the ECHA for any vertebrate data required.

6. The required testing will be completed either independently or arranged by the SIEF.

7. Once all the data and information has been gathered, the compilation of the TD will be carried out in International Uniform Chemical Information Database (IUCLID) 5 format, and if in quantities greater than 10 tonnes per annum, the CSR will also be collated.

8. If the MOD does not agree with the decisions of the SIEF regarding the registration dossier, he may enact the “opt-out” clause and submit an individual registration instead of a joint registration with other SIEF members.

9. The completed TD and CSR are then submitted to the ECHA as a registration dossier via the REACH-IT system.

10. Updating of a registration will occur when new information on a substance becomes available, or at the request of the European Commission.

4.1 Pre-Registration

The option to pre-register was designed to allow manufacturers or importers of “phase-in substances” (substances already manufactured or placed on the market in the EU) to benefit from extended registration deadlines. The extended deadline for registration is dependant on the tonnage and the classification of the substance (e.g. Carcinogenic, Mutagenic or toxic to Reproduction (CMR) or R50-53: very toxic to aquatic organisms). All substances on the European List of Notified Chemical Substances (ELINCS) were deemed as already registered.

The pre-registration function was available between June and December 2008, coming to an end on the 1st December 2008. It is now available once again, but only for late pre-registration purposes (where previous manufacture occurred before 1st June 2007 and/or the first manufacture or import of the substance occurs after 1st December 2008).

The number of pre-registrations was heavily underestimated by ECHA, with nearly 2.7 million pre-registrations for 150,000 substances being recorded. Phase-in substances that have not been pre-registered are illegal to market until such time that full registration has been completed.

4.2 Information Gathering Approach for Registration

The flow diagram presented in Figure 4 demonstrates the options that are available to the MOD or Defence Industry Partners for the data gathering and evaluation phase of REACH registration. Information may be derived internally by testing and computer modelling (i.e.

Quantitative Structure-Activity Relationships ((Q)SAR) and Read Across referred to in Section 4.2.1), or externally within the SIEF.

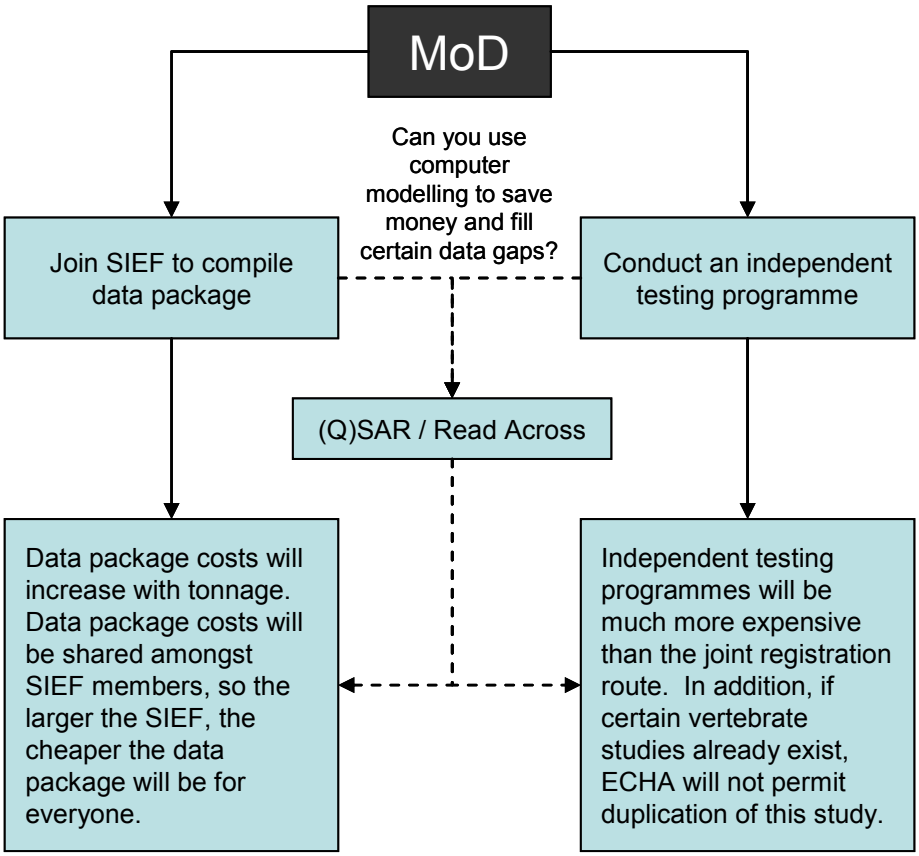

Figure 4 - Potential approaches to information gathering under REACH.

There are two main options available to the MOD for gathering data for preparation of the REACH registration dossier, and a third option for filling data gaps. These are:

a. Join the relevant SIEFs to obtain data and share the associated costs of registration;

b. Conduct an independent registration and full testing programme.

Experimental data will be collated from available sources and reviewed, or obtained via a strategic testing programme, either independently or in conjunction with the SIEF.

The third option is the use of computer models, such as (Q)SAR, to fill certain data gaps. The use of computer models is being encouraged by the regulators to reduce animal testing and thus may provide a cheaper and more ethical approach to producing certain endpoints. It is not advisable to use models to produce the majority of the data package used for the registration dossier, as the models themselves rely on “accurate experimental data” when producing results for different endpoints.

4.2.1 (Q)SAR/ Read Across

There are two major forms of computer modelling that are recommended in REACH; (Q)SAR and Read Across.

(Q)SAR programs are designed to use physicochemical/ structural information to predict chemical properties.

The other form of computer modelling is Read Across, which predicts chemical properties based on experimental data available on similar substances. In order to use modelling as a prediction tool, the information base-set from which the calculations are made must be reliable.

In the case of both (Q)SAR and Read Across, the information already available on the substance structure and properties must be sufficient to allow comparison with other substances.

Whilst computer modelling may be useful in some instances, it is important to consider the reliability of the data when considering the information for regulatory purposes.

4.3 Testing programme

The size and complexity of the testing programme will depend on which REACH tonnage band the substance is being registered under, and the volume of data already available for use in the dossier.

General lists of data endpoints that are required for registration under the REACH tonnage thresholds are presented in REACH Annexes VII to X of the REACH Regulation. However, every substance registered will not require all data endpoints listed in the REACH REACH Annexes, as certain intrinsic properties of the chemical make some of the pre-requisite tests irrelevant or impossible to perform. In addition, or other similar, equivalent or more detailed data endpoints may already exist. In this situation, a suitably qualified person can write “data waivers” that will justify why these data endpoints have been excluded and incorporated as part of the TD (see Section 4.4).

4.4 Technical Dossier (TD) compilation

A TD is a necessary requirement for all substances under REACH across all tonnage bands (Article 10 of REACH).

The TD 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 1-10 tonne per annum threshold, the TD shall also contain exposure related information for the substance;
- The “end product” TD must be in IUCLID 5 format.

4.5 Chemical Safety Report (CSR) compilation

A Chemical Safety Assessment (CSA) must be carried out for all chemicals that exceed the 10 tonne per year threshold. The CSA will be documented in the CSR which 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 (Article 10 of REACH).

The CSA will consist of three main components:

- Human health hazard assessment;
- Environmental hazard assessment;
- Persistent-Bioaccumulative-Toxic/ very Persistent-very Bioaccumulative (PBT/vPvB) assessment.

The basic process designed for performing the CSA is outlined in Figure 5.

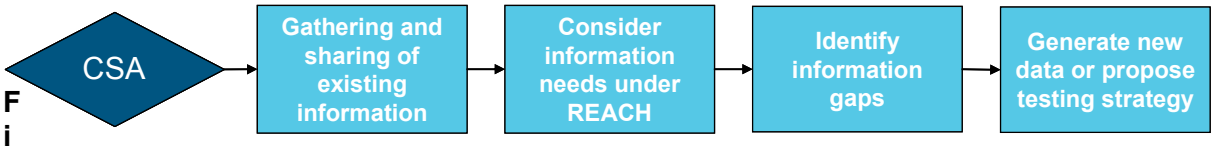

Figure 5 - Flowchart demonstrating CSA process.

Once the CSR is complete, all Safety Data Sheets should be reviewed and updated/extended as required by the Regulation.

4.5.1 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;
- CMR effects.

Based on all the available information, other effects shall be considered when necessary. The hazard assessment will comprise the following 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.

4.5.2 Environmental Hazard Assessment

The environmental hazard assessment will assess the available ecotoxicology and environmental fate data.

The environmental hazard assessment will comprise the following steps, each of which make up a significant component of the CSR:

- Evaluation of data;
- Classification and labelling;
- Hazard assessment for all environmental compartments;
- Derivation of the Predicted No-Effect Concentration (PNEC);
- Environmental exposure assessment.

4.5.3 PBT/ vPvB/ other toxicity criteria

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

PBT properties of the substance have been focussed on in the legislation to encourage industry to assess the potential long-term impacts of substances, in a move to avoid past pollution events that could have been prevented using these assessments.

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.

The criteria for PBT and vPvB are outlined in Table 1.

Classification	Property	Criteria
PBT	Persistence	Half-life in marine water is > 60 days, or
		Half-life in fresh or estuarine water is > 40 days, or
		Half-life in marine sediment is > 180 days, or
		Half-life in fresh or estuarine sediment is > 120 days, or
		Half-life in soil is > 120 days
	Bioaccumulation	Bioconcentration Factor (BCF) is > 2000
	Toxicity	The long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01ng/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.
vPvB	Persistence	Half-life in marine, fresh or estuarine water is > 60 days, or
		Half-life in marine, fresh or estuarine sediment is > 180 days, or
		Half-life in soil is > 180 days
	Bioaccumulation	Bioconcentration Factor (BCF) is > 5000

Table 1 - Showing criteria for determining PBT/ vPvB properties of substances.

4.5.3.1 Other Toxicity Criteria: CMR

Substances may be classified as CMR using the criteria presented in Table 2.

Classification	Level of hazard		
	Category 1	Category 2	Category 3
Carcinogens	For substances and preparations that are known to be carcinogenic to humans	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.	Substances and preparations which are a concern to humans because of possible carcinogenic effects, but for which available information is insufficient to classify them as Category 2.
Mutagens	Substances and preparations that are known to be mutagenic to humans	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.	Substances and preparations which are a concern to humans because of possible mutagenic effects, but for which available information is insufficient to classify them as Category 2.
Reprotoxins	Substances and preparations that are known to be toxic to reproduction to humans	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.	Substances and preparations which are a concern to humans because of possible toxic effects to reproduction, but for which available information is insufficient to classify them as Category 2.

Table 2 - Criteria for substances classified as CMR.

4.6 Risk Characterisation and Management

The information from the human and environmental assessments will be used to quantify, where required, human exposure, Predicted Environmental Concentrations (PECs) and PNECs for the purpose of calculating the chemical risk characterisation ratio (RCR). Using the data chosen for the registration, the risk assessments will then be conducted for each exposure scenario generated.

If a situation should arise where the RCR is greater than 1, further action will be required and the risk assessment refined.

There are several options available to the registrant at this stage. It may be possible to reduce the RCR by using more reliable data, as the initial assessment may be based on "worst case" assumptions. Therefore the registrant may be able to demonstrate that the substance is not as hazardous as previously assumed, increasing the PNEC.

If it is not possible to reduce the RCR through testing, the other option is to reduce potential exposure by introducing Risk Management Measures (RMMs). These are a set of processes that are put in place to reduce human or environmental exposure, which therefore leads to the substance posing a lower risk. This presents the possibility of reducing the performance or usability of the chemical or product, and should be considered carefully prior to implementing RMMs.

4.7 Submission of a Substance Registration

After completion of the TD and the CSR, the Registration Dossier then needs to be submitted to ECHA (the Agency) via REACH-IT prior to the relevant full registration deadline (Articles 10-14 of REACH). Once submitted, the Agency will send the registrant a unique submission number.

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

- The technical completeness check;
- 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 where the manufacture takes place or the importer is established (for example, the HSE in the UK), that the registration has been submitted. All the relevant information relating to the registration will be available on the ECHA website.

Once complete, a registration has no pre-determined period of validity. However, it is the responsibility of the registrant to ensure that the dossier is updated when necessary. For example if a new registrant submits additional information on a substance already registered.

4.8 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:

a. **Dossier Evaluation -** 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.

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

4.9 Authorisation

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

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

- CMR category 1 or 2 in accordance with Directive 67/548/EEC;
- PBT;
- vPvB;
- Substances (such as those having endocrine disrupting properties or those having PBT and vPvB properties, which do not meet the requirements of the above categories) for which there is scientific evidence of probable serious effects to human health or the environment (Article 59).

There are four key steps in the Authorisation process:

1. Identification of substances of very high concern (SVHCs). Substances of very high concern will be identified on the basis of criteria previously described. Either the Member State CAs or ECHA will prepare a dossier in accordance with REACH Annex XV. Interested parties can comment on substances for which a dossier has been

prepared. The substances identified in this process will be placed on the "candidate list".

2. Prioritisation Process. Substances on the "candidate list" are prioritised to determine which ones should be subject to Authorisation. After the selection of these substances, decisions will be made on the "sunset date" by when a substance can no longer be used without Authorisation, and on any specific uses of the substances which do not require Authorisation due to existing controls or legislation.

3. Applications for Authorisation. Applications for Authorisation need to be made within the set deadlines for each use that is not exempted from the Authorisation requirement. The CSR (unless already submitted as part of Registration) and an analysis of possible alternative substances or technologies must be included. Planned or current research and development to develop such alternatives should be included. Further information may include substitution plan or a socio-economic analysis of the substance.

4. Granting of Authorisations. Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. If the risk is not adequately controlled, the substance may still be authorised if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternatives. All Authorisations will be reviewed after a certain time-limit which will be decided on a case-by-case basis. A substance subject to Authorisation will not be authorised for general purposes, but specific uses at specific quantities will be authorised based on an application made by an EU legal entity. Authorisation is necessary for every use and is independent of the quantity of the substance involved. Authorisation is granted by ECHA on a case by case basis and for a pre-determined time period.

4.9.1 Application for Authorisation

There are two ways to apply for an Authorisation:

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

b. 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 downstream users (DUs) of the substance and may be made by one or several applicants, for one or several uses (Article 62). A fee must be paid accompanying each application. Further information is available in REACH Annex VI of EC Regulation 340/2008 on fees and charges payable to ECHA pursuant to REACH.

The application for Authorisation shall include all relevant documentation, including an analysis of alternatives and where suitable alternatives are available, substitution plans including a timetable for proposed action by the applicant. Research and development plans may also be part of the application, if appropriate (Article 62(4)).

The application may include a socio-economic analysis and a justification for not considering risks to human health and the environment in specific cases (Article 62(5)).

4.9.2 Application for Exemption from Chemical Authorisation

Applications for exemption from the Authorisation of substances under REACH should be made using the same process described in Section 2.5.1.

In addition to the supporting business case required for normal exemptions, an analysis of possible alternative substances or technologies including research and development that is foreseen or already in progress to develop such alternatives should also be supplied. This requirement aligns with the REACH Authorisation application requirements, described in Section 4.9.1.

As with general exemption applications, successful applicants for Authorisation exemption must demonstrate that the risk from the use of this substance is properly controlled throughout its life cycle, by preparing an equivalent to a REACH dossier (see Section 5).

The exemption application form and guidance notes are available from the MOD internet site, internally via the CESO (DE&S) intranet site or by contacting destech-qsep-REACH@MOD.uk.

4.10 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.

4.10.1 Application for Exemption from Chemical Restrictions

Applications for exemption from the Restrictions placed on substances listed in REACH Annex XVII of REACH should be made using the same process described in Section 2.5.1.

In addition to the supporting business case required for normal exemptions, an analysis of possible alternative substances or technologies including research and development that is foreseen or already in progress to develop such alternatives should also be supplied. As with general exemption applications, successful applicants for Restriction exemption must demonstrate that the risk from the use of this substance is properly controlled throughout its life cycle, by preparing an equivalent to a REACH dossier (see Section 5).

Should a substance that has been exempted from Authorisation be moved to REACH Annex XVII, the existing exemption should be modified for exemption from Restriction under REACH at the next certificate review.

The exemption application form and guidance notes are available from the MOD internet site, internally via the REACH (DE&S) intranet site or by contacting destech-qsep-REACH@MOD.uk.

4.11 Substance Safety Data Sheets (SDS)

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 substance CSA. 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 COMPLIANCE PROCESS 2: EXEMPTION

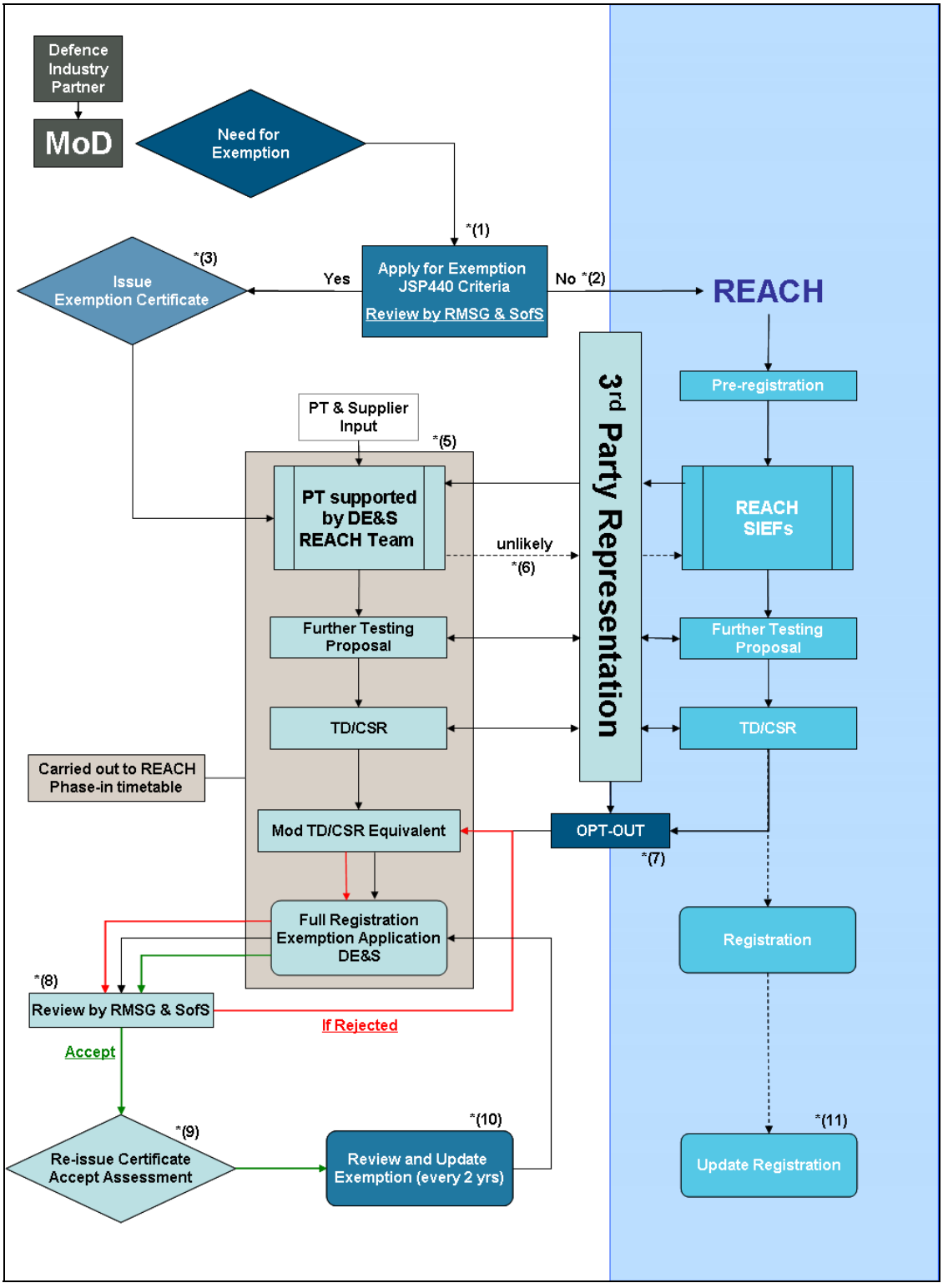

Figure 6 - Processes required for achieving compliance when applying for exemption from REACH.

Notes from Figure 6:

1. Applications for an exemption certificate for a phase-in substance should have been made by the MOD prior to the pre-registration deadline (1st December 2008). For substances that are manufactured or imported for the first time after the 1 December 2008, they may benefit from using a late pre-registration facility, described in Section 4.1. New applications for exemptions for substances that will exceed the 5 kg value for the MOD, and the 1 tonne threshold for Defence Industry Partners should be made as soon as possible, see Section 2.5.

2. After review, DE&S may deem that the application is not valid for exemption and the PT and/or Defence Industry Partner must arrange for late pre-registration, if applicable, and/or registration under REACH. Applications for exemption may be rejected for not meeting the requirements for defence exemption as outlined in the Statutory Instrument.

3. The exemption certificate (valid for 2 years after each issue) will be issued under Statutory Instrument 2008 No. 2852. Please note that the internal process described in Figure 6 must be completed by the equivalent REACH deadline in Figure 1.

4. The internal processes analogous to REACH processes may then be carried out within the MOD. This may also involve a Third Party Representative (TPR) joining the REACH SIEF for a substance for the purpose of acquiring data, thus protecting the MOD's identity.

5. Although unlikely to happen for security reasons, there is the possibility for suitably insensitive data to be offered to SIEFs for financial recompense.

6. Towards the end of the SIEF, the TPR can enact the opt-out clause. The "opt-out" clause essentially releases you from the obligation of joint registration, and usually the party opting-out will register separately from the rest of the SIEF members. The TPR may then return to the MOD with all data and information required for an internal equivalent of a REACH registration dossier.

7. A review for completeness will then be carried out by DE&S, who will assess that all the relevant data and information required by the REACH regulations are held in the MOD registration. If the requisite data and assessments have not been completed then the application will be rejected.

8. If successful, the certificate will be re-issued. A review of the certificate will occur regularly and may require resubmission of the registration exemption application if there are alterations such as new data or information becoming available on the substance, or achieving a new tonnage threshold. If rejected, the application must be amended and resubmitted.

9. To ensure that the exemption certificate contains up to date information, a review of the exemption certificate will be conducted every 2 years. This will be a simple task of checking that the substance has not been placed on the list of substances that require Authorisation. This review will also be used to update the data held on the internal database should any new data become available, or further data is added as a new tonnage threshold is achieved. Further guidance on the review periods will be given on a case-by-case basis for each exemption.

10. REACH requires the TDs and CSRs to be live documents being updated as new data become available, or at the request of the European Commission.

6 SUBSTANCES CURRENTLY UNDER PRODUCT AND PROCESS ORIENTED RESEARCH AND DEVELOPMENT (PPORD)

To carry out scientific research and development on a substance, or PPORD, certain actions will be required under REACH.

First, it is essential to understand the difference between scientific research and development and PPORD:

a. **Scientific research and development** means "*any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year".*

b. **PPORD** is defined as "*any scientific development related to product development or the further development of a substance, on its own, in a preparation or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance"*.

6.1 Scientific Research and Development

As REACH defines scientific research and development as involving substances under the 1 tonne per year threshold, there are no requirements for registration under REACH. This dispensation from REACH also applies for substances subject to Authorisation and Restrictions (Article 56(3)).

Nevertheless, the manufacturer or importer of a substance for the purpose of research and development, who places the substance on the market, needs to notify the Agency. The notification will require information related to its classification and labelling if the substance meets the classification as dangerous (Article 113). This is required by the 30th November 2010 or, for substances not yet on the market at that date, as soon as the substance is on the market (Article 116).

Where appropriate, suppliers of such substances might need to provide a safety data sheet or other relevant information to the users of the substance (Article 116).

6.2 PPORD

When carrying out PPORD on substances below the 1 tonne per year threshold, the requirements are the same as for scientific research and development (Section 6.1), except that Authorisations and Restrictions may apply. If Authorisations and Restrictions do apply to the PPORD substance, the company involved in the research and development should check REACH Annexes XIV and XVII to see if the Authorisations and Restrictions also apply to PPORD.

Substances manufactured or imported on their own, in preparations or in articles in a quantity greater than or equal to 1 tonne per year for the purpose of PPORD can be exempt from the requirements of REACH registration for a period of up to 5 years. To achieve this exemption, a company must submit a PPORD notification to ECHA, and the exemption may be extended for another 5 years if approved at the end of the first 5 years. If Authorisations and Restrictions do apply to the PPORD substance, the company involved in the research and development should check REACH Annexes XIV and XVII to see if the Authorisations and Restrictions also apply to PPORD.

6.3 Notification for PPORD

Where a PT or Defence Industry Partner wishes to conduct PPORD on a substance manufactured or imported above the 1 tonne per year threshold, a notification must be submitted to ECHA. If, however, the PPORD is considered Defence Sensitive, an application for exemption from this requirement should be submitted to DE&S.

In either case, the application should include the following information:

- The identity of the manufacturer or importer of substances, preparations or articles;
- The identity of the substance(s);
- The classification of the substance(s);
- The estimated quantity of the substance(s);
- The list of customers if the substance is placed on the market.

If this application is to be submitted to ECHA, it will have to be accompanied by the relevant fee which may be found in the Guidance on REACH fees on the ECHA website.

Applications for exemption from the requirements of a PPORD notification should be made using the same process described in Section 2.5.1. Please include the information described above in the application form.

The exemption application form and guidance notes are available from the MOD internet site, internally via the REACH (DE&S) intranet site or by contacting destech-qsep-REACH@MOD.uk.

7 SUBSTANCES CONTAINED IN ARTICLES

Substances contained in articles have slightly different requirements under REACH than substances on their own or in preparations.

An article is defined as "*an object for which the shape, surface or design determines its function more than its chemical composition*", and is of particular concern when there is intended release of a substance, for example a welding rod that is consumed during use and transportation protection waxes used in pipe ends that must be removed prior to use of the pipes.

Registering substances in articles is obligatory only if the following conditions are met:

- The substance is intended to be released from the article during normal and foreseeable conditions of use;
- The total amount of the substance present in the article with intended release is produced/imported at a quantity greater than or equal to 1 tonne per year.

In addition, ECHA may decide that the producer or importer of an article must register a substance, if the amount of the substance exceeds 1 tonne per year even if there is a suspicion that it may be released from the article resulting in risks to human health or the environment during its life cycle (including disposal).

Notification is required for substances contained in articles when the substance is placed on the candidate list for Authorisation, and both of the following conditions are met:

- The substance present in the article is produced or imported in a quantity ≥1 tonne per year;
- The substance is present in the article above a concentration of 0.1 % (w/w).

Notification will not be required if the producer or importer can exclude exposure of the substances to humans and the environment during normal and foreseeable conditions of use (including disposal) or if the substance has already been registered for that use.

If an article is produced within the EU, all the substances composing the article should already be registered. The main concern for PTs and Defence Industry Partners are articles imported into the EU in the finished state, where component substances may not be registered in that supply chain.

Figure 7 presents the process for determining the required actions to gain REACH compliance for substances in articles, either through ECHA or internally through the MOD (exemption certificate).

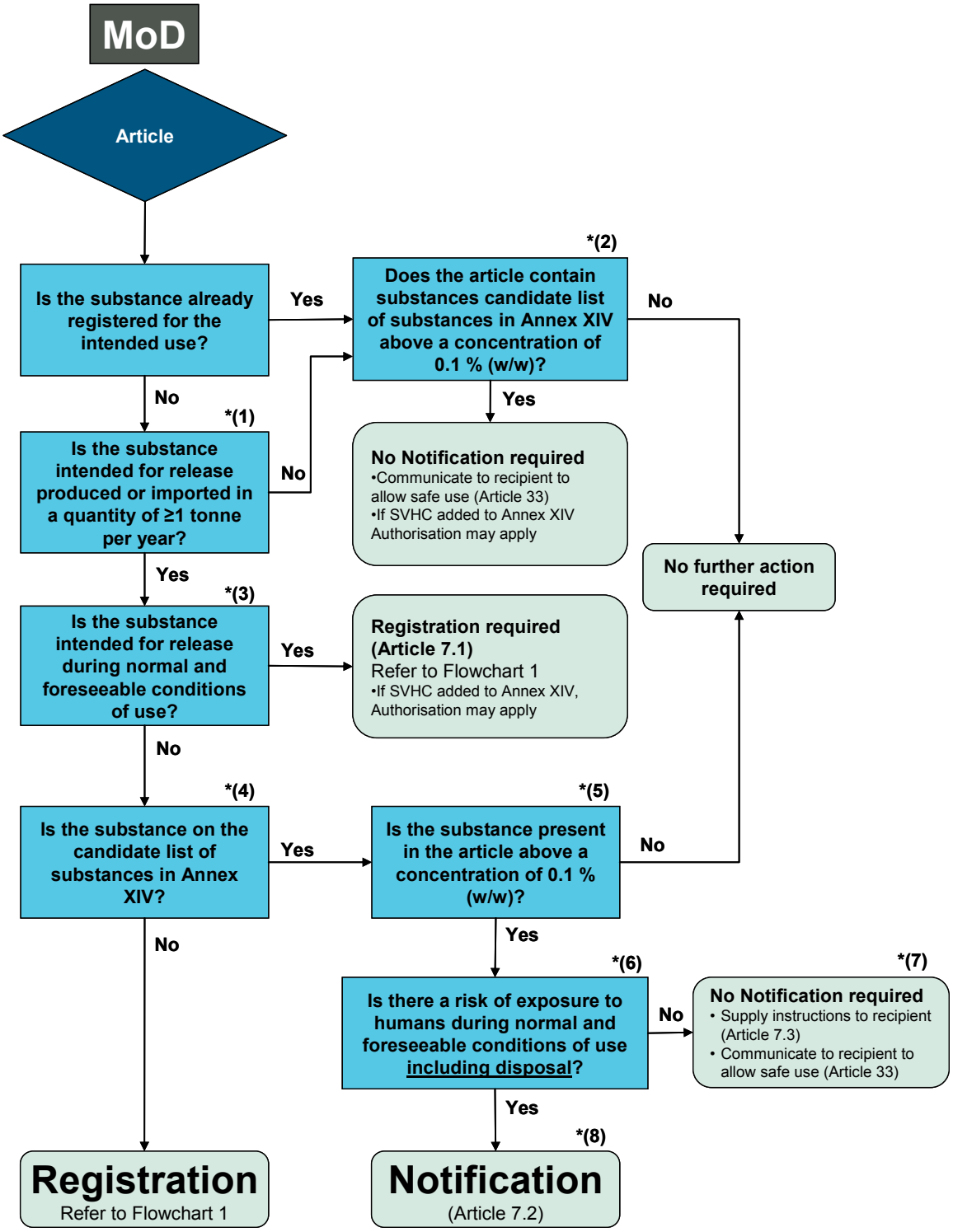

Figure 7 - Process to decide whether a substance contained in an article will require registration or notification, either through ECHA or internally via the MOD.

Notes for Figure 7:

1. The calculation determining whether the substance intended for release reaches the 1 tonne threshold requiring REACH registration includes the total amount of the substance contained in an article and not the amount expected to be released under normal and foreseeable conditions of use. This tonnage must include all the articles in the supply chain that are manufactured/imported on an annual basis.

2. Substances will be introduced to the candidate list for Authorisation (REACH Annex XIV) by the ECHA over time. The first substances will be listed in early 2009 and the list will be added to on an annual basis. It is essential to monitor this list to ensure that any substances used are not placed on this list thus requiring further action by manufacturers or importers of a substance.

3. Substances intended for release from articles during their normal intended use include, for example, a welding rod that is consumed during use and transportation protection waxes used in pipe ends that must be removed prior to use of the pipes.

4. See Note 2.

5. Regardless of whether the substance is manufactured/imported at a quantity of greater than or equal to 1 tonne per year, if the substance is contained in an article at a final concentration of less than or equal to 0.1 % (w/w), no further action under REACH is required.

6. Even if the substance is not intended for release under normal and foreseeable conditions of use, if there is a possibility that the substance may be released during disposal or misuse, further action (see Footnote 7) may be required.

7. Although notification to ECHA or internally via the MOD is not required, the recipients (DUs) of the article should be contacted in order to supply them with instructions on safe use and disposal.

8. Notification is different from registration (Article 7.2) and requires the following:

- The identity of the manufacturer or importer of the article;
- The identity of the substance;
- The classification of the substance;
- The estimated quantity of the substance;
- The list of recipients, including their contact details.

8 GUIDANCE FOR DOWNSTREAM USERS

For the first time in European chemical legislation, REACH imposes obligations on DUs. For a DU to continue using a substance in a given way, they must ensure that their use is included in registration, otherwise that use will not be covered by the legislation. Figure 8 presents guidance for DU's through the processes required for contacting suppliers regarding their preparations for REACH. **This process should be used only where the MOD is a DU of a substance where no exemption has been sought.**

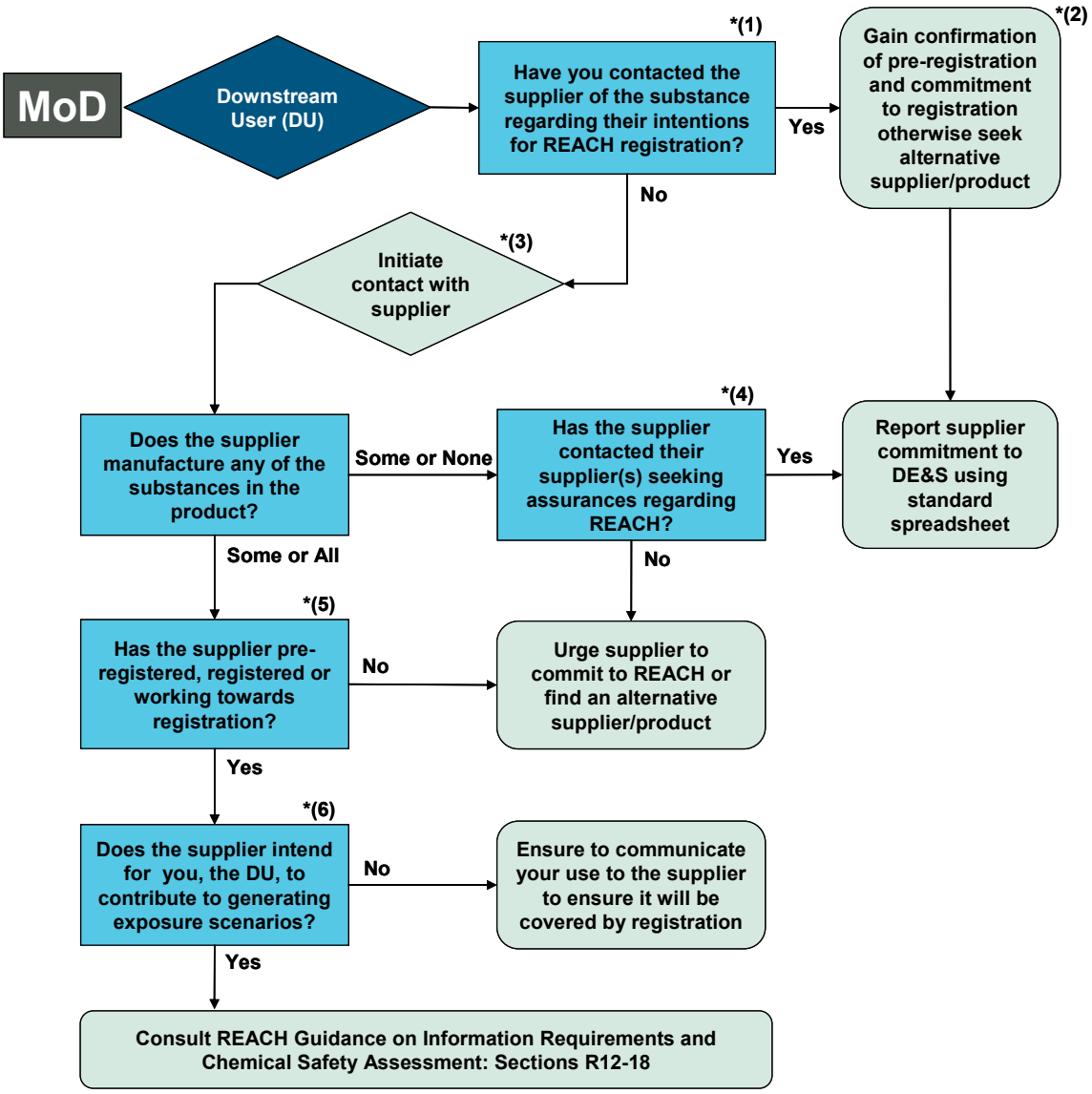

Figure 8 - Guidance for processes a DU must carry out to seek assurance from suppliers regarding their intentions to pre-register and register chemical substances under REACH.

Notes for Figure 8:

1. It is essential to contact suppliers of your products to seek assurances that they will not be lost from the market due to REACH in order to prevent loss of supply.

2. Pre-registration checks should cover both the December 2008 deadline for phase-in substances, and late pre-registration for new manufacturers and non phase-in substances.

3. DE&S has supplied all Directors and PTs with a standard questionnaire and covering letter to be sent to suppliers. The questionnaire is designed to seek all the information needed to assess the REACH readiness of suppliers for specific substances. Once a response is received it will be up to the individual PTs to decide on any further action to be taken (e.g. pressing supplier to conduct registration, seeking an alternative supplier or product).

4. If a supplier does not manufacture certain substances used in their products, it is essential to know whether confirmation of continued supply has been sought up the supply chain. If your supplier has not carried out any such investigations, be sure to press them to do so or seek an alternative supplier who can confirm that all the components of their products will be registered.

5. A supplier should have already pre-registered. If not seek an alternative supplier or product. Many suppliers may have yet to decide upon full-registration, given the cost and resources involved. Where a supplier will not yet commit to full registration, ensure to monitor the situation leaving time to switch supplier or product prior to the registration deadline.

6. Generating exposure scenarios is an integral part of the CSA, and ensures that the risk and hazard assessment has been conducted for all potential routes of exposure of the substance to humans and the environment. A manufacturer or supplier may request DUs to contribute to the generation of an exposure scenario to include in the Registration Dossier, or may request you to describe your use of the substance so that they can carry out the task.

DUs should communicate with their suppliers as soon as reasonably practicable to seek assurances regarding the pre-registration and registration of chemical substances contained in their products. A supplier that manufactures the substances used in their products should be able to inform a DU at least whether he has pre-registered a substance, and in many cases their intention regarding full registration of a substance.

Where a supplier sources chemical substances externally, he must also seek assurances from other parties up the supply chain, regarding the continued supply of the substance(s) after the forthcoming REACH deadlines. When contacting a supplier, the DU should also enquire regarding whether these similar assurances have been sought from their supply chain.

Another important piece of information to request from suppliers is whether they expect you, the DU, to contribute to generating exposure scenarios where relevant during registration. Ensuring that a specific use is covered by registration is essential.

9 ARTICLES APPLICABLE FOR REACH REGULATIONS EXEMPTIONS

This section of the Guidance Document provides a list of articles from the REACH Regulations for which an exemption application may cover. Note that not all of the articles may apply to each specific exemption application.

9.1 Articles of the REACH Regulations for which exemption may apply when manufacturing or importing a substance considered Defence Sensitive.

Article 5 Restriction No data, no market

Article 6 Restriction General obligations to register substances on their own or in preparations

Article 7 Restriction Registration and notification of substances in articles

Article 8 Restriction Only Representative of a non-Community manufacturer

Article 10 Restriction Information to be submitted for general registration purposes

Article 11 Restriction Joint submission of data by multiple registrants

Article 12 Restriction Information to be submitted depending on tonnage

Article 13 Restriction General requirements for generation of information on intrinsic properties of substances

Article 14 Restriction Chemical safety report and duty to apply and recommend risk reduction measures

Article 17 Restriction Registration of on-site isolated intermediates

Article 18 Restriction Registration of transported isolated intermediates

Article 19 Restriction Joint Submission of data on isolated intermediates by multiple registrants

Article 20 Restriction Duties of the Agency

Article 21 Restriction Manufacturing and import of substances

Article 22 Restriction Further duties of registrants

Article 23 Restriction Specific provisions for phase-in substances

Article 25 Restriction Objectives and general rules

Article 28 Restriction Duty to pre-register for phase-in substances

Article 29 Restriction Substance information exchange fora

Article 30 Restriction Sharing of data involving tests

Article 31 Restriction Requirements for Safety Data Sheets

Article 32 Restriction Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required

Article 33 Restriction Duty to communicate information on substances in articles

Article 34 Restriction Duty to communicate information on substances and preparations up the supply chain

Article 35 Restriction Access to information for workers

Article 36 Restriction Obligation to keep information

Article 37 Restriction Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

Article 38 Restriction Obligation for downstream users to report information

Article 39 Restriction Application of downstream user obligations

Article 40 Restriction Examination of testing proposals

Article 41 Restriction Compliance check of registrations

Article 42 Restriction Check of information submitted and follow-up to dossier evaluation

Article 43 Restriction Procedure and time periods for examination of testing proposals

Article 44 Restriction Criteria for substance evaluation

Article 45 Restriction Competent authority

Article 46 Restriction Requests for further information and check of information submitted

Article 47 Restriction Coherence with other activities

Article 48 Restriction Follow-up to substance evaluation

Article 49 Restriction Further information on on-site isolated intermediates

Article 50 Restriction Registrants' and downstream users' rights

Article 51 Restriction Adoption of decisions under dossier evaluation

Article 52 Restriction Adoption of decisions under substance evaluation

Article 53 Restriction Cost sharing for tests without an agreement between registrants and/or downstream users

Article 54 Restriction Publication of information on evaluation

Article 56 Restriction General Provisions (Authorisation)

Article 57 Restriction Substances to be included in REACH Annex XIV

Article 58 Restriction Inclusion of substances in REACH Annex XIV

Article 59 Restriction Identification of substances referred to in Article 57

Article 60 Restriction Granting of Authorisations

Article 61 Restriction Review of Authorisations

Article 62 Restriction Applications for Authorisations

Article 63 Restriction Subsequent applications for Authorisations

Article 64 Restriction Procedure for Authorisation decisions

Article 65 Restriction Obligations of holders of Authorisations

Article 66 Restriction Downstream users

Article 67 Restriction General Provisions (Restrictions)

Article 68 Restriction Introducing new and amending current Restrictions

Article 69 Restriction Preparation of a proposal

Article 70 Restriction Agency opinion: Committee for Risk Assessment

Article 71 Restriction Agency opinion: Committee for Socio-economic Analysis

Article 72 Restriction Submission of an opinion to the commission

Article 73 Restriction Commission decision

Article 112 Restriction Scope (Classification and labelling)

Article 113 Restriction Obligation to notify the Agency

Article 114 Restriction Classification and labelling inventory

Article 115 Restriction Harmonisation of classification and labelling

Article 116 Restriction Transitional Arrangements

Article 138 Restriction Review (Transitional and final provisions)