



Department
of Energy &
Climate Change



REACH GUIDANCE DOCUMENT

FOR

THE OFFSHORE INDUSTRY

Version Seventeen – March 2016

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Introduction

Basic overview of REACH

The REACH (**R**egistration, **E**valuation, **A**uthorisation and restriction of **C**hemicals) Regulation (EC) No. 1907/2006 entered into force on 1 June 2007. The Regulation can be accessed from: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&from=en>.

Management of the EU REACH Regulation's requirements at EU level will be handled by the European Chemicals Agency (ECHA). Day-to-day operation of REACH in each Member State is overseen by their Competent Authorities (see Section below on the '**Enforcement of REACH in the UK**').

REACH aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances placed on the EU market. It imposes obligations on manufacturers / importers of substances and downstream users to evaluate and control the risks associated with their use. In this context, the core components of REACH consist of:

(i) A pre-Registration phase which closed on **1 December 2008**. Failure to pre-Register substances meant that companies had to submit a full Registration dossier to the ECHA if they wished to continue supplying 'phase-in' substances in quantities of 1 tonne or more after 2008 (the same scenario applied to 'new (non-phase-in)' substances) - otherwise the placing of such substances on the EU market is banned. However, pre-Registration is still available, but only to companies who started to produce a phase-in substance at 1 tonne or more per year *for the first time* after 1 December 2008, but not within 12 months of the relevant Registration deadline (see item (ii) below).

The ECHA has provided a database of pre-Registered substances (available at: <http://echa.europa.eu/information-on-chemicals/pre-registered-substances>) which is designed to help companies identify the right Substance Information Exchange Forums (SIEFs) - using contact details supplied to the ECHA (as part of the pre-Registration process) - when preparing for the submission of joint Registration dossiers for their substances.

(ii) Registration with the ECHA on a central database of all substances which any individual company manufactures or imports into the EU in quantities greater than 1 tonne per year. Arrangements are in place (dependent on pre-Registration and the annual tonnages involved) to phase-in the Registration of substances currently manufactured or placed on the market - to which previous deadlines of 2010 and 2013 applied, with a final Registration deadline in 2018 (see paragraph below). Registration requires the submission of a technical dossier which may contain proposals for testing of a chemical substance.

The final (third) full REACH Registration phase closes on 31 May 2018 and concerns phase-in substances manufactured / imported in the EU in quantities ≥ 1 tonne per year per manufacturer or importer at least once after 1 June 2007.

As with substances that required Registering in accordance with the previous phases in 2010 and 2013, any substances meeting the above criteria for the third (full) Registration phase which are not Registered - if required by the specified deadline - cannot be legally manufactured, imported or used within the EU as from 1 June 2018.

The ECHA has made available a database containing information on substances Registered under the EU REACH Regulation - the database is accessible from: <http://echa.europa.eu/information-on-chemicals/registered-substances>.

See [Chapter Two](#) 'Principle Elements of REACH' - Sections 3.3 and 3.4 for further details on the REACH Registration deadlines.

(iii) Dossier evaluation which consists of a mandatory review of testing proposals submitted (primarily for substances supplied or manufactured in quantities greater than 100 tonnes per year). There is also a compliance check on a proportion of Registration dossiers. Dossier evaluation will be carried out by the ECHA.

(iv) Substance evaluation which consists of the additional evaluation of substances where it is felt that these may pose a risk to human health and / or the environment but further information is needed. Substance evaluation will be co-ordinated by the ECHA. Member States' competent authorities will carry out the evaluation.

(v) Authorisation for the continued use of substances of very high concern (SVHC). Companies will need to apply for Authorisation for specific uses where the risks can be adequately controlled or where there is a socio-economic case for continuing with the use of SVHC. In both cases, an analysis of possible alternatives is required, and where substitution is possible, a substitution plan must be submitted. All other non-Authorised uses of SVHC will be prohibited.

(vi) Restrictions on manufacture, marketing and use of substances where the risks to human health and the environment are deemed to be unacceptable.

Since the entry into force of the EU REACH Regulation, a variety of supplemental Commission legislation on REACH and other relevant regulatory measures on chemicals (e.g. biocides) have been introduced - see details in [Appendix 3](#).

Enforcement of REACH in the UK

On 1 December 2008, the REACH Enforcement Regulations 2008 entered into force. The Regulations are at: <http://www.legislation.gov.uk/uksi/2008/2852/contents/made>. Links to UK legislation for enforcing REACH and other relevant EU regulatory measures on chemicals are provided at [Appendix 4](#) (this also includes the Energy Act 2008 Modifications Order 2010 (described in the third paragraph below) plus amendments to the REACH Enforcement Regulations 2008 which were introduced in 2013 and 2014).

The UK Regulations apply - as appropriate - to all offshore installations (including fixed and floating platforms, floating production storage and off-loading systems, and floating storage units - but not ships) within the UK territorial sea and the United Kingdom Continental Shelf (UKCS). The Offshore Oil & Gas Environment and Decommissioning Branch of DECC's Energy Development Unit regulate the use / discharge of chemicals under the Offshore Chemicals Regulations (OCR) which implemented the OSPAR Harmonised Mandatory Control System (HMCS) for controlling offshore chemicals (OSPAR - The Convention for the Protection of the Marine Environment of the North-East Atlantic). The OCR were amended in 2011 so that they now cover all operational discharges and non-operational releases of offshore chemicals. The Offshore Chemicals (Amendment) Regulations 2011 entered into force on 30 March 2011 - see details at: <http://www.legislation.gov.uk/uksi/2011/982/contents/made>.

The Energy Act 2008 (Consequential Modifications) (Offshore Environmental Protection) Order 2010 - which entered into force on 1 July 2010 - applies the requirements of the UK REACH Enforcement Regulations and OCR to offshore installations involved in Carbon Capture and Storage (CCS) and gas unloading / storage activities (the Order is at: <http://www.legislation.gov.uk/uksi/2010/1513/contents/made>).

The HSE is the UK Competent Authority for REACH and is working closely with Defra plus other Government Departments and Agencies on the policy / enforcement aspects. HSE enforces maritime Health and Safety Regulations which apply to offshore installations. To ensure a consistent regime, the offshore enforcement of REACH will be carried out by those who are familiar with enforcement requirements in similar circumstances to that required by REACH. Therefore, HSE and DECC will enforce offshore the aspects of REACH relating to health / safety and environmental protection - using their respective onshore administrative procedures and offshore inspectors to check compliance with the relevant provisions. In this regard, DECC sits on the REACH Enforcement Liaison Group (established by the HSE) to ensure that a proportionate and consistent method of enforcement is adopted. In addition, the HSE has a very comprehensive website providing guidance on REACH - the website is accessible from: <http://www.hse.gov.uk/reach/index.htm>.

From an offshore environmental protection perspective, the OSPAR HMCS and REACH requirements will run in parallel. To this end, the HMCS approach to controlling offshore

chemicals has been appropriately harmonised with the provisions of the EU REACH Regulation (see paragraph below for further details on the harmonisation process). Accordingly, the UK REACH Enforcement Regulations contain certain provisions from, and make references to, the OCR so effectively OCR (and hence the HMCS) will be the mechanism for supporting the application of the environmental protection elements of REACH to offshore installations. It should, however, be noted that DECC's regulatory regime for offshore chemicals only extends to sea areas that are under the Department's legal jurisdiction (e.g. certain territorial waters around the UK and the sea as designated under section 1(7) of the Continental Shelf Act 1964). It does not, for instance, extend to Scottish controlled waters - in so far as this specific area is concerned, REACH will be enforced by an authorised body (i.e. Marine Scotland) on behalf of the Scottish Government. The relevant articles for offshore enforcement and by which body are detailed in the offshore column of Schedule 1 (Table of REACH provisions) to the UK REACH Enforcement Regulations.

With regard to the harmonisation of the HMCS with the requirements of REACH, the OSPAR Oil Industry Committee (OIC) closely monitored the implementation of the EU REACH Regulation and reviewed its consequences for the HMCS. As a result of debates at OIC 2009, it was agreed that additional work to progress the HMCS / REACH harmonisation process should be undertaken by an intersessional correspondence group - ICG-REACH. Following two ICG-REACH meetings (in May and October 2009), the UK submitted three papers to OIC 2010 on the alignment of the OSPAR chemical management regime with the EU REACH Regulation. The three papers comprising two Recommendations and one set of Guidelines (subsequently revised in 2012) were accepted by OIC and endorsed (subject to very minor changes) by the OSPAR Commission in September 2010. The two Recommendations and revised Guidelines are:

- OSPAR Recommendation 2010/3 (as subsequently amended by Recommendation 2014/17) on a Harmonised Offshore Chemical Notification Format (HOCNF);
- OSPAR Recommendation 2010/4 on a Harmonised Pre-Screening Scheme for Offshore Chemicals; and
- Revised OSPAR Guidelines (2012/05) [Updated 2015] for Completing the HOCNF. These Guidelines replace the previous version 2010-5.

The new Recommendations and revised Guidelines came into effect in January 2011 and January 2012 respectively. Links to the Recommendations and revised Guidelines are provided at [Appendix 6](#).

In a related development, at the OSPAR OIC meeting in March 2016 the Contracting Parties agreed to changes to the HMCS pre-screening process to improve harmonisation with the EU REACH Regulation. Further details on the proposed changes are accessible via the OSPAR OIC 2016 Summary Record at:

<http://www.ospar.org/meetings/archive/offshore-industry-committee-2016>.

Additional changes to the HMCS pre-screening process are expected to be discussed at the OSPAR OIC meeting in 2017.

Any queries on the application of REACH should, in the first instance, be directed to the UK REACH Competent Authority helpdesk - **e-mail:** UKREACHCA@hse.gsi.gov.uk. Queries on DECC's offshore enforcement role can be sent to David Foskett - **e-mail:** david.foskett@decc.gsi.gov.uk. Where responses from HSE are provided to offshore Operators / chemical suppliers on any aspects of REACH policy and / or enforcement, we would be grateful if these could be copied to David Foskett as this would be useful for the purposes of monitoring decisions that get closed out and for updating this guidance document.

Executive Summary

The purpose of this guidance document is to set-out the various obligations under REACH on all actors in the offshore sector. The document - prepared by the DECC REACH Working Group (comprising the Offshore Oil & Gas Environment and Decommissioning Branch of DECC's Energy Development Unit, CEFAS, EOSCA, Halliburton, Champion Technologies, and Oil & Gas UK (the current situation regarding the Working Group is explained in the penultimate paragraph of the Executive Summary)) - provides generic guidance on the core components of REACH (i.e. Registration, Evaluation / Authorisation and Restriction of substances) which are described in three main Chapters:

- Chapter One - The Scope of REACH;
- Chapter Two - Principle Elements of REACH; and
- Chapter Three - Post-Registration aspects of REACH (outlining, in particular, the roles of the ECHA).

There are also six appendices covering other important REACH and, where appropriate, additional chemical-related topics as follows:

- [Appendix 1](#) - Specific REACH issues pertaining to the offshore sector (this includes details of issues closed out from meetings and correspondence between HSE / DECC / industry representatives plus relevant aspects of a BMT Cordah report (commissioned by Oil & Gas UK) on concerns raised by the offshore industry).
- [Appendix 2](#) - REACH-related developments.
- [Appendix 3](#) - Supplemental Commission Legislation on REACH and other relevant EU regulatory measures on chemicals [Including proposed revisions and expected new measures].
- [Appendix 4](#) - UK Regulations for the enforcement of REACH and other EU regulatory measures on chemicals.
- [Appendix 5](#) - Guidance from the ECHA and other sources on REACH plus additional EU regulatory measures on chemicals e.g. biocides (links are also included, as appropriate, throughout this document).
- [Appendix 6](#) - OSPAR Recommendation 2010/3 (as subsequently amended by Recommendation 2014/17) on a Harmonised Offshore Chemical Notification Format (HOCNF) and OSPAR Recommendation 2010/4 on a Harmonised Pre-Screening Scheme for Offshore Chemicals Plus the revised OSPAR Guidelines (2012/05) [Updated 2015] for Completing the HOCNF. The purpose of these Recommendations

and revised Guidelines is to align the OSPAR chemical management regime with the EU REACH Regulation.

References to manufacturers / importers and downstream users should be taken to mean suppliers of offshore chemicals and Operators respectively (although, suppliers could also be deemed downstream users where they obtain substances for formulating into their own products). This document should not be considered a definitive guide and should therefore, be used in conjunction with the EU REACH Regulation and other relevant EU regulatory measures on chemicals, as well as the more detailed guidance published on the ECHA's website plus guidance made available from other sources, as this will ensure full understanding of the specific obligations on each actor in the offshore industry supply chain.

This guidance document will be 'live' and amended (along the timeline of REACH implementation) in accordance with any pertinent developments concerning the offshore enforcement of the EU REACH Regulation's provisions and those associated with other relevant EU legislation on chemicals.

It is also the case that the REACH Working Group (REACH WG) has now been subsumed by DECC's Chemicals Working Group (CWG) which primarily discusses the UK's implementation of the OSPAR HMCS and comprises Government Agencies, the offshore industry and chemical suppliers. This new arrangement will enable REACH enforcement issues to be discussed with a larger number of stakeholders - although where specific topics cannot be resolved by the CWG and require special attention then the REACH WG will be reinstated to take such issues forward. Notwithstanding this, periodic DECC / CEFAS / EOSCA updates on REACH will continue to be circulated to key stakeholders. The notes of DECC REACH WG meetings are available from: http://webarchive.nationalarchives.gov.uk/20121217150421/og.decc.gov.uk/en/olgs/cms/environment/env_policy/reach_wking_gp/reach_wking_gp.aspx.

Comments / suggestions on this guidance document are welcome and should be sent to David Foskett at DECC - e-mail: david.foskett@decc.gsi.gov.uk.

Definitions

Actors in the supply chain: All manufacturers and / or importers and / or downstream users in a supply chain.

Article: An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. An article is the article as produced or imported rather than parts of an article or a homogenous material within it.

Candidate list: List of substances of very high concern for potential inclusion in Annex XIV of REACH, which itself lists substances subject to Authorisation.

Chemical Abstracts Service number: A CAS Registry Number (sometimes known as a "CAS Number") is the unique chemical substance identifier that enables efficient links to the broad chemical literature and which is also used as a substance identifier in commerce (i.e. in regulatory Registrations).

Competent Authority: The authority or authorities or bodies appointed by Member States to carry out the tasks allocated to them by REACH as well as other legislation on chemicals and responsible for cooperating with the Commission and ECHA in the implementation of the EU's chemicals regulatory regime.

Distributor: Any legal entity established within the European Union (EU), including a retailer who only stores and places on the market a substance on its own or in a preparation for third parties.

Downstream User: Any legal entity established within the EU, other than the manufacturer or the importer, who uses a substance either on its own or in a preparation, in the course of industrial or professional activities. A distributor or consumer is not a downstream user.

Exposure Scenario: The set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls - or recommends downstream users to control - exposures to humans and the environment. These exposure scenarios may cover one specific process or use, or several processes / uses as appropriate.

Identified use: The use of a substance on its own or in a preparation that is intended by an actor in the supply chain (including their own use or that which is made known to them in writing by a downstream user).

Import: The physical introduction of chemical substances into the EU customs territory.

Importer: Any legal entity established within the EU who is responsible for the import of chemical substances. An Only Representative has the same status under REACH as an importer.

Intended to be released: Releases are deliberately planned and have a specific function for the article, which is not the main function of the object, but an additional attribute. If a release is incidental, this is not an intended release. In cases where an intended release of substances is the main function of an object, it is regarded as a container with substances / preparations inside but not an article.

Intermediate: A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. This includes:

(a) **Non-isolated intermediate** - An intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipe-work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) is / are stored after the manufacture.

(b) **On-site isolated intermediate:** An intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site operated by one or more legal entities.

(c) **Transported isolated intermediate:** An intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

Legal entity: Any legal or natural individual, partnership, proprietorship, corporation, association or other organisation that has, in the eyes of the law, the capacity to make a contract or an agreement and the abilities to assume an obligation and to pay off its debts. A legal entity under the law is responsible for its actions and can be sued for damages.

Manufacturer: Any legal entity established within the EU who manufactures a substance within the EU.

Manufacturing: Production or extraction of substances in the natural state.

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

Non-phase-in substance: A substance which does not meet the criteria under REACH for a 'phase-in' substance.

Notified substance: A substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC (implemented in the UK by the Notification of New Substances Regulations) on the classification, packaging and labelling of dangerous substances.

Only Representative: Only Representatives can be appointed by non-EU manufacturers / producers of substances, preparations or articles whose products are imported into the EU. Only Representatives carry out the obligations of importers of substances from those non-EU manufacturers. Importers in the same supply chain are in this case considered to be downstream users. An Only Representative is fully liable for fulfilling all obligations of importers for the substances they are responsible for as a Registrant. These do not only relate to Registration but also to all other relevant obligations such as pre-Registration, communication in the supply chain, notification of Substances of Very High Concern, classification and labelling and any obligations concerning applications for Authorisations and / or restrictions pertaining to appropriate substances.

The Only Representative must have a sufficient background in the practical handling of the non-EU supplier's substances and the information related to them. The Only Representative must keep available up-to-date information on quantities imported and customers sold to as well as information on the supply of the latest update of the Safety Data Sheet. When appointing an Only Representative, it is necessary for the non-Community manufacturer to provide their Only Representative with up-to-date information on the list of EU importers which should be covered by the Only Representative's Registration and the quantities imported into the EU. The non-Community manufacturer should also inform all the EU importers in the same supply chain that they have appointed an Only Representative to conduct the Registration thus eventually relieving the importers from their Registration obligations. A non-Community manufacturer can only appoint one Only Representative per substance. The Only Representative's Registration should clearly specify which quantity of the imported substance it covers (i.e. either the entire import into the Community from a given non-Community manufacturer, or just specified quantities within that total).

An Only Representative can represent one or several non-Community manufacturers. If they act on behalf of several non-Community manufacturers they must submit a separate Registration for each of the substance manufacturers. The tonnage of the substance to be Registered in each Registration is the total of the tonnages of the substance covered by the contractual agreements with the Only Representative and the specific non-Community manufacturer that they represented. By making separate submissions, the confidential business information of the non-Community manufacturer can be preserved and equal treatment with EU manufacturers can be ensured. For more information on the roles / responsibilities of Only Representatives and non-Community manufacturers use the links to the Registration Guidance provided in [Chapter Two](#) 'Principle Elements of REACH' - Section 3.1 ('What is Registration?').

Phase-in substance: A substance which meets at least one of the following criteria:

(a) It is listed in the European Inventory of Existing Commercial Chemical Substances.

(b) It was manufactured in the EU or in the countries acceding to the EU on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer at least once in the 15 years before the entry into force of the EU REACH Regulation, provided the manufacturer or importer has documentary evidence of this.

(c) It was placed on the market in the EU, or in the countries acceding to the EU on 1 January 1995 or on 1 May 2004, before entry into force of the EU REACH Regulation by the manufacturer or importer and was considered as having been notified in accordance with Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in REACH, provided the manufacturer or importer has documentary evidence of this.

Placing on the market: Supplying or making available substances, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

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

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

(b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a “monomer unit” means the reacted form of a monomer substance in a polymer.

Preparation: A mixture or solution composed of two or more substances.

Producer of an article: Any legal entity who makes or assembles an article within the EU.

Product and Process Orientated Research and Development: Any scientific development related to product development or the further development of a substance on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and / or to test the fields of application of the substance.

REACH Implementation Projects: Technical guidance documents and IT-tools developed for the ECHA, industry and Competent Authorities by the EU in collaboration with stakeholders.

Recipient of an article: An industrial or professional user, or a distributor, being supplied with an article but does not include consumers.

Registrant: The manufacturer or the importer of a substance or the producer or importer of an article submitting a Registration for a substance.

Registrant's own use: An industrial or professional use by the Registrant.

Risk management measure: Action taken to reduce or avoid direct and indirect exposure of substances to humans and the different environmental compartments.

Site: A single location, in which, if there is more than one manufacturer of a substance(s), certain infrastructure and facilities are shared.

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

Substances of Very High Concern: The following substances are considered to be of very high concern under REACH:

(a) Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction according to Directive 67/548/EEC (category 1 or 2 substances).

(b) Substances which are persistent, bioaccumulative and toxic according to Annex XIII of REACH.

(c) Substances which are very persistent and very bioaccumulative according to Annex XIII of REACH.

(d) Substances which have endocrine-disrupting, persistent, bioaccumulative and toxic or very persistent and very bioaccumulative properties, which give rise to an equivalent level of concern to those of other substances listed in (a) – (c).

Sunset date: The date(s) from which the placing on the market or the use of a substance shall be prohibited unless an Authorisation is granted which should take account, where appropriate, of the production cycle specified for that use.

Supplier of a substance or a preparation: Any manufacturer, importer, downstream user or a distributor placing on the market a substance on its own or in a preparation.

Supplier of an article: Any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market.

Third Party Representative: A Third Party Representative can be appointed by a manufacturer, importer or where relevant a downstream user to allow the potential Registrant to remain anonymous in the data sharing process. It is nevertheless up to the manufacturer or importer of the substance to submit the actual Registration documentation, as a Third Party Representative cannot Register a substance for the entity being represented in the data sharing discussions.

Use: Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

Use and exposure category: An exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use.

Acronyms

CA

Competent Authority

CAS

Chemical Abstracts Service

CMR

Carcinogenic, mutagenic or toxic for reproduction

CSA

Chemical Safety Assessment

CSR

Chemical Safety Report

DECC

Department of Energy and Climate Change

Defra

Department for Environment, Food and Rural Affairs

DU

Downstream User

ECHA

European Chemicals Agency

GHS

Globally Harmonised System for the classification and labelling of chemicals

EINECS

European Inventory of Existing commercial Chemical Substances

ELINCS

European List of Notified Chemical Substances

ES

Exposure Scenario

HSE

Health and Safety Executive

IUCLID

International Uniform Chemical Information Database

IUPAC

International Union of Pure and Applied Chemistry

OR

Only Representative

PBT

Persistent, bioaccumulative and toxic.

PPORD

Product and Process Orientated Research and Development

RIPs

REACH Implementation Projects

RMM

Risk Management Measure

SDS

Safety Data Sheet

SIEF

Substance Information Exchange Forum

SFF

SIEF Formation Facilitator

SVHC

Substances of Very High Concern

TGD

Technical Guidance Document (resulting from a RIP)

TPR

Third Party Representative

vPvB

Very persistent and very bioaccumulative

CHAPTER ONE

The Scope of REACH

1.0 Scope of REACH

1.1 REACH lays down obligations which apply to the manufacture, import, placing on the market and use of chemical substances on their own, in preparations or in articles. However, only substances are subject to the requirements to Register in REACH – **preparations and articles are not**. When contained in a preparation, each individual substance needs to be Registered, either by the substance manufacturer or the importer of the substance or preparation (into the EU) when reaching the threshold of 1 tonne per year. In contrast, substances that have been Registered by the manufacturer or the importer and that are being mixed into a preparation by a downstream user (DU), do not need to be Registered again by the DU. For more detailed information see '[Guidance for Substances in articles](#)'.

1.2 Certain substances are exempt from the provisions of REACH. These are:

(A) **Substances exempted from the EU REACH Regulation**

- **Substances under customs supervision** - Substances (on their own, in a preparation or in an article) in temporary storage, in transit, in a free zone or in a free warehouse on the EU territory which are only transiting through the EU and remain under customs supervision while waiting to leave the EU are not subject to the provisions of REACH.
- **Waste** - Waste as defined in the Waste Framework Directive 2008/98/EC (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:EN:PDF>) is not considered a substance under REACH. However, REACH does not exempt waste per se from its provisions. For instance, when a Chemical Safety Assessment (CSA) is required for a (manufactured or imported) substance, this must include the whole lifecycle of the substance including the waste stage. To manage risks from chemical substances, recommended waste management measures have to be communicated through the supply chain via Safety Data Sheets (SDSs). In addition, if waste is recovered, then at the point at which it ceases to be waste the recovery becomes a 'manufacture' under REACH.
- **Non isolated intermediates** - These substances are not covered by REACH. Nevertheless, where quantities of the same substance are used in other operations or under other conditions, those quantities cannot be regarded as 'non-isolated intermediates' and the relevant requirements under REACH must be fulfilled.

- **Transported dangerous substances** - REACH exempts the carriage of ‘dangerous substances’ and ‘dangerous substances in preparations’ by rail, road, inland waterway, sea or air. It is important to note that for all other activities (i.e. manufacture, import and use) relating to the concerned substances, the REACH requirements will apply (unless covered by an appropriate exemption).

(B) Substances exempt from Registration

REACH exempts certain substances that are adequately regulated under other EU legislation, or that generally present such low risks as not to require Registration. The substances exempted from Registration are further described below:

- **Substances included in Annex IV of the EU REACH Regulation** - Annex IV lists the substances for which it is understood that sufficient information is available to consider them as causing minimum risk to human health and the environment. These substances are typically of natural origin. Substances included in Annex IV are exempted from the Registration provisions.
- **Substances covered by Annex V of the EU REACH Regulation** - Annex V lists the broad categories of substances for which Registration is deemed unnecessary. They are exempted from the Registration provisions, but not necessarily from Authorisation or restrictions. The Registration exemption applies to substances if they meet the exemption conditions in Annex V.
- **Recycled or recovered substances already Registered** - REACH exempts substances resulting from a waste recovery process providing they are already Registered and safety data information required by REACH for those substances is available to the establishment undertaking recovery operations.
- **Re-imported substances** - Where a substance is first manufactured in the EU, then exported (i.e. to be formulated into a preparation) and subsequently brought back into the EU again (i.e. to be marketed or for further processing) then providing it was already Registered before export it does not need to be Registered again (i.e. avoiding ‘double Registration’).
- **On-site intermediates and transported isolated intermediates** - On-site isolated intermediates and transported isolated intermediates generally benefit from reduced Registration requirements. Specific Registration obligations and information requirements for certain types of isolated intermediates are described in Chapter 3 of Title II of the EU REACH Regulation. For further information - see [‘Guidance for intermediates’](#).
- **Polymers** - Owing to the especially extensive number of different polymer substances on the market, and since polymer molecules are generally regarded as representing a low concern in relation to their high molecular weight, this

group of substances is exempted from Registration. Manufacturers and importers of polymers are nevertheless required to proceed with the Registration of the monomers or other substances used for the manufacture of the polymers. For more information - see [‘Guidance for monomers and polymers’](#).

- **Substances used for the purpose of PPORD** - To support industry’s capacity for innovation, one of the objectives of REACH is to promote research and development. Registration requirements will not apply for five years to substances manufactured or imported for the purposes of PPORD although such manufacturers or importers will need to notify ECHA with certain information. For more detailed advice - see [‘Guidance on PPORD’](#).
- **Substances regarded as being Registered** - Certain substances or uses of substances are regarded as Registered (see more details in Section C below).

(C) Substances regarded as Registered

Certain substances or uses of substances are regarded as being Registered and therefore, no Registration under REACH will be required for these substances / their uses. This applies to:

(i) Active substances in biocidal products covered by **Directive 98/8/EC** - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:123:0001:0063:EN:PDF> which was replaced by **Regulation (EU) No. 528/2012** (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF>) as from 1 September 2013 - see further information on the **Biocides Regulation (EU) No. 528/2012** plus additional Commission legislation relating to Regulation (EU) No. 528/2012 and Directive 98/8/EC in [Appendix 3](#).

According to Article 57 of the Biocides Regulation (EU) No. 528/2012, in addition to the active substances referred to in Article 15(2) of the EU REACH Regulation, active substances manufactured or imported for use in biocidal products Authorised for placing on the market in line with Articles 27, 55 or 56 of the Biocides Regulation (EU) No. 528/2012 are regarded as being Registered and the Registration as completed for manufacture or import for use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5, Title II of the EU REACH Regulation.

In accordance with Article 86 of the Biocides Regulation (EU) No. 528/2012, active substances included in Annex I to Directive 98/8/EC are also deemed to have been approved under the Biocides Regulation (EU) No. 528/2012 and shall be included in the list referred to in Article 9(2) of that Regulation. Under the transitional provisions in Article 92 of the Biocides Regulation (EU) No. 528/2012, biocidal products for which an Authorisation or Registration in accordance with Articles 3, 4, 15 or 17 of Directive 98/8/EC was granted before 1 September 2013 can continue to be made available on the market and used subject, where applicable, to any conditions of

Authorisation or Registration stipulated under that Directive until the expiry date of the Authorisation or Registration or its cancellation. The Biocides Regulation (EU) No. 528/2012 applies to all other biocidal products from 1 September 2013.

Some types of products that were not within scope of Directive 98/8/EC are (as from 1 September 2013) now within the scope of the Biocides Regulation (EU) No. 528/2012. Companies placing such 'newly within scope' products onto the market will have to take action to comply with the regulatory requirements or remove the products from the market to the timeline set within the Regulation. In this context, newly in scope products comprise, amongst others, the in-situ generation of a biocide where there is no supply of a precursor chemical - such as sodium hypochlorite generated from sea water (see related information in [Appendix 1](#) items A2 and A4 part (iii)). The Biocides Regulation (EU) No. 528/2012 includes transitional provisions in Article 93 for such products that are newly within scope. Further detailed advice from the HSE on products newly within the scope of the Biocides Regulation (EU) No. 528/2012 is available at: <http://www.hse.gov.uk/biocides/newly-under-scope-products.htm>.

Regulation (EC) No. 2032/2003 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003R2032:20070104:EN:PDF>) - this Regulation lists active substances which were already on the market on 14 May 2000 and for which information was submitted with a view to including them in the Commission's review programme of active substances for use in biocidal products. However, if a decision was taken for one of the active substances on the lists of Regulation (EC) No. 2032/2003 not to include it in Annex I of Directive 98/8/EC, the active substance loses the exemption and must be Registered under REACH, since its manufacturer will not have submitted the required information to allow full assessment under Directive 98/8/EC (which was replaced by Regulation (EU) No. 528/2012 from 1 September 2013). Note however that:

- Only the quantities of active substances for use in biocidal products are exempted from the REACH Registration obligation. If they are used in a non-biocidal product, they are not exempted. This means that if a manufacturer who previously manufactured an active substance only for the purpose of biocides then puts the same substance on the market but for other purposes (not exempted from Registration) they would have to prepare a full Registration dossier, including all relevant information e.g. the CSR.
- Only active substances can qualify for the exemption whereas other substances used for producing biocidal products are not exempted from the REACH Registration requirement.

The ECHA has been charged with including on its database the information submitted in the framework of Directive 98/8/EC and the Biocides Regulation (EU) No. 528/2012 - which is equivalent to Registration dossier data. This is to ensure that this data can be valorised where appropriate.

(ii) Active substances in plant protection products (e.g. pesticides) covered by **Directive 91/414/EEC** (this has no relevance to the offshore industry, so no additional information needs to be provided in this guidance document).

(iii) Notified substances according to **Directive 67/548/EEC** (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:EN:HTML>) i.e. under the NONS (Notification of New Substances) scheme). Directive 67/548/EEC introduced a notification requirement for so-called new substances, which were substances not appearing on EINECS. The EINECS list contains, in principle, all substances on the Community market on 18 September 1981. Notifications made in accordance with Directive 67/548/EEC contain a lot of the technical dossier information which the EU REACH Regulation aims to have assembled by Registrants via the Registration requirement. This is the reason why such notifications are regarded as Registrations. The ECHA assigned Registration numbers to notifications by 1 December 2008. Owners of notifications made under Directive 67/548/EEC can request their Registration number using the 'Claim Notified Substances' module available on the ECHA's website (further details can be accessed at: <http://echa.europa.eu/en/support/dossier-submission-tools/reach-it/industry-user-manuals>). Manufacturers or importers of polymers which were notified under Directive 67/548/EEC are encouraged to read the '[Guidance for monomers and polymers](#)'.

Legal entities are therefore advised to check whether they submitted notifications for their substances to a Member State competent authority in line with the national legislation implementing Directive 67/548/EEC. If this is the case, then they have official notification numbers on file which were allocated by the Member State competent authority. The substances will in that case also appear on ELINCS.

Notification under Directive 67/548/EEC was only required if a substance was placed on the EU market or imported into the EU. However, if a substance was merely manufactured in the EU, but not placed on the market, a notification would not have been made - **these substances will have to be Registered under REACH**. Substances that would have been subject to notification under Directive 67/548/EEC cannot benefit from the phase-in periods under REACH. Moreover, when the manufacture / import volume of the notified substance reaches the next tonnage threshold as defined in Article 12 of the EU REACH Regulation, an update of the Registration for that substance will have to be submitted to the ECHA.

Please note - A notification under Directive 67/548/EEC is nominal so that only the notifier benefits from being considered Registered. Any other parties manufacturing or importing the substance but who have not notified it, must Register it under REACH, unless there is another exemption that applies to them.

1.3 Information on exempt substances relating to the offshore sector is contained in [Appendix 1](#).

CHAPTER TWO

Principle Elements of REACH

2.0 Principle elements of REACH

2.1 The main elements of the REACH regime are:

- Pre-registration;
- Registration;
- Evaluation of substances;
- Authorisation of substances; and
- Restriction of substances.

2.2 Pre-Registration Phase

2.3 The pre-Registration phase for substances started on 1 June 2008 and ended on 1 December 2008. Failure to pre-Register substances meant that companies had to submit a full Registration dossier to the ECHA if they wished to continue supplying 'phase-in' substances in quantities of 1 tonne or more after 1 December 2008 (the same full Registration scenario also applied to 'new (non-phase-in)' substances) - otherwise the manufacture and placing of such substances on the EU market is prohibited. Pre-Registration is still available (so-called 'late pre-Registration') but only to companies who started to produce or import a phase-in substance at 1 tonne or more per year *for the first time* after 1 December 2008. However, this does not apply if it is within 12 months of the relevant phase-in Registration deadline for a given tonnage band. For more detailed information - see the ['Guidance on pre-Registration'](#).

3.0 Registration Phase

3.1 **What is Registration?** - Registration is required for all substances manufactured or imported in quantities of 1 tonne or more per year *by that Registrant* unless they are exempt from the scope of Registration. This requirement applies irrespective of whether substances are classified as hazardous or not. Registration requires manufacturers, importers and Only Representatives to collate information on the substances they manufacture or import and, where appropriate, to use that information to assess the potential hazards. With this information on the properties of the substance, and by working with others in the supply chain, the manufacturer, importer or Only Representative can, when appropriate, assess any risks to human health and / or the environment and develop appropriate risk management measures for the various uses of the substance. This information is sent to the ECHA as an electronic summary file (a Registration dossier). For more in-depth information - see the ['Guidance on Registration'](#) (specific details on the roles / responsibilities of Only Representatives and non-Community manufacturers can be found on pages 21 - 26 of the Registration Guidance).

3.2 For ‘phase-in substances’ that have been pre-Registered, a transitional regime applies which allows their continued manufacture or import and use (see Sections 3.3 and 3.4 on ‘Registration deadlines’).

3.3 **The deadlines for Registration** - These depend on whether the substances fall into one of the following two categories:

(a) **Phase-in substances**: REACH creates a special transition regime for phase-in substances. For these substances - and subject to pre-Registration requirements - the earlier Registration deadlines in 2010 and 2013 applied, as does the final deadline in 2018 (see details in the table in Section 3.4).

(b) **Non phase-in substances**: All substances not fulfilling any of the criteria for phase-in substances are considered ‘non phase-in substances’. Non phase-in substances do not benefit from the transitional regime provided for phase-in substances and need to be Registered before they can be manufactured, imported or placed on the EU market. It is important to note that the Registration of non phase-in substances will first require the submission of an inquiry dossier to determine whether a Registration for the same substance has already been submitted (see Section 3.7 part (b) on the ‘Article 26 Inquiry’ process).

3.4 **Deadlines for the implementation of REACH: ‘Phase-in’ Substances (applicable only if a substance was pre-Registered between 1 June and 1 December 2008, or is a ‘late pre-Registration’ after 1 December 2008)**

Date	Activity
30 November 2010	<p>Deadline for the Registration of phase-in substances manufactured / imported in the EU in quantities \geq 1,000 tonnes per year per manufacturer or importer at least once after 1 June 2007.</p> <p>Substances meeting the above criteria which were not Registered - if required by the specified deadline - could not legally be manufactured, imported or used within the EU as from 1 December 2010.</p>
30 November 2010	<p>Deadline for the Registration of phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction (category 1 or 2) and manufactured / imported in the EU in quantities \geq 1 tonne per year per manufacturer or importer at least once after 1 June 2007.</p> <p>Substances meeting the above criteria which were not Registered - if required by the specified deadline - could not legally be manufactured, imported or used within the EU as from 1 December 2010.</p>
30 November 2010	<p>Deadline for the Registration of phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment and manufactured / imported in the EU in quantities \geq 100 tonnes per year per manufacturer or importer at least once after 1 June 2007.</p> <p>Substances meeting the above criteria which were not Registered - if required by the</p>

	specified deadline - could not legally be manufactured, imported or used within the EU as from 1 December 2010.
31 May 2013	Deadline for the Registration of phase-in substances manufactured / imported in the EU in quantities \geq 100 tonnes per year per manufacturer or importer at least once after 1 June 2007. Substances meeting the above criteria which were not Registered - if required by the specified deadline - could not legally be manufactured, imported or used within the EU as from 1 June 2013.
31 May 2018	Deadline for the Registration of phase-in substances manufactured / imported in the EU in quantities \geq 1 tonne per year per manufacturer or importer at least once after 1 June 2007. Substances meeting the above criteria which are not Registered - if required by the specified deadline - cannot legally be manufactured, imported or used within the EU as from 1 June 2018.

3.5 When Registration is / is not needed

Example of when Registration is needed:

- A manufacturer of a substance who also uses that substance is a manufacturer and a DU. They have a duty to Register each substance manufactured in quantities of 1 tonne or more per year, unless exemptions apply, and will have to include information on their own use(s) and any identified uses of their customers in the Registration.
- An importer of a preparation has to Register those substances which are present in the imported preparation in quantities of 1 tonne or more per year, unless exemptions apply. They will have to include information in their Registration on the identified use(s) of the substance(s) in the preparation (although there is no need for importers of preparations to Register the preparations).

Example of when Registration is not needed:

- Any person who is using substances which they have not manufactured or imported is a DU and has no obligation to Register such substances. However, if they continue to place that substance on the market, they will still need to ensure that the substance has in fact been Registered (or pre-Registered) by an actor further up their supply chain. (The Registrant has in any event a duty to pass the Registration number down the supply chain.)
- An importer of a substance, a preparation or an article, who is importing from a non-EU company who has appointed an 'Only Representative' will be considered a DU and therefore does not need to Register.
- A manufacturer or importer of a substance which is exempted from Title II of REACH has no obligation to Register that substance.

3.6 The Registration Process – an Overview

3.7 **Data Sharing** - A key objective of REACH is the acquisition of data (including using the minimum number of animal tests, and only where unavoidable) on the properties of substances manufactured, supplied and used in the EU. To reduce the

amount of animal testing, Registrants are required to share information on substances, which can be achieved via one of two mechanisms:

(a) The Substance Information Exchange Forum (SIEF): A SIEF is comprised of all legal entities who:

- have pre-Registered a phase-in substance;
- have Registered a phase-in substance early;
- are the data-holders for a substance for which the ECHA holds a data package; and
- are downstream users (DUs) and other stakeholders (data-holders) who have and wish to share relevant information with potential Registrants.

SIEFs will be formed automatically within REACH-IT, comprising all the above stakeholders for each substance. There is no option to opt out of a SIEF, but a company can decide how active it wishes to be within it. A SIEF will have the following aims:

- to facilitate - for the purposes of Registration - the exchange of relevant information between potential Registrants and others with a view to sharing animal test data, thereby avoiding the duplication of studies; and
- to agree, if possible, the classification and labelling of a substance.

Each SIEF shall be operational until 31 May 2018 (the last Registration deadline under REACH).

To ensure the effective operation of a SIEF, a SIEF Formation Facilitator (SFF) may be chosen to manage activities and initiate communications / organise meetings - although, more than one member of the SIEF may indicate that they wish to be the SFF. A SFF is not a legal requirement under REACH.

Once a SIEF is active, a 'Lead Registrant' must be identified (the SFF does not need to be the same as the Lead Registrant). This is a legal requirement under REACH. The Lead Registrant's role is to produce the joint Registration data dossier to which the other joint Registrants will refer when making their individual Registrations. The Lead Registrant will submit the complete joint dossier to the ECHA containing the required data for physico-chemical, toxicological and environmental properties, at the same time as submitting his own individual Registration. Individual Registrations contain information specific to each company; for example, their identified uses / production volumes or their 'version' of the substance (i.e. to account for different impurities). In these submissions, instead of test summaries, they simply refer back to the joint dossier.

It is possible for a company to appoint a Third Party Representative (TPR) to represent them in a SIEF (i.e. to protect commercial confidentiality or to provide expertise in negotiating the data-share). However, a TPR cannot Register substances on a company's behalf. Therefore, companies using a TPR retain the legal liability for their own Registration.

For more in-depth information - see the [‘Guidance on Data-sharing’](#). Additional information clarifying aspects relating to SIEFs and the SIEF formation process is contained in the ECHA's [‘Fact Sheet: Getting Started in Substance Information Exchange Forums \(SIEFs\) - Top Tips’](#)

(b) Article 26 Inquiry: This data-sharing mechanism is used for non phase-in substances or for phase-in substances which have not been pre-Registered; both of which must be Registered for supply to start or continue. Prior to a Registration being submitted, an inquiry must first be sent to the ECHA to determine whether there has been a previous Registration or inquiry for the same substance. This is required in accordance with Article 26 of the EU REACH Regulation and is done via REACH-IT (see Section 3.13 for link to REACH-IT Guidance). The outcome of the inquiry will depend on whether the substance was previously Registered, or if others are also interested in Registration.

If there is an existing Registration, the ECHA can release any physico-chemical, toxicological or environmental data that they have held for 12 years or more. To access data held for less time, potential Registrants will have to seek permission from the original data holder. If duplicate inquiries are made, the ECHA will put the potential Registrants in touch with each other so that a joint submission can be undertaken.

When, due to a failure to pre-Register, a duty holder has had to Register a substance so that manufacture / supply can continue, then following Registration they will be added to the existing SIEF for that substance. This enables other potential Registrants to use the information that this 'early Registrant' has submitted to the ECHA. More information on the inquiry process is available in the [‘Guidance on Data-sharing’](#)

3.8 The Registration Dossier - There are two components to the Registration dossier - a Technical Dossier and a Chemical Safety Report (CSR). A CSR is only required for substances Registered in the 10 tonne per annum tonnage band or above. Both of these components are described below:

(a) The Technical Dossier - This contains a set of information about:

- the identity of the manufacturer / importer;
- the identity of the substance and information on the manufacture and use of the substance;

- the hazard classification and labelling of the substance;
- guidance on its safe use;
- robust study summaries of the information on the intrinsic properties of the substance (i.e. physicochemical, toxicological and ecotoxicological properties) derived from applying Annexes VII to XI of the EU REACH Regulation;
- an indication as to whether the information on manufacture and use, the classification and labelling, the (robust) study summaries and / or, if relevant, the CSR has been reviewed by an assessor;
- proposals for further testing, if relevant; and
- for substances Registered in quantities between 1 tonne and 10 tonnes - exposure related information for the substance (i.e. main use categories, type of uses, significant routes of exposure).

This information should then be compared against the information requirements outlined in Annexes VI to X of the EU REACH Regulation, which specify the information required for the different tonnage bands. The higher the tonnage the more information on the intrinsic properties of the substance is required. For example, in the 10 tonnes or more per annum band, the data needed is specified in Annexes VI, VII & VIII; at 100 tonnes or more the data requirements are set out in Annexes VI, VII, VIII and IX.

In instances where not all of the required information is available, Registrants needing information should (with other potential Registrants) determine suitable ways forward to fill data gaps. Registrants are required only to submit (or have access to) the information relevant to their tonnage band.

It is important to remember that it will not always be necessary to satisfy an information requirement by conducting animal tests. In fact, REACH specifically requires that animal testing is the last resort where absolutely unavoidable. Non-animal alternative test options must be considered and used where possible, such as *in-vitro* tests, using data from similar substances (known as read-across), using predicted properties / values obtained from existing models that assess chemical structures (known as Quantitative / Qualitative Structure-Activity Relationships (QSAR) or Quantitative Structure Property Relationships (QSPR)), or using arguments for not conducting a test based on properties (i.e. extreme pH) or exposure (known as waiving arguments). All of these techniques are explained more in Annex XI of the EU REACH Regulation and in the '[Guidance on information requirements and chemical safety assessment](#)' as well as in the UK REACH Competent Authority's '[Information leaflet on animal testing](#)' - <http://www.hse.gov.uk/reach/resources/18animaltesting.pdf>. Where there is more

than one Registrant (i.e. in SIEFs), agreement should be reached on the cost / conduct of any testing that is deemed necessary.

In circumstances where testing is required, this new information should be generated in line with the requirements of Annexes VII or VIII of the EU REACH Regulation. To fulfil the information requirements under Annexes IX or X (for the higher volume substances), then a testing proposal should be submitted as part of the Registration dossier which the ECHA will consider. Testing should only commence after the testing plan has been approved by the ECHA.

(b) Chemical Safety Report (CSR) - The CSR is the document resulting from the Registrant's Chemical Safety Assessment (CSA) for substances manufactured or imported in quantities ≥ 10 tonnes per annum. The CSR can be submitted separately or as part of a joint submission covering all uses. The CSR includes various hazard assessments and for substances meeting the criteria for classification as 'dangerous' the CSA must also consider exposure assessment and risk characterisation, including the development of Exposure Scenarios (ESs).

A CSA for a CSR should encompass:

- human health hazard assessment;
- physicochemical properties assessment;
- environmental hazard assessment; and
- assessment of whether the substance is PBT or vPvB.

For the CSR it will also be necessary to include information on the manufacturing processes (for substances made in the EU) and identified uses of the substance. Identified uses include those of: a company (i.e. manufacturer / importer / supplier); a company's customers; and any other uses made known to a company by DUs. To explore uses it is essential to communicate with DUs (however, they are not obliged to divulge details about their uses) - see other obligations in respect to DUs under Sections 3.10 parts (a) & (b), 3.11 and 3.12.

If a substance is classified as dangerous in accordance with **Regulation (EC) No. 1272/2008** on revised rules for the classification, labelling and packaging of substances (see details in [Appendix 3](#)) or fulfils the PBT or vPvB criteria in Annex XIII of the EU REACH Regulation as set out in **Regulation (EU) No. 253/2011** (see details in [Appendix 3](#)), the CSR must also include:

- **an exposure assessment:** to establish the Derived No Effect Levels (DNELs) for relevant routes of human exposure and the Predicted No Effect Concentrations (PNECs) for environmental exposure - this all entails the development of ESs and

associated exposure estimation (DNELs and PNECs are derived early-on in the CSR i.e. this stage involves the development of ESs); and

- **risk characterisation:** where the exposure of each human population and environmental compartment being exposed is compared with the appropriate DNEL or PNEC. Concern is indicated if the estimated exposure is higher than the relevant DNEL or PNEC. If the first estimate indicates risk, the Registrant has the choice of either:
 - refining the hazard assessment by obtaining more data; or
 - refining the exposure assessment by ensuring that the exposure estimation is realistic and reflects the use conditions defined in the initial ES (models or monitoring data can be used to this end); or
 - refining the ES by introducing more stringent risk management measures (RMMs) or changing the use conditions in the ES.

For more information on CSRs and Classification, Labelling and Packaging of Substances (CLP) - see the '[Guidance on information requirements and chemical safety assessment](#)' and '[Guidance on CLP](#)'.

3.9 EOSCA Generic Exposure Scenario Tool (EGEST) - In recognition of the REACH Registration requirement for ESs (assessing the potential health / environmental risks of chemical substances) to be appended to Safety Data Sheets (SDS), EOSCA has developed a generic ES tool known as EGEST for use by the offshore sector. Details on EGEST and the software can be accessed (free of charge) from: <http://www.eosca.eu/software/egest/> and <http://www.eosca.eu/software/> respectively. EGEST is a high-level first pass assessment designed to cover a large number of chemicals, with the ultimate aim of highlighting those substances of most concern for which the results of initial exposure scenarios might require more detailed assessments to satisfy the obligations of REACH. EOSCA intends to monitor progress on generic exposure scenarios and solicit feedback from stakeholders on EGEST. Accordingly, it is possible that EGEST will require further developments - to run alongside the REACH implementation timetable. For further information on EGEST contact the EOSCA Secretary at: secretary@eosca.eu.

3.10 Other Duties of Registrants - These relate to:

(a) Registrants duty of communication with - and provision of Safety Data Sheets (SDS) to - Downstream Users (DUs): In order to prepare their Registration dossier it is important that the Registrant communicates with their DUs. In particular they will need information about their uses and the RMMs they have already put in place. Tentative ESs could be used for the communication with DUs in order to refine the ES.

When supplying a substance or a preparation to another party or parties, the supplier has to provide a SDS to all the DUs and distributors they have supplied as of 1 June 2007, as soon as the substance on its own or in the preparation falls within one of the following categories:

- it meets the criteria for classification as dangerous; or
- it is PBT or vPvB; or
- it is included in the candidate list of substances (for eventual inclusion in Annex XIV of the EU REACH Regulation) which may be subjected to Authorisation.

In addition, a supplier of a substance could be requested at any time by a DU to provide a SDS for any preparation which does not meet the criteria for classification as dangerous but which contains:

- $\geq 1\%$ (by weight) for non-gaseous preparations (or $\geq 0.2\%$ by volume for a gaseous preparation) of a substance posing human health or environmental hazard, or
- for non-gaseous preparations $\geq 0.1\%$ (by weight) of a PBT or vPvB (or if it has been included in the candidate list of substances which may be subjected to Authorisation), or
- a substance for which there are EU workplace limits.

It is therefore highly recommended that each supplier of such substances prepares a SDS for those preparations. When supplying a substance on its own, the SDS has to be prepared for the substance itself. When supplying a substance in a preparation, the SDS has to be prepared for the preparation. In particular, the final ES developed for identified uses as part of the CSA has to be communicated to the Registrant's customers as an annex to the SDS, as this provides instructions on the RMMs that should be in place in order to ensure the adequate control of risks.

(b) Provision of other information to Downstream Users (DUs): When supplying a substance or a preparation for which a SDS is not required, the supplier still has to provide the following additional information to all the DUs and distributors they supplied as of 1 June 2007:

- the Registration number (see [Chapter Three](#) for details on the ECHA's post-Registration obligations), if available;
- if the substance is subject to Authorisation and the details of the granted Authorisation, or appropriate information if Authorisation has been denied;

- the details of any relevant restriction; and
- any other available and relevant information about the substance that is necessary to enable appropriate RMMs to be identified and applied.

3.11 **Downstream Users' Obligations** - DUs are required to consider the safety of their uses of substances, based primarily on information from their suppliers, and to apply appropriate RMMs. DUs will therefore need to communicate effectively with their suppliers to get the information they need in the SDS supplied to them. In addition, DUs must alert those entities up the supply chain if they become aware of any hazards from substances or inaccurate safety advice in the SDSs.

3.12 To get the relevant information, DUs can make their uses known to their suppliers so that the suppliers can include these uses in their CSAs as identified uses or pass the request on up the supply chain. A DU can also choose to keep their use confidential or decide to use a substance outside the conditions described in the ESs communicated to them. In these cases, the DU will have to perform a CSA developing the ESs for their intended uses and, if necessary, a refinement of the supplier's hazard assessment. This obligation does not apply if the DU uses less than 1 tonne of the substance per year. However, a DU relying on the 1 tonne exemption still needs to consider the use(s) of the substance and identify, apply and recommend appropriate RMMs. For more information - see the ['Guidance for DUs'](#).

3.13 **Submitting a Registration** - The technical dossier must be compiled using the IUCLID software (<http://iuclid.eu/>) - see also ['Guidance on IUCLID 5'](#). The IUCLID software can be downloaded (free of charge) and the appropriate structured template should be used for the tonnage band involved. If the tonnage of a substance is 10 tonnes per year or greater, and a CSR is required, this should be a stand-alone document attached to the IUCLID dossier. All dossier submissions / correspondence regarding the Registration will occur via a Registrant's REACH-IT account. More information is also available in the Registration part of the ['Guidance on REACH-IT'](#).

3.14 **Applicable fees** - Registrants will be obliged to pay a fee in accordance with **Regulation (EU) No. 254/2013** (amending **Regulation (EC) No. 340/2008**) which sets out the fees companies will be charged by the ECHA for operations under REACH - see details on the current and previous Fees Regulations in [Appendix 3](#).

3.15 In effect, the key objective of **Regulation (EU) No. 254/2013** is to further reduce REACH-related fees and charges for micro, small and medium-sized enterprises (SMEs).

3.16 **Access to information and confidentiality** - A large amount of basic information, data and results of studies carried out in the Registration process will be made available free of charge by the ECHA. However, if a Registrant successfully claims confidentiality on Registration of a substance, the following information will not be included on the ECHA's website:

- the degree of purity of substances;
- total tonnage bands;
- study summaries; and
- certain information in SDS.

3.17 Further, the ECHA will not normally disclose (whether on its website or otherwise) information where disclosure may harm an organisation's or a person's commercial interests and includes: **(i)** the full composition of preparations; **(ii)** precise uses, functions and applications of substances or preparations; **(iii)** tonnages marketed; and **(iv)** details of links in the supply chain.

CHAPTER THREE

Post-Registration aspects of REACH

4.0 Post-Registration - What happens next?

4.1 Once the ECHA receives a Registration dossier, it will be responsible for the following:

(a) Assigning a submission number: For any submission, the ECHA will assign a submission number to the Registrant. This is just an acknowledgement number and is **NOT** the Registration number. It should be used as a reference in all correspondence relating to the Registration until a Registration number is assigned.

(b) Completeness check and invoicing procedures: The completeness check process comprises:

- **Technical completeness check** - This process is aimed at checking the technical completeness of the dossier. The main purpose of this check is for the ECHA to make sure that, depending on the tonnage range, all the information (as required under REACH) has been provided. After submission to the ECHA each received dossier is screened for technical completeness depending on the legal requirements for the type of dossier concerned. The system checks if all required fields are filled-in and that all testing proposals, derogation statements and waving statements are included. In the case of a negative result, the ECHA will verify the outcome of the completeness check to make sure that the decision is fully correct. In this context, a Technical Completeness Check (TCC) Plug-in Tool has been made available within IUCLID 5 - the TCC Tool (which will help companies to ensure that their Registration dossiers pass the completeness check) is at: <http://iuclid.eu/index.php?fuseaction=home.news&type=public&id=52>). See also '[Guidance on IUCLID 5](#)'.
- **Financial completeness check** - The ECHA will monitor the payment of the fee as specified in the invoice. If a Registrant fails to pay the full amount by the deadline indicated on the invoice, the ECHA shall set a second reasonable deadline. If the Registrant fails to meet the second deadline, the Registration dossier shall be rejected. There could be circumstances, such as internal procedures or periods of limited service within a company, under which timely payment could be problematic. In that case it is recommended to prepare the payment of the fee due before submitting the dossier so that the ECHA will receive the proof of payment in time before finalising the completeness check after submission of the dossier.

At least 5% of all Registrations will also be selected at random to undergo a full compliance check (a rigorous check that the information required is present, scientifically valid and of the appropriate quality). Within 3 weeks of the submission date, the ECHA will either contact the Registrant to inform them that the dossier is not complete or issue a Registration number (see parts (c) & (d) below). For phase-in substances, manufacture or import can continue during this 3 week assessment period. For non-phase-in substances, manufacture or import (at > 1 tonne per annum) can start once the 3 week assessment period has ended. For phase-in substances submitted near the deadline, this assessment period is extended to 3 months.

(c) Rejection of a Registration dossier: If the ECHA decides that a Registration dossier is not complete, the Registrant will be sent a report indicating the missing information and giving a deadline for the submission of this additional information. The Registrant should then add this information to the dossier and re-submit the entire dossier to the ECHA before the set deadline. A new submission date will be assigned and a new completeness check will be done.

Where the Registrant fails to complete their Registration for the second time within the deadline set, the ECHA will reject the Registration (see Sections 4.6 and 4.7 on the Appeals process). The Registration fee will not be reimbursed and the company will not be allowed to manufacture or import the substance within the EU. If a Registrant still wishes to Register the substance, it will need to start from the beginning of the process, possibly including paying the fee again.

(d) Acceptance of a Registration dossier: Once a Registration is deemed complete, it will be automatically assigned a Registration number and this will be sent by the ECHA to the Registrant without delay. The date of Registration will be the same as the latest submission date. Registrants should use this Registration number in all further correspondence relating to the Registration.

4.2 Informing the relevant Member State Competent Authority - The ECHA has to notify the Competent Authority of the Member State within which the manufacture takes place or the importer is established, that the Registration has been submitted and that the Registration dossier together with the submission or Registration number and date as well as the result of the completeness check is available in the ECHA database. If the manufacturer has production sites in more than one Member State, all relevant Member States will be notified. The ECHA will also notify the Competent Authorities of the Member States about any request for further information including deadlines set and when any further information submitted by the Registrant is available on the ECHA database.

4.3 Procedures in the case of a Registration update - Once a Registration is in place for a substance, it is the Registrant's responsibility to ensure that it is kept up-to-date. A Registrant may wish to update a Registration for various reasons such as:

- the substance composition has changed;
- the tonnage band has increased,
- additional information coming to light (e.g. about classification and labelling); or
- the company's information has changed.

4.4 This new information should be submitted to the ECHA without undue delay. For some types of update a fee is charged. A Registration may also need to be updated as a result of a decision that has been made by the ECHA e.g. following the submission of testing proposals (in this case, the ECHA will issue a deadline for completion of the update).

4.5 In addition, existing Registrants will be informed by the ECHA if a new Registrant for the same substance submits new information. Earlier Registrants will be expected to consider this information and update their Registration if appropriate. When submitting an update, this should also be done via REACH-IT on the ECHA website. The entire dossier should be submitted again, including all the new information in the appropriate sections.

4.6 **Appeals process** - When a Registrant disagrees with any ECHA decisions, they can appeal against those decisions to the ECHA's Board of Appeal. All appeals must contain a statement of the grounds on which the appeal is based. The appeal may also be filed in writing by a person other than the Registrant if the decision is of direct and individual concern to another person.

4.7 The appeal will subsequently be examined by the ECHA in consultation with the Board of Appeal and the result communicated to the Registrant (or another person if appropriate) in accordance with **Commission Regulation (EC) No. 771/2008** on the rules pertaining to the Board of Appeal of the ECHA (see details in [Appendix 3](#)). If the result is still not to the liking of the party concerned, an action may be brought before the Court of First Instance or the Court of Justice, contesting the decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the ECHA.

4.8 Evaluation of Substances

4.9 Substance evaluation involves further investigation into the characteristics of higher risk substances. The ECHA, in co-ordination with the Competent Authorities of Member States, may clarify suspicions of risks to human health or the environment by requesting further information. To promote a consistent approach, the ECHA, in co-operation with Member States, has developed guidance on the prioritisation of substances for further evaluation - more information is available in the '[Guidance on Priority Setting for Evaluation](#)' (although note situation concerning that Guidance document as explained in Appendix 5).

4.10 Any draft decision prepared by a Competent Authority of a Member State requesting further information on a substance must either be accepted by all other Member States' Competent Authorities, in which case the ECHA takes the decision, or if an agreement cannot be reached the European Commission takes the decision. Evaluation may lead authorities to the conclusion that action needs to be taken under the restrictions or Authorisation procedures in REACH, or that information needs to be passed on to other authorities responsible for relevant legislation.

4.11 Authorisation of Substances

4.12 Authorisation is required for continued uses of particularly hazardous substances (also known as substances of very high concern (SVHC)). These are substances that are (or will be) listed in Annex XIV of the EU REACH Regulation - see latest **Regulation (EU) No. 895/2014** which amends Annex XIV in [Appendix 3](#). Substances eligible for inclusion in Annex XIV include those that:

- cause cancer, mutations, or reproductive problems (CMRs);
- are persistent, bio-accumulative and toxic (PBTs);
- are very persistent and very bio-accumulative (vPvBs); or
- have probable serious effects for humans and / or the environment which are of equivalent concern to the other categories (for example, endocrine disruptors).

4.13 SVHC listed in Annex XIV will be given a sunset date (likely to be around 3 - 4 years from the date of listing in Annex XIV) after which manufacturers, importers or DUs cannot place on the market or use any of these substances unless that use has been specifically Authorised by the European Commission. Some uses i.e. as intermediates or biocides, are not subject to Authorisation.

4.14 Applications for an Authorisation by the Commission are made via the ECHA, and must be submitted no later than 18 months **before** the sunset date for that substance - see more details in the '[Guidance on the preparation of an application for an Authorisation](#)'. Applications can be made by manufacturers, importers and / or DUs of the substance in question. They may be single or joint applications for one or more substances. In similar vein to Registration, a scale of fees applies to Authorisation applications, based on size of company and the number of applicants and substances involved (further details are given in **Regulation (EU) No. 254/2013** - see details in [Appendix 3](#)). Any Authorisation will extend only to specific permitted uses of the substance. In determining whether the use of a hazardous substance is to be Authorised, the following factors will be taken into consideration:

- Control of risks - For CMR substances, an Authorisation may be granted if the producer or importer can show that the risks of the substance can be adequately controlled i.e. minimum exposure thresholds are established below which no adverse effects are shown.
- Socio-economic benefits - where adequate control cannot be shown (e.g. for PBTs and vPvBs), an Authorisation may be granted if the socio-economic benefits of continued use outweigh the risks to human health and / or the environment (see further information in the '[Guidance on the preparation of a socio-economic analysis as part of an application for an Authorisation](#)').
- Possible alternative substances – an analysis of possible safer alternatives must be undertaken, and where they exist a substitution plan must be included with the Authorisation application.

4.15 The intention of Authorisation is to remove SVHC from the market over time, and replace them with suitable safer alternatives. Additional information on the Authorisation process can be found in the UK REACH Competent Authority's '**Information leaflet on Authorisation**' - <http://www.hse.gov.uk/reach/resources/19authorisation.pdf>.

4.16 Restriction of Substances

4.17 Restrictions on the use of specific dangerous substances within Europe made under the previous EU chemicals control regimes have been carried over into Annex XVII of the EU REACH Regulation, and cover the marketing and use of around 1,000 substances, including a ban on the marketing to the public of about 900 CMRs.

4.18 Under REACH, the Commission, Member States and the ECHA are all able to initiate restrictions by preparing a detailed technical dossier of information on substances where a risk is posed to human health and / or the environment that is not adequately controlled and needs to be addressed on an EU-wide basis. Where the procedure is initiated, the ECHA is required to evaluate the proposal for restriction (in consultation with interested parties) and then give the Commission its opinion on the proposal. The final decision on whether or not to adopt the restriction sits with the Commission. If adopted, restrictions are then entered in Annex XVII of the EU REACH Regulation.

APPENDIX 1

Specific REACH issues pertaining to the offshore sector

(A) Registration

A1. Who has the obligation to Register under REACH?

Article 6(1) of the EU REACH Regulation indicates that any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a Registration to the ECHA. With regard to the definition of a ‘manufacturer’, Article 3(9) of REACH states that: ‘Manufacturer’ means any natural or legal person established within the Community who manufactures a substance within the Community.

For example, where a Registerable substance is produced on an offshore installation (and subsequently used or placed on the market) which is operated by one company (i.e. the Duty Holder) on behalf of the main Operator the responsibility for Registering the substance lies with the Duty holder as they are the company who actually make (manufacture) the substance. However, where a Duty Holder plans to undertake Registration, it is strongly recommended that they liaise with the Operator prior to submitting any dossiers to the ECHA, to ensure compliance with the Offshore Chemicals Regulations where permits for the use and / or discharge of operational chemicals are issued to the Operator - not the Duty Holder. The Operator may also be able to provide a significant degree of assistance in the preparation of the REACH Registration dossier.

A2. The formation of consortia by offshore sector companies for REACH Registration

A consortium for the pre-Registration of sodium hypochlorite (see latest situation on this substance under item A4 part (iii) below and [Chapter One](#) - Section 1.2 part (C) item (i)) for offshore Operators was formed / managed by BMT Cordah. A key issue is identifying other Operators who pre-Registered and possibly wish to Register similar substances. It is suggested that (in addition to the SIEF activation process as referred to in [Chapter Two](#) - Section 3.7 part (a)) Operators contact Oil & Gas UK and identify the substances they have already pre-Registered and then compile these lists and contact like-minded parties to see if they are interested in forming consortia.

A3. What are the options for correcting errors in pre-Registration submissions that are discovered during the course of the pre-SIEF sameness checking process (i.e. if a submitted CAS number is the same chemically, but another CAS better describes the physical state of the substance, can the potential Registrant be allowed to join the correct SIEF)?

A pre-Registrant who has possibly poorly defined their substance during the pre-Registration process can use the 'similar substances' tab in REACH-IT (pre-Registration > substance identification) to enter the correct SIEF. Nevertheless, this does not alter what has been pre-Registered and it would be an enforcement issue for the relevant Member State Competent Authority to decide if the initial pre-Registration is valid. In the scenario in question, where the correct chemical substance has been pre-Registered, but an alternative CAS name may better describe its physical state, it would seem likely that using the 'similar substances' tab would be acceptable and that the pre-Registration would be accepted as valid. However, if the chemical identity of the pre-Registered substance is different from the one that should have been pre-Registered (as an example, copper sulphite instead of copper sulphate), then this approach may not be acceptable. Therefore, the ECHA solution does allow a company to get into the correct SIEF, but does not allow an incorrect pre-Registration to be changed.

A4. Annex V exemptions

(i) Substances processed in their natural state: Crude oil, gas, natural gas, methane, condensate, natural gas condensate, liquefied natural gas (LNG), natural gas liquids, liquefied petroleum gas (LPG), propane, butane, and *iso*-butane as derived from hydrocarbon production, are extracted / processed in their natural form and not chemically modified. In this regard:

- the addition of chemicals to stabilise substances such as crude oil and to sweeten natural gas / condensate are not considered to alter their 'natural status'; and
- the definition of 'not chemically modified substance' under Article 3(40) of the EU REACH Regulation includes substances that undergo chemical processes to remove impurities.

Therefore, on the basis of these factors, all of the above substances should be exempt from the Registration requirements of REACH.

(ii) By-products: Substances that are stripped from the hydrocarbon stream (i.e. mercury / sulphur) and disposed of as waste would be exempt from the Registration requirements of the EU REACH Regulation. If such substances were subsequently placed / sold on the market then they would have to be Registered accordingly. In this context, under **Regulation (EC) No. 1102/2008** on the banning of exports of metallic mercury and certain mercury compounds / mixtures ("the EU Mercury Regulation"), the export outside of Europe of any mercury that is gained as a by-product of industrial processes

was banned from 15 March 2011 (see EU Mercury Regulation at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:304:0075:0079:EN:PDF>). The EU Mercury Regulation is enforced in the UK through the UK Mercury Export and Data (Enforcement) Regulations 2010 (available at: <http://www.legislation.gov.uk/ukxi/2010/265/contents/made>). A guidance document for the offshore industry on the obligations of the EU Mercury Regulation has also been produced which is at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/422852/Offshore_Industry_Guidance_on_the_EU_Mercury_Legislation.pdf. **Please note:** The Registration obligations of REACH would still apply to any mercury that might be traded / exported (as a product) within the EU.

(iii) Sodium hypochlorite: This is generated in-situ on offshore installations (i.e. via electrochlorination units) primarily for the purpose of controlling biological activity in seawater. Once generated the substance would invariably be utilised immediately before seawater is discharged back into the environment. Due to the nature of this process, there is no human exposure to the sodium hypochlorite and the environment is exposed to inert seawater (any hydrogen - which is explicitly exempt from Registration - that may also be present is vented to the atmosphere). The sodium hypochlorite is not usually isolated nor placed on the market. Consequently, under these specific conditions, sodium hypochlorite (and other products of the electrolysis process) should, in the UK's opinion, be exempt from the Registration obligations of REACH (in accordance with Annex V, paragraph 3).

Even though the position of some Member States on the issue of sodium hypochlorite generation differs from the UK's (certain Member States believe the in situ generation of sodium hypochlorite should be subject to the appropriate requirements of REACH on the basis that the sole purpose of the electrochlorination units is to manufacture sodium hypochlorite for the manufacturer's (e.g. Operator's) own use and subsequent disposal (i.e. whilst the electrochlorination unit is an article, the sodium hypochlorite generated is not considered to be a mere side effect of the use of that article, as it is the article's only function)) and notwithstanding the points raised in item A2 above, it is nevertheless the case (as briefly explained in [Chapter One](#) - Section 1.2 part (C) item (i)) that sodium hypochlorite is subject to the requirements on 'newly within scope' products under the Biocides Regulation (EU) No. 528/2012.

In a related development, representatives from Oil & Gas UK, EOSCA and the Energy Institute have met with the HSE to discuss issues pertaining to the EU Biocidal Products Regulation (BPR) and the generation of in-situ sodium hypochlorite. It has been confirmed that a manufacturer of equipment used for the process would be submitting a BPR Active Approval for the use of the equipment and that it could take 4-5 years to gain approval. Whilst not actually provided for in the legislation, the HSE indicated that it was content for equipment manufacturers to complete the Product Authorisation for their plant, rather than the Operators as the legislation requires. Oil & Gas UK advised that it was compiling a list of equipment types used on offshore installations and intended to contact suppliers to verify if they would support Operators under the BPR.

Please note: Ethane, which is fractionated as a separate stream from the hydrocarbon process, is not exempt under Annex V of the EU REACH Regulation because it does not fall within the categories of ‘natural gas’, ‘natural gas condensate’, or ‘LPG’.

A5. Registration for Recovery Operations

(i) MEG / TEG cleaned-up by an Operator (i.e. the removal of salty contamination) on site for re-use would not require Registration.

(ii) If an Operator passes used MEG / TEG - under a waste transfer notification - to another for clean-up / re-use, the third party’s cleansing process would be classified as ‘recovery’, which would benefit from the Article 2(7)(d) exemption when another Registrant (anywhere in Europe) Registers the same substance.

A6. If a platform has a Bio-Fouling Copper Chlorine unit does the copper need to be Registered under REACH (i.e. the copper is stripped from a sacrificial anode and is therefore not technically manufactured)?

Copper anti-fouling units work by producing copper ions as a biocide in its own right (good marine anti-fouling properties). They should not be confused with sodium hypochlorite generator units that use a different electrode which does not corrode. The copper ions that are released - as a function of the copper (electrode based) anti-fouling devices - could not be considered a substance (being neither copper metal nor a full copper salt) and should therefore, be exempt (under Annex V, paragraph 3) from the Registration requirements of the EU REACH Regulation.

A7. What is the status of PLONOR substances under REACH?

PLONOR substances are considered to “Pose Little Or NO Risk” to the Environment. This is a designation assigned to substances by OSPAR’s Offshore Industry Committee, based on physico-chemical and ecotoxicological parameters. PLONOR chemicals do not have to be risk assessed under the Offshore Chemicals Regulations. However, the PLONOR designation has no status under the EU REACH Regulation - therefore, substances designated PLONOR by OSPAR may still require Registration under REACH. The only equivalent status afforded by REACH is given in Article 2(7)(a), where substances which are considered to cause minimum risk (and for which there is sufficient information already available) are listed in Annex IV of the EU REACH Regulation and Registration is not required. The amended Annex IV (see details in [Appendix 3](#)) currently lists 40 substances. Only 6 PLONOR substances (OSPAR Commission, 2204-10E) are currently included in Annex IV. These are:

CAS No.	EINECS No.	Annex IV name	PLONOR name
50-70-4	200-061-5	D-glucitol	Sorbitol
50-81-7	200-066-2	Ascorbic acid	Ascorbic acid
63-42-3	200-599-2	Lactose	Lactose
8002-43-5	232-307-2	Lecithins	Lecithin

9005-25-8	232-679-6	Starch	Pregelatinized potato starch
65996-61-4	265-995-8	Cellulose pulp	Cellulose fibre

A8. Is Registration required for current stocks of chemicals already purchased and being used that are no longer manufactured?

Existing stocks will not require Registration if they are for an offshore Operator's / chemical manufacturer's own industrial use. However, if any stocks are to be later placed on the market (i.e. sold to third parties) then Registration will be required.

A9. Do Operators need to individually check Registration of the products used?

Operators, as Downstream Users (DUs), should check with suppliers that any products that are currently being used have been pre-Registered or Registered and will continue to be available. It is an offence for a supplier to market substances that have not been pre-Registered or fully Registered under REACH in accordance with the prescribed deadlines.

Additionally, Operators should be aware that although they may request a pre-Registration or Registration number from their suppliers, the suppliers are not obliged to communicate this information.

(B) REACH Compliance - General Issues

B1. How does REACH affect the continued supply of chemicals for the offshore industry?

Unless included under the exemptions listed in Annexes IV and V, or covered by existing EU legislation, all chemicals used by anyone (including the offshore industry) will be subject to the provisions laid down by REACH. If a manufacturer or importer chose not to pre-Register a 'phase-in' substance by the 1 December 2008 deadline, then they had to submit a full Registration dossier to the ECHA if they wished to continue manufacturing, importing or supplying the substances in quantities of 1 tonne or more - otherwise that substance or any products containing it will not be legally available within the EU. However, 'late pre-Registration' is available but only to companies who started to produce a phase-in substance at 1 tonne or more per year *for the first time* after 1 December 2008, but not within 12 months of the relevant phase-in Registration deadline - note paragraph below.

The first and second REACH (full) Registration phases for certain pre-Registered substances manufactured / imported / supplied in volumes equivalent to or greater than 1,000 tonnes per year and 100 tonnes per annum closed on 30 November 2010 and 31 May 2013 respectively. Substances meeting the relevant criteria which were not Registered - if required by the specified deadlines - could not legally be manufactured, imported or used within the EU as from 1 December 2010 and 1 June 2013. The final Registration deadline is 31 May 2018 for phase-in substances manufactured / imported in the EU in quantities ≥ 1 tonne per year.

B2. What measures must be taken to comply with the EU REACH Regulation?

This depends on an Operator's position within the supply chain. Operators may have obligations as manufacturers, importers or DUs. The specific obligations in the EU REACH Regulation are:

- Manufacturers and Importers have the same responsibilities for Registration, and a list of these can be found in Title II, Chapter 1 of the EU REACH Regulation. Further Information may be found in Annexes VI - X on the standard information requirements.
- DU obligations are detailed in Articles 37 - 39 and 111.
- Suppliers' / distributors' obligations are covered in Articles 31, 34, 36, 37 and 111.

In all cases, it is important to keep in mind Article 5 of the EU REACH Regulation which emphasises the fact that substances on their own, in preparations or in articles shall not be manufactured in the EU or placed on the market unless they have been Registered in accordance with the relevant provisions of REACH.

B3. What measures can be taken to mitigate the effects of REACH?

The timelines that have been outlined in the EU REACH Regulation are realistic, however, careful planning and preparation will minimise the effort that is required for compliance. The only way to mitigate the effects and impacts is for offshore Operators to identify their obligations, put strategies in place to address and meet those obligations, and to seek assurances from chemical manufactures / suppliers.

B4. How in practice can Operators as Downstream Users consider their uses of substances?

REACH requires that substances are not only Registered, but they are only deployed for uses which have been identified and assessed. These uses will be assessed through Exposure Scenarios (ESs), and the intention is that DUs should support and contribute to the process of developing ESs. EOSCA has developed a generic exposure scenario tool for oilfield chemicals to support their members (see details under [Chapter Two](#) - Section 3.9). Operator input has been sought, however, EOSCA would be open to additional input from Operators to further develop the ES tool.

B5. Who has to develop exposure scenarios for offshore chemical use?

The manufacturer or importer of the chemical develops the exposure scenarios, although it is advisable for Operators (as DUs) to communicate their uses of the chemical upstream so that it may be included in the Chemical Safety Assessment. A DU may be required to prepare their own Chemical Safety Report in accordance with Annex XII of the EU

REACH Regulation for any uses not supported by their suppliers, or for any uses that suppliers advise against.

B6. Does an offshore sector company have to satisfy themselves that any chemicals are REACH compliant, where operations are being carried out by third party contractors?

Legally the responsibility for REACH compliance lies with any natural or legal person within the EU who uses the substance in the course of industrial or professional activities. This is supported by the definition of a DU in Article 3(13) of the EU REACH Regulation. As the substance is not being directly used by the offshore company, they have no legal obligation to check for REACH compliance. However, as mentioned in item B7 below, an offshore company will have an interest for reasons of business risk to ensure that third party contractors are operating in accordance with REACH.

B7. What are an offshore sector company's REACH obligations where they have representatives on a mobile drilling rig, manned by drilling contractors?

The drilling contractor is responsible for ensuring the chemicals are REACH compliant, as it is the contractor and not the offshore company that is actually using the chemical. This is supported by the definition of a DU in REACH Article 3(13). The licensed / approved Operator will nevertheless have an interest for reasons of business risk to ensure that their contractors are operating in accordance with REACH.

(C) Import

C1. What constitutes import under REACH?

Import is defined in Article 3 of the EU REACH Regulation as “the physical introduction of substances into the customs territory of the Community”.

C2. Mobile Drilling Rigs (MDRs) – classification as importers / re-importers

(i) Operators responsible for the movement of MDRs entering EU (including EEA) waters from non-EU waters would be classed as either: **(a)** importers (for new / non-EU sourced substances); or **(b)** re-importers (for EU sourced substances) and so should Register all the substances that they intend to use, unless the original suppliers have already fully Registered them.

(ii) Substances used in transport mode only, or being brought in (not used) and taken back out of EU waters should not need to be Registered.

(iii) Registered substances taken out of EU waters for use and then brought back in again by the same Operator would not be classified as re-imported – so no actions would be required under REACH.

(iv) Operators of MDRs entering EU waters after 1 December 2008 for the purpose of undertaking exploration activities could still benefit from the extended Registration deadlines for re-imported (phase-in) substances, if they undertake 'late pre-Registration' of the substances in accordance with REACH - note paragraph below.

However, where any re-imported (phase-in) substances were pre-Registered and they fulfilled the criteria under the first and second REACH (full) Registration phases, then in-line with the requirements set out under item B1 above, such substances had to be Registered with the ECHA by 30 November 2010 and 31 May 2013 respectively.

- In terms of ensuring compliance by MDRs, under DECC's Offshore Chemicals Regulations the use of any substances requires authorisation - hence, there will be an opportunity to ensure alignment with REACH via the revised HMCS approach.
- It is recognised that the average number of instances per year involving the movement of MDRs into / out of EU waters are very low. Consequently, the possibility for breaches of the EU REACH Regulation's provisions - bearing in mind that DECC (in liaison with the HSE) can adopt a pragmatic approach to offshore enforcement - is perceived as being only a minor problem and one that could have potentially existed until the end of November 2010 or maybe 31 May 2013 (the first and second REACH (full) Registration deadlines for large volume substances).

C3. If an Operator imports a chemical from outside the EU which is not yet Registered does the duty for Registration fall on the Operator?

In this situation as the manufacturer is from outside the EU, the Operator holds the legal obligation for Registration, unless the non-EU manufacturer has appointed an Only Representative which is covering the supply chain the Operator is within.

APPENDIX 2

REACH-related developments

(A) ECHA developments on REACH and other related topics (December 2015 to March 2016)

December 2015

(i) ECHA scientists backed a joint German-Norwegian proposal for wide-ranging restrictions on PFOA. The Committee for Socio-Economic Analysis (SEAC) and the Committee on Risk Assessment (RAC) supported restricting the manufacture, marketing and use of PFOA, with its salts and related compounds, following its draft opinion from September 2015. See SEAC Statement at: http://echa.europa.eu/view-article/-/journal_content/title/seac-concludes-on-three-restriction-proposals-and-three-authorisation-applications. PFOA is classed as a substance of very high concern (SVHC) under the EU REACH Regulation, and the Commission is pushing for global controls on the substance. It is often used to produce, amongst other things, fire-fighting foams.

(ii) According to a report by the ECHA, around 13% of companies did not fulfil some of their Registration obligations under the EU REACH Regulation in 2013 / 2014 - the ECHA report is available from: http://echa.europa.eu/documents/10162/13577/ref_3_report_en.pdf. The report indicates that most of the cases involved companies which missed just one or two substance Registrations - however, 2% of companies failed to make any Registrations at all.

The ECHA investigated 1,169 companies and 5,746 substances in all Member States in cooperation with national authorities. In 2014, preliminary results of the project found that 17% of companies had not fulfilled their Registration obligations. Similarly to those results, the new findings show that the majority of non-compliance was with Only Representative (OR) firms (companies that Register chemicals on behalf of downstream users and importers). A separate ECHA investigation found that 32% of 104 OR firms did not comply with their specific information duties under REACH. Importers were often found to be non-compliant due to a lack of awareness / familiarity of their Registration obligations under REACH.

(iii) The ECHA also:

- Updated the list of substances that might be chosen for compliance checks. The list - which now includes altogether 50 new substances - is at: http://echa.europa.eu/view-article/-/journal_content/title/update-to-the-list-of-substances-potentially-subject-to-compliance-checks.

- Announced that the Agency had added another five substances to the Candidate List of substances of very high concern (SVHCs) for Authorisation - see further details at: http://echa.europa.eu/view-article/-/journal_content/title/five-new-substances-of-very-high-concern-added-to-the-candidate-list.
- Published updated guidance relating to the presence of hazardous chemicals in product components following a landmark EU Court ruling. The updated guidance - accessible via: http://echa.europa.eu/view-article/-/journal_content/title/guidance-on-substances-in-articles-updated - was issued to reflect a ruling by the EU Court in September 2015 (details at: <http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14>) that existing rules to notify the presence of substances of very high concern (SVHCs) over a concentration of 0.1% applies to components of a product as well as the assembled whole. The updated guidance only corrects the parts of the guidance with references to the 0.1% limit that are no longer consistent with the conclusions of the Court's judgement. Producers must communicate information on SVHCs in each of a product's specific components, while importers are obliged to collect this information. The ECHA noted that components are defined as 'articles' when they are given a special shape, surface or design during the production process, or as long as they do not become waste. A more comprehensive update will be issued at the end of 2016 following a full consultation process. This will constitute a more general update and re-structuring of the guidance document, plus new examples that are aligned with the Court's judgement.

January 2016

The ECHA issued:

- A statement relating to an update of the EU REACH Regulation's Registration rules - further details are available from: http://echa.europa.eu/view-article/-/journal_content/title/registrants-of-the-same-substance-must-be-part-of-the-same-registration.
- An announcement that the Agency had selected nearly 300 substances from REACH Registrations for further scrutiny by the Member State competent authorities - see more information at: http://echa.europa.eu/view-article/-/journal_content/title/echa-shortlists-substances-for-possible-regulatory-acti-1. The Member States competent authorities will carry out a manual examination of the dossiers they prioritise to decide whether there is a need for regulatory action.

February 2016

(i) According to an ECHA report, the substance evaluation process under the EU REACH Regulation was generally working well but could be improved - the report is available from: http://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf. The report indicates that the process could be enhanced through prioritising work to target uses or forms of exposure of potential concern and then find substances that correspond

to such criteria. The report recommends that relevant dossiers should be checked for quality before evaluation starts.

Substance evaluation is triggered when Member States and the ECHA have concerns about a substance and its use patterns but there is not enough information available to make a conclusion about its risk. The process has been in place since 2012.

About 50 substances are evaluated annually by Member State authorities. Following the evaluation, they could conclude that current regulation is sufficient or could propose appropriate national or EU-level risk management options. These might include restriction or Authorisation under REACH. The Community Rolling Action Plan (CoRAP) specifies which substances are to be evaluated over a three-year period. The report also suggests that the ECHA could better explain why substances have been included in CoRAP and why decisions have been taken after substance evaluation. The report's findings will feed into the ECHA's more general review of REACH implementation due later in 2016.

(ii) An investigation of the first substances banned under Annex XIV of the EU REACH Regulation has identified only three cases of non-compliance - see ECHA Statement and report at: http://echa.europa.eu/view-article/-/journal_content/title/forum-first-pilot-project-on-authorisation-finds-only-three-cases-of-non-compliance and http://echa.europa.eu/documents/10162/13577/first_forum_pilot_project_authorisation_en.pdf respectively. MDA and musk xylene have been banned for use in the EU since 21 August 2014, the earliest such 'sunset date' on the REACH 'Authorisation list'. No firms applied for Authorisation to continue using the substances after the sunset date. National enforcement authorities from 18 Member States inspected compliance in the first half of 2015, carrying out 235 on-site inspections.

The ECHA reported that micro, small and medium-sized companies made up 71% of those inspected. Just over half of the firms were chemicals manufacturers. The working group that carried out the project recommended that the Commission should provide clarifications of exemptions, including for intermediates, scientific research and substances in low concentrations in mixtures. The ECHA indicated that the project was a successful first step towards the enforcement of Authorisation under REACH. There are now 31 substances on the Authorisation list, of which 14 have already passed their sunset date. Only one substance, trichloroethylene will reach its sunset date in 2016, but 12 such deadlines are due in 2017.

(iii) The ECHA also:

- Released Registration data to support development of non-test methods - see further details at: http://echa.europa.eu/view-article/-/journal_content/title/echa-gives-out-registration-data-to-support-development-of-non-test-methods.
- Published a Statement reminding businesses of the 1 September 2016 deadline to Register under the Biocides Regulation (EU) No. 528/2012 active substances used for

treated articles - see the Statement at: http://echa.europa.eu/view-article/-/journal_content/title/apply-for-approval-of-active-substances-used-for-treating-articles-by-1-september-2016. Companies will need to submit a complete dossier on the active substance to the ECHA by the specified date to continue to place a treated article on the EU market. For articles containing active substances that are already approved for that particular use there is no new obligation. However, articles incorporating biocides that are not so approved, or under evaluation, or eligible for simplified Authorisation, cannot be sold legally after 1 March 2017. The latest Registration deadline under the Biocides Regulation of 1 September 2015 for firms to be approved as biocides suppliers is currently not being enforced because of low awareness among affected businesses. A six-month grace period has been granted after business associations warned that widespread non-compliance was likely. Since the deadline, 60 more firms have Registered.

March 2016

The ECHA:

- Announced that it will refrain from further updates to REACH guidance documents that impact Registration from 31 May 2016 onwards - see announcement at: http://echa.europa.eu/view-article/-/journal_content/title/echa-stabilises-guidance-two-years-ahead-of-the-2018-reach-deadline.
- Earmarked more hazardous and potentially hazardous substances for risk assessment by Member States - see Statement with links to list at: http://echa.europa.eu/view-article/-/journal_content/title/member-states-to-evaluate-39-priority-substances-in-2016. New entries to the Community Rolling Action Plan (CoRAP) for 2016 to 2018 include 19 potential endocrine disruptors. For 12 of the new entries, exposure to the environment is cited as one of the grounds for concern. Seven of these are suspected of being persistent, bioaccumulative and toxic or very persistent and very bioaccumulative. The majority of new entries are placed on the market in quantities of 1,000 to 10,000 tonnes per year. Substances are added to the CoRAP based on risk-based criteria which take account of the level of exposure as well as hazard information. Evaluations can result in proposals for risk management measures.
- Called for views on 2015 substance evaluation draft decisions - further details can be accessed at: http://echa.europa.eu/view-article/-/journal_content/title/registrants-should-get-ready-to-comment-on-2015-substance-evaluation-draft-decisions.
- Issued a list of more than 100 analytical methods for establishing compliance with REACH restrictions, suitable both for regulators and companies facing inspections - the document is available at: http://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf. The document consists of methods specified by the EU REACH Regulation itself, as well as those published by national, European or international standards bodies, used by technical organisations and regulators and certain internal methods used by laboratories within the EU.

(B) ECHA consultations on REACH and other related issues (December 2015 to March 2016)

December 2015

The ECHA:

- Launched a rolling consultation concerning proposed restrictions to limit or ban the manufacture, placing on the market or use of certain substances, under the EU REACH Regulation, due to unacceptable risks to human health and the environment - the consultation and related closing dates for responses are at: <http://echa.europa.eu/web/guest/restrictions-under-consideration>.
- Launched a rolling open invitation presenting active substances considered eligible for inclusion in the biocides review programme under the EU Biocidal Products Regulation (EU) No. 528/2012 that await notification by interested companies - the invitation and associated closing dates for responses are at: <http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/existing-active-substance/successful-declarations-of-interest>.

February 2016

The ECHA:

- Launched a consultation on 27 applications from firms seeking Authorisation for 39 continued uses of chemicals that will be banned in the EU in 2017 - the consultation is at: http://echa.europa.eu/view-article/-/journal_content/title/public-consultations-launched-for-applications-for-authorisation with a closing date for comments of 6 April 2016 (further information is also available at: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation>). The next step will be for the ECHA's expert committees to consider the applications.
- Launched a consultation seeking views on proposals to declare certain chemicals as substances of very high concern (SVHC) - the consultation is accessible at: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification> with a closing date for responses of 14 April 2016. The chemicals proposed for classification as SVHC include:
 - The polycyclic aromatic hydrocarbon benzo[a]pyrene (due to its carcinogenic, mutagenic, reprotoxic, persistent and bioaccumulative properties). The toxin is not normally produced intentionally but occurs as an impurity in other substances.
 - Plasticiser Dicyclohexyl phthalate (DCHP) (because of its toxicity to reproduction and endocrine disruption). The substance is used in the manufacture of sealants, and for stabilising explosives.

March 2016

The ECHA launched a rolling consultation on Member State proposals to include certain substances in the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008, Annex VI, Part 3 (list of harmonised classifications) - details on the consultation and associated closing dates for responses are at:

<http://echa.europa.eu/harmonised-classification-and-labelling-consultation>. The comments received in response to the consultation will inform the scientific opinion of the ECHA's Committee for Risk Assessment (RAC), which would then be sent to the Commission. In the case of a final approval of the proposals, manufacturers, importers and suppliers of the substances would have to abide by the classification, labelling and packaging requirements set out in the EU CLP Regulation.

(C) Commission developments on REACH and other associated topics (December 2015 to March 2016)

December 2015

The Commission:

(i) Formally adopted its new Circular Economy Package (CEP) - see Press Release and other associated CEP information at: http://europa.eu/rapid/press-release_IP-15-6203_en.htm ; http://ec.europa.eu/priorities/jobs-growth-investment/circular-economy/docs/communication-action-plan-for-circular-economy_en.pdf ; and [http://europa.eu/rapid/press-release MEMO-15-6204_en.htm](http://europa.eu/rapid/press-release_MEMO-15-6204_en.htm) respectively. On the issue of chemicals in the CEP, the Commission indicated that the interaction of legislation on waste, products and chemicals must be assessed. In this context, the Commission intends - during 2017 - to analyse how to overcome unnecessary barriers while preserving the high level of protection of human health and the environment. In a related development, at a Council meeting on 16 December 2015, the majority of Environment Ministers confirmed that, in their view, the Commission's updated CEP was an improvement on its predecessor. Many Ministers particularly welcomed the fact that the new proposal makes different demands of different Member States depending on their circumstances. Environment Ministers are expected to finalise their position on the proposed CEP on 20 June 2016.

(ii) Indicted that it would not change its plans in relation to endocrine disrupting chemicals, after the EU Court condemned as illegal its delay in taking action - see Statement and other related details at:

<http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-12/cp150145en.pdf>
and

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=160359&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=660214> respectively.

In a case taken by Sweden, supported by the Council and European Parliament, the EU Court found that the Commission failed to fulfil its clear, precise and unconditional obligation under the 2012 Biocides Regulation to specify the scientific criteria for identifying endocrine disruptors by 13 December 2013. The Court criticised the

Commission's decision to delay action to carry out an impact assessment. However, the Commission defended the delay stating that the issue was highly complex and that the objective will be to conclude the impact assessment in 2016, with decisions concerning the criteria for identifying endocrine disruptors following thereafter - see Commission impact assessment update and webpage at:

http://ec.europa.eu/health/endocrine_disruptors/docs/impactassessment_chemicalsubstancesselection_en.pdf and
http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm.

January 2016

The Commission selected six 'model demonstrator regions' in Europe to lead the way towards sustainable chemical production in Europe. The selected regions include Scotland, and South and Eastern Ireland - see further details at:

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8641&lang=en&title=Commission-selects-6-model-regions-to-lead-the-way-toward-a-sustainable-chemical-industry. The six regions were selected from 28 applicants in EU regions and will receive advisory support from the European Sustainable Chemicals Support Service (ESCS), led by the Commission and CIRCE (Center for Intelligent Research in Crystal Engineering). The aim is to encourage investments in sustainable chemicals production in Europe that will contribute to the development of the circular economy. The selection of the regions resulted from a call by the Commission in September 2015 for expressions of interest from regional organisations interested in developing ambitious strategies to support sustainable chemicals in Europe.

February 2016

The Commission pledged (during a European Parliament debate) to hasten adoption of overdue criteria for identifying endocrine disrupting chemicals (EDCs) in response to an EU court ruling that the three-year delay is illegal - see video of debate at:

<http://www.europarl.europa.eu/ep-live/en/plenary/video?debate=145444476295&streamingLanguage=en> and reactions from the European Parliament's Greens (European Free Alliance) and S&D Group at: <http://www.greens-efa.eu/public-health-endocrine-disruptors-15113.html> and <http://www.socialistsanddemocrats.eu/newsroom/no-more-delays-regulating-endocrine-disruptors-says-jytte-guteland> respectively. The Commission plans to bring forward the criteria (a delegated act applicable to biocides) by Summer 2016.

March 2016

The Commission:

- Launched a consultation to assess current chemicals regulation excluding REACH - the consultation is at: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8695 with a closing date for responses of 27 May 2016. The consultation aims to highlight any areas where legislation overlaps or where rules have become obsolete in a bid to improve performance, lower costs and reduce unnecessary burden on businesses. The

consultation on the regulatory fitness of chemicals legislation excludes REACH because it was evaluated as part of the 2012 REACH Review and will be looked at again in 2017. However, the fitness consultation covers PBT (persistent, bioaccumulative and toxic) and vPvB (very bioaccumulative) chemicals due to their hazardous and wide-ranging impact even though they are covered by REACH. The fitness consultation also examines the complex interplay of legal acts, which includes areas such as the CLP Regulation and product-specific and sectoral legislation, related to particular uses of chemicals in downstream industries.

- Promised to step up efforts to review existing active biocides available on the EU market before the 2012 Biocidal Products Regulation (BPR) came into force. The review was due for completion in 2015, but the Commission pushed the deadline back to 2024. In its latest report on the BPR (see details at: http://ec.europa.eu/health/biocides/docs/2016_report_sustainableuse_biocides_en.pdf), the Commission urged Member States to renew their efforts to ensure the review was completed by 2024. In addition, the Commission has indicated that it would support the approval process for biocides by ensuring that once active substances were approved, product Authorisations would be granted, amended or cancelled within three years and there would be more investment in regulation enforcement. The report states that the completion of the ongoing assessment of all the active substances that were already on the market when the BPR entered into force and the Authorisation of biocidal products containing these active substances, would be the first and main priority with a view to promoting the sustainable use of biocidal products. The report also emphasises that Member States will need to invest additional resources on enforcement activities to ensure that no product is illegally placed on their market and that biocidal products are properly labelled.
- Extended proposals on regulatory cooperation under the TTIP trade agreement with the US, announcing wholesale changes to the EU decision making process - see proposal plus explanation and benefits at: http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154377.pdf; http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154378.pdf; and http://trade.ec.europa.eu/doclib/docs/2016/march/tradoc_154379.pdf respectively.

Under revised proposals, US authorities would have the right to scrutinise all new EU legislation at the stage preceding the regulatory process - before draft laws are considered by the elected EP and Council. Two new proposals have been outlined by the Commission, one on regulatory cooperation and another on good regulatory practices. The proposals confirm the use of 'mutual recognition' where US products could enter the EU market without having to comply with EU rules in areas such as chemicals. Environmental law group CIEL has stated that the proposals would hamper the EU's implementation of the REACH Regulation, repeating similar warnings by MEPs in 2015.

However, the Commission has moved to allay concerns over TTIP lowering environmental regulatory standards. It has indicated that information exchanged between the EU and US when drafting new regulation, including for chemicals, should not override the block's different fundamental principles of risk assessment and management.

The Commission has stressed that cooperation should not hamper regulator autonomy as regulators would freely decide whether to cooperate, and to what extent. NGOs have redoubled their fierce opposition to the proposals. A letter sent to the Commission by 45 signatories including Greenpeace and the Corporate Europe Observatory argues that the provision for US authorities to scrutinise EU law before it has been considered by elected EU bodies is a threat to democracy - see letter at: <http://corporateeurope.org/international-trade/2016/03/ttip-regulatory-cooperation-threat-democracy>.

- Announced that it is planning to tackle Member States failure to comply with EU environmental law through a new system of biennial implementation reviews. In a 'roadmap' document (published on 14 March 2016), the Commission pledged to table formal plans for such a review system by the end of 2016 - see further information on the roadmap at: http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_env_088_environmental_implementation_review_en.pdf. The reviews would allow the Commission to raise implementation problems with national authorities before a breach of EU law occurs. Under the proposals, the Commission will prepare reports on each country every two years, which will reflect knowledge of the environmental situation and the challenges to address the core implementation gaps, and prepare the ground for high-level bilateral country dialogues between the Commission and the Member States concerned.

The roadmap indicates that Member States will be able to check these reports and make comments on them before publication. The Commission will also periodically table papers at the Environment Council which will review key implementation challenges common to a number of countries. The roadmap sets out the rationale for the Commission's proposed 'soft law' approach, arguing that a legislative option with similar objectives cannot be imagined, as the purpose of the initiative is to improve the implementation of the existing environmental acquis and policy through means complementary to enforcement. The roadmap indicates that the Commission will publish a policy paper on the matter in June 2016.

(D) Other general developments - including additional reports and submissions to the Commission - concerning REACH plus other related issues (December 2015 to March 2016)

December 2015

(i) The European Environment Bureau (EEB) accused the ECHA of undermining the aims of the EU REACH Regulation by approving Authorisations for continued use of

banned hazardous substances by default - see EEB Statement and report at: <http://www.eeb.org/index.cfm/news-events/news/obsolete-chemicals-will-remain-on-eu-market-unless-chemicals-law-tightened-warns-new-report/> and <http://www.eeb.org/index.cfm/library/a-roadmap-to-revitalise-reach/> respectively. The ECHA responded to the criticism stating that it was unfounded - see ECHA webpage explaining Authorisation at: <http://echa.europa.eu/regulations/reach/authorisation>. The EEB noted that all Authorisations applied for to-date have been granted by the Commission or have been recommended for approval by the ECHA, even though Authorisation was supposed to happen only in exceptional circumstances when the benefits outweigh the risks and there is no possible alternative. According to the EEB, this supported a 'business-as-usual' approach by which Authorisations become permits to pollute, and creates an economic disadvantage for companies that have invested in safer alternatives. The EEB has called on the Commission to give a clear mandate to the ECHA to give favourable opinions only for specific, well documented and well justified applications and to reject applications for broad uses of substances of very high concern (SVHC) at the conformity check stage.

However, the ECHA confirmed that its committees spend considerable amounts of time scrutinising applications before finalising their opinions in what is a demanding scientific process. The ECHA also emphasised that the opinions of its committees are not political and that it was possible for them committees to give negative opinions (i.e. not recommending an Authorisation). The EEB also criticised what it perceived to be as slow progress in listing chemicals as candidates for phase-out, or SVHC, and in moving these forward for phase-out through adding them to the REACH 'Authorisation List'. The ECHA indicated that it adds new substances to the candidate list every year and has also prepared a recommendation every year to enable a steady flow of substances to the Authorisation list (it also supported Member State assessments of substances).

(ii) The nanotechnology industry warned that an EU classification of materials as nano when they are at least 50% nano form will be difficult to implement in the absence of reliable measurement methods - a Statement from the Nanotechnology Industry Association (NIA) is at: http://www.nanotechia.org/sites/default/files/20151208_nia_opinion_jrc_nanomaterial_definition.pdf. The EU's Joint Research Centre (JRC) argued earlier in 2015 that varying thresholds for the particle number fraction in the definition of nanomaterials were an option as part of the Commission's review of the current 2011 definition. The NIA cited the JRC's statement that lowering the current threshold would be problematic as it would allow naming the material after one of its minority components. NGOs argued that the threshold should be lowered as it allows some substances with potential nano properties to evade scrutiny. The NIA also called for the defining size range of 1-100nm to remain unchanged as it was the case that often no validated methods were available for companies to identify a material's nano-specific properties.

However, the NIA has backed a number of the JRC's proposals, such as changing the definition of a particle to a 'minute solid piece of matter', where melting temperature would serve as the defining criterion of solidity, to provide more clarity. Companies have

come under criticism in recent months for resisting requests for additional nanomaterial information by the ECHA, spurring calls for the Commission to publish its much delayed review of nanomaterials in the REACH Annexes. In related developments, the Danish Environmental Protection Agency:

- announced that the perceived risks of nanomaterials are overstated - further information is available at: <http://eng.mst.dk/about-the-danish-epa/news/news-archives/2015/dec/results-of-4-years-activities-on-nano-are-now-available>; and
- published a report assessing the administrative burdens on businesses with a reporting obligation to the Danish Nanomaterials Product Register - see the report at: <http://www2.mst.dk/Udgiv/publications/2015/12/978-87-93435-09-4.pdf>.

(iii) A coalition of countries (Austria, Belgium, Denmark, Germany, France, Holland, Sweden, Norway and Finland) under the 'REACH-up initiative' called for stronger EU chemicals regulation ahead of the Environment Council meeting on 16 December 2015 - see note at: <http://data.consilium.europa.eu/doc/document/ST-14952-2015-INIT/en/pdf>. According to the Luxembourg Presidency and other countries a conference organised by the REACH-up initiative in November 2015 gave a clear signal that actions to improve implementation and chemical safety were necessary.

Many suggestions for improved chemicals regulation were made at the conference, including to speed up work on making Registration dossiers compliant, and to deal with the presence of problematic substances in articles. The countries participating in the REACH-up initiative stated that they wanted the incoming Dutch Presidency to convene a policy debate on the conference outcomes. In addition, the countries wanted to see a report on the operation of REACH and a Council agreement on this subject. The conference outcomes (as indicated in the note from the REACH-up initiative) also included a call for greater coherence and integration across different pieces of legislation and better use of the information in REACH in the context of other legislation, in order to increase efficiency in chemicals policies and enhance innovation, growth, the circular economy and resource efficiency.

(iv) CONCAWE published a report titled 'Hazard classification and labelling of petroleum substances in the European Economic Area - 2015' which is accessible from: https://www.concawe.eu/uploads/Modules/Publications/rpt_15-9.pdf.

January 2016

A collation of NGOs sent a letter to the Commission criticising the delay in the establishment of EU criteria for the identification / determination of endocrine disrupting substances - see the letter at: <http://www.eeb.org/index.cfm/library/ngo-response-to-edc-ruling/>.

February 2016

(i) The European Committee for Standardisation (CEN) announced that it planned to develop a new Guide which would provide support to Technical Committees on how to develop requirements in product standards that can contribute to minimising the use of hazardous chemicals in products, and thereby reducing health and environmental risks arising from exposure to chemicals - further information can be accessed from: <http://www.cen.eu/work/areas/env/pages/guidechemicalsproducts.aspx>. The final deliverables constituting a horizontal CEN Guide on how to address chemicals in product standards and a strategy for the implementation of the Guide will be issued in 2017.

(ii) ChemSec published a report titled 'The Bigger Picture - Assessing economic aspects of chemicals substitution (2016)' which can be accessed from: http://chemsec.org/wp-content/uploads/2016/03/The_bigger_picture_160217_print.pdf.

(iii) The European Topic Centre for Ecotoxicology and Toxicology of Chemicals published its 2015 Annual Report - see the report at: http://www.ecetoc.org/uploads/Publications/Annual%20Reports/ECETOC_2015_Annual_Report.pdf.

March 2016

A report by Ecofys indicated that the competitiveness gap between the EU chemical industry and major competitors will not be closed by the climate plans submitted by important chemical producing countries in the run-up to the Paris Climate Agreement - see the report at: <http://www.ecofys.com/files/files/ecofys-2016-alone-under-an-absolute-cap.pdf>. The report assesses the implications for chemical industry competitiveness of the intended nationally determined contributions (INDCs) submitted by, amongst others, the EU. According to the report, emission caps and carbon pricing imposed via the EU-ETS have already placed EU chemical businesses at a disadvantage with competing markets. The report concludes that the situation does not look likely to change based on the INDCs. The report highlights that only in Europe, still, is there a serious carbon price. EU carbon prices are expected to increase in the 2021 - 2030 period, while the free allowances available to the chemical sector will shrink at an annual 2.2% from 2021 onwards. The report states that low-carbon technologies could help European producers to bridge the gap with competitors, but it remained an open question as to whether such applications will be realised and manufactured in Europe. The report also notes that official support for low-carbon innovation is hardly mentioned in the INDCs, including Europe's plan.

APPENDIX 3

Supplemental Commission Legislation on REACH and other relevant EU regulatory measures on chemicals **[Including proposed revisions and expected new measures]**

(A) Supplemental REACH Legislation and other relevant EU regulatory measures on chemicals

Commission Regulation (EU) No. 2016/266 (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0266&from=EN>) entered into force on 4 March 2016 and applies directly in Member State law. The Regulation amends and updates EU Regulation 440/2008/EC (see details further down below - which sets out test methods to determine the physico-chemical properties, toxicity and eco-toxicity of substances to be applied for the purposes of the EU REACH Regulation), in order to include new and updated alternative test methods recently adopted by the Organisation for Economic Co-operation and Development (OECD), and to reduce the number of animals used for experimental purposes. It contains twenty new test methods: one new method for the determination of a physico-chemical property, eleven new test methods and three updated test methods for the assessment of ecotoxicity, and five new test methods to assess the environmental fate and behaviour.

Commission Implementing Decision (EU) 2016/107 (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0107&from=EN>) confirms that Cybutryne (an algaecide particularly used in antifouling paint) is no longer approved as a biocide for use in antifouling products for aquatic equipment due to the fact that it is a toxic and persistent substance. The Decision entered into force on 17 February 2016 and applies directly in Member State law.

Commission Implementing Regulation (EU) 2016/9 (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN>) lays down specific duties and obligations for parties to agreements where the sharing of information and associated costs are required under the EU REACH Regulation. The Regulation entered into force on 26 January 2016 and applies directly in Member State law.

Commission Delegated Regulation (EU) 2015/2229 (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2229&from=EN>) amends Annex I to the Prior Informed Consent (PIC) Regulation (EU) No. 649/2012 (see details further down below) concerning the export and import of hazardous chemicals. The amending Regulation entered into force on 1 February 2016. For firms wishing to continue exporting the chemicals covered by the PIC Regulation without interruption, a notification had to be submitted in December 2015.

Commission Implementing Regulation 2015/1731/EU (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_252_R_0012&from=EN) approves medetomidine as an existing active substance for use in biocidal products for product-type 21 ('antifouling products', as established by the Biocides Regulation (EU) No. 528/2012/ (see details further down below) from 1 January 2016, subject to the specifications and conditions set out in the Annex to the Regulation. The Regulation entered into force on 19 October 2015 and applies directly in Member State law.

Commission Implementing Regulation (EU) No. 2015/864 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_139_R_0001&from=EN) amends the EU REACH Fees Regulation 340/2008/EC (see details further down below)) to adapt the standard fees and charges in line with the average annual inflation rate of 1.5%. The Regulation entered into force on 25 June 2015 and applies directly in Member State law. It does not, however, apply to valid submissions pending on that date.

Commission Regulation (EU) No. 2015/830 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_132_R_0004&from=EN) amends the EU REACH Regulation, replacing Annex II, which lays down requirements for the compilation of safety data sheets used to provide information on chemical substances and mixtures in the EU. Safety data sheets provided to any recipient before 1 June 2015 may continue to be used and need not comply with the EU Regulation until 31 May 2017. The EU Regulation entered into force on 1 June 2015 and applies directly in Member State law.

Commission Implementing Decision 2015/411/EU (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D0411&from=EN>) provides that paints and coatings that incorporate cationic polymeric binders with quaternary ammonium compounds intended to confer to those paints a biocidal function shall be considered biocidal products under the Biocides Regulation (EU) No. 528/2012, while these cationic polymeric binders will themselves not be considered biocidal products. The EU Decision entered into force on 1 April 2015.

Commission Implementing Regulation (EU) No. 2015/419 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_068_R_0008&from=EN) approves tolylfluanid as an active substance for use in biocidal products for product-type 21 ('Antifouling products' as established by the Biocides Regulation (EU) No. 528/2012 (see details further down below)) from 1 June 2015, where authorisations are to be subject to the specifications and conditions set out in the Annex to the EU Regulation. The EU Regulation entered into force on 2 April 2015 and applies directly in Member State law.

Commission Implementing Regulation (EU) No. 2015/407 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_067_R_0006&from=EN) approves propan-2-ol as an active substance for use in biocidal products for, among other things, disinfectants and algacides which are not intended for direct application to humans or animals, as defined in Annex V to the Biocides Regulation (EU) No. 528/2012 from 1 July 2016, where authorisations are to be subject to the specifications and conditions set out in the Annex to the EU Regulation. The EU Regulation entered into force on 1 April 2015 and applies directly in Member State law.

Commission Regulation (EU) No. 2015/282 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_050_R_0001&from=EN) amends Annexes VIII, IX and X of the EU REACH Regulation, which set out standard information requirements for substances manufactured or imported in quantities of 10, 100 and 1,000 tonnes or more respectively, so as to specify how the Extended One-Generation Reproductive Toxicity Study (EOGRTS) - a new test method developed to assess the reproductive toxicity of chemical substances - is to be used for the purposes of the EU REACH Regulation. The EU Regulation entered into force on 13 March 2015 and applies directly in Member State law.

Commission Implementing Regulation (EU) No. 1091/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_299_R_0006&from=EN) approves tralopyril as a new active substance for use in biocidal products for product-type 21 ('Antifouling products') from 1 April 2015, where authorisations are to be subject to the specifications and conditions set out in the Annex. Such specific conditions include ensuring that measures to minimise user exposure are taken, among other things. The Regulation entered into force on 7 November 2014 and applies directly in Member State law.

Commission Delegated Regulation (EU) No. 1078/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_297_R_0001&from=EN) amends Annex I (List of Chemicals) of the Prior Informed Consent (PIC) Regulation (EU) No. 649/2012, so as to take into consideration regulatory action taken pursuant to the EU REACH Regulation and the Plant Protection Products Regulation with regard to certain chemicals. The Regulation entered into force on 5 November 2014 and applies directly in Member State law from 1 December 2014.

Commission Delegated Regulation (EU) No. 1062/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_294_R_0001&from=EN) repeals and replaces Regulation (EC) No. 1451/2007, which laid down detailed rules for a review programme of existing biocidal active substances under the Biocides Directive 98/8/EC,

so as to adapt the rules for the continuation of the review programme under the Biocidal Products Regulation (EU) No. 528/2012 following its repeal of the Biocides Directive 98/8/EC. Transitional measures for substance / product-type combinations eligible for inclusion in the review programme are provided for. The Regulation entered into force on 30 October 2014 and applies directly in Member State law.

Commission Regulation (EU) No. 900/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_247_R_0001&from=EN) amends and updates Regulation (EC) No. 440/2008 (see details further down below) which sets out test methods to determine the physico-chemical properties, toxicity and eco-toxicity of substances to be applied for the purposes of the EU REACH Regulation, in order to include new and updated alternative test methods recently adopted by the Organisation for Economic Co-operation and Development (OECD), and to reduce the number of animals used for experimental purposes. The Regulation contains six new test methods for the determination of toxicity and other health effects including a developmental neurotoxicity study, an extended one-generation reproductive toxicity study, a transgenic rodent in vivo gene mutation assay, an in vitro test to assess effects on the synthesis of steroid hormones, as well as two in vivo methods to assess oestrogenic and (anti)androgenic effects. The Regulation entered into force on 24 August 2014 and applies directly in Member State law.

Commission Regulation (EU) No. 895/2014 (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0895&from=EN>) amends Annex XIV (List of substances subject to Authorisation) of the EU REACH Regulation so as to add eight substances classified as carcinogenic and one classified as toxic for reproduction to Annex XIV. The Regulation entered into force on 22 August 2014 and applies directly in Member State law.

Commission Decision 2014/459/EU (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0459&from=EN>) allows certain countries - to whom the Decision is addressed - to place on the market biocidal products containing copper for certain uses (primarily the prevention of biofouling in water inlet / pumps of ships and offshore oil and gas platforms), subject to the conditions provided for by Article 5(3) of Regulation (EC) No. 1451/2007. The EU Decision is addressed to Croatia, Spain, Ireland and Greece.

Commission Decision 2014/395/EU (details at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0395&from=EN>) allows certain countries - to whom the Decision is addressed - to place on the market biocidal products containing copper for certain uses (primarily the control of Legionella and other harmful organisms in water and the prevention of biofouling in water inlet / pumps of ships and offshore oil and gas platforms), subject to the conditions provided for by Article 5(3) of Regulation (EC) No. 1451/2007. The Decision is addressed to Belgium, Denmark, Germany, Estonia, Ireland, France, Italy, Latvia, Luxembourg, Malta, Poland, Finland, Sweden and the UK.

Commission Regulation (EU) No. 492/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_139_R_0001&from=EN) lays down supplementary rules for the renewal of a national authorisation of a biocidal product or a biocidal product family that has been subject to mutual recognition in accordance with Article 4 of the Biocides Directive 98/8/EC or with Articles 33 and 34 of the Biocides Regulation (EU) No. 582/2012 (which repealed and replaced the Biocides Directive 98/8/EC from 1 September 2013 - see details further down below), or of a national authorisation granted through such mutual recognition. The Regulation entered into force on 3 June 2014 and applies directly in Member State law.

Commission Regulation (EU) No. 437/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_128_R_0011&from=EN) approves 4,5-Dichloro-2-octyl-2H-isothiazol-3-one as an active substance for use in biocidal products for product-type 21 ('Antifouling products') from 1 January 2016, where authorisations are to be subject to the specifications and conditions set out in the Annex. Such specific conditions include ensuring that non-professional users are supplied with appropriate gloves, among other things. The Regulation entered into force on 20 May 2014 and applies directly in Member State law.

Commission Decision 2014/227/EU (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_124_R_0006&from=EN) specifies a list of active substances that will not be approved under the Biocides Regulation (EU) No. 582/2012 (see details further down below) for the product-types indicated in the Annex. The EU Decision entered into force on 15 May 2014.

Commission Regulation (EU) No. 334/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:JOL_2014_103_R_0004&from=EN) amends the Biocides Regulation (EU) No. 528/2012 (see details further down below) with respect to certain conditions for access to the market, by among other things, allowing similar biocidal products to be part of a biocidal product family if they can be satisfactorily assessed based on identifiable maximum risks and minimum level of efficacy, clarifying certain terms and making a number of technical amendments. The Regulation entered into force on 25 April 2014 and applies directly in Member State law. Article 1, point 24, which amends and replaces Article 94 (Transitional measures concerning treated articles) and Article 95 (Transitional measures concerning access to the active substance dossier) of the Biocides Regulation (EU) No. 528/2012 applied from 1 September 2013.

Commission Regulation (EU) No. 317/2014 (details at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_093_R_0024_01&from=EN) amends Annex XVII of the EU REACH Regulation, which in its entries 28 to 30, prohibits the sale to the general public of substances that are classified as carcinogenic, mutagenic or

reproductive toxicant (CMR) categories 1A or 1B or of mixtures containing them in concentration above specified concentration limits. Annex XVII is amended in accordance with Annexes I, II and III to the Regulation in order to update or include a number of new harmonised classifications of CMR substances. The Regulation entered into force on 17 April 2014, where Annex I applies directly in Member State law from 1 April 2014, Annex II from 1 January 2015 and Annex III from 1 April 2016.

Commission Regulation (EU) No. 260/2014 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:081:0001:0253:EN:PDF>) amends Commission Regulation (EC) No. 440/2008 (see information further down below) which sets out test methods to determine the physico-chemical properties, toxicity and eco-toxicity of substances to be applied for the purposes of the EU REACH Regulation, in order to include new and updated alternative test methods adopted by the Organisation for Economic Co-operation and Development (OECD), and thereby reduce the number of animals used for experimental purposes. The Regulation entered into force on 22 March 2014 and applies directly in Member State law.

Commission Regulation (EU) No. 167/2014 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:054:0010:0013:EN:PDF>) amends Annex I (regarding dangerous chemicals subject to notification requirements before export) to the Dangerous Chemicals Export and Import Regulation (EC) No. 689/2008, so as to allow for regulatory action that has been taken with regard to certain chemicals pursuant to the Biocides Regulation (EU) No. 528/2012 and the REACH Regulation. The Regulation entered into force on 14 March 2014 and applied directly in Member State law from 1 May 2014.

Commission Decision 2014/85/EU (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:045:0022:0023:EN:PDF>) permits the Netherlands, Poland, Spain and the UK to allow biocidal products containing copper (EC No 231-159-6; CAS No 7440-50-8) to be placed on the market for specific uses indicated in the Annex (which includes uses for preventing the growth of organisms in the main water inlet for offshore oil and gas platforms, where that use is essential to avoid blocking the inlet of water used for, inter alia, processing, drinking water and bathing water production, and fire-fighting).

Commission Regulation (EU) No. 92/2014 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:032:0016:0018:EN:PDF>) approves zineb as an active substance for use in biocidal products for product-type 21 (Antifouling products), where authorisations are to be subject to the specifications and conditions set out in the Annex to the EU Regulation. Such specific conditions include the establishment of safe operational procedures and appropriate organisational measures for industrial or professional users. The Regulation entered into force on 21 February 2014 and applies directly in Member State law.

Commission Regulation (EU) No. 88/2014 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:032:0003:0005:EN:PDF>) specifies the data requirements and procedures to be followed for the purpose of amending, at the request of an applicant, Annex I to the Biocides Regulation (EU) No. 528/2012, in order to include active substances in categories 1, 2, 3, 4, 5 or 6 of that Annex, or make amendments to the relevant restrictions in those categories. The Regulation entered into force on 21 February 2014 and applies directly in Member State law.

Commission Regulation (EU) No. 944/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF>) amends the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 (see details further down below), so as to take into account the fifth revised edition of the UN Globally Harmonised System (GHS) of Classification and Labelling of Chemicals, and to update the two tabulated lists of harmonised classification and labelling of hazardous substances in Annex VI - Part 3. The Regulation entered into force on 23 October 2013, although it applies directly in Member State law on different dates, and transitional periods are provided for to allow Operators to adapt to the new classification, labelling and packaging provisions introduced by the Regulation.

Commission Delegated Regulation (EU) No. 837/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:234:0001:0002:EN:PDF>) amends the Biocides Regulation (EU) No. 528/2012 (see details further down below), so as to include in Annex III (which lists the information requirements for the Authorisation of biocidal products) proof that technical equivalence has been established. Technical equivalence must be established to ensure that active substances in a biocidal product, which have been manufactured in a different location or according to a different process (including from different starting materials) from those active substances that have been evaluated for the purpose of approval, do not have significantly more hazardous properties than the substance which has been evaluated. The Regulation entered into force on 23 September 2013 and applies directly in Member State law.

Commission Regulation (EU) No. 758/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:216:0001:0058:EN:PDF>) amends the Chemicals Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 (see details further down below), so as to correct errors found in Annex VI ('Harmonised classification and labelling for certain hazardous substances') that have arisen as a result of previous amendments introduced by Commission Regulation (EC) No. 790/2009 for the purposes of adaptation to technical and scientific progress. Suppliers are not required to re-label or repackage substances listed in Annex VI, or substances or mixtures containing them, where they have been placed on the market before 13 August 2013. The Regulation entered into force on 13 August 2013.

Commission Delegated Regulation (EU) No. 736/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:204:0025:0025:EN:PDF>) amends the Biocides Regulation (EU) No. 528/2012 (see Regulation further down below) so as to provide for the continuation of the work programme for the systematic examination of all existing active substances used in biocidal products, with the aim of achieving the programme's finalisation by 31 December 2024 (in accordance with the latest time estimates from the Commission). The Regulation entered into force on 20 August 2013 and applies directly in Member State law.

Commission Regulation (EU) No. 613/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:173:0034:0037:EN:PDF>) amends Regulation (EC) No. 1451/2007 - which laid down rules for the second phase of the 10 year review programme under the Biocides Directive 98/8/EC - so as to take account of the fact that different definitions and change in understandings of the term 'biocidal products' may have led some persons to fail to notify an existing active substance / product-type combination in a product placed on the market, or to take over the role of participant, in the objectively justified belief that the product is excluded from the scope of the Biocides Directive (repealed / replaced from 1 September 2013 by Regulation (EU) No. 528/2012 - see details further down below) or that it falls under a different product-type. The Regulation allows for such persons to submit a dossier for examination under the review programme in such cases, subject, where relevant, to prior notification, in order to avoid the market withdrawal of products for which a justified interpretation as regards its character as a biocidal product or its correct product-type is subsequently contested by Member States or the Commission. The Regulation entered into force on 16 July 2013 and applies directly in Member State law. Article 1, points 2, 4 and 7, however, applied from 1 September 2013.

Commission Regulation (EU) No. 564/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:167:0017:0025:EN:PDF>) establishes the structure / amount of the fees payable to the ECHA under the Biocides Regulation (EU) No. 528/2012 and the associated conditions for payment. It covers work done by the ECHA in relation to the approval and renewal of approval of active substances and for the Authorisation of biocidal products. It also provides for fee reductions for small and medium enterprises (SMEs). The Regulation entered into force on 9 July 2013 and applies directly in Member State law.

Commission Regulation (EU) No. 348/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:108:0001:0005:EN:PDF>) amends Annex XIV ('List of substances subject to Authorisation') of the EU REACH Regulation, so as to add entries for eight substances of very high concern (SVHC). Manufacturers and importers must seek Authorisation from the ECHA if they wish to continue to use the substances or place them on the market. The Regulation entered into force on 21 April 2013 and is directly applicable in all Member States.

Commission Regulation (EU) No. 354/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:109:0004:0013:EN:PDF>) lays down the procedures for making changes to the information submitted in initial applications for the authorisation of biocidal products or biocidal product families made in accordance with the Biocides Directive 98/8/EC or the Biocides Regulation (EU) No. 528/2012. The Regulation entered into force on 9 May 2013 and applies directly in all Member States from 1 September 2013.

Commission Regulation (EU) No. 254/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:079:0007:0018:EN:PDF>) amends the REACH Fees Regulation (EC) No. 340/2008 (see information further down below) in order to: **(i)** adapt the standard fees and charges in line with the average annual inflation rate of 3.1%; **(ii)** further reduce fees and charges for micro, small and medium-sized enterprises (SMEs); and **(iii)** make a number of clarifications. The Regulation entered into force on 22 March 2013 and applies directly in Member State law.

Commission Decision 2013/85/EU (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:045:0030:0031:EN:PDF>) prohibits the placing on the market of biocidal products containing certain active substances, as set out in the Annex, with effect from 1 February 2014. As such, the substances, and relevant product types, will not be included in Annexes I, IA or IB to the Biocides Directive 98/8/EC which list active and basic substances that have been agreed with requirements at the EU level for inclusion in biocidal products.

Commission Regulation (EU) No. 73/2013 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:026:0011:0016:EN:PDF>) amending Annexes I and V to Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals so as to reflect changes made to the EU REACH Regulation. The Regulation entered into force on 15 February 2013 and applied in Member State law from 1 April 2013.

Commission Directive 2012/43/EU (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:327:0034:0036:EN:PDF>) amending the Biocides Directive 98/8/EC (as amended from 1 September 2013 by Commission Regulation (EU) No. 528/2012 (the new EU Biocides Regulation) - see Regulation further down below) so as to update the headings to all entries for active substances that may be approved for inclusion in biocidal products listed under Annex I. The Directive entered into force on 17 December 2012 and Member States had to transpose the provisions into national law by 31 March 2013.

Commission Regulation (EU) No. 848/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:253:0005:0007:EN:PDF>) amending Annex XVII (Restrictions) to the EU REACH Regulation, so as to prohibit the manufacture, placing on the market, or use in substances or in mixtures of certain phenylmercury compounds after 10 October 2017, if the concentration of mercury in the

mixtures is equal to or greater than 0.01% by weight. In addition, articles or any parts thereof containing one or more of those substances may also not be placed on the market after 10 October 2017 if the concentration of mercury in the articles or any part thereof is equal to or greater than 0.01% by weight. The Commission Regulation entered into force on 10 October 2012 and applies in Member State law from 10 October 2017.

Commission Regulation (EU) No. 847/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:253:0001:0004:EN:PDF>) amending Annex XVII (Restrictions) to the EU REACH Regulation, so as to prohibit the placing on the market of certain mercury-containing and mercury-using measuring devices intended for industrial and professional uses after 10 April 2014. Derogations apply to certain devices including, among others, those thermometers that are exclusively intended to perform tests according to standards that require the use of mercury thermometers, which may be placed on the market until 10 October 2017. The Regulation entered into force on 10 October 2012 and applied in Member State law from 10 April 2014.

Commission Regulation (EU) No. 835/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:252:0001:0003:EN:PDF>) amending Annex XVII (Restrictions) to the EU REACH Regulation, so as to limit the restriction on the use of cadmium and its compounds to the types of plastic material listed in entry 23 of Annex XVII before the adoption of Commission Regulation (EU) No. 494/2011 (see details further down below), which had imposed the restrictions, as suitable alternatives do not yet exist and to allow for additional assessment. The Regulation entered into force on 19 September 2012 and applied directly in Member State law from 10 December 2011.

Commission Decision 2012/483/EU (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:226:0006:0007:EN:PDF>) which sets a new deadline for the submission of dossiers for certain substances to be examined under the 14-year work programme referred to in Article 16(2) of the Biocides Directive 98/8/EC.

Commission Regulation (EU) No. 649/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:201:0060:0106:EN:PDF>) concerning the export and import of hazardous chemicals will repeal / replace the EU Prior Informed Consent (PIC) Regulation 689/2008/EC which implements the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals in international trade (the ‘Rotterdam Convention’). The new Regulation entered into force on 16 August 2012 and applies directly in Member State law from 1 March 2014. The Rotterdam Convention allows parties to monitor and control the trade and use of certain hazardous chemicals, and to decide whether or not to accept the importation of certain hazardous chemicals, or to place conditions on their import, in order to protect human health or the environment. The ECHA will be responsible for assessing import and export notifications. Its work will be funded through the EU budget and voluntary contributions

from Member States. By 2019, the Commission will consider whether the Agency should charge a fee for its services.

Commission Regulation (EU) No. 640/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:193:0001:0066:EN:PDF>) - amends and updates EU Regulation 440/2008/EC (which sets out test methods to determine the physico-chemical properties, toxicity and eco-toxicity of substances to be applied for the purposes of the EU REACH Regulation - see information on initial Regulation further down below) - in order to include new and revised alternative test methods adopted by the Organisation for Economic Co-operation and Development (OECD), and thereby reduce the number of animals used for experimental purposes. The Regulation entered into force on 23 July 2012 and applies directly in Member State law.

Commission Regulation (EU) No. 618/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:179:0003:0010:EN:PDF>) - amends (for the purposes of adaptation to technical and scientific progress) Annex VI (Part 3) of the EU Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 (see CLP Regulation further down below) in order to update the two lists of harmonised classification and labelling of hazardous substances. The Regulation entered into force on 31 July 2012 and the amendments applied directly in Member State law from 1 December 2013 (or potentially earlier in accordance with Article 2).

Commission Regulation (EU) No. 528/2012 (the EU Biocides Regulation) - details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF> - lays down rules for the establishment at EU level of a list of active substances that may be used in biocidal products, the mutual recognition of Authorisations within the EU, the making available on the market and the use of biocidal products within one or more Member States or the European Union, and the placing on the market of treated articles. It applies to biocidal products (a list of which are set out in Annex V with descriptions) and treated articles, except where excluded in Article 2(2), and repealed and replaced the Biocides Directive 98/8/EC from 1 September 2013. The Regulation entered into force on 17 July 2012 and applied directly in Member State law from 1 September 2013.

Commission Regulation (EU) No. 125/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:041:0001:0004:EN:PDF>) - amending Annex XIV (Authorisation list) of the EU REACH Regulation so as to add entries for eight substances of very high concern (SVHC). Manufacturers and importers must seek Authorisation from the ECHA if they wish to continue to use these substances or place them on the market. The Regulation entered into force on 18 February 2012 and is directly applicable in all Member States.

Commission Decision 2012/78/EU (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:038:0048:0050:EN:PDF>) - prohibits - from 1 February 2013 - the placing on the market of biocidal products containing certain substances, as set out in the Annex. As such, the substances, and

relevant product types, will not be included in Annexes I, IA or IB to the Biocides Directive 98/8/EC, which list active and basic substances that have been agreed at EU level for inclusion in biocidal products.

Commission Regulation (EU) No. 109/2012 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:037:0001:0049:EN:PDF>) - amending Annex XVII (Restrictions) of the EU REACH Regulation in respect to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) - entered into force on 1 March 2012. The Regulation applied in Member States from 1 June 2012.

Commission Regulation (EU) No. 494/2011 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:134:0002:0005:EN:PDF>) - amending Annex XVII (Restrictions) of the EU REACH Regulation in respect to the substance cadmium. The Regulation clarifies existing provisions concerning paint (containing zinc as well as with respect to painted articles) and extends the prohibition of the use of cadmium to all articles made from polyvinyl chloride (PVC). However, a derogation is granted for mixtures produced from PVC waste (referred to as 'recovered PVC') to allow their placing on the market for use in certain construction products. A higher limit value for cadmium is also granted for these construction products. The Regulation entered into force on 10 June 2011 and applied directly in Member State law from 10 January 2012.

Commission Regulation (EU) No. 366/2011 (accessible from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:101:0012:0013:EN:PDF>) - which entered into force on 5 May 2011 - amends Annex XVII (entry 60) of the EU REACH Regulation so as to ban the placing on the market and the use of acrylamide in concentrations equal or greater than 0.1% by weight in grouts and for all grouting applications after 5 November 2012. The restrictions relating to acrylamide have been introduced due to identified risks to the aquatic compartment and concerns regarding the risk to workers and humans exposed via the environment, as the substance is both a carcinogen and a mutagen.

Commission Regulation (EU) No. 286/2011 (available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:0001:0053:EN:PDF>) adapts the technical provisions and criteria in the Annexes to the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 to the third revised edition of the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The third revised edition contains amendments concerning, among other things, the provisions for the allocation of hazard statements and for the labelling of small packaging, new sub-categories for respiratory and skin sensitisation, the revision of the classification criteria for long-term hazards (chronic toxicity) to the aquatic environment and a new hazard class for substances and mixtures hazardous to the ozone layer. The Regulation entered into force on 19 April 2011 and applied directly in Member State law from 1 December 2012 for substances, but applies from 1 June 2015 for mixtures.

Commission Regulation (EU) No. 252/2011 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:069:0003:0006:EN:PDF>) amends Annex I of the EU REACH Regulation, which sets out the details of how to carry out a chemical safety assessment and document it in a chemical safety report, so as to adapt it to the criteria for classification and other relevant provisions laid down in the CLP Regulation (EC) No. 1272/2008. The Regulation entered into force on 15 April 2011 and applied directly in Member State law from 5 May 2011. However, for Registrations submitted prior to 5 May 2011, the chemical safety report had to be updated in accordance with the Regulation by 30 November 2012 at the latest. Article 22(5) of the EU REACH Regulation did not apply to those updates.

Commission Regulation (EU) No. 253/2011 (accessible from: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:069:0007:0012:EN:PDF>) amends the criteria under Annex XIII of the EU REACH Regulation for classifying a substance as persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB). The new criteria applied from 19 March 2011. The ECHA uses the Annex XIII criteria to classify substances as vPvB or PBT, which means they can be placed on the Authorisation list of substances of very high concern (SVHC). The revised rules introduce a wider 'weight of evidence' approach, which means that more information has to be considered prior to classification. From 19 March 2011, companies had to apply the new criteria in their Chemical Safety Assessments. They also had to update already submitted assessments within two years.

Commission Regulation (EU) No. 214/2011 (accessible at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:059:0008:0014:EN:PDF>) amends the Dangerous Chemicals Export and Import Regulation (EC) No. 689/2008 with respect to Annex I (which sets out those dangerous chemicals subject to prior informed consent (PIC) notification before export) and Annex V (which bans the export of substances from the EU that are banned for use within the EU) to reflect amendments made to the EU REACH Regulation. The Regulation entered into force on 24 March 2011 and applied directly in Member State law from 1 May 2011.

Commission Regulation (EU) No. 207/2011 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:058:0027:0028:EN:PDF>) amends the EU REACH Regulation so as to remove superfluous references to diphenylether, pentabromo derivative and perfluorooctane sulfonates (PFOS) in Annex XVII (Restrictions), due to their inclusion in the Persistent Organic Pollutants (POPs) Regulation (EC) No. 850/2004 via Regulation (EU) No. 756/2010. The Regulation entered into force on 6 March 2011 and applies directly in Member State law.

Commission Regulation (EU) No. 143/2011 (available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:044:0002:0006:EN:PDF>) - which entered into force on 21 February 2011 - amends Annex XIV ('list of substances subject to Authorisation') to the EU REACH Regulation, so as to add entries for six substances of very high concern (SVHC) and thereby require manufacturers and

importers to seek an Authorisation if they wish to continue to use these substances or place them on the market. In particular, these entries specify the date by which an application for Authorisation must be received by the ECHA - where the latest application date will be set at least 18 months before the point at which use and placing on the market will be prohibited.

Commission Regulation (EU) No. 453/2010 (accessible at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:133:0001:0043:EN:PDF>) - which entered into force on 20 June 2010 - amends the EU REACH Regulation, in order to adapt the requirements for safety data sheets (set out in Annex II) to the criteria for chemical classification and labelling set out in the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 in phases, commencing on 1 December 2010 for suppliers of substances and 1 June 2015 for suppliers of mixtures.

Commission Regulation (EU) No. 440/2010 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:126:0001:0005:EN:PDF>) concerning the fees payable under the CLP Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures. The Regulation establishes the level, and rules for payment, of fees to the ECHA by manufacturers, importers and downstream users of a substance or mixture, where a request is made to use an alternative chemical name or a proposal is submitted to harmonise the classification and labelling of a substance. Such fees are payable in accordance with the Classification, Labelling and Packaging (CLP) Regulation for work performed by the ECHA - small and medium-sized enterprises (SMEs), as defined in Article 2, may benefit, however, from a reduced level of fees. The Regulation entered into force on 25 May 2010.

Commission Regulation (EC) No. 790/2009 (available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:EN:PDF>) amending (for the purposes of its adaptation to technical and scientific progress) Regulation (EC) No. 1272/2008 on the classification, labelling and packaging (CLP) of substances and mixtures (see CLP Regulation further-down below). The Regulation updates the two lists of harmonised classification and labelling of hazardous substances in Part 3 of Annex VI to the CLP Regulation to delete entries for certain substances and to include both updated classifications for substances already subject to harmonised classification and new harmonised classifications. These amendments reflect the adaptation of the Dangerous Substances Directive 67/548/EEC to technical and scientific progress by Directives 2008/58/EC and 2009/2/EC. The Regulation (EC) No. 790/2009 entered into force on 25 September 2009 and the amendments to the CLP Regulation (EC) No. 1272/2008 in Article 1 applied directly in all Member States from 1 December 2010. Suppliers could apply the harmonised classifications, and adapt labelling and packaging, before 1 December 2010.

Commission Regulation (EC) No. 761/2009 (accessible at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:220:0001:0094:EN:PDF>) amending, for the purpose of its adaptation to technical progress, Regulation (EC) No.

440/2008 (see details further-down below) which laid down test methods to be applied under REACH. The Regulation includes changes to certain test methods and adds several new test methods adopted by the OECD. The Regulation entered into force on 27 August 2009.

Commission Regulation (EC) No. 552/2009 amending Annex XVII (Restrictions) of the EU REACH Regulation entered into force on 27 June 2009. The Regulation (at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:EN:PDF>) makes a number of amendments to Annex XVII in order to: (i) harmonise restrictions on substances with those in other EU Directives; and (ii) remove duplication of restrictions where substances are controlled under other EU Directives.

Commission Regulation (EC) No. 134/2009 replacing Section 3 of Annex XI to the EU REACH Regulation entered into force on 20 February 2009. The Regulation (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:046:0003:0005:EN:PDF>) allows for the omission of testing under Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X to provide greater clarity and define what constitutes adequate justification for such an omission.

Corrigendum to REACH (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:036:0084:0084:EN:PDF>) - issued in February 2009 - cancels and replaces the Corrigendum of 31 May 2008, which redrafted Article 3(20)(c) of the REACH Regulation (EC) No.1907/2006 (as amended by Regulation (EC) No. 1354/2007) but erroneously modified the scope of the phase-in definition of substances classified as ‘no-longer polymers’.

Commission Regulation (EC) No. 1272/2008 on revised rules for the Classification, Labelling and Packaging (CLP) of substances and mixtures entered into force on 20 January 2009. The Regulation (available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>) replaces Title XI of REACH (Classification and Labelling Inventory), makes a few other supplementary changes to REACH, and implements the UN Globally Harmonised System (GHS) for CLP. The re-classification and labelling of most substances had to be completed by 1 December 2010. The deadline for mixtures is 1 June 2015. Existing legislation on CLP will be repealed on 1 June 2015 - during a transitory period existing systems and the CLP rules will be applied in parallel.

Commission Regulation (EC) No. 987/2008 on amending the EU REACH Regulation as regards Annexes IV and V entered into force on 12 October 2008. The Regulation (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:EN:PDF>) amended and replaced Annex IV and Annex V, which both list substances that are exempt from the obligations in Titles II (Registration), V (Downstream users) and VI (Evaluation) of REACH.

Commission Regulation (EC) No. 771/2008 (available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:206:0005:0013:EN:PDF>) laying down rules pertaining to the Board of Appeal of the ECHA entered into force on 5 August 2008.

Commission Regulation (EC) No. 465/2008 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:139:0008:0009:EN:PDF>) on testing and information requirements for PBTs entered into force on 30 May 2008.

Commission Regulation (EC) No. 466/2008 (available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:139:0010:0011:EN:PDF>) requiring firms to submit data on EU priority substances entered into force on 30 May 2008.

Commission Regulation (EC) No. 440/2008 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0440:EN:HTML>) on testing methods pursuant to the EU REACH Regulation entered into force on 30 May 2008 (see latest amendments to this Regulation introduced by Regulation (EU) No. 900/2014 further above).

Commission Regulation (EC) No. 340/2008 (details at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:107:0006:0025:EN:PDF>) on the ECHA fees that companies will pay for operations under REACH entered into force on 20 April 2008 - see new Commission Fees Regulation (EU) No. 254/2013 further above.

(B) Expected new measures

(i) During 2016, the Commission will propose an implementing Regulation for simplifying the REACH Authorisation process.

(ii) By mid-2016, the Commission will make proposals for any changes that might be needed to the EU's regulatory approach to endocrine disrupters.

(iii) During 2017, the Commission will carry out another review of REACH to determine whether or not it should be further amended to extend the requirements of Chemical Safety Assessments and Chemical Safety Reports for substances identified as being CMRs.

(iv) By 2019, the Commission will undertake additional REACH-related reviews on:
(a) the requirements for Chemical Safety Assessments for other substances; **(b)** animal testing methods for PBT and vPvB substances; and **(c)** the information requirements for suppliers.

APPENDIX 4

UK Regulations for the enforcement of REACH and other EU regulatory measures on chemicals

UK Implementing Legislation	
The REACH Enforcement Regulations 2008	http://www.legislation.gov.uk/uksi/2008/2852/contents/made
The Energy Act 2008 (Consequential Modifications) (Offshore Environmental Protection) Order 2010	http://www.legislation.gov.uk/uksi/2010/1513/contents/made
The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013	http://www.legislation.gov.uk/uksi/2013/1506/contents/made
The Biocidal Products (Fees and Charges) Regulations 2013	http://www.legislation.gov.uk/uksi/2013/1507/contents/made
The REACH Enforcement (Amendment) Regulations 2013	http://www.legislation.gov.uk/uksi/2013/2919/contents/made
The REACH Enforcement (Amendment) Regulations 2014	http://www.legislation.gov.uk/uksi/2014/2882/contents/made
The Classification, Labelling and Packaging of Chemicals (Amendments to Secondary Legislation) Regulations 2015	http://www.legislation.gov.uk/uksi/2015/21/contents/made

APPENDIX 5

Guidance from the ECHA and Other Sources on REACH plus additional EU regulatory measures on chemicals

[Please note: Sections A & B contain links to the core ECHA Guidance. Extra Guidance from the ECHA on other various aspects pertaining to REACH and additional EU regulatory measures on chemicals (e.g. biocides) is also accessible via the ECHA's Homepage – a link to which is provided in the first entry of Section A.]

(A) ECHA Guidance

ECHA (Homepage) - <http://echa.europa.eu/web/guest/about-us;jsessionid=740D01684F49F0C58A80D0B695B755CE.live2>.

Frequently Asked Questions (FAQ) - <http://echa.europa.eu/web/guest/support/faqs>.
Updated guidance regarding FAQ on the REACH Regulation.

ECHA Guidance on pre-Registration - <http://echa.europa.eu/regulations/reach/registration/data-sharing/pre-registration> -
Guidance on the (late) pre-Registration of substances after the initial 1 December 2008 deadline.

ECHA Guidance (in a nutshell): Registration data and dossier handling - http://echa.europa.eu/documents/10162/17224/nutshell_guidance_registration_en.pdf. Guidance aims to provide a simple and concise introduction, for manufacturers, importers and representatives, on the requirements of the REACH Regulation in relation to the information content of Registration dossiers for chemical substances, particularly with regard to the information requirements (such as the data on physicochemical, toxicological and ecotoxicological properties) and the Chemical Safety Assessment. In addition, the Guidance provides assistance in the preparation and submission of a Registration dossier, and outlines essential follow-up activities required by the ECHA and Registrants upon the submission of a Registration (see detailed Guidance on Registration below).

ECHA Guidance on Registration - http://echa.europa.eu/documents/10162/13629/registration_version2_draft_march_clean_en.pdf. Guidance explains when and how to Register a substance under the REACH Regulation.

ECHA Factsheet: Guidance on Data sharing - http://echa.europa.eu/documents/10162/13631/data_sharing_en.pdf. Factsheet supplements the detailed Guidance on data sharing by providing a short summary of key aspects for manufacturers and importers of chemical substances. Under the REACH

Regulation, multiple Registrants of the same substance are required to share data in the context of their Registration.

ECHA Guidance (in a nutshell): Data sharing -

http://echa.europa.eu/documents/10162/13631/nutshell_guidance_data_sharing_en.pdf. Guidance aims to explain in simple terms the main principles and obligations relating to data sharing and the joint submission of data under the REACH Regulation for Registrants of phase-in and non-phase-in substances, so as to enable producers, importers and / or users of chemical substances to determine whether they will need to refer to the full Guidance on data sharing (below).

ECHA Guidance on Data sharing -

http://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf. Guidance describes data sharing mechanisms required under the REACH Regulation, both within the same Substance Information Exchange Forum (SIEF) and between different SIEFs for phase-in substances and between multiple Registrants of the same non-phase-in substances.

ECHA Guidance (in a nutshell): Compilation of Safety Data Sheets -

http://echa.europa.eu/documents/10162/13643/sds_nutshell_guidance_en.pdf. Guidance provides an overview of the obligations related to the Safety Data Sheets (SDS) as foreseen by Article 31 and Annex II of the REACH Regulation. The Guidance describes in simple terms the main principles to be applied in the compilation of SDSs and the obligations that suppliers of substances and mixtures have to fulfil when providing an SDS to their customers. See full Guidance on the compilation of SDS below.

ECHA Guidance on the compilation of Safety Data Sheets -

http://echa.europa.eu/documents/10162/13643/draft_guidance_sds_to_peg_201304_en.pdf. Guidance provides information on compiling Safety Data Sheets (SDS), so as to fulfil the obligations under Article 31 and Annex II of the REACH Regulation.

ECHA Guidance (in a nutshell): Downstream Users -

http://echa.europa.eu/documents/10162/13634/du_nutshell_guidance_en.pdf. Guidance aims to introduce in simple and concise terms the obligations for Downstream Users under the REACH Regulation. The Guidance explains in brief how to identify Downstream Users roles and illustrates the different circumstances that Downstream Users may encounter. The Guidance describes the obligations to be fulfilled and the actions that Downstream Users can choose to take according to their situation. In particular, principles and requirements concerning communication of information on mixtures are outlined. See full Guidance for Downstream Users below.

ECHA Guidance for Downstream Users -

http://echa.europa.eu/documents/10162/966058/du_guidance_draft_en.pdf. Guidance describes requirements for Downstream Users under the REACH Regulation.

ECHA Factsheet: Key information for recipients of substances covered by Article 2(7) of the REACH Regulation - Communication obligations for certain substances exempted from Registration under REACH -

http://echa.europa.eu/documents/10162/13655/reach_factsheet_on_communication_obligation_en.pdf. Factsheet provides information regarding the implications arising from the exemption of certain chemical substances from Registration requirements according to Article 2(7) of the REACH Regulation. See related Guidance directly below.

ECHA Guidance for Annex V: Exemptions from obligation to Register -

http://echa.europa.eu/documents/10162/13564/draft_update_of_guidance_for_annex_v_entry_9_2012_clean_en.pdf. Guidance provides advice regarding the interpretation of criteria found under Article 2(7)(b) of the REACH Regulation (as amended by Regulation (EC) No. 987/2008) for exempting substances covered by Annex V from Registration, downstream user and evaluation requirements.

ECHA Factsheet: Getting Started in Substance Information Exchange Forums (SIEFs) - Top Tips -

http://echa.europa.eu/documents/10162/17096/reach_factsheet_siefs_en.pdf. Factsheet provides information regarding the SIEFs that are to be formed by companies intending to Register substances under REACH. Factsheet addresses some of the problems that have arisen in relation to SIEFs and aims to highlight potential solutions.

ECHA News Alert - Recommendations to Lead Registrants

http://echa.europa.eu/documents/10162/17096/na_10_19_dcg_lr_20100416_en.pdf.

A news alert which provides practical recommendations for ensuring that Lead Registrants submit lead dossiers in time. Lead Registrants are advised to inform all Substances Information Exchange Forum (SIEF) members of the date on which they intend to submit the lead dossier and a 'cut-off-date' at which point the dossier will be frozen.

ECHA Guidance on intermediates -

http://echa.europa.eu/documents/10162/17224/intermediates_en.pdf. Guidance provides information on when and how the specific provisions for the Registration of intermediates can be used under the REACH Regulation, where intermediates are substances that are manufactured for and consumed in or used for chemical processing in order to be transformed into other substances.

ECHA News Alert - Clarifying the definition of intermediates -

http://echa.europa.eu/documents/10162/17095/na_10_30_guidance_on_intermediates_20100601_en.pdf. A news alert clarifying the definition of intermediates.

ECHA Guidance for monomers and polymers -

http://echa.europa.eu/documents/10162/13632/polymers_en.pdf. Updated Guidance describes specific provisions regarding polymers and monomers contained under the REACH Regulation.

ECHA Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD) -

http://echa.europa.eu/documents/10162/13632/ppord_en.pdf. The Guidance is part of a series of Guidance documents which aim to assist users in complying with their obligations under the REACH Regulation. In particular, the Guidance focuses on specific provisions under REACH for substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD). See related Guidance directly below.

ECHA Guidance: Data submission manual 5 - How to complete a technical dossier for Registrations and PPORD notifications -

http://echa.europa.eu/documents/10162/17248/compl_tech_dossier_manual_en.pdf. Guidance is intended to assist Registrants and notifiers in the preparation of Registration and PPORD dossiers in accordance with the REACH Regulation. In particular, the aim of the Guidance is to help potential Registrants and notifiers identify which of the IUCLID 5 fields are of prime importance in relation to the technical completeness check.

ECHA Guidance: For implementation of Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals -

http://echa.europa.eu/documents/10162/21784135/guidance_pic_en.pdf. Guidance provides information to help users comply with their obligations under the Prior Informed Consent (PIC) Regulation (EU) No. 649/2012, which implements the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals in international trade. The EU PIC Regulation further makes a number of additional provisions to control the trade, import and use of certain hazardous chemicals, in order to better protect the environment and human health.

ECHA Guidance (in a nutshell): Requirements for substances in articles

http://echa.europa.eu/documents/10162/17224/nutshell_guidance_articles2_en.pdf. Guidance aims to provide managers and decision-makers of companies producing, importing and / or supplying articles in the European Economic Area (EEA) with a brief explanation of the law applicable to substances in articles under the REACH Regulation, particularly if they have little experience with chemicals regulatory affairs. Articles are defined as an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. Such articles include most of the commonly used objects in industry such as electronic equipment. The Guidance is intended to support the main Guidance on substances in articles (below).

ECHA Guidance on the requirements for substances in articles -

http://echa.europa.eu/documents/10162/13632/articles_en.pdf. Guidance (which has been updated to reflect a ruling by the EU Court in September 2015 (details at: <http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14>) relating to the presence of hazardous chemicals in product components) explains and illustrates those provisions of the REACH Regulation that apply to substances in articles,

where an article is defined (under Article 3(3) of REACH) as an object which during production is given a special shape, surface or design that determines its function to a greater degree than does its chemical composition. In particular, the Guidance will assist producers and importers of articles to identify whether they have obligations under REACH in relation to Registration and notification according to Article 7, and in respect to article supply chain communication according to Article 33.

ECHA Guidance on the application of the classification, labelling and packaging (CLP) criteria under the CLP Regulation (EC) No. 1272/2008 for substances and mixtures - http://echa.europa.eu/documents/10162/13562/clp_en.pdf. Guidance provides information for the benefit of manufacturers or importers on their obligations under the Chemical Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 regarding the application of classification and labelling criteria for physical, health and environmental hazards.

ECHA Guidance on the application of the CLP criteria - Third draft (to generate Version 4.0) for second PEG [Part 2: Physical Hazards] - http://echa.europa.eu/documents/10162/13562/clp_3rd_atp_chapter_2_phys_chem_en.pdf. Guidance provides information on the generation and interpretation of test data for physical hazards arising from chemical substances. It represents Part 2 ('Physical Hazards') of the Guidance on the application of the classification and labelling criteria under the Chemicals Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 (see details on the CLP Guidance above).

ECHA Guidance on the application of the CLP criteria - Second draft (to generate Version 4.0) for second PEG [Part 3: Health Hazards] - http://echa.europa.eu/documents/10162/13562/draft_guidance_peg_clp_hh_rev4_v2_201303_en.pdf. Guidance provides information on the generation and interpretation of test data for health hazards arising from chemical substances. It represents Part 3 ('Health Hazards') of the Guidance on the application of classification and labelling criteria under the Chemicals Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 (see details on the CLP Guidance above and information directly below pertaining to the application of the CLP criteria in respect to 'human health hazards').

ECHA Guidance on the application of the CLP criteria - Further development of the RIP 3.6 Guidance [Human health hazards (Specific concentration limits)] - http://echa.europa.eu/documents/10162/13564/draft_guidance_clp_hh_caracal_clean_v3_en.pdf. Guidance presents further modifications to the Guidance on the application of the chemicals CLP criteria, particularly concerning corrections to Part 1 ('General Principles for Classification') and an update of Part 3 ('Health Hazards'), as well as the inclusion of a new Annex VI.

ECHA Guidance on the preparation of dossiers for harmonised classification and labelling (CLH) under the CLP Regulation (EC) No. 1272/2008 - http://echa.europa.eu/documents/10162/13562/draft_clh_peg_201311_en.pdf. Guidance provides information for the benefit of Member State Competent Authorities

and manufacturers, importers and downstream users on the preparation of a dossier containing proposals for harmonised classification and labelling (CLH) of substances in accordance with the Chemical Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008.

ECHA Guidance: Frequently Asked Questions about the CLP Regulation (EC) No. 1272/2008 - <http://echa.europa.eu/web/guest/support/faqs/clp-frequently-asked-questions>. Guidance which outlines answers to a number of frequently asked questions on the Chemical Classification, Labelling and Packaging (CLP) Regulation. Among other things, the Guidance covers who the CLP Regulation applies to and the requirements relating to labelling and notification.

ECHA Factsheet: Guidance for the identification and naming of substances under the REACH Regulation and the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008- http://echa.europa.eu/documents/10162/17236/substance_en.pdf. Factsheet which provides a structured overview on the identification and naming of substances under the REACH and CLP Regulations, so as to assist companies who manufacture in, or import chemical substances into, the EU.

ECHA Guidance (in a nutshell): Identification and naming of substances under the REACH Regulation and the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 - http://echa.europa.eu/documents/10162/17235/nutshell_guidance_substance_en.pdf. Guidance which presents a simple and concise introduction on how to identify and name a substance under the REACH and CLP Regulations. The ‘Guidance in a nutshell’ is aimed at managers and decision-makers of companies producing or importing chemical substances in the EU, particularly those belonging to the Small and Medium Enterprises (SME) category. More detailed information can be found in the full Guidance below.

ECHA Guidance for the identification and naming of substances under the REACH Regulation and the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008 - http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf. Guidance describes how manufacturers and importers should name and identify substances in the context of the REACH and CLP Regulations.

ECHA Tool - Preparation of Chemical Safety Assessments and Chemical Safety Reports - <http://chesar.echa.europa.eu/>. A tool which is intended to help companies to prepare their Chemical Safety Assessments (CSA) and Chemical Safety Reports (CSR), which are required for substances manufactured or imported at a volume equal to or above 10 tonnes per year under the REACH Regulation. The Chemical Safety Assessment and Reporting (CHESAR) Tool may be downloaded and used as a plug-in to the International Uniform Chemical Information Database (IUCLID 5) Tool (<http://iuclid.eu/>).

ECHA Guidance on the Chemical Safety Report (CSR): An illustrative example [Part 1, introductory note and Part 2, illustrative CSR] -

http://echa.europa.eu/documents/10162/13634/csr_illustrative+example_en.pdf.

Guidance provides information on aspects to be considered when undertaking a Chemical Safety Assessment for a CSR on environmental and human exposure as required under the REACH Regulation.

ECHA Guidance (in a nutshell): Chemical Safety Assessment -

http://echa.europa.eu/documents/10162/17224/nutshell_guidance_csa_en.pdf

Guidance aims to provide an overview for industry of the general provisions of a Chemical Safety Assessment (CSA) in the context of REACH. In particular, the Guidance outlines what a CSA consists of and how it is performed / documented. A CSA is the process that identifies and describes the conditions under which the manufacturing and use of a substance is considered to be safe and consists of three major steps: (i) hazard assessment; (ii) exposure assessment; and (iii) risk characterisation. The Guidance is intended to support the main Guidance on CSA (directly below).

ECHA Guidance on Information Requirements and Chemical Safety Assessment -

<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>.

Guidance on the information requirements under the REACH Regulation with regard to substance properties, exposure, use and risk management measures, in the context of a Chemical Safety Assessment. This package of Guidance documents contains advice on: (i) the collection of the available information regarding the intrinsic properties of the substance to be Registered; (ii) the assessment of this information against the requirements specified by REACH; (iii) the identification of data gaps; and (iv) the generation of the additional information required to fill the data gaps.

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Part B: Hazard Assessment -

http://echa.europa.eu/documents/10162/17224/inforeq_csr_b_draft_chap_b8_final_20110831_en.pdf.

Guidance provides assistance to manufacturers and importers of substances requiring an exposure assessment under the REACH Regulation, by presenting information on the required scope of the exposure assessment based on the outcome of the hazard assessment. In particular, this version of the Guidance includes a new Chapter B.8 ('Scope of Exposure Assessment') which forms part of a package of Chemical Safety Assessment related Guidance documents (described below) that explain the information requirements under REACH with regard to substance properties, exposure, uses and risk management measures, in the context of a Chemical Safety Assessment.

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Part C: PBT / vPvP Assessment -

http://echa.europa.eu/documents/10162/13643/information_requirements_part_c_en.pdf. Guidance provides information for Registrants under the REACH Regulation on

how to assess whether or not a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Part D: Exposure scenario building -

http://echa.europa.eu/documents/10162/17224/information_requirements_part_d_en.pdf. Guidance provides information on exposure scenario building and the format of a Chemical Safety Report in the context of information requirements under the REACH Regulation, so as to ensure that the information content of the exposure scenario is generated, stored, processed, communicated and analysed in a transparent / efficient way.

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Part E: Risk characterisation -

http://echa.europa.eu/documents/10162/13564/inforeg_csr_part_e_draft_201207_en.pdf. Guidance provides information for Registrants under the REACH Regulation on risk characterisation. The Guidance forms part of a package of Guidance documents that describe the information requirements with regard to substance properties, exposure, uses and risk management measures, in the context of a Chemical Safety Assessment.

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.5: Adaptation of information requirements -

http://echa.europa.eu/documents/10162/17224/information_requirements_r5_en.pdf Guidance provides information on the different options available under the REACH Regulation to adapt information requirements.

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.6: QSARs and grouping of Chemicals -

http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf Guidance provides advice on new non-animal testing approaches such as QSAR and grouping that facilitate the evaluation of the intrinsic properties of chemicals.

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7a: Endpoint Specific Guidance -

http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf Guidance describes information requirements regarding physico-chemical properties (set out under the REACH Regulation) and presents different human health and environmental end points. The ECHA has also published extra Guidance presenting:

- An updated Chapter R.7.7 ('mutagenicity and carcinogenicity') to the main Guidance (directly above) - the additional Guidance is at:
http://echa.europa.eu/documents/10162/13643/ir_csa_r7a_muta_draft_peg_2_01305_en.pdf
- An updated Chapter R.7.2 (Skin, eye and respiratory tract irritation/corrosion) within the main Guidance.

See other related supplemental Guidance directly below.

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Appendix R7-1: Recommendations for nanomaterials applicable to Chapter R.7a [Endpoint Specific Guidance] –

http://echa.europa.eu/documents/10162/13632/appendix_r7a_nanomaterials_en.pdf.

Guidance presents advice for Registrants under the REACH Regulation regarding the preparation of Registration dossiers for nanomaterials, so as to supplement the Chapter R.7a ‘endpoint specific Guidance’ (see Guidance above).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7b: Endpoint Specific Guidance -

http://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf.

Guidance provides advice to Registrants on aquatic pelagic toxicity testing and the application of an Integrated Testing Strategy (ITS) for aquatic toxicity. Guidance is primarily concerned with the gathering of data and information on substances to enable an environmental hazard assessment to be completed in order to determine, amongst other things, potential PBT toxicity (see related supplemental Guidance directly below).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Appendix R7-1: Recommendations for nanomaterials applicable to Chapter R.7b [Endpoint Specific Guidance] –

http://echa.europa.eu/documents/10162/13632/appendix_r7b_nanomaterials_en.pdf.

Guidance presents advice for Registrants under the REACH Regulation regarding the preparation of Registration dossiers for nanomaterials, so as to supplement the Chapter R.7b ‘endpoint specific Guidance’ (see Guidance above).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7c: Endpoint Specific Guidance -

http://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

Guidance provides advice to Registrants on the assessment of all available data on: (i) the aquatic bioaccumulation of substances and their potential long-term toxicity effects for birds; and (ii) the inherent toxic potential of specific substances to terrestrial living organisms (see related supplemental Guidance directly below).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Appendix R7-2: Recommendations for nanomaterials applicable to Chapter R.7c [Endpoint Specific Guidance] –

http://echa.europa.eu/documents/10162/13632/appendix_r7c_nanomaterials_en.pdf.

Guidance presents advice to Registrants under the REACH Regulation regarding the preparation of Registration dossiers for nanomaterials, so as to supplement the Chapter R.7c ‘endpoint specific Guidance’ (see Guidance above).

ECHA Guidance on DNEL / DMEL derivation from human data [Chapter R.8: Characterisation of dose [concentration] - Response for human health] -

[http://echa.europa.eu/documents/10162/17224/r8_dnel_hd_draft_rev1-](http://echa.europa.eu/documents/10162/17224/r8_dnel_hd_draft_rev1-1_after_peg_en.pdf)

[1 after_peg_en.pdf](http://echa.europa.eu/documents/10162/17224/r8_dnel_hd_draft_rev1-1_after_peg_en.pdf). Guidance provides information on dose / concentration response for

human health (with particular regard to extracting derived no-effect levels (DNELs) or derived minimal effect levels (DMELs) from human data), in the context of risk characterisation under the REACH Regulation (see related supplemental Guidance directly below).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Appendix R8-15: Recommendations for nanomaterials applicable to Chapter R.8: Characterisation of dose [concentration]-Response for human health -
http://echa.europa.eu/documents/10162/13643/appendix_r8_05-2012_en.pdf.

Guidance presents advice for Registrants under the REACH Regulation regarding the preparation of Registration dossiers for nanomaterials, so as to supplement the Chapter R.8 ‘Characterisation of dose [concentration]-response for human health’ Guidance (see Guidance above).

ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.10: Characterisation of dose [concentration]-Response for environment -
http://echa.europa.eu/documents/10162/13632/information_requirements_r10_en.pdf. Guidance describes the information requirements under the REACH Regulation with regard to substance properties, exposure, use, risk management, and the Chemical Safety Assessment (see supplemental Guidance directly below).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Appendix R10-2: Recommendations for nanomaterials applicable to Chapter R.10: Characterisation of dose [concentration]-response for environment -
http://echa.europa.eu/documents/10162/13643/appendix_r10_05-2012_en.pdf.

Guidance presents advice for Registrants under the REACH Regulation regarding the preparation of Registration dossiers for nanomaterials, so as to supplement the Chapter R.10 ‘Characterisation of dose [concentration]-response for environment’ Guidance (see Guidance above).

ECHA Guidance on Information Requirements and Chemical Safety Assessment [Chapter R.12: Use descriptor system] -
http://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf.

Guidance which provides assistance to manufacturers and importers of substances requiring an exposure assessment under REACH (who are required to develop, assess and communicate exposure scenarios covering the entire life cycle of the substance) by setting up a system to help develop short titles of exposure scenarios, so as to flag up their scope and applicability.

ECHA Guidance on Information Requirements and Chemical Safety Assessment [Chapter R.14: Occupational exposure estimation] -
http://echa.europa.eu/documents/10162/17224/draft_chapter_r14_version2_rev2_en.pdf. Guidance provides information on conducting an occupational exposure assessment under the REACH Regulation, with particular regard to what information is needed for the assessment at the different levels and how to deal with it (see related supplemental Guidance directly below).

ECHA Guidance on Information Requirements and Chemical Safety Assessment - Appendix R14-4: Recommendations for nanomaterials applicable to Chapter R.14: Occupational exposure estimation -

http://echa.europa.eu/documents/10162/13643/appendix_r14_05-2012_en.pdf

Guidance presents advice for Registrants under the REACH Regulation regarding the preparation of Registration dossiers for nanomaterials, so as to supplement the Chapter R.14 'Occupational exposure estimation' Guidance (see Guidance above).

ECHA Guidance on Information Requirements and Chemical Safety Assessment [Chapter R.15: Consumer exposure estimation] -

http://echa.europa.eu/documents/10162/17224/r15_update_version_2_rev20_en.pdf

Guidance provides assistance to manufacturers and importers of substances requiring an exposure assessment under the REACH Regulation, by outlining a procedure for the estimation of consumer exposure to substances (either on their own, in preparations or in articles).

ECHA Guidance on Information Requirements and Chemical Safety Assessment [Chapter R.16: Environmental exposure estimation] -

http://echa.europa.eu/documents/10162/17224/information_requirements_r16_en.pdf

Guidance provides assistance to manufacturers and importers of substances requiring an exposure assessment under the REACH Regulation with regard to estimating environmental exposure (in terms of releases to air and water and at local and regional scale, fate and distribution of the releases and calculation of exposure concentrations).

ECHA Guidance on Information Requirements and Chemical Safety Assessment [Chapter R.18: Estimation of exposure from waste life stage] -

http://echa.europa.eu/documents/10162/17224/csr_r18_guidance_update_full_en.pdf

Guidance which provides assistance to manufacturers and importers of substances requiring an exposure assessment under the REACH Regulation, by setting out information relating to REACH requirements for substances (on their own, in preparations or in articles) in the waste life stage. These requirements are limited due to the fact that waste, as defined under the Waste Framework Directive 2008/98/EC, is not classified as a substance, preparation or article under Article 3 of the REACH Regulation.

ECHA Guidance on the Data submission manual - Part 19: How to submit a Chemical Safety Report (CSR) as part of a joint submission -

http://echa.europa.eu/documents/10162/17248/dsm_19_how_joint_csr_en.pdf

Guidance provides practical information on the joint submission of a Chemical Safety Report (CSR) under the REACH Regulation, with particular focus placed on the chapters relating to use, exposure assessment and risk characterisation.

ECHA Report concerning Communication on the safe use of chemicals -

http://echa.europa.eu/documents/10162/17203/clp_study_en.pdf. Report examines the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels. The report was

submitted to the Commission in accordance with Article 34(1) of the EU Classification, Labelling and Packaging (CLP) Regulation.

ECHA Roadmap - Enhancing the quality of information communicated on the safe use of chemicals - http://echa.europa.eu/view-article/-/journal_content/title/echa-and-stakeholders-set-out-actions-to-improve-chemical-safety-reports-and-safety-data-sheets. Roadmap aims to improve the quality of information communicated in the exposure scenarios included in Chemical Safety Reports and in extended Safety Data Sheets (these documents hold essential information on the safe use of chemical substances and mixtures for downstream users, authorities and REACH Registrants alike).

ECHA Guidance - Exposure scenario for Chemical Safety Report and communication example: Consumer use of a substance in cleaning products - http://echa.europa.eu/documents/10162/17234/es_for_consumer_20110829_en.pdf. Guidance provides practical examples of how to generate exposure scenarios (ESs) for a substance that is commonly used in cleaning products by consumers, once a consumer and environment exposure assessment and risk characterisation has been completed. The REACH Regulation requires manufacturers or importers of the substance to document the ES in the Chemical Safety Report (CSR) and attach it to the safety data sheet (SDS) if that substance is placed on the market. The example ES set out in the Guidance document should be useful for both Registrants and downstream users receiving extended SDSs for Registered REACH substances.

ECHA Guidance - Exposure scenario for Chemical Safety Report and communication example: Professional use of a substance in floor coatings - http://echa.europa.eu/documents/10162/17235/es_professional_use_20110829.pdf. Guidance provides practical examples of how to generate exposure scenarios (ESs) for a substance that is commonly used in floor coating products and is applied by workers, once a worker and environment exposure assessment and risk characterisation has been completed. The REACH Regulation requires manufacturers or importers of the substance to document the ES in the Chemical Safety Report (CSR) and attach it to the safety data sheet (SDS) if that substance is placed on the market. The example ES set out in the Guidance document should be useful for both Registrants and downstream users receiving extended SDSs for Registered REACH substances.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 - Volume I: Identity / physico-chemical properties / analytical methodology - Part A: Information Requirements - http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ir_part_vol_i_part_a_en.pdf. Guidance describes the information requirements for active substances and biocidal products in accordance with Title 1 of Annexes II and III of the Biocidal Products Regulation.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 - Volume II: Efficacy Part A: Information Requirements -
http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ir_part_vol_ii_part_a_en.pdf. Guidance describes the information requirements for active substances and biocidal products in accordance with Title 1 of Annexes II and III of the Biocidal Products Regulation.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 - Volume III: Human health Part A: Information Requirements -
http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ir_part_vol_iii_part_a_en.pdf. Guidance describes the information requirements for active substances and biocidal products in accordance with Title 1 of Annexes II and III of the Biocidal Products Regulation.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 -Volume III: Human Health - Part B: Risk Assessment -
http://echa.europa.eu/documents/10162/15623299/biocides_guidance_human_health_ra_iii_partb_en.pdf. Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances and products with respect to human health risk assessment.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 -Volume IV: Environment - Part A: Information Requirements -
http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ir_part_vol_iv_part_a_en.pdf. Guidance describes the information requirements for active substances and biocidal products in accordance with Title 1 of Annexes II and III of the Biocidal Products Regulation.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 - Volume IV: Environment - Part B: Risk Assessment (active substances) -
http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ra_vol_iv_part_b_en.pdf. Guidance provides technical advice on how to perform the hazard and exposure assessment and risk characterisation for biocidal active substances with respect to environmental risk assessment.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 - Guidance on applications for technical equivalence -
http://echa.europa.eu/documents/10162/15623299/guidance_applications_technical_equivalence_en.pdf. Guidance informs potential applicants about their obligations resulting from the provisions of Article 54 of the Biocidal Products Regulation - such as when they need to apply for an assessment of technical equivalence and on the procedural steps in making that application. The Guidance also informs potential applicants about the assessment conducted by the ECHA and the approach used for assessing the technical equivalence of the alternative source of an active substance versus its reference source.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 - Volume V: Guidance on active substances and suppliers (Article 95 list) - http://echa.europa.eu/documents/10162/15623299/biocides_guidance_active_substance_suppliers_en.pdf. Guidance describes the obligations under Article 95 of the Biocidal Products Regulation and explains the regulatory consequences.

ECHA Guidance on the Biocidal Products Regulation (EU) No. 528/2012 - Volume V: Guidance on active micro-organisms and biocidal products - http://echa.europa.eu/documents/10162/15623299/biocides_guidance_micro_organisms_en.pdf. Guidance provides information on how to comply with the requirements of the Biocidal Products Regulation, in particular in relation to active micro-organisms and biocidal products. It replaces the 2005 ‘Technical notes for guidance on data requirements for micro-organisms including viruses and fungi’ addendum to the technical notes for guidance on data requirements relating to the previous Biocides Directive 98/8/EC.

ECHA Transitional Guidance on mixture toxicity assessment for biocidal products for the environment - http://echa.europa.eu/documents/10162/15623299/biocides_transitional_guidance_mixture_toxicity_en.pdf. Transitional Guidance addresses the assessment of the mixture toxicity of products, as well as synergistic effects by applying a tiered scheme for the adequate consideration of mixture effects during the environmental risk assessment of biocidal products. It is applicable for the authorisation of products under the Biocides Regulation (EU) No. 528/2012. The Guidance has been developed by the ECHA and the Member States Competent Authorities and takes into account the elements described in the Technical Notes for Guidance for Biocides under the Biocides Directive 98/8/EC.

ECHA Transitional Guidance on efficacy assessment of preservatives - http://echa.europa.eu/documents/10162/15623299/biocides_transitional_guidance_of_efficacy_preservatives_en.pdf. The aim of the Transitional Guidance document is to help with the practical aspects of designing and performing laboratory trials for testing the efficacy of preservatives, and is applicable for the authorisation of products under the Biocides Regulation (EU) No. 528/2012. The Guidance is intended to make the general testing principles understood so that they can then be applied in all types of preservative testing. It has been developed by the ECHA and the Member States Competent Authorities and takes into account the elements described in the Technical Notes for Guidance for Biocides under the Biocides Directive 98/8/EC.

ECHA Guidance: Transitional guidance on efficacy assessment for product type 21 antifouling products - http://echa.europa.eu/documents/10162/15623299/biocides_transitional_guidance_of_efficacy_pt_21_en.pdf. Guidance deals with the methodology for the evaluation of efficacy tests for antifouling products that is applicable for the authorisation of products under the Biocides Regulation (EU) No. 528/2012. It has been developed by the ECHA and the Member States Competent Authorities and takes into account the elements

described in the Technical Notes for Guidance for Biocides under the Biocides Directive 98/8/EC.

ECHA Guidance: Transitional Guidance on evaluation of environmental RMM for disinfectants products type 1-5 - <http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/transitional-guidance?panel=pt15>.

Transitional Guidance aims to gather and harmonise possible Risk Mitigation Measures (RMM) for disinfectants - product type (PT) 1-5, so as to present a set of possible RMM that can be used for all Authorisations submitted under the Biocides Regulation (EU) No. 528/2012.

ECHA Factsheet: Guidance on waste and recovered substances -

http://echa.europa.eu/documents/10162/17224/waste_rec_en.pdf. Factsheet provides a short summary of key aspects relating to waste and recovered substances under the REACH Regulation. The factsheet is intended to supplement the detailed Guidance below.

ECHA Guidance on waste and recovered substances -

http://echa.europa.eu/documents/10162/17224/waste_recovered_en.pdf. Guidance provides information for manufacturers and importers on obligations relating to recovered substances under REACH. In particular, the Guidance aims to clarify the status of materials that have been recovered, ceased to be waste and are subject to obligations under the REACH Regulation for substances, mixtures or articles.

ECHA Guidance on priority setting for Evaluation - The Guidance document has been made obsolete and removed from the ECHA website. It has been replaced by current and updated information available on the ECHA Evaluation web-pages accessible directly via the following links:

<http://echa.europa.eu/web/guest/regulations/reach/evaluation> and <http://echa.europa.eu/web/guest/about-us/the-way-we-work/procedures-and-policies/public-procedures>.

ECHA Recommendations on the Interaction between Member States and Registrants under Substance Evaluation -

http://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf. The aim of the Recommendations is to give Guidance for a common approach and create a level playing field for interactions among the evaluating Member States and Registrants. The Recommendations complement the leaflet 'Substance evaluation under REACH - Tips for Registrants and Downstream Users' (see details directly below).

ECHA Leaflet: Substance Evaluation under REACH - Tips for Registrants and Downstream Users -

http://echa.europa.eu/documents/10162/13628/sub_eval_under_reach_leaflet_en.pdf
The leaflet provides practical advice for Registrants who hold a Registration for a substance included in the Community Rolling Action Programme (CoRAP) and for

Downstream Users of such substances on how to participate in the substance evaluation process.

ECHA Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern -

http://www.echa.europa.eu/documents/10162/13638/svhc_en.pdf. Guidance describes how Member State Competent Authorities or the ECHA can prepare an Annex XV dossier to identify a substance of very high concern.

ECHA Guidance on the preparation of an application for an Authorisation -

http://echa.europa.eu/documents/10162/17229/authorisation_application_en.pdf.

Guidance which describes how to prepare an application for an Authorisation relating to the use of substances of very high concern (SVHC) included in Annex XIV ('list of substances subject to Authorisation') under the REACH Regulation. In particular, the Guidance relates to the mixture of an analysis of alternatives, a substitution plan and how interested third parties can contribute to the Authorisation process. The Guidance is primarily intended for manufacturers, importers and downstream users who place on the market or use an Annex XIV substance, as well as third parties that may have information on alternative substances or alternative technologies. See related Guidance directly below.

ECHA Guidance on the preparation of a socio-economic analysis as part of an application for Authorisation -

https://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf. Guidance describes the process of undertaking a socio-economic analysis as part of an Authorisation application under the REACH Regulation, and thereby supplements the Guidance above on preparing an Authorisation application. A socio-economic analysis describes and analyses both the positive and negative effects of granting an Authorisation compared with a refusal, so as to establish whether the socio-economic benefits of continued use of the substance outweigh the risks of continued use for human health and the environment.

ECHA Guidance on IUCLID 5 -

http://echa.europa.eu/documents/10162/17224/iuclid_en.pdf. Guidance describes how to use IUCLID 5 and how to prepare the dossiers for different REACH Regulation requirements. The ECHA has also published additional Guidance on other aspects of IUCLID 5 - see full details at:

<http://iuclid.echa.europa.eu/index.php?fuseaction=home.documentation>. See also specific related Guidance directly below.

ECHA Guidance - Data submission manual - Part 18: How to report the substance identity in IUCLID 5 for Registration under REACH -

http://echa.europa.eu/documents/10162/17248/substance_id_report_iuclid_en.pdf.

Guidance provides technical assistance on reporting and structuring substance identification information in an IUCLID 5 dossier, so as to enable the Registration of a substance under the REACH Regulation.

ECHA Guidance - Data submission manual - Part 20: How to prepare and submit a substance in articles notification using IUCLID 5 -

http://echa.europa.eu/documents/10162/13653/dsm_20_notif_sia_en.pdf. Guidance provides information on the preparation and submission of a notification dossier for substances in articles using IUCLID 5.

ECHA Guidance on REACH-IT - <http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it>. REACH-IT provides an online company homepage to submit Registration dossiers on chemicals. It also allows the ECHA and Member States authorities to review the dossiers. See related Guidance directly below.

ECHA Guidance on REACH-IT Data submission manual - Part 16: Confidentiality claims - How to make confidentiality claims and how to write Article 119(2) confidentiality claim justifications -

http://echa.europa.eu/documents/10162/17248/dsm_16_confidentiality_claims_en.pdf. Guidance provides information on making a confidentiality claim relating to information on Registered substances submitted under the REACH Regulation, on the basis that publication of certain information would be potentially harmful to the commercial interests of the Registrant or any other party concerned. These justifications will be assessed by the ECHA in accordance with Article 119(2) of REACH and the information will not be published in the event the justification is acceptable.

ECHA Guidance: Frequently Asked Questions (FAQs): Technical aspects in REACH-IT - <http://echa.europa.eu/web/guest/support/faqs/reach-it-frequently-asked-questions>. Guidance provides responses to FAQs on technical aspects in REACH-IT, which has been updated to provide practical information and instructions on how to pay invoices to the ECHA to comply with the REACH Regulation (as a late payment of the fee renders dossiers incomplete and leads to a rejection of the Registration. Registration fees will also not be reimbursed in such instances).

ECHA Factsheet: Avoid your REACH-IT account being blocked -

http://echa.europa.eu/view-article/-/journal_content/title/avoid-blocking-your-reach-it-account. Factsheet which explains how Registrants can avoid having their REACH-IT accounts blocked and how to proceed in cases where an account is already blocked. For security reasons, REACH-IT accounts are blocked after five unsuccessful login attempts, and the factsheet details the ways in which individuals may regain access which depends on their role as a REACH-IT user.

ECHA Guidance: Information toolkit -

<http://echa.europa.eu/web/guest/support/information-toolkit>. Guidance provides practical information and tools to enable Registrants to use existing information to predict the properties of substances using non-test methods (where the scientific arguments for using non-standard data or predicted properties data should be fully described in the Registration dossier), as a first step to meeting information requirements under the

REACH Regulation. The information toolkit brings together documents, practical information and prediction methodologies.

ECHA Guidance: Factsheet - Toll manufacturer under the REACH Regulation - http://echa.europa.eu/documents/10162/13634/factsheet_toll_manufacturer_en.pdf.

Guidance aims to describe the requirements under the REACH Regulation that may apply to toll manufacturers. The Guidance gives some initial advice on how compliance may be facilitated for toll manufacturers and for companies who are contracting others to toll manufacture on their behalf.

(B) ECHA Practical Guides and additional Quick Guides

ECHA Guidance - Practical guide 1: How to report *in vitro* data - http://echa.europa.eu/documents/10162/17250/pg_report_in_vitro_data_en.pdf.

Guidance provides information on reporting *in vitro* data (comprising of alternative testing methods that could reduce, refine or replace the use of laboratory animals) for the purposes of obtaining adequate information on the properties of chemical substances under the REACH Regulation.

ECHA Guidance - Practical guide 2: How to report weight of evidence - http://echa.europa.eu/documents/10162/17250/pg_report_weight_of_evidence_en.pdf.

Guidance provides information on the ‘weight of evidence’ concept and how it may be used in making conclusions on the properties of a substance for the purposes of meeting information requirements relating to the Registration of a substance under the REACH Regulation.

ECHA Guidance - Practical guide 3: How to report robust study summaries - http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf.

Guidance provides information on the preparation of individual Robust Study Summaries for all endpoints required as part of the International Uniform Chemical Information Database (IUCLID) Registration dossier, so as to demonstrate the safe use of substances and fulfil the information requirements under Articles 10 and 12 of the REACH Regulation.

ECHA Guidance - Practical guide 4: How to report data waiving - http://echa.europa.eu/documents/10162/17250/pg_report_data_waiving_en.pdf.

Guidance provides an introduction to fulfilling standard information requirements under Annexes VI to X of the REACH Regulation, with particular regard to instances where the Registrant may be allowed to adapt or waive these requirements.

ECHA Guidance - Practical guide 5: How to use and report (Q)SARs - http://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf.

Guidance provides an overview of important considerations when predicting properties of substances using (Quantitative) Structure-Activity Relationship ((Q)SAR) models, as defined under the REACH Regulation.

ECHA Guidance - Practical guide 6: How to report read-across and categories -
http://echa.europa.eu/documents/10162/17250/pg_report_readacross_en.pdf.

Guidance provides information on the practical aspects of using a read-across or category approach for fulfilling the information requirements under the REACH Regulation.

ECHA Guidance - Practical guide 7: How to notify substances to the Classification and Labelling Inventory -

http://echa.europa.eu/documents/10162/17235/pg_7_clp_notif_en.pdf. Guidance provides information on how to notify substances to the Classification and Labelling Inventory under the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008, where notification applies to all hazardous substances and to all non-hazardous substances subject to Registration under the REACH Regulation whenever they are placed on the EU market.

ECHA Guidance - Practical Guide 8: How to report changes in identity of legal entities -

http://echa.europa.eu/documents/10162/17235/pg_8_legal_entity_change_en.pdf.

Guidance which provides information on the reporting requirements placed on those companies that change their name or legal personality following the submission of pre-Registrations, Registrations or Inquiries under the REACH Regulation.

ECHA Guidance - Practical guide 9: How to do a Registration as a member of a joint submission - The ECHA has temporarily withdrawn *Practical Guide 9: How to do a Registration as a member of a joint submission*.

The information on this document is outdated after the latest release of REACH-IT. Visit the Joint Submission Member Support Page - <http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/Joint+submission+of+data+by+multiple+registrants> - to find the relevant manuals for creating, checking and submitting IUCLID dossiers using REACH-IT as a member of a joint submission.

ECHA Guidance - Practical guide 10: How to avoid unnecessary animal testing -
http://echa.europa.eu/documents/10162/17250/pg_avoid_animal_testing_en.pdf.

Guidance which provides chemical manufacturers and importers with information on how to avoid unnecessary testing on animals, including alternative and non-test methods for assessing the properties of chemical substances in order to provide the information required by the REACH Regulation.

ECHA Guidance - Practical guide 12: How to communicate with the ECHA in dossier evaluation -

http://echa.europa.eu/documents/10162/17235/pg_12_how_to_comm_with_echa_in_dossier_evaluation_en.pdf. Guidance describing the purpose of a dossier evaluation and the process to be used, as well as highlighting the opportunities and obligations that Registrants have in making sure that their dossiers are compliant with the REACH Regulation. Further, the Guidance provides information on how and when Registrants

should react to communications sent by the ECHA relating to the evaluation of their Registration dossier.

ECHA Guidance - Practical Guide 13: How Downstream Users can handle exposure scenarios -

http://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf.

Guidance provides information for downstream users of chemicals to consider when checking the Safety Data Sheet (SDS) received from their suppliers to determine whether their use (of substances on their own or in a mixture) and their conditions of use are covered.

ECHA Guidance - Practical Guide 14: How to prepare toxicological summaries in IUCLID and how to derive DNELs-

https://echa.europa.eu/documents/10162/13655/pg_14_on_hazard_endpoint_en.pdf.

Guidance provides information on how to fill in the toxicological summaries in section 7 of IUCLID and on how to derive DNELs (Derived No Effects Levels).

ECHA Guidance - Practical Guide 15: How to undertake a qualitative human health assessment and document it in a Chemical Safety Report -

[http://echa.europa.eu/documents/10162/13655/pg_15_qualitative-](http://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf)

[human_health_assessment_documenting_en.pdf](http://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf). Guidance provides information on undertaking a qualitative human health assessment for substances for which a threshold cannot be established, under the REACH Regulation. Qualitative assessments are often required for irritants / corrosives, sensitisers, carcinogens, mutagens and reproductive toxicants.

ECHA Guidance: Practical Guide on the Biocidal Products Regulation -

http://echa.europa.eu/documents/10162/21742587/pg_on_bpr_en.pdf. Guidance provides practical information on the requirements of the Biocidal Products Regulation (EU) No. 528/2012 and how best to fulfil them.

ECHA Guidance: Quick guide to finding information on the new chemicals

legislation - http://echa.europa.eu/documents/10162/17234/quick_guide_en.pdf.

Guidance which provides an overview of information sources relating to EU chemicals legislation, with particular regard to the REACH Regulation and the Classification, Labelling and Packaging (CLP) Regulation.

(C) Other Sources of Guidance

EU Commission - http://ec.europa.eu/environment/chemicals/reach/reach_en.htm.

The Commission has issued the following:

- Technical Guidance Notes for implementation of Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:065:0001:0064:EN:PD>

F. Guidance also covers interaction between this Regulation and other EU legislative measures such as REACH.

UK REACH Competent Authority (CA) Website -

<http://www.hse.gov.uk/reach/index.htm>. The HSE has issued the following:

The Government Chemist -

The Government Chemist has published updated Guidance providing advice for businesses, particularly small and medium-sized enterprises (SMEs), regarding the measurement implications under the REACH Regulation, taking into account the notification requirements under the EU Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008. The Guidance is accessible at:

http://www.governmentchemist.org.uk/dm_documents/REACH_FAQ_V2_approved_2W9Y1.pdf.

European Chemical Industry Council (CEFIC) Website - <http://www.cefic.be/>.

Includes Guidance relating to:

- The joint submission of intermediates - http://cefic.be/Files/Publications/Joint-submission-of-intermediates_230710.pdf. Guidance paper provides clarification on a number of points regarding the joint submission of intermediates under the REACH Regulation in the form of questions and answers.
- The development and use of specific environmental release categories (SPERCs) - <http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/SPERCs-Specific-Environmental-Release-Classes.pdf> - where environmental release categories were introduced as generic, broadly applicable emission scenarios under Chapter R.16 [Environmental Exposure Estimation] of the REACH Guidance on Information Requirements and CSA.
- Recommendations for the splitting of Substance Information Exchange Forums (SIEFs) - http://www.cefic.be/Files/Publications/Splitting-SIEFs_final%20%282%29.pdf. This provides information on splitting a SIEF under the REACH Regulation in relation to a particular substance - due to differences identified in composition that necessitate the establishment of two separate SIEFs.
- The obligations and liabilities of the Lead Registrant (LR) in a SIEF under REACH - http://cefic.be/Files/Publications/Cefic_Liabilities%20LR_explanatory%20notes_01%2012%2009.pdf. The Guidance document also analyses the relationship between the LR and other SIEF members.
- REACH guide on exposure assessment / communication in the supply chains (Parts 1-3) - <http://cefic.org/Files/Publications/Doc-1-Part-1-to-3-Practical-Guidance-Final.pdf>.

UK Chemical Industry (subsidiary of the Chemicals Industries Association (CIA)) - REACHReady - <http://www.reachready.co.uk/>.

EINECS - https://eurl-ecvam.jrc.ec.europa.eu/laboratories-research/predictive_toxicology/information-sources/ec_inventory and <http://echa.europa.eu/information-on-chemicals/ec-inventory>.

ELINCS - <http://echa.europa.eu/information-on-chemicals/ec-inventory>.

APPENDIX 6

OSPAR Recommendation 2010/3 (as amended by Recommendation 2014/17) on a Harmonised Offshore Chemical Notification Format (HOCNF) to align the OSPAR HMCS with the EU REACH Regulation

Document can be accessed via:

<http://www.ospar.org/convention/agreements?q=OSPAR+Recommendation+2010%2F3&t=32283&a=7458&s=3>

OSPAR Recommendation 2010/4 on a Harmonised Pre-Screening Scheme for Offshore Chemicals to align the OSPAR HMCS with the EU REACH Regulation

Document can be accessed via:

<http://www.ospar.org/convention/agreements?q=OSPAR+Recommendation+2010%2F4+&t=32283&a=7458&s=3>

Revised OSPAR Guidelines (2012/05) [Updated 2015] for Completing the HOCNF

Document can be accessed via (need to scroll down the webpage to locate the document and then click on the title 'Guidelines'):

<http://www.ospar.org/work-areas/oic/chemicals>

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