



Standard Procedure

(Issue Eleven)

NL PROTOCOL

PART 1: CORE ELEMENTS

OCNS 011

Cefas Pakefield Road
Lowestoft
Suffolk
NR33 0HT

History of Procedure

Issue	Date Issued	Changes
1	01/05/07	New procedure, titled "OCNS PROTOCOL MAY 2007 NL007-0105"
2	23/04/09	Comprehensive update and re-write, with procedure split into two parts and retitled "NL PROTOCOL", under procedure number ORR 011. New section included in Part 1 to cover The Global Approach. Guidance on surfactants included in Appendix 2. Information on field trials organised into an appendix, with further appendices covering QSARs and SQL Templates.
3	01/7/11	Updated with information from the latest OSPAR Protocols, revised ORR Team details, CMR and SDS check flow charts and latest Product Templates. Participation of NOGEPa now included in Section 4.
4	05/09/11	Details of "2 out of 3" criteria added to Section 4.6 of Part 2
5	18/06/12	Updated internet links and email addresses
6	13/09/12	Procedure renamed OCNS 011. References to CLP classifications included, figures renumbered, disclaimer added, document references and links updated, Cefas ORR team updated to OCNS, updated text in Section 7 re. older studies, details of REACH Registration check revised.
7	14/01/13	Minor changes. Updated internet links
8	06/01/14	Updated contacts for DECC and SSM. Additional text covering polymers inserted in Section 2. Clarified the application of the 5% minimum peak area criterion in the OECD 117 method in section 2.1. Minor changes to links within document, and Table 1

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9	16/04/15	Clarification of REACH Annexes V and XIV application. Updated HOCNF document reference. Update to Cefas job roles (Table 3). Minor text revisions to improve clarity.
10	1/01/17	Updated details for UK regulator (now BEIS) and latest example templates and OSPAR documents shown. Minor changes to links within document, and text revisions to improve clarity.
11	1/01/19	Updated in line with latest OSPAR documents, Cefas procedures and SSM contact details. Participation of NOGEPa removed from Section 4, and Appendix 3 deleted from Part 2. Facility for suppliers to request fast track registrations deleted from Part 1. Minor text revisions to improve clarity.
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APPENDICES

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ATTACHMENTS

OIC 2007, paper OIC 07/3/3-E, “Bioconcentration Factors of Surfactants”

DISCLAIMER

This document has been prepared in order to assist the suppliers of offshore chemicals for use in The Netherlands to comply with the relevant requirements of The Netherlands Mining Regulations. It is however stressed that the information in this document provides guidance only and does not constitute legal advice. NOGEPa, SSM and Cefas accept no liability with regard to the contents of this document.

1 Introduction

All Contracting Parties to the 1992 OSPAR Convention are committed to the objective of preventing and eliminating marine pollution. Each country is committed to taking the necessary measures to protect the maritime area against the adverse effects of human activities (such as the offshore oil & gas industry), so as to safeguard human health and of conserving marine ecosystems and, when practicable, restoring marine areas which have been adversely affected.

Under Article 4 of Annex III of the Convention, Contracting Parties are required to provide for a system of monitoring and inspection to assess compliance with authorisation or regulation as provided by the Convention. Monitoring of discharges of substances from offshore installations is part of the regulation adopted in the OSPAR Decision 2000/2, the first stage of which is the registration of those substances.

This document describes:

- The procedure through which data is submitted to Cefas for the registration of an offshore chemical.
- How the completeness of that data is checked.
- The responsibilities of the parties involved.
- How the correctness of the data is checked.
- Pre-screening
- Hazard/risk assessment.
- Ranking

Additional protocol information that is specific to particular countries is covered in separate addenda to this document.

2 Scope

Submissions relating to the use and discharge of offshore chemicals (as defined by OSPAR Agreement 2002-6) on offshore oil and gas platforms in countries where the registration and hazard assessment of such chemicals is undertaken by Cefas, i.e. UK and NL maritime area of the North Sea

Note: This document forms part of a contract between Cefas, SSM and NOGEP. All references in this document to the registration of offshore chemicals in UK waters, on behalf of the Department for Business, Energy and Industrial Strategy (BEIS), are for illustrative purposes only, and do not constitute any form of contractual obligations involving that body.

3 Background

The Offshore Chemicals Notification Scheme (OCNS) was originally introduced in 1979. In 1993, the UK Government introduced a revised scheme, which classified chemicals using test protocols approved by OSPAR to assess toxicity, biodegradation and partitioning. This was modified in detail, in early 1996, to meet the requirements of the OSPAR Harmonised Offshore Chemical Notification Format (HOCNF), which co-ordinates the testing requirements for oilfield chemicals throughout the NE Atlantic sector.

In June 2000, OSPAR introduced Decision 2000/2 on a Harmonised Mandatory Control System for the Use and Reduction of the Discharge of Offshore Chemicals. In the UK this is administered under the Offshore Chemical Regulations 2002 (OCR 2002), which came into force on 15th May 2002 and were updated in 2011.

At the heart of OSPAR Decision 2000/2 are two documents, which are defined by, and regularly updated by OSPAR Recommendations:

The Harmonised Pre-Screening Scheme for Offshore Chemicals, which facilitates the substitution of chemicals with certain characteristics by less hazardous alternatives ,[OSPAR Recommendation 2017/1](#)

and

The Harmonised Offshore Chemical Notification Format (HOCNF), which sets out the information requirements that must be fulfilled in order to register a chemical for use within the OSPAR region (OSPAR Recommendation 2010/3, as amended by Recommendation 2014/17).

Decision 2000/2 and its supporting Recommendations entered into force on 16 January 2001. In addition to pre-screening, the Decision requires offshore chemicals to be ranked according to their calculated Hazard Quotients (HQ - ratio of Predicted Environmental Concentration (PEC) to Predicted No Effect Concentration (PNEC), which are calculated by the CHARM (Chemical Hazard Assessment and Risk Management) mathematical model. (In the UK, this work is carried out on behalf of the Department for Business, Energy and Industrial Strategy (BEIS) by a multidisciplinary team at the Cefas Lowestoft Laboratory, in the course of the registration of each chemical). This process must be executed before any permit to discharge the relevant chemical is granted (see Guidance Notes on the Offshore Chemical Regulations 2002[as amended 2011]). Such permits constitute part of the environmental impact assessment process required under EU law (Council Directive 85/337/EEC of 27 June 1985).

Since the 1st January 2007, Cefas has also performed the technical and administrative services necessary to evaluate and register Harmonised Offshore

Chemical Notification Format (HOCNF) forms for offshore chemicals used and discharged in the Netherlands' part of the North Sea. Cefas is commissioned to conduct this task by the Inspector General of Mines (IGM) of the State Supervision of Mines (SSM), acting on behalf of the Netherlands Minister of Economic Affairs, in accordance with paragraph 9.2 and 9.3 of the Netherlands Mining Regulations.

Cefas process and store the HOCNF data in the Cefas OCNS database. This database provides an integrated registration system for information on offshore chemicals used and discharged in the United Kingdom (UK) and Netherlands (NL) sectors of the North Sea.

The following parties are involved in the HOCNF registration process:

- The regulator, i.e. the relevant governmental department that is responsible for controlling the use and discharge of offshore chemicals in the country concerned.
- Cefas, Offshore Chemicals Notification Scheme (OCNS) team
- Chemical Supplier / Manufacturer

4 Responsibilities

4.1 The Regulator

4.1.1 The Department for Business, Energy and Industrial Strategy (BEIS)

BEIS is responsible for ensuring that all chemicals used by the oil exploration and production industry on the UK costal shelf are registered, and their environmental hazard evaluated before their use and discharge is permitted. This task is conducted as part of the UK's legal obligations to OSPAR decision 2000/2 as covered by the Offshore Chemicals Regulations (2002, as amended 2011).

Contact details:

Mark Shields (Environmental Manager)

E-mail: mark.shields@BEIS.gsi.gov.uk

Telephone: 01224 254101

Address:

AB1 Building
48 Huntly Street
Aberdeen
AB10 1SH

General Contact Details:

Fax: 01224 254100

e-mail: emt@BEIS.gsi.gov.uk

4.1.2 The Minister of Economic Affairs / the Netherlands State Supervision of Mines (SSM)

Paragraph 9.3 of the Mining Regulations states that the Minister of Economic Affairs is responsible for the registration of offshore chemicals. The Minister has **delegated this responsibility** to the Inspector General of Mines, heading the State Supervision of Mines (SSM).

Cefas is contracted to perform the technical and administrative services necessary to evaluate HOCNF forms and to register this information in an integrated system, but the responsibility for the registration remains with SSM at all times.

In addition, the Minister of Economic Affairs has delegated the Inspector General of Mines with the responsibility to issue permits and or accept notification of the use and discharge of chemicals offshore from the Netherlands. On behalf of the Minister, the Inspector General of Mines reserves the right to withdraw registration of a chemical from the registration list at any time but only in case this registration does not comply with the Netherlands policy with regard to the use and discharge of chemicals offshore. The withdrawal of registration must be justified and communicated to the supplier of concern. In this event, the operator shall by article 9.2.2b of the Mining Regulations not use or discharge the offshore chemical in the Netherlands coastal shelf.

In accordance to the OSPAR Recommendation 2005/2, the Netherlands allow new chemicals on the OSPAR list of Chemicals for priority action to be registered for use but will not grant permission for them to be discharged.

The contact person at SSM for the registration of offshore chemicals is:

Janine Killaars.

Staatstoezicht op de Mijnen / State Supervision of Mines

P.O. Box 24037

2490 AA The Hague

Netherlands

Telephone: +31 (070) 379 8400

E-mail: [J.J.Killaars@minez.nl]

4.2 Cefas, OCNS team

Cefas administers the registration of offshore chemicals for contracted regulators through the appraisal of data in the HOCNF forms, followed by the hazard assessment of the chemicals.

The registration process comprises the following :

- the receipt of a completed HOCNF data set;
- confirmation of the completeness of the HOCNF. The completeness check is recorded in a database table.
- assessing the correctness of the data;
- processing of the HOCNF data set in accordance with the OCNS system, including HMCS pre-screening and either a CHARM or Non-CHARM assessment;
- confirming the processing of the HOCNF data to the supplier by issuing a template and registration number. The entry of the completed dataset and issuing of an authorisation note and template confirms the correctness of the data supplied.
- To publish on the Cefas website a list of chemicals registered (<https://www.cefas.co.uk/cefas-data-hub/offshore-chemical-notification-scheme/>)

The Cefas OCNS Team are also responsible for:

- ensuring a prompt response to informal communications from the suppliers/producers of offshore chemicals concerning the progress of their product registrations. All written communications to and from Cefas with respect to the OCNS are stored electronically.
- Providing scientific advice, especially when dealing with “expert judgement” issues.
- Provision of access for Marine Scotland and SSM to the data to support permitting in the UK and NL respectively.

More details, including the breakdown of responsibilities within the OCNS Team, are given in [Appendix 1](#).

Contact details for Cefas OCNS Team:

OCNS

Cefas (Centre for Environment, Fisheries & Aquaculture Science)

Pakefield Road

Lowestoft

Suffolk NR33 0HT

Tel: 44 (0) 1502 567759 Fax 44 (0) 1502 513865

E-mail: ocns.chems@cefas.co.uk

4.3 Chemical Supplier / Manufacturer

The chemical supplier / manufacturer is responsible for supplying all required HOCNF data, in accordance to the relevant OSPAR guidelines, to the OCNS Team to allow an offshore chemical to be registered.

The chemical supplier has the responsibility to provide:

- a completed HOCNF and Safety Data Sheet (SDS) containing all correct and required information to the Cefas OCNS Team. E-mail is the preferred mode of communication.
- any additional information or chemical data that the Cefas OCNS Team requires. This can include, but is not limited to, GLP (or equivalent) test data reports and chemical data.
- Letters of access. It is the supplier's responsibility to ensure that any letters of access from third party chemical companies have been sent to Cefas and are valid for use. Cefas will not enter into correspondence with any third party.
- timely communication with the OCNS Team when additional data have been requested.
- Cefas OCNS Team with current contact details, including a postal address, telephone number and e-mail address.

All applications for the registration of chemical preparations must be submitted on Harmonised Offshore Chemical Notification Format (HOCNF) forms. The format should be in accordance with Appendix 1 of the OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF), as amended

by Recommendation 2014/17. Cefas will only accept data on the most recent version of the HOCNF form.

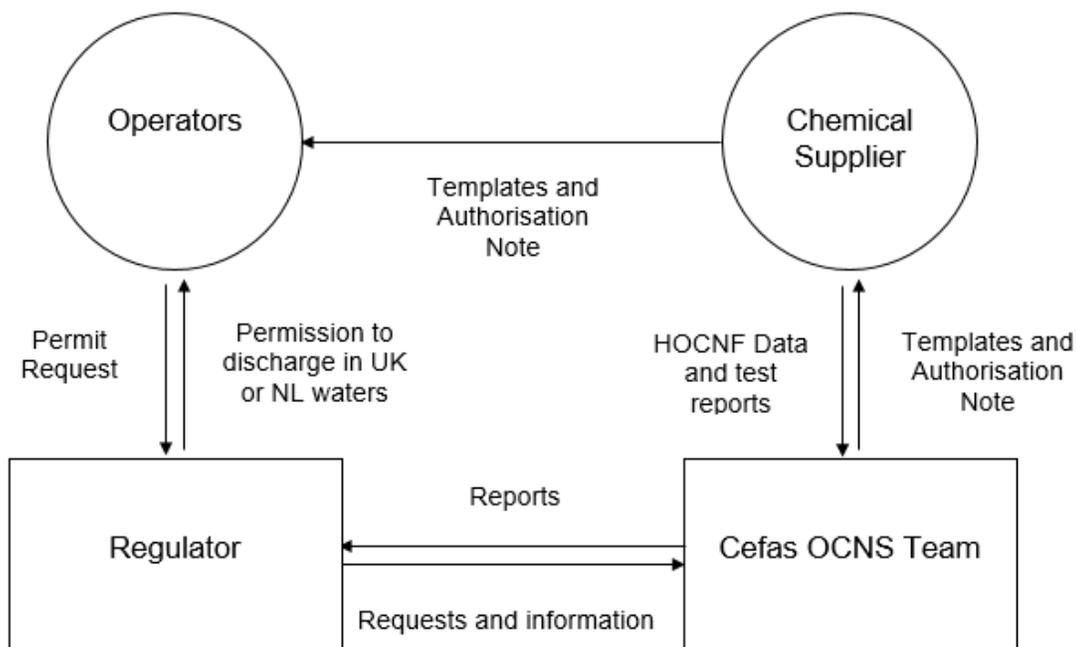
It is the responsibility of the chemical supplier to ensure the submitted HOCNF is complete and correct. If it is deficient in any respect, Cefas will inform the supplier (see [Completeness Checks](#) and [Correctness Check](#)).

5 Communication

Communications between all customers/stakeholders and the Cefas OCNS Team must be conducted through one of the following methods:

- e-mail (Preferred)
- telephone
- letter

Figure 1. Schematic showing the OCNS communication paths with relevant parties.



6 The Registration Process Overview

The registration of an offshore chemical is initiated by the supplier sending a completed HOCNF form to Cefas. This form must be in compliance with OSPAR Recommendation 2010/3 (as amended by OSPAR Recommendation 2014/17), and modified versions will not be accepted.

On receipt by Cefas, all electronic communications are filed electronically by company and product. Any hard copies subsequently made are shredded at the end of the registration process (when the template is issued to the supplier).

If a HOCNF corresponds to a new offshore chemical, the name of the chemical preparation is entered into the database when the HOCNF is placed in the certification queue*. If a HOCNF corresponds to an existing chemical it is placed in the certification queue directly. The certification queue operates on a strict first in, first out basis. Only SSM or BEIS may request that a HOCNF be fast-tracked, and operators who believe they have a case for requesting fast track HOCNF processing should contact the relevant regulator in the first instance. Cefas guarantee an 8-week turn around for all complete and correct HOCNFs received, once the HOCNF has passed the Completeness Check.

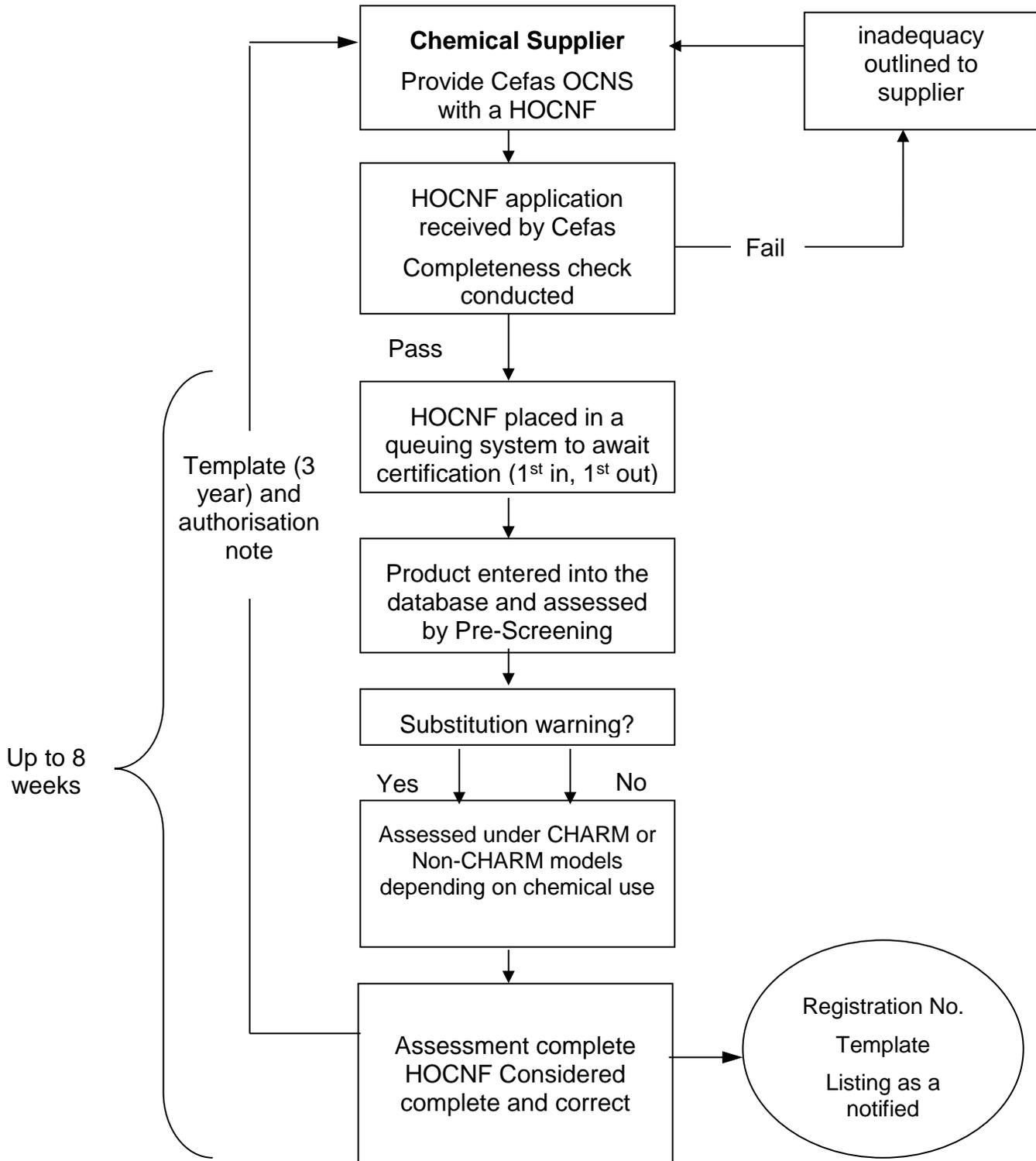
If the HOCNF is incomplete, the certification process is halted until the requested information is received.

Based on the HOCNF, Cefas will assess the completeness and correctness of the information based on OSPAR Agreement 2012-05. If both are satisfactory, the product will be entered onto the OCNS database. Provided that the regulator is satisfied with the data submitted, the product is then certified.

The OCNS registration process is summarised in Figure 2.

**It is noted that in all sections of this protocol where the word "certification" is used, it is to denote the issue of a product template, and does not imply the operation of any certification standards issued by any accrediting body.*

Figure 2. The OCNS registration process



NOTE: Elements of the registration process that are specific to individual countries are described in subsequent parts to this protocol.

7 Completeness Checks

Prior to chemical hazard assessment, HOCNFs are checked for completeness. This check is conducted in order to ensure that the chemical supplier has addressed all of the issues relevant to the particular chemical, and includes:

- that the percentage composition add up to 100% .
- that the composition includes, for each substance, details of molecular weight, EINECS/ELINCS or REACH number, and CAS number
- that the Confirmation Statement has been authorised and dated, and
- that any relevant [Letters of Access](#) that have been received are associated with the HOCNF.
- whether SDS is attached. It must also be established that the SDS complies with Annex II of EC Regulation 1907/2006 and its amendments, using the checking process shown in Figure 3.
- The product and supplier name are checked against the database and any naming issues are identified.
- A check that the substances meet their registration/pre-registration obligations under REACH, or that the supplier has responded to Cefas enquiries relating to these matters.

If the HOCNF fails these checks, Cefas will advise the supplier and the HOCNF will not be entered into the certification queue. The processing of the HOCNF is therefore halted until the supplier has satisfactorily addressed all issues. If the HOCNF passes the completeness checks, it will be placed in the certification queue, to await assessment.

The progress of the completeness check is recorded in a database table. All new studies (completed after 16th January 2001) submitted on HOCNF for newly registered products must provide all of the data specified in OSPAR recommendation 2010/3 and its agreements. All studies completed after 1 January 2009 must comply with OSPAR Agreement 2005-12. Older studies and literature data will be accepted for the purpose of the HMCS at the discretion of the regulator i.e. provided the studies are considered to be scientifically valid and compliant with European Chemicals Agency (ECHA) 'Guidance on information requirements and Chemical Safety Assessment', Chapter R4: Evaluation of available information, Section R.4.2: Reliability of Information. QSAR data are also acceptable provided suitable validation data are provided to support the value submitted (See [Appendix 3](#)).

The requirements for each section of the HOCNF are specified in Section 8. The criteria for assessing the completeness of HOCNF relating to pipe dopes & jacking greases, hydraulic fluids & closed system chemicals, acids and bases are given in [Appendix 2](#)

An entry must be made on the HOCNF for all mandatory fields. However, for the purpose of the completeness check, “not available” or “not determined” are considered satisfactory responses where a datum has not been determined or is irrelevant.

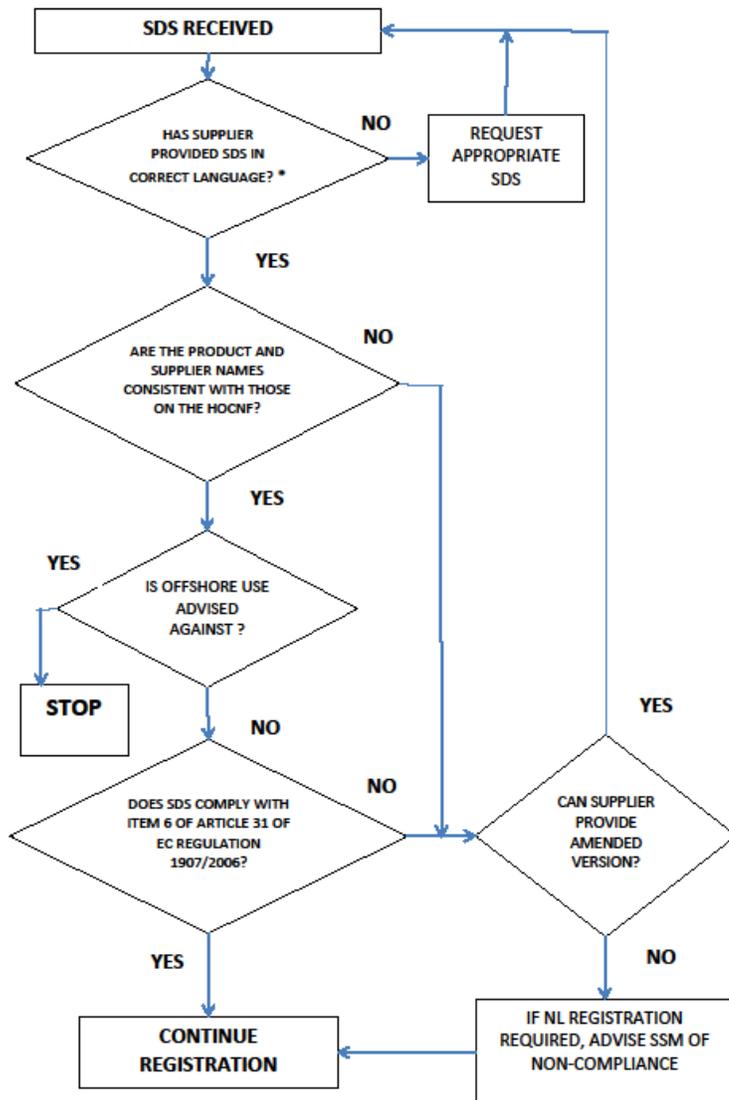


Figure 3: Safety Data Sheet Check Procedure

* Suppliers must provide an SDS in English, plus (if NL Registration is required) an additional copy in Dutch

8 HOCNF Completeness Check Requirements

In the following section, completion is described as Mandatory, Conditional or Optional, where:

Mandatory requires that the section must be completed, unless specific exemptions (included therein) apply.

Conditional requires that the section must be completed under certain circumstances only. These circumstances are stated in the table.

Optional indicates that completion is not required.

	Section 1.1 – 1.2	Requirement	Action if data are missing
1.1	State trade name(s)	Mandatory	Contact supplier
1.2	Name	Mandatory	Contact supplier
	Company number (e.g UK company number, NL Chamber of Trade number)	Mandatory	Contact supplier
	Postal address	Mandatory	Contact supplier
	Phone number	Mandatory	Contact supplier
	Emergency phone (24 hours)	Mandatory	Contact supplier
	Facsimile number	Optional	None
	Email address	Mandatory	Contact supplier
	OSPAR Countries where preparation is used	Mandatory	Contact supplier
	Alternative trade names used in those countries	Mandatory	Contact supplier

Section 1.3

		Requirement	Action if data are missing
	SDS Check box	Mandatory	Contact supplier if SDS missing, and request SDS, compliant with current EU regulations

Section 1.4: Use & Discharge

	Section 1.4	Requirement	Action if data are missing
	Application group	Mandatory	Contact supplier
	Function	Mandatory	Contact supplier
	Process system	Mandatory	Contact supplier
	Normal dose rate	Mandatory	Contact supplier
	Flow	Mandatory	Contact supplier
	Probable scale of use (per installation)	Mandatory.	Contact supplier
	Closed or Open system	Mandatory	Contact supplier
	If open, estimated discharge (%)	Conditional. The box must be completed for open systems.	Contact supplier
	Frequency of treatment	Mandatory	Contact supplier
	Probable amount of substance/preparation discharged:	Mandatory	Contact supplier
	Duration of discharge	Mandatory	Contact supplier
	Total estimated amount of discharge (tonnes):	Mandatory	Contact supplier

Section 1.5: Fate

	Section 1.5	Requirement	Action if data are missing
1.5	Explain the likely fate of substance/preparation	Mandatory	Contact supplier

Section 1.6: Composition

	Section 1.6	Requirement	Action if data is missing
1.6a)	Substance name (and trade name where applicable)	Mandatory	Contact supplier
	Percentage Composition	Mandatory. NB Concentration ranges are not allowed, and the composition total must add up to 100 %.	Contact supplier
	CAS Number	Mandatory	Contact supplier
	EINECS or ELINCS or REACH Registration no.	Mandatory	Contact supplier
	Molecular Weight	Mandatory*	Contact supplier
	REACH Annex IV	Conditional. The box must be ticked if the component is listed in the relevant REACH Annex.	Contact supplier
	REACH Annex V	Conditional. The box must be ticked if the component complies with the relevant requirements of the relevant REACH Annex.	Contact supplier
	PLONOR	Conditional. The box must be ticked if the component is on the PLONOR list.	None**
	Comments	Optional	None

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	Section 1.6	Requirement	Action if data is missing
1.6b)	Substance name (and trade name where applicable)	Mandatory	Contact supplier
	OSPAR LCPA	Conditional. The box must be ticked if the product contains any substance that is on the OSPAR list of Chemicals for Priority Action.	None**
	OSPAR LSPC	Conditional. The box must be ticked if the product contains any substance that is on the OSPAR list of Chemicals of Possible Concern.	None**
	REACH Annex XIV	Conditional. The box must be ticked if the substance must be authorised under REACH for offshore use	Contact supplier
	REACH Annex XVII	Conditional. The box must be ticked if the component is listed in the relevant REACH Annex.	Contact supplier
	Surfactant	Conditional The box must be ticked if the product contains any substance that is classed as a surfactant (See Appendix 2)	None**
	Heavy metals or heavy metal compound	Conditional. The box must be ticked if the product contains any substance that is a heavy metal, or compound thereof.	None**
	Organohalogen compounds	Conditional. The box must be ticked if the product contains any substance that is an organohalogen compound	None**
	Radioactive substances.	Conditional. The box must be ticked if the product contains any substance that is radioactive.	None**

*For polymers, the supplier should provide all available information such as number average and weight average molecular weights, levels of branching and substitution. and also EO:PO ratios where available, supplemented where possible with analytical data e.g. Gel Permeation Chromatography traces.

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**It is noted that the presence of the substances highlighted in this table is monitored during the correctness check, and any omissions are dealt with at that stage.

If any of the tick boxes in Section 1.6b) are ticked, the following checks must also be conducted:

	CAS No/name	Conditional	Contact supplier
	Compound/contaminant	Conditional	Contact supplier
	Concentration (ppm)	Conditional	Contact supplier
	Intentional additive (Y/N)	Conditional	Contact supplier
	Analytical methodology	Conditional	Contact supplier
	If surfactant, Fraction released	Conditional	Contact supplier
	If surfactant, Documentation/reference to laboratory test	Conditional	Contact supplier

Section 1.7: General Physical Properties

	Section 1.7	Requirement	Action if data is missing
	If liquid, state whether single substance or preparation	Conditional	Contact supplier
	If mixture of solid and liquid, state whether suspension/emulsion/other.	Conditional	Contact supplier
	Does the preparation separate in sea water to give floating/sinking/soluble materials/no.	Mandatory	Contact supplier
	If other, please describe	Conditional. This box must be completed if the preceding entry is "no".	Contact supplier

Part 2: Ecotoxicological information

At the start of this section, the supplier is required to indicate:

- a) Whether the product is comprised exclusively of PLONOR substances*, and
- b) Whether ecotoxicological information has already been submitted by the supplier to the competent national authorities.
- c) Whether the substance (or all substances of which the preparation is composed) is registered under REACH (EC Regulation 1907/2006) for specific use and discharge on offshore installations.

*Where “PLONOR substance” means a substance that:

- i. is specified on the PLONOR list,
- ii. is specified on Annex IV of REACH, or
- iii. meets the criteria for REACH Annex V substances defined by OSPAR Agreement 2012-05.

If “yes” is answered in response to either or both questions a) or b), no responses to the information requested in Section 2 are required.

If “no” is answered in response to both questions a) and b), AND the substance is a polymer, it is not necessary to provide the information requested in Section 2, unless requested to do so by Cefas on the basis of expert judgement. In the absence of information, the polymer will be assessed by default as non-biodegradable, non-toxic and non-bio-accumulative. Alternatively, suppliers may provide test data instead. Where valid test data are provided, they shall take precedence over the default assessment. (Further information is included in OSPAR Agreement 2012-05).

For all other responses, the information required is as shown below. If “yes” is answered in response to question c), the information provided must be the specific ecotoxicological information registered under REACH, if that is legally available.

Section 2.1: Partitioning and bioaccumulation potential

This section is not applicable to inorganic substances, substances on the PLONOR list and surfactants (See [Appendix 2](#)). For all other substances, the information required is as shown below:

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2.1.1	LogPow	Requirement	Action if data is missing
	Substance	Mandatory	Contact supplier
	Peak No	Mandatory, if "OECD 117" entered for "Methodology", below.	
	Log Pow	Mandatory	Contact supplier
	% area under peak	Mandatory, if "OECD 117" entered for "Methodology", below. The % area under all peaks should be provided.	Contact supplier
	Weighted average Log Pow	Conditional. This figure should be provided if the substance is a complex mixture of members of a homologous series AND if "OECD 117" is entered for "Methodology", below. All peaks that contribute an area of 5% or more to the total peak area should be taken into consideration in the calculation of the weighted average Log Pow. The weighed average Log Pow and the 5% minimum peak area criterion is valid only for substances or mixtures (e.g. tall oils) consisting of homologues (e.g. series of alkanes).	Contact supplier
	Lab ID	Mandatory.	Contact supplier
	Methodology/protocol/ Literature data	Mandatory	Contact supplier
	Report ID	Mandatory	Contact supplier
	Comments on results	Conditional. This box should be used to include any BCF data, stating relevant values, species, test laboratory, report number and protocol	None

Section 2.2: Biodegradability

Biodegradability studies are only relevant for organic and organometallic substances, PLONOR excepted. For complex mixtures, individual information for all deliberately added substances should be given on separate data sheets (from HOCNF).

		Requirement	Action if data is missing	
2.2.1	Substance	Mandatory (for organic substances)	Contact supplier	
	Day	Mandatory	Contact supplier	
	Screening Test	Reference substance	Mandatory unless Simulation Test Data are provided. (min 4 values for reports completed after 16 Jan 2001)	Contact supplier
		Test substance %	Mandatory unless Simulation Test Data are provided.. (min 4 values for reports completed after 16 Jan 2001)	Contact supplier
		Reference substance %	Mandatory unless Simulation Test Data are provided.. (min 4 values for reports completed after 16 Jan 2001)	Contact supplier
	Simulation test	Test substance DT ₅₀	Mandatory unless Screening Test Data are provided	Contact supplier
		CO ₂ profile	Mandatory unless Screening Test Data are provided	Contact supplier
	Lab ID.	Mandatory. The laboratory name and address must be provided.	Contact supplier	
	Method	Mandatory. Details of the protocol used, or relevant literature data must be provided.	Contact supplier	
	Report ID	Mandatory.	Contact supplier	
	Comments on results	Optional	None	

Section 2.3: Aquatic toxicity

This section is a mandatory field, and must be completed for all substances, including inorganic, other than those on the PLONOR list or REACH Annex IV or those meeting the criteria for REACH Annex V substances defined by OSPAR Agreement 2012-05.

Algae	Requirement	Action if data is missing
Test species	Mandatory.	Contact supplier
Results	Mandatory.	Contact supplier
Report details	Mandatory.	Contact supplier
Comments on results	Optional.	None

Crustacean	Requirement	Action if data is missing
Test species	Mandatory.	Contact supplier
Results	Mandatory.	Contact supplier
Report details	Mandatory.	Contact supplier
Comments on results	Optional.	None

Fish	Requirement	Action if data is missing
Test species	Mandatory*.	Contact supplier
Results	Mandatory*.	Contact supplier
Report details	Mandatory*.	Contact supplier
Comments on results	Optional.	None

*Fish toxicity data is mandatory, unless testing another species has already identified the substance as toxic.

Sediment reworker

This section is a conditional field, and must only be completed if the substance is either:

- a “sinker”*
- has a log P_{ow} result > 4
- has a K_{oc} > 1000
- is a surfactant (See [Appendix 2](#))
- or is known to adsorb to particles or be deposited in the sediment (e.g. contains surface active substances of the type which enhance adsorption to particles)

(*A “sinker” is any substance that is denser than sea water, but not soluble in it)

Sediment reworker	Requirement	Action if data is missing
Preparation / substance	Conditional	Contact supplier
Test Species	Conditional.	Contact supplier
Results	Conditional	
Report details	Conditional	
Nominal or measured exposure	Conditional	Contact supplier
Comments on results	Optional.	None

Part 3:Confirmation statement

	Requirement	Action if data is missing
Date	Mandatory	Contact supplier
Name	Mandatory	Contact supplier
Position in company	Mandatory	Contact supplier
Company	Mandatory	Contact supplier

NOTE: Matters relating to the NL requirements concerning test report quality are discussed in Part 2 of this Protocol.

9 Correctness Check**9.1 Persistence/Bioaccumulation/Toxicity Data**

After a HOCNF form has been submitted to Cefas and passed through a completeness check, it is subjected to a correctness check.

The correctness check of the HOCNF information is assessed against the requirements of OSPAR recommendation 2010/3 (as amended by OSPAR Recommendation 2014/17), and its agreements.

The check is initiated by defining the chemical substances that are in the chemical formulation from their chemical names and CAS numbers. The assessors evaluate the ecotoxicological information completed in Section 2 of the HOCNF form and when required, they also compare the data on the HOCNF with information held in the OCNS database chemical dictionary and various web based chemistry resources. These resources may include but are not limited to:

1. Hawley's Condensed Chemical Dictionary ISBN 0-442-01131-8
2. Handbook of Environmental Data on Organic Chemicals, Verschueren, ISBN 0-442-01916-5
3. Handbook of Industrial Surfactants, Fourth Edition, ISBN 1-890595-90-X
4. Chemicals Suppliers' Catalogues
5. CRC Handbook of Chemistry and Physics - Rubber Handbook - ISBN 0-8493-0475-X
6. OSPAR website <http://www.ospar.org/>
7. ECHA web site <http://echa.europa.eu/>
8. IUPAC website <https://iupac.org/>
9. STN FIZ website <http://www.fiz-karlsruhe.de/>
10. ChemID website <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
11. OECD website <http://www.oecd.org/>
12. Industrial Surfactants Electronic Handbook – Synapse Information Resources
13. C.J. van Leeuwen & T.G. Vermeire, (Eds.), “Risk Assessment of Chemicals, An Introduction”, 2nd edition, Springer (Dordrecht) 2007. ISBN: 987-1-4020-6101-1)

In addition, the wider scientific literature may be consulted via Cefas library resources, Chemicals Suppliers resources and the British Library.

Where any uncertainty exists as to the exact identity of the components in an offshore chemical, the assessor will contact the supplier to request clarification of the specific query. Cefas will attempt to verify the information on the HOCNF fully.

(It is noted that suppliers of an offshore chemical may be unable to supply full data for components supplied by a third party, for reasons of confidentiality. In these circumstances, the data are obtained through a Letter of Access. (See Appendix 1, Confidentiality Issues)

The assessors review the data on the persistence, bioaccumulation and toxicity of the substances in the offshore chemical as these data are entered into the database. Each individual is trained to critically evaluate the scientific data against study protocols and REACH quality requirements. Where the assessors require further information to evaluate the correctness of the data in the HOCNF, they will ask the supplier to provide the complete laboratory report.

Only final reports that are in compliance with the requirements of the relevant REACH registration, or with the European Chemicals Agency (ECHA) 'Guidance on information requirements and Chemical Safety Assessment', Chapter R4: Evaluation of available information, May 2008 (as amended) are acceptable. This is in accordance with the statement made by the supplier in Section 3 of the HOCNF submitted to CEFAS for registration.

Where there is a requirement for additional expertise to evaluate the correctness of the data submitted on the HOCNF the assessors may approach senior members of the team (The Risk Assessors or Senior Scientific Advisor) for advice on how to resolve any outstanding issues. Any issues that are beyond the agreements reached in the OSPAR framework will be discussed with the relevant regulator contact person for further guidance.

9.2 Safety Phrases

During the correctness check, the H- and P- statements (previously R- and S-Phrases) quoted on the Safety Data Sheet are entered into the data base. The correctness of the information in respect of the carcinogenic, mutagenic and reprotoxic properties of substances on the HOCNF are evaluated against the latest versions of the following reference sources:

1. Lijst van mutagene stoffen (List of mutagenic substances)
2. Lijst van Kankerverwekkende stoffen en processen (List of carcinogenic substances and processes)
3. Niet-limitatieve lijst van voor de voortplanting giftige (Non-limiting list of substances toxic for reproduction)

Updated twice each year, these lists

(<https://zoek.officielebekendmakingen.nl/stcrt-2012-12185.html>)were established by the Netherlands Ministry of Social Affairs , but refer to the IARC list of carcinogenic substances

(<http://monographs.iarc.fr/ENG/Classification/index.php>).

Any substance that appears on the List of mutagenic substances must feature the hazard statement H340 as defined by EC Regulation 1272/2008 (previously risk phrase R46 as defined by EC Directive 67/548).

Any substance that appears on the List of carcinogenic substances and processes must feature either of the hazard statements H350 (R45) or H350i (R49).

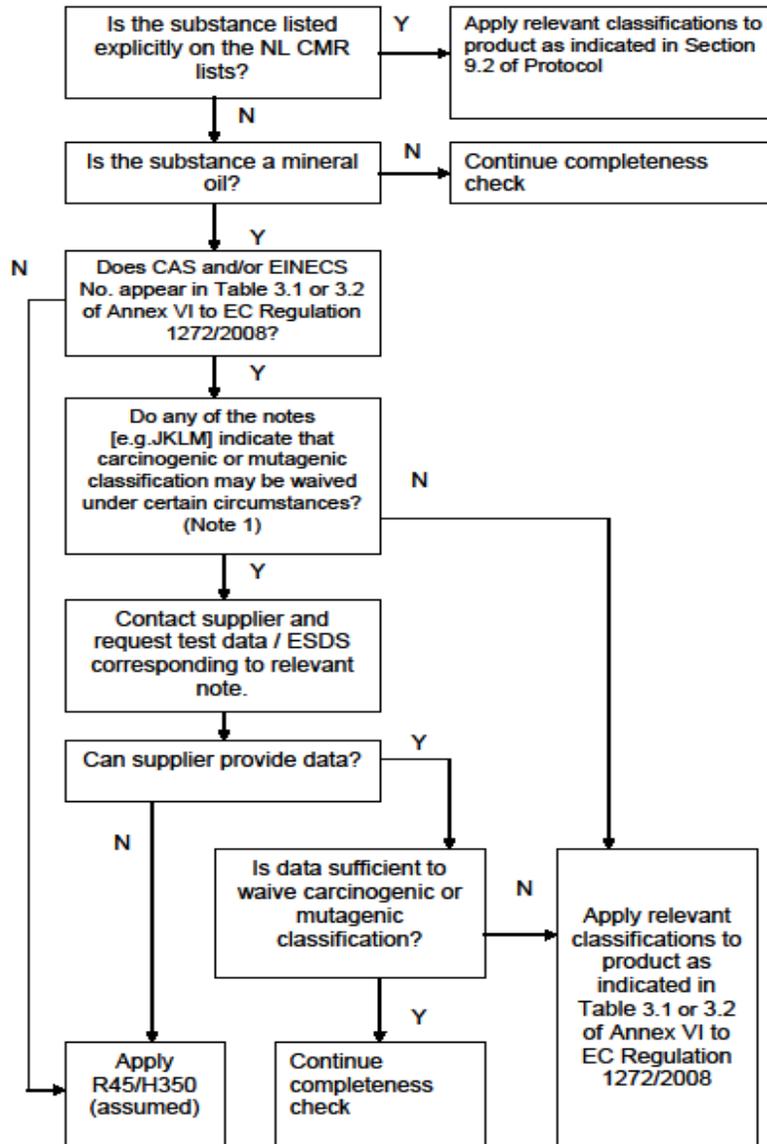
Any substance that appears on the Non-limiting list of substances toxic for reproduction must feature the hazard statements H360F (R60), H360D (R61), H361F (R62), H361D (R63) or H362 (R64), applied according to the instructions given in the list itself.

NOTE: It is essential that the lists are studied in detail, and attention paid to the instructions provided therein. For example, mineral oils may be classed as carcinogenic, depending on the levels of key compounds such as benzene and benzo[a]pyrene. Where a supplier claims such species to be absent, satisfactory evidence to support this claim must be provided.

This process is summarised in Figure 4.

On completion of the data entry process, the data will be considered to be complete and correct.

Figure 4: Processing Procedure for CMR Substances



Note 1: Where:

K < 0.1% 1,3-butadiene

J < 0.1% benzene

M < 0,005% benzo [a] pyrene

L < 3% DMSO-extract.

The meaning of these and other Notes is explained in Part 1 of Annex VI to EC Regulation 1272/2008

10 Pre-Screening

NOTE: Elements of the pre-screening process that are specific to individual countries are described in subsequent parts to this protocol.

Data submitted on a HOCNF are subjected to pre-screening (in accordance with OSPAR Recommendation 2017/1 with the aim of:

1. substituting, and phasing out the discharges of those substances which are hazardous;
2. regulation and control.

Pre-Screening is carried out on a substance-by-substance basis, which classifies each substance as shown in Figure 5. The product is then assigned the category of its most hazardous constituent substance.

If the chemical product fails Pre-Screening, the final template will be flagged with a substitution warning.

A product will be deemed to fail pre-screening if it contains any substance that:

- a. is listed in the OSPAR list of Chemicals for Priority Action; or
- b. is on the OSPAR List of Chemicals of Possible Concern (LSPC); or
- c. it is, or contains a substance that is on the Authorisation List established pursuant to REACH (Annex XIV), or
- d. its offshore use is covered by restrictions under Annex XVII to REACH; or
- e. is considered by the authority, to which the application has been made, to be of equivalent concern for the marine environment as substances covered by the previous sub-paragraphs based for example on its inclusion on the REACH Candidate List of Substances of Very High Concern for Authorisation; or
- f. is inorganic and has a LC50 or EC50 less than 1 mg/l; or
- g. has an ultimate biodegradation (mineralization) of
 - less than 20% in OECD 306, Marine BODIS or any other accepted marine protocols; or
 - less than 20% in 28 days in freshwater (OECD 301 and 310);
 or
- h. if half-life values derived from simulation tests submitted under REACH (EC 1907/2006) are greater than 60 and 180 days in marine water and sediment respectively (e.g. OECD 308, 309 conducted with marine water and sediment as appropriate), or
- i. meets two of the following three criteria:

(i) biodegradation: less than 60% in 28 days (OECD 306 or any other OSPAR-accepted marine protocol); or in the absence of valid results for such tests;

less than 60% (OECD 301B, 301C, 301D, 301F, Freshwater BODIS); or
less than 70% (OECD 301A, 301E);

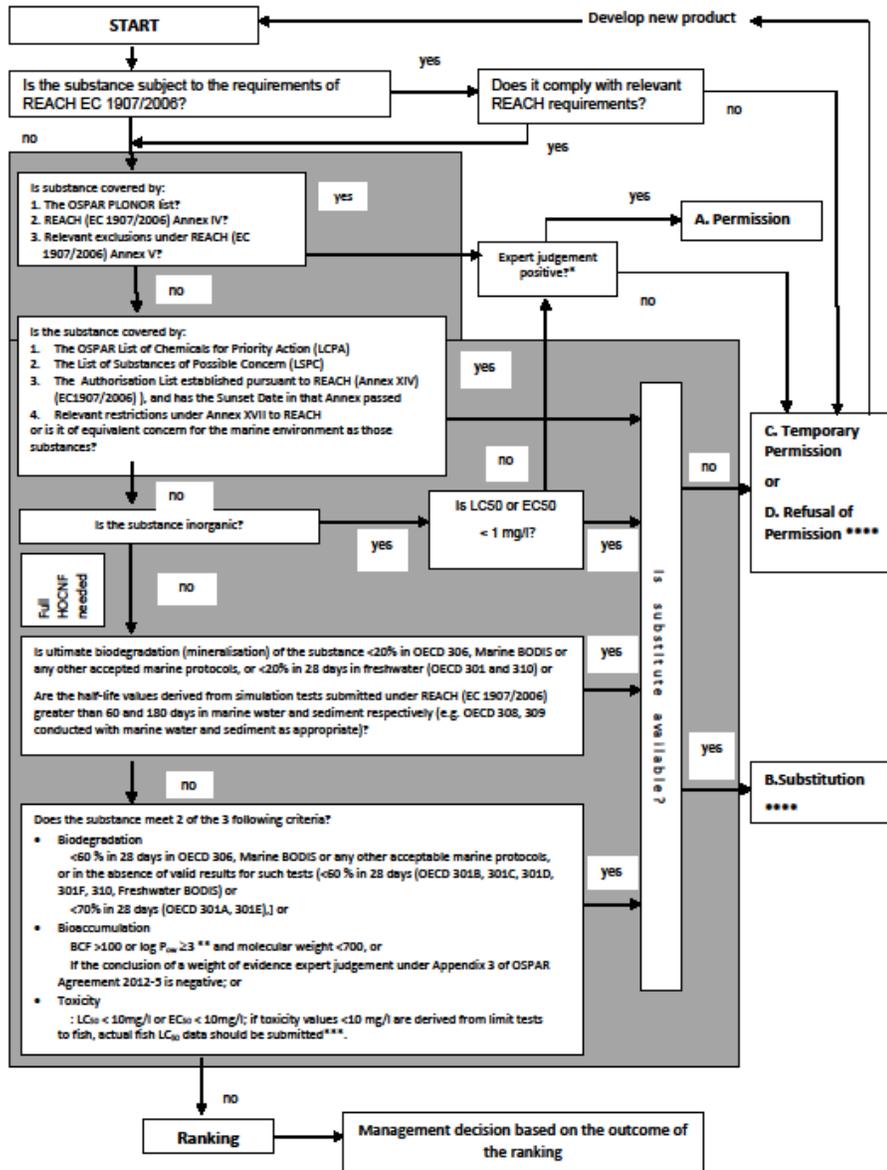
(ii) bioaccumulation: $BCF > 100$ or $\log P_{ow} \geq 3$ and molecular weight < 700 ; or if the conclusion of a weight of evidence judgement under Appendix 3 of OSPAR Agreement 2012-05 is negative; or

(iii) toxicity: $LC50 < 10\text{mg/l}$ or $EC50 < 10\text{mg/l}$; if toxicity values $< 10\text{mg/l}$ are derived from limit tests to fish, actual fish $LC50$ data should be submitted;

The outcome of pre-screening may be affected by the application of “Global Approach” principles, under which the PBT properties of each substance are compared with those of the same substance, as reported in support of existing or previous registrations. The data are then reviewed and substitution warnings applied/removed accordingly. The procedure that is undertaken is explained in the next section. →

Note: For additional information the assessment of pipe dopes, jacking greases, hydraulic fluids, mineral acids & bases and surfactants see [Appendix 2](#)

Figure 5: The Harmonised Pre-Screening Scheme (shaded) as Part of the Whole Harmonised Mandatory Control System for Offshore Substances set out in the applicable OSPAR Decision



Explanatory notes to Figure 5:

- * In accordance with the precautionary principle, expert judgement on a PLONOR substance should take into account sensitive areas, where the discharge of certain amounts of such a PLONOR substance may have unacceptable effects on the receiving environment.
- ** The figure ≥ 3 means the result of an OECD 107 test or the highest reported log P_{ow} from the range of values in an OECD 117 test.
- ***For further guidance on fish toxicity testing, please refer to OSPAR Guidelines for Completing the HOCNF (OSPAR Agreement 2012-05).

11 The Global Approach

In the preceding section, it has been explained how hazard assessment of an offshore chemical is conducted, based on the test data provided by the chemical supplier on the HOCNF. However, the reproducibility of the tests involved is imperfect, especially with regard to the OECD306 test for biodegradability.

In order to provide the most accurate pre-screening of the chemicals submitted for assessment, Cefas therefore takes account of the data it holds for similar substances. This is known as The Global Approach, which is based on the Weight of Evidence principles described by [ECHA Practical guide: How to use alternatives to animal testing to fulfil your information requirements for REACH registration](#) and in Sections R.4 and R.7a-R.7c of the [Guidance on Information Requirements and Chemical Safety Assessment](#) provided under REACH legislation.

The procedure adopted is as follows:

Biodegradation:

Where multiple biodegradation screening test results of equivalent quality exist a positive result is accepted over negative results.

This application of the global approach may result in the removal of a substitution warning.

References: OSPAR Agreement 2012-05, paragraph 10, OECD 27 Section 4.3.5 Conflicting Results from Screening Tests

Toxicity:

Where there are less than 3 values for the same endpoint and they are within 1 order of magnitude the lowest value will take precedence.

Where there are greater than 3 values for the same endpoint and they are within 1 order of magnitude the geometric mean will be calculated and used in the assessment

This application of the global approach may result in the application of a substitution warning via the 2 out of 3 box (see Figure 5).

References: OSPAR Agreement 2012-05, paragraph 12, OECD 27 Section 3.4 Weight of Evidence

Bioaccumulation (BCF Tests):

A BCF value will take precedence over any other data and will be compared to HMCS criteria. Where more than one BCF value occurs the highest value will take precedence.

Consideration of global BCF data could remove or apply a substitution warning based partly on Log P_{ow} data, since BCF data always takes precedence over Log P_{ow} data.

References: OSPAR Agreement 2012-05, paragraph 11, OECD 27 Section 5.4 Conflicting Data and Lack of Data

Bioaccumulation (Log P_{ow}):

Where only LogPow data are available the highest value will take precedence. The relevance of WOE approaches conducted under REACH or HMCS will be evaluated on a case by case basis.

This application of the global approach may result in the application of a substitution warning via the 2 out of 3 box (see Figure 5).

References: OSPAR Agreement 2012-05, paragraph 11, OECD 27 Section 5.4 Conflicting Data and Lack of Data

It is stressed that the applicability of the Global Approach is only valid where the data being compared relate to the same substance. Expert judgement is used to ensure that this is the case, assisted by data base searches and discussions with suppliers, where required.

12 Ranking

NOTE: Elements of the ranking process that are specific to individual countries are described in subsequent parts to this protocol.

Ranking of the offshore chemicals is conducted according to their calculated Hazard Quotients (HQ). For each chemical, the HQ is the ratio of Predicted Environmental Concentration (PEC) to Predicted No Effect Concentration (PNEC), which is calculated by the CHARM (Chemical Hazard Assessment and Risk Management) mathematical model (See CHARM User Guide, Version 1.4, CHARM Implementation Network 2004). The CHARM assessment utilises one of

a series of algorithms to generate the HQ value, dependent upon the particular function of the relevant chemical.

Where the relevant chemical is a preparation, HQs are calculated for each component substance, allowing for the percentage of the total composition that each substance contributes. The greatest substance HQ determines the HQ for the product

Non - CHARM-able offshore chemicals

Non-CHARM assessments are carried out where there is no CHARM algorithm applicable to the substance in question, such as inorganic chemicals, oil-based drilling fluids or those on the PLONOR list.

In the non-CHARM assessment, the chemical product is awarded an OCNS letter-grouping (A-E) determined by the worst-case toxicity and log P_{ow} / biodegradation data, A representing the highest environmental hazard and E the lowest.

The OCNS letter groupings are assigned through a two-stage process as described below:

Stage 1: Initial Grouping

The initial group is determined using Table 1. All submitted toxicity data for the substance are compared with the table and the value giving the worst case 'Initial Grouping' (i.e. the test giving the most toxic response) is used as the initial Group for the substance.

Table 1: Initial OCNS grouping

Initial Grouping	A	B	C	D	E
Result for Aquatic toxicity data (ppm)	<1	≥1-10	>10-100	>100-1,000	>1,000
Result for sediment toxicity data (ppm)	<10	≥10-100	>100-1,000	>1,000-10,000	>10,000

Aquatic toxicity refers to the *Skeletonema costatum* EC₅₀, *Acartia tonsa* LC₅₀, and *Scophthalmus maximus* (juvenile turbot) LC₅₀ toxicity tests.

Sediment toxicity refers to the *Corophium volutator* LC₅₀ test.

Stage 2: Adjustment for environmental performance to determine final Group

The final grouping is determined using Table 2. The column that applies to the candidate product is selected and the initial Group adjusted accordingly. If the classification should theoretically move beyond Group A or E, the product will be assigned to that particular Group.

Table 2: Adjustment criteria for OCNS grouping

Increase by 2 Groups e.g. From C to E	Increase by 1 Group e.g. From C to D	Do not adjust initial grouping	Decrease by 1 group e.g. From C to B	Decrease by 2 groups e.g. From C to A
Substance is readily biodegradable and is non-bioaccumulative	Substance is inherently moderately biodegradable and is non-bioaccumulative	Substance is poorly biodegradable and is non-bioaccumulative or Substance is readily biodegradable and bioaccumulates	Substance is moderately biodegradable and bioaccumulates	Substance is poorly biodegrade and bioaccumulates

Definitions of terms used in the classification table:

Readily biodegradable - Results of >X% biodegradation in 28 days to an OSPAR HOCNF accepted ready biodegradation protocol.

Moderately biodegradable - Results of >20% and <X% to an OSPAR HOCNF accepted ready biodegradation protocol.

Poorly biodegradable - Results from OSPAR HOCNF accepted ready biodegradation protocol are <20%.

Where X is equal to:

- 60 % in 28 days in OECD 306, Marine BODIS or any other acceptable marine protocols, or in the absence of valid results for such tests
- 60 % in 28 days (OECD 301B, 301C, 301D, 301F, Freshwater BODIS) or
- 70% in 28 days (OECD 301A, 301E)

Non-bioaccumulative/non-bioaccumulating - Log P_{ow} <3, or results from a bioaccumulation test (preferably using *Mytilus edulis*) demonstrates a satisfactory rate of uptake and depuration, or the molecular mass is >700.

Bioaccumulative/Bioaccumulates - Log P_{ow} >3, or results from a bioaccumulation test (preferably using *Mytilus edulis*) demonstrates an unsatisfactory rate of uptake and depuration, and the molecular mass is <700.

Aquatic toxicity test result - LC/EC50 data for *Skeletonema costatum*, *Acartia tonsa* or *Scophthalmus maximus* (Juvenile turbot) (units = ppm or mg/litre)

Sediment toxicity test result - LC50 data for *Corophium volutator* (units = ppm or mg/Kg).

13 Issue, Extension and Withdrawal of Templates

As soon as the assessment process has been finished, its outcome must be reported through the issue of a template. The assessors generate this by completing a proforma to confirm that all sections of the database have been completed, specifying the version of the template, the OCNS group of the product and issued a letter of authority. This is then sent to the supplier electronically. The administrator then shreds any hard copy of the HOCNF and proforma. For further information regarding the template see [Appendix 3](#).

The certification period lasts for a maximum period of 3 years, and products cannot be re-certified earlier than 6 months before their expiry date.

Temporary certifications will only be issued to current products, where the supplier requires additional time to conduct toxicity testing or for field trials of new offshore chemicals. The period of temporary certification for testing is for a maximum of 3 months subject to a letter from the testing laboratory that the tests are commissioned, and is the only type of extension granted. Applications for field trials will be assessed individually and a registration period of six months awarded as appropriate.

14 OSPAR References

Decisions and Recommendations

- OSPAR Decision 2000/2 [OSPAR Decision 2000/2 on a Harmonised Mandatory Control System for the Use and Discharge of Offshore Chemicals \(as amended by OSPAR Decision 2005/1\)](#)
- OSPAR Decision 2000/3 [OSPAR Decision 2000/3 on the Use of Organic-phase Drilling Fluids \(OPF\) and the Discharge of OPF-Contaminated Cuttings](#)
- OSPAR Decision 2005/1 [OSPAR Decision 2005/1 amending OSPAR Decision 2000/2 on a harmonised mandatory control system for the use and reduction of the discharge of offshore chemicals](#)
- OSPAR Recommendation 2005/2 [OSPAR Recommendation 2005/2 on Environmental Goals for the Discharge by the Offshore Industry of Chemicals that Are, or Contain Added Substances, Listed in the OSPAR 2004 List of Chemicals for Priority Action](#)
- OSPAR Recommendation 2006/3 [OSPAR Recommendation 2006/3 on Environmental Goals for the Discharge by the Offshore Industry of Chemicals that Are, or Which Contain Substances Identified as Candidates for Substitution](#)

OSPAR Recommendation 2010/3 [OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format \(HOCNF\) as amended by Recommendation 2014/17](#)

OSPAR Recommendation 2017/1 [OSPAR Recommendation 2017/1 on a Harmonised Pre-Screening Scheme for Offshore Chemicals](#)
(this recommendation replaces OSPAR Recommendation 2016/4)

Other Agreements

OSPAR Agreement 2012-05 [OSPAR Agreement 2012-05 OSPAR Guidelines for Completing the Harmonised Offshore Chemical Notification Format \(HOCNF\)](#) (this agreement replaces Agreements 2003-1, 2005-13, 2008-5 and 2010-05)

OSPAR Agreement 2005-12 [OSPAR Guidelines for Toxicity Testing of Substances and Preparations Used and Discharged Offshore](#)
(this agreement replaces agreement 2002-3)

OSPAR Agreement 2002-6 [Common Interpretation on which Chemicals are Covered and not Covered by the Harmonised Mandatory Control System under OSPAR Decision 2000/2](#)

OSPAR Agreement 2002-4 [Further Guidance on the Assessment of the Toxicity of Substances under the Harmonised Pre-Screening Scheme of OSPAR Recommendation 2000/4](#)

OSPAR Agreement 2013-06 [OSPAR List of Substances Used and Discharged Offshore which Are Considered to Pose Little or No Risk to the Environment \(PLONOR\) list.doc](#)

15 Glossary

AT	Applied Technology
AN	Authorisation Note
Cefas	Centre for Environment, Fisheries and Aquaculture Science
CHARM	Chemical Hazard Assessment and Risk Management model
:	CHARM (Chemical Hazard Assessment And Risk Management) Version 1.4 2004 – CHARM Implementation Network (CIN) (Accessible via the EOSCA web site,
BEIS	Department for Business, Energy and Industrial Strategy (previously known as the Department of Energy and Climate Change).
HMCS:	Harmonised Mandatory Control Scheme
HOCNF	Harmonised Offshore Chemical Notification Format
HQ:	Hazard Quotient which is equal to the generic PEC / PNEC calculated by CHARM as mentioned in paragraph 7, III, Appendix 1 to the OSPAR Decision 2000/2
IGM	Inspector General of Mines
OCNS	Offshore Chemicals Notification Scheme
OIC	Offshore Industry Committee
OSPAR	Oslo and Paris commission (http://www.ospar.org)
LOA	Letter of Access
LCPA	OSPAR List of Chemicals for Priority Action.
NL	Netherlands
NOGEPA	Netherlands Oil and Gas Exploration and Production Association
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SLA	Service Level Agreement
SSM	State Supervision of Mines in the Netherlands
UK	United Kingdom

APPENDIXES

Appendix 1: Cefas OCNS Team

The various day-to-day aspects of operating and administering the OCNS are handled by the Cefas OCNS Team, based at the Lowestoft laboratory in Suffolk, United Kingdom.

The roles and responsibilities of the individuals in the multi-disciplinary team are based on their level of training and experience of the OCNS. Cefas Applied Technology (AT) provides *ad-hoc* IT support and database management to the OCNS Team. The Cefas OCNS roles and responsibilities are shown in Table 3.

Table 3. The OCNS Team roles and responsibilities matrix.

Role ► Responsibility ▼	OCNS Administrator	Chemical Hazard Assessor	Risk Assessor	Project Manager	Database and IT support	Portfolio Lead	Senior Scientific Advisor
Project Management	-	-	-	X	-	-	
Customer Liaison	-	-	X	-	-	X	
Completeness Check	X	X	X	-	-	-	
Correctness Check	-	X	X	-	-	-	
OCNS Office Administration	X	X	X	-	-	-	
HOCNF Data processing*	-	X	X	-	-	-	
Advice to SSM	-	-	X	X	-	-	X
Low level database interrogations	-	X	X	-	-	-	
High level database interrogations	-	-	X	-	-	-	
Technical advice to the team	-	-	X	X	-	-	X
Permit and ES review	-	-	X	X	-	-	
Web site content maintenance	-	X	X	-	-	-	
Database backup and restore	-	-	-	-	X	-	
Database maintenance and technical support	-	-	-	-	X	-	

*Full completeness and correctness check

The Portfolio Lead is responsible for representing SSM interests within Cefas.

The Project Manager has responsibility for overall delivery of the project.

The Senior Scientific Advisor has final responsibility for all matters concerning the scientific operation of the Netherlands OCNS by Cefas.

These responsibilities include:

1. Ensuring the availability and application of resources;
2. Technical Supervision of the OCNS Team; Acting as a contact to SSM.

The OCNS administrators are responsible for managing the receipt of HOCNFs and entering them in the assessment queue. The administrators are also responsible for completeness checking, and routine communications with suppliers.

Assessment of HOCNF data is conducted by the Chemical Hazard Assessors and Risk Assessors in the OCNS Team. The assessors have a high degree of training in the science relevant to offshore chemical registration gained prior to joining Cefas, and also from on-going professional development at Cefas. Members of the team regularly attend training sessions and seminars on offshore chemistry and microbiology from industry experts. Chemical Hazard Assessors concentrate on processing HOCNFs, processing and analysing the data, dealing with enquiries and problems by telephone and email. Chemical Hazard Assessors are also responsible for the generation of templates and authorisation notes.

In addition to carrying out the same types of work as the Chemical Hazard Assessors, Risk Assessors are responsible for conducting permit reviews for the UK Department for Business, Energy and Industrial Strategy (BEIS), maintaining the OCNS Website, providing technical support to SSM and BEIS, reviewing technical issues and advising on best practice and the implications of actions taken.

The OCNS Team hold regular meetings during which information and knowledge are shared and issues are resolved.

All members of the team have a watching brief to ensure that the team mailbox is regularly reviewed and maintained. In the absence of the administrator, all other members of the OCNS Team are able to complete the tasks assigned to this role.

Delegated Authority

Cefas Applied Technology (AT) is responsible for:

1. The “backing-up” of OCNS electronic files and electronic documents;
2. Database management

Equipment

The OCNS Team work in a secure office environment and require desks, lockable filing facilities, individual telephones, a fax machine, individual personal computers (PCs), a printer, a scanner, and access to meeting room facilities. The PCs used by the team, have password-protected access to a purpose built database used for registering preparations, e-mail and access to the Internet. The data share drive (C6336/Data Storage/e-HOCNFs) and email box (ocns.chems@cefas.uk) that the OCNS Team use are only accessible to members of the team and the IT system administrators.

Confidentiality Issues

The members of the OCNS Team engaged in the day-to-day processing of HOCNF data will not be involved in any other work that may compromise the impartiality of the service they provide. In the event of Cefas being approached by a chemical supplier, operator or other organisation involved with the oil industry to tender for work in which OCNS Team members may be engaged, approval will be sought for the individual involvement from SSM and BEIS. Cefas expect that SSM and BEIS will not unreasonably withhold permission for the OCNS Team members to engage in work where Cefas can demonstrate that no conflict of interest exists.

All Cefas' staff have signed the UK Official Secrets Act. Only individuals in the OCNS Team and AT database support team have access to the data in the OCNS database. No member of the Cefas OCNS Team will use information from the OCNS database for work outside of the remit of the OCNS.

All HOCNF data submitted to the OCNS, which are assigned by the owner of the data to be confidential, are treated as confidential. No confidential HOCNF information will be disclosed to any third party outside of the Cefas OCNS Team, BEIS, Marine Scotland or SSM except under the provisions of Summary Record OIC 2006 2.4.6: and Summary Record OIC 2007 3.3.4-3.3.5

- contracting parties (CPs) may discuss with other CPs information contained within HOCNFs for the development of SMART goals for substances identified for substitution
- only nominated third parties from CPs will be able to exchange confidential information which is contained on a HOCNF to other nominated 3rd parties and the names of those third parties will have been notified to the OSPAR Secretariat

Two members of the Cefas OCNS Team are nominated third parties for both the Netherlands and the UK.

The Cefas nominated third parties will only enter into discussions with other CP or their nominated third parties regarding confidential data when requested to do so in writing by the relevant CP(s) for which they act.

In addition, the Cefas OCNS Team also regularly receives other proprietary information in relation to its work; this information is also deemed to be commercially confidential.

All confidential data supplied to Cefas as part of the OCNS will only be made available to the members of the OCNS Team, and those individuals that are involved in permitting the use of these offshore chemicals in the country or countries for which use of the chemical is registered on the OCNS database. Each country will accept chemicals registered in the other country on permit applications.

Where a chemical supplier is utilising confidential chemicals or formulations from a third party supplier Cefas will manage this situation by the use of a "Letter Of Access (LOA)", and neither of the two companies' confidential data will be divulged to the other supplier. In this procedure Cefas will act in accordance with OSPAR agreement 2012-05. By way of illustration, where a chemical supplier is re-branding an existing chemical preparation (that is produced by a 3rd party supplier), for which OCNS holds the HOCNF data, the OCNS Team can assess the re-branded preparation using this data without disclosing any information to the chemical supplier.

For the OCNS Team to proceed with this process, the 3rd party company must provide a LOA, giving permission to OCNS to use their HOCNF data for the second company's product.

The LOA must include the following information:

- Company headed letter, stating the company name, address and contact details
- A statement identifying the data in question and the product(s) that will utilise it
- The name of the company re-branding or incorporating the original product

The LOA should be sent to the OCNS administrator at the same time as the chemical supplier re-branding the preparation submits the HOCNF. If the LOA is not submitted by the time of registration, the HOCNF will be held until such time the LOA is received.

The Cefas OCNS Team will not request or advocate the 3rd party chemical supplier to provide the LOA; it is the responsibility of the chemical supplier who is re-branding the preparation to ensure that the 3rd party company sends the LOA to the Cefas OCNS Team in timely manner.

The Cefas OCNS Team makes use of the data that is the subject of the LOA to conduct the completeness and correctness checks on the HOCNF data thus registering the product, but will not disclose the data to the first party company. If the HOCNF dataset is not complete with the inclusion of the data that is subject of the LOA the assessment clock will stop and the missing data will be requested via the first party supplier who submitted the HOCNF.

Appendix 2: Special Assessment criteria for "Pipe Dopes & Jacking Greases", "Hydraulic Fluids Strong Mineral Acids & Bases" and "Surfactants"

Pipe-dopes & Jacking Greases

Products used as pipe dopes or jacking greases are composed of a grease component with a number of additives. Although the grease component itself is composed of several components it is treated as a single substance for the purpose of the HOCNF. It is therefore only necessary to test the grease component as a single substance for toxicity and degradation. The additives however must be tested separately.

Hydraulic fluids and other chemicals used in closed systems

Hydraulic fluids and other chemicals applied in closed systems, i.e. closed well head controls, are not subject to the registration requirements on the basis of paragraph 9.3 of the Netherlands Mining Regulations and are not subject to the permitting requirements as stated in paragraph 9.2 of the Mining Regulations. Whenever these chemicals have to be refreshed, all fluid has to be collected to be disposed onshore.

Hydraulic fluids and other chemicals applied in open systems, i.e. open well head controls, are subject to the registration and permitting requirements as set out in paragraphs 9.2 and 9.3 of the Mining Regulations.

Strong mineral acids and bases

The requirements for data concerning the ecotoxicology of strong mineral acids and bases are the same as those for non-PLONOR substances. However the effective impact of discharging these substances is dependent not only on the toxic potential of the substance, but also strongly dependent of the buffer capacity of the medium in to which it is discharged, because their toxic impact has been related to the change in the pH they cause. The implementation of extra toxicity tests with strong mineral acids and bases is therefore not considered necessary.

Cefas use expert judgment to assess the environment impact of strong mineral acids and bases. **Suppliers are therefore advised that not supplying ecotoxicity data for strong acids and bases is acceptable.** It should be noted however that there are literature data available for some strong mineral acids and bases.

Surfactants

Any substance that is flagged in Section 1.6 as a surfactant will be assumed to be bioaccumulative irrespective of the results of any OECD107 or OECD117 tests (unless BCF test data are supplied that refutes this assumption). The term “surfactant” is defined under OSPAR Agreement 2012-05 (Appendix I). Where dispute exists over whether a substance is or is not a surfactant, Cefas may stipulate that a supplier conduct surface tension measurement according to OECD 115. According to EC Council Regulation 440/2008 from 30 May 2008, if the surface tension of water (nominally 72.75mN/m at 20°C) is reduced below 60mN/m under the conditions of this method, the substance should be regarded as a surfactant.

The HMCS pre-screening scheme designates substances with $\text{Log } P_{\text{OW}} > 3$ or Bioconcentration Factor (BCF) > 100 as potentially bioaccumulative, with only substances having a molecular weight greater than 700 being exempt from this classification. As it is not possible to utilise the OECD 107 and OECD 117 methodologies for determining a $\text{Log } P_{\text{OW}}$ for surfactants, the application of the precautionary principle determines that in the absence of other evidence, these substances are assumed to be bioaccumulative.

Substitution warnings are therefore applied to surface active substances with a molecular weight < 700 that either exhibit high toxicity or are not readily biodegradable because their potential to bioaccumulate is unknown.

However this had led to a marked increase in the number of substitution warnings applied to surfactants since a great many such substances exhibit high toxicity. As a result of this the HMCS allows a Weight of Evidence approach to the assessment of the bioaccumulation potential of surfactants. The bioaccumulation assessment scheme under HMCS (documented in OSPAR Agreement 2012-05) is presented in Figure 6.

Suppliers who intend to conduct a weight of evidence assessment of bioaccumulation potential and present this as part of their HOCNF data set should present their approach to Cefas for review before any work is conducted. General guidance for the type of approach that may be acceptable is outlined in the following references:

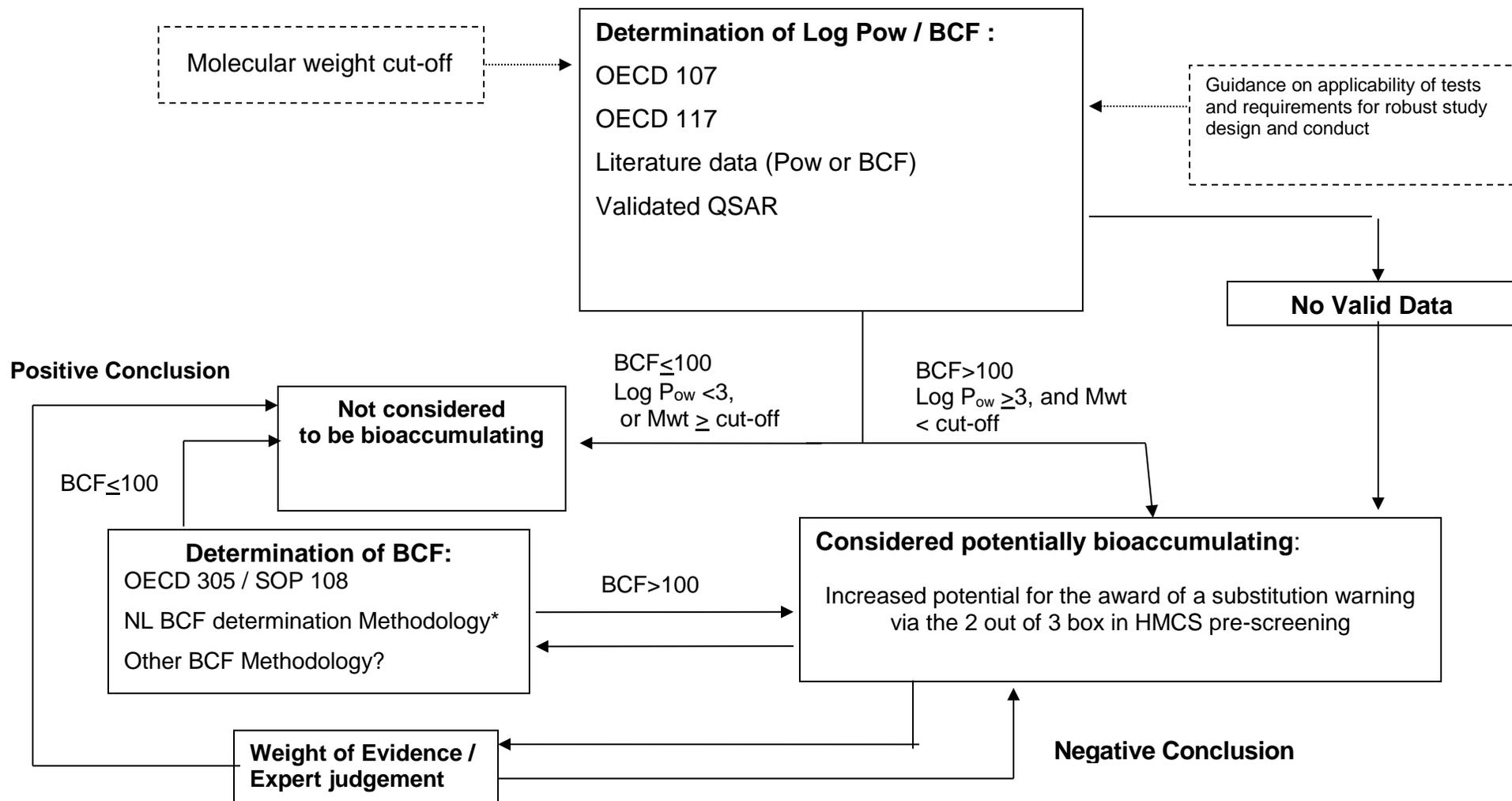
de Wolf W, Comber M, Douben P, Gimeno S, Holt M, et al. (2007) Animal Use Replacement, Reduction, and Refinement: Development of an Integrated Testing Strategy for Bioconcentration of Chemicals in Fish. Integrated Environmental Assessment and Management: Vol. 3, No. 1 pp. 3-17

Millais AJ, Rycroft RJ, Tolhurst MA, Sheahan DA Bioconcentration: Comparison of methods for assessing potential hazards of offshore chemicals. Chemistry in the Oil Industry X, 5-7 November 2007.

[ECHA Practical Guide: How to use alternatives to animal testing to fulfil your information requirements for REACH registration](#), European Chemicals Agency 2016

Figure 6 Bioaccumulation Assessment Methodology for HMCS:

*Reference: OIC 2007, paper OIC 07/3/3-E (included as a separate attachment to this protocol)



Appendix 3: The Use of Quantitative Structure-Activity Relationships (QSARs)

In certain circumstances, it may be preferable to obtain HOCNF data by calculation through the use of Quantitative Structure Activity Relationships (QSARs) rather than experimental measurement. To be acceptable for registration of offshore chemicals, all QSAR calculations must be fully validated. A part of the validation exercise for an acceptable QSAR assessment must include demonstration that the method is directly applicable to the substance concerned.

Validation must either:

- Demonstrate that the training-set on which the QSAR is based is directly relevant to the substance for which it is being used to predict a parameter.

Or

- Demonstrate that the calculation method is able to calculate the parameter of interest for members of a homologous series of substances (structurally related to the substance of interest), for which experimentally determined data may be found in the literature. The experimentally determined literature values need not come from studies conducted to GLP, but in such cases Cefas will make a quality assessment and take weight-of-evidence approach during the evaluation of these data.

Note: Guidance on the use of QSARs is provided in “Guidance on information requirements and chemical safety assessment: [Chapter R.6: QSARs and grouping of chemicals](#)”, issued by the European Chemicals Agency (ECHA), May 2008, in support of REACH legislation.

Appendix 4: OCNS Templates

Examples of the OCNS Templates as of January 2017 are shown in this appendix. These comprise one template for a dummy product that was assessed using CHARM algorithms (see Section 12), and one for which CHARM is not applicable (a “non-CHARMable” product).

On all templates, five boxes are featured. Reading from top to bottom:

- The first box contains only the registered name of the product
- The second box contains the name and address of the supplier
- The third box shows the product’s registration number, and the version number of the template, and the expiry date of the template. The version number of the template. Only the template with the highest version number should be used when completing a permit application (this can be verified from the ranked list found at <http://www.cefas.defra.gov.uk/ocns/>)
- The fourth and fifth boxes display a synopsis of relevant HOCNF data regarding the product’s hazard assessment. This section is described further under the relevant example template below.

Note also that:

- The countries for which the product is registered is determined from the logos on the top line (BEIS logo indicates UK Registration, SSM logo indicates NL Registration. Where both logos are shown, the product is registered for use in both countries).
- Immediately below the third box, relevant product warnings are indicated, along with (if applicable) NL Pre-screening category details and UK National Plan levels.
- For products that are assessed using CHARM, the fourth box includes details of the relevant algorithm(s) and sub-algorithm(s) used in the assessment (Drilling, Production, Cementing, Completion), and the resulting Hazard Quotient (HQ).
- For “non-CHARMable” products, the outcome of the assessment is reflected in the OCNS Group that is applicable to the product (see Section 12). This is shown in the fourth box.



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Product Widget

ACME Industries, 1 ACME Road, ACME, AB1 2CD, United Kingdom

Registration No: 23850 Version No: 1 Expiry Date: 6/12/2013

This product contains one or more substitutable substances. UK National Plan Level 3 NL HMCS Prescreening Category: D Product Warnings Other than Substitution: O-VII

HQ	Application	Process	%	Dosage	Worst Aquatic Toxicity Test	Number Of Aquatic Toxicity Tests
1.43e-001	Completion/workover	Std operation	20.00	1000 ppm	0.1	3
2.37e-002	Drilling	17½	20.00	0.4 ppb	0.1	3
1.76e+000	Drilling	12¼	20.00	0.4 ppb	0.1	3
1.76e+000	Drilling	8½	20.00	0.4 ppb	0.1	3
2.09e-003	ProductionInj	Gas	20.00	1 ppm	0.1	3
2.27e-003	ProductionInj	Oil	20.00	1 ppm	0.1	3
2.09e-001	ProductionStd	Gas	20.00	1 ppm	0.1	3
2.20e-001	ProductionStd	Oil	20.00	1 ppm	0.1	3

Application	Surfactant Type	Drilling Mud Density kg/m3	Sediment Reworker Result:	Biodegradation Value/ %	Time/Days	Protocol	Minimum Log Po/w	Koc	Koc Protocol	Organic C Content
Completion/workover	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Drilling	N/A	N/A	N/A	56	28	OECD 306	0	N/A	N/A	N/A
Drilling	N/A	N/A	N/A	56	28	OECD 306	0	N/A	N/A	N/A
ProductionInj	Non Surfactant	N/A	N/A	56	28	OECD 306	0	N/A	N/A	N/A
ProductionStd	Non Surfactant	N/A	N/A	56	28	OECD 306	0	N/A	N/A	N/A



Department for
Business, Energy
& Industrial Strategy



State Supervision of Chemicals
Ministry of Economic Affairs

Product Widget 2

ACME Industries, 1 ACME Road, ACME, AB1 2CD, United Kingdom

Registration No: 23851 Version No: 1 Expiry Date: 08/12/2013

NL HMCS Prescreening Category: P

<i>Application Process System</i>	<i>Dose Rate</i>	<i>Worst Aquatic Toxicity Test</i>	<i>Number of Aquatic Toxicity Tests</i>	<i>OCNS Group</i>	<i>100% PLOFOR</i>
<i>CHARM is not applicable to this process system</i>	<i>1000000 ppm</i>	<i>N/A</i>	<i>N/A</i>	<i>E</i>	<i>Yes</i>

<i>Application</i>	<i>Surfactant Type</i>	<i>Drilling Mud Density kg/m3</i>	<i>Sediment Reworker</i>	<i>Biodegradation Value/ %</i>	<i>Time/Days</i>	<i>Protocol</i>	<i>Minimum Log Po/w</i>	<i>Koc</i>	<i>Koc Protocol</i>	<i>Organic C Content</i>
<i>CHARM N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>

Appendix 5: Field trials

Field trial use of products not previously notified under the OCNS, or of novel blends of existing notified products, may be allowed after a consultation process with Cefas and the appropriate regulator. In assessing such applications, Cefas will require the submission of Sections 1 and 3 of the HOCNF pro-forma and will have regard to the environmental significance of any discharges that may result from the proposed use. Trials will usually relate to a specific site and last for a limited duration. However, in certain circumstances permission to use novel products on a range of well conditions may be allowed if environmental impacts are judged to be limited to acceptable levels. The appropriate regulator will advise on the scale and scope of such risk assessments on a case-by-case basis.

As an absolute minimum in Section 2 of the HOCNF, Cefas also requires toxicity data from **at least** one appropriate toxicity test plus a detailed description of the use and fate of the product, otherwise the trial product cannot be assigned to a temporary OCNS Group.

In cases which the Regulatory authorities judge likely to produce a significant discharge, the results of any **two** appropriate toxicity tests should be submitted (including a sediment reworker test where relevant).

Biodegradation data and bioaccumulation data requirements for all field trials should be discussed with Cefas prior to the submission of the HOCNF.

Following successful trials, classification for general use will require the submission of a full HOCNF data set.

This process is intended to encourage the development of alternative products, which may otherwise be discouraged by the costs of comprehensive testing.