Centre for Environment Fisheries & Aquaculture Science

Cefas

Netherlands (NL) PROTOCOL

Standard Operating Procedure for Offshore Chemical Hazard Assessment

Part 1: Core Elements

OCNS 011

Issue 13

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Cefas Document Control

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Version control history

Version	Date	Comment
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
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.
12	23/11/20	Updated in line with latest OSPAR documents. Additional information regarding the correctness check phase and the liaison with suppliers during registration.
13	22/11/2022	Updated in line with latest OSPAR documents. Updated website links. Updated format and glossary section. Update of SSM contact details. Updated Roles and Responsibilities in Table 6.

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. State Supervision of Mines (SSM) and the Centre for Environment, Fisheries and Aquaculture Science (Cefas) accept no liability regarding the contents of this document.

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1. Introduction

All Contracting Parties to the 1992 OSPAR Convention (hereafter referred to as 'the 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 offshore chemicals.

The focus of this document is on this first stage and describes:

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

This document contains the core elements of work undertaken under the OSPAR Offshore Chemical Notification Scheme (OCNS). Information that is specific to the Netherlands is covered in NL Protocol Part 2: Elements specific to the Netherlands.

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. United Kingdom (UK) and Netherlands (NL) maritime area of the North Sea.

Note: This document forms part of a contract between Cefas and SSM. 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.

The 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 North-East Atlantic sector.

In June 2000, OSPAR introduced Decision 2000/2 (as amended by Decision 2005/1) 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. For the Netherlands 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.

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 with less hazardous alternatives, OSPAR Recommendation 2017/01 (as amended by Recommendation 2019/04) and,*
>
> *"The Harmonised Offshore Chemical Notification Format (HOCNF), which sets out the information requirements that must be fulfilled to register a chemical for use within the OSPAR region (OSPAR Recommendation OSPAR Recommendation 2010/3, as amended by Recommendation 2014/17, and recommendation 2019/03 and 2021/08)."*

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.).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).

In the UK the hazard assessment of chemical products used offshore by the Oil and Gas Industry is carried out on behalf of Department for Business, energy and Industrial Strategy (BEIS) by multidisciplinary team at the Cefas Lowestoft Laboratory. 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 on the Netherlands' continental shelf. 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 UK and 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.

3. Responsibilities

3.1. The Regulator

3.1.1. 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 continental shelf.

In accordance with 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 point of contact at SSM for the registration of offshore chemicals is:

J.R. Judith Van Gorp
Staatstoezicht op de Mijnen / State Supervision of Mines
P.O. Box 24037
2490 AA Den Haag/The Hague
Netherlands
Telephone: +31625364814
E-mail: [j.vangorp@sodm.nl]

3.1.2. 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 continental 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 amended by OSPAR Decision 2005/1) as covered by the Offshore Chemicals Regulations (2002, as amended 2011).

Contact details:
Mark Shields (Environmental Manager)
E-mail: mark.shields@BEIS.gov.uk
Telephone: 01224 254101
Address: Department for Business, Energy and Industrial Strategy, AB1 Building, Crimon Place, Aberdeen, AB10 1BJ, United Kingdom.
General Contact Details:
Fax: 01224 254100
E-mail: emt@BEIS.gov.uk

3.2. Centre for Fisheries, Environment and Aquaculture Science (Cefas).

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 and Safety Data Sheet(s).
- 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 Harmonised Mandatory Control Scheme (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.
- publishing on the Cefas website a list of chemicals registered https://www.cefas.co.uk/data-and-publications/ocns/

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

3.3. Chemical Supplier/Manufacturers

The chemical supplier / manufacturer is responsible for supplying all required HOCNF data, in accordance with 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, Good Laboratory Practice (GLP) (or equivalent) test data reports, chemical data and Letters of Access (LoA). It is the supplier's responsibility to ensure that any LoA 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.
- provide 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 HOCNF forms. The format should be in accordance with OSPAR Recommendation 2010/03 (HOCNF), as amended by OSPAR Recommendation 2014/17,2019/03 and 2021/08. Cefas will only accept data on the current 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 and will not progress until the deficit is rectified (see Completeness Checks and Correctness Check).

4. Communication

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

- Email (Preferred)
- Telephone (arranged meetings or telecoms)
- Letter

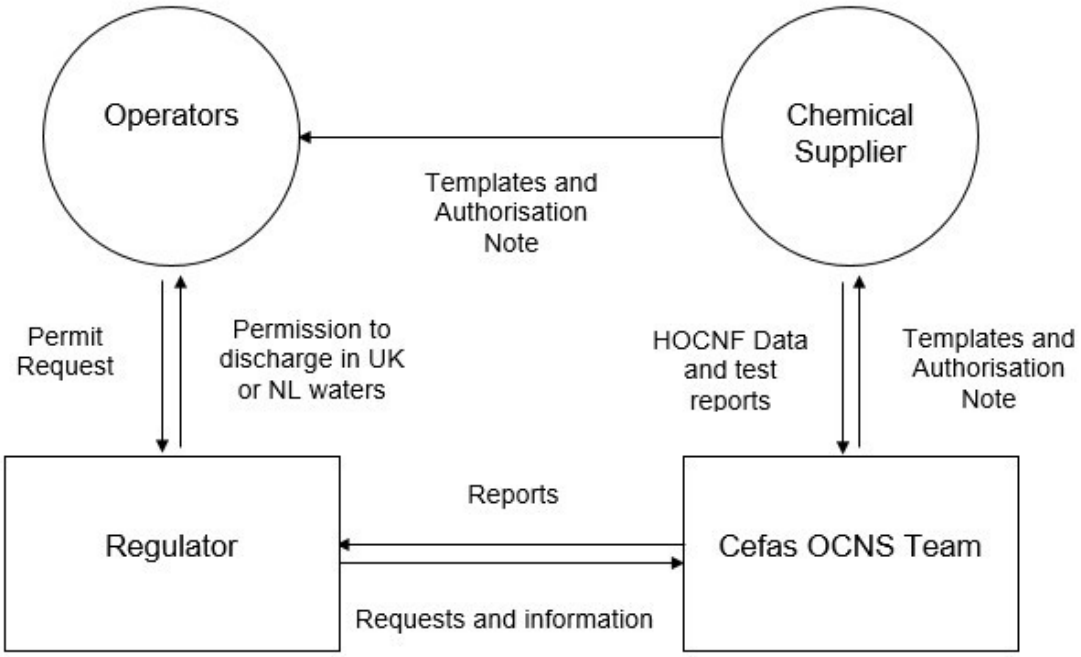


Figure 1. Schematic showing the OCNS communication paths with relevant parties

5. 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 2010/03 (as amended by OSPAR Recommendation 2014/17, 2019/03 and 2021/08), and modified versions of the HOCNF template will not be accepted.

On receipt by Cefas, all electronic communications are filed electronically in designated company/product folders. The access to these documents is limited to the Cefas team who is involved in hazard and risk assessment of chemical products. We are committed to a paperless process but on occasion, if hard copies are subsequently made, they 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, a new record is created with the name of the chemical preparation and entered into the database when the HOCNF is placed in the certification[1] queue. If a HOCNF corresponds to an existing chemical on the database, its arrival date is recorded in the database, and it is placed in the certification queue. 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, as updated in 2021. If both are satisfactory, the product will be entered onto the OCNS database. Provided that Cefas is satisfied with the data submitted, the product is then certified.

The OCNS registration process is summarised in Figure 2.

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

[1] 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.

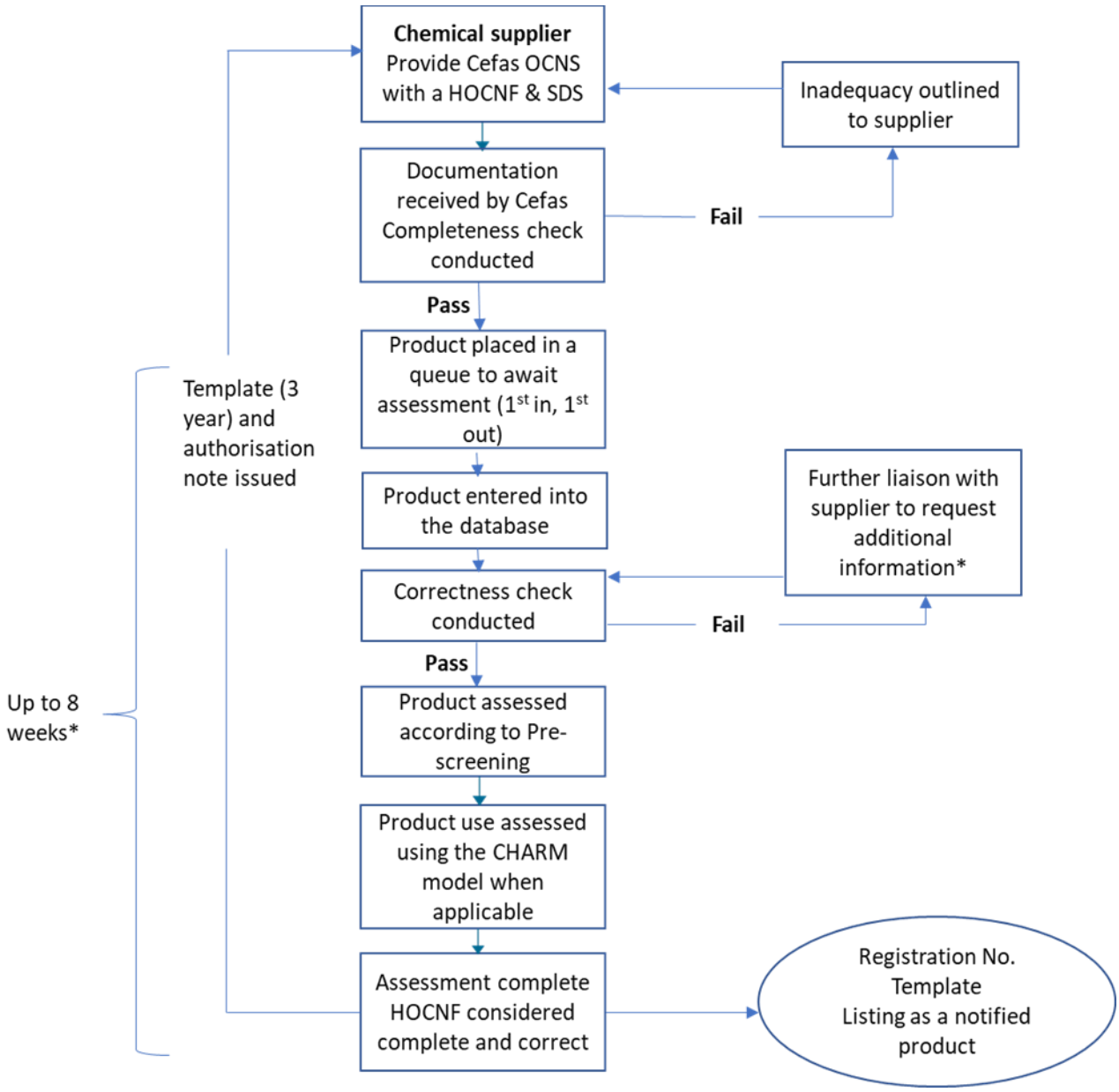


Figure 2 The OCNS registration process. The time taken by the supplier to provide any additional information requested is not considered in the guaranteed 8-week turnaround

6. 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 adds up to 100%.
- that the composition includes, for each substance, details of molecular weight, EINECS/ELINCS or REACH number, and CAS number.
- that bioaccumulation, biodegradation and ecotoxicity data have been provided for all organic substances in the product (unless there is a LoA in place or the substances are on the Pose Little or No Risk to the marine environment (PLONOR) list, on REACH Annex IV or fulfil specific requirements of REACH Annex V).
- that ecotoxicity data have been provided for all inorganic substances in the product (unless there is a LoA in place or the substances are on the PLONOR list, on REACH Annex IV or fulfil specific requirements of REACH Annex V).
- that any relevant LoAs that have been received are associated with the HOCNF.
- that the Confirmation Statement has been authorised and dated.
- 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.

With the exception of the LoAs, 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 an Excel spreadsheet. 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 (as amended) and its agreements. All studies completed after 1 January 2009 must comply with OSPAR Agreement 2005-12 (replaced by OSPAR Agreement 2021-07). 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. Non-testing data obtained from computational methods such as quantitative structure-activity relationship (QSAR) 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.

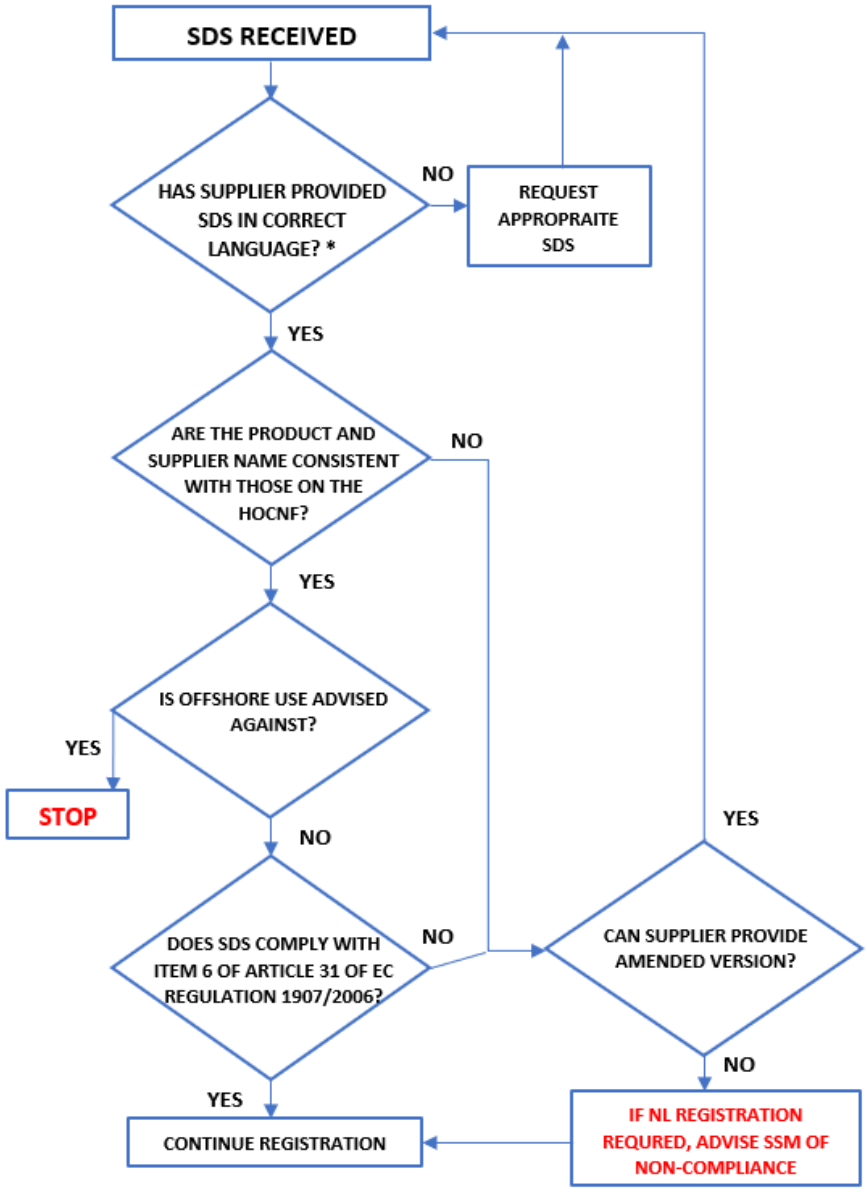


Figure 3 Safety Data Sheet Check Procedure. Suppliers must provide an SDS in English, plus (if NL Registration is required) an additional copy in Dutch

6.1. HOCNF Completeness Check Requirements: Part 1

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.

For polymers, the supplier should provide all available information such as number average and weight average molecular weights, levels of branching and substitution and EO:PO (ethylene oxide: propylene oxide) ratios where available, supplemented where possible with analytical data e.g., Gel Permeation Chromatography traces, or another valid test to determine the molecular weight for the substance.

Table 1 HOCNF Completeness Check Requirements: Part 1 General Information. The presence of the substances highlighted in this table is monitored during the correctness check, and any omissions are dealt with at that stage

HOCNF section	Section title	Requirement	Action if data are missing
1.1 Trade Name	State trade name(s)	Mandatory	Contact supplier
1.2 Supplier information	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
	Email address	Mandatory	Contact supplier

HOCNF section	Section title	Requirement	Action if data are missing
	OSPAR Countries where preparation is used	Mandatory	Contact supplier
	Alternative trade names used in those countries	Mandatory	Contact supplier
	SDS Check Box	Mandatory	Contact supplier if SDS missing, and request SDS, compliant with current EU regulations
1.3 SDS	Application group	Mandatory	Contact supplier
1.4 Use & Discharge	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

HOCNF section	Section title	Requirement	Action if data are missing
	Total estimated amount of discharge (tonnes)	Mandatory	Contact supplier
	Frequency of treatment	Mandatory	Contact supplier
	Probable amount of substance/preparation discharged:	Mandatory	Contact supplier
	Duration of discharge	Mandatory	Contact supplier
1.5 Fate	Explain the likely fate of substance/ preparation	Mandatory	Contact supplier
1.6a Composition	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

HOCNF section	Section title	Requirement	Action if data are missing
	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
1.6b content	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

HOCNF section	Section title	Requirement	Action if data are missing
	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
	Plastic substances	Conditional. The box must be ticked if the product contains any substance that is plastic.	None

HOCNF section	Section title	Requirement	Action if data are missing
	Microplastic substances	Conditional. The box must be ticked if the product contains any substance that is microplastic.	None
	Nanomaterials	Conditional. The box must be ticked if the product contains any substance that is a nanomaterial. Conditional.	None
	Compliance with / Regulated by BPR	Conditional. The box must be ticked if the product contains any substance that is intended as a biocidal active in a biocidal product and it is compliant with the Biocidal Products Regulation.	None
	CASN/name	Conditional subject to a tick box being ticked in section 1.6b	Contact supplier
	Compound/contaminant	Conditional subject to a tick box being ticked in section 1.6b	Contact supplier

HOCNF section	Section title	Requirement	Action if data are missing
	Concentration (ppm)	Conditional subject to a tick box being ticked in section 1.6b	Contact supplier
	Intentional additive (Y/N))	Conditional subject to a tick box being ticked in section 1.6b	Contact supplier
	Analytical methodology	Conditional subject to a tick box being ticked in section 1.6b	Contact supplier
	If surfactant, Fraction released	Conditional subject to a tick box being ticked in section 1.6b	Contact supplier
Section 1.7 General Physical Properties	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	Mandatory	Contact supplier

HOCNF section	Section title	Requirement	Action if data are missing
	give floating / sinking / soluble materials / no.		
	If other, please describe.	Conditional. This box must be completed if the preceding entry is 'No'.	Contact supplier

6.2. HOCNF Completeness Check Requirements: Part 2

This section contains ecotoxicological information. At the start of Part 2, the supplier is required to indicate:

a) Whether the product is comprised exclusively of PLONOR substances[2], 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.

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-bioaccumulative. Alternatively, suppliers may

[2] 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.

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 in Table 2. 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.

Table 2 HOCNF Completeness Check Requirements: Part 2 Ecotoxicological information

HOCNF Section	Section title	Requirements	Action if data are missing
2.1 Partitioning and bioaccumulation potential	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	Contact supplier
2.1.1 LogPow	Substance	Mandatory	Contact supplier
	Peak No	Mandatory, if “OECD 117” entered for “Methodology”, below.	Contact supplier
	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	Contact supplier

HOCNF Section	Section title	Requirements	Action if data are missing
		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 weighted 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)	
	Lab ID	Mandatory.	Contact supplier
	Methodology/protocol/ Literature data	Mandatory	Contact supplier
	Report ID	Mandatory	Contact supplier
2.2 Biodegradability	Biodegradability	Biodegradability studies are only relevant for organic and organometallic substances. For complex mixtures, individual information for all deliberately added substances should be given on separate data sheets (from HOCNF)	Contact supplier
2.2.1 Aerobic/ biodegradability (mandatory for	Substance	Mandatory unless Simulation Test Data are provided. (Min 4	Contact supplier

HOCNF Section	Section title	Requirements	Action if data are missing
all organic substances)		values for reports completed after 16 Jan 2001)	
	Day	Mandatory unless Simulation Test Data are provided. (Min 4 values for reports completed after 16 Jan 2001)	Contact supplier
	Screening Test: Reference Substance Test Substance % 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} 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	Aquatic Toxicity	This section is a mandatory field, and must be completed for all substances, including	

HOCNF Section	Section title	Requirements	Action if data are missing
		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	
	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 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)

6.3. HOCNF Completeness Check Requirements: Part 3

The supplier is expected to provide information including a contact name, company and position as in Table 3

Table 3 HOCNF Completeness Check Requirements: Part 3 Confirmation Statement

Section title	Requirements	Action if data are 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.

7. Correctness Check

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

7.1. Persistence/Bioaccumulation/Toxicity Data

If the HOCNF in question is associated with a LoA which has not been received, the chemical supplier registering the product will be notified at this stage and the registration paused until the LoA has been received. The correctness of any HOCNF information is assessed against the requirements of OSPAR recommendation 2010/03 (as amended by OSPAR Recommendation 2014/17, 2019/03 and 2021/08), and its agreements.

The correctness 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
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 https://chem.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: 987-1-40206101-1)

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 LoA. (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. The scientific data is critically evaluated 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, December 2011 (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.

7.2. REACH Registration Requirements & Biocidal Product Regulation (BPR) Checks

During the correctness check phase, a check is carried out to ensure that the substances meet their registration obligations under REACH, or that the supplier has responded to Cefas enquiries relating to these matters. If a substance is a biocidal active, additional checks may apply to ensure that the substance complies with GB (Great Britain) BPR and EU BPR directive (EU) 528/2012.

7.3. Use and Discharge and Fate of product

During the correctness check phase, the data relating to a product's exact application (submitted in section 1 of the HOCNF) are also evaluated to ensure that the product being registered is assessed using the correct CHARM algorithm (if applicable).

Where there is a requirement for additional expertise to evaluate the correctness of the data submitted on the HOCNF, these will be subjected to further technical assessment during a meeting which may include other specialist advisors within Cefas (e.g. analytical chemistry or ecotoxicology). Any issues or resolutions thereof that concern the OSPAR framework will be discussed with the relevant regulator contact person for further guidance and or approval.

7.4. Additional Liaison with chemical suppliers

If any inadequacies are identified during the correctness check phase resulting in Cefas requesting further information from the supplier relating to any of the points discussed in paragraphs 9.1 to 9.3, the time taken for the supplier to address the request will not be considered as part of the 8-week turn around stipulated in section 6.

7.5. 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 database. The correctness of the information in respect of the carcinogenic, mutagenic and reprotoxic properties of substances on the HOCNF are evaluated against the following lists as published bi-annually[3]:

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)

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.

[3] These lists were established by the Netherlands Ministry of Social Affairs, but refer to the IARC list of carcinogenic substances. Available at: http://monographs.iarc.fr/ENG/Classification/index.php (Accessed 11th October 2022)

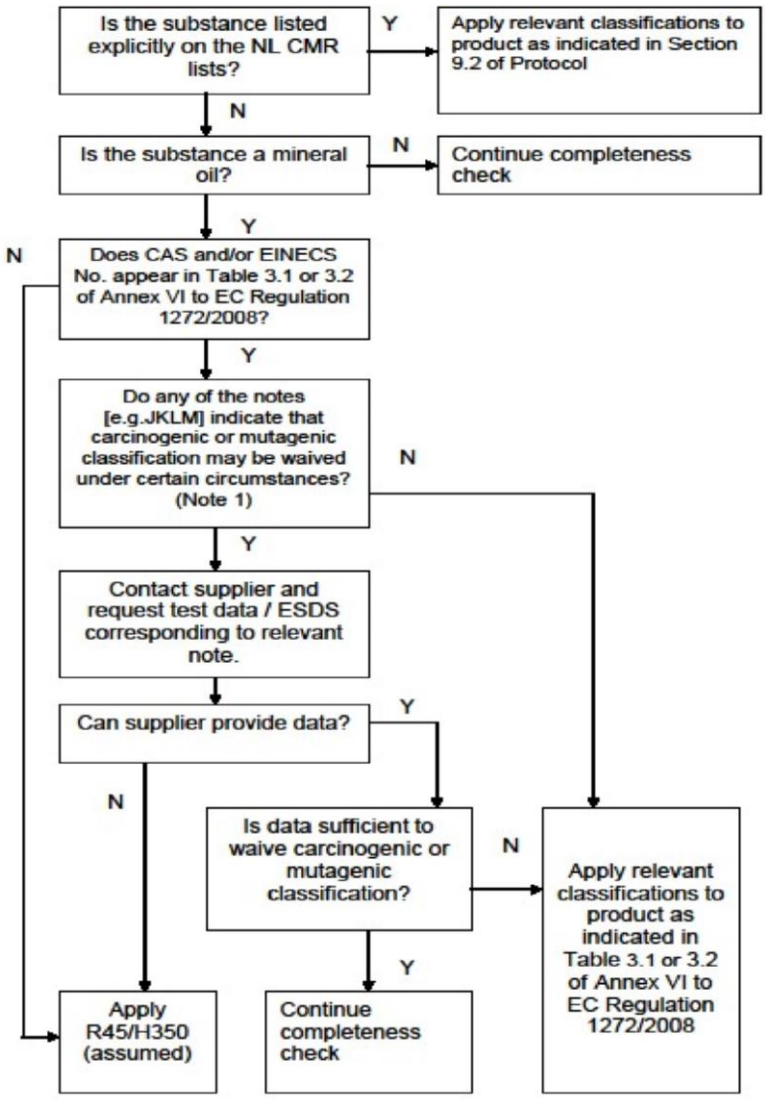


Figure 4 Processing Procedure for CMR Substances. K <0.1% 1,3-butadiene, J <0.1% benzene, M <0.005% benzo[a]pyrene, L <3% DMSO-extract. The meaning of these and other Notes is explained in Part 1 of Annex VI to EC Regulation 1272/2008.

8. 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 2017/01 (as amended by OSPAR Recommendation 2019/04) with the aim of:

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

1. is listed in the OSPAR list of Chemicals for Priority Action; or
2. is on the OSPAR List of Chemicals of Possible Concern (LSPC); or
3. it is, or contains a substance that is on the Authorisation List established pursuant to REACH (Annex XIV), or
4. its offshore use is covered by restrictions under Annex XVII to REACH; or
5. 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;
6. or is inorganic and has a LC50 or EC50 less than 1 mg/l; or
7. 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
8. 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
9. meets two of the following three criteria:
    a) 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)
    b) bioaccumulation: BCF > 100 or log P_{ow} ≥ 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
    c) toxicity: LC50 < 10mg/l or EC50 < 10mg/l; if toxicity values <10 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 Persistent, Bioaccumulative and Toxic (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.

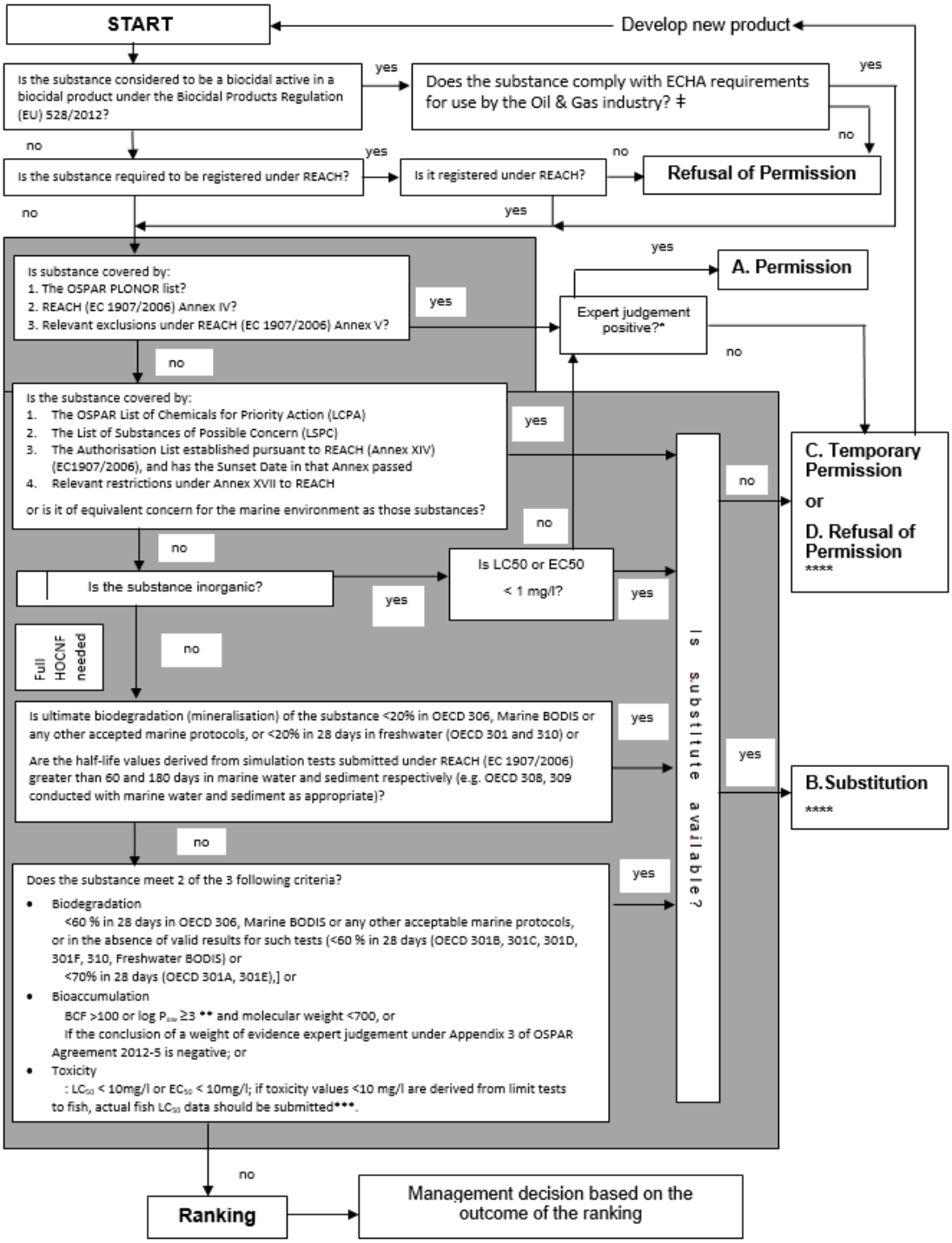


Figure 5 The Harmonised Pre-Screening Scheme (shaded) as Part of the Whole Harmonised Mandatory Control System for Offshore Substances set out in the applicable OSPAR Decision

Explanatory notes to Figure 5:

* In accordance with the precautionary principle, expert judgement on a PLONOR/Annex IV/Annex V substance should take into account sensitive areas, where the discharge of certain amounts of the substance may have unacceptable effects on the receiving environment, or any relevant REACH restrictions.

** 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.

**** CHARM may be used as a decision supporting tool + expert judgement.

ǂ For the purposes of pre-screening, ECHA requirements are considered to be met if the biocidal active substance is included in (and not withdrawn from) the ECHA list of active substances and suppliers in accordance with Article 95 of the BPR, for a Product Type considered to be appropriate for an offshore chemical by the relevant Contracting Party. If required by the Contracting Party, the name of the supplier of the biocidal active substance must also be included, which may differ from that of the chemical supplier submitting the HOCNF in order to register an offshore chemical.

9. 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 OECD 306 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[4] and (in Sections R.4 and R.7a-c of the REACH Chemical Safety Assessment[5]).

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[6].

Toxicity:

Where there are less than or equal to 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)[7].

Bioaccumulation (BCF Tests):

An experimental 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.

[4] ECHA Weight of Evidence Principles. Available at: https://echa.europa.eu/documents/10162/13655/practical_guide_how_to_use_alternatives_en.pdf/148b30c7-c186-463c-a898-522a888a4404 (Accessed 11th October 2022)
[5] REACH Chemical Safety Assessment. Available at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment (Accessed 11th October 2022)
[6] OSPAR Agreement 2012-05, paragraph 10, OECD Series on Testing and Assessment: Ecotoxicity Testing No. 27 Section 4.3.5 Conflicting Results from Screening Tests
[7] OSPAR Agreement 2012-05, paragraph 12, OECD Series on Testing and Assessment: Ecotoxicity Testing No. 27 Section 3.4 Weight of Evidence

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[8].

Bioaccumulation (Log P_{ow}):

Where only LogPow data are available the highest value will take precedence. The relevance of Weight Of Evidence (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)[9].

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. The global approach only applies to the UK national plan and does not apply to HMCS categories.

[8] OSPAR Agreement 2012-05, paragraph 11, OECD Series on Testing and Assessment: Ecotoxicity Testing No. 27 Section 5.4 Conflicting Data and Lack of Data.

[9] OSPAR Agreement 2012-05, paragraph 11, OECD Series on Testing and Assessment: Ecotoxicity Testing No. 27 Section 5.4 Conflicting Data and Lack of Data

10. 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 1.5, CHARM Implementation Network 2017). 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.

10.1. Non-CHARMable 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 4. All submitted toxicity data for the substance are compared with the toxicity ranges in the table, and the range that the worst-case toxicity value falls in provides the ‘Initial Grouping’ (i.e. the test giving the most toxic response) for the substance.

Table 4 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) 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 5. Using the narrative in the second row that applies to the substance the initial Group is adjusted accordingly by the information above it. If the classification should theoretically move beyond Group A or E, the product will be assigned to that particular group.

Table 5 Adjustment of initial OCNS grouping (A-E) is dependent on substance being poorly, moderately or readily biodegradable and if it bioaccumulates.

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 not 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 biodegradable 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, or
- 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).

11. 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. This is then sent to the supplier electronically. The administrator then shreds any hard copy of the HOCNF. For further information regarding the template see Appendix 4.

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 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.

12. Decisions and Agreements

12.1. OSPAR Decisions and Recommendations

Decision 2000/2 on a Harmonised Mandatory Control System for the Use and Discharge of Offshore Chemicals (as amended by OSPAR Decision 2005/1). Available at: http://www.ospar.org/documents?d=32742 (Accessed 11th October 2022).

Decision 2000/3 on the Use of Organic phase Drilling Fluids (OPF) and the Discharge of OPF Contaminated Cuttings. Available at: http://www.ospar.org/documents?d=32321 (Accessed 11th October 2022).

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. Available at: http://www.ospar.org/documents?d=32767 (Accessed 11th October 2022).

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. Available at: http://www.ospar.org/documents?d=32772 (Accessed 11th October 2022).

Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) as amended by OSPAR Recommendation 2014/17, 2019/03 and 2021/08. Available at: http://www.ospar.org/documents?d=33027 (Accessed 11th October 2022).

Recommendation 2017/01 on a OSPAR Recommendation 2017/01 on a Harmonised Pre-screening Scheme for Offshore Chemicals (as amended by OSPAR Recommendation 2019/04). Available at: https://www.ospar.org/documents?d=40981 (Accessed 11th October 2022).

12.2. Other Agreements

OSPAR Guidelines for Completing the Harmonised Offshore Chemical Notification Format (HOCNF) (updated 2021). Available at: https://www.ospar.org/documents?d=33043 (Accessed 11th October 2022).

Common Interpretation on which Chemicals are Covered and not Covered by the Harmonised Mandatory Control System under OSPAR Decision 2000/2. Available at: http://www.ospar.org/documents?d=32731 (Accessed 11th October 2022).

Guidance on the Assessment of the Toxicity of Substances used and discharged offshore under the Harmonised Pre-Screening Scheme for offshore chemicals of OSPAR Recommendation 2017/01, as amended by OSPAR Recommendation 2019/04 (replaces Agreements 2002-04). Available at: https://www.ospar.org/documents?v=46426 (Accessed 11th October 2022).

OSPAR List of Substances Used and Discharged Offshore which Are Considered to Pose Little or No Risk to the Environment (PLONOR) list.doc (updated 2021). Available at: http://www.ospar.org/documents?d=32939 (Accessed 11th October 2022).

13. Glossary

Acronym	Explanation
AT	Applied Technology
AN	Authorisation Note
CAS	Chemical Abstracts Service
CASN	Chemical Abstracts Service Number
Cefas	Centre for Environment, Fisheries and Aquaculture Science
CHARM	Chemical Hazard Assessment and Risk Management model
CHARM	Chemical Hazard Assessment And Risk Management (Version 1.5 2017-CHARM Implementation Network (CIN) (Accessible via the EOSCA web site
BEIS	Department for Business, Energy and Industrial Strategy
BPR	Biocidal Products Regulation
CP	Contracting Party
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Chemical Substances
ELINCS	European List of Notified Chemical Substances
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
IGM	Inspector General of Mines

OCNS	Offshore Chemicals Notification Scheme
OECD	The Organisation for Economic Co-operation and Development
OIC	Offshore Industry Committee
OSPAR	Oslo and Paris commission
LoA	Letter of Access
LCPA	OSPAR List of Chemicals for Priority Action
LSPC	OSPAR List of Substances of Possible Concern
NL	Netherlands
PBT	Persistent, Bioaccumulative, Toxic
PEC	Predicted Exposure Concentration
PNEC	Predicted No Effect Concentration
PLONOR	Poses Little or No Risk to the marine environment
QSAR	Quantitative Structure-Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
SMART	Specific, Measurable, Achievable, Relevant, Time-bound
SSM	State Supervision of Mines in the Netherlands

APPENDICES

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 6.

Table 6 The OCNS Project Team roles and responsibilities matrix with regards to registrations of chemicals

Role/ Responsibility	Chemical Hazard Assessor	Risk Assessor	Project Manager	Database and IT support	Portfolio Lead	Lead Scientific Advisor
Project Management			X			
Customer Liaison			X		X	X
Completeness Check	X	X				
Correctness Check	X	X				
OCNS Office Administration	X	X				
HOCNF Data processing*	X	X				
QC/QA checks		X				X
Advice to Regulator		X	X			X

Simple database interrogations	**X**	**X**				**X**
Complex level database interrogations		**X**				**X**
Technical advice to the team		**X**				**X**
Permit and ES review		**X**				**X**
Web site content maintenance		**X**				
Database backup and restore				**X**		
Database maintenance and technical support				**X**		
Publication of the Definitive Ranked List of Registered Products		**X**				

*Full completeness and correctness check

The Portfolio Lead is responsible for representing customer (BEIS, SSM) interests within Cefas. The Project Manager has responsibility for overall delivery of the project. The Lead Scientific Advisor (Principal Investigator) 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 contact to SSM.

The OCNS Chemical Hazard Assessors and Risk Assessors are responsible for managing the receipt of HOCNFs and entering them in the assessment queue. This process also includes 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. Furthermore, Risk Assessors carry out Quality Control (QC) and Quality Assurance (QA) checks of the hazard assessment and risk assessment outputs. The Risk Assessor who is the designated Data Steward also publishes the Definitive Ranked List of Registered Products.

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

The OCNS mailbox is manned daily by the team and regularly reviewed and maintained.

Equipment

The OCNS Team have secure working methods that ensure team members have access to, individual telephones, individual personal computers (PCs) and access to meeting room facilities when required. 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 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 project 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 project team and AT database support team have access to the data in the OCNS database. The regulator BEIS as well as Marine Scotland who conduct the risk assessment for chemical used offshore in the UK have read only access to limited sections of the database to be able to check the chemical product assessment results. No member of the Cefas OCNS project 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 project 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(s) 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 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 project 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 inbox or mailbox 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 project 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 rebranding the preparation to ensure that the 3rd party company sends the LoA to the Cefas OCNS project team in timely manner.

The Cefas OCNS project 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 5 of OSPAR Agreement 2002-06 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 into 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 1.6b as a surfactant will be assumed to be bioaccumulative irrespective of the results of any OECD 107 or OECD 117 tests (unless experimental BCF test data are supplied that refutes this assumption) and provided its molecular weight is less than 700. 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 Log P_{OW} ≥ 3 or BCF > 100 as potentially bioaccumulative, with only substances having a molecular weight greater than 700 [10] being exempt from this classification. As it is not possible to utilise the OECD 107 and OECD 117 methodologies for determining a Log P_{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 (2007) Bioconcentration: Comparison of methods for assessing potential hazards of offshore chemicals. Chemistry in the Oil Industry X, 5-7 November 2007.
- ECHA Practical Guide – European Chemicals Agency Version 2.0 – July 2016. Available at: https://echa.europa.eu/documents/10162/13655/practical_guide_how_to_use_alternatives_en.pdf/148b30c7-c186-463c-a898-522a888a4404 (Accessed 11th October 2022)

[10] If the molecular weight distribution of a substance indicates that the maximum proportion of molecular weight <700 is below or equal to 10%, the substance will also be assessed as “non-bioaccumulative”.

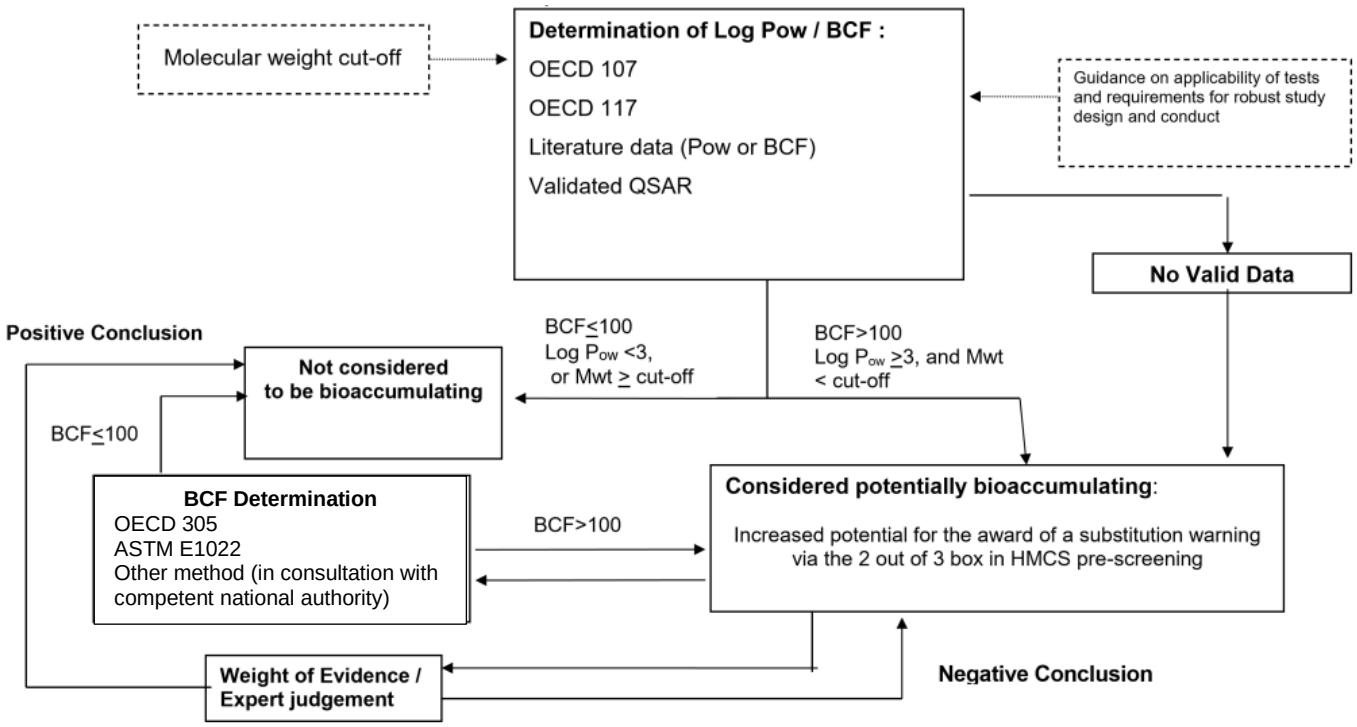


Figure 6 Bioaccumulation Assessment Methodology for HMCS

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: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9 issued by the European Chemicals Agency (ECHA), May 2008, in support of REACH legislation.

Appendix 4: OCNS templates

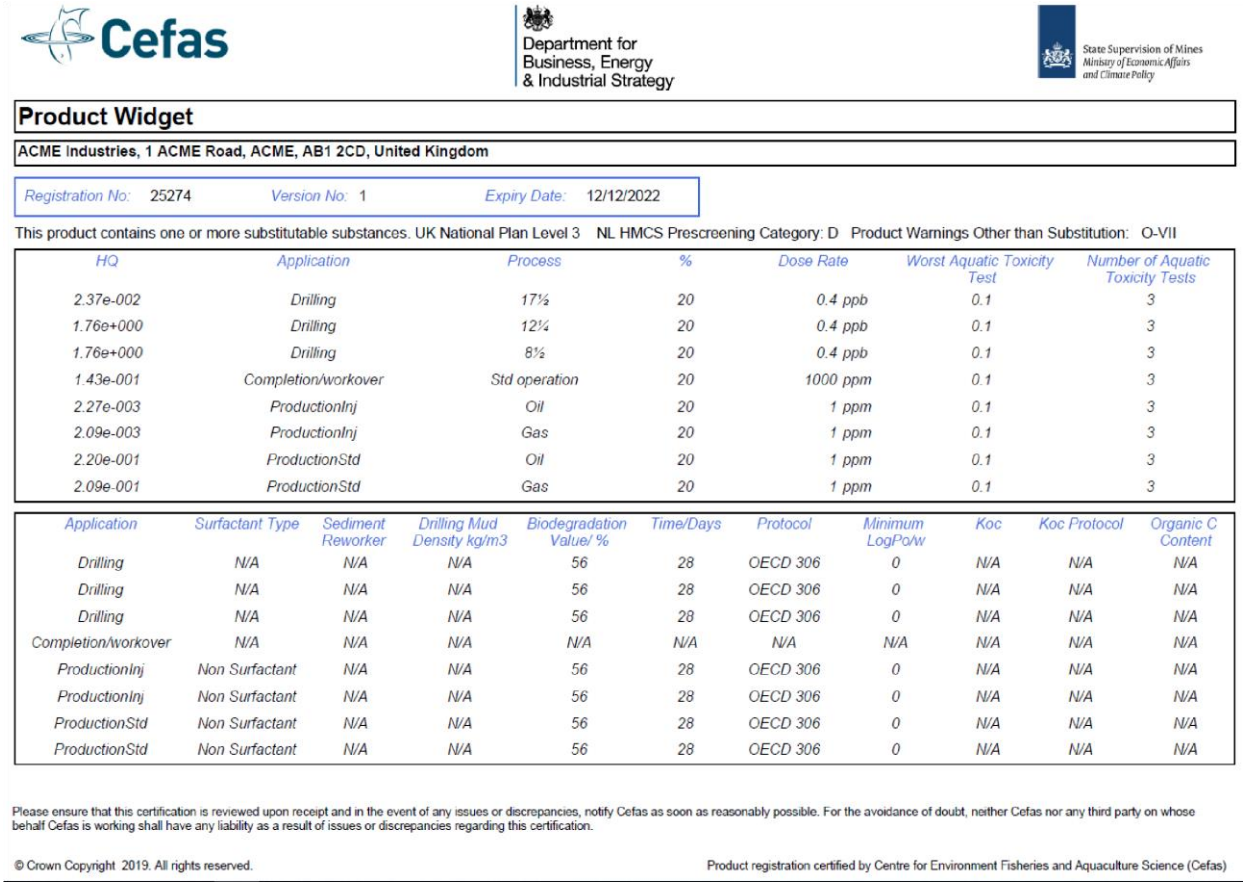
Examples of the OCNS Templates are shown in this appendix. These comprise one template for a dummy product that was assessed using CHARM algorithms (see Section 12), and one for which CHARM is not applicable (a “non-CHARMable” product).

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.co.uk/data-and-publications/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.

Also note 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.



Cefas

Department for Business, Energy & Industrial Strategy

State Supervision of Mines
Ministry of Economic Affairs and Climate Policy

Product Widget

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

Registration No: 25274 Version No: 1 Expiry Date: 12/12/2022

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

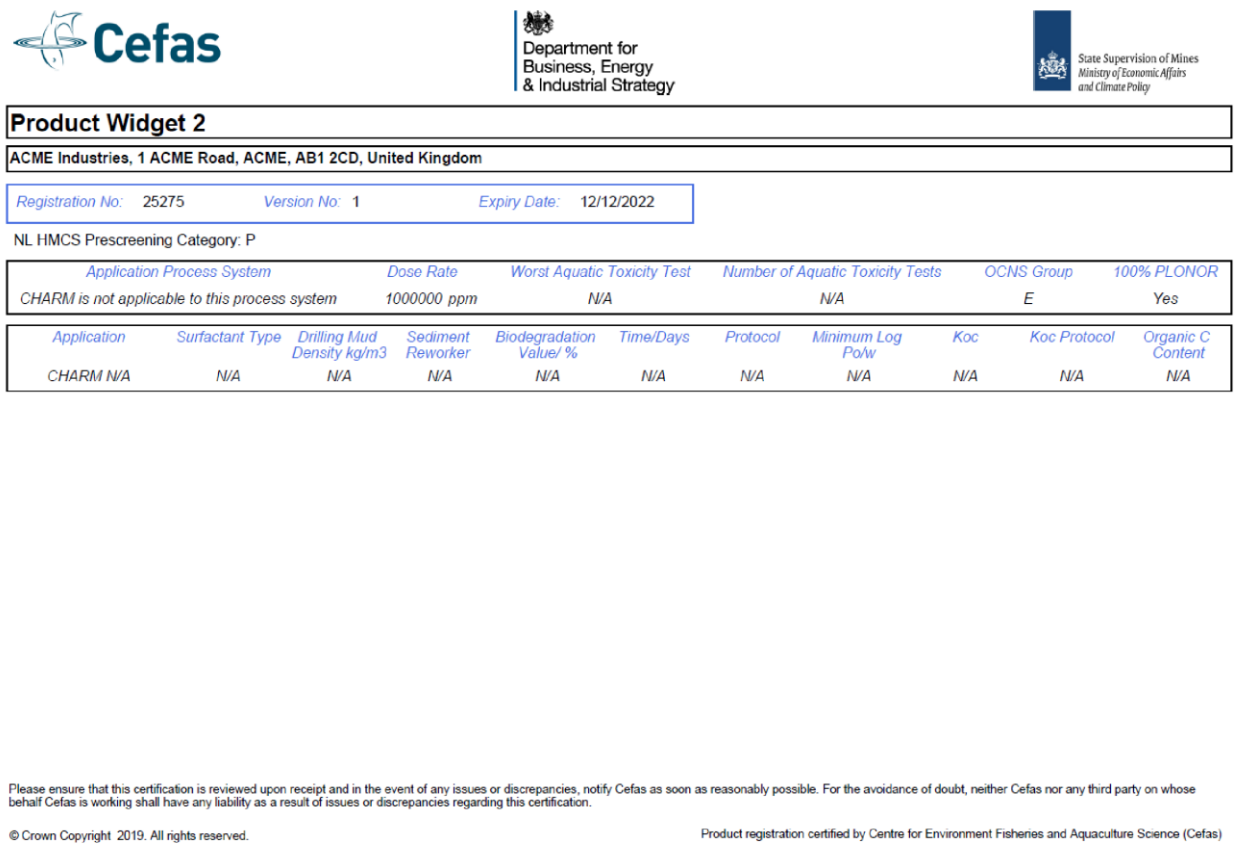
HQ	Application	Process	%	Dose Rate	Worst Aquatic Toxicity Test	Number of Aquatic Toxicity Tests
2.37e-002	Drilling	17½	20	0.4 ppb	0.1	3
1.76e+000	Drilling	12¼	20	0.4 ppb	0.1	3
1.76e+000	Drilling	8½	20	0.4 ppb	0.1	3
1.43e-001	Completion/workover	Std operation	20	1000 ppm	0.1	3
2.27e-003	ProductionInj	Oil	20	1 ppm	0.1	3
2.09e-003	ProductionInj	Gas	20	1 ppm	0.1	3
2.20e-001	ProductionStd	Oil	20	1 ppm	0.1	3
2.09e-001	ProductionStd	Gas	20	1 ppm	0.1	3

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

Please ensure that this certification is reviewed upon receipt and in the event of any issues or discrepancies, notify Cefas as soon as reasonably possible. For the avoidance of doubt, neither Cefas nor any third party on whose behalf Cefas is working shall have any liability as a result of issues or discrepancies regarding this certification.

Product registration certified by Centre for Environment Fisheries and Aquaculture Science (Cefas)

Figure 7 Template for product assessed using CHARM algorithms



Cefas

Department for Business, Energy & Industrial Strategy

State Supervision of Mines
Ministry of Economic Affairs and Climate Policy

Product Widget 2

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

Registration No: 25275 *Version No:* 1 *Expiry Date:* 12/12/2022

NL HMCS Prescreening Category: P

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

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

Please ensure that this certification is reviewed upon receipt and in the event of any issues or discrepancies, notify Cefas as soon as reasonably possible. For the avoidance of doubt, neither Cefas nor any third party on whose behalf Cefas is working shall have any liability as a result of issues or discrepancies regarding this certification.

Product registration certified by Centre for Environment Fisheries and Aquaculture Science (Cefas)

Figure 8 Template for product for which CHARM is not applicable

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 as for routine registrations 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.

Centre for Environment Fisheries & Aquaculture Science

Cefas

World Class Science for the Marine and Freshwater Environment

We are the government's marine and freshwater science experts. We help keep our seas, oceans and rivers healthy and productive and our seafood safe and sustainable by providing data and advice to the UK Government and our overseas partners. We are passionate about what we do because our work helps tackle the serious global problems of climate change, marine litter, over-fishing and pollution in support of the UK's commitments to a better future (for example the UN Sustainable Development Goals and Defra's 25-year Environment Plan).

We work in partnership with our colleagues in Defra and across UK government, and with international governments, business, maritime and fishing industry, non-governmental organisations, research institutes, universities, civil society and schools to collate and share knowledge. Together we can understand and value our seas to secure a sustainable blue future for us all and help create a greater place for living.

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