Centre for Environment Fisheries & Aquaculture Science

Cefas

Netherlands (NL) PROTOCOL - Standard Procedure for Offshore Chemical Hazard Assessment

Part 2: Elements Specific to the Netherlands

OCNS 011

Issue 13

Authors: Sylvia Blake, Nicola Geary, Malgorzata Wilczynska

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Submitted to:	Judith Van Gorp - SSM
Date submitted:	21/11/2022
Project Manager:	Alex Papachlimitzou
Report compiled by:	Nicola Geary, Malgorzata Wilczynska
Quality control by:	Sylvia Blake
Approved by and date:	Sylvia Blake 21/11/2022
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Version control history

Version	Date Issued	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 sections included in Part 2 to cover GLP, Assessment of Data Quality and the collection of REACH data.
3	01/7/11	Updated with information from the latest OSPAR Protocols.
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. Disclaimer added. Paragraph deleted from Section 7 and grammatical changes

		to Section 8. Additional clause added to Appendix 3. New section added covering biocide checks.
7	14/01/13	Minor changes
8	06/01/14	Minor changes to links within document.
9	16/04/15	REACH Annex XIV interpretation clarified. Section 9 deleted
10	01/01/17	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	01/01/19	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 & Cefas procedures. References to the Random Report Audit removed. Product Audit Report template deleted from Part 2.
13	21/11/22	Updated in line with latest OSPAR documents & Cefas procedures. Updated Figure 1 and 2 format

Contents

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.

1. Introduction

The procedure through which offshore chemicals are registered with Cefas is described in the Offshore Chemical Notification Scheme (OCNS) Protocol, Part 1: Core Elements (document reference OCNS 011 Part 1). In this Part 2 of NL Protocol, additional elements of the registration process are described that are specifically required by the State Supervision of Mines (SSM) in the light of the submissions for granting permits to use and discharge offshore chemicals in the Netherlands (NL) offshore waters.

2. Scope

Registration of offshore chemicals in relation with submissions for permits to use and discharge of offshore chemicals (as defined by OSPAR Agreement 2002-06 as amended to include jacking grease) in NL offshore waters.

3. Background

A full account of the development of the Offshore Chemicals Notification Scheme (OCNS) is presented in the OCNS Protocol, Part 1: Common Elements (document reference OCNS 011 Part 1).

4. Netherlands Pre-Screening Categories

Each substance will be awarded a NL Harmonised Mandatory Control Scheme (HMCS) Substance level category based on the scheme shown in the Table 1 below:

A more detailed description of this process is shown in the flow diagram in Figure 1. It should be noted that:

- Water is assigned the HMCS category W.
- REACH Annex V substances will only be assigned HMCS Category P if their hazards can be shown not to require the provision of PBT (Persistent, Biodegradation and Toxicity) test data. Further guidance is provided in paragraph 34 of OSPAR Agreement 2012-05 (OSPAR Guidelines for Completing the Harmonised Offshore Chemical Notification Format (HOCNF) as updated in 2021).

The product level NL HMCS category for each offshore chemical will be derived from all the substance level NL HMCS categories that are relevant to that product. The system for assigning the product level category is shown in the flow diagram in Figure 2.

Table 1 NL HMCS Substance Level Category Criteria.

	Criteria	Substance level NL HMCS category
4.1	Substance: • On PLONOR list, • Listed under REACH Annex IV or Complies with relevant exclusions under REACH (EC 1907/2006) Annex V*	P
4.2	Substance on List of Chemicals for Priority Action, List of Chemicals of Possible Concern, the Authorisation List (Annex XIV) or relevant restrictions under Annex XVII to REACH**	A
4.3	Inorganic substances with LC50 less than 1mg/l	B
4.4	Inorganic substances with LC50 greater or equal to 1mg/l	E
4.5	Organic substances with biodegradation less than 20% or REACH half-lives greater than 60 days (marine water)/180 days (sediment)	C
4.6	Organic substances meeting 2 out of 3 PBT 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} ≥ 3 and molecular weight <700; or if the conclusion of a weight of evidence judgement under Appendix 3 of OSPAR Agreement 2012-5 is negative; or	D

	(iii) 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;	
4.7	Other organic substances	R

*See paragraph 34 of OSPAR Agreement 2012-05.

**Applicable if its offshore use is covered by restrictions under Annex XVII to REACH

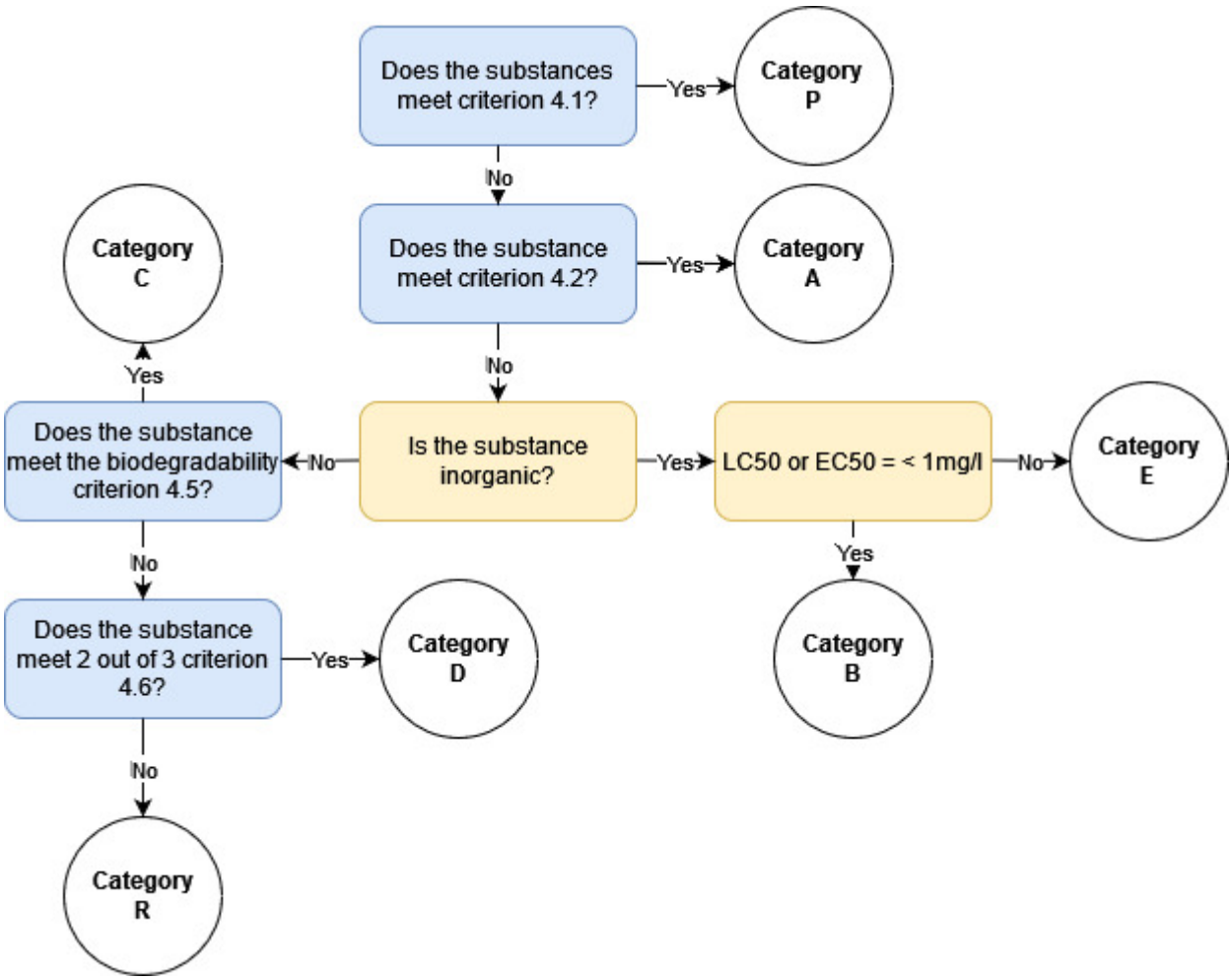

Figure 1 Substance level HMCS category

Note: The meanings of criteria 4.1 to 4.6 are provided in the preceding section.

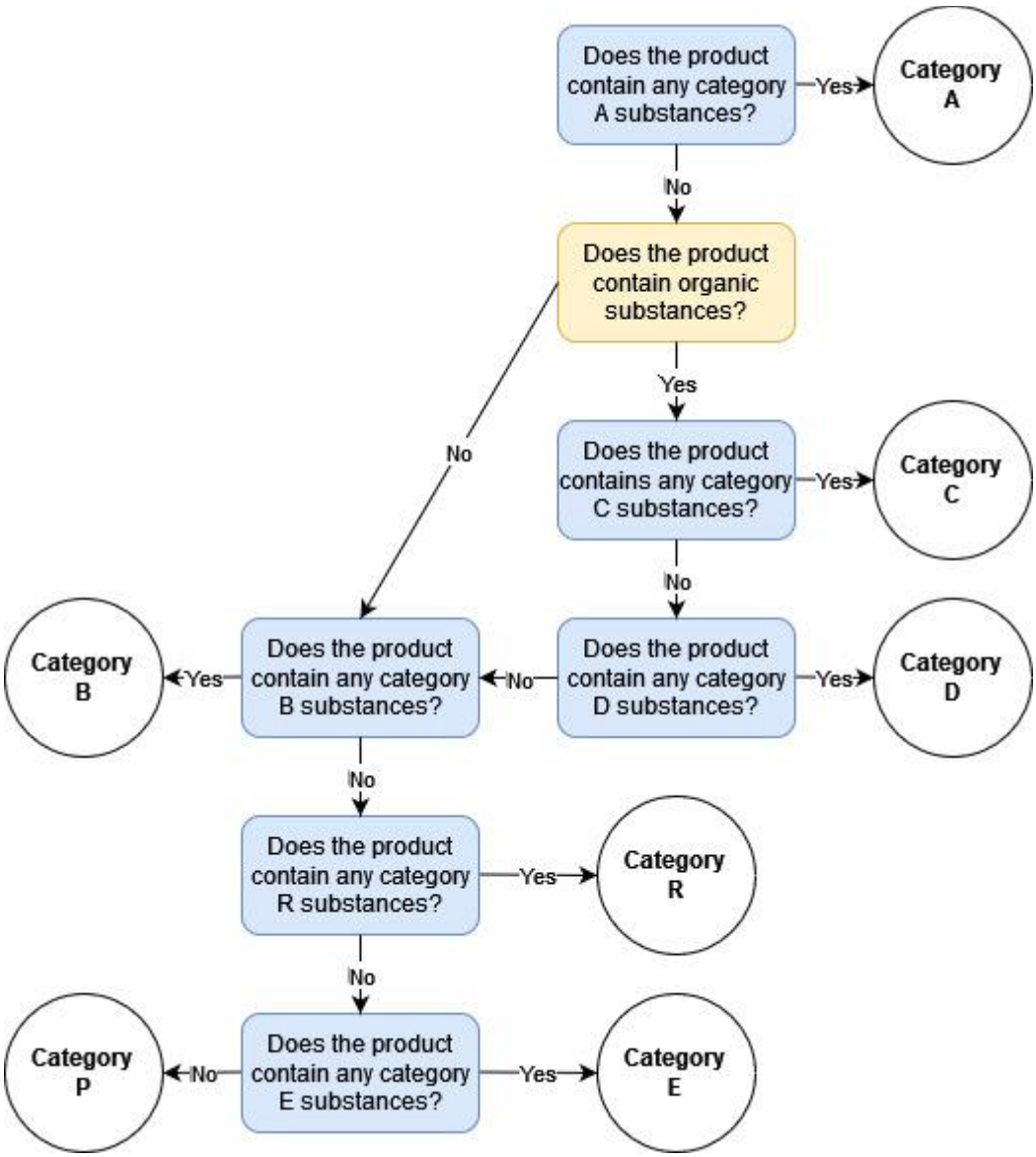

Figure 2 Product Level HMCS category

5. Netherlands Ranking System

The NL ranking list is prepared in accordance with Appendix 1 Chapter III paragraph 7 of the OSPAR Decision 2000/2 (as amended by OSPAR Decision 2005/1) i.e., ranking of the offshore chemicals will be by the CHARM (Chemical Hazard Assessment and Risk Management) hazard quotient (HQ), calculated using the standardised reference oil/gas platforms and dilution factors defined in CHARM V1.5. The results of these calculations, together with the uncertainty factors identified by CHARM, are to be considered by authorities when establishing:

1. The NL ranked list of offshore chemicals, which is:
    a. subject to regular review and evaluation by the NL competent authorities, taking into account the progress within the OSPAR strategy with regard to Hazardous Substances;
    b. grouped in function categories according to the categorisation in the annual reporting system for the use and discharge of chemicals from offshore installations
2. The appropriate regulatory action in accordance with the provisions stipulated in paragraphs 3.1 to 3.4 of the OSPAR Decision 2000/2 (as amended by OSPAR Decision 2005/1).

The ranking order is based on the risk management policy adopted by the Netherlands government, which is described in Appendix 1 of NL Protocol Part 2: Elements specific.

6. Mechanism to establish Ranking List

The Netherlands list of Ranked Chemicals should contain only offshore chemicals that do not contain any substitutable substances according to the OSPAR Pre-screening criteria described in the OSPAR Recommendation 2017/1 (as amended by OSPAR Recommendation 2019/04) i.e. classified as NL HMCS Product level category R (See Section 4) and for which a suitable CHARM algorithm exists (Further details of CHARM calculations are given in the OCNS Protocol, Part 1: Common Elements (document reference OCNS 011 Part 1), Section 12. The largest HQ calculated for the 3 drilling sections (17.5 / 12.25 / 8.5-inch diameter of the bore hole) in the drilling algorithm will be used for the purpose of ranking drilling products.

The ranked list will be divided into the different function categories, described in the Appendix 2 of the OSPAR Agreement 2012-05 on completing the HOCNF guidelines, as updated in 2021 (or as mentioned in § 1.4 of the HOCNF format). Consequently, the Netherlands competent authorities shall establish a list for each function category, showing the ranking order from high HQ values to low HQ values.

Offshore chemicals on each specific function list having a HQ value calculated according to CHARM of more than 3 are considered as unacceptable while those with HQ values greater than 1 and not more than 3 are ranked as acceptable / high concern. Offshore chemicals having values greater than 0.03 and not more than 1 are ranked acceptable / little concern while those with HQ values equal or less than 0.03 are ranked negligible risk level / no concern.

7. Good Laboratory Practice

It is the responsibility of the chemical supplier to ensure that all commissioned tests comply with the requirements of the relevant REACH registration or are in compliance with the European Chemicals Agency (ECHA) 'Guidance on information requirements and Chemical Safety Assessment,' Chapter R4: Evaluation of available information, December 2011 (as amended)". The latter document refers to Good Laboratory Practice (GLP), as laid down in the OECD principles of GLP, first issue 26th of July 1983 and subsequently as EU Directive 87/18/EEC and 2004/10/EC.

Good Laboratory Practice embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported, and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.

Guidance on the requirements of GLP is provided by the GLP Monitoring Authority.

8. Test substance characterisation

The OSPAR Guidelines for Toxicity Testing of Substances and Preparations Used and Discharged Offshore (OSPAR Agreement 2021-07) states that the supplier must present the testing laboratory with accurate scientific name and full description/characterisation of the chemical to be tested.

In addition, the OECD Guidelines for Testing of Chemicals, like the OECD 306 for biodegradability in seawater or OECD 117 for determining the Partition Coefficient (n-octanol/water), specify minimum requirements for the identification of the test material, which are also required by the test protocol to be included in the final test report.

In addition, it is a requirement of GLP that each test and reference item should be appropriately identified (e.g., code, chemical abstracts service registry number (CAS number), name, biological parameters etc.). Furthermore, for each regulatory study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known. This information should be clearly stated in the final report for a study, along with evidence that the identity of the test substance was confirmed by the test laboratory.

9. Assessment of Data Quality

The quality of the data used in support of an application for registration will, under certain circumstances, be subjected to detailed scrutiny. This will involve the examination of test reports.

A test report is recalled if, when compared with data for similar substances*, a test result reported on the HOCNF for a substance would lead to a change in the status of the substance with respect to any of the pre-screening criteria listed in Section 10 of Part 1 of this Protocol (i.e., items f to i from that section).

Any report that is requested must be checked in order to verify that it is either in compliance with the requirements of the relevant REACH registration, or in compliance with the European Chemicals Agency (ECHA) 'Guidance on information requirements and Chemical Safety Assessment,' Chapter R4: Evaluation of available information, May 2011 (as amended).

In parallel, it must be established that the equivalent test reports relating to similar substances* also meet these criteria.

NOTE: Report quality will be assessed using the approach of the National Institute for Public Health and the Environment (RIVM) in the Netherlands, who use the Klimisch's scoring system (Klimisch et al (1997)) for reliability of data (see P.G.P.C. Zweers and T.G. Vermeire, "Data: Needs, Availability, Sources and Evaluation", Chapter 8 in 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). Using this scheme, only well documented tests reports generated according to internationally accepted testing guidelines or in which the test parameters are documented, are scored "reliable without restrictions" and accepted for HMCS registration.

If a test report meets the criteria, the data will be considered valid.

If any test report fails to satisfy the criteria, the supplier will be notified, and:

a) Where the test report is being used in support of an application for registration of a new chemical, the application will be suspended until new data has been submitted by the supplier that meets the criteria, or

b) Where the test report is being used in support of an existing registration, the supplier will be expected to submit new data that meets the criteria. Temporary certifications will be issued to current products to allow suppliers time to do this.

*A similar substance is one that, based on expert judgment (carried out in accordance with REACH guidance), and all available data, is expected to produce a similar test result to the substance in question.

Appendices

Appendix 1 Premises for risk management policy applied in the Netherlands

The NL risk policy is applicable not only for substances used in offshore chemicals (i.e., meeting the Ranking Box Pre-Screening Criteria in OSPAR Recommendation 2017/01 (as amended by OSPAR Recommendation 2019/04) but also for all substances used in other sectors of the industry. The following text however only addresses the offshore chemicals which meet the OSPAR Pre-Screening criteria for Ranking.

Risk management policy in the Netherlands is based on the assessment of the potential impact of substances; rather than preparations on ecosystems. The reason for this is the lack of scientific knowledge with regard to physical - chemical interactions of substances, when a mixture of substances is discharged into an ecosystem (e.g., The North Sea). Safety factors are applied to take into account these interactions (i.e., a precautionary approach). Therefore, this risk policy does not address the risk of discharges of offshore chemicals, consisting of more than one substance.

Maximum Permissible Risk level / Negligible Risk Level

According to the Netherlands' policy the PEC (Predicted Exposure Concentration) / PNEC (Predictive No Effect Concentration) ratio of one is defined to be the maximum permissible risk level (MTR) while the negligible risk level. (VR) is defined as 0.01 x MTR. The long-term objective of the Netherlands' policy for the North Sea is never to exceed the negligible risk level. Consequently, the generic risk quotient (HQ) determined by the CHARM model at 500 m for discharges of chemicals from oil & gas platforms on the NL North Sea should not exceed the negligible risk level. Due to the uncertainty in the CHARM model, the maximum permissible risk level or MTR is defined to be MTRCHARM: = 3 and therefore VRCHARM: = 0.03.

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OGL

Pakefield Road, Lowestoft, Suffolk, NR33 0HT

The Nothe, Barrack Road, Weymouth DT4 8UB

www.cefas.co.uk | +44 (0) 1502 562244

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