Standard Procedure

(Issue Ten)

NL PROTOCOL

PART 2: ELEMENTS SPECIFIC TO THE NETHERLANDS

OCNS 011

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History of Procedure

Issue	Date Issued	Changes
1	01/05/07	New procedure, titled “OCNS PROTOCOL MAY 2007 NL007-0105“
2	15/04/09	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	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.
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DISCLAIMER

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

1 Introduction

The procedure through which offshore chemicals are registered with Cefas is described in the OCNS Protocol, Part 1: Core Elements (document reference OCNS 011 Part 1. In this addendum to that protocol, additional elements of the registration process are described that are specifically required by the State Supervision of Mines in the light of the submissions for granting permits to use and discharge offshore chemicals in the Netherlands 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 2002-6, 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 HMCS Substance level category based on the scheme shown in the table 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 E.
- REACH Annex V substances will only be assigned HMCS Category P if their hazards can be shown not to require the provision of PBT test data. Further guidance is provided in paragraph 33 of OSPAR Guidelines for Completing the Harmonised Offshore Chemical Notification Format.doc
- 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

	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 Candidate List of Substances of Very High Concern for Authorisation 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 $P_{ow} \geq 3$ 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 (iii) toxicity: LC_{50} < 10mg/l or EC_{50} < 10mg/l; if toxicity values <10 mg/l are derived from limit tests to fish, actual fish LC_{50} data should be submitted;	D
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.

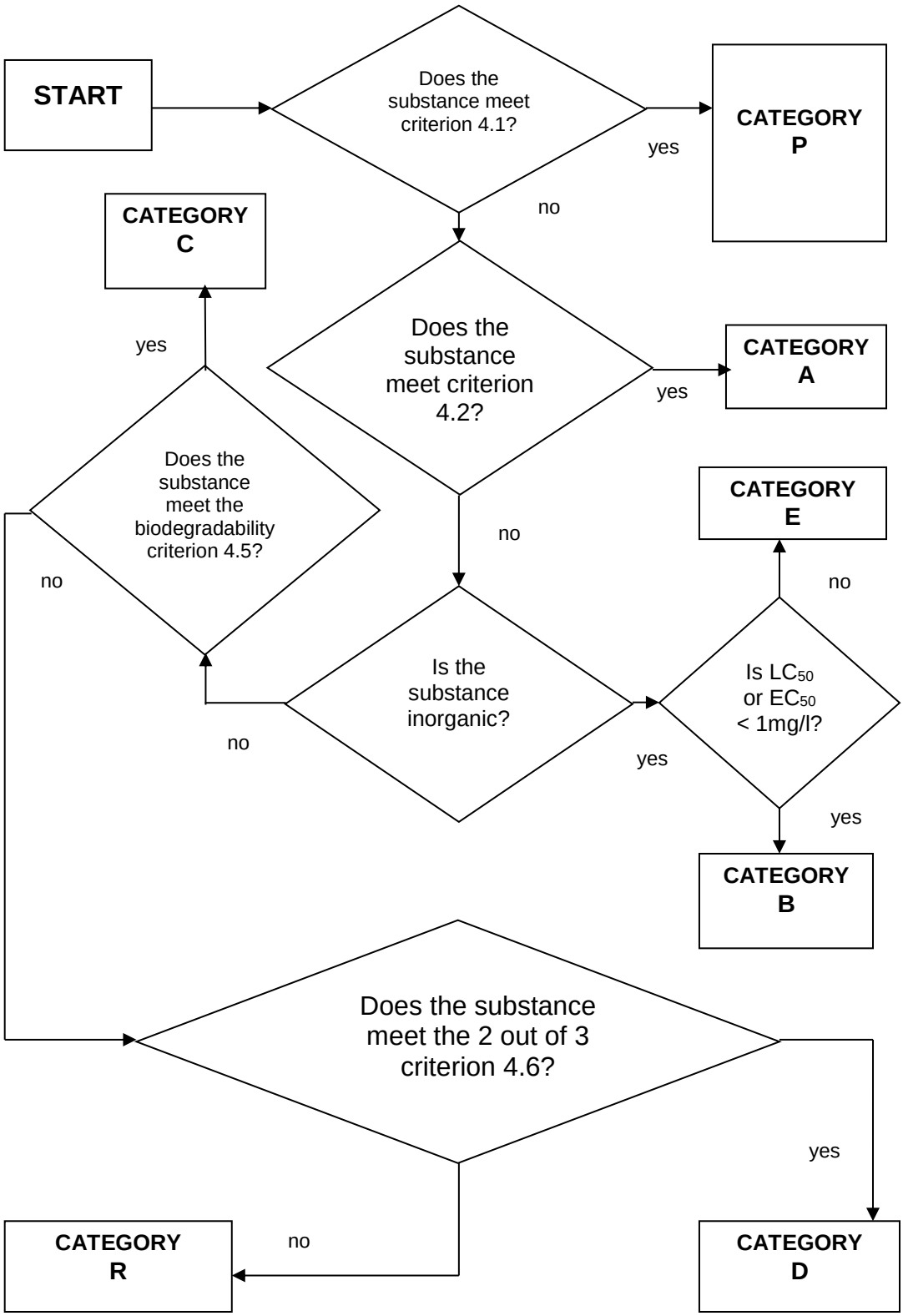
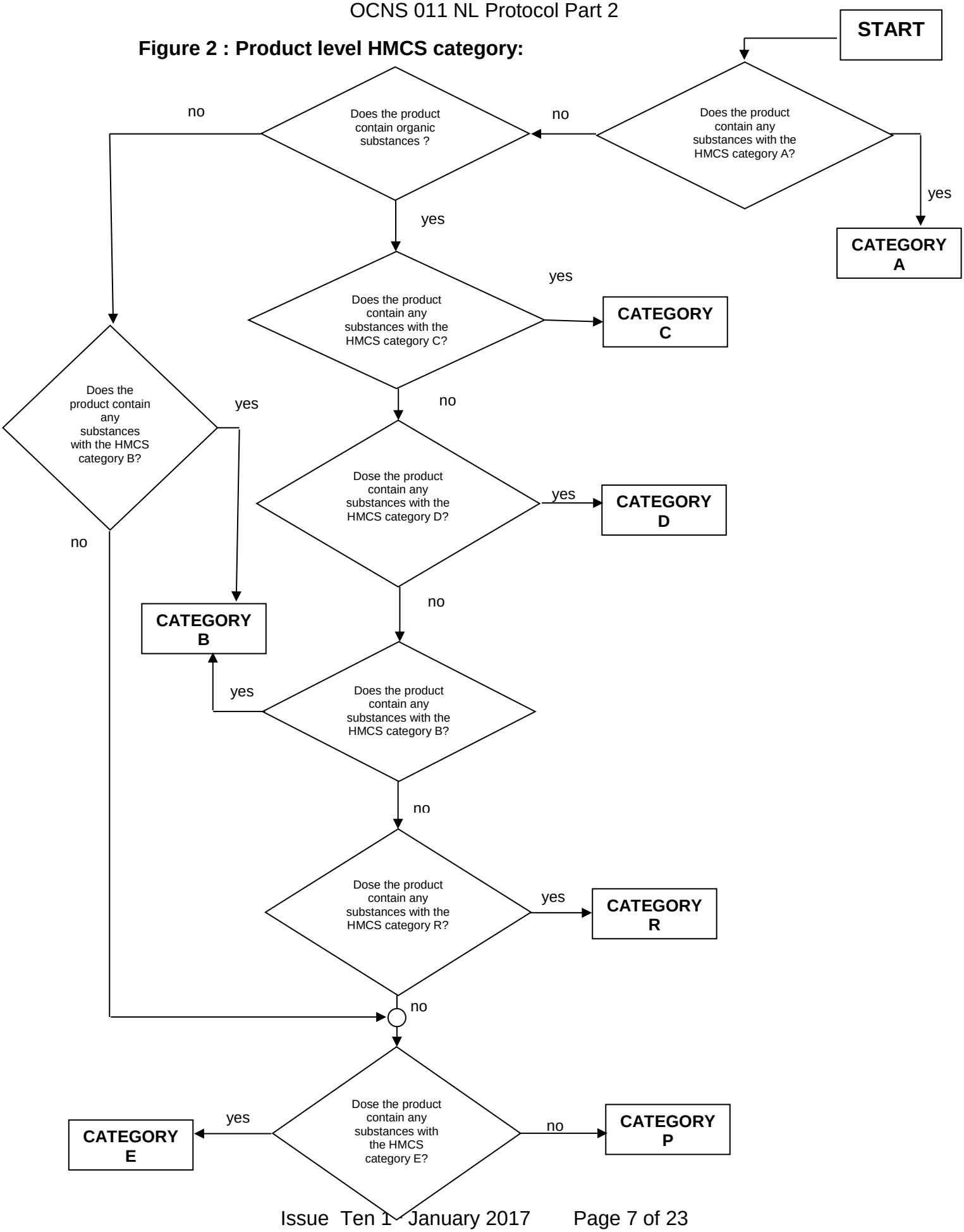


Figure 2 : Product level HMCS category:



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 i.e. ranking of the offshore chemicals will be by the CHARM hazard quotient (HQ), calculated using the standardised reference oil/gas platforms and dilution factors defined in CHARM V1.4. The results of these calculations, together with the uncertainty factors identified by CHARM, are to be taken into account 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. and the appropriate regulatory action in accordance with the provisions stipulated in paragraphs 3.1 to 3.4 of the OSPAR Decision 2000/2.

The ranking order is based on the risk management policy adopted by the Netherlands government, which is described in Appendix 2 of this protocol.

6 Mechanism to establish Ranking Lists

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 2016/04 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 (or as mentioned in § 1.4 of the HOCNF format). Consequently the NL 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 be 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 be in compliance with the European Chemicals Agency (ECHA) 'Guidance on information requirements and Chemical Safety Assessment', Chapter R4: Evaluation of available information, May 2008 (as amended)". The latter document makes reference 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.

The OSPAR Guidelines for Toxicity Testing of Substances and Preparations Used and Discharged Offshore (Reference number: 2005-12) states that the supplier should present the testing laboratory with data on the physical properties of the substance / preparation which is 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.

Tests carried out in the past which are not of good quality and in compliance with the principles of Good Laboratory Practice are subject to a time scheme to update the quality of the tests. This time scheme is derived from REACH and is based on the REACH registration deadlines. This is because REACH specifies only tests of good quality should be in hazard and risk assessment, (e.g. the Klimisch scoring system, referenced in Section 8).

8 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 e to h from that section).

It is noted that reports may, in addition, be called in as a part of the Random Report Audit (see Section 10).

Any report that is recalled 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 2008 (as amended).

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

> *NOTE: The criteria to be used to assess "sufficient quality" depend upon the REACH registration deadline for the relevant substance (see Section 7). Prior to the deadline, quality will be assessed by Cefas using expert judgment. Subsequently, assessment will be conducted in line with 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.*
>
> *In addition, beyond the relevant REACH deadline, the application of the Global Approach (see Part 1, Section 11 of this protocol) will be reviewed in strict adherence to OECD 27, and all test data thereby cited must comply with the quality requirements stated above.*

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 or recertification of an existing one, 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, within a timescale that is in line with that of the REACH registration of the substance.

*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.

9

This section has been intentionally left blank.

10 Random Report Audit

A maximum of 10 products will be selected each year for their base datasets to be audited against GLP, test protocol requirements and HOCNF submitted. This audit will be conducted on all test reports for all substances in the selected products. The outline for the product audit report is given in Appendix 1.

An annual summary of all audited reports will be prepared and submitted to SSM and NOGEPA by end of the second full working week of December in the same year as the audit was conducted. The summary report will address any inadequacies found in the reports, and include the following statistics:

- Number of reports received
- Required reports that were not received (%)
- Reports that could not be unambiguously linked to the HOCNF (%)
- Executing laboratories that do not match the HOCNF (%)
- Test compounds that could not be unambiguously linked to the HOCNF (%)
- No GLP statement present (%)
- Protocols not as required (%)
- Serious anomalies in determination of end points (%)
- Minor anomalies in determination of end points (%)
- Cases of data not included (%)
- Cases of data transferred incorrectly (%)
- Total number of reports required

11 Biocidal Products legislation elements to be checked by Cefas

As part of the registration process, Cefas will also undertake enquiries into compliance with EU Biocidal Products legislation. For relevant substances, these enquiries will comprise:

- Is this substance added to function as a biocide?
- If no, please indicate function of substance
- If yes, please indicate the relevant Product Type (PT) for which it has been registered, or describe the application of the biocidal substance

Appendix 1 Product Audit Report Format

2XXX Random Sampling – Report

Product:

Supplier:

Date on HOCNF:

Check performed on:

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This report is intended for internal use at SSM only.

Contents

Overview of the received reports vs. reports in HOCNF

Composition of the product according the HOCNF:

Component no.	Component	CAS no.	EINECS/ELINCs no.	PLONOR (Y/N)
1.				
2.				
3.				
4.				
5.				
6.				

Number of reports from which the information is used in the HOCNF:

Number of reports received:

Reports received by [method] on the [date] from [contact].

Report no.	Component no.	Test	Report received	Report in HOCNF	Remarks
1					
2					
3.					
4.					
5.					
6					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					
16.					
17.					
18.					
19.					

Report no.	Laboratory in test report	Laboratory in HOCNF	Remarks
1			
2			
3			
4			
5			
6			

Substances tested vs. substances in the HOCNF

Report no.	Substance in HOCNF	Substance tested	Remarks
1			
2			
3			
4			
5			
6			

GLP procedures

Report no.	**GLP signature (Y/N)**		**Remarks**
	SD	QA	
1			
2			
3			
4			
5			
6			

Application of test protocols

Report no.	Protocol as required (Y/N)	Protocol according to HOCNF	Protocol used in test report	Remarks
1				
2				
3				
4				
5				
6				

Determination of endpoints from the test results

Report no.	Remarks
1	
2	
3	
4	
5	
6	

Transfer of parameters from the test reports onto the HOCNF

Report no.	All data included? (Y/N)	Data included correctly? (Y/N)	Remarks
1			
2			
3			
4			
5			
6			

APPENDIX 2 Premises for risk management policy applied in the Netherlands

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 2016/04) 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 the Netherlands' policy the PEC / PNEC ratio of one is defined to be the maximum permissible risk level (MTR) while the negligible risk level. (VR) is defined as 0,01xMTR. 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.

Appendix 3: Procedure for Amending the Protocol

This procedure covers the process to be followed in the event that changes to the Netherlands Protocol result in changes in the process and/or charge which affect the Schedule of work between Cefas and NOGEPA.

1. When SSM become aware that a change will be required to the protocol SSM shall consult NOGEPA as soon as possible (i.e. in advance of changes to protocol being implemented).

2. SSM shall instruct Cefas to make an impact assessment on process and work and prices.

3. Cefas to communicate outcome of assessment to both SSM and NOGEPA.

4. SSM and NOGEPA shall consult with each other on the assessment and agree an implementation plan for the change to the protocol. If necessary, discussions between SSM and NOGEPA will continue (with further input from Cefas when requested) until agreement is reached. In the event that SSM and NOGEPA do not agree Cefas shall continue to provide the services under the existing protocol unless the legal implications of doing so dictate otherwise. In this event Cefas will cease work until the issue is resolved. Stopping work in such circumstances Cefas shall not be considered to be in breach of contract.

5. Once the implementation plan has been agreed SSM shall instruct Cefas to update the protocol. Cefas shall draft the amended protocol and circulate it to SSM and NOGEPA prior to implementation.

6. Where the change to the protocol results in a required change to the schedule of work and/ or prices an amendment to the Contract between NOGEPA and Cefas shall be agreed and signed prior to implementation of the changed protocol.

7. Cefas shall not implement changes to the protocol until the amended protocol and contract amendment have been agreed between the parties (i.e. points 5 and 6 above)

8. The procedure outlined above can be waived when changes are required that are a) minor and b) do not affect the meaning of the document (for example, the updating of internet links). Where such a change is made, it will be recorded in the History of Procedure section as a minor change, and Cefas will inform SSM and NOGEPA when this occurs.