



Standard Procedure

(Issue two)

NL PROTOCOL


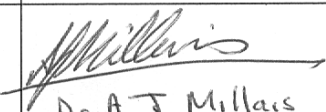
PART 2: ELEMENTS SPECIFIC TO THE NETHERLANDS

ORR 011

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Issue and Validation

Production summary

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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.
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1 Purpose

The procedure through which offshore chemicals are registered with Cefas is described in the OCNS Protocol, Part 1: Common Elements (document reference SEP 2008 NL008-0930). 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 SEP 2008 NL008-0930).

4 Netherlands Pre-Screening Categories

Each substance will be awarded a NL HMCS Substance level category based on the following scheme:

Criteria	Substance level NL HMCS category
Substance on list of Chemicals for priority action	A
Substance on PLONOR list	P
Inorganic substances with LC50 less than 1mg/l	B
Inorganic substances with LC50 greater or equal to 1mg/l	E
Organic substances with biodegradation less than 20%	C
Organic substances meeting 2 out of 3 PBT criteria	D
Other organic substances	R

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

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- Water is assigned the HMCS category E.
- Hydraulic fluids on the Netherlands TR3 list (See [SSM Internet](#)) are automatically awarded a product HMCS category of X, unless they have been registered by Cefas.
- 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

Figure 1: Substance level HMCS category

Note Water is assigned HMCS category E. TR3 list products are automatically awarded a product HMCS category of X, unless product already registered and having a complete and correct HOCNF, i.e. CEFAS registration number and template issued. This scheme applies to all substances in the offshore chemical:

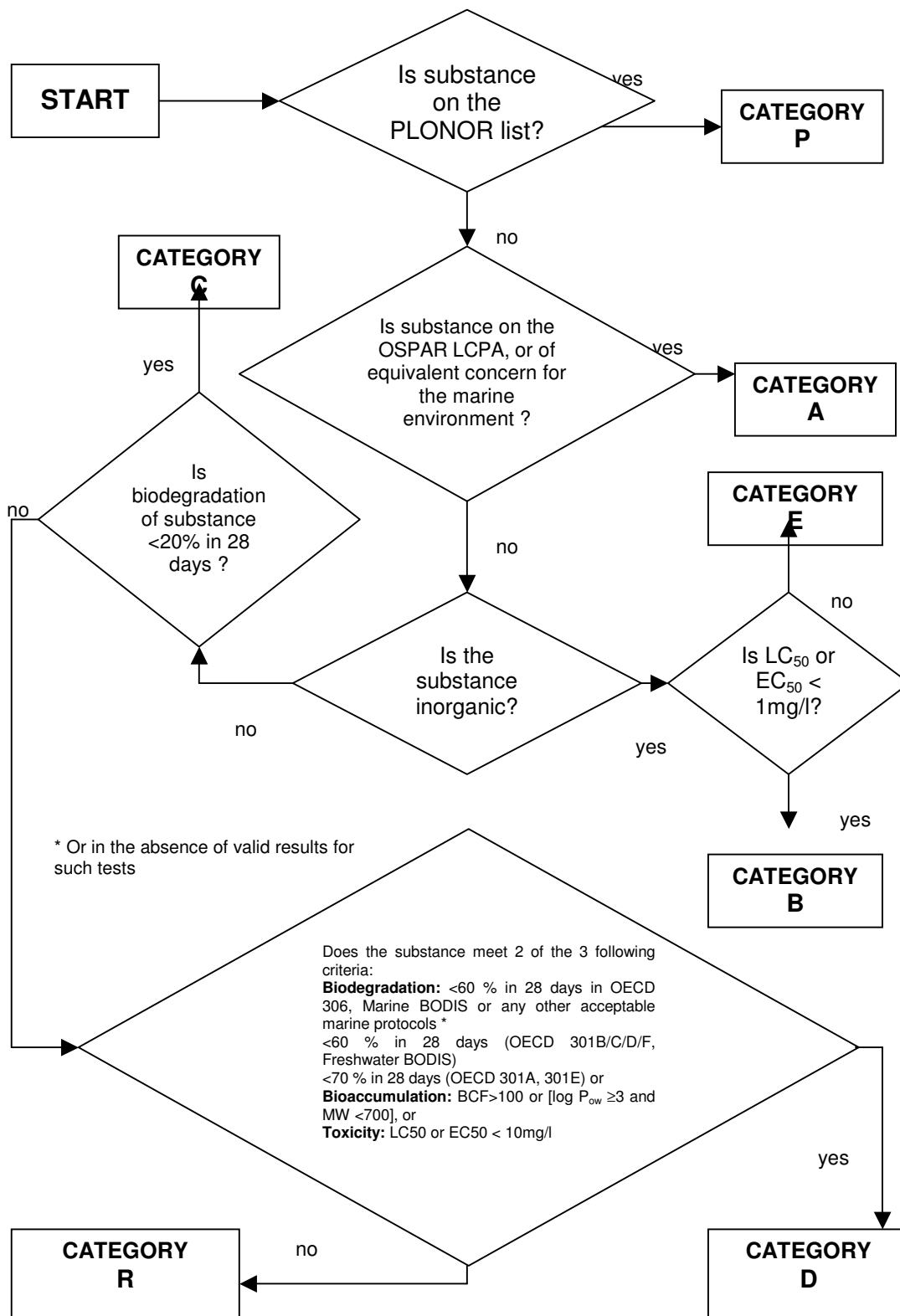
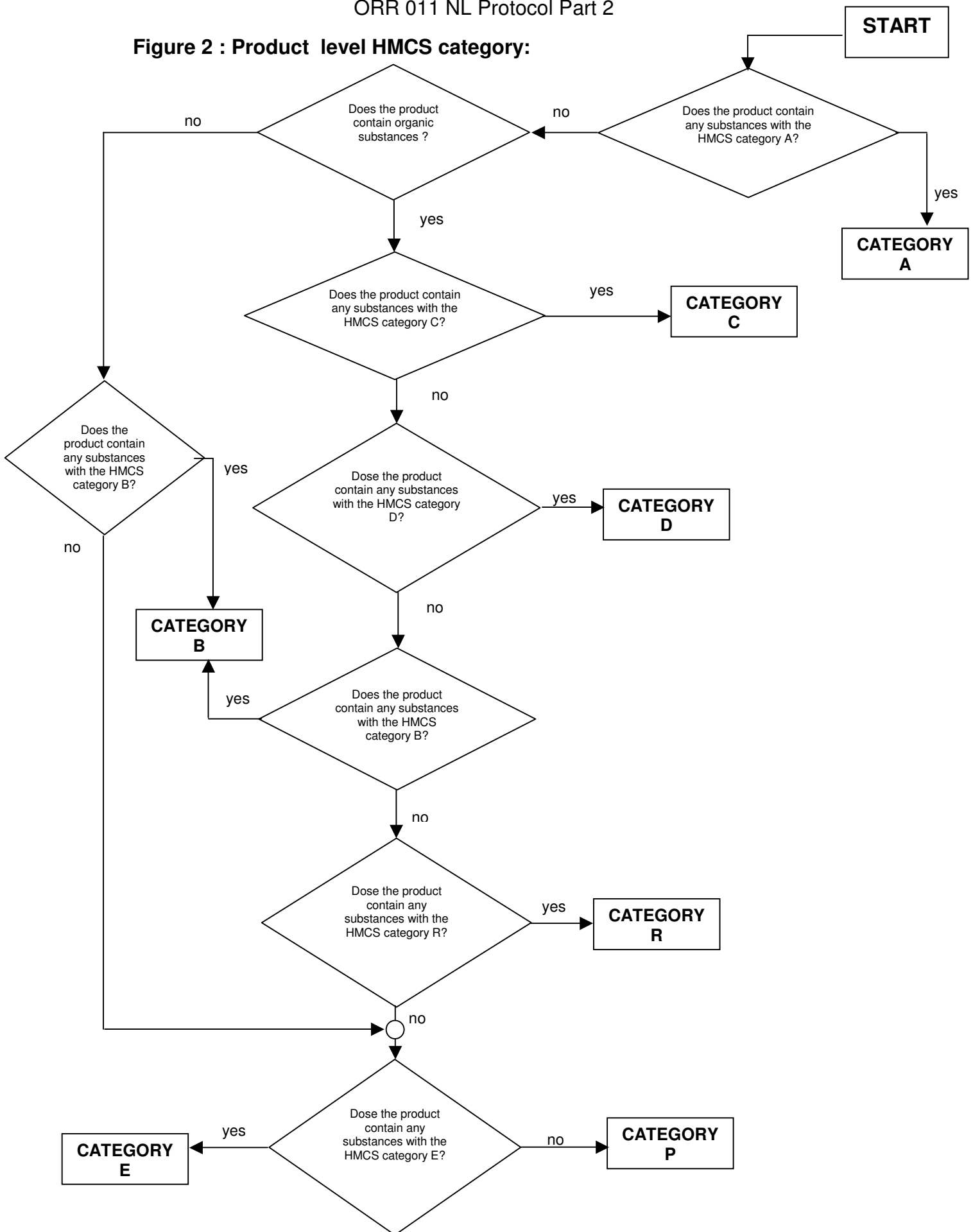


Figure 2 : Product level HMCS category:



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, is 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 2008/1 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 SEP 2008 NL008-0930), Section 11. 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 2008-05 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

All commissioned tests should comply with OSPAR Agreement 2005-12 and OSPAR Agreement 2005-13 (as amended by the OSPAR Agreement 2008-5), and should be in compliance with the principles of 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 (GLP) 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](#), and it is the responsibility of the chemical supplier to ensure that any tests cited in a HOCNF comply with these requirements.

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). Therefore SSM

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has agreed with the industry in the Netherlands to apply the following scheme in order to improve the test data quality:

Substance Group Criteria ¹	Transition period (dated from 1/6/07)	Deadline for HMCS data quality improvement
<p>REACH: > 1 tonne per year: new substances which have not been produced or imported within the EU before</p> <p>OSPAR: all substances which have not yet been produced within or imported into the OSPAR Countries before</p>	<p>REACH: No transition period and registration from the 1st of June</p> <p>OSPAR: from 1st of January 2009 all tests not yet commissioned before 31st of December 2008 should comply with GLP criteria when registering at CEFAS 2008</p>	<p>With immediate effect</p>
<p>REACH and OSPAR: > 1000 tonnes per year produced or imported within the EU</p> <p>> 1 tonne per year CMR-substances</p> <p>> 100 tonnes per year N; R50/53 substances, LCPA or NL HMCS Pre-screening category A</p>	<p>3½ years</p>	<p>1st December 2010</p>
<p>REACH: > 100 tonne per year produced or imported within the EU</p> <p>OSPAR: all Candidates for substitution substances according to the NL HMCS Pre-screening categories B/C/D,</p>	<p>6 years</p>	<p>1st June 2013</p>
<p>REACH: > 1 tonne per year produced or imported within the EU</p> <p>OSPAR: all other substances, most of them having the NL HMCS Pre-screening categories which according to OSPAR are not liable for substitution (typically category R substances).</p>	<p>11 years</p>	<p>1st June 2018</p>

¹ Criteria are based on REACH deadlines and also OSPAR HMCS pre-screening criteria

Data compliant with this scheme should be presented on a HOCNF at the next registration of the product after completion of the constituent substances' REACH registrations. The contracting parties reserve the right to request REACH-compliant data at any time after the REACH registration deadline for any substance.

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 c, d, e i), e ii) or e iii 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:

- i) GLP-compliant, and
- ii) Of sufficient quality.

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 both of the criteria i) and ii), the data will be considered valid.

If any test report fails to satisfy either of the criteria i) or ii), 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 both of the criteria i) and ii).

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 both of the criteria i) and ii), 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 REACH Elements to be checked by CEFAS

Answers to the following queries should be captured by CEFAS during the registration process and taken up in the data set (or Flat Excel File):

- *Are you a 'downstream user' in the sense of REACH? Yes or No*
- *If No, are you a 'manufacturer' or an 'importer' in the sense of REACH? Yes or No*
- *If you are a 'downstream user', did you (pro-actively) identify your uses and communicate these to your upstream suppliers? Yes / No*
- *If you are neither a 'downstream user' nor a 'manufacturer' or an 'importer' in the sense of REACH, could you provide the reasons why not?*

NOTE: If you are a 'manufacturer' or an 'importer' you must provide all your registration data to SSM

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 by end of the second full working week of December in the same year as the audit was conducted. The summary report will 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 (%)

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- 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

Appendix 1 Product Audit Report Format

2XXX Random Sampling – Report

Product:

Supplier:

Date on HOCNF:

Check performed on:

CONFIDENTIAL

This report is intended for internal use at SSM only.

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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.					

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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 2008/1) but also for all substances used in other sectors of the industry. The following text is 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 / 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 $MTR_{CHARM} = 3$ and therefore $VR_{CHARM} = 0.03$.