



OSPAR Guidelines for Completing the Harmonised Offshore Chemical Notification Format (HOCNF)

(Reference number: 2010-05)¹

Introduction

1. The Harmonised Offshore Chemical Notification Format (HOCNF)² applies to all chemicals used in connection with offshore exploration and production activities in the OSPAR maritime area. The paragraph numbers in these guidelines refer to the paragraph numbers of Annex 1 of Recommendation 2010/3. Exact chemical composition of preparations will be held in commercial confidence in the relevant governmental bodies, and will not be published or transmitted to third parties.

Data Requirements

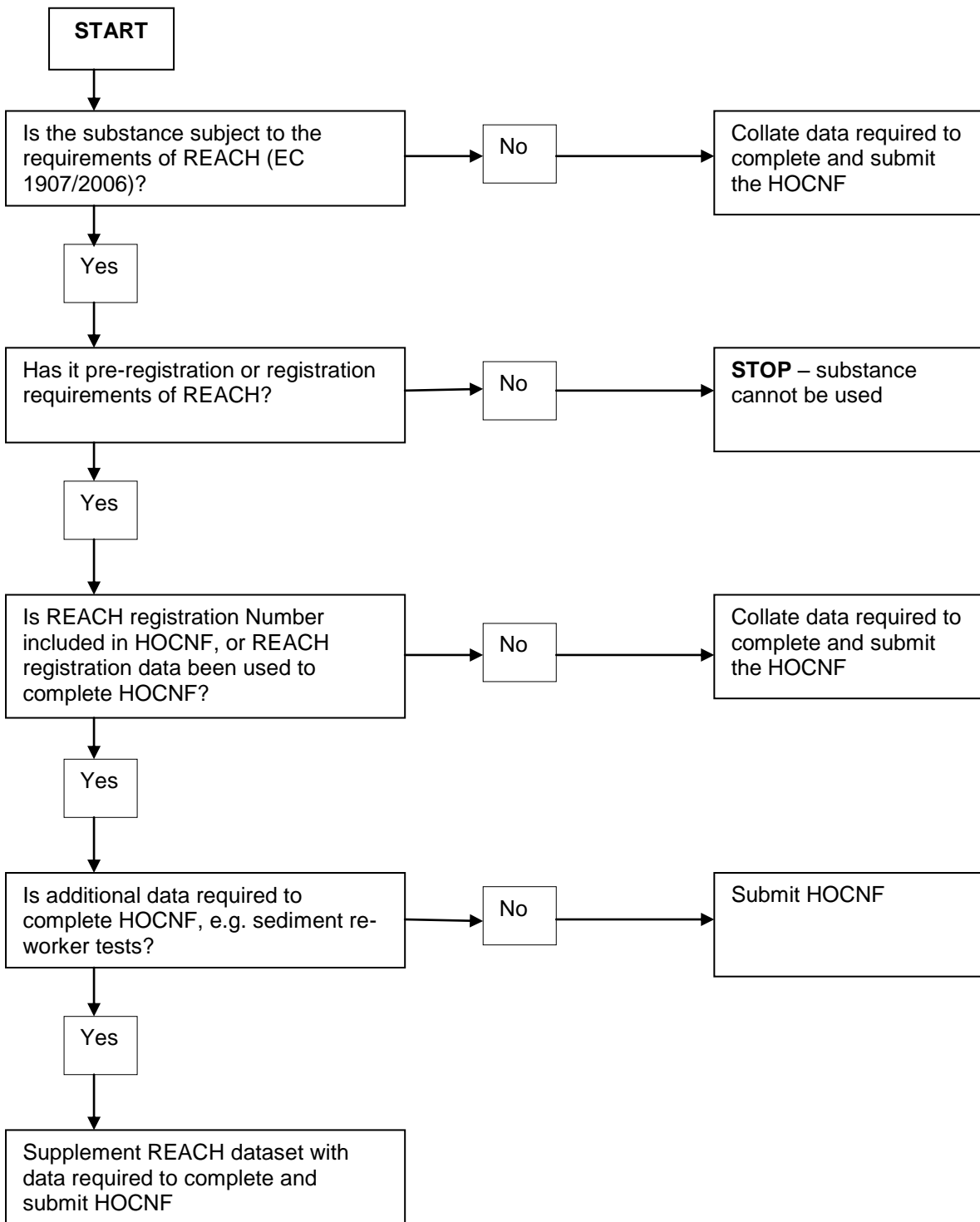
2. For the purpose of these OSPAR guidelines, the following data requirements apply:
- All mandatory information designated in Annex 1 of OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF), must always be provided;
 - "Conditional data" become mandatory when the defined conditions mentioned in Annex 1 of OSPAR Recommendation 2010/3, or in these guidelines are met;
 - It is essential that all substances included on a HOCNF also fully comply with the relevant requirements of REACH for that substance. Suppliers are therefore advised to follow the REACH compliance flowchart shown in Figure 1 (overleaf) before they commission relevant tests or complete the HOCNF with existing data.
3. The amended OSPAR guidelines relate to the provisions and requirements stipulated in Annex 1 of OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF), and the reference numbers mentioned in the headings and subheadings refer to that Annex.
4. When compiling data for the HOCNF, the 'REACH Guidance on information requirements and chemical safety assessment'³ provide a good source of information on how to characterise the hazard and risk profile of a substance. In particular the REACH Guidance on information requirements and chemical safety assessment documents under Part B: hazard assessment (R2 – 7), Part B: hazard assessment (R9 - 10), Part C: PBT and vPvB assessment (R11) and Part D: Exposure assessment (R14 – 18) may be particularly useful sources of information.

¹ This update of the Guidelines replaces OSPAR Agreement 2008/05 as from 1 January 2011

² cf. Annex 1 of OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF)

³ http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm#B

Figure 1: REACH Harmonisation Flowchart



Letters of Access

5. Where any information is not fully known by the Company completing the HOCNF, because the information is proprietary to the supplier, the Company may request that the proprietary information is provided directly to the Competent Authority by the supplier. This would involve the supplier sending the

Competent Authority a Letter of Access (LoA), permitting the Competent Authority to use the information as part of the required data set.

6. The LoA from the supplier should contain, or reference, all the information that the Company registering the product has indicated will be submitted by the supplier.

7. The LoA and any supplementary supporting information, should be forwarded to the Competent Authority and cross-referenced using a common identifier, so that the Competent Authority can link the LoA to the relevant HOCNF.

8. The Competent Authority will confirm to the Company whether the composite LoA and HOCNF is complete and correct.

Harmonisation of REACH and HMCS data

9. Where HMCS data have not been used to derive the REACH data, and the endpoints derived from the two datasets do not agree, the competent national authority will have to be satisfied of the 'sameness' of the substances, and of the equivalence, adequacy, reliability and relevance of the data for the HMCS, taking account of the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R4: Evaluation of available information, May 2008 (as adopted). The decision on which data takes precedence in pre-screening will be made as follows:

10. Biodegradation: For screening tests a positive result will take precedence over a negative result. Simulation tests will be assessed in line with paragraph 55 of this guidance

11. Bioaccumulation: A BCF value will take precedence over any other data and will be compared to HMCS criteria. Where more than one BCF value occurs the highest value will take precedence. Where only LogP_{ow} data are available and there are less than 3 values the highest value will take precedence. Where there are greater than 3 values the geometric mean will be calculated and used in the assessment. The relevance of WOE approaches conducted under REACH or HMCS will be evaluated on a case by case basis.

12. Toxicity: Where there are less than 3 values for the same endpoint and they are within 1 order of magnitude the lowest value will take precedence. Where there are greater than 3 values for the same endpoint and they are within 1 order of magnitude the geometric mean will be calculated and used in the assessment

13. PNEC values and deterministic risk quotients: These will not be calculated in a directly comparable way by HMCS and REACH. The use of these values for ranking and risk management will be at the discretion of the competent national authority.

PART 1: General information on substances and preparations

§ 1.1 State the trade name or trade names of the substance or preparation

§ 1.2 State the supplier and provide background information as regards the substance or preparation

§ 1.3 The Safety Data Sheet (SDS) must be attached to the HOCNF format. Confirm this by ticking the box "Yes"

§ 1.4 Use and discharge

14. If the chemical is suitable for assessment by CHARM, choose an application from one of the CHARM algorithms (utility and stimulation chemicals are assessed using the "Completion/Workover" algorithm). Complete column 1 of the table in § 1.4 of the HOCNF.

15. If the submitted chemical is not suitable for assessment by CHARM, advice should be sought from the competent national authority on information that may be required in addition to that requested in the HOCNF, to allow assessment by models other than CHARM.

16. Information on the quantities used and discharged and on application categories is required, based on either standardised reference installations or, where appropriate; on site specific use and discharge.

17. The entries "state function(s) of the substance/preparations" and "to which process system will the chemical be applied?" should confirm the function of the chemical and its mode of use. The function is defined as the process for which the substance/preparation is normally or primarily used, e.g. drilling fluid, biocide, scale-inhibitor, demulsifier, and should be one of those listed Appendix 2. If none of the listed functions are appropriate, enter the function as 'other' and provide a description confirming the mode of use, fate and effect. The application process stream should define the process stream into which production chemicals will be dosed; or list the sections of a well in which the drilling chemicals will be used; or should reflect one of the four CHARM sub-algorithms for cementing or completion chemicals. Complete columns 2 and 3 of the table in § 1.4 of the HOCNF.

18. For water based drilling chemicals, all the well sections in which the product is likely to be used should be stated. The normal dose rate should be based on optimal technical performance and the hazard assessment based on the appropriate sections of a standard well included in the CHARM model (17 1/2", 12 1/4" and 8 1/2" sections) or, where appropriate, on site specific information. Units should be clearly stated. Complete columns 3 and 4 of the table in § 1.4 of the HOCNF.

19. For production chemicals, state either "water" or "total fluids" as the process system into which the chemical will be applied. "Total fluids" should be selected for chemicals dosed into single-phase hydrocarbon streams (either oil or gas) and the dosage should be based on the sum of the produced water and hydrocarbon production for the appropriate CHARM model platform. "Water" should be selected for injection chemicals and surfactants. State also whether the production chemical is to be used on a gas or oil platform. Complete columns 3 and 4 of the table in § 1.4 of the HOCNF.

20. For all cementing chemicals except spacers, "mixwater" should be stated as the process system. For chemicals used in spacer fluids, enter "spacer" as the function of the chemical. Complete column 2 of the table in § 1.4 of the HOCNF.

21. For completion chemicals, enter the function "surface and well cleaning" for products used as rig washes or "other completion/workover" for any other products used in completion and workover operations. Complete this information in column 2 of the table in § 1.4 of the HOCNF.

22. If a product is used in several different applications, data on function, process stream dosage, discharges etc. must be provided for each application in additional tables in accordance with § 1.4 of the HOCNF.

23. A substance/preparation should be assigned to the category "closed system" only if it remains within a reactor or is transferred from vessel to vessel through closed pipework and therefore accidental spillage is the only likely cause for human exposure or environmental contamination. Substances/preparations that are used in closed systems, but as a consequence of normal use might be released into the environment after use or where significant discharges into the environment cannot be excluded during use, should be assigned to the "open system". If it is assigned "open system" then specify the estimated discharge as a percentage of the use or fraction released. Complete the information in columns 7 and 8 of the table in § 1.4 of the HOCNF.

24. If the above sections have been filled in as indicated, then no more information is required to run the CHARM model. However, an estimation of the "frequency of treatment", "probable scale of use per installation (specify units)", "Probable amount of substance/preparation discharged (specify units)" and "Total estimated amount of discharge (tonnes)" must be reported in columns 6, 9, 10, 11 and 12 of the table in § 1.4 of the HOCNF to inform site-specific risk assessment.

25. Data in §1.4 must be provided for all offshore chemicals (as appropriate)

§ 1.5 Fate

26. A description of the likely fate of the substance/preparation must be explained in general terms. This must include whether the substance/preparation is likely to change its form on use and/or will end up in the sediment, the water column, the air or biota.

§ 1.6 Composition

§ 1.6a) Composition

27. All applications must include the names and data for all deliberately added substances within a preparation. Sufficient information must also be available to operators to allow them to properly assess the chemicals they intend to use.

28. When providing data to non-governmental organisations, information regarding composition should be the same as that normally provided in a Safety Data Sheet (SDS).

29. The full chemical composition must be provided when submitting the form to government bodies. The complete and precise composition of the substance or preparation must be reported, including each "active" substance, "inert" substance, solvent and additive substance and their proportions, using CAS numbers and recognised chemical formulae or recognised chemical names for all substances. EINECS, or ELINCS or REACH numbers must also be provided if they are available. Please note that trade names will not be accepted by the government bodies. Trade names are; however, useful additional information and should also be provided where possible.

30. The molecular weights of the named constituent substances must be provided, together with percentage composition of the constituents (in accordance with the allowed variation⁴). Percentage composition is derived from the weight of the substance in the preparation divided the total weight of the preparation. The resultant figure is then multiplied by 100 to get the percentage composition. It is important that the sum total of the data in column 2 (percentage composition) adds up to 100.

31. All substances known to be deliberately added, including those present at less than 1% by weight of an entire preparation, should be declared. Impurities are not considered to be deliberately added. However, residue substances from the manufacturing process and other impurities present at greater than 1% should be declared as part of the formulation. Substances (except those stated in paragraph §1.6.b of the OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF), that are not deliberately added and are present at less than 1% by weight should not be declared.

32. Where a CAS number is not available for a polymer, provide the CAS number (and the EINECS, or ELINCS or REACH numbers if they are available) for the monomer on which it is based. If the molecular weight is not available for a polymer, provide the molecular weight of the monomer. Where there is a molecular weight range for polymers or complex mixtures, the mean value should be provided with an explanation of how this value has been arrived at (e.g. GPC, MS, calculation). Monomers should also be assessed separately if they are present at levels that require them to be declared.

33. Substances which are on the latest OSPAR List of Substances / Preparations Used and Discharged Offshore Which are Considered to Pose Little or no Risk to the Environment (PLONOR) must also be declared (the OSPAR PLONOR list can be found on the OSPAR website at www.ospar.org).

34. Where generic descriptions are provided, such as tall oil soaps, polyoxyalkylated glycols, phenol/formaldehyde resins, reaction-products, copolymer series the source materials must be also be provided, together with the best description of the range of major substances/preparations present. Where solvents or other additives are refinery or petrochemical products consisting mainly or entirely of hydrocarbons, the generic description (e.g. straight-chain alkenes, 3-5 ring aromatics) must be provided together with the concentrations of any aromatics, and the method or methods used for determination of the components should be stated. In such cases, this information must be completed in the "Comment" box.

§ 1.6b) Contents

35. For substances/preparations where knowledge of the raw materials and the manufacturing processes involved indicate that one or more of the named the substances will be present, please tick the appropriate box. Supportive evidence must be provided, where available, in the next table of § 1.6b).

⁴ Concentration ranges:

Declared concentration range of the constituent	Permitted variation in initial concentration of the constituent
≤2,5%	±15%
>2,5≤10%	±10%
>10≤25%	±6%
>25≤50%	±5%
>50≤100%	±2,5%

36. The latest version of the OSPAR List of Chemicals for Priority Action (OSPAR LCPA) and the latest version of the OSPAR List of substances of possible concern (OSPAR LSPC) can be downloaded from the OSPAR website at www.ospar.org.

§ 1.7 General physical properties

37. Enter details of the physical state of the substance or preparation. Most of the general physical properties are described in the Safety Data Sheet (SDS).

Part 2 Ecotoxicological information

38. Ecotoxicological information can be mandatory or conditional. If the offshore chemical is on the PLONOR List or all the relevant ecotoxicological information has already been submitted to the authority, Part 2 of Annex 1 to OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) need not be completed. Reference should be provided to the document in which this information is given.

39. Whenever possible, ecotoxicological data should be derived from tests performed according to recognised international standard protocols or guidelines (e.g. OSPAR guidelines, ISO test guidelines and OECD test guidelines) and conducted by laboratories working in compliance with the current OECD principles of Good Laboratory Practice (GLP) at the time of testing. Test laboratories must also follow the OSPAR Guidelines for Toxicity Testing of Substances and Preparations Used and Discharged Offshore (Reference number: 2005-12) whenever samples are received for testing. The testing laboratories must also confirm to the supplier, in every case, that the validity criteria for the reference test have been met.

40. Other types of information may be sufficient for completing the HOCNF especially when used in a *Weight of Evidence* approach. Such information could include:

- a. Data from *in vitro* or *in vivo* studies that have not been generated in accordance with the latest adopted/accepted version of the corresponding (validated) test method or to GLP (or equivalent)
- b. QSAR model outputs
- c. SAR model outputs, read across and category approaches.

41. Where data of type 40a are presented they should be evaluated for completeness and quality to assess whether they fulfil the requirements of the HOCNF Guidelines for the substance in question, and whether they are therefore appropriate for use in HMCS pre-screening and CHARM calculations as required. The evaluation of these data should be conducted according to (draft) ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R4: Evaluation of Available Information, May 2008⁵.

42. Data of type 40b may be used instead of testing when the following conditions are met:

- i. Results are derived from a QSAR model whose scientific validity has been established in line with the OECD principles of QSAR validation,
- ii. The substance falls within the applicability domain of the QSAR model,
- iii. Results are adequate of the purpose of pre-screening and CHARM assessment as required,
- iv. Adequate and reliable documentation of the applied method is provided.

⁵ http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r4_en.pdf?vers=20_08_08

The ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.6: QSAR and Grouping of Chemicals, May 2008⁶ should be followed when using QSAR for HMCS purposes.

43. Similarly, when using data of type 40c for HMCS purposes, the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.6: QSAR and grouping of Chemicals, May 2008 should be followed.

44. If REACH data for the substance is available and this data has been used in the HOCNF submission, the competent national authority may conduct a Weight of Evidence evaluation (Reference to ECHA REACH document R.7b and R.7c) for OSPAR Registration purposes. If REACH Registration data for the substance is not available, then the Weight of Evidence evaluation will only be possible if the competent national authority is satisfied of the sameness (Reference: ECHA Guidance for identification and naming of substances under REACH, June 2007) of the substance.

§ 2.1 Partitioning and bioaccumulation potential

45. N-octanol water partitioning data must be provided for all organic substances with the exception of surfactants. For preparations, information for all the deliberately added substances is required. The data can be derived by measuring, estimating or calculating the partitioning of the substances between water and n-octanol (P_{ow}).

46. $\log P_{ow}$ is used for two purposes. In the pre-screening (OSPAR Recommendation 2010/4) it is used to advise on bioaccumulation potential, and in the CHARM model it is used to estimate how a substance partitions between oil and water with the aim of predicting the environmental concentration (PEC). As a consequence of this dual use of $\log P_{ow}$ data, whenever a range of $\log P_{ow}$ values is quoted in a test report, the maximum and minimum value must be stated in the HOCNF. The maximum values will be used for estimating bioaccumulation potential in the pre-screening scheme and the minimum value will be used as an indication of the potential of the substance to partition into the water phase.

47. A standard shake flask method for the determination of P_{ow} is OECD Guidelines for Testing of Chemicals, 1981-107. The shake flask method is applicable for substances that are water soluble and which do not dissociate or associate. The method is not applicable for lipophilic organic substances (of low water solubility), preparations, complex substances, organo-metallic compounds and surface-active agents. $\log P_{ow}$ values in the range -2 to 4 can be measured by this method.

48. A standard HPLC method for the estimation of the $\log P_{ow}$ is OECD Guidelines for Testing of Chemicals, 1989 - 117. This method is applicable for preparations and complex substances (for complex substances the $\log P_{ow}$ range needs to be stated). Ionisable substances should be measured in their non-ionised form under appropriate pH conditions (pH range of natural seawater). The HPLC method is not applicable to strong acids and bases, metal complexes, substances reacting with the eluent or surface-active agents. $\log P_{ow}$ values in the range 0 to 6 can be estimated using the HPLC method.

49. Reliable methods are now available for calculation of $\log P_{ow}$ for many types of organic substances and often laboratory testing can be avoided. Examples of reliable methods are CLOGP, LOGKOW and AUTOLOGP (cf. European Commission, Technical guidance documents on risk assessment in support of the Commission Directive 93/67/EEC on risk assessment for new notified substances; Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances; and Directive 98/8/EC of the

⁶ http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08

European Parliament and of the council concerning the placing of biocidal products on the market (Part II. Published April 2003). Care should be taken when using models to assess substances for which the protocols have not been verified. Calculations should be fully validated and justified. The latest version of relevant Technical Guidance Documents under the REACH Regulation should also be consulted where appropriate, including the Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment, May 2008.

50. If the calculated or experimentally determined $\log Pow \geq 3$, bioaccumulation will be assumed unless experimental bioconcentration factor (BCF) tests indicate the opposite. While high molecular weight compounds are less likely to bioaccumulate a precise threshold is not recognised; OSPAR has agreed to recognise MW 700 as a limit for bioaccumulation as given in the EU TGD Part II BCF data are relevant for all deliberately added substances with a $\log Pow > 3$. The BCF is determined on the basis of the ratio of animal tissue concentration to water concentration of the test substance at equilibrium, or on the basis of the ratio of the uptake and depuration rate constants. The competent national authority should be consulted beforehand to ensure that the proposed test method is suitable. In general, for fully water miscible substances, either a fish or a bivalve mollusc bioaccumulation test would normally be appropriate (e.g. OECD 305 or ASTM E1022), whereas for substances that give rises to suspended particles. a filter feeding organism such as a bivalve mollusc would be more appropriate.

51. A variety of approaches may be appropriate for assessing the potential for substances to bioaccumulate. A more detailed assessment scheme for the HMCS, which applies substitution warnings to those substances that are likely to exhibit a potential to bioaccumulate, is detailed in Appendix 3 of these guidelines.

§ 2.2 Biodegradability

52. Data on biodegradability in the marine environment are relevant for all organic substances. For preparations or complex mixtures, individual information for all the deliberately added substances is required. Data on the rate of hydrolysis of a substance, with pH conducted to OECD guideline 111, may be useful in assessing the abiotic degradation of some substances. These data may be submitted to the competent national authority and the applicability of the data will be assessed by expert judgement on a case-by-case basis.

53. If the substance is found not to be readily biodegradable, or if a ready aerobic biodegradation test has not been performed, it will be assumed that the substance is persistent in aerobic conditions unless a simulation test (e.g. OECD 308, OECD 309) is performed which indicates the opposite. The relevance of an inherent biodegradation test should be agreed in consultation with the competent national authority.

54. Substances for which no biodegradation data are available shall be tested according to the standard test methods for biodegradability, according to either OECD Guidelines for Testing of Chemicals, 1992, 306, or any of the four protocols published in the report "Biodegradability of chemical substances in seawater. Results of the four OSPARCOM ring tests, final report, Elf Akvamiljö, November 1996." The OSPAR ring test is available on the OSPAR website at www.ospar.org. In the absence of valid results for such tests, authorities may accept data from freshwater tests according to OECD Guidelines for Testing of Chemicals, 1992, 301 A-F and freshwater BODIS tests, if these data are already available.

55. In a screening test, the highest value for the percentage biodegradation during the period of testing shall be used as a measure of the biodegradation potential provided that the value is not an outlier. The substance will be considered persistent if:

- i biodegradation is <20% in OECD 306, Marine BODIS or any other accepted marine protocols or <20 % in 28 days freshwater (ready test).
- ii Half-life values derived from aquatic simulation tests (e.g. OECD 308, 309) indicate persistence to REACH (EC 1907/2006) Annex XIII criteria

56. Tests on substances known to be toxic to microbes (e.g. biocides) should follow the recommendations in Annex II of OECD 1992 301.

57. Biodegradability tests on poorly soluble materials should follow the recommendations set out in ECETOC Technical Report No. 20 (1986), Annex III of OECD 1992 301 and ISO Guidance Document ISO 10634.

§ 2.3 Aquatic toxicity

58. Toxicity data must be provided for all substances. Marine data should be provided where possible but competent national authorities can also accept freshwater toxicity data in lieu of marine data, provided the freshwater tests are carried out using test species mentioned in the OECD 201, 202 and 203 guidelines or any other suitable internationally-accepted protocol.

59. The relevance of toxicity test data other than that specified in the notification format should be agreed in consultation with the competent national authority. However, for freshwater data or non-OSPAR marine data, application of safety factors may be necessary, as required by the CHARM model. For certain substances, additional marine toxicity data may be required at any time, if evidence casts doubt on the relevance of the existing test data.

60. Substance-based testing on representative algal, crustacean and fish species is mandatory⁷. The full OSPAR marine toxicity data set comprises:

- a. Algae
Skeletonema costatum; or to ISO/DIS protocol 10253
Phaeodactylum tricornutum;
- b. Crustacea
Acartia tonsa; or to ISO protocol TC 147/SC5/WG2
Tisbe battaglia;
- c. Fish
Scophthalmus maximus (juveniles); or to Part B of the OSPAR Protocols on Methods for
Cyprinodon variegatus (juveniles) the Testing of Chemicals Used in the Offshore
Industry (published by OSPAR in 1995, available
from the OSPAR web site at www.ospar.org)

61. Where there are no existing fish toxicity test data, it is recommended that a limit test is conducted using the LC50 or EC50 of the most sensitive species of the other taxonomic groups that have been tested. If no significant mortality occurs in this limit test (when compared with the control), it is unnecessary to

⁷ If testing another species has already identified a substance for substitution, the fish test is not mandatory although it may still be required at the discretion of the competent authority

undertake a full toxicity test and the end point of the fish test should be reported as greater than the concentration tested (> limit concentration).

62. Most substances exhibit a fairly similar degree of toxicity to both algae and crustacea but there are occasions where a substance appears to be very much more toxic to one class of organism than the other. Should the apparent toxicity be found to be due to a physical effect such as chelation and not toxicity, OSPAR recommends that the limit test should be conducted at the LC50 or EC50 concentration of the other species that was tested.

63. A comparative suite of alternative marine or freshwater species are also acceptable if tests are conducted according to recognised protocols such as the OECD 201, 202 and 203 guidelines or any other suitable internationally-accepted protocol.

64. An additional sediment reworker test must be carried out, using *Corophium spp*, as described in Part A of the OSPAR Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry, for substances which:

- a. are "sinkers"; or
- b. have a $K_{OC} > 1000$ (see 2.5); or
- c. have a $\log Pow > 4$; or
- d. are in any other way known to adsorb to particles or end up in the sediment; or
- e. contain surfactants.

Part 3 Confirmation statement

65. The confirmation statement is a written declaration renewable every three years to confirm that:
- a. The information in the form still applies precisely to the substance/preparation being manufactured or supplied under that specific trade name. Any change in formulation, by the addition of any new substance, or the removal of any existing substance, other than by trace quantities (<100 ppm or <0,01%), necessitates the immediate action to consider whether new data are required. Any change in composition, i.e., in the concentrations of a substance, unless within the previously accepted range of variability, similarly necessitates the immediate evaluation of the new composition. Any change of name, coding or number requires an immediate declaration that the existing format now applies to this renamed preparation;
 - b. All laboratory tests results and data referred to in Annex 1 to OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF) as amended by OSPAR recommendations 2005/3 2008/2 and 2010/X were either in compliance 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, May 2008 (as adopted)
66. Suppliers may be asked at any time to submit samples of a substance/preparation to government bodies for analysis or testing. Offshore users may also be asked at any time to submit to government bodies a sample of the preparation currently in use.
67. Before the renewal date, the notifier should consult the competent national authorities. More relevant data, or data not previously supplied, for a substance/preparation, may be required, irrespective of any previous approval for use.

Glossary and Definitions of Terms

1. For the purpose of these guidelines and for the purpose of the Harmonised Offshore Chemical Notification Format (HOCNF) as at Annex 1 of OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF):

- a. "authority" means the competent national authority of a Contracting Party to the OSPAR Convention;
- b. "discharge" means the operational release of offshore chemicals or their degradation and transformation products into the maritime area;
- c. "EINECS" means European Inventory of Existing Commercial Chemical Substances;
- d. "ELINCS" means European List of Notified Chemical Substances;
- e. "Limit test" means a fish toxicity test conducted at a single concentration rather than a range of concentrations (as described in the OSPAR agreement 2005-11)
- f. "offshore chemicals" means all chemicals intentionally used in connection with offshore exploration and production activities in the maritime area. Offshore chemicals comprise both substances and preparations;
- g. "PLONOR" means the OSPAR List of Substances/Preparations Used and Discharged Offshore Which are Considered to Pose Little or No Risk to the Environment
- h. " P_{ow} " is equivalent to K_{ow} and means the partition coefficient of a substance between octanol and water, measured or calculated according to the HOCNF;
- i. "preparation" means a mixture or solution composed of two or more substances;
- j. "SDS" means Safety Data Sheet compiled in accordance with Annex II as laid down in Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/104/EC and 2000/21/EC. (OJ L 396, 30.12.2006, p. 1).
- k. "sinkers" means those chemicals with a density greater than that of sea water and with a low water solubility;
- l. "substance" means a chemical element and its compounds, in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- m. "Surfactant" means any substance, which has surface-active properties according to test method A.5 in Regulation EC 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) of 30 May 2008, and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces.

- n. "trace" means a substance is represented with less than 0,01 % (<100 ppm) in a preparation;
- o. "use", in relation to an offshore chemical, means any intentional application of the chemical in connection with offshore exploration and production activities in the maritime area under normal operating conditions.

2. Further definitions and information can be found in:

- OSPAR Decision 2000/2 on a Harmonised Mandatory Control System for the Use and Reduction of the Discharge of Offshore Chemicals;
- OSPAR Recommendation 2010/4 on a Harmonised Pre-screening Scheme for Offshore Chemicals;
- OSPAR Recommendation 2010/3 on a Harmonised Offshore Chemical Notification Format (HOCNF);

which are available for downloading from the OSPAR web site at www.ospar.org.

Functions of Chemicals referred to in paragraph 11 of the OSPAR Guidelines for completing the HOCNF

Acidity Control Chemical	Lost Circulation Material
Antifoam (Hydrocarbons)	OPF Additive
Antifoam (Water Injection)	OPF Base Oil
Asphaltene Dissolver	OPF Base Synthetic
Asphaltene Inhibitor	OPF Oil based Drilling fluid
Biocide	OPF Synthetic-based Drilling Fluid
Brine (Completion)	Oxygen Scavenger
Carrier Solvent	Pipe Dope
Cement or Cement Additive	Pipe Release Chemical
Coagulant	Pipeline Hydrotest Chemical
Coolant or Coolant Additive	Pipeline Pigging Chemical
Corrosion Inhibitor	Proppant
Crosslinking Chemical	Scale Dissolver
Cuttings Wash Fluid	Scale Inhibitor
Defoamer (Drilling)	Shale Inhibitor / Encapsulator
Demulsifier	Thinner
Deoiler	Tracer chemical
Detergent / Cleaning Fluid	Viscosifier
Dispersant	Water Based Drilling Fluid Additive
Drilling Lubricant	Water Based Drilling Fluid
Dye	Water Clarifier
Emulsifier	Wax Inhibitor
Filter Cake Removal Chemical	Wax Dissolver
Filter Media or Filter Media Additive	Weighting Chemical
Filtrate Reducer	Well Stimulation Chemical
Flocculant	Well Bore Clean-up Chemical
Fluid Loss Control Chemical	Other
Gas Hydrate Inhibitor	
Gelling Chemical	
Hydraulic Fluid	
Hydrogen Sulphide Scavenger	
Jacking grease	

* This appendix was agreed in a written procedure between OIC Heads of Delegation following the meeting of OIC 2003. The written procedure was completed on 2 May 2003.

Bioaccumulation Assessment Methodology for substances for HMCS

