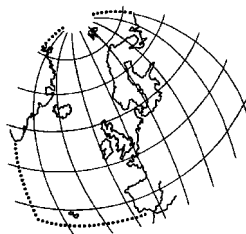


# **Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC)**



OSPAR Commission  
2002

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the “OSPAR Convention”) was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992. The Convention entered into force on 25 March 1998. It has been ratified by Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, Netherlands, Norway, Portugal, Sweden, Switzerland and the United Kingdom and approved by the European Community and Spain.

*La Convention pour la protection du milieu marin de l'Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d'Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. La Convention a été ratifiée par l'Allemagne, la Belgique, le Danemark, la Finlande, la France, l'Irlande, l'Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d'Irlande du Nord, la Suède et la Suisse et approuvée par la Communauté européenne et l'Espagne.*

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# Contents

Contents	3
Executive Summary	5
Récapitulatif	6
1. Introduction	7
1.1 Background and Purpose of DYNAMEC	7
1.2 Development of DYNAMEC	7
1.3 Procedures for the Application of DYNAMEC	8
2. Initial Selection of Substances	9
2.1 The initial selection carried out for the first time	9
2.2 The List of Substances of Possible Concern	9
2.3 Procedure for considering new information on substances already on the List of Substances of Possible Concern	10
2.4 Procedure for selecting new substances of possible concern	10
2.5 Procedure for selecting substances via the Safety Net Procedure	11
3. Ranking of Substances	11
3.1 The ranking carried out for the first time	11
3.2 Procedure for re-ranking the substances on the List of Substances of Possible Concern	12
4. Prioritisation of Substances	13
4.1 The prioritisation carried out for the first time	13
4.2 Future recommendations with respect to priority substances	13
References	14
Annex 1: Overview of the Steps and Procedures within the DYNAMEC Mechanism	15
Annex 2: Text accompanying the "OSPAR List of Substances of Possible Concern" as published on the OSPAR Web Site	16
Annex 3: Cut-Off Values for the Selection Criteria Used in the Initial Selection Procedure of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances	19
Annex 4: Guidance on How to Apply the Safety Net Procedure for the Inclusion of Substances in the List of Substances of Possible Concern	22



## **EXECUTIVE SUMMARY**

Since September 1998, work has been undertaken within the OSPAR Commission to establish a dynamic selection and prioritisation mechanism for hazardous substances (DYNAMEC). During its first application, an initial selection procedure and a ranking procedure were developed and applied in a pragmatic way in order to identify priority substances from 2000 onwards and adding them to the OSPAR List of Chemicals Identified for Priority Action which was first established in 1998 (Annex 2 to the OSPAR Strategy with regard to Hazardous Substances).

Work in 2000-2002 on the further development of DYNAMEC has led to the establishment of the OSPAR List of Substances of Possible Concern. This list which was agreed at OSPAR 2002 is a result of the initial selection and is published on the OSPAR web site with an invitation to those who have an interest in these substances to submit any new relevant information to OSPAR which might be useful for OSPAR's work on hazardous substances. To this end, data sheets for all substances of possible concern are also accessible on the OSPAR web site and reflect the current knowledge of OSPAR about the hazardous properties of these substances. On the basis of new information, the list will be updated from time to time. The OSPAR List of Substances of Possible Concern has replaced the OSPAR 1998 List of Candidate Substances (Annex 3 to the OSPAR Strategy with regard to Hazardous Substances).

Furthermore, procedures have been established for (i) considering new information on substances already on the List of Substances of Possible Concern and (ii) selecting new substances of possible concern for inclusion in this list. The cut-off values for persistence, bioaccumulation and toxicity (PBT) agreed by the OSPAR Commission in 2001 are used in these procedures. Where substances do not meet all the PBT criteria, they can be considered for inclusion in the List of Substances of Possible Concern via the Safety Net Procedure provided that suitable monitoring data and associated information are presented which demonstrate the presence of the substances in the marine environment. There is still a need to develop criteria for the inclusion of endocrine disrupting chemicals in the DYNAMEC procedure as they could be substances of an equal level of concern. The application of all these procedures requires a certain amount of expert judgement.

The OSPAR Commission will decide if and when an updated List of Possible Concern will be ranked on the basis of the EU Water Framework Directive Combined Monitoring-based and Modelling-based Priority Setting Procedure (COMMPS). Likewise in its first application for OSPAR, the algorithms and weighting factors of this procedure might need to be modified in order to render them more suitable for the marine environment. On the basis of the outcome of the ranking and suitable expert judgement, the Commission will decide on any further hazardous substance that should be added to the OSPAR List of Chemicals Identified for Priority Action and subsequently the further necessary actions required to achieve the objective of the OSPAR Strategy with regard to Hazardous Substances within its timeframe of 2020.

This publication draws together all the procedures and criteria developed in the framework of the dynamic selection and prioritisation mechanism for hazardous substances and serves as a manual for the application of the DYNAMEC mechanism. It will be updated as soon as changes are made to this mechanism.

## RÉCAPITULATIF

Depuis septembre 1998, des travaux ont été effectués dans le cadre de la Commission OSPAR dans le but de créer un mécanisme dynamique de sélection des substances dangereuses et de classement de celles-ci en fonction des priorités (mécanisme DYNAMEC). Lors de sa première mise en oeuvre, une procédure de sélection initiale et une méthode de classification ont été élaborées et appliquées dans des conditions pragmatiques, afin de déterminer les substances prioritaires à compter de l'an 2000 et de les inscrire sur la Liste OSPAR des produits chimiques devant faire l'objet de mesures prioritaires, liste dressée à l'origine en 1998 (Annexe 2 à la Stratégie OSPAR visant les substances dangereuses).

Les travaux effectués en 2000-2002 sur la poursuite de l'élaboration du mécanisme DYNAMEC ont abouti à la mise sur pied de la Liste OSPAR de substances potentiellement préoccupantes. Cette liste, convenue à OSPAR 2002, est le résultat de la sélection initiale et est publiée sur le site web d'OSPAR, parallèlement à une invitation, lancée à quiconque a un intérêt dans ces substances, à soumettre tout nouveau renseignement pertinent à OSPAR, renseignement susceptible d'être utile à ses travaux sur les substances dangereuses. A cette fin, les fiches de caractéristiques de toutes les substances potentiellement préoccupantes sont aussi accessibles sur le site web d'OSPAR, fiches sur lesquelles figurent les connaissances en possession d'OSPAR sur les propriétés de dangerosité de ces substances. La liste sera mise à jour de temps à autre sur la base des nouveaux éléments d'information. La Liste OSPAR des substances potentiellement préoccupantes a remplacé la Liste OSPAR 1998 des substances candidates (Annexe 3 à la Stratégie OSPAR visant les substances dangereuses).

De plus, des procédures ont été instaurées pour (i) considérer les nouveaux éléments d'information sur les substances d'ores et déjà inscrites sur la Liste des substances potentiellement préoccupantes et (ii) sélectionner de nouvelles substances potentiellement préoccupantes à inscrire sur cette liste. Les seuils de coupure de la persistance, de la bioaccumulation et de la toxicité (valeurs PBT) convenus par la Commission OSPAR en 2001 sont appliqués dans le cadre de ces procédures. Lorsque des substances ne répondent pas à tous les critères de PBT, leur inscription sur la Liste des substances potentiellement préoccupantes peut être considérée, ceci par le biais de la procédure du filet de sécurité, sous réserve que soient présentés des données issues de la surveillance et des renseignements connexes pertinents prouvant que ces substances sont présentes dans le milieu marin. Il reste à fixer des critères d'inscription des produits chimiques perturbateurs du système endocrinien dans la procédure du DYNAMEC, ceci car il pourrait s'agir de substances donnant lieu à un niveau équivalent de préoccupation. L'application de toutes ces procédures exige un certain niveau de jugement par des experts.

La Commission OSPAR décidera s'il y a lieu de classer les substances inscrites sur la Liste des substances potentiellement préoccupantes sur la base de la Procédure de fixation des priorités associant surveillance et modélisation (procédure COMMPS) de la Directive communautaire européenne cadre relative à l'eau. De même, lorsqu'elle sera appliquée pour la première fois aux fins d'OSPAR, il se peut qu'il faille modifier les algorithmes et les coefficients de pondération de cette procédure afin de les adapter au milieu marin. En se fondant sur la classification et sur un jugement d'experts adéquat, la Commission décidera de l'inscription de toute nouvelle substance sur la Liste OSPAR des produits chimiques devant faire l'objet de mesures prioritaires ainsi que, ultérieurement, des nouvelles mesures qui s'imposeraient pour atteindre l'objectif de la Stratégie OSPAR visant les substances dangereuses dans les délais prévus à cet effet, soit d'ici 2020.

La présente publication rassemble toutes les procédures et tous les critères élaborés dans le cadre du mécanisme dynamique de sélection des substances dangereuses et de classement de celles-ci en fonction des priorités et constitue un guide de l'application du mécanisme DYNAMEC. Elle sera mise à jour dès que des modifications seront apportées à ce mécanisme.

## 1. INTRODUCTION

### 1.1 Background and Purpose of DYNAMEC

1. The OSPAR Ministerial Meeting in 1998 agreed on the OSPAR Strategy with regard to Hazardous Substances<sup>1</sup> ("the strategy"), which sets out, *inter alia*, (i) the definition of hazardous substances, (ii) the objective of OSPAR with respect to hazardous substances and (iii) the timeframe in which this objective should be achieved. At the same meeting, Ministers declared in the Sintra Statement<sup>2</sup> that the OSPAR Commission would:

- a. develop a dynamic selection and prioritisation mechanism in order to tackle first the substances and groups of substances which cause most concern;
- b. use this mechanism to up-date by 2000 the 1998 OSPAR List of Chemicals for Priority Action, which comprises 15 substances or group of substances (Annex 2 of the strategy).

2. In line with the provisions, definitions and requirements set out in the strategy, the purpose of the DYNAMEC mechanism can be described as a tool to enable the OSPAR Commission in a transparent manner and on the basis of sound information:

- a. to select those hazardous substances that need to be addressed by the Commission under the strategy;
- b. to identify from those hazardous substances the ones which should be given priority in OSPAR's work.

### 1.2 Development of DYNAMEC

3. After the OSPAR Ministerial Meeting in 1998, the OSPAR Ad-hoc Working Group on the Development of a Dynamic Selection and Prioritisation Mechanism for Hazardous Substances<sup>3</sup> was tasked to develop the DYNAMEC mechanism, apply this mechanism for the first time and prepare proposals which substances could be prioritised by the Commission. DYNAMEC carried out this task in a pragmatic way.

4. DYNAMEC's work is briefly described in the following chapters as far as this is relevant for understanding the DYNAMEC mechanism. Other tasks of DYNAMEC e.g. the preparation of advice to OSPAR 2000 with respect to the selection of substances for priority action and preparatory work for risk assessment for the marine environment are not described in this publication. This has been reported in the OSPAR Briefing Document on the work of DYNAMEC<sup>4</sup>. The Ad-hoc Working Group DYNAMEC has reported to the Working Group on Diffuse Sources (DIFF) and the Programmes and Measures Committee (PRAM) of the OSPAR Commission.

5. The working method of DYNAMEC meant that most of the individual steps in the DYNAMEC mechanism (see the overview in figure at Annex 1) had to be developed, tested and revised in parallel rather than in sequence and that some elements could not be covered exhaustively. This has been done in close cooperation with the European Commission bearing in mind its activities under the EC chemicals legislation and the selection and prioritisation of hazardous substances under the Water Framework Directive. The documentation of the DYNAMEC mechanism was also rather piecemeal and scattered in a large number of meeting documents. There was therefore a need to further develop the DYNAMEC mechanism and document the procedures for its application in an instruction manual.

6. Since the restructure of OSPAR's working procedures and arrangements in 2000, the Working Group on Priority Substances (SPS) is tasked to apply and maintain the DYNAMEC mechanism; more specifically: to prepare and maintain the List of Substances of Possible Concern and the ranked list(s) of substances of possible concern. It should be noted that the steps and procedures of this dynamic mechanism may be

adjusted on the basis of new experiences. There may be a need to further develop e.g. procedures on how to use modelling-based QSARs where experimental data on the persistence, liability to bioaccumulate and toxicity do not exist and criteria for the inclusion of endocrine disrupting chemicals in DYNAMEC as they could be substances of an equal level of concern. Furthermore, SPS provides advice to the Commission - on the Commission's specific request - on further substances to be selected for priority action. The elements and procedures of DYNAMEC (the Provisional Instruction Manual for the DYNAMEC Mechanism)<sup>5</sup> are included in this publication. SPS reports the outcome of its work to the Hazardous Substances Committee (HSC), which then prepares recommendations for the selection and prioritisation of hazardous substances for ultimate decision by the OSPAR Commission<sup>6</sup>.

### 1.3 Procedures for the Application of DYNAMEC

7. This document describes the procedures and timetable for the application of the DYNAMEC mechanism. The document focuses on the following procedures:

- a. ***initial selection of substances;***
  - (i) to consider new information on substances already on the List of Substances of Possible Concern;
  - (ii) to consider information on new substances and decide whether they should be added to the List of Substances of Possible Concern;
  - (iii) to consider information on substances proposed for addition to the List of Substances of Possible Concern via the Safety Net Procedure.
- b. ***ranking of substances;***
- c. ***prioritisation of substances.***

8. The procedures as described below, focus on the regular application and maintenance of the DYNAMEC mechanism, including the List of Substances of Possible Concern and the ranked list(s) of substances of possible concern.

9. Before putting these procedures into operation, it will be necessary for SPS to clearly identify what operators are needed to carry out the specified tasks and to estimate the resource implications and timescales involved. This will be necessary for the Commission to reach a view on future developments.

10. In order to carry out this important part of its working programme, SPS convenes an intersessional correspondence group called Informal Group of DYNAMEC Experts (IGE) and has established appropriate practical arrangements for this group (see paragraphs 2.3 - 2.5) to carry out work prior to the annual SPS meeting. The IGE should preferably work by e-mail correspondence but could meet in a face-to-face meeting. Taking into account the work carried out by the IGE, SPS decides on the inclusion in, or the exclusion from substances on the List of Substances of Possible Concern. In order to avoid unreasonable delay in modifying the publicly available List of Substances of Possible Concern and the associated fact sheets as at paragraphs 2.3, 2.4 and 2.5 below, the outcome of the work of the IGE may also be endorsed by a written procedure of SPS or at a meeting of HSC in place.

11. The procedures mentioned in paragraphs 2.3 - 2.5 will be used on a trial basis and will be improved and modified in the light of experience gained.



## 2. INITIAL SELECTION OF SUBSTANCES

### 2.1 The initial selection carried out for the first time<sup>7</sup>

12. The initial selection was originally established in three complementary ways:
- a. the 246 substances (or groups of substances) in the 1998 OSPAR List of Candidate Substances (Annex 3 to the OSPAR Strategy with regard to Hazardous Substances) were examined against a set of cut-off values for persistence, liability to bioaccumulate and toxicity and ("PBT criteria")<sup>8</sup>, which are part of the strategy's definition of hazardous substances. ("Bioaccumulation" is the development of increasingly high concentrations of a substance as you go higher in the food web, as the substance is taken in through food and not broken down or excreted);
  - b. all substances in the Nordic Substance Database (about 18 000 substances), the Danish Miljøstyrelsen QSAR database (more than 166 000 substances) and the database of the Netherlands' BKH/Haskoning report (about 180 000 substances) were examined against the PBT cut-off values;
  - c. a "safety-net" procedure<sup>9</sup> was applied to identify other substances (or groups of substances) which do not fulfil all the PBT criteria, but which give rise to an equivalent level of concern. Proposals from Contracting Parties were examined by an informal group of experts and, if judged appropriate, included in the initial selection of substances.
13. The results of this initial selection of substances were examined by experts in order to check the plausibility and consistency of the substance-specific data, and to exclude those substances that had been incorrectly selected.
14. The result was a draft preliminary list of about 400 substances of possible concern - that is, a list of those substances which have to be treated as hazardous for the purposes of the strategy. In order to produce a realistic list for priority action, substances were flagged up if they had intrinsic properties similar to Persistent Organic Pollutants (POPs) or were suspected of being endocrine disruptors (and therefore clearly give rise to a high level of concern) or were already being addressed in other forums (and therefore OSPAR should consider whether to await the outcome in that forum, before deciding whether to initiate specific OSPAR action).

### 2.2 The List of Substances of Possible Concern

15. Following further work by SPS, the List of Substances of Substances of Possible Concern has been established<sup>10</sup>. This list and the underlying fact sheets are published on the OSPAR web site in order to promote active contributions to the process of initial selection, not only from Contracting Parties and observers of OSPAR but also from the general public. The text to accompany this publication is at Annex 2.
16. In principle, it is the responsibility of the relevant industries (producers, formulators and downstream users) to provide reliable information on substances, to validate information and to produce draft fact sheets for hazardous substances. Furthermore, industry should guarantee public access to information on hazards and risks of substances and public participation in assessing and classifying substances. Although industry is gradually taking up these responsibilities, it seems not yet feasible to incorporate these responsibilities into the instruction manual.
17. Fact sheets for all substances on the List of Substances of Possible Concern are available on the OSPAR web site, which contain all relevant and available information on identification of the substance, PBT characteristics, indication which PBT information has been used for the initial selection, production volumes, use patterns, flags, remarks made by SPS and current rank. Confidential information is not

presented in these fact sheets. The list and the fact sheets are subject to continuous amendment; therefore they are not presented here but on the OSPAR web site.

### **2.3 Procedure for considering new information on substances already on the List of Substances of Possible Concern**

18. Contracting Parties, observers (industry and other NGOs) and the general public could submit any relevant additional information on substances of possible concern. Amended or additional information should be submitted using the original fact sheet (to be downloaded from the OSPAR web site) indicated with revision marks.

19. Amended fact sheets (including supporting information on original test reports or publications) should be sent in electronic form to the Secretariat not later than 8 weeks before the meeting of the Working Group on Priority Substances (SPS)<sup>11</sup>.

20. The Secretariat should send them to the Informal Group of DYNAMEC Experts (IGE) not later than 7 weeks before the SPS meeting.

21. The IGE should examine the comments made (mainly on the technical issues) and should prepare advice to SPS to consider whether the provided information was of acceptable accuracy. The information will be assessed against the cut-off values for the selection criteria used in the initial selection procedure of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances at Annex 3<sup>12</sup>. Furthermore, the IGE should indicate any consequent adjustments on the List of Substances of Possible Concern (deselecting of substances) and the consideration for these adjustments.

22. The IGE should report on the outcome of its work to SPS. A report of the IGE should be sent to the Secretariat for submission to SPS not later than 3 weeks before the SPS meeting.

23. SPS should examine the advice of the IGE and decide on any adjustments on the information on the fact sheets and any adjustments on the List of Substances of Possible Concern.

24. In accordance with the agreements of SPS, the Secretariat should publish the revised fact sheets and the List of Substances of Possible Concern on the OSPAR web site not later than 3 weeks after the SPS meeting.

### **2.4 Procedure for selecting new substances of possible concern**

25. Contracting Parties, observers (industry and other NGOs) and the general public could submit a filled-in fact sheet for any substance not yet on the List of Substances of Possible Concern, by using the format for fact sheets (to be downloaded from the OSPAR web site).

26. Fact sheets (including supporting information of original test reports or publications) should be sent in electronic form to the Secretariat not later than 8 weeks before the meeting of the Working Group on Priority Substances (SPS).

27. The Secretariat should send them to the Informal Group of DYNAMEC Experts (IGE) not later than 7 weeks before the SPS meeting.

28. The IGE should examine the accuracy of the information on the fact sheets and should prepare advice to SPS to consider whether the substances should, or should not be added to the List of Substances of Possible Concern. The information will be assessed against cut-off values for the selection criteria used in the initial selection procedure of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances at Annex 3<sup>12</sup>.

29. The IGE should report on the outcome of its work to SPS. A report of the IGE should be sent to the Secretariat for submission to SPS not later than 3 weeks before the SPS meeting.

30. SPS should examine the advice of the IGE and decide on the accuracy of the proposed fact sheets and any adjustments on the List of Substances of Possible Concern.

31. In accordance with the agreements of SPS, the Secretariat should publish the fact sheets on the OSPAR web site and adjust the List of Substances of Possible Concern not later than 3 weeks after the SPS meeting.

## **2.5 Procedure for selecting substances via the Safety Net Procedure**

32. Contracting Parties, observers (industry and other NGOs) and the general public could submit a filled-in fact sheet (including the considerations for inclusion) for any substance not yet on the List of Substances of Possible Concern, by using the format for fact sheets (to be downloaded from the OSPAR web site). Guidance on how to apply the Safety Net Procedure for the inclusion of substances in the List of Substances of Possible Concern is at Annex 4<sup>13</sup>

33. Fact sheets should be sent in electronic form to the Secretariat not later than 8 weeks before the meeting of the Working Group on Priority Substances (SPS).

34. The Secretariat should send them to the Informal Group of DYNAMEC Experts (IGE) not later than 7 weeks before the SPS meeting.

35. The IGE should examine the accuracy of the information on the fact sheets and should prepare advice to SPS for consideration whether the substances should, or should not be added to the List of Substances of Possible Concern.

36. The IGE should report on the outcome of its work to SPS. A report of the IGE should be sent to the Secretariat for submission to SPS not later than 3 weeks before the SPS meeting.

37. SPS should examine the advice of the IGE and decide on selection of additional substances via the Safety Net Procedure and on any adjustments on the List of Substances of Possible Concern.

38. In accordance with the agreements of SPS, the Secretariat should publish the fact sheets on the OSPAR web site and adjust the List of Substances of Possible Concern not later than 3 weeks after the SPS meeting.

## **3. RANKING OF SUBSTANCES**

### **3.1 The ranking carried out for the first time<sup>14</sup>**

39. To rank the substances (or group of substances) in this initial selection, they were characterised by their production volumes, use patterns and/or measured occurrence in the environment. The level of potential concern with regard to each substance was indicated by:

- a. an effect score (relative toxicity and liability to bioaccumulate - the effect score was calculated by considering direct and indirect effects on aquatic organisms (toxicity and bioaccumulation potential) as well as indirect effects on humans via ingestion of contaminated food (carcinogenicity, mutagenicity and adverse effects on reproduction as well as chronic effects resulting from oral uptake));
- b. an exposure score (relative level of predicted or measured occurrence in the environment - an environmental exposure volume was calculated by using a modified version of the European

Risk Ranking Method (EURAM) algorithm; subsequently, this environmental exposure volume was scaled from >0 to 10 in order to obtain the exposure score).

40. The mathematical product of the effect exposure scores is an indicator for the relative risk from each substance. The calculated results were then reviewed by the group of experts. The ranking algorithms were based on those which had been established for the Combined Monitoring-based and Modelling-based Priority Setting (COMMPS)<sup>15</sup> procedure in the context of the Water Framework Directive of the EC. Some algorithms or weighting factors were modified in order to render them more suitable for the marine environment. Conservative default values were used in cases where certain substance-specific data were not known.

41. The substance-specific data needed for the ranking were taken from a variety of sources such as (i) the IUCLID database maintained by the European Chemicals Bureau, (ii) the Nordic Product Register, (iii) data collected, assessed and used in the context of the COMMPS-ranking, (iv) the Danish QSAR Database. In general, the highest-quality data were chosen in cases where more than one data set for a substance was available.

42. Because of commercial confidentiality, the assessment of the outcome of the ranking and the data used could only be undertaken and validated by a limited number of experts.

43. The ranking results were presented in 4 lists of ranked substances in:

- a. water, based on measured environmental concentration and the properties of the substances;
- b. water, based on modelled exposure scores (based on calculation from production volumes and use patterns);
- c. sediments, based on measured environmental concentration and the properties of the substances; and for
- d. sediments, based on modelled exposure scores (based on calculation from production volume and use pattern).

### **3.2 Procedure for re-ranking the substances on the List of Substances of Possible Concern**

44. The 2003 meeting of the Working Group on Priority Substances should consider whether there is sufficient new information available for the substances of possible concern that would justify re-ranking of these substances before the meeting of the OSPAR Commission in 2004.

45. Once SPS is requested by the Commission for advice on further substances to be selected for priority action, the Secretariat should forward this request to the European Commission (EC) not later than 7 weeks before the meeting of SPS.

46. The EC should carry out a ranking exercise for all substances on the List of Substances of Possible Concern. If it is not possible to rank a certain substance (due to lack of information on exposure), the EC should give a ranking based on intrinsic properties and any other relevant information available.

47. The EC should report on the outcome of its work to SPS. A report of the EC should be sent to the Secretariat for submission to SPS not later than 3 weeks before the SPS meeting.

48. SPS should examine the advice of the EC and decide on any adjustments on the ranked list(s) of substances of possible concern.

49. In accordance with the agreements of SPS, the Secretariat should publish the fact sheets on the OSPAR web site and adjust the ranked List(s) of Substances of Possible Concern not later than 3 weeks after the SPS meeting.

## 4. PRIORITISATION OF SUBSTANCES

### 4.1 The prioritisation carried out for the first time

50. Starting point for the identification of priority substances was the OSPAR List of Chemicals for Priority Action, which was adopted at the Ministerial meeting of the OSPAR Commission in 1998. This first list contained 15 substances or groups of substances. These were already well known hazardous substances for which the Commission would carry forward the drawing up of programmes and measures with a view to continuously reducing their discharges, emissions and losses.

51. To facilitate the discussions for a further selection of priority substances, a "selection box" of 80 substances was extracted in a pragmatic way by (i) combining a selection of the 48 top-ranked substances from each of the 4 ranked lists, (ii) excluding from this selection substances already on Annex 2 of the strategy and (iii) adding all those initially selected substances which fulfilled the most stringent selection criterion (selection I) or which were flagged as endocrine disruptors. They were then grouped as follows:

Group	Description
A	substances of very high concern (i.e. POP-like substances or substances with PBT profile, selection I) and indication of production, use or occurrence in the environment
B	Other initially selected substances (with less severe PBT profile) and indication of use or exposure
C	substances of very high concern (i.e. POP-like substances or substances with PBT profile, selection I) with <u>no</u> indication of use or exposure
D	Other initially selected substances with <u>no</u> indication of use or exposure
E	substances with PBT properties but which are heavily regulated or withdrawn from the market
F	endocrine disruptors, which do not meet P or B criteria or natural hormones
-	substances which do not meet the initial selection criteria (and which should be deleted from the draft preliminary list of substances of possible concern) or substances already on Annex 2 of the strategy

52. Those substances, which had been initially selected as a result of reliance on QSAR data and/or experimental data about which confidence might be doubted, were identified as A\* and B\*. There was a need to obtain further information in particular on PBT for the substances categorised as A\* and B\* in order to decide whether these substances should be prioritised.

53. Following the collection of further information on these substances and advice from the IGE on this information, the OSPAR Commission in 2002 has until now added a further 36 substances to the OSPAR List of Chemicals for Priority Action. Thirteen substances were deleted from the draft List of Substances of Possible Concern, or not included in the List of Substances of Possible Concern. From the substances initially selected and ranked in 2000, 3 substances are still subject to consideration for inclusion on the priority list or deletion from the List of Substances of Possible Concern.

### 4.2 Future recommendations with respect to priority substances

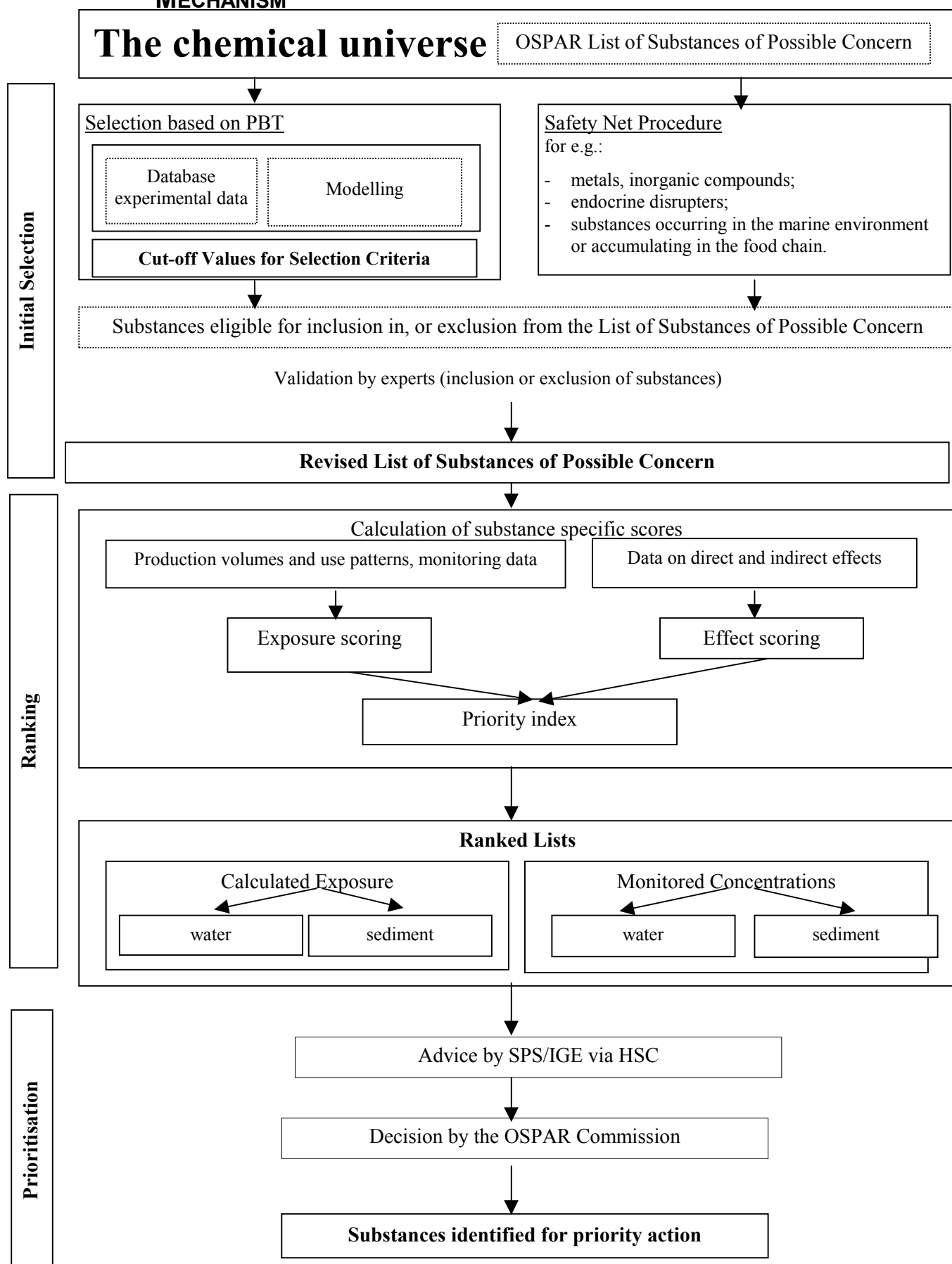
54. Once the OSPAR Commission has decided that the List of Substances of Possible Concern should be re-ranked, SPS should, on the basis of this re-ranking and the information in the updated fact sheets, propose to HSC a list of substances which might be further added to the OSPAR List of Chemicals for Priority Action and an explanatory memorandum relating to this proposal.

## REFERENCES

(indicated as endnotes in the text)

- <sup>1</sup> Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 34.
  - <sup>2</sup> Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 45.
  - <sup>3</sup> Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 10.
  - <sup>4</sup> Briefing document on the work of DYNAMEC; meeting document OSPAR 00/5/2, Annex 1.
  - <sup>5</sup> Summary Record of HSC 2002 (HSC 02/11/1), Annex 8.
  - <sup>6</sup> For the organisational structure of OSPAR and its subsidiary bodies see the OSPAR web site [www.ospar.org](http://www.ospar.org).
  - <sup>7</sup> Further more detailed information about the initial selection is given in the Report on the Intersessional Work on the Initial Selection, presented by the Nordic Countries and the Netherlands at DYNAMEC February 2000 (meeting document DYNAMEC 00/3/1).
  - <sup>8</sup> In accordance with the Strategy with regard to Hazardous Substances:
    1. "Toxicity" is defined as the capacity of a substance to cause toxic effects, to organisms or their progeny such as:
      - a. reduction in survival, growth and reproduction;
      - b. carcinogenicity, mutagenicity or teratogenicity;
      - c. adverse effects as result of endocrine disruption.Depending on the exposure time and life cycle of the target organism, toxicity can be classified as:
    - a. acute toxicity: lethal and/or sublethal toxicity resulting from intermittent or continuous exposure to a substance or mixture of substances for a period substantially shorter than the life cycle of the organism in question (e.g. 96h LC50 for a fish with a life cycle measured in months or years);
    - b. subchronic toxicity: sublethal (and possibly also lethal) toxicity resulting from intermittent or continuous exposure to a substance or mixture of substances for a period which is a substantial proportion of the life cycle of the organism in question (e.g. 21 day reproductive NOEC for a crustacean with a life cycle measured in weeks or months);
    - c. chronic toxicity: sublethal toxicity resulting from intermittent or continuous exposure to a substance or mixture of substances for a period not less than the life cycle of the organism in question (e.g. lifecycle reproductive NOEC for a fish which includes measurements of the F1 generation).
  2. A substance is defined to be "persistent" if its conversion or the conversion of its degradation products is slow enough to permit long-term occurrence and widespread distribution in the marine environment.
  3. "Bioaccumulation" is defined as the enrichment of a substance in an organism and includes "bioconcentration" from environmental concentrations and additional uptake via the foodchain.
- <sup>9</sup> Summary Record of DYNAMEC 2000 (DYNAMEC 00/10/1), §§ 3.8-3.9.
- <sup>10</sup> The OSPAR List of Substances of Possible Concern (reference number: 2002-17) has replaced the 1998 OSPAR List of Candidate Substances (Annex 3 to the OSPAR Strategy with regard to Hazardous Substances; reference number: 1998-16).
- <sup>11</sup> An annual overview of the meeting schedule of OSPAR including the date of the SPS meeting is published on the OSPAR web site.
- <sup>12</sup> Summary Record of OSPAR 2001 (OSPAR 01/18/1), Annex 6.
- <sup>13</sup> Summary Record HSC 2002 (HSC 02/11/1), Annex 7.
- <sup>14</sup> Further more detailed information about the ranking is given in the Results of the Risk-based Ranking of the Substances on the DYNAMEC "Draft Initial List of Substances of Possible Concern", which was presented by the EC at DYNAMEC February 2000 (meeting document DYNAMEC 00/4/1).
- <sup>15</sup> Study on the prioritisation of substances dangerous to the aquatic environment: I. Revised proposal for a list of priority substances in the context of the water framework directive (COMMPS procedure); II. Assessment of options on statistical treatment and evaluation of monitoring data within the COMMPS procedure (Catalogue number: CR-24-99-510-EN-C; ISBN 92 828 7981 X).

## ANNEX 1: OVERVIEW OF THE STEPS AND PROCEDURES WITHIN THE DYNAMEC MECHANISM



## **ANNEX 2: TEXT ACCOMPANYING THE "OSPAR LIST OF SUBSTANCES OF POSSIBLE CONCERN" AS PUBLISHED ON THE OSPAR WEB SITE**

(Reference number: 2002-17)

### **Introduction**

1. This web page is intended to inform visitors to the OSPAR web site about the OSPAR List of Substances of Possible Concern, and its role in OSPAR's efforts to tackle hazardous substances in the aquatic environment. The "question and answer" format is intended to give readers a quick overview of the list, the criteria used to develop it, and its robustness and status. A contact procedure is given for readers who could provide data and information to improve the list.

### **What is the status of the List of Substances of Possible Concern?**

2. The OSPAR List of Substances of Possible Concern is a dynamic working list and will be regularly revised, as new information becomes available. This may lead to exclusion of substances present on the current version of the OSPAR List of Substances of Possible Concern and to inclusion of other substances if data on persistence, toxicity and liability to bioaccumulate (or evidence that they give rise to an equivalent level of concern) show that they should be added. This version of the OSPAR List of Substances of Possible Concern was last revised on dd.mm.yyyy.

### **Why has the List of Substances of Possible Concern been published?**

3. The OSPAR Commission is publishing this List of Substances of Possible Concern in order to enable the transparency of its decisions on which substances to classify as chemicals for priority action, and to provide an opportunity for any errors or omissions in the data on which those decisions were based to be put right. Our goal is to keep this information up-to-date and accurate. If errors or omissions are brought to our attention, they will be corrected.

### **What is OSPAR doing to stop pollution by hazardous substances?**

4. OSPAR's main objective for hazardous substances is to prevent pollution of the maritime area by continuously reducing their releases with the ultimate aim of achieving concentrations which are near background levels for those substances which occur naturally (e.g. lead, mercury) or close to zero for man-made substances. OSPAR has developed a strategy (the Strategy with regard to Hazardous Substances – *LINK*) to achieve this objective, and is making every endeavour to move towards the cessation by the year 2020 of discharges, emissions and losses of hazardous substances which could reach the marine environment.

### **How are relevant chemicals being identified and targeted?**

5. In order to tackle the hazardous substances which are of possible concern to the marine environment, and to prioritise the substances of highest concern for immediate action, OSPAR has developed a selection and prioritisation mechanism. This is described in the publication on the Dynamic Selection and Prioritisation Mechanism for Hazardous Substances (DYNAMEC) as published on the OSPAR web site [*LINK to DYNAMEC publication*].



## **How is the selection and prioritisation of these chemicals carried out, and how does the List of Substances of Possible Concern fit into this process?**

6. The selection and prioritisation mechanism consists of 3 basic steps:

- step 1: an initial selection step which by a worst case screening procedure identifies certain hazardous substances on the basis of their intrinsic hazardous properties of persistence, liability to bioaccumulate and toxicity (P, B and T)<sup>1</sup>. *[LINK to definitions of P, B and T in the glossary of the Strategy with regard to Hazardous Substances]* These have been placed on the List of Substances of Possible Concern” because they could adversely affect marine ecosystems;
- step 2: a step which ranks these substances of possible concern according to their actual occurrence and effects in the marine environment;
- step 3: a step which selects those substances from the ranked list judged to require priority action by OSPAR. *[LINK to the current OSPAR List of Chemicals for Priority Action]*

## **Are persistence, liability to bioaccumulate and toxicity the only criteria for selecting substances?**

7. A number of substances which do not meet the full P, B and T criteria have already been added to the List of Substances of Possible Concern because it has been recognised that they give rise to a similar level of concern (for example, endocrine disruptors, or shown to be widely spread in the marine environment by monitoring). The procedures with which OSPAR may add further substances to the list on the basis of equivalent concern are still under development.

## **How does the List of Chemicals for Priority Action relate to the List of Substances of Possible Concern?**

8. The List of Substances of Possible Concern consists of the substances which have been selected on the basis of their intrinsic hazardous properties (step 1). The substances on the List of Chemicals for Priority Action are those which the OSPAR Commission has to date determined require priority action, based primarily on recommendations from DYNAMEC’s ranking process and expert judgement as to which substances represent the highest concern due to the amount produced, the degree of hazardous properties and/or the actual occurrence in the marine environment (steps 2 and 3). As the work of OSPAR progresses, it is envisaged that the List of Chemicals for Priority Action will be further updated with substances from the List of Possible Concern in order that the objectives of the Strategy can be progressively met.

## **Where does the information about hazardous properties come from, and is it reliable?**

9. The substances on the OSPAR List of Substances of Possible Concern have been identified by a worst case screening of a number of databases with experimental data on P, B and T. However, when experimental data are not available, substances have been identified by employing different models (QSARs: Quantitative Structure Activity Relationships) which estimate these values on the basis of chemical structure. The screening is not exhaustive as not all possible data sources have been available or because of limitations in the models employed. Furthermore, some substances may falsely have been selected due to data errors or outliers.

10. The P, B and T criteria used for the selection of the Substances of Possible Concern are described in DYNAMEC. *[LINK to the cut-off values for the PBT criteria in the DYNAMEC publication]*

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<sup>1</sup> Cut-off values for the selection criteria used in the initial selection procedure of the OSPAR dynamic selection and prioritisation mechanism for hazardous substances; Summary Record OSPAR 01/18/1, Annex 6

**Is the underlying data used to select substances onto the List of Substances of Possible Concern available?**

11. The underlying data used for the selection of the Substances of Possible Concern can be found on the relevant fact sheets.

**Have the data on the List of Substances of Possible Concern been validated?**

12. Expert judgement has been undertaken for only a part of the substances. Data for most of the substances have only been subjected to a preliminary scrutiny to ensure that they are sufficiently credible to indicate a possible concern. Therefore, there is still considerable room for improvement and confirmation of the data, that were used in a worst case screening procedure, especially if appropriate experimental values are available which may replace QSAR estimates. The extent to which the data for a certain substance has been scrutinised is indicated in the box “remarks” of the fact sheet for that substance.

**What steps is OSPAR taking to improve the data?**

13. OSPAR is keen to update the list and the fact sheets with more good quality data, and has been working with industry trade associations and OSPAR Contracting Parties to obtain such information. The more the list and the fact sheets become updated and validated with good quality data, the better the list will act as a tool to flag up those substances which are likely to be of concern to the marine environment.

**What type of data would be of interest to OSPAR?**

14. OSPAR is keen to get more good quality data with regard to their intrinsic properties (P, B and T) of these substances, or other substances with similar properties. However, OSPAR also does need information with regard to the production and use of these substances, and information on their occurrence in the environment.

**What can I do if I have information which might contribute to this process?**

15. Visitors to this web site who have information which would enable OSPAR to update its List of Substances of Possible Concern are invited to contact the OSPAR Secretariat [[LINK to secretariat@ospar.org](mailto:secretariat@ospar.org)] who will advise them further regarding the submission of relevant information. An empty fact sheet for the submission of such information [[LINK to empty fact sheet on the web page](#)] and a glossary explaining the content of the fact sheet [[LINK to the glossary on the web page](#)] are available for downloading.

**Disclaimer**

16. The Commission accepts no responsibility or liability whatsoever with regard to the contents of the list or the supporting data sheets. Efforts have been made to ensure that the information given is as accurate as possible, but it is not necessarily comprehensive, complete, accurate or up-to-date.

17. This disclaimer is not intended to limit the liability of the Commission contrary to any obligations imposed by applicable national law nor to exclude liability for matters which may not be excluded under that law.

### ANNEX 3: CUT-OFF VALUES FOR THE SELECTION CRITERIA USED IN THE INITIAL SELECTION PROCEDURE OF THE OSPAR DYNAMIC SELECTION AND PRIORITISATION MECHANISM FOR HAZARDOUS SUBSTANCES

(Reference Number: 2001-1)

1. The intrinsic properties of individual substances, specifically whether they are persistent (P), toxic (T) or liable to bioaccumulate (B), determine whether they fall within the definition of hazardous substances given in the OSPAR Strategy with regard to Hazardous Substances. These three intrinsic properties (PBT criteria) are used, along with cut-off values for each, as the criteria for selecting substances<sup>2</sup> in the Initial Selection Procedure of the Dynamic Selection and Prioritisation Mechanism. The cut-off values for each of these criteria are as follows:

Persistence (P): ..... Half-life ( $T_{1/2}$ ) of 50 days<sup>3</sup> **and**

Liability to Bioaccumulate (B): .....  $\log K_{ow} \geq 4$  or  $BCF \geq 500$  **and**

Toxicity (T).....  $T_{aq}$ : acute  $L(E)C_{50} \leq 1$  mg/l, long-term  $NOEC \leq 0,1$  mg/l

**or**

$T_{mammalian}$ : CMR or chronic toxicity

2. This selection is a combination of the least stringent criteria considered during the development of the Initial Selection Procedure. For aquatic toxicity, contrary to the EC classification, mammalian toxicity is added in addition to the criteria for the aquatic environment (counts for all selections). For bioaccumulation the selected cut-off value is the same as that proposed for international harmonisation<sup>4</sup> in classification and labelling. For persistence, the principal criterion is that the substance has a half-life in the freshwater or marine environment of 50 days or more. However, in the absence of data on the half-life of a substance, the approach described in Appendix 1 has been agreed which allows the use of other experimental data, or in the absence of this, data from biodegradation models.

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<sup>2</sup> Substances are selected through the Initial Selection Procedure for inclusion on the Draft Preliminary List of Substances of Possible Concern.

<sup>3</sup> In the absence of data on half lives, alternative approaches have been agreed, as described in Appendix 1, which allow the use of different types of available information on the biodegradability of a substance.

<sup>4</sup> The process for and the results of the OECD Global Harmonisation of Classification Criteria can be found on the Internet at <http://www.oecd.org/ehs/Class/HCL6.htm>.

## **Persistency Criteria within the Hazardous Substances Strategy**

1. The persistence of a substance reflects the potential for long-term exposure of organisms but also the potential for the substance to reach the marine environment and to be transported to remote areas. In order to assess the persistence for the marine environment in the context of the OSPAR Hazardous Substances Strategy an approach is applied that allows the use of different types of available information on the biodegradability of a substance. In this approach three different levels of information are defined:

- Level 3: Experimental data on persistence in the marine environment
- Level 2: Other experimental data
- Level 1: Data from biodegradation estimation models

2. An explanation of the type of information that is relevant within these levels and the relevant cut-off values is given below. It must be noted that this approach reflects existing knowledge on biodegradation and should be considered as a pragmatic approach that makes optimal use of the available data and methods. Clearly, more research is needed to better estimate persistence in the marine environment from existing biodegradation tests. Moreover, other degradation mechanisms such as hydrolysis and photolysis should be taken into account if they are relevant.

### **Level 3: Experimental data on persistence in the marine environment**

3. In principle persistence in the marine environment should be assessed in relevant simulation test systems that determine the half-life under relevant environmental conditions. Freshwater half-lives are also of relevance, especially when emissions to the marine areas are via rivers. The determination of the half-life should include assessment of metabolites with PBT-characteristics. The half-life should be used as the first and main criterion for determining whether substances should be regarded as persistent in the context of the Hazardous Substances Strategy. Hence appropriate half-life data override data from levels 1 and 2. A cut-off value of 50 days should be used in fresh water (as a transport medium) as well as in the marine environment once the substances has reached this compartment<sup>5</sup>.

### **Level 2: Other experimental data**

4. The available information relating to biodegradability is however dominated by test results on Ready Biodegradability (OECD Test Guideline 301 a-d- or equivalent) and to a lesser extent by data on the Inherent Biodegradability (OECD TG 302 a-c or equivalent). Actual half-life data are hardly ever available. The conditions for degradation in the marine environment are very far from the conditions applied in these standard tests. Hence, extrapolation of the existing biodegradation information (either measured data from ready and inherent tests or results from QSAR modelling) to degradation rates in the marine environment is very difficult, and care should be taken not to over interpret the outcome of the ready/inherent tests. However, in order to use the available information to select potentially persistent substances the results of different types of tests should be used in the following way:

- when results from inherent tests are available that indicate that the substance does not fulfil the criteria this is a clear indication that the substance can reach the marine environment and be persistent under marine conditions, and that its initial selection is warranted.
- when only test results from ready biodegradation test are available indicating that the substance does not fulfil the criteria the substance is also initially selected. However, it is recognised that there is an urgent need for (industry to provide) better realistic data in order to determine the real potential for persistency. It must be noted that in this case it is not proposed that inherent tests are performed but rather to go directly to Level 3 testing.

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<sup>5</sup> Current data determined under marine as well as under freshwater conditions, if available, need to be assessed on a case by case basis.

- data from inherent tests that fulfil the pass criteria for these tests may still be persistent under marine conditions. However, in order to make the best use of available information it can be accepted that the results of two specific tests are used when they fulfil certain criteria. These tests are<sup>6</sup>:
  - ♦ Zahn-Wellens Test (OECD 302B): Pass level for ultimate degradation must be reached within 7 days, log-phase should be no longer than 3 days, percentage removal in the test before degradation occurs should be below 15%, not tested with pre-adapted micro-organisms
  - ♦ MITI II -test (OECD 302C): Pass level for ultimate degradation must be reached within 14 days, log-phase should be no longer than 3 days, not tested with pre-adapted micro-organisms.

5. A case by case assessment is needed in order to decide that a substance can be deselected for persistency using the results from the above mentioned inherent tests.

#### **Level 1: Data from biodegradation estimation models**

6. For many chemicals no experimental data are available at all, which makes the initial selection of these substances problematic. Fortunately, models are available such as the SYRACUSE BIOWIN model that can be used to estimate the potential for biodegradation in the environment. It is proposed that rather stringent cut-off levels are used in order to select those substances for which there is a fair level of concern regarding their potential for persistence in the marine environment. A combination of two BIOWIN models are used for the application of QSARs in the initial selection mechanism. The first model (BIOWIN 1) indicates that a substance is not rapidly degradable in the environment. The second model (BIOWIN 3) indicates that ultimate biodegradation in the environment is expected to occur in weeks to months where the exact cut-off point is “calibrated” on the basis of the data base for 1,2,4-trichlorobenzene, a substance that is known for being rather persistent under environmental conditions. In model terms the cut-off values are  $BPP1 < 0,5$  and  $BPP3 < 2,2$ . It is recognised that further work in the development of biodegradation QSARs is needed and that experience with the proposed cut-off values would be beneficial for the future application of QSAR models within DYNAMEC’s initial selection mechanism.

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<sup>6</sup> The criteria for the inherent tests are similar to the criteria defined in the EC Technical Guidance Documents for Risk Assessment of New and Existing Substances.

## **ANNEX 4: GUIDANCE ON HOW TO APPLY THE SAFETY NET PROCEDURE FOR THE INCLUSION OF SUBSTANCES IN THE LIST OF SUBSTANCES OF POSSIBLE CONCERN**

*(Reference number: 2002-10)*

### **Introduction**

1. DYNAMEC 1999 had agreed to establish a Safety Net Procedure, in which expert judgement would be used to add substances to the List of Substances of Possible Concern. Arrangements for the submission of proposals for substances to be considered through this safety net procedure were made at DYNAMEC September 1999 and at DIFF 1999. The experience gained by Informal Group of DYNAMEC Experts (IGE) in reviewing these proposals indicated a need for agreed guidance to be taken into account:

- a. by Contracting Parties and observer organisations when making proposals for inclusion of substances on the List of Substances of Possible Concern;
- b. by experts when reviewing these proposals in the context of the application of the Safety Net Procedure with a view to improving clarity, transparency and consistency in their judgements.

### **Guidance**

#### ***General aspects***

2. In contrast to the clearly defined cut-off criteria for persistence, liability to bioaccumulate and toxicity (PBT)<sup>7</sup> it is impossible to establish quantitative rules and criteria to be applied within the Safety Net Procedure. Proposals for addition of substances to the List of Substances of Possible Concern have to be reviewed on a case-by-case basis and the following criteria are intended only as qualitative guidance for experts.

3. It is the responsibility of the Contracting Party or observer organisation making a proposal for inclusion to supply the experts with the rationale for the proposal, supported by the necessary scientific and technical background data. Without such supporting data, the proposal should not be considered by the experts (inclusion of substances for policy reasons is outside the remit of the DYNAMEC mechanism).

#### ***Occurrence in the marine environment***

4. Occurrence of a substance in the marine environment can be taken as a qualitative criterion in addition to the defined PBT criteria. This means that substances which do not meet all the criteria for persistence, bioaccumulation and toxicity (the PBT criteria) can be considered for inclusion in the List of Substances of Possible Concern, via the safety net procedure, provided that suitable monitoring data and associated information are provided which demonstrate the presence of the substance in the marine environment. Such information must be sufficiently extensive and reliable to enable experts (who will include experts on marine monitoring) to advise the OSPAR Commission that the substances give rise to a level of concern equivalent to that for, and require a similar approach as, substances which do meet all three sets of the PBT criteria.

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<sup>7</sup> See Summary Record OSPAR 01/18/1, § 4.8 and Annex 6: Cut-Off Values for the Selection Criteria Used in the Initial Selection Procedure of the OSPAR Dynamic Selection and Prioritisation Mechanism for Hazardous Substances.

5. Supporting information will therefore be needed on the location of sampling, the sampling and analytical methods used, quality assurance techniques applied and the suspected reasons for the findings which support inclusion of the substance in the list. Sampling should be recent, and should be sufficient to enable experts to satisfy themselves that the substance is present, or causing substance-specific effects in biota, on a scale causing reasonable concern from the point of view of the maritime area, or a recognisable sub-region, as a whole. In addition to direct evidence from sampling, the presence of a substance can be deduced if evidence shows that it is produced/imported in high volumes and released in widely dispersive uses that are likely to bring about inputs to the marine environment.

### ***Metals***

6. Because persistence and bioaccumulation cannot be used as criteria for metals, the question of whether a specific metal (inorganic compound) represents a possible concern for the marine environment has, in general, to be addressed by experts in the safety net procedure. Criteria that can be taken into account in this process include, *inter alia*:

- a. whether or not the metal is an essential element;
- b. whether it is found in concentrations in the marine environment clearly exceeding natural background concentrations (taking into account the local/regional variations of these natural background levels);
- c. its speciation and the bioavailability of its various forms.

### ***Substances with a high log Kow (>6)***

7. Until such time as criteria on very persistent and very bioaccumulative substances are established, there is no guidance on substances with a high log Kow (>6).

### ***Groups of substances***

8. Recognising the definition of “group of substances” given in the OSPAR Strategy with regard to Hazardous Substances, single substances:

- a. having a structure similar to substances selected on the basis of PBT criteria and for which similar activity may be assumed; but
- b. which themselves would not be selected on the basis of the agreed PBT criteria;

should be reviewed to determine whether they may be treated together with the PBT-selected substance in the further selection process.

### ***Endocrine disruptors***

9. In view of:

- a. the requirements set out in the OSPAR Strategy with regard to Hazardous Substances as regards selection and prioritisation of endocrine disrupting chemicals;
- b. the ongoing work within other international organisations as regards endocrine disruptors and the efforts underway to develop reliable tools and procedures to identify, select and prioritise endocrine disruptors;
- c. the fact that 15 of the potential endocrine disruptors given in the lists 6 and 7 of Annex 3 of the OSPAR Strategy with regard to Hazardous Substances would not fulfil the PBT selection criteria;
- d. the serious impacts that endocrine disrupting chemicals can have at very low concentrations and their potential wide-spread effects on populations, even if exposure is low, time-limited or affects only certain stages of an organism’s life cycle;

all potential endocrine disruptors given in lists 6 and 7 of Annex 3 of the OSPAR Strategy with regard to Hazardous Substances should automatically be included (and clearly flagged) in the list of substances of possible concern (see also §§ 4.5-4.7 in DYNAMEC 00/3/1<sup>8</sup>);

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<sup>8</sup> Extract of DYNAMEC 00/3/1:

- § 4.5 With regard to endocrine disruptors, the OSPAR Strategy indicates that the Commission will develop or adopt, as part of the selection mechanism, a means of identifying substances, which give reasonable grounds for concern that they are endocrine disruptors, and apply this means of identification to relevant substances. DYNAMEC 1998 also emphasised that the development of a routine identification and selection mechanism for endocrine disrupting substances was needed so that this could be incorporated in the OSPAR dynamic selection and prioritisation mechanism for hazardous substances.
- § 4.6 Various international forums currently contribute to the development of testing and assessment tools for identification and quantification of endocrine disruption. However, no internationally agreed criteria are available at present. As soon as those criteria become available, they should be incorporated in the criterion for toxicity.
- § 4.7 In expectation of the development of criteria for endocrine disruption, it is proposed to automatically select substances on the OSPAR List of Potential Endocrine Disruptors - parts A and B - as substances of possible concern for the marine environment and consequently subject these to the ranking algorithm. However, if a substance has been selected exclusively on the basis of possible endocrine disruption, this effect will be flagged.