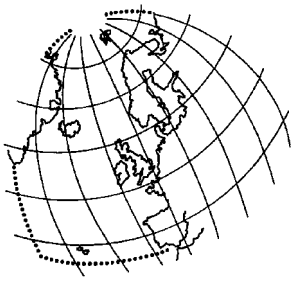


BRIEFING DOCUMENT ON THE WORK OF DYNAMEC AND THE DYNAMEC MECHANISM FOR THE SELECTION AND PRIORITISATION OF HAZARDOUS SUBSTANCES *

Contents

* OSPAR 2000 agreed that this briefing document should be made available on the OSPAR web site (cf. Summary Record OSPAR 00/20/1, § 5.7)

1. INTRODUCTION

1.1 Background and Purpose of DYNAMEC

1. The OSPAR Ministerial Meeting in 1998 agreed on an OSPAR Strategy with regard to Hazardous Substances[1] ("the strategy"), which sets out, *inter alia*, (i) a 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[2] that the OSPAR Commission would:

a. develop a dynamic selection and prioritisation mechanism (cf. Terms of Reference for an OSPAR Ad Hoc Working Group on the Development of a Dynamic Selection and Prioritisation Mechanism for Hazardous Substances[3]), 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 current OSPAR List of Chemicals for Priority Action, which comprises 15 substances or group of substances (cf. 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.

2. DESCRIPTION OF THE ELEMENTS OF THE DYNAMEC MECHANISM

3. The DYNAMEC mechanism consists of a variety of interrelated steps and procedures, which are described under the following headings and sub-headings (cf. also the simplified overview in Figure 1 at Appendix 1).

2.1 Initial Selection [4]

2.1.1 The chemical universe as starting point

4. There are approximately 250 000 man-made chemicals (the so-called 'chemical universe'). Clearly it would not be possible to rank all of these substances and the vast majority would, in any case, not be of concern for the marine environment. Therefore, as a first step, DYNAMEC took as the basis and starting point for the initial selection the chemicals included in:

a. the Nordic Substance Database (approx. 18 000 substances);

b. the Danish EPA QSAR database (more than 166 000 substances);

c. the data base of the Netherlands's BKH/Haskoning report (approx. 180 000 substances).

2.1.2 Step 1: The selection of substances

2.1.2.1 PTB selection criteria and cut-off values

5. 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 strategy. These three intrinsic criteria (PTB criteria) were determined for all the substances considered in the initial selection step, and DYNAMEC established a set of cut-off values to be applied to these criteria (cf. Appendix 2).

6. Taking into account the overall structure and purpose of the strategy, the least stringent selection criteria and cut-off values (selection V) were applied to make an initial selection of hazardous substances from the above mentioned data bases.

7. In a separate exercise, selection V was applied to the 246 substances (or groups of substances) listed in Annex 3 of the strategy ("OSPAR 1998 List of Candidate Substances"). The outcome of this investigation showed that only 61 substances were identified as substances of possible concern, whereas the remaining 185 substances were not selected, mainly because of (i) a lack of data and (ii) their low to very low potential for bioaccumulation (cf. PRAM 00/3/20).

8. Subsequently to the establishment and application of the PTB criteria as outlined above, the criterion for persistency to be used in the initial selection process (cf. Appendix 2) was further elaborated to render it more suitable for the marine environment. The current status as regards the criterion for persistency is given in the attachment to Appendix 2.

2.1.2.2 The Safety Net Procedure

9. The definition of hazardous substances in the strategy refers not only to (i) substances or groups of substances that are toxic, persistent and liable to bioaccumulate but also to (ii) other substances or groups of substances which are assessed by the Commission as requiring a similar approach as substances referred to in (i), even if they do not meet all the criteria for toxicity, persistence and bioaccumulation, but which give rise to an equivalent level of concern.

10. In order to select those substances which give rise to an equivalent level of concern, DYNAMEC agreed to supplement the selection based on PTB criteria by a safety net procedure. In this procedure, proposals from Contracting Parties for substances which, in their view, give rise to an equivalent level of concern (e.g. because of their occurrence in the marine environment or their accumulation in the foodchain), were examined by DYNAMEC experts and, if judged appropriate, included in the initial selection of substances.

11. The safety net procedure also addressed those substances (e.g. metals, inorganic compounds, endocrine disrupters), for which criteria, in addition to those of persistency and bioaccumulation, may be applicable.

2.1.3 Step 2: Quality assurance

12. The result of the initial selection of substances was examined by a group of experts established by DYNAMEC in order to check the plausibility and consistency of the substance-specific data and to exclude those substances that had been incorrectly selected.

2.1.4 List of Substances of Possible Concern

13. The ultimate outcome of the initial selection is a list of substances of possible concern, i.e. a list of those substances which, for the purpose of the strategy, have to be treated as hazardous for the marine environment. However, it should be noted that the status of this list is by nature not definite and that it will have to be revisited from time to time as further information becomes available. This may result in additions or deletions in the light of improved knowledge.

14. A first Draft Preliminary List of Substances of Possible Concern was established at DYNAMEC September 1999 (cf. Annex 5 to DYNAMEC(2) 99/10/1). This draft preliminary list was further revised in the light of further intersessional work (*inter alia* as regards the definition of selection criteria V for persistency). The current preliminary list contains 402 substances (cf. PRAM 00/3/Info.1) and is still subject to further elaboration and refinement in the 2000/2001 intersessional period.

2.1.4.1 Factsheets for substances of possible concern

15. DYNAMEC agreed that, in general, fact sheets for all substances of possible concern should be prepared. These factsheets should give comprehensive but concise background information for each of the substances, such as a description of their physico-chemical properties, (where available) production / use volumes, etc. A first set of fact sheets for the substances on the Draft Preliminary List of Substances of Possible Concern agreed at DYNAMEC September 1999 was circulated to Contracting Parties in September 1999. Subsequently, the further development of the factsheets focused on the substances to be considered by OSPAR 2000 for priority action (cf. "selection box" under section 3.1 below), and further work in the 2000/2001 intersessional period will be necessary to complete factsheets for all substances of possible concern and to find relevant data to fill gaps on existing fact sheets.

2.1.4.2 Flagging

16. For a number of reasons the various substances and groups of substances identified by the initial selection will give rise to differing levels of concern. In particular they may:

a. have intrinsic properties similar to Persistent Organic Pollutants (POPs) and fulfil the most restrictive set of cut-off points for the PTB criteria (selection I). Those substances clearly give rise to a high level of concern;

b. have suspected endocrine disrupting properties;

c. already be adequately addressed in other forums, which means that OSPAR should be able to evaluate whether to (i) await the outcome of that action or (ii) initiate specific OSPAR action.

17. In order to produce a credible list which is both sufficiently comprehensive in listing the substances which are a threat to the marine environment, and sufficiently realistic as to what can be achieved within OSPAR with the available resources, it was agreed that any substances falling into one or more of the categories described above should be flagged and thus be made clearly visible for consideration in the further work on the revision of the OSPAR List of Chemicals for Priority Action.

18. Due to the restricted time available, not all of the substances on the current draft Preliminary List of Substances of Possible Concern have been flagged, particularly with regard to whether adequate action has been or is being undertaken in other forums (cf. PRAM 00/3/Info.1). Nevertheless, the flagging of the substances to be considered by OSPAR 2000 for priority action (cf. "selection box" under section 3.1 below) has been carried out to the extent possible.

2.2 Ranking [5]

2.2.1 Basic principles of the ranking

19. In order to rank the substances or group of substances on the draft Preliminary List of Substances of Possible Concern, they were characterised with respect to their production volumes, use patterns and/or measured occurrence in the environment. The level of potential concern with regard to each substance is indicated by an effect score (relative toxicity and liability to bioaccumulate) and by an exposure score (relative level of predicted or measured occurrence in the environment). The mathematical product of the exposure and the effect score is an indicator for the relative risk with regard to each substance. The process included automated data processing, which was followed by expert judgement (e.g. on the basis of fact sheets).

20. DYNAMEC agreed that (i) calculated exposure estimations and (ii) monitored freshwater/limnic concentrations, both for the (iii) aquatic phase and the (iv) sediment, should be taken into account in the ranking process.

21. The ranking algorithms were based on those which had been established for the Combined Monitoring-based and Modelling-based Priority Setting (COMMPS) procedure in the context of the draft 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 were certain substance specific data were not known.

2.2.1.1 Exposure scoring

22. For each substance, 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 index.

2.2.1.2 Effect scoring

23. For each substance, an effect index 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).

2.2.1.3 Relative rank

24. A priority index was calculated by multiplying the exposure index with the effect index. This priority index then determined the relative rank of the substance on the four ranking lists.

2.2.2 Data used in the ranking

25. The substance-specific data (e.g. on production / use volumes) 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 and other sources. In general, the highest-quality and most stringent data were chosen in cases where more than 1 data set for a substance was available.

26. A significant obstacle that had to be overcome was that access to data on production / use volumes for certain substances was restricted for reasons of confidentiality. This meant that the application of the ranking algorithm, the assessment of the outcome of the ranking and the data used could only be undertaken and validated by a limited number of experts.

2.2.3 Application of the ranking algorithms

27. The above ranking procedure was applied to those substances on the first draft Preliminary List of Substances of Possible Concern established at DYNAMEC September 1999, for which information on production and use and/or monitoring data were available (241 out of 367).

28. The revised draft Preliminary List of Substances of Possible Concern prepared at DYNAMEC 2000 has not yet been taken into account in the ranking. DYNAMEC included some 34 further substances or groups of substances in this list, for which data and information is available to rank them. However, it is unlikely that many of these additional substances would (i) have a high ranking score or (ii) fall into the subset of substances to be considered by OSPAR 2000 for priority action (cf. "selection box" under section 3.1 below).

29. For those substances where sufficient information was not available to carry out the ranking, further action cannot be undertaken until either adequate information becomes available or some other approach to determining the status of these substances under the strategy is agreed.

2.2.4 Outcome of the ranking

30. The ranking results in 4 lists (cf. DYNAMEC 00/4/1):

a. a ranking list for water based on measured environmental concentration and the properties of the substances;

b. a ranking list for water based on modelled exposure scores (based on calculation from production volumes and use patterns);

c. a ranking list for sediments based on measured environmental concentration and the properties of the substances; and

d. a ranking list for sediments based on modelled exposure scores (based on calculation from production volume and use pattern).

3. ADVICE TO OSPAR WITH RESPECT TO THE SELECTION OF SUBSTANCES FOR PRIORITY ACTION

31. Although the selection of substances for priority action is ultimately a policy decision and therefore has to be carried out by the Commission itself, it was agreed that DYNAMEC should provide information and expert advice to support the revision, at OSPAR 2000, of the OSPAR List of Chemicals for Priority Action (cf. Annex 2 of the strategy).

3.1 "Selection box" of 80 substances

32. In the Sintra Statement, Ministers declared that the Commission would develop the necessary programmes and measures within 3 years after agreeing on the need for OSPAR action on a substance or group of substances (cf. Sintra Statement). This timeframe, together with the limited resources available to Contracting Parties and the Commission, restrict the number of new priority substances that can be addressed under OSPAR at a time.

33. Furthermore, HOD recognised that there would be substances in the ranked list(s) which would be of relatively lower concern on the basis of their intrinsic properties, and that it would be a matter for future decision (when progress has been made with the List of Chemicals for Priority Action) how much effort OSPAR needed to devote to these substances.

34. To facilitate the discussions at OSPAR 2000, 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 selection criteria I or which were flagged as endocrine disruptors.

35. There were 5 initially selected substances (cf. Appendix 4) which might have been ranked high enough to be considered as priority substances, but which could not enter the “selection box” since, due to time constraints, they had not been ranked.

3.2 Grouping of the "selection box" substances

36. DYNAMEC experts examined the 80 substances on the basis of further elaborated fact sheets and established the basis for a pragmatic grouping of these substances as follows:

Group	Description
A	substances of very high concern (i.e. POP-like substances or substances with PTB profile, selection I) and indication of production, use or occurrence in the environment
B	Other initially selected substances (with less severe PTB profile) and indication of use or exposure

C substances of very high concern (i.e. POP-like substances or substances with PTB profile, selection I) with no indication of use or exposure

D Other initially selected substances with no indication of use or exposure

E substances with PTB properties but which are heavily regulated or withdrawn from the market

F endocrine disrupters, 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

37. 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, are given in brackets and indicated with a star (*).Further information about the work carried out by the DYNAMEC experts was presented to PRAM 2000 in a separate document (cf. PRAM 00/3/24).

38. The breakdown of the 80 substances given in Appendix 3 can be summarised as follows:

Group A	5	**Group A***	13
Group B	7	**Group B***	7
Group C	8		
Group D	7		
Group E	20		
Group F	6		
Deleted substances	7		
Overall Total	**80**		

3.3 Recommendations *

3.3.1 Recommended substances to be considered at OSPAR 2000

39. It is recommended that when revising the OSPAR List of Chemicals for Priority Action, OSPAR 2000 might consider in the first instance the 12 substances in groups A and B as given in Appendix 3.

3.3.2 Recommendations with respect to substances which were initially selected as a result of reliance on QSAR data and/or experimental data about which confidence might be doubted

40. It is further recommended that:

a. the 20 substances in groups A * and B * (cf. Appendix 3) should not presently be considered as chemicals for priority action;

b. Contracting Parties and observers should be invited to provide more reliable data for these substances in the 2000/2001 intersessional period (at least 3 months prior to OSPAR 2001). OSPAR 2001 should consider whether:

(i) in the light of a review of any additional data **made** available, these substances might be added to the list of chemicals for priority action;

(ii) in the light of any additional data **not** becoming available, to add these substances to the list of chemicals for priority action.

* OSPAR 2000 adopted the recommendations made in this section (cf. Summary Record OSPAR 00/20/1, Annexes 6 and 7).

3.3.3 Recommendations with respect to substances with no indication of use or exposure

41. It is further recommended that:

a. the 15 substances in groups C and D (cf. Appendix 3) should not presently be considered as chemicals for priority action;

b. Contracting Parties and observers should be invited to identify and make available data for these substances in the 2000/2001 intersessional period (at least 3 months prior to OSPAR 2001). OSPAR 2001 should then consider whether:

(i) in the light of a review of any data on use or exposure **made** available, these substances might be added to the list of chemicals for priority action;

(ii) in the light of any additional data **not** becoming available, to add these substances to the list of chemicals for priority action.

It should be noted that some of the substances in groups C and D were initially selected as a result of reliance on QSAR data and/or experimental data about which confidence might be doubted.

3.3.4 Recommendations with respect to substances with PTB properties but which are heavily regulated or withdrawn from the market

42. Furthermore, OSPAR is invited to consider to initiate monitoring activities with respect to some of the heavily regulated substances in group E (cf. Appendix 3) with a view to determining whether concentrations observed in the environment result from (i) historic uses, (ii) unintended or by-production emissions and discharges or (iii) long range (atmospheric) transport.

4. RISK ASSESSMENT FOR THE MARINE ENVIRONMENT

43. Once the Commission has identified and selected a substances for priority action, § 5.3 of the strategy sets out the steps to be taken in order to identify the scope and extent of the necessary programmes and measures and their development. These steps, for the purpose of this document named "risk assessment", include the identification of the sources and the pathways to the marine environment of the substances and the use of an appropriate combination of monitoring, modelling, risk characterisation and risk assessment techniques to establish the scale of the threat.

4.1 Draft Framework for a Common OSPAR/EC Approach on Risk Assessment Methodology for the Marine Environment

44. DYNAMEC recognised that there was a need to develop methodology suitable for the purpose of assessing the risk of hazardous substances in the marine environment. Drawing on the relevant elements in the existing EU Technical Guidance in support of Directive 93/67/EEC on Risk Assessment for New and Notified Substances and Regulation EC 1488/94 on Risk Assessment for Existing Substances (TGD), DYNAMEC developed a Draft Framework for a Common OSPAR/EC Approach on Risk Assessment Methodology for the Marine Environment (cf. Annex 6 to DYNAMEC(2) 99/10/1).

45. This draft framework provides guidance for Contracting Parties on how to carry out a marine risk assessment for a priority substance by outlining (i) the background, (ii) the basic principles, (iii) the objectives and protection goals, (iv) the data requirements and interpretation, (v) the approaches to marine risk assessment and (iv) the implementation.

46. The draft framework furthermore sets out a three stage procedure which recognises that, depending on the concerns that can arise over the differing spatial scales from the point of release of a hazardous substance, assessments have to be carried out in a local, regional or open sea approach.

47. For POP-like substances (i.e. those fulfilling the criteria and cut-off values for selection I, cf. Appendix 2), which are produced in significant volumes and give rise to a high level of concern, the

methodology limits the risk assessment to an evaluation of the sources and pathways of the substance concerned (open-sea approach). For other substances, the more traditional type of PEC/PNEC approach should be applied, particularly when assessing the risk on a local or regional level.

48. Although the draft framework is currently being reviewed by experts in an EU TGD subgroup on marine risk assessment, it should nevertheless be used by Contracting Parties in the next intersessional period for identifying the scope and extent of programmes and measures with respect to the new substances, which will be chosen by OSPAR 2000 for priority action.

5. FURTHER ELABORATION AND REFINEMENT OF THE PRODUCTS DEVELOPED BY DYNAMEC

49. In order to deliver the requested products in the limited time available, DYNAMEC had to follow a very pragmatic approach, which meant that most of the steps and procedures had to be developed, tested and applied in parallel without the possibility of repeated revisions. It was agreed that there was a need for further detailed discussion and elaboration of a number of technical issues relating to (i) the various steps and procedures of the DYNAMEC mechanism and (ii) the assessment of risk in the marine environment. How this further work will be carried out in the 2000/2001 intersessional period will be addressed as part of the ongoing review of the OSPAR working procedures and arrangements for the core block of work related to hazardous substances.

REFERENCES (indicated as endnotes in the text)

1 Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 34

2 Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 45

3 Summary Record of OSPAR/MMC 1998 (OSPAR 98/14/1), Annex 10

4 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 (cf. DYNAMEC 00/3/1).

5 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 (cf. DYNAMEC 00/4/1).

List of relevant Summary Records (in chronological order)

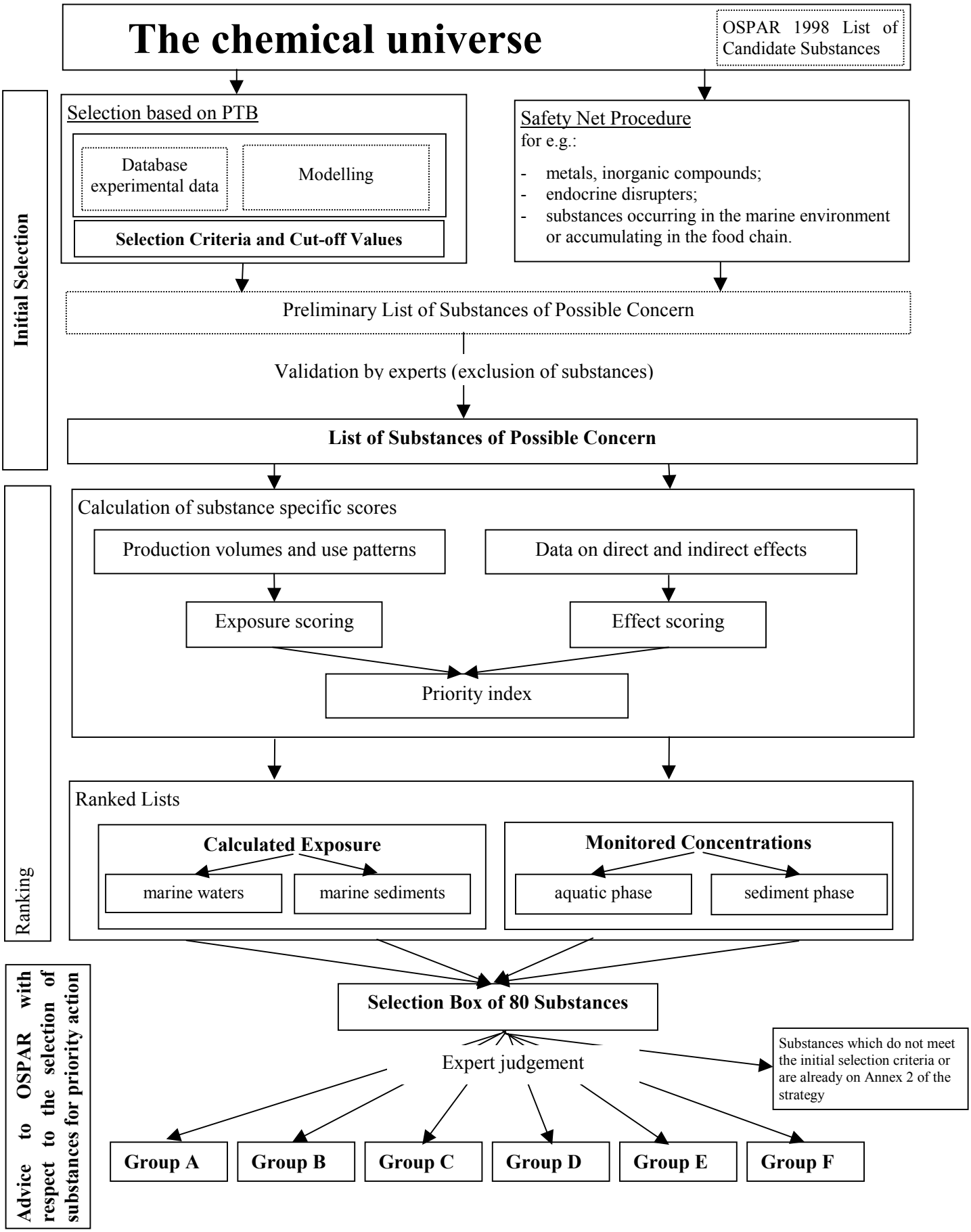
Meeting	Summary Record number
OSPAR/MMC 1998	OSPAR 98/14/1
DYNAMEC 1998	DYNAMEC 98/9/1
HOD November 1998	HOD(4) 98/10/1
DYNAMEC March 1999	DYNAMEC(1) 99/10/1
HOD May 1999	HOD(1) 99/12/1
OSPAR 1999	OSPAR 99/15/1
DYNAMEC September 1999	DYNAMEC(2) 99/10/1
DIFF 1999	DIFF 99/11/1
HOD November 1999	HOD(2) 99/10/1
DYNAMEC February 2000	DYNAMEC 00/10/1
PRAM 2000	PRAM 00/12/1

Note concerning the availability of the above mentioned documentation:

With exception of the Summary Records of HOD, all other Summary Records are available to the public on the OSPAR web site for downloading.

Meeting documents mentioned in this briefing document might be made available on request.

Figure 1: Simplified Overview of the Steps and Procedures within the DYNAMEC mechanism and the work carried out under DYNAMEC



Appendix 2

Selection criteria and cut-off values with respect to Persistency, Toxicity and Liability to Bioaccumulate ("PTB criteria") [1]

Selection criteria

Selection I has the most stringent cut-off values and will select the most severe PTBs. This selection includes POP-like criteria without atmospheric degradation, hydrolysis and vapour pressure.

Selection II is the same as I except for aquatic toxicity, where the threshold is set ten times higher. Less toxic substances will thus be selected, still it is the same threshold that is used in the classification and labelling system for identifying substances that are 'very toxic to aquatic organisms' (R50).

Selection III is the same as II but with a lower threshold for bioaccumulation (see paragraph 2.1). More substances will thus be selected in III than in II.

Selection IV is the same as II, but with a lower threshold for persistence (see paragraph 2.1). The lower thresholds for bioaccumulation and biodegradation, in selection III and IV respectively, are also in line with the classification criteria for the aquatic environment, either as they stand in the substance directive or as proposed for international harmonisation[2]. All selections, however, are more stringent than the classification criteria as only one parameter at a time is given the lower threshold in our selections, while the other two parameters are kept at the more stringent level.

Selection V the cut-off values are all in line with the classification and labelling criteria as proposed for international harmonisation. The selection V is a combination of the least stringent criteria of selection I-IV. For aquatic toxicity, the most stringent cut-off value of the classification criteria is taken. Contrary to the EC classification, mammalian toxicity is added in addition to the criteria for the aquatic environment (counts for all selections). For persistence, the criterion is that the substance is not readily biodegradable. For bioaccumulation the selected cut-off value is the same as that in classification and labelling.

Cut-off values

Selection	Applied cut-off values
I	P: Not inherently biodegradable **and** B: log K_{ow}>=5 or BCF>=5000 **and** T_{aq}: acute L(E)C_{50}=<0,1 mg/l, long-term NOEC=<0,01 mg/l **or** $T_{mammalian}$: CMR or chronic toxicity
II	P: Not inherently biodegradable **and** B: log K_{ow}>=5 or BCF>=5000 **and** T_{aq}: acute L(E)C_{50} =<1 mg/l, long-term NOEC=<0,1 mg/l **or** $T_{mammalian}$: CMR or chronic toxicity
III	P: Not inherently biodegradable **and** B: log K_{ow}>=4 or BCF>=500 **and** T_{aq}: acute L(E)C_{50} =<1 mg/l, long-term NOEC =< 0,1 mg/l **or** $T_{mammalian}$: CMR or chronic toxicity
IV	P: Not readily biodegradable **and** B: log K_{ow}>=5 or BCF>=5000 **and** T_{aq}: acute L(E)C_{50}=<1 mg/l, long-term NOEC=<0,1 mg/l **or** $T_{mammalian}$: CMR or chronic toxicity
V	P: Not readily biodegradable-**and** B: log K_{ow}>=4 or BCF>=500 **and** T_{aq}: acute L(E)C_{50}=<1 mg/l, long-term NOEC=<0,1 mg/l **or** $T_{mammalian}$: CMR or chronic toxicity

[1] Subsequently to the establishment and application of these PTB criteria, the criterion for persistency to be used in the initial selection process was further elaborated to render it more suitable for the marine environment. The current status as regards the criterion for persistency is given in the attachment to Appendix 2.

[2] 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 Criterion within the Hazardous Substances Strategy

INTRODUCTION

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 suggested 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 on what type of information 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 to make optimal use of the available data and methods. Clearly, more research is needed to better estimate the 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 the persistence in the marine environment should be assessed in relevant simulation test systems that determine the half-life under relevant environmental conditions. Especially when emissions to the marine areas are via rivers, freshwater half-lives are also of relevance. The determination of the half-life should include assessment of metabolites with PTB-characteristics. The half-life should be used as the first and main criterion in order to determine whether substances should be regarded as persistent in the context of the Hazardous Substances Strategy. Hence appropriate half-life data override data from the other levels of information.
A cut-off value of 50 days is suggested in fresh water (as a transport media) as well as in the marine environment once the substances has reached this compartment[3].

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 overinterpret the outcome of the ready/inherent tests. However, in order to use the available information to select potentially persistent substances it is proposed to use the results of different types of information 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

[3] Further discussion is still needed on the cut-off values that are to be used for half-lives in sediment. Current data determined under marine as well as under freshwater conditions, if available, need to be assessed on a case by case basis.

real potential for persistency. It must be noted that in this case it is not propagated to perform inherent test but rather to go directly to Level 3 testing.

- 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 to use the results of two specific tests when they fulfil certain criteria. These tests are[4]:
  - 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 the environment. It is proposed to use rather stringent cut-off levels in order to select those substances for which there is a fair level of concern regarding their potential for persistence in the marine environment. For this first application of QSARs in the initial selection mechanism a combination of two BIOWIN models is suggested. 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 is 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 DYNAMECs initial selection mechanism.

[4] The criteria for the inherent tests are similar to the criteria defined in the EU Technical Guidance Documents for Risk Assessment of New and Existing Substances

Breakdown of the 80 substances of the "selection box" drawn from the ranked lists of the initially selected substances

Group A – Substances of very high concern (i.e. POP-like substances or substances with PTB profile, selection I) and indication of production, use or occurrence in the environment

CAS No	Name	IUPAC name	Remarks
732-26-3	dodecylphenol	phenol, 2,4,6-tris(1,1-dimethylethyl)-	
115-32-2	dicofol	benzenemethanol, 4-chloro-.alpha.-(4-chlorophenyl)-.alpha.-(trichloromethyl)-	EU Dir 91/414 but not on a priority list
115-29-7	endosulphan	6,9-methano-2,4,3-benzodioxathiepin, 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-,3-oxide	EU Dir 91/414 first list and draft EU Water Framework Dir first priority list
72-43-5	methoxychlor	benzene,1,1'-(2,2,2-trichloroethylidene)bis(4-methoxy	EU Dir 91/414 second list
140-66-9	octylphenol	phenol, 4-(1,1,3,3,tetramethylbutyl)-	draft EU Water Framework Dir first priority list

Group A*- Substances of very high concern (i.e. POP-like substances or substances with PTB profile, selection I) and indication of production, use or occurrence in the environment, but which have been initially selected as a result of reliance on QSAR data and/or experimental data about which confidence might be doubted

CAS No	Name	IUPAC name	Remarks
85-22-3		benzene, pentabromoethyl	
2104-64-5	EPN	phosphonothioic acid, phenyl-, O-ethyl O-(4-nitrophenyl) ester	
2227-13-6	tetrasul	benzene, 1,2,4-trichloro-5-[(4-chlorophenyl)thio]-	
22832-87-7	miconazole nitrate	1-H-imidazole, 1-[2-(2,4-dichlorophenyl)-2-[(2,4-dichlorophenyl)methoxy]ethyl]-,mononitrate	
51000-52-3		neodecanoic acid, ethenyl ester	
335-57-9		heptane, hexadecafluoro-	
355-43-1		hexane, 1,1,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodo-	
512-04-9	diosgenin	spirost-5-en-3-ol, (3beta, 25R)-	
4904-61-4		1,5,9-cyclododecatriene	
55525-54-7		urea, N,N'-bis[(5-isocyanato-1,3,3-trimethylcyclohexyl)methyl]-	
59447-55-1		2-propenoic acid, (pentabromophenyl)methyl ester	
1582-09-8	trifluralin	benzenamine, 2,6-dinitro-N,N-dipropyl-4-trifluoromethyl)-	EU Dir 91/414 but not on a priority list and draft EU Water Framework Dir first priority list
23593-75-1	clotrimazole	1H-imidazole, 1-[(2-chlorophenyl)diphenylmethyl]-	EU Dir 91/414 first priority list

Group B – Other initially selected substances (with less severe PTB profile) and indication of use or exposure

CAS No	Name	IUPAC name	Remarks
107-46-0	HMDS	disiloxane, hexamethyl-	
77-47-4		1,3-cyclopentadiene, 1,2,3,4,5,5-hexachloro-	EU Reg 793/93 4th priority list
79-94-7	TBBA	phenol, 4,4'-(1-methylethylidene)bis[2,6-dibromo-	EU Reg 793/93 4th priority list
120-82-1		benzene, 1,2,4-trichloro-	EU Reg 793/93 earlier priority list and Draft Water Framework Dir first priority list
87-61-6	trichlorobenzene	benzene, 1,2,3-trichloro-	EU Draft Water Framework Dir first priority list
108-70-3	1,3,5-trichlorobenzene	benzene, 1,3,5-trichloro-	EU Draft Water Framework Dir first priority list
98-51-1	4-tert-butyltoluene	benzene, 1-(1,1-dimethylethyl)-4-methyl-	OECD SIDS data gathering (Japan)

Group B*– Other initially selected substances (with less severe PTB profile) and indication of use or exposure, but which have been initially selected as a result of reliance on QSAR data and/or experimental data about which confidence might be doubted

CAS No	Name	IUPAC name	Remarks
294-62-2		cyclododecane	
603-35-0		phosphine, triphenyl-	
90604-37-8		alcohols, C11-15-branched	
97280-83-6	isododecane	dodecane, branched	
793-24-8	6PPD	1,4-benzenediamine, N-(1,3-dimethylbutyl)-N'-phenyl-	German BUA report
3861-47-0	loxynil octuroate	octanoic acid, 4-cyano-2,6-diiodophenyl ester	EU Dir 91/414 first priority list
2921-88-2	chlorpyrifos	Phosphorothioic acid, O,O-diethyl O-(3,5,6-trichloro-2-pyridyl) ester	EU Dir 91/414 first priority list and Draft Water Framework Dir first priority list

Group C – Substances of very high concern concern (i.e. POP-like substances or substances with PTB profile, selection I) with no indication of use or exposure

CAS No	Name	IUPAC name	Remarks
28680-45-7	Heptachlorobornene	bicyclo[2.2.1]hept-2-ene, heptachloro-	
36065-30-2		benzene, 1,3,5-tribromo-2-(2,3-dibromo-2-methylpropoxy)-	
1321-65-9		naphthalene, trichloro-	PCNs polychlorinated naphthalenes
1335-87-1		naphthalene, hexachloro-	PCNs polychlorinated naphthalenes
1335-88-2		naphthalene, tetrachloro-	PCNs polychlorinated naphthalenes
2234-13-1		naphthalene, octachloro-	PCNs polychlorinated naphthalenes
32241-08-0		naphthalene, heptachloro-	PCNs polychlorinated naphthalenes
70124-77-5	flucythrinate	benzeneacetic acid, 4-(difluoromethoxy)-.alpha.-(1-methylethyl)-, cyano(3-phenoxyphenyl)methyl ester	EU Dir 91/414 not on a priority list

Group D - Other initially selected substances with no indication of use or exposure

CAS No	Name	IUPAC name	Remarks
122-14-5	fenitrothion	Phosphorothioic acid, O,O-dimethyl O-(3-methyl-4-nitrophenyl) ester	
465-73-6	isodrin	1,4,5,8-dimethanonaphthalene, 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-, (1.alpha.,4.alpha.,4a.beta.,5.beta.,8.beta.,8a.beta.)-	
1825-21-4		Pentachloroanisole	
91081-53-7		rosin, reaction products with formaldehyde	
67306-03-0	fenpropimorph	morpholine, 4-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]-2,6-dimethyl-	EU Dir 91/414 but not prioritised
67564-91-4	fenpropimorph	morpholine, 4-[3-[4-(1,1-dimethylethyl)phenyl]-2-methylpropyl]-2,6-dimethyl-, cis-	EU Dir 91/414 but not prioritised
333-41-5	diazinon	Phosphorothioic acid, O,O-diethyl O-[6-methyl-2-(1-methylethyl)-4-pyrimidinyl] ester	EU Dir 91/414 second list

Group E - Substances with PTB properties but which are heavily regulated or withdrawn from the market

CAS No	Name	IUPAC name	Remarks
50-29-3	p,p' DDT	benzene, 1,1'-(2,2,2-trichloroethylidene)bis[4-chloro-	Substance restricted under Dir 76/769 or Dir 79/117
53-19-0	o,p' DDD	benzene, 1-chloro-2-[2,2-dichloro-1-(4-chlorophenyl)ethyl]-	Substance restricted under Dir 76/769 or Dir 79/117
57-74-9	chlordane	4,7-methano-1H-indene, 1,2,4,5,6,7,8,8-octachloro-2,3,3a,4,7,7a-hexahydro-	Substance restricted under Dir 76/769 or Dir 79/117
67-72-1		Hexachloroethane	Substance restricted under Dir 76/769 or Dir 79/117
72-54-8	p,p' DDD	benzene, 1,1'-(2,2-dichloroethylidene)bis[4-chloro-	Substance restricted under Dir 76/769 or Dir 79/117
72-55-9	p,p' DDE	benzene, 1,1'-(dichloroethenylidene)bis[4-chloro-	Substance restricted under Dir 76/769 or Dir 79/117
76-44-8	heptachlor	4,7-methano-1H-indene, 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-	Substance restricted under Dir 76/769 or Dir 79/117
118-74-1		Hexachlorobenzene	Substance restricted under Dir 76/769 or Dir 79/117
309-00-2	aldrin	1,4,5,8-dimethanonaphthalene, 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-, (1.alpha.,4.alpha.,4a.beta.,5.alpha.,8.alpha.,8a.beta.)-	Substance restricted under Dir 76/769 or Dir 79/117
789-02-6	o,p' DDT	benzene, 1-chloro-2-[2,2,2-trichloro-1-(4-chlorophenyl)ethyl]-	Substance restricted under Dir 76/769 or Dir 79/117
1836-75-5	nitrofen	benzene, 2,4-dichloro-1-(4-nitrophenoxy)-	Substance restricted under Dir 76/769 or Dir 79/117
3424-82-6	o,p' DDE	benzene, 1-chloro-2-[2,2-dichloro-1-(4-chlorophenyl)ethenyl]-	Substance restricted under Dir 76/769 or Dir 79/117
8001-35-2	toxaphene	toxaphene	Substance restricted under Dir 76/769 or Dir 79/117
51630-58-1	fenvalerate	benzeneacetic acid, 4-chloro-.alpha.-(1-methylethyl)-,cyano (3-phenoxyphenyl)methyl ester	Substance restricted under Dir 76/769 or Dir 79/117
61788-33-8	PCT	terphenyl, chlorinated	Substance restricted under Dir 76/769 or Dir 79/117
95-94-3		benzene, 1,2,4,5-tetrachloro-	Substance apparently not produced
133-49-3		benzenethiol, pentachloro-	Substance apparently not produced
634-66-2		benzene, 1,2,3,4-tetrachloro-	Substance apparently not produced

87-68-3	hexachloro-1,3-butadiene	1,3-butadiene, 1,1,2,3,4,4-hexachloro-	Substance apparently not produced and EU Draft Water Framework Dir first priority list
608-93-5	pentachlorobenzene	benzene, pentachloro-	Substance apparently not produced and EU Draft Water Framework Dir first priority list

Group F - Endocrine disruptors (which do not meet P or B criteria) or natural hormones

CAS No	Name	IUPAC name	Remarks
50-28-2	estradiol,beta	Oestradiol	Suspected Endocrine Disruptor
53-16-7	estrone	Oestron	Suspected Endocrine Disruptor
56-53-1	DES	diethylstilbestrol	Suspected Endocrine Disruptor
57-63-6		17-ethynylestradiol	Suspected Endocrine Disruptor
95-76-1	3,4-dichloroanilin e	benzeneamine, 3,4-dichloro-	EU risk assessment under Reg 793/93 almost complete
98-54-4	butylphenol	Phenol, 4-(1,1-dimethylethyl)-	Suspected Endocrine Disruptor

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

CAS No	Name	IUPAC name	Remarks
319-85-7	beta-HCH	cyclohexane, 1,2,3,4,5,6-hexachloro-	Substance already on Annex 2 and on EU Draft Water Framework Directive first priority List
855-53-5	SCCP	alkanes, C10-13, chloro-	Substance already on Annex 2 and on EU Draft Water Framework Directive first priority List
128-37-0	BHT	phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl-	Not meeting initial selection V
61789-53-5		nitriles, coco	Not meeting initial selection V
67700-98-5		amines, C10-16-alkyldimethyl	Not meeting initial selection V
91465-08-6	lambda-cyhalothrin	Cyclopropanecarboxylic acid, 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-, cyano(3-phenoxyphenyl)methyl ester, [1.alpha.(S*),3.alpha.(Z)]-(.+-.)-	Not meeting initial selection V
118712-89-3	transfluthrin	Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, (2,3,5,6,-tetrafluorophenyl)methyl ester, (1R-trans)-	Not meeting initial selection V

Appendix 4

Initially selected substances which may have ranked high enough to be considered as priority substances but did not enter the selection box because they were not ranked due to time constraints *

CAS No	Name	IUPAC name	Remarks
50-63-5	Chloroquine bis(phosphate)	1,4-pentanediamine, N(4)-(7-chloro-4-quinolinyl)-N(1),N(1)-diethyl-, phosphate (1:2)	
101-20-2	Triclocarban	Urea, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl)-	
57966-95-7	Cymoxanil	Acetamide, 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)-	
85535-85-9	Chlorinated paraffine, chlorine content 50%	Alkanes, C14-17, chloro	
85509-19-9		Flusilazole	

* Subsequently to finalising this briefing document, Germany has ranked these substances or groups of substances. The outcome of this ranking exercise will be taken into account in the 2000/2001 intersessional period, *inter alia*, when refining the DYNAMEC mechanism.