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Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DECISION

establishing the list of priority substances in the field of water policy

(presented by the Commission)

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SUMMARY

According to Article 16 (formerly Article 21) of the proposed European Parliament and Council Directive establishing a framework for community action in the field of water policy¹ (hereafter referred as the Water Framework Directive, WFD), the Proposal setting out a first list of priority substances shall be submitted by the Commission by 31 December 1999. For these priority substances the **‘combined approach’** has to be applied according to the proposed WFD (Art. 10, formerly Art. 12a), i.e. harmonised European water quality standards and emission controls will be elaborated for all substances.

The priority list should be based on the risk to the **aquatic ecosystem and to human health via the aquatic environment**. There are three options in the proposed WFD to identify the priority substances. Of these the only practically feasible one within a reasonable short time is the option which requires a “simplified risk-based assessment procedure based on scientific principles” taking account of intrinsic hazards to substances and of the exposure to ecosystems based on monitoring and on modelling data.

On this basis, a procedure called **COMMPS** (**combined monitoring-based and modelling-based priority setting**) has been elaborated in collaboration with a consultant (Fraunhofer Institute for Environmental Chemistry and Ecotoxicology, Germany herein simply referred to as the Fraunhofer Institute). The basic idea is to rank substances for which sufficient data are available according to their **relative risk** to the aquatic environment in an automated manner and to apply expert judgement for the final selection of priority substances.

Experts from Member States, Scientific Committee for Toxicity, Ecotoxicity and the Environment-CSTEE, European Chemicals Bureau-ECB, industry, water suppliers and environmental organisations discussed the COMMPS procedure in meetings held in February and July 1998. At the meeting in July 1998 a first study by the Fraunhofer Institute, which illustrated the effectiveness of the COMMPS procedure, was presented. Following comments and additional information provided by the above-mentioned experts the Fraunhofer Institute undertook a thorough revision of the COMMPS procedure which also took into account the expertise of a statistician who was contracted by the Commission. The revised Fraunhofer study exploited about **750,000 surface water monitoring data items** and about **70,000 sediments monitoring data items**. Data were provided by all 15 Member States and by the European Union of National Associations of Water Suppliers and Waste Water Services (EUREAU). Modelling data were provided by the European Chemicals Bureau and are therefore fully compatible with the database used for the prioritisation of existing substances.

¹ N.B.: The Political Agreement of the Council of 2 March 1999 has been revised and numbers of Articles have been changed in the Council Common Position of 22 October 1999.

The revised COMMPS study contains the following risk-based ranking lists:

- One list using an exposure estimation based on **surface water monitoring** data (monitoring-based list)
- One list using an exposure estimation based on **surface water modelling** data (modelling-based list)
- One list using an exposure estimation based on **sediment monitoring** data (sediment list)
- Several ranking lists for **metals** based on different exposure and effects scenarios (metal lists)

The different exposure scenarios were combined with the effects of the substances taking into account **eco-toxicological effects** to aquatic organisms (direct effects), **bioaccumulation** (indirect effects) and **toxicity** (effects on human health). From the different ranking lists the Fraunhofer Institute selected a subset of high ranked “candidate priority substances” and made a substance by substance judgement in order to identify the substances which they recommend for inclusion into the first priority list.

The revised COMMPS study was presented and discussed at an expert meeting on 19 April 1999. There was general agreement that the recommended list is based on the best scientific evidence possible within the given time. Following comments by the experts, the Commission revised the recommended list by the Fraunhofer Institute and finalised the attached Proposal for a **European Parliament and Council Decision establishing the list of priority substances in the field of water policy**.

EXPLANATORY MEMORANDUM

1. INTRODUCTION

1. In 1997 the Commission proposed a European Parliament and Council Directive establishing a framework for Community action in the field of water policy. The Council reached a Common Position on this proposal on 22 October 1999². Once adopted, this Directive will be the basic legislation for the protection of the European aquatic environment.
2. Article 10 (new)/12a (old) and Article 16 (new)/21 (old)³ of the proposed European Parliament and Council Directive establishing a framework for community action in the field of water policy (referred to hereafter as WFD) lay down the Community strategy for the establishment of harmonised quality standards and emission controls of dangerous substances (combined approach). It will replace, within a certain transition period, the emission control policy established under Council Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community⁴ and the Directives adopted within its framework.
3. Directive 76/464/EEC presently comprises the main Community instrument for controls of dangerous substances discharged into surface waters. In 1982, the Communication from the Commission to the Council on dangerous substances which might be included in List I of Council Directive 76/464/EEC⁵ presented approximately 130 substances for Community action, which had been selected on the basis of their high production volumes as well as their toxicity, persistence and bioaccumulation. Following the publication of this list, 17 substances were regulated under daughter directives (82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC)⁶ adopted within the frame of Council Directive 76/464/EEC.
4. The further development of daughter directives became increasingly difficult for several reasons. Firstly, it was generally felt that the single medium approach of Directive 76/464/EEC would be, at least for large installations, an insufficient account of the overall environmental protection, which should also include emissions to the air and to waste as well as other aspects such as rational use of energy. Secondly, Directive 76/464/EEC introduced the

² Council Common Position of 22 October 1999 (OJ C 343, 30.11.1999, p. 1).

³ N.B.: Political Agreement of the Council, Council document 6404/99 ENV 68 PRO-COOP 46 – Interinstitutional file: 97/0067 (SYN) of 2 March 1999 (herein referred as old) has been revised and numbers of Articles have been changed in the Council Common Position of 22 October 1999 (herein referred as new).

⁴ OJ L 129, 18.5.1976, p. 23.

⁵ OJ C 176, 14.7.1982, p. 3.

⁶ OJ L 81, 27.3.1982, p. 29; OJ L 291, 14.10.1983, p. 1; OJ L 74, 17.3.1984, p. 49; OJ L 274, 17.10.1984, p. 11; OJ L 221, 7.8.1986, p. 51 (amended OJ L 158, 25.6.1988, p. 35 and OJ L 219, 14.8.1990, p. 49).

option to apply either technically-defined emission controls or quality objectives. This was contrary to the increasing evidence that only a 'combined approach' incorporating both instruments would be adequate for a high level of protection. Thirdly, Directive 76/464/EEC did not provide a rational and systematic approach for the prioritisation of substances for which Community measures should be developed.

5. The adoption of Council Directive 96/61/EC establishing an integrated system of pollution prevention and control⁷ (IPPC Directive) for larger installations, successfully dealt with the first problem, but left the latter problems unresolved. In 1997, the Commission proposal for the introduction of a Directive on emission controls for small and medium sized enterprises was met with low support during a consultation of the Member States and was criticised for its perceived rigidity and abandonment of the subsidiary principle. These developments led the Commission to the final conclusion that the best option would be a replacement of the regime of Directive 76/464/EEC by an appropriate amendment of the proposed WFD.
6. The measures of Article 16 (new)/Article 21 (old) of the proposed WFD establish the implementation of the combined approach, defined in Article 10 (new)/Article 12a (old) of the WFD, at Community level. The combined approach requires the introduction of two independent types of measures: the control of emissions at the source and the setting of quality standards as a means of measuring the success of the former.
7. Furthermore, Article 16 (new)/Article 21 (old) contains, for the first time, a legal framework and a clear methodological basis for the prioritisation of substances for which the setting of quality standards and emission controls at Community level is envisaged.
8. In its original proposal of the WFD in 1997, the Commission set the ambitious deadline of 31 December 1998 for the completion of a proposal establishing the list of priority substances in the field of water policy (hereafter referred as priority list). It still, however, faced significant criticism for proposing a prioritisation procedure feared to be overly time-consuming by virtue of its complexity, and, thereby, significantly hampering the further development of Community measures. In response to this, at the soonest possible date, the Commission initiated expert discussions on the development of a generally accepted prioritisation algorithm. During three rounds of expert discussions from February 1998 to April 1999, the combined monitoring-based and modelling-based priority setting (COMMPS) procedure was developed in collaboration with a consultant and was applied in the identification process of the proposed priority substances.
9. The priority list of substances will play a key role in the establishment of future controls for the protection of Community water bodies. As a major legal consequence of the adoption of priority substances, the Commission must come forward with proposals for emission controls and quality

⁷ OJ L 257, 10.10.1996, p. 26.

standards within the time period specified in Article 16 (new)/Article 21 (old) of the proposed WFD. The Commission holds the view that the most appropriate legal instrument for enacting the priority list is a European Parliament and a Council Decision.

10. The following gives a brief presentation of the rationale for the selection of the proposed substances.

2. CONCEPT

2.1. The basic approach

Article 16 (new)/Article 21 (old) paragraph 2 of the proposed WFD introduces three optional strategic routes for establishing priority substances:

- (1) Risk assessments carried out under Council Regulation (EEC) No. 793/93⁸, Council Directive 91/414/EEC⁹ and Council Directive 98/8/EC¹⁰ of the European Parliament and of the Council;
- (2) Targeted risk-based assessment (following the methodology of Council Regulation (EEC) No. 793/93) focusing solely on aquatic eco-toxicity and on human toxicity via the aquatic environment;

or, where this proves impracticable within the time scale,

- (3) A simplified risk-based assessment procedure based on scientific principles taking particular account of:
 - evidence regarding the intrinsic hazard of the substance concerned and, in particular, its aquatic eco-toxicity and human toxicity via aquatic exposure routes;
 - evidence from monitoring of widespread environmental contamination and
 - other proven factors which may indicate the possibility of widespread environmental contamination, such as production, use volume of the substance concerned and use pattern

11. While the final objective of the Proposal for a Water Framework Directive with respect to hazardous substances remains an issue for discussion in the future stages of negotiations, the above mentioned selection strategy had not received significant criticism from the European Parliament and has been taken over by the Council of Ministers in the Common Position of 22 October 1999.

⁸ OJ L 84, 5.4.1993, p. 1. (Existing Chemicals Regulation).

⁹ OJ L 230, 19.8.1991, p. 1. (Plant Protection Products Directive).

¹⁰ OJ L 123, 24.4.1998, p. 1. (Biocide Directive).

12. Risk assessments under Council Regulation (EEC) No. 793/93 and under Council Directive 91/414/EEC are substance-by-substance assessments on the basis of a well-established, but time-consuming procedure. Consequently, risk assessments have been finalised for only a relatively few substances. Under Council Directive 98/8/EC, no risk assessments have been carried out to present date. It is, therefore, clear that the present status of risk assessments does not provide a sufficiently broad basis for the establishment of the aquatic priority list.
13. Targeted or ad-hoc risk assessments are generally believed to be less time consuming since they should be less extensive. However, there is no generally agreed procedure for carrying out such assessments and the length of time required may still be substantial. It then becomes obvious that, of the three routes summarised above, only route c is practically applicable within a reasonably short time.
14. Taking route c as a basis, the **combined monitoring-based and modelling-based priority setting** (COMMPS) procedure has been designed as a scientifically based, simplified risk-based prioritisation method.

2.2. Technicalities of the automated priority ranking under COMMPS

15. The technical details of the COMMPS procedure were described in the Commission working document M0498WD1 and in the research Report (Declaration ref.: 98/788/3040/DEB/E1) “Revised Proposal for a list of Priority Substances in the Context of the Water Framework Directive (COMMPS Procedure)” prepared by the Fraunhofer Institute for Environmental Chemistry and Ecotoxicology, Germany (referred to as COMMPS report hereafter). The following paragraphs provide a brief summary of the technical procedure.
16. Risk, in its common meaning, is the combination of the likeliness with which an adverse event will occur and the severity of the consequences it causes. For aquatic ecosystems, it can be expressed, in more technical terms, as the product of the concentration of a substance found in the aquatic environment and the intrinsic hazard it causes for that system. The idea of the COMMPS procedure is to establish a list of substances ranked on the basis of their **relative risk** to the aquatic ecosystem. The rank of a substance is determined by multiplying a score corresponding to the environmental exposure by a score corresponding to the degree of the hazardous effects the substance may cause. In a subsequent step, the priority substances are selected from this ranking list by expert judgement, which takes into account additional information about the environmental concerns related to these substances.
17. Aquatic ecosystems consist of several subsystems. Of these, the aquatic compartment (surface water) and the sediment compartment are the two major subsystems dealt with in the COMMPS procedure on a systematic basis.

2.2.1. *Candidate Substances*

18. The substances subjected to the COMMPS procedure were selected from various official lists and monitoring programmes. The basic idea of this “list-based approach” is to ensure that substances that have already been identified as being of concern and for which sufficient information is normally available are chosen. Substances from the following lists are included in the COMMPS procedure:
 - List 1 and 2 of Council Directive 76/464/EEC
 - Annex 1A and 1D of the Third North Sea Conference
 - Priority lists 1-3 identified under Council Regulation No 793/93
 - OSPAR list of candidate substances
 - HELCOM list of priority substances
 - Priority lists under Council Directive 91/414/EEC
19. In addition, all substances for which monitoring data were available were included in the COMMPS procedure.
20. These substances were subjected to the following assessment steps in the COMMPS procedure.

2.2.2. *Priority ranking lists for the aquatic compartment (lists A+B)*

21. For the calculation of the **aquatic exposure score**, two major sources of exposure data were exploited in COMMPS monitoring data and modelling data. However, modelling data were only used if monitoring data were inadequate or inexistent. For plant protection products and metals only monitoring-based assessment was carried out because analysed data were more than sufficient and no appropriate models were available.
22. For the COMMPS report, **monitoring data were** collected from all 15 Member States and from European water suppliers. A total of about 752.000 single data of 330 substances (including metals) were provided and assessed. Since the monitoring networks operated by Member States are not designed in a harmonised fashion, stringent assessment rules had to be incorporated in the COMMPS procedure to ensure the statistical relevancy of the data used. Monitoring data were examined for plausibility, representativeness and statistical significance. As a result of this assessment, a considerable part of the provided data had to be sacrificed. For example, the COMMPS criterion for representativeness requires that a substance is monitored in at least three Member States or in at least two different trans-boundary river basins involving two or more Member States. This criterion has resulted in the reduction of the overall number of substances by about 70% because for many substances there was monitoring data provided by only one Member State. Following the selection of monitoring data, an aggregated mean value was calculated for each sampling station. To obtain

the exposure score, the 90-percentile over these aggregated mean values was taken. It was normalised such that the maximum possible score was 10. In total, a ranking list of 86 substances was elaborated.

23. The large number of substances excluded on statistical grounds highlights the importance of using **modelling data** as an additional and complementary source of information. In the interest of consistency, the COMMPS procedure makes use of the EURAM exposure model, which was developed for the priority setting of existing chemicals under the Council Regulation No. 793/93/EEC. This model provides exposure scores at a European continental scale on the basis of known production volumes, use patterns, environmental distribution and degradation processes. The European Chemicals Bureau provided exposure data for 318 of the candidate substances. For the other candidate substances the calculation of exposure scores was not feasible because the required input data were not available. A number of substances were excluded from the ranking procedure as they are plant protection products, inorganic metal compounds or protected by confidentiality rules agreed with the industry. However, most of the plant protection products and metals have been already assessed in the monitoring-based list. Finally, 123 substances were included in the modelling-based ranking list.
24. The **aquatic effect score** used in COMMPS is a combined score taking into account direct and indirect effects on aquatic organisms as well as effects on human health. Direct toxic effects are expressed in terms of no-effect concentrations, which were derived from ecotoxicological test data according to the rules set out in Annex V of the proposed WFD. Indirect effects caused by substances, which accumulate in biological organisms, are expressed in terms of the bioconcentration factor or the water/octanol partition coefficient. Effects to human health via the aquatic exposure route, such as drinking water consumption or exposure during leisure activities, are expressed in terms of R-phrases characterising carcinogenicity, mutagenicity and teratogenicity as well as chronic effects through oral uptake. The overall effect score assigned to each substance is normalised such that the maximum score is 10. The relative weight of the direct, indirect and human health effect being 5:3:2, respectively.
25. The database of effects data used for the COMMPS procedure has been thoroughly discussed and up-dated in collaboration with experts. Particular emphasis was given to achieving consistency with current work on risk assessments and priority setting under Council Regulation (EEC) No. 793/93 and under Council Directive 91/414/EEC.
26. The **aquatic final score** measuring the relative risk of a substance to the aquatic compartment is calculated in the COMMPS procedure as the product of the aquatic exposure and the aquatic effect score. Since two different sources of exposure data were used complementarily, two lists were generated, one based on monitoring data, the other based on modelling data.

2.2.3. *Priority ranking list for the sediment compartment (list C)*

27. Substances with a strong tendency to accumulate in **sediments** may occur in the aquatic compartment only in small concentrations and may, therefore, obtain a low score on the aquatic priority list. It is for this reason that a separate ranking list for the sediment compartment has been established in the COMMPS procedure.
28. The **sediment exposure score** was computed in the COMMPS procedure in full analogy to the aquatic compartment. For the COMMPS report, about 69.000 sediment monitoring data of 221 substances were collated from 10 different Member States. Following the examination of plausibility, representativeness and statistical significance, data for 60 substances were finally available for the ranking procedure. This means that the exclusion rate was similar to the one obtained for aquatic data.
29. Because of the unavailability of appropriate models and the uncertainties inherent in both the effects and exposure calculations, no modelling approach was applied in the COMMPS procedure for the sediment compartment; i.e. the exposure score was solely based on sediment monitoring data.
30. The **sediment effect score** was determined in the same way as for the aquatic compartment. However, one of the major limitations for the direct effects assessment is the scarce availability of data on the effects on sediment-dwelling organisms or “bottom-feeding” fish. Therefore, sediment related no-effect values were computed through a transformation of aquatic ecotoxicity data by using the known water-sediment partition coefficients.
31. The **final sediment score** was calculated in the same way as the aquatic final score, taken as the product of the sediment exposure score and the sediment effect score.
32. In summary, the following risk-based ranking lists were established in the COMMPS procedure on an automated basis:
 - List A: One list of aquatic organic pollutants based on aquatic monitoring data.
 - List B: One list of aquatic organic pollutants based on modelling results for the aquatic compartment.
 - List C: One list of organic pollutants adsorbed by sediments based on monitoring data in sediments or suspended solids.
 - List D: Several lists for metals based on aquatic monitoring data are established under the assumption of various exposure and effect scenarios.

2.2.4. *Priority ranking list of metals (list D)*

33. **Metals** occur in nature in varying local concentrations and forms. The bio-availability of metals by aquatic organisms depends highly on these

preconditions. Moreover, many organisms have developed active mechanisms for the intake and excretion of metals by which they are able to adapt to the local background conditions. On these grounds, it is difficult to compute a fully satisfactory risk score. For the purpose of the COMMPS report, a series of ranking scenarios were produced based on certain ideal assumptions for exposure and effects with respect to metal background values and ratios of dissolved versus total metal concentrations. To account for the principal differences between metals and organic compounds, the ranking lists for metals were established separately from the ones for organic pollutants. A significant amount of monitoring data was available for metals and it was, therefore, not necessary to use modelling data for the ranking of metals. The results of the different ranking scenarios were used in the expert judgement step to select the priority metals.

2.3. Expert judgement for the selection of priority substances

34. In the second step of the COMMPS procedure, priority substances were selected from the four risk-based ranking lists. For this purpose, the COMMPS report identified a subset of substances with the highest scores as **candidate priority substances**. Substances which are widely restricted based on Council Directives 76/769/EEC and 79/117/EEC¹¹ or not in use in Member States and which can, therefore, be regarded as “historic pollutants” (such as DDT or aldrin, dieldrin and isodrin) were eliminated. Also, some substances occurring normally as mixtures were clustered into a single group (such as trichlorobenzenes or PAHs).
35. The exclusion of “historic pollutants” was done on a case-by-case decision proposed by the consultant and thereafter reviewed by expert judgement. Apart from a wide restriction in the EU legislation, all excluded substances are regulated under the UN-ECE POP Protocol¹² and are under discussion for a global ban under the UNEP-POP convention¹³. In addition, the proposed Water Framework Directive requires the Member States to identify substances of concern for the different river basins. For these substances the ‘combined approach’ has to be applied. This means that if the reason for not achieving ‘good ecological status’ of the surface water is due to the contamination of sediments by ‘historic pollutants’, the Member State has to report this in the ‘river basin management plan’ and include remedial action in the ‘programme of measures’.

¹¹ OJ L 262, 27.9.1976, p. 201 (Council Directive 76/769/EEC on the approximation of laws, regulations and administrative provisions of Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations).

OJ L 33, 8.2.1979, p. 36 (Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances).

¹² United Nations – Economic Commission for Europe: Protocol to the 1979 Convention on long-range transboundary air pollution on persistent organic pollutants (POP). Aarhus (Denmark), 24 June 1998.

¹³ United Nations Environment Programme: International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants (under negotiation).

36. The COMMPS report provides a recommendation for the selection of priority substances from the candidate priority lists. This recommendation was discussed with experts from Member States, industry and other stakeholders as well as the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) and the European Chemicals Bureau (ECB) in the meeting of 19 April 1999. In response to the comments of the experts received by the Commission and the opinion of the CSTEE of 28.9.1999, the following conclusion can be drawn:

2.3.1. *Selection of substances from list A (organic substances based on aquatic monitoring data):*

37. List A contains 20 candidate substances obtained on the basis of the final scores for the aquatic environment. Each individual substance was assigned a number corresponding to its priority on the ranking list, rank 1 signifying the highest priority, and so on. The 20th candidate substance (simazine) has a priority of 39 as opposed to 20 due to the elimination and grouping of individual substances. The exposure values of the candidate substances are based on well-assessed monitoring data. For most of the substances, except for some poly-aromatic hydrocarbons, the effects scores were derived from test data instead of default values. On these grounds, the high priority of the substances is well founded. Convincing arguments were raised in the expert discussions justifying the exclusion of a few substances from the priority list or, alternatively, their inclusion in a modified form. This concerns the following substances or groups of substances:

38. Poly-aromatic hydrocarbons (PAH): The individual substances rank from 1 to 55. Some of these substances are intentionally produced and used, such as naphthalene and anthracene, all with high priorities. Most of the other PAH with a high priority are distributed in the environment mainly as unintentional by-products of certain activities such as combustion processes. For these substances, it is a common practice to identify certain individual compounds as indicative parameters. For example, in Council Directive 98/83/EC on the quality of water intended for human consumption¹⁴, limit values for a subset of 5 individual compounds were established. It is, therefore, proposed that, the first priority list should include naphthalene and anthracene as individual compounds because they are produced in high volumes in the European Union. The other PAH should be listed as a group, specifying those individual compounds as indicative parameters which are regulated under Council Directive 98/83/EC and in addition fluoroanthene.

39. Heptachlor: This insecticide has a priority of 10 on the aquatic ranking list. The marketing and use of this substance as a plant protection product is prohibited under Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances¹⁵. Heptachlor is included in the POP (persistent organic pollutants) list adopted under the UN-ECE convention on long-range

¹⁴ OJ L 330, 5.12.1998, p. 32.

¹⁵ OJ L 33, 8.2.1979, p. 36.

transport of air pollutants. However no indication was found of production and use of heptachlor in Europe. Heptachlor can, therefore be considered as a “historic pollutant” similar to aldrin or dieldrin and, consequently, be excluded from the priority list.

40. Monochloronitrobenzenes: After the finalising of the COMMPS report, it was found that the high priority of 14 found for one of the isomers (3-chloronitrobenze) was due to a dimension error in the reported data of a Member State. A recalculation resulted in a priority of 66 on the ranking list. Therefore, monochloronitrobenzenes are excluded from the priority list.
41. Trichlorobenzenes: This group consists of three different isomers of which only one (1,2,4-trichlorobenzene) has a priority higher than the substance with the lowest rank that was included in the final list (i.e. simazine). Since trichlorobenzenes are produced in the form of a technical mixture involving all three isomers, it is proposed to include trichlorobenzenes in the priority list as a group, specifying 1,2,4-trichlorobenzene as an indicative parameter.
42. Endosulfan: The technical mixture of this broad-spectrum insecticide consists of several isomers of which only one, the alpha isomer, has a priority higher than simazine. Since endosulfan is produced as a technical mixture involving all isomers, it is proposed to include endosulfan in the priority list as a group, specifying its alpha-isomer as an indicative parameter.
43. Technical hexachlorocyclohexane (HCH) consists of different isomers of which only the gamma-isomer acts as an insecticide. Lindane is a mixture, which contains at least 99% of this isomer. Council Directive 79/117/EEC prohibits the marketing or use as a plant protection product of technical HCH, except of lindane. There is only one production site of lindane in Europe located in Eastern Europe. While some isomers of HCH have priorities higher than simazine, lindane itself appears with a lower priority (rank 45) on the ranking list. However, since it is likely that the isomers of HCH found with high priorities are distributed into surface waters via the use of technical lindane, it is proposed to include HCH as a group in the priority list, specifying the gamma isomer as an indicative parameter.
44. To summarise, the inclusion of the following substances from list A in the first priority list is proposed (indicative parameter for group of substances in brackets):
 - PAH (benzo(a)pyrene, benzo(b)fluoranthene, benzo(g,h,i)perylene, benzo(k)fluoranthene, indeno(1,2,3-cd)pyrene, fluoroanthene)
 - Naphthalene
 - Anthracene
 - Pentachlorophenol
 - Chlorpyrifos

- Hexachlorobenzene
- Trichlorobenzenes (1,2,4-trichlorobenzene)
- Chlorfenvinphos
- Diuron
- Trifluralin
- Trichloromethane
- Dichloromethane
- 1,2-dichloroethane
- Isoproturon
- Endosulfan (alpha-Endosulfan)
- Alachlor
- Hexachlorobutadiene
- Hexachlorocyclohexane (gamma-HCH, lindane)
- Atrazine
- Simazine

2.3.2. *Selection of substances from list B (organic substances based on aquatic modelling exposure data):*

45. List B contains 20 candidate substances obtained on the basis of the final scores. Since no substances were excluded or clustered into a group, the priority of the 20th substance is 20 on the original ranking list. The model-based exposure rank of a substance may be based on one or several default values for production volume, use pattern, degradation and distribution. Consequently, expert judgement must play a significant role in deciding whether the priority of a substance obtained on the basis of modelling data is justified. In the light of the data provided in the COMMPS report and the opinion of experts, the following proposal for the inclusion or exclusion of the candidate substances in the final priority list is made:
46. Hypochlorite (sodium salt), chlorine, dimethyl sulfate and epichlorhydrin are excluded because they exhibit a high reactivity or tendency for hydrolysis in water not reflected in the exposure model.
47. Perboric acid (sodium salt), mineral oils, tetraethyl lead, tallow-alkylamines, bis(hydroxylammonium)-sulfate and diethylphthalate (DEP) are excluded because of high uncertainty of the ranking (defaults were used for production volume, use pattern and distribution) and/or because there is no additional

information available which allows for verification of the likeliness of their high priority.

48. Aniline, dibutyltin dichloride and 4,4'-methylendianiline are excluded because either monitoring data or modelling data on a regional scale is available suggesting that the substance would have a lower priority on the monitoring-based ranking list than those substances which were selected from this list.
49. Benzene: This substance has the highest possible human health score due to its potential carcinogenicity. It was argued in the expert discussion that the major route for the carcinogenic effects is inhalation rather than exposure through water. However, the effect score for benzene is based on risk phrase R45, which explicitly includes intake routes other than inhalation. Benzene has been identified as a relevant parameter under Council Directive 98/83/EC on the quality of water intended for human consumption, thereby recognising that there is a significant health concern for benzene via the drinking water route. For these reasons, it is proposed to include benzene in the first priority list.
50. C₁₀₋₁₃-chloroalkanes: The inclusion of this group of substances is supported by the outcome of the risk assessment under Council Regulation No. 793/93 which demonstrates that, for the aquatic ecosystem as well as for non-compartment specific effects relevant to the food chain, there is a need for specific measures to limit the risks. Therefore, it is proposed to include this group of substances in the priority list.
51. Nitrobenzene: The relatively high priority of this substance on the modelling-based list can most likely be attributed to the use of default values for the production volume and use pattern. In the expert discussions it was pointed out that the additional evidence of the rank is based on monitoring data from only one Member State, with approximately 15% of the data being above the determination limit. In the light of these arguments and taking into account the high biodegradability of the compound, it is proposed to exclude nitrobenzene until additional evidence for the high exposure is available.
52. Di(2-ethylhexyl)phthalate (DEHP): This substance was excluded from the monitoring-based ranking because the monitoring data failed to meet the criterion of representativeness. The high priority on the modelling-based list (rank 14) was examined by comparison with the approximate score based on the regional exposure value given in the draft risk assessment report under the Council Regulation No. 793/93. On this basis, DEHP would have a higher priority than the substance with the lowest rank that was included in the final list on the monitoring-based list (i.e. simazine). It is noted that some of the data used in the draft risk assessment report have been questioned by industry, arguing that monitoring as well as test data may be biased or even wrong because the extremely low solubility of DEHP has not been taken into account adequately. Even though the debate is still ongoing, it is emphasised that the data of the draft risk assessment report which are used for the above-mentioned conclusion have not been modified so far. Moreover it is noted that the draft risk assessment report demonstrates clearly that local

concentrations of DEHP in water and sediments close to points source discharges may exceed the no-effect concentrations considerably. In addition, endocrine disrupting property of DEHP is discussed by experts. It is therefore proposed to include DEHP in the priority list.

53. Nonylphenol: While tert-octylphenol has a priority of 19 on the modelling-based list, the related substance, nonylphenol, only has a priority of 38 and 39. The reason for two ranks in the modelling-based list is due to different technical products (i.e. nonylphenol with CAS-No. 25154-52-3 and 4-nonylphenol, branched with CAS-No. 84852-15-3). In addition, both substances are degradation products of Alkylphenolethoxylates (APEOs) where nonylphenolethoxylates come to 70-90% of the total production volume of APEOs. The monitoring data for both substances fails to meet the criterion of representativeness and the substances are, therefore, not included in the monitoring-based list. If approximate ranks were calculated for these substances on the basis of available monitoring data, the resulting priorities on the monitoring-based ranking list would be 21 and 34 for nonyl- and octylphenol, respectively. This indicates that both substances would have higher priorities than the substance with the lowest monitored rank that was included in the final list (i.e. simazine). Moreover, both substances have been reported as suspected endocrine disrupters. For these reasons, it is proposed to include both substances in the priority list. Since the major isomers of the technical products are the para-isomers of nonylphenol and tert-octylphenol, these isomers are selected as indicative parameters.
54. Tributyltin compounds (TBT): Tributyltin compounds have not been ranked on the modelling-based list as a consequence of data confidentiality. They also failed to meet the criterion of representativeness for the monitoring-based ranking list. Only two Member States reported aquatic and sediment concentrations above the determination limit. It is remarkable, that TBT would have a priority 1 on the aquatic monitoring-based ranking list if these data were used, neglecting representativeness. In the expert discussion, it was emphasised that TBT, use in antifouling paints for ships, represents a significant risk to sediments and biota in marine and coastal waters. Such data were not included in the COMMPS procedure, as monitoring data of marine sediments and biota are not sufficiently comparable for use in the systematic ranking of substances for surface waters. However, two countries submitted new data of coastal and marine sediments as well as marine biota showing high concentrations of TBT. For example, TBT concentrations in coastal sediments up to about 400 (Denmark) or even 100.000 (Norway) microgram TBT-ion per kilogram dry weight sediment have been reported for coastal sediments, which are hundreds times above the no-effect value estimated for sediments on the basis of aquatic freshwater data provided in the COMMPS report. Similar observations were made in the sediment of harbours in many Member States. TBT is generally acknowledged for having a significant endocrine disrupting potential as demonstrated by its well-established link with the imposex phenomenon in marine and freshwater snails. For these reasons, it is proposed that TBT should be included in the priority list as a group, as suggested by several Member States, with the ionic TBT as indicative parameter.

55. To summarise, it is proposed to include the following additional substances from the modelling-based ranking in the priority list (indicative parameter for group of substances in brackets):

- Benzene
- C₁₀₋₁₃-chloroalkanes (no indicative parameter available yet)
- Di(2-ethylhexyl)phthalate (DEHP)
- Octylphenols (para-tert-octylphenols)
- Nonylphenols (para-nonylphenols)
- Tributyltin compounds (ionic TBT)

2.3.3. *Selection of substances from list C (organic substances based on sediments monitoring data):*

56. List C contains 10 candidate substances obtained on the basis of the final scores. The priority for the 10th substance (octylphenol) had the rank 39. The exposure values are based on well-assessed monitoring data. The effects data were estimated on the basis of aquatic test data. Within this approximation, the high priority of the substances is well founded. Most of the substances have already been identified on the basis of aquatic monitoring or modelling data.

57. In addition, following substances of list C are proposed for inclusion in the priority list:

- Pentachlorobenzene
- Brominated diphenylether (no indicative parameter available yet)

2.3.4. *Selection of metals from list D (based on aquatic monitoring data):*

58. List D contains the five metals with the highest scores for the different exposure and effect scenarios investigated in the COMMPS report. The ranking pattern for the three metals with the highest scores (nickel, lead, cadmium) is notably similar for the different scenarios. This is reflected by the fact that the priority numbers for the three metals in the different scenarios average close to the values 1, 2 and 3, respectively (1.2 for nickel, 1.8 for lead, 3.3 for cadmium), i.e. the variation of the ranks in the different lists is small. The other two elements (arsenic and copper) have priorities, which vary considerably in the different ranking scenarios. This seemingly demonstrates that the ranking depends significantly on variations of local conditions and different speciations. Therefore, it is proposed that in the absence of additional information confirming the high rank of these elements, the substances should not be included in the first priority list.

59. Mercury has a remarkably low priority on the aquatic risk-based list, independent of the various ranking scenarios. In fact, in most of the

scenarios, it has the lowest priority, never occupying a position beyond priority 5. This reflects the apparent success of past measures against mercury pollution. However, in the expert discussion, it was argued that mercury has a strong tendency to bioaccumulate, mainly in organically bound form, in biota and via the food chain. These effects are not detectable by the COMMPS procedure, as monitoring data of biota is not sufficiently comparable to be used for the ranking of substances on a systematic basis. In addition, mercury has a strong tendency to accumulate on the suspended solids and in the sediment. A systematic assessment of available sediment data was not possible due to the lack of direct effect data for sediment. An indicative comparison with quality objectives set for suspended solids in the International Commission for the Protection of the Rhine (ICPR) was done. The 90-percentile concentration of mercury in European suspended solids and sediments was 12 times higher than the ICPR quality objectives. Many Member States confirmed that mercury is still a substance of concern in their national pollution reduction programmes. Due to the above-mentioned reasons, it is proposed that mercury should be included in the first priority list as proposed by several Member States and in the CSTEE comments of 28.9.1999.

60. To summarise, the following metals are proposed for inclusion in the priority list with all their compounds and specifications:
- Nickel
 - Lead
 - Cadmium
 - Mercury

3. FUTURE DEVELOPMENTS OF COMMPS

3.1. General remarks

61. Article 16 (new)/Article 21 (old)¹⁶ of the proposed WFD sets out a dynamic mechanism for the prioritisation of substances for Community action. It requires that the list of priority substances shall be reviewed at least every 6 years or more frequently if this is deemed necessary. Consequently, the COMMPS procedure must be regarded as a dynamic instrument open to continuous modifications and improvements. For the purpose of the establishment and review of the priority list, the Commission shall take account of any information, which comes to its attention. This includes, in particular, recommendations made by the Scientific Committee for Toxicity, Ecotoxicity and the Environment (CSTEE), Member States, the European Environment Agency, Community research programmes, international organisations to which the Commission is party, European business

¹⁶ See 2.

organisations including those representing small and medium-enterprises or European environmental organisations.

62. In the light of these obligations, the Commission will continue its co-operation with the concerned parties and will direct specific research activities into the further development of the COMMPS procedure, as a result of which a revision of the first priority list will be made as required by the future WFD.
63. It should be noted that, as new evidence emerges, the Commission may, pursuant to Article 16 (new)/Article 21 (old), paragraph 7 of the WFD adopt strategies for any other pollutants or groups of pollutants not listed as priority substances.
64. Along these remarks, the following key issues can be identified for future developments:

3.2. Marine water compartment

65. The marine environment is not addressed in the proposed WFD per se, but the measures and controls of land-based and coastal sources will inevitably have a significant effect on the reduction of discharges to marine waters. Therefore, as far as European-based pollution is concerned, the Commission considers the controls envisaged pursuant to Article 16 (new)/Article 21 (old) of the proposed WFD its major contribution to the implementation of the strategy on hazardous substances in the North-East Atlantic and the Baltic Sea (Helsinki Convention) adopted at the 1998 Ministerial Meeting under the OSPAR convention. The Commission takes an active part in the present work of prioritisation of substances under the OSPAR convention. If this exercise identifies the need for action on other substances than those proposed for the first priority list, the Commission will consider, on a case-by-case basis either the amendment of the priority list or the application of Article 16 (new)/Article 21 (old), paragraph 7 of the proposed WFD.

3.3. Groundwater compartment

66. The groundwater compartment is not considered in the current version of COMMPS on a systematic basis since there are neither appropriate exposure models nor sufficiently representative monitoring data available. The discussion of the proposed WFD has clearly demonstrated that there is a need for a more systematic and standardised assessment of groundwater bodies across Europe. The proposed WFD is expected to contribute to this and has already stimulated intense discussions at expert level. For example, the initiative of the European Environment Agency to establish a harmonised water-monitoring network (Eurowaternet) has addressed groundwater as one of its major targets.

3.4. Database

67. Two apparent obstacles for the full use of the COMMPS procedure are limited knowledge and accessibility of data. The European Chemicals

Bureau in ISPRA is continuously engaged in extending and reviewing its database on existing chemicals. For example, an attempt is currently being made to reach an agreement with the industry on lifting confidentiality for production data. Such an agreement would allow for the inclusion of substances in the COMMPS procedure for which there are only a few producers and importers and which are, therefore, presently inaccessible for open discussion.

3.5. Other issues

68. Among the areas requiring basic research, the statistical assessment of monitoring data, the development of specifically designed exposure models as well as the effects assessment of new types of pollutants, for which adequate and generally agreed test methods are lacking (e.g. endocrine disrupting substances), are yet to be elaborated.
69. The co-ordination of national monitoring programmes is an essential task for the future. The exclusion of many substances, because they were monitored in only one or two Member States, led to loss of information on the status of the aquatic environment. In fact, many more monitoring data do exist in the many Member States but the databases are not co-ordinated or the information is not even available in electronic form. In general, there is a huge lack of additional information, e.g. detection/determination limit, sampling and analyses methods use. European Guidelines would, e.g. for definitions and procedures, be an additional tool to improve data quality. The initiatives of the Eurowaternet (EEA) and within the proposed WFD include already some key elements, however, they have to be further elaborated.

3.6. Revision

70. A continuous revision of the priority list is not favourable in order to assure a realistic timeframe and work programme of the Commission and the Member States. Quality objectives and emission controls have to be elaborated for each substance on the list by the Commission. The Member States have to set up monitoring programmes. In the next step effective reduction programmes and measures to improve European water quality in relation to the selected priority substances have to be established and implemented. This should be prior to any increase in the number of substances on the priority list. In this light the review cycle of 6 years as formulated in the proposed WFD is a realistic obligation. Nevertheless, the above-mentioned reasons may lead to an earlier need to review the priority list if the fulfilment of the corresponding obligations can be assured by Commission and Member States.

4. PROPOSED PARLIAMENT AND COUNCIL DECISION

71. The list of priority substances, identified in accordance with the procedure set out in Article 16 (new)/Article 21 (old) of the proposed WFD, will comprise the major basis for the development of emission controls and harmonised quality standards for the protection of the aquatic environment at

Community level. It should be adopted with strong support by all institutions. The adoption of the priority list does not require any additional measures for Member States. A Council and Parliament Decision is, therefore, the most appropriate legal form for the adoption of the priority list.

5. LEGAL BASIS

72. The establishment of priority substances is the first step in introducing the strategy against water pollution set out in Article 16 (new)/Article 21 (old) of the proposed WFD. As the future WFD, it falls under Article 175 (1) of the Treaty.

6. BUSINESS IMPACT ASSESSMENT

73. The list of priority substances does not put any additional obligation on Member States beyond the ones already imposed by Council Directive 76/464/EEC and by the proposed Water Framework Directive. Therefore, this proposal will not result in additional costs for Member States. On the contrary, the method elaborated for the prioritisation of substances may be used by Member States in support of their task of identifying pollutants of concern at river basin level under Article 7 of Council Directive 76/464/EEC and under the proposed Water Framework Directive, effectively contributing to a cost-saving implementation of these Directives.

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DECISION

establishing the list of priority substances in the field of water policy

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular to Article 175 (1) thereof,

Having regard to the Proposal from the Commission¹⁷,

Having regard to the opinion of the Economic and Social Committee¹⁸,

Having regard to the opinion of the Committee of the Regions¹⁹

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Council Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community²⁰ and the Directives adopted within its framework represent presently the major Community instrument for the control of point and diffuse discharges of dangerous substances;
- (2) The Community controls under Council Directive 76/464/EEC have been replaced, harmonised and further developed by the Directive of the European Parliament and Council establishing of a framework for Community action in the field of water policy²¹
- (3) The Directive of the European Parliament and of the Council establishing a framework for Community action in the field of water policy, hereby introduces in Article 16 (2) a scientifically based methodology for identifying priority substances on the basis of their risk to aquatic ecosystems;
- (4) The methodology set out in the Directive of the European Parliament and Council establishing of a framework for Community action in the field of water policy enables, as a most practical option, the application of a simplified risk-based assessment procedure based on scientific principles taking particular account of

¹⁷ OJ C 184, 17.6.1997, p. 20, OJ C 16, 20.1.1998, p. 14 and OJ C 108, 7.4.1998, p. 94.

¹⁸ OJ C

¹⁹ OJ C

²⁰ OJ L 129, 18.5.1976, p. 23.

²¹ OJ L

- evidence regarding the intrinsic hazard of the substance concerned and, in particular, its aquatic ecotoxicity and human toxicity via aquatic exposure routes,
 - evidence from monitoring of widespread environmental contamination and
 - other proven factors which may indicate the possibility of widespread environmental contamination, such as production, use volume and use pattern of the substance concerned;
- (5) The Commission has, on this basis, developed a combined monitoring-based and modelling-based priority setting (COMMPS) scheme, in collaboration with experts of interested parties, involving the Scientific Committee for Toxicity, Ecotoxicity and the Environment, Member States, EFTA countries, the European Environment Agency, European business associations including those representing small and medium-sized enterprises and European environmental organisations;
 - (6) A first list of 32 priority substances or groups of substances has been identified on the basis of the COMMPS procedure, following a publicly open and transparent discussion with the interested parties;
 - (7) The expeditious adoption of this list is desirable in order to allow for the timely and continuing implementation of Community controls of dangerous substances pursuant to the strategy set out in Article 16 of the European Parliament and Council Directive establishing a framework for Community action in the field of water policy;
 - (8) The list of priority substances adopted under this Decision shall replace the list of substances in the Communication from the Commission to the Council on dangerous substances which might be included in List I of Council Directive 76/464/EEC²²;
 - (9) The identification of priority substances targeted to the establishment of controls of emissions into surface waters from land-based sources contributes to the Community commitments under international conventions for the protection of marine waters, in particular to the implementation of the Strategy with regard to hazardous substances adopted at the 1998 OSPAR Ministerial Meeting under the Convention for the protection of the marine environment of the North-East Atlantic pursuant to Council Decision 98/249/EC²³;
 - (10) The COMMPS procedure is designed as a dynamic instrument for the prioritisation of dangerous substances open to continuous improvements and modifications with a view of possible revision and adaptation of the first priority list within at the latest within 6 years of its adoption,

²² OJ C 176, 14.7.1982, p. 3.

²³ OJ L 104, 3.4.1998, p. 1.

HAVE ADOPTED THIS DECISION:

Article 1

The list of priority substances in the field of water policy is hereby established and is set out in the Annex to this Decision.

Article 2

The list of priority substances established by this decision replaces the list of substances in the Communication from the Commission to the Council of 22 June 1982 on dangerous substances which might be included in List I of Council Directive 76/464/EEC.

Article 3

The list of priority substances in the field of water policy shall, on its adoption by the European Parliament and the Council, become Annex X to European Parliament and of the Council Directive establishing a framework for Community action in the field of water policy.

Article 4

This Decision shall enter into force on the day after its publication in the *Official Journal of the European Communities*.

Article 5

This Decision is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

List of priority substances in the field of water policy ²⁴

	CAS number	EU number	Name
(1)	15972-60-8	240-110-8	Alachlor
(2)	120-12-7	204-371-1	Anthracene
(3)	1912-24-9	217-617-8	Atrazine
(4)	71-43-2	200-753-7	Benzene
(5)	n.a.	n.a.	Brominated diphenylether ²⁵
(6)	7440-43-9	231-152-8	Cadmium and its compounds
(7)	85535-84-8	287-476-5	C ₁₀₋₁₃ -chloroalkanes ²⁵
(8)	470-90-6	207-432-0	Chlorfenvinphos
(9)	2921-88-2	220-864-4	Chlorpyrifos
(10)	75-09-2	200-838-9	Dichloromethane
(11)	107-06-2	203-458-1	1,2-Dichloroethane
(12)	117-81-7	204-211-0	Di(2-ethylhexyl)phthalate (DEHP)
(13)	330-54-1	206-354-4	Diuron
(14)	115-29-7	204-079-4	Endosulfan
	959-98-8	n.a.	(alpha-endosulfan)
(15)	118-74-1	204-273-9	Hexachlorobenzene
(16)	87-68-3	201-765-5	Hexachlorobutadiene
(17)	608-73-1	210-158-9	Hexachlorocyclohexane
	58-89-9	200-401-2	(gamma-isomer, Lindane)

²⁴ Where groups of substances have been selected, typical individual representatives are listed in brackets as indicative parameters. The establishment of controls will be targeted to these individual substances, without prejudicing the inclusion of other individual representatives where appropriate.

²⁵ These groups of substances normally include a considerable number of individual compounds. Presently, appropriate indicative parameters cannot be given.

CAS Chemical Abstract Service.

EU number, i.e. European Inventory of Existing Commercial Chemical Substances (EINECS) or European List of Notified Chemical Substances (ELINCS).

n.a. not applicable.

(18)	34123-59-6	251-835-4	Isoproturon
(19)	7439-92-1	231-100-4	Lead and its compounds
(20)	7439-97-6	231-106-7	Mercury and its compounds
(21)	91-20-3	202-049-5	Naphthalene
(22)	7440-02-0	231-111-4	Nickel and its compounds
(23)	25154-52-3	246-672-0	Nonylphenols
	104-40-5	203-199-4	(4-(para)-nonylphenol)
(24)	1806-26-4	217-302-5	Octylphenols
	140-66-9	n.a.	(para-tert-octylphenol)
(25)	n.a.	n.a.	Polyaromatic hydrocarbons
	50-32-8	200-028-5	(Benzo(a)pyrene,
	205-99-2	205-911-9	Benzo(b)fluoroanthene,
	191-24-2	205-883-8	Benzo(g,h,i)perylene,
	207-08-9	205-916-6	Benzo(k)fluoroanthene,
	206-44-0	205-912-4	Fluoroanthene,
	193-39-5	205-893-2	Indeno(1,2,3-cd)pyrene)
(26)	608-93-5	210-172-5	Pentachlorobenzene
(27)	122-34-9	204-535-2	Simazine
(28)	87-86-5	201-778-6	Pentachlorophenol
(29)	688-73-3	211-704-4	Tributyltin compounds
	36643-28-4	n.a.	(Tributyltin-cation)
(30)	12002-48-1	234-413-4	Trichlorobenzenes
	120-82-1	204-428-0	(1,2,4-Trichlorobenzene)
(31)	67-66-3	200-663-8	Trichloromethane (Chloroform)
(32)	1582-09-8	216-428-8	Trifluralin