

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 16 December 2003

concerning national provisions on the use of short-chain chlorinated paraffins notified by the Kingdom of the Netherlands under Article 95(4) of the EC Treaty

(notified under document number C(2003) 4749)

(Only the Dutch text is authentic)

(Text with EEA relevance)

(2004/1/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 95(6) thereof,

Whereas:

I. FACTS

- (1) By letter of the Permanent Representation of the Kingdom of the Netherlands to the European Union of 17 January 2003, the Dutch Government, referring to Article 95(4) of the Treaty, notified to the Commission its national provisions on the use of short chain chlorinated paraffins (hereinafter referred to as SCCPs) that it deems necessary to maintain after the adoption of Directive 2002/45/EC of the European Parliament and of the Council of 25 June 2002 amending for the 20th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (SCCPs) ⁽¹⁾.

1. ARTICLE 95(4) AND (6) OF THE TREATY

- (2) Article 95(4) and (6) of the Treaty provides:

‘4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

(.....)

⁽¹⁾ OJ L 177, 6.7.2002, p. 21.

6. The Commission shall, within six months of the notification approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction to trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a Decision by the Commission within this period the national provisions referred to in paragraphs 4 (...) shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.'

2. DIRECTIVE 2002/45/EC

- (3) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations⁽²⁾, as amended, establishes rules restricting the marketing and use of certain dangerous substances and preparations.
- (4) According to Article 1(1), the Directive applies to the dangerous substances and preparations listed in Annex I. Article 2 provides that Member States shall take all necessary measures to ensure that the dangerous substances and preparations listed in Annex I may only be placed on the market or used subject to the conditions specified therein.
- (5) Directive 76/769/EEC has been amended on several occasions, *inter alia*, to add new dangerous substances and preparations to Annex I thereto, thereby introducing the restrictions on their marketing and/or use necessary to protect human health and/or the environment.
- (6) Adopted on the legal basis of Article 95 of the Treaty, Directive 2002/45/EC has inserted in Annex I to Directive 76/769/EEC a new point 42 concerning alkanes, C10 to C13, chloro (SCCPs), laying down rules on the marketing and use of these substances.
- (7) According to point 42.1, SCCPs may not be placed on the market for use as substances or as constituents of other substances or preparations in concentrations higher than 1 %:
 - in metalworking,
 - for fat liquoring of leather.
- (8) Point 42.2 provides that before 1 January 2003 all remaining uses of SCCPs will be reviewed by the European Commission, in cooperation with the Member States and the OSPAR Commission, in the light of any relevant new scientific data on risks posed by SCCPs to health and the environment and that the European Parliament will be informed of the outcome of this review.
- (9) Article 2(1) provides that Member States shall adopt and publish, not later than 6 July 2003, the laws, regulations and administrative provisions necessary to comply with this Directive and that they shall forthwith inform the Commission thereof and that they shall apply those measures from 6 January 2004 at the latest.

⁽²⁾ OJ L 262, 27.9.1976, p. 201.

3. NATIONAL PROVISIONS

- (10) The national provisions notified by the Netherlands were introduced by Decision of 3 November 1999, laying down rules prohibiting certain uses of short-chain chlorinated paraffins (Chlorinated Paraffins Decision, Chemicals Substances Act (WMS)) (Staatsblad van het Koninkrijk der Nederlanden, Jaargang 1999, 478).
- (11) Article 1 provides that the Decision applies to chlorinated alkanes with a chain of from 10 to 13 inclusive carbon atoms and a chlorination degree of not less than 48 % by weight.

Under Article 2(1), SCCPs referred to in Article 1 may not be used:

- (a) as plasticisers in paints, coatings or sealants;
- (b) in metal-working fluids;
- (c) as flame-retardant in rubber, plastics or textiles.

However, under Article 2(2) SCCPs may continue to be used until 31 December 2004 in dam sealants or as flame-retardants in conveyor belts for exclusive use in mining.

- (12) These provisions were notified to the Commission at the draft stage on 8 March 1999 under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations ⁽³⁾. The Netherlands pointed out that the introduction of the envisaged provisions was necessary in order for it to comply with its international obligations under the Convention for the prevention of marine pollution from land-based sources (the Paris Convention) and the Paris Commission (PARCOM) Decision 95/1 of June 1995 on the phasing out of SCCPs taken in implementation thereof, to which the Kingdom of the Netherlands is Contracting Party ⁽⁴⁾. Five Member States ⁽⁵⁾ and the European Commission issued observations, whereas Spain issued a detailed opinion. All these Member States except Denmark and Austria opposed the introduction of the envisaged national provisions and so did the European Commission.

4. BACKGROUND INFORMATION ON SCCPS

- (13) Chlorinated paraffins are chemical substances manufactured from the chlorination of straight chain paraffins or alkanes. They are often divided into several groups depending on the chain length of the starting material and the amount of chlorine in the final product. Three major groups are short, medium and long chained chlorinated paraffins (SCCPs, MCCPs and LCCPs, respectively). SCCPs are manufactured from straight chain paraffins of chain length C10 to C13. The commercial SCCPs can contain between 49 and 71 % chlorine as an average. They can be marketed and used in their pure form but they can also be present as impurities in other substances and preparations, especially MCCPs ⁽⁶⁾.

⁽³⁾ OJ L 204, 21.7.1998, p. 37.

⁽⁴⁾ Under the Paris Convention the Contracting Parties committed themselves to take all possible steps to prevent and combat marine pollution from land-based sources. All Member States of the European Community except Austria, Greece, Luxembourg and Italy are signatories to the Convention. The European Community is also Contracting Party. The Paris Commission (PARCOM), composed of representatives of each of the Contracting Parties, is responsible for the administration of the Convention. Article 18(3) provides that the commission can adopt programmes and measures for the prevention or the reduction of pollution from land-based sources by certain chemical substances listed in Annex A, Part I, II and III, to the Convention. Adopted on the legal basis of Article 18(3), PARCOM Decision 95/1 provides for the phasing out of certain uses of SCCPs according to the following time frame: use as plasticisers in paints and coatings, use in metal working fluids, use as flame retardants in rubber, plastics and textiles by 31 December 1999; use as plasticise in sealants and as flame retardants in conveyor belts for exclusive use in mining by 31 December 2004. Of the eleven Member States of the European Community which are Contracting Parties to the Paris Convention all but the United Kingdom have committed themselves to PARCOM Decision 95/1. The European Community is not Party to the PARCOM Decision. The Paris Convention was replaced by the new Convention for the protection of the marine environment of the North-East Atlantic (OSPAR Convention, 1992). Under the new Convention, a new OSPAR commission replaced the Paris Commission.

⁽⁵⁾ Italy, Denmark, United Kingdom, Austria and Germany.

⁽⁶⁾ Directive 2002/45/EC lays down a concentration limit of 1 % for SCCPs as constituent of other substances and preparations.

- (14) In the European Community SCCPs are mainly used as additives in metal working fluids. Other uses are as flame-retardants in rubber formulations and as additives for paints and other coating systems. Minor uses are as fattening and softening agents in the leather industry, impregnation agents in the textiles industry and as additives for sealing compounds.
- (15) Due to their toxicity and their apparent persistence and tendency to bioaccumulation, SCCPs are among the substances for which measures aimed at combating pollution are envisaged under the Paris Convention (now OSPAR Convention) ⁽⁷⁾. During the early 1990s, the Paris Commission expressed a concern over the emissions of SCCPs to the marine environment and started to consider regulatory measures on the use of these substances. At that time, the European producers submitted a proposal for a voluntary agreement with a view to phasing out the supply of SCCPs intended for metal working fluids applications and encouraging the downstream industry to use products less damaging to the aquatic environment. The negotiations were not successful and the Paris Commission (PARCOM) finally adopted Decision 95/1. The United Kingdom opposed this Decision pointing out that it was not supported by an appropriate assessment of the risks.
- (16) By Commission Regulation (EC) No 1179/94 ⁽⁸⁾, SCCPs were included in the first list of priority substances to be subjected to risk evaluation under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽⁹⁾, with the United Kingdom acting as rapporteur.
- (17) The risk assessment report on SCCPs produced by the United Kingdom was finalised in September 1997, after review by the Member States' technical experts ⁽¹⁰⁾. The report, which considered all scientific evidence available until 1996, including that on which PARCOM Decision 95/1 was based, highlighted certain environmental risks to aquatic organisms from the use of SCCPs in metalworking and leather finishing, for which it suggested that risk reduction measures should be considered. The remaining current uses were not considered to raise a concern for both the environment and human health, although further information and testing were considered to be needed to adequately characterise certain possible environmental risks from the use of SCCPs in rubber.
- (18) The risk assessment report produced by the United Kingdom was submitted to the SCTEE (Scientific Committee on Toxicity Ecotoxicity and the Environment) for peer review. In its opinion of 27 November 1998 ⁽¹¹⁾, the CSTEE confirmed the scientific validity of the results of the risk assessment.

⁽⁷⁾ See footnote 4.

⁽⁸⁾ OJ L 131, 26.5.1994, p. 3.

⁽⁹⁾ OJ L 84, 5.4.1993, p. 1. This regulation establishes, *inter alia*, a Community procedure for the evaluation of the risks of existing substances, i.e. substances appearing on the European Inventory of Existing Commercial Substances (OJ C 146, 15.6.1990, p. 1). Under this Regulation, lists of priority substances to be subjected to Community risk evaluation are to be adopted through a Commission Regulation specifying, for each substance, the Member State responsible for the evaluation (Member State rapporteur). Specific procedures and methodologies have to be followed in carrying out the assessment of the real or potential risks to man and the environment from the substances concerned. These are specified in Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of the risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (OJ L 161, 26.6.1994, p. 3) and further detailed in the Technical Guidance Document on risk assessment for new and existing substances (TGD — <http://ecb.jrc.it/existing-chemicals/>). The results of the risk evaluation and, where appropriate, the recommended strategy are finally adopted at Community level, normally in the form of a Commission Recommendation. On the basis of the risk evaluation and the recommended strategy so adopted, the Commission is then to decide to propose Community measures in the framework of Directive 76/769/EEC or in the framework of other relevant existing Community instruments.

⁽¹⁰⁾ The Member States' experts meet regularly in order to review risk assessment reports with a view to preparing the measures to be adopted according to the Committee procedure laid down in Council Regulation (EEC) No 793/93.

⁽¹¹⁾ Opinion of the CSTEE on the results of the risk assessment of SCCPs carried out in the framework of Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances — Opinion expressed at the sixth CSTEE plenary meeting, Brussels, 27 November 1998. http://europa.eu.int/comm/food/fs/sc/sct/out23_en.html

- (19) By Commission Directive 98/98/EC ⁽¹²⁾, SCCPs have been classified as dangerous substances under Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽¹³⁾. In particular, they are classified as carcinogens, category 3, and are labelled with the risk phrase R 40 (Possible risk of irreversible effects) and the symbol Xn (harmful). They are also classified as dangerous for the environment and are labelled with the risk phrase R 50/53 ('very toxic to aquatic organisms' and 'may cause long-term adverse effects in the aquatic environment') and the symbol N ('dangerous for the environment').
- (20) The risk assessment report on SCCPs was finalised in October 1999 ⁽¹⁴⁾. The results of the risk assessment of SCCPs and the corresponding risk reduction strategy were adopted at Community level through Commission Recommendation 1999/721/EC of 12 October 1999 ⁽¹⁵⁾ in accordance with under Regulation (EEC) No 793/93. The relevant parts of the Recommendation are reproduced below.

1. RISK ASSESSMENT

A. Human health

The conclusion of the evaluation of the risks to man for WORKERS, CONSUMERS and MAN EXPOSED VIA THE ENVIRONMENT is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the population mentioned above are not expected. The main route of potential worker exposure during production and use is via dermal exposure. Inhalation is also a potential route of exposure during use of metal working fluids and hot-melt adhesives containing the substance. Risk reduction measures already being applied in the framework of the workplace or other relevant Community legislation in force are considered sufficient,
- consumer exposure, which may occur by contact with leather goods treated with the substance and from non-professional use of metal working fluids, was considered not to be of concern.

B. Environment

The conclusion of the evaluation of the risks to the environment for AQUATIC (sediment) and TERRESTRIAL ECOSYSTEM is that there is a need for further information and/or testing. This conclusion is reached because:

- there is a need for better information to adequately characterise the risk to sediment compartment arising from production of the substance and its use in rubber, to the soil and sediment compartments arising from the formulation and use of metal working fluids and leather finishing products, and to the soil and sediment compartments at regional level.

⁽¹²⁾ OJ L 355, 30.12.1998, p. 1. This Directive adds, *inter alia*, SCCPs to Annex I to the latter Directive. This is an index of dangerous substances for which harmonised classification and labelling have been agreed at Community level according to the procedure laid down in Article 4(3) of the same Directive.

⁽¹³⁾ OJ 196, 16.8.1967, p. 1.

⁽¹⁴⁾ 'European Union Risk Assessment Report, CAS No: 85535-84-8, EINECS No: 287-476-5, alkanes, C₁₀₋₁₃, chloro, first priority list, volume: 4 — European Commission Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau, Existing substances Institute for Health and Consumer Protection, Joint Research Centre, European Commission' — <http://ecb.jrc.it/existing-chemicals/>.

⁽¹⁵⁾ OJ L 292, 13.11.1999, p. 42.

The information requirements are:

- experimental determination of the K_{oc} (*),
- monitoring data in soil and sediment near sources of release,
- toxicity testing on soil and sediment dwelling organisms if the abovementioned information does not remove the concern for the abovementioned compartments.

The conclusion of the evaluation of the risks to the environment for MICRO-ORGANISMS in the SEWAGE TREATMENT PLANT and ATMOSPHERE is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the evaluation of the risks to the environment for AQUATIC (excluding sediment) ECOSYSTEM and NON-COMPARTMENT SPECIFIC EFFECTS RELEVANT TO THE FOOD CHAIN is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on the local aquatic environmental spheres mentioned above as a consequence of exposure arising from formulation and use of metal working fluids containing the substance and leather finishing products containing the substance,
- concerns for non-compartmental specific effects relevant to the food chain arising from the formulation and use of leather finishing products containing the substance and from use of metal working fluids containing the substance.

II. STRATEGY FOR LIMITING RISKS for the ENVIRONMENT

Marketing and use restrictions should be considered at Community level for the substance to protect the environment from the use and formulation of products, in particular for use in metal working and leather finishing. Further work is necessary to establish those uses for which derogations can be justified. The measures identified to protect the environment will also reduce human exposure.

(*) Organic carbon partition coefficient, a parameter which represents the distribution of a compound between organic carbon in the soil (e.g. humic acid) and water.'

- (21) On 20 June 2000 the Commission adopted a proposal for an amendment of Directive 76/769/EC with a view to introducing the marketing and use restrictions suggested by the Community risk assessment, which finally led to the adoption of Directive 2002/45/EC.
- (22) As required by point 42.2 of Annex I to Directive 76/769/EEC, as introduced by Directive 2002/45/EC, the Commission started the review of the remaining uses of SCCPs. In this context, the Commission requested the United Kingdom, as Member State rapporteur for SCCPs in the framework of Regulation (EEC) No 793/93, to gather and review all new relevant available data and, if appropriate, to update the Community risk assessment report. Furthermore, the Commission asked the OSPAR Secretariat whether there were any new scientific data on risks posed by SCCPs which might modify the conclusions of the previous risk assessment. The Commission finally asked the SCTEE whether the latter was aware of any new available scientific evidence which could influence the results of the risk assessment and might call for a modification of its conclusions.

- (23) In its opinion of 22 December 2002, the SCTEE concluded that the review of new knowledge on SCCPs does not highlight any need to change the conclusions of the Community risk assessment ⁽¹⁶⁾.
- (24) In February 2003, a draft updated risk assessment report on SCCPs was produced by the United Kingdom as a follow-up to Directive 2002/45/EC and was subsequently submitted to the Member States' technical experts ⁽¹⁷⁾ for review. The final version was made available in late July 2003. This report reviews the data on the environmental exposure, fate and effects of SCCPs that have become available since the original risk assessment was completed and reassesses the risks from the uses other than those subject to the marketing and use restrictions laid down in Directive 2002/45/EC. The two opinions of the SCTEE referred to above (recitals 18 and 23) have also been considered. By contrast to the original risk assessment, the updated risk assessment covers the risks to the marine environment, both at local and at wider scale. The latter aspect has been evaluated in relation to the newly finalised criteria for the identification of persistent or very persistent, bioaccumulative or very bioaccumulative and toxic (PBT, vPBT, PvBT or vPvBT) substances ⁽¹⁸⁾. It also considers in detail the emissions of SCCPs over the lifetime of products containing them.
- (25) The report focuses on the environmental risks and comprises two parts. The first part illustrates the assessment carried out on the basis of the PEC/PNEC values ratios ⁽¹⁹⁾ (hereinafter referred to as 'classical risk assessment'). The second part addresses the evaluation of SCCPs against the PBT criteria and assesses the risks to the wider marine environment (hereinafter referred to as 'PBT assessment').
- (26) The results of the updated risk assessment are reproduced below:

'(x) (i) There is a need for further information and/or testing.

The worst-case PEC/PNEC ratios indicate a possible risk to surface water and sediment (from the formulation and use (application) of backcoatings for textiles), soil (from the formulation and use in rubber and textiles and from regional sources of "waste remaining in the environment") and secondary poisoning (from formulation and use in rubber and textiles, and from use in paints and coatings), as well as marine ecosystems (from all uses of short-chain chlorinated paraffins, except for use in sealants, formulation of paints and production sites). There is a need for further specific exposure information, in order to refine the release estimates. In particular, information could be provided on:

- actual releases from the compounding and conversion of rubber,
- the amounts of short-chain chlorinated paraffins used at typical textile compounding (formulation) and backcoating sites,
- releases from backcoating formulation and textile backcoating sites,
- releases from paint application sites, and
- emissions during use and disposal of products.

⁽¹⁶⁾ Opinion of the SCTEE on 'SCCPs' — Follow-up to Directive 2002/45/EC, opinion expressed at the 35th SCTEE plenary meeting, Brussels, 17 December 2002. http://europa.eu.int/comm/food/fs/sc/sct/out23_en.html

⁽¹⁷⁾ See footnote 10.

⁽¹⁸⁾ According to the TGD (see footnote 9), substances displaying PBT properties are considered to have the potential to pollute the wider marine environment, thus requiring measures to control emissions.

⁽¹⁹⁾ This risk-assessment methodology, outlined in Commission Regulation (EC) No 1488/94 and further detailed in the Technical Guidance Document (see footnote 9) consists in calculating the ratios between the predicted environmental concentration (PEC) of a given substance and the predicted no effect concentration (PNEC) of that substance in any specific environmental compartment, ratios above 1 highlighting a situation of real or potential risks, depending on the uncertainties surrounding the PEC and PNEC values.

The substance meets the screening criteria for consideration as a PBT substance, and so a simulation test for biodegradability could also be performed to determine the half-life in the marine environment. Additional toxicity data would allow the PNEC for both marine water and sediment to be revised, but the need to gather such data is less important than the determination of persistence. In addition, consideration could be given to carrying out further biodegradation testing of short-chain chlorinated paraffins in soil.

Note: Measurements indicate that the substance is widely distributed in the environment. The trend in levels is unknown, and they could be related to former uses that are now controlled. In addition, a clear risk has not been identified on the basis of these measurements. Nevertheless, the occurrence of short-chain chlorinated paraffins in the Arctic and marine predators mean that these findings remain a concern. Whilst it is not possible to say whether or not on a scientific basis there is a current or future risk to the environment, in light of:

- data indicating presence in biota,
- the apparent persistence of the substance (based on laboratory tests),
- the time it would take to gather the information, and
- the fact that it could be difficult to reduce exposure if the additional information confirmed a risk,

consideration could be given at a policy level about the need to investigate precautionary risk management options now in the absence of measured environmental half-life data, to reduce the inputs to water (and soil from the application of sewage sludge), including from “waste remaining in the environment”. This could be reconsidered should an environmental simulation test show that the persistence criterion is not fulfilled. In connection with this, it should be noted that the substance appears to meet the screening criteria for consideration as a candidate persistent organic pollutant (POP) under international conventions.

- (x) (ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those that are being applied already.

This conclusion applies to the assessment of:

- the local surface water compartment for production sites, compounding and conversion of rubber, formulation and use of sealants, the formulation and use of paints and coatings, and at the regional level (it should be noted that there are some uncertainties in the PNEC for this endpoint and, if a more conservative interpretation of the data were taken, possible risks would be identified for production sites, compounding and conversion of rubber and industrial application of paints and coatings),
- the local sediment compartment for production sites, formulation and use of sealants, the formulation and use of paints and coatings, and at the regional level,
- the assessment of waste water treatment plants from all uses,
- the atmospheric compartment and wastewater treatment processes for production and all uses,
- the local terrestrial compartment for production sites and formulation and use of sealants and formulation and use of paints, and the regional agricultural soil compartment (it should be noted that there are some uncertainties in the PNEC for this endpoint and if a more conservative interpretation of the data were taken, possible risks would be identified for industrial use of paints), and
- secondary poisoning for production sites, use of sealants and formulation of paints.’

- (27) Requested by the Commission to review the updated risk assessment report and to clarify certain specific issues relevant for the assessment of the notified national provisions, on 3 October 2003 the SCTEE adopted its opinion thereof ⁽²⁰⁾. In formulating this opinion, the SCTEE considered also the study 'Ecotoxicological advice on chlorinated paraffins' commissioned by the Dutch government and the OSPAR priority substance series on SCCPs (OSPAR COMMISSION, 2001) and the UNECE ad hoc expert group substance dossier on SCCPs (Final Draft II, 2003). As regards the PBT assessment, the SCTEE considers that though there are still uncertainties associated with the classification of SCCPs as PBT substances, on the basis of weight of evidence, and taking particular note of evidence on the occurrence of SCCPs in environmental compartments and top predators in remote places, this classification is appropriate and unlikely to be changed by more work. However, the SCTEE reiterates its concerns that PBT classification cannot be the sole basis for risk management, expressing the view that more detailed analysis of risk and, minimally, the sources, routes and pathways into the marine environment are necessary to that effect. As regards the 'classical risk assessment' the SCTEE notes that this assessment, though based on a number of worst case assumptions with respect to releases and exposures, has extended the areas of concern to the risks from the aquatic environment, sediment and soil from back coating of textiles and in rubber. The SCTEE also observes that for soil and sediment, in contrast with the report, an extra factor of 10 should be applied the PEC/PNEC ratios, which would make all RQs for the soil and sediment compartments greater than 1. However, the SCTEE considers that the PNEC values used to assess the risks for these environmental compartments are not reliable. The SCTEE argues that risk management decisions would be more reliably based on experimentally derived PNEC and is of view these data could be collected relatively rapidly. The SCTEE points out further inadequacies in the assumptions associated with secondary poisoning. In conclusion, the SCTEE, though acknowledging that the uses of SCCPs not currently subject to controls under the existing Community risk reduction measures may give cause for concern in terms of environmental effects, considers that the available data are not adequate to justify risk reduction measures and suggests that further information and testing are necessary to adequately assess the risks.
- (28) As a follow-up to the above developments, the Commission, pursuant to Article 10 of Regulation (EEC) 793/93 ⁽²¹⁾, is preparing a regulation with a view to obliging industry to provide the missing data and information, thus allowing for a more reliable reassessment of the risks. Following review by the Member States' technical experts, the new updated risk assessment will, if appropriate, be subsequently submitted to the SCTEE for peer review.
- (29) In addition to the Community measures referred to above, SCCPs are considered by other Community legislation. In view of their human toxicity and aquatic toxicity, of their widely detected presence in the aquatic environment and of the fact that they are already subject to PARCOM Decision 95/1, SCCPs were included by Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC ⁽²²⁾ among the priority hazardous substances within the meaning of Article 16(3) of the latter Directive. Under this Directive, specific measures must be adopted at Community level with a view to the cessation or phasing out of discharges, emissions and losses within 20 years after their adoption. To date no such measures have been adopted as regards SCCPs.

⁽²⁰⁾ Opinion of the CSTEE on 'The scientific basis of the national provisions on short chain chlorinated paraffins (SCCPs) being more restrictive than those laid down in Directive 2002/45/EC that The Netherlands intends to maintain in accordance with Article 95(4) of the EC Treaty' — Adopted by the CSTEE by written procedure on 3 October 2003. http://europa.eu.int/comm/food/fs/sc/sct/out200_en.pdf.

⁽²¹⁾ According to the Regulation manufacturers and importers have as a general rule to submit to the rapporteur certain information or to carry out testing. Article 10 provides that when, for the purpose of risk evaluation, the rapporteur considers it necessary to request the manufacturers or importers to submit further information or to carry out further testing, it shall inform the Commission accordingly and a decision thereof is taken in accordance with the procedure laid down in Article 15.

⁽²²⁾ OJ L 331, 15.12.2001, p. 1.

II. PROCEDURE

- (30) At the time of adoption of Directive 2002/45/EC, the Dutch delegation voted against that Directive, stating, in a voting declaration made on 24 April 2002, that the implementation of a Directive on SCCPs would make it impossible for the Netherlands to discharge its international obligations under the Paris Convention and PARCOM Decision 95/1.
- (31) By letter of the Permanent Representation of the Kingdom of The Netherlands to the European Union of 17 January 2003, the Dutch Government, referring to Article 95(4) of the Treaty, notified to the Commission its national provisions on the use of SCCPs that it intends to maintain after the adoption of Directive 2002/45/EC.
- (32) By letter of 25 March 2003, the Commission informed the Dutch Government that it had received the notification under Article 95(4) of the Treaty and that the six-month period for its examination under Article 95(6) started on 22 January 2003, the day following the day on which the notification was received.
- (33) By letter of 15 April 2003, the Commission informed the other Member States of the notification received from the Netherlands. The Commission also published a notice regarding the notification in the *Official Journal of the European Union* ⁽²³⁾ in order to inform other interested parties of the national provisions that the Netherlands intends to maintain as well as of the grounds invoked to that effect.
- (34) In February 2003, the United Kingdom produced the first draft of the updated risk assessment report on SCCPs referred to in Section I(4) of the present Decision.
- (35) On 17 July 2003, pursuant to Article 95(6), the Commission notified the Kingdom of the Netherlands of its Decision 2003/549/EC of the same date, whereby it extended the period referred to in the first subparagraph of the said Article to approve or reject the notified national provisions for a further period expiring on 20 December 2003. The Commission considered that, in the absence of an actual danger to human health, such an extension was justified by the need to consult the SCTEE with a view to clarifying as far as possible the issues arising out from the draft updated risk assessment report.
- (36) In late July 2003 the United Kingdom produced the final version of updated risk assessment report on SCCPs, which was subsequently submitted to the SCTEE for review, together with the evidence submitted by the Kingdom of the Netherlands in support of its notification.
- (37) On 3 October 2003 the CSTEE adopted the opinion referred to in Section I(4) of the present Decision.

III. ASSESSMENT

1. ADMISSIBILITY

- (38) In Decision 2003/549/EC referred to above, the Commission concluded that the application submitted by the Kingdom of the Netherlands is admissible. Reference is made to that Decision for the purposes of the present Decision. It is nonetheless useful to recall the aspects in which the notified national provisions are incompatible with the requirements of Directive 2002/45/EC.
- (39) In summary, the notified national provisions depart from the requirements of Directive 2002/45/EC in the following respects:
- the use of SCCPs with a chlorination degree of not less than 48 % as plasticising substances in paints, coatings or sealants and as flame-retardant substances in rubber, plastics or textiles, which is not to be subjected to restrictions on the marketing and use under the Directive, is prohibited in the Netherlands,

⁽²³⁾ OJ C 100, 26.4.2003, p. 20.

- the use in metal working fluids of substances and preparations in which SCCPs with a chlorination degree of not less than 48 % are present as constituents, which is not to be subjected to restrictions on the marketing and use under the Directive if SCCPs are present in a concentration below 1 %, is prohibited in the Netherlands.

2. MERITS

- (40) In accordance with Article 95(4) and (6), first subparagraph, of the Treaty, the Commission must ascertain that all the conditions enabling a Member State to maintain its national provisions derogating from a Community harmonisation measure provided for in that Article are fulfilled.
- (41) In particular, the Commission has to assess whether or not the national provisions are justified by the major needs referred to in Article 30 of the Treaty or relating to the protection of the environment or the working environment and do not exceed what is necessary to attain the legitimate objective pursued. In addition, when the Commission considers that the national provisions fulfil the above conditions, it must verify, pursuant to Article 95(6), whether or not the national provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market.
- (42) It has to be noted that, in the light of the time frame established by Article 95(6) of the EC Treaty, the Commission, when examining whether the national measures notified under Article 95(4) are justified, has to take as a basis 'the grounds' put forward by the notifying Member State. This means that, according to the provisions of the EC Treaty, the responsibility of proving that the national measures are justified lies with the requesting Member State which seeks to maintain them. Given the procedural framework established by Article 95 of the EC Treaty, including in particular a strict deadline for a decision to be adopted, the Commission normally has to limit itself to examining the relevance of the elements which are submitted by the requesting Member State, without having to seek itself possible reasons of justifications.
- (43) However, where the Commission is in the possession of information in the light of which the Community harmonisation measure from which the notified national provisions derogate may need to be reviewed, it can take such information into consideration in the assessment of the notified national provisions.

2.1. JUSTIFICATION ON GROUNDS OF MAJOR NEEDS REFERRED TO IN ARTICLE 30 OR RELATING TO THE PROTECTION OF THE ENVIRONMENT OR THE WORKING ENVIRONMENT

- (44) The Netherlands considers that the maintenance of its national provisions is necessary to protect the aquatic environment and human health from the risks arising from the current uses of SCCPs. Reference is made to the precautionary principle. In the view of the Netherlands, this principle has to be interpreted to mean that it cannot be expected to wait until a serious problem occurs, especially in view of the importance of high-quality ground and surface water for public health. The Netherlands recalls that SCCPs are extremely dangerous substances and are classified as dangerous for both human health and the environment under Directive 67/548/EEC. They are also considered to be persistent and particularly harmful to the aquatic environment under the OSPAR Convention. In view of their presence in the environment it was decided to phase out their uses through the Paris Commission (now OSPAR Commission) Decision 95/1. The Netherlands points out that SCCPs pose a serious threat to the Dutch aquatic environment. This would be clearly highlighted in a study by a Dutch toxicology consultant enclosed in the notification submitted by the Netherlands. Public health is also claimed to be at risk due to the fact that both surface water and groundwater are widely used for the abstraction of drinking water in the Netherlands.
- (45) In assessing whether the national provisions are justified, as claimed by the Netherlands, on grounds of human health and environmental protection, the Commission previously considered in its Decision 2003/549/EC that consideration has to be given not only to the evidence submitted by the Netherlands but also to all relevant evidence in the Commission's possession and, in particular, to the results of the risk assessments carried out in the framework of Regulation (EEC) No 793/93 and all other available evidence.

- (46) In reiterating this view, the Commission recalls that since the date of that Decision the final version of the updated risk assessment report on SCCPs and the related SCTEE's opinion of 3 October 2003 referred to in Section I(4) have been made available. This information, in view of its relevance for the assessment of the national provisions, has also to be taken into consideration.
- (47) As far as the evidence submitted by the Netherlands is concerned, the Commission previously examined the Dutch study enclosed in the notification file and concluded in its Decision 2003/549/EC that, in contrast with what the Netherlands claims, it does not highlight a risk for the Dutch aquatic environment and the Dutch population and hence does not support the grounds invoked by the Netherlands for maintaining the national provisions. This study will therefore not be considered further.
- (48) Overall, the evidence considered by the Commission for the purpose of the assessment of the national provisions include: the original risk assessment of SCCPs produced by the United Kingdom in 1997 and the related SCTEE's opinion of 27 November 1998, the conclusions of the risk assessment of SCCPs, as adopted in Recommendation 1999/721/EC, the updated risk assessment of SCCPs produced by the United Kingdom in late July 2003, the outcome of the discussions thereof held by the Member States' Technical Committee and the SCTEE's opinion of 3 October 2003. It has to be noted that in formulating the latter opinion, the SCTEE, upon request from the Commission, also examined the study submitted by the Netherlands.

2.1.1. *Human health*

- (49) The original risk assessment report on SCCPs finalised in 1997 and the related opinion of the SCTEE of 27 November 1998 do not highlight concerns for human health from all uses of SCCPs that are prohibited under the national provisions. No concern for human health in relation to these uses was either expressed in the subsequent conclusions of the risk assessment adopted at Community level in 1999 ⁽²⁴⁾ or the SCTEE's opinion of 22 December 2002. It has to be noted that in formulating the latter opinion, the SCTEE considered both the new information on SCCPs as well as the foreseeable beneficial impacts resulting from the implementation of the restrictions laid down in the recently adopted Directive 2002/45/EC. Finally, the absence of concerns from human health from all remaining uses of SCCPs was confirmed by the subsequent final version of the updated risk assessment report produced by the United Kingdom in late July 2003 and the related SCTEE's opinion of 3 October 2003, which also considered the study submitted by the Netherlands.
- (50) In the light of the foregoing, and in the absence of any other evidence to the contrary, it can be concluded that the national provisions are not justified by the need to protect human health.

2.1.2. *Environment*

- (51) The national provisions have to be assessed in relation to each of the aspects in which they are more restrictive than the requirements of Directive 2002/45/EC, starting with the prohibition of the uses of SCCPs as constituent of other substances and preparations in metal-working.

⁽²⁴⁾ See recital 20 of the present Decision.

2.1.2.1. Prohibition on the use of SCCPs as constituents of other substances and preparations in metal-working

- (52) Directive 2002/45/EC allows the use of SCCPs as constituent of other substances and preparations in metal-working in concentrations up to 1 %. This limit value, not included in the original Commission's proposal, was finally introduced to prevent medium chain chlorinated paraffins (MCCPs) from falling into the scope of the Directive. MCCPs contain SCCPs as constituents or as impurities in concentrations ranging from 0,3 to 1 % and 'may have similar applications to SCCPs and are used as replacements for SCCPs as extreme pressure additives in metalworking fluids, as plasticisers in paint and as additives in sealants' ⁽²⁵⁾. The Community legislator considered that this concentration limit would ensure an adequate level of environmental protection without affecting possible future measures on MCCPs awaiting the outcome of the on-going Community risk assessment of the latter substances ⁽²⁶⁾.
- (53) Neither the original risk assessment report on SCCPs, nor the related opinion of the SCTEE of 27 November 1998 and the conclusions of the risk assessment adopted through Recommendation 1999/721/EEC ⁽²⁷⁾ clarify whether this concentration limit is sufficiently protective. In its opinion of 22 December 2002, the SCTEE, after carefully reviewing the new information on SCCPs and also expressly considering the restrictions laid down in Directive 2002/45/EC, does not call into question that concentration limit.
- (54) Requested by the Commission to clarify this issue, the CSTEE concludes in its opinion of 3 October 2003 that this use of SCCPs may still lead to unacceptable risks.
- (55) It can therefore be concluded that the national provisions, in so far as they prohibit the use of SCCPs as constituent of other substances and preparations in metal-working can be justified by the need to protect the environment.
- (56) In addition, in the absence of any further information suggesting the legitimated objective pursued can be attained by less restrictive measures, such as, in particular, a lower concentration limit for SCCPs as constituents of other substances and preparations, it can be concluded that the national provisions do not appear to exceed what is necessary to attain that objective.

2.1.2.2. Prohibition of the use of SCCPs as substances and as constituents of other substances and preparations in the remaining uses

- (57) The prohibition of the remaining uses of SCCPs as substances will be assessed first.
- (58) The original risk assessment report on SCCPs and the related opinion of the SCTEE of 27 November 1998 do not highlight risks to the environment from uses of SCCPs in applications other than in metal-working and for leather finishing. This conclusion is upheld by the Commission in Recommendation 1999/721/EEC ⁽²⁸⁾. No need to change these conclusions, was expressed by the SCTEE in its opinion 22 December 2002, after careful evaluation of the new information on SCCPs and also taking into account the foreseeable beneficial impacts resulting from the implementation of the restrictions laid down in the recently adopted Directive 2002/45/EC.

⁽²⁵⁾ See OSPAR Commission document on SCCPs, 2001, paragraph 33.

⁽²⁶⁾ MCCPs are subject to risk assessment in the framework of Regulation (EEC) 793/93, with the United Kingdom acting as Member State rapporteur.

⁽²⁷⁾ See recital 20 of the present Decision.

⁽²⁸⁾ See recital 20 of the present Decision.

- (59) The conclusions of the final updated risk assessment report produced by the United Kingdom in late July 2003 diverge from those of the previous assessments. This report reassesses in a more comprehensive way the environmental risks associated with these uses on the basis of new data and information. In addition to a new assessment of the environmental risks carried out using the traditional PEC/PNEC-based methodology (hereinafter referred to as 'classical risk assessment'), an evaluation is provided of the risks to the wider marine environment in relation to the criteria for the identification of PBT substances (the latter is hereinafter referred to as 'PBT assessment'). The updated report therefore supersedes the previous reports and the related subsequent opinions for the common parts, which have therefore to be disregarded for the purposes of the assessment of the national provisions.
- (60) The Commission previously examined the first version of this report, in the form of a draft, as made available to it by the United Kingdom in February 2003, and in Decision 2003/549/EC concluded that it gave unclear indications as to whether the available information constituted sufficient scientific evidence to justify the recourse to risk reduction measures. In addition, the Commission observed that the draft report did not fully identify the uses of SCCPs giving rise to concern nor the extent to which risk reduction measures could be justified to adequately address those concerns.
- (61) The final version of the report, though clarifying certain aspects of the risk assessment, still contains unclear indications. On the one hand, the results of the 'classical risk assessment' are not considered as being sufficiently reliable. Likewise, the 'PBT assessment' is not considered to be conclusive. On the other hand the view is expressed that the wide distribution of SCCPs in the environment, combined with the likely PBT properties of these substances, raise a concern which could justify recourse to precautionary control measures to reduce inputs to water and soil.
- (62) The Member States' technical experts, after reviewing the updated report and noting the remaining uncertainties, expressed the view that immediate consideration should be given to risk reduction measures.
- (63) In its opinion of 3 October 2003 the SCTEE arrives at different conclusions. Unlike the rapporteur and the Member States' technical experts, the SCTEE considers that the data and information relevant to the 'PBT assessment', though supporting the classification of SCCPs as PBT substances, do not provide a sufficient scientific basis for risk reduction measures. Turning to the results of the 'classical risk assessment', the SCTEE, despite the remaining uncertainties, agrees with the assessment that there are possible environmental risks from the use of SCCPs in textiles and rubber. In addition, the SCTEE points out that there may be concerns from all other uses of SCCPs with respect to the likely impacts on soil and sediments. However, the SCTEE does not consider that the available data and information constitute a sound scientific basis for risk reduction measures. Rather, in view of the fact that the data needed to reduce the remaining uncertainties could be collected relatively rapidly, the SCTEE expresses the view that reduction measures should await the outcome of a new reassessment conducted on the basis of adequate PEC and PNEC values.
- (64) It appears from the foregoing that there are still uncertainties in the evaluation of the risks from the remaining uses of SCCPs. While the opinions diverge as to the interpretation of the available information in terms of justification for risk reduction measures, there is agreement that all remaining uses of SCCPs, though for different reasons and to varying degrees, are identified as giving rise to potential concerns.
- (65) The Commission recalls that a situation of scientific uncertainty as to the existence of a risk may justify maintaining precautionary protective measures necessary to ensure the desired level of protection during a limited period of time to the extent that this period is necessary to resolve the scientific uncertainties⁽²⁹⁾. It is clear that such a situation exists with regard to the potential risks from the remaining uses of SCCPs. Furthermore the potential concerns expressed suggest that the Commission cannot exclude that Directive 2002/45/EC, which allows these uses, may be insufficient to ensure the level of protection pursued by the Netherlands.

⁽²⁹⁾ Communication from the Commission on the precautionary principle (COM(2000)1).

- (66) In these circumstances and taking into account the precautionary principle, it can be concluded that the national provisions, in so far as they prohibit the remaining uses of SCCPs, can remain in place for a limited period of time in order not to interrupt existing measures that may appear justified in the light of a forthcoming risk assessment. This conclusion appears all the more justified as SCCPs are identified as priority hazardous substances under Directive 2000/60/EC, for which measures aimed at the cessation or phasing out of discharges, emissions, and losses are recognised to be necessary in order to ensure an enhanced protection and improvement of the aquatic environment.
- (67) The conclusion above applies to the prohibition of the remaining uses of SCCPs as substances. As far as the prohibition of use of SCCPs as constituents of other substances and preparations is concerned, it has first to be noted that these uses are not covered by the updated risk assessment report. Requested by the Commission to clarify whether these uses pose a risk, the SCTEE, in its opinion of 3 October 2003, concludes for the negative, except for the use in plastics, where possible problems may occur.
- (68) It can therefore be concluded that the national provisions, in so far as they prohibit the use of SCCPs as constituents of other substances and preparations in the remaining applications, except in plastics, are not justified by the need to protect the environment.
- (69) It remains to be assessed whether the national provisions, to the extent that the Commission considers that they can be temporarily maintained, do not exceed what is necessary to attain the legitimate objective pursued. In this regard, the Commission observes that discussions are on-going in the framework of Directive 2000/60/EC in order to identify the appropriate cost-effectiveness and proportionate emissions control measures of SCCPs and that, to date, it has not been possible to identify measures less restrictive than the national provisions capable of ensuring that the level of exposure of the environment to SCCPs from the remaining current uses is effectively kept to a minimum. On the basis of the available information, the national provisions appear to constitute the only available measure to ensure the maintenance of the high level of environmental protection pursued by the Netherlands.
- (70) On the basis of the available information and pending the identification of the risk reduction measures mentioned above, it can therefore be concluded that the national provisions are not disproportionate to the legitimate objective pursued.
- (71) The Commission will examine whether to adapt Directive 2002/45/EC and/or to propose the appropriate measures as required by Directive 2000/60/EC taking into account any additional information mentioned above.

2.2. ABSENCE OF ARBITRARY DISCRIMINATION OR OF ANY DISGUISED RESTRICTION ON TRADE BETWEEN MEMBER STATES AND OF ANY OBSTACLE TO THE FUNCTIONING OF THE INTERNAL MARKET

2.2.1. *Absence of arbitrary discrimination*

- (72) Article 95(6) obliges the Commission to verify that the envisaged measures are not a means of arbitrary discrimination. According to the jurisprudence of the Court of Justice, in order for there to be no discrimination, similar situations must not be treated in different ways and different situations must not be treated in the same way.
- (73) The national provisions are general and apply to the uses of SCCPs regardless of whether the substances are manufactured in the Netherlands or are imported from other Member States. In the absence of any evidence to the contrary, it can be concluded that the national provisions are not a means of arbitrary discrimination.

2.2.2. *Absence of a disguised restriction on trade*

- (74) National measures which restrict the use of products to a greater extent than a Community directive would normally constitute a barrier to trade, in so far as products that are legally placed on the market and used in the rest of the Community are not expected, as a result of the prohibition on use, to be placed on the market in the Member State concerned. The preconditions laid down in Article 95(6) are intended to prevent restrictions based on the criteria set out in paragraphs 4 and 5 thereof from being applied for inappropriate reasons, and constituting in effect economic measures to impede the importation of products from other Member States, that is to say, a means of indirectly protecting national production.
- (75) As previously established, the true aim of the national provisions is the protection of the environment from the risks associated with the uses of SCCPs. In the absence of any evidence suggesting that the national provisions constitute in effect a measure intended to protect national production, it can be concluded that they are not a disguised restriction to trade between Member States.

2.2.3. *Absence of obstacles to the functioning of the internal market*

- (76) This condition cannot be interpreted in such a way that it precludes the approval of any national measure likely to affect the establishment of the internal market. Indeed, any national measure derogating from a harmonisation measure aiming at the establishment and operation of the internal market constitutes in substance a measure likely to affect the internal market. Consequently, in order to preserve the useful character of the procedure laid down in Article 95 of the Treaty, the concept of obstacle to the functioning of the internal market must, in the context of Article 95(6), be understood as a disproportionate effect in relation to the pursued objective.
- (77) It has been established that the national provisions can be temporarily maintained on grounds relating to the protection of the environment and that, on the basis of the available information, they appear to constitute the only available measure to ensure the maintenance of the high level of protection pursued by the Netherlands. The Commission therefore considers that, pending the identification of appropriate risk reduction measures, it can conclude that the condition relating to the absence of obstacles to the functioning of the internal market is fulfilled.

IV. CONCLUSION

- (78) In the light of the foregoing, it can be concluded that the national provisions:
- can be temporarily maintained on grounds relating to the protection of the environment and do not exceed what is necessary to attain the objective pursued in so far as they prohibit the use of SCCPs as constituents of other substances and preparations in metal working fluids or intended for use as flame retardants in plastics, as plasticising substances in paints, coatings and sealants, and as flame-retardant substances in textiles,
 - are not justified on grounds relating to the protection of the environment in so far as they prohibit the use of SCCPs as constituents of other substances and preparations in concentrations lower than 1 % intended for use as plasticisers in paints, coatings and sealants, and as flame-retardants in rubber or textiles.
- (79) In addition, the national provisions, in so far as they can be temporarily maintained, are not a means of arbitrary discrimination or a disguised restriction on trade between Member States and do not constitute an obstacle to the functioning of the internal market.

- (80) The Commission therefore considers that the national provisions, to the extent specified above, can be approved. However, in view of the specific circumstances under which the national provisions have been assessed, the Commission considers that their approval has to be limited in time. As reported in Section I(4) of the present Decision, initiatives are under way to gather the information necessary to remove or to reduce the uncertainties surrounding the risk evaluation of SCCPs. It cannot therefore be ruled out that the national provisions will not appear to be justified in the light of the new information. The approval should extend to the time needed to gather and to carefully evaluate the necessary information. The Commission considers that a period expiring on 31 December 2006 is necessary to that effect. The approval will expire at that date,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions on SCCPs notified by the Netherlands on 21 January 2003 pursuant to Article 95(4) are approved in so far as they do not apply to the use of SCCPs as constituents of other substances and preparations in concentrations lower than 1 % intended for use as:

- plasticisers in paints, coatings or sealants,
- flame retardants in rubber or textiles.

Article 2

This Decision shall apply until 31 December 2006.

Article 3

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 16 December 2003.

For the Commission

Erkki LIIKANEN

Member of the Commission
