II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 17 July 2003

extending the period referred to in Article 95(6) of the EC Treaty in relation to the national provisions on the use of short-chain chlorinated paraffins notified by the Netherlands under Article 95(4)

(notified under document number C(2003) 2539)

(Only the Dutch text is authentic)

(Text with EEA relevance)

(2003/549/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 Office of the Permanent Representative 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 European Parliament and Council Directive 2002/45/EC of 25 June 2002 amending for the 20th time Council Directive 76/769/EEC [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.

(…)

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

[1] OJ L 177, 6.7.2002, p. 21.

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. According to Article 1(1), the Directive applies to the dangerous substances and preparations listed in Annex I.

(4) 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 or use that are necessary to protect human health or the environment.

(6) Adopted on the legal basis of Article 95 of the Treaty, European Parliament and Council Directive 2002/45/EC has inserted in Annex I to Directive 76/769/EEC a new point 42 concerning Alkanes, C_{10}-C_{13}, chloro (SCCPs), laying down rules on the marketing and use of these substances.

(7) Recital 1 of the Directive states that 'limitations already adopted or planned by certain Member States on the use of short-chain chlorinated paraffins (SCCPs) following PARCOM (Convention for the Prevention of Marine Pollution from Land-Based Sources) Decision 95/1 directly affect the completion and functioning of the internal market; it is therefore necessary to approximate the laws of the Member States in this field and consequently to amend Annex I to 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 taking into account Community risk-assessments and the relevant scientific evidence in support of PARCOM Decision 95/1'.

(8) Recitals 2 and 3 recall the background to the Directive, stating that 'SCCPs are classified as dangerous to the environment, since they are very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment' and that 'the Commission has adopted a Recommendation, in the framework of Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ([3]), calling for specific measures to restrict the use of SCCPs, in particular in metalworking fluids and leather finishing products, in order to protect the aquatic environment' respectively.

(9) 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.

(10) 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.

(11) Article 2(1) provides that Member States shall adopt and publish, not later than 6 of 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]) OJ L 84, 5.4.1993, p. 1.

3. **National provisions**

(12) 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).

(13) 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:

— as plasticisers in paints, coatings or sealants,

— in metal-working fluids,

— 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.

(14) 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 ([4]). 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 ([5]). Five Member States ([6]) 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**

(15) 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 C 10 to C 13. 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 ([7]).

(16) 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.

([4]) OJ L 204, 21.7.1998, p. 37.

([5]) 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 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.

([6]) Italy, Denmark, United Kingdom, Austria and Germany.

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

(17) SCCPs are classified as dangerous substances under 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 ([8]). 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').

(18) 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) ([9]). 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.

(19) By Commission Regulation (EC) No 1179/94 ([10]), 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 ([11]), with the United Kingdom acting as rapporteur.

(20) The risk assessment report produced by the United Kingdom was submitted to the Member States' Technical Experts ([12]) for review. Finalised in September 1997, the report ([13]), 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 aquatic 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.

(21) The risk assessment report was subsequently submitted to the CSTEE (Scientific Committee on Toxicity Ecotoxicity and the Environment) for peer-review. In its Opinion of 27 November 1998 ([14]), the CSTEE confirmed the scientific validity of the results of the risk assessment. Those results and the corresponding risk reduction strategy were finally adopted at Community level through Commission Recommendation 1999/721/EC of 12 October 1999 under Regulation (EEC) No 793/93. The relevant parts of the Recommendation are reproduced below.

([8]) OJ 196, 16.8.1967, p. 1.

([9]) See footnote 5.

([10]) Commission Regulation (EC) No 1179/94 of 25 May 1994 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No 793/93 (OJ L 131, 26.5.1994, p. 3).

([11]) OJ L 84, 5.4.93, 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. 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, 26.6.94, p. 3). 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.

([12]) 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 established by Council Regulation 793/93/EEC.

([13]) 'European Union Risk Assessment Report, alkanes, C^{10-13}, chloro', Chemicals Bureau, Institute for Health and Consumer Protection, Joint Research Centre, European Commission.

([14]) CSTEE's opinion on the results of the risk assessment of SCCPs carried out in the framework of Council Regulation (EEC)793/93 on the evaluation and control of the risks of existing substances — Opinion expressed at the 6th CSTEE pleanry meeting, Brussels, 27 November 1998. http://europa.eu.int/comm/food/fs/sc/sct/out23_en.html

'I. 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.

The information requirements are:

— experimental determination of the K_{oc} ([15]),

— monitoring data in soil and sediment near sources of release,

— toxicity testing on soil and sediment dwelling organisms if the above mentioned information does not remove the concern for the above mentioned 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.'

([15]) 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.

(22) 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 by the European Parliament and the Council of Directive 2002/45/EC.

(23) 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 the risk assessment of SCCPs in the framework of Regulation 793/93/EC, 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 CSTEE 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.

(24) In its opinion of 22 December 2002, the CSTEE concluded that the review of new knowledge on SCCPs does not highlight any need to change the conclusions of the Community risk assessment ([16]).

(25) In February 2003, the United Kingdom produced a draft updated risk assessment report on SCCPs as a follow up to Directive 2002/45/EC. The draft 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 re-assesses 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 CSTEE referred to above (points 21 and 24) have also been considered. By contrast to the original risk assessment, the new draft updated risk assessment covers the risks to the marine environment and considers in detail the emissions of SCCPs over the lifetime of products containing them.

(26) The results of the draft updated draft risk assessment are reproduced below:

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

For surface water, sediment, soil and secondary poisoning, as well as marine ecosystems, there is a need for further specific exposure information, in order to refine the release estimates for the local (rubber, paints/coatings and textiles) and regional (all uses) scenarios. 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 textile compounding and backcoating sites,

— releases from paint formulation and application sites, and

— emissions during use and disposal of products.

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),

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

— 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, formulation and use of sealants, the formulation and use of paints and coatings, and at the regional level,

— 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, and

— secondary poisoning for use of sealants.'

(27) 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 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 [17] 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 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.

II. **PROCEDURE**

(28) 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.

(29) By letter of the Office of the Permanent Representative of the Kingdom of The Netherlands to the European Union of 17 January 2003, the Dutch Government 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.

(30) 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.

(31) 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* [18] 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.

[17] OJ L 331, 15.12.2001, p. 1.
[18] OJ C 188, 8.8.2002, p. 2.

III. **ASSESSMENT**

1. **Admissibility**

(32) Article 95(4) concerns cases in which the national provisions are notified in relation to a Community harmonisation measure, they were adopted and entered into force before the adoption of the latter and the maintenance of which would be incompatible with it.

(33) The national provisions were notified in relation to Directive 2002/45/EC, a harmonisation measure adopted on the basis of Article 95 of the Treaty. They were adopted and entered into force in 1999, therefore before the adoption of that Directive. As regards the issue as to whether and to which extent the national provisions are incompatible with the Directive, the Netherlands takes the view that its national provisions are only partially incompatible with those laid down in the Directive 2002/45/EC. In its view, the harmonisation provisions of Directive 2002/45/EC relate exclusively to the applications which it expressly restricts ([19]), i.e. the use of SCCPs in metalworking and for the fat liquoring of leather. The Netherlands claims that this interpretation is borne out by the wording of the Directive and follows logically from the precautionary principle ([20]). In this specific regard, the Netherlands argues that if Directive 2002/45/EC were assumed to be a measure of total harmonisation, new uses of SCCPs which could pose significant risks to human health and the environment would have to be allowed on an unregulated basis. The Netherlands concludes that its national provisions, in so far as they cover uses other than those subject to the restrictions laid down in Directive 2002/45/EC, fall outside the harmonisation requirements of the latter and need not be considered for the purposes of Article 95(4) of the Treaty.

(34) The Commission does not share the views expressed by the Netherlands. According to a well-established case law, a Community measure has to be interpreted in the light of the objectives pursued. Directive 2002/45/EC is based on Article 95(1) of the Treaty, which is the legal basis for the adoption of harmonisation measures having as their object the establishing and functioning of the internal market. It is clear from recital 1 of that Directive that its main objective is to remove the obstacles to the completion and the functioning of the internal market resulting from the limitations already adopted or planned by certain Member States on the use of SCCPs following PARCOM Decision 95/1. It is also clear from recital 3 that Directive 2002/45/EC is based on the results of the Community risk-assessment of SCCPs, which covered all current uses of SCCPs. The Commission therefore considers that Directive 2002/45/EC has to be interpreted as having introduced a harmonisation of all the current uses of SCCPs covered by the Community risk assessment, thus preventing Member States from introducing or maintaining national restrictions on the use of SCCPs going further than those laid down in that Directive.

(35) A comparison between the notified national provisions and Directive 2002/45/EC is drawn in the following table:

	Directive 2002/45/EC	National provisions
SCCPs as plasticisers in paints, coatings or sealants	No prohibition or restriction on use	Use of SCCPs with a chlorination degree ≥ 48 % totally banned
SCCPs as flame retardant in rubber, plastics or textiles	No prohibition or restriction on use	Use of SCCPs with a chlorination degree ≥ 48 % totally banned

([19]) See pages 2 and 6 of the application notified by the Netherlands.
([20]) See page 3 of the application notified by the Netherlands.

	Directive 2002/45/EC	National provisions
SCCPs in metal-working fluids	Use of SCCPs as substances totally banned.	Use of SCCPs with a chlorination degree ≥ 48 % as substances totally banned.
		Use of SCCPs with a chlorination degree < 48 % as substances not covered
	Use of SCCPs as constituents of other substances or preparations banned if the concentration of SCCPs exceeds 1 %	Use of SCCPs with a chlorination degree ≥ 48 % as constituents of other substances and preparations totally banned
		Use of SCCPs with a chlorination degree < 48 % as constituents of other substances and preparations not covered
SCCPs for fat liquoring of leather	Use of SCCPs as substances totally banned	Use not covered
	Use of SCCPs as constituents of other substances or preparations banned if the concentration of SCCPs exceeds 1 %	Use not covered

(36) It emerges from the table above that the notified national provisions diverge 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 plasticizing 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;

— 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.

(37) The national provisions do not cover either the use of SCCPs as substances or as constituents of other substances and preparations for the fat liquoring of leather or the use of SCCPs with a chlorination degree below 48 % as substances or as costituents of other substances and preparations in metal-working fluids. According to the information in the possession of the Commission, these uses are still unregulated and therefore allowed in the Netherlands. In this regard, the Commission recalls that Article 95(4) can only be invoked in relation to national provisions being incompatible with a Community harmonisation measure and not to the absence of national regulatory measures the introduction of which is required under a Community harmonisation measure. The application submitted by the Netherlands under Article 95(4) is therefore without prejudice to the obligations incumbent upon the Netherlands to timely and correctly transpose into the Dutch legal order the provisions of Directive 2002/45/EC.

(38) Furthermore Article 95(4) requires that the notification of the national provisions be accompanied by a description of the grounds relating to one or more of the major needs referred to in Article 30 or to the protection of the environment or the working environment. The application submitted by the Netherlands contains an explanation of the reasons relating to the protection of the environment and human health which, in the opinion of the Netherlands, justify the maintenance of its national provisions.

(39) In the light of the foregoing, the Commission considers that the application submitted by the Netherlands with a view to obtaining authorisation to maintain its national provisions on SCCPs is admissible.

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. In particular, the national provisions have to be 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, must not be a means of arbitrary discrimination or a disguised restriction on trade between Member States and must not constitute an obstacle to the functioning of the internal market.

(41) According to Article 95(6), first subparagraph, the Commission shall take a decision within six months of the notification. However, under Article 95(6), third subparagraph, the Commission may notify to the Member State concerned that this period may be extended for a further period of up to six months if this is justified by the complexity of the matter and there is no danger for human health.

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*

(42) The Netherlands considers that its national provisions are 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 its view, 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. They 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 and, in view of their presence in the environment it was decided to phase out their uses through 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.

(43) In assessing whether the national provisions fulfil the conditions laid down in Article 95(4), the Commission considers that due consideration must be given not only to the supporting evidence submitted by the Netherlands but also to all relevant data and information 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 referred to in Section I.4 of the present Decision.

2.2. *Recourse to Article 95(6), third subparagraph, of the Treaty*

(44) After a careful examination of these data and information, the Commission considers that the conditions laid down in Article 95(6), third subparagraph, are met in order for it to have recourse to the possibility of extending the six-month period within which it has to approve or reject the national provisions provided for by that Article.

2.2.1. Justification based on the complexity of the matter

(45) It emerges from the examination of the notification file submitted by the Netherlands that the only supporting evidence enclosed is the Dutch study mentioned above. Finalised in 1996, this study focuses on the risks of SCCPs in the Netherlands. However, in contrast with what the Netherlands claims, this study does not highlight a risk for the Dutch aquatic environment and the Dutch population. On the contrary, it upholds the conclusions of a previous report ([21]) that 'based on the scanty information on exposure and effect levels, chlorinated paraffins do not seem to present a significant risk to humans and ecosystems in the Netherlands'. This study does not therefore appear to support the grounds invoked by the Netherlands for maintaining the national provisions.

([21]) 'Explanatory report chlorinated paraffins' (Sloof et al., 1992).

(46) As reported above, the original Community risk assessment report on SCCPs finalised in 1999 does not highlight concerns for both human health and the environment from the uses of SCCPs other than in metal-working and for leather finishing which would justify risk reduction measures. These conclusions were confirmed by the CSTEE in its opinion of 27 November 1998. After careful evaluation of the new information on SCCPs, while also expressly considering the provisions of Directive 2002/45/EC, the CSTEE concluded in its opinion 22 December 2002 that this information does not highlight any need to change the conclusions of the Community risk assessment.

(47) However, the conclusions of the draft updated risk assessment report produced by the United Kingdom in February 2003 diverge from the conclusions of the original Community risk assessment report.

(48) This draft report considers further data and provides a more comprehensive analysis of the risks from the uses of SCCPs other than those subject to the marketing and use restrictions laid down in Directive 2002/45/EC. Although this document is expressly referred to as a draft and is only intended for further discussions and review by the Member States' experts ([22]) in the framework of Regulation (EEC) No 793/93, the Commission considers that it is relevant for its assessment of the justification of the national provisions under Article 95(4).

(49) The draft report highlights certain possible environmental risks from all uses of SCCPs, except in sealants. However, further exposure information and testing are considered to be necessary in order to obtain more reliable results. The report also highlights potential risks to the marine environment in relation to the likely PBT properties of SCCPs. These substances have been identified as being potentially persistent or potentially very persistent, very bioaccumulative and toxic. The report suggests that further testing could be performed although considerable time would be necessary to conclude on a more solid scientific basis that the substance is actually persistent. Use in rubber, paints and textiles, and products in use over extended periods of time have been identified as being potential sources and pathways to the marine environment. Finally, the draft report identifies potential risks to soil from various sources, suggesting that consideration could be given to carrying out further biodegradation testing of SCCPs in this environmental compartment. Despite these scientific knowledge gaps, the United Kingdom expresses the view that the available data highlighting the potential risks to the marine environment and soil raise a serious concern and suggests that consideration could already be given to precautionary risk management measures.

(50) The results of the draft updated risk assessment indicate that the relevant available data and information are still not sufficient to conclude that the environmental risks highlighted therein actually exist and that further information and testing would be necessary to reduce the uncertainties of the risk assessment. On the other hand, the concerns expressed by the United Kingdom seem to suggest that these data and information may justify consideration of risk reduction measures based on a precautionary approach. However, the draft report neither fully identifies the uses of SCCPs which give rise to concern nor the extent to which risk reduction measures could be justified to adequately address those concerns.

(51) In view of the provisional character of the draft updated risk assessment report and the consequent unclear indications that emerge from it, the Commission considers that an examination of this draft by the CSTEE (as well as of all other possible relevant available information) is necessary with a view to clarifying as far as possible the issues raised by the results of the draft updated risk assessment report and subsequently assessing the notified national provisions. The Commission Decision under Article 95(6), first subparagraph, should therefore await the outcome of this review. In these circumstances and in view of the fact that the updated draft risk assessment report was made available to the Commission after the notification of the national provisions, the Commission considers that it is justified to extend the six-month period within which it has to approve or reject the national provisions for a further period in order to allow for a careful evaluation of all available relevant evidence and to draw the consequences as regards the national provisions. To this end, a period expiring on 20 December 2003 is necessary.

([22]) See footnote 12.

2.2.2. Absence of danger to human health

(52) As indicated above, neither the study referred to in the application submitted by the Netherlands nor the relevant available data and information in the Commission's possession highlight an actual danger to human health.

(53) Therefore, the Commission considers that the condition of absence of danger to health is met.

IV. **CONCLUSION**

(54) In the light of the foregoing, the Commission concludes that the application that the Netherlands notified to it on 21 January 2003 with a view to obtaining approval of its national provisions on the use of SCCPs is admissible.

(55) However, in view of the complexity of the matter and of the absence of evidence highlighting a danger for human health, the Commission considers it justified to extend the period referred to in Article 95(6), first subparagraph, for a further period expiring on 20 December 2003,

HAS ADOPTED THIS DECISION:

Article 1

Pursuant Article 95(6), third subparagraph, of the Treaty, the period referred to in the first subparagraph of the said Article to approve or reject the national provisions on SCCPs notified by the Netherlands on 21 January 2003 pursuant to Article 95(4) is extended until 20 December 2003.

Article 2

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 17 July 2003.

For the Commission
Erkki LIIKANEN
Member of the Commission