COMMISSION DECISION

of 26 October 1999

on The National Provisions Notified By The Kingdom Of Sweden Concerning The Limitation To The Placing On The Market And Use Of Creosote

(notified under document number C(1999) 3426)

(Only the Swedish text is authentic)

(Text with EEA relevance)

(1999/834/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. THE FACTS

1. Community legislation: Directive 94/60/EC

(1) 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 [1], as last amended by Commission Directive 1999/77/EC [2], provides for the prohibition and restriction of the use of certain dangerous substances and preparations. Directive 76/769/EEC is regularly amended to include in its Annex additional substances, which are dangerous to health and environment.

(2) European Parliament and Council Directive 94/60/EC [3], which amends Directive 76/769/EEC for the 14th time, harmonises amongst others the use and marketing of creosote and similar coal tar distillates, as well as preparations containing them, by limiting the content of one specific component, Benzo[a]pyrene (hereinafter B[a]P), and water extractable phenols when used for wood-treatment (point 32 in the Annex to Directive 94/60/EC). The limit for B[a]P is fixed at a maximum of 50 ppm (= 0,005 %) by mass and the limit for water extractable phenols is fixed at a maximum of 3 % (= 30 g/kg) by mass. Wood treated with creosote not respecting those limits may not be placed on the market.

(3) However, by derogation, the Directive allows for the use of creosote and preparations containing creosote with up to 500 ppm (= 0,05 %) by mass and water extractable phenols up to 30 g/kg for wood treatment in industrial installations. Such substances may not be sold to the general public and containers have to be labelled with the phrase 'For use in industrial installations only'. Wood treated this way and placed on the market for the first time can only be used in industrial and professional applications, except in certain cases where its use is excluded, e.g. inside buildings, in contact with products intended for human or animal consumption, in playgrounds and in other outdoor places for public pleasure or where there is a risk of contact with skin. Old treated wood commercialised for a second time can be used irrespective of the creosote-type applied except in the cases mentioned before.

2. The Swedish national provisions

(4) Under the Swedish legislation, creosote and preparations containing creosote are considered as pesticides.

(5) The Swedish provisions concerning the marketing and use of creosote and wood treated with creosote are included in two different legal instruments:

1. Order (1985:836) on pesticides, issued on 7 November 1985 and last amended by order (1995:208) establishing general provisions on the marketing and use of pesticides

2. National Chemicals Inspectorate regulation KIFS 1990:10 on wood treated with preservatives, especially sections 7—11, concerning wood treated with preservatives containing creosote.

[1] OJ L 262, 27.9.1976, p. 201.
[2] OJ L 207, 6.8.1999, p. 18.
[3] OJ L 365, 31.12.1994, p. 1.

(6) Section 3 of Order (1985:836) stipulates that the Chemicals Inspectorate must approve pesticides before they can be sold, transferred or used. The same applies to the import of pesticides from countries that are not members of the European Union. Section 5 states the basic requirements for approval: The substance must pass an assessment with regards to health and environment protection and it must be shown that it is required for the purposes in the intended area of application. An approval is limited in time (five years) and may be subject to conditions. On approval of a pesticide, the Chemicals Inspectorate establishes the requirements with regards to labelling and other product information, handling, and other special conditions to prevent harm.

(7) On the basis of assessment concerning health and environment, the pesticide is attributed to one of three classes:

Class 1: Products for professional use by persons with a special licence only

Class 2: Products for professional use only

Class 3: Products for general use

(8) The rules on labelling and other product information, handling of the pesticide and other special conditions to prevent harm are notified together with the approval (section 7).

(9) The order also establishes that a fee must be paid in order to obtain an approval, and that any new information on health and environmental effects must be notified.

(10) Application of these rules has resulted in wood preservatives containing creosote being approved in Sweden only for use in industrial installations for pressure impregnation. Such installations are subject to special competence requirements. A series of earlier approvals for general use were revoked with effect from 1 January 1986 based on the classification of creosote as potential human carcinogen by the International Agency for Research on Cancer (IARC).

(11) Four individual products are approved for exclusive industrial use in Sweden. The decisions on approval did not specify a particular limit for B[a]P content, but according to the information submitted by the Swedish authorities, the approved products all have B[a]P contents of less than 50 ppm, in some cases less than 10 ppm. The phenol content in all products is less than 3 %.

(12) For treated wood, section 7 (in conjunction with section 6) of the Chemical Inspectorate's regulations KIFS 1990:10 establishes the following restrictions on its use, which entered into force on 1 January 1992.

(13) If fewer than 30 years have elapsed since impregnation with creosote, the timber is permitted for professional use only as railway sleepers or for round timber for transmission lines (e.g. power lines) or marine installations. Thereafter, the timber may also be used for non-professional purposes for certain specified applications: when the wood is buried in or otherwise in permanent contact with damp soil or water, when the wood in used for the construction of jetties or other marine applications. These rules apply irrespective of the B[a]P content in the wood preservative used for treatment.

(14) Section 8 prohibits the professional marketing, sale and transfer of timber for the purposes that are prohibited under the regulations. Section 9 lays down rules for the marketing of treated wood: anyone who, in the course of business activities, transfers wood treated with preservatives has to provide written information on the following:

1. relevant restrictions on use according to sections 5 to 7;
2. the installation, in which the wood preservation treatment was carried out;
3. active ingredients of the wood preservative;
4. woodworking procedures for which the wood is suitable and/or is not suitable;
5. health risks during woodworking and other handling of the wood;
6. suitable safety precautions;
7. measures for the disposal of waste wood.

(15) According to section 10, these indications must be attached to each bundle of wood placed on the market. Where wood treated with preservatives is offered for sale in bulk to customers, who fetch it on the spot, the information must be displayed at he storage site of the wood. Additionally, a sheet with information is to be made available free of charge for anyone collecting the

wood. The regulation applies also to imported wood, exported wood is exempted from most of the provisions contained in sections 4 to 11.

3. **Comparison between the Swedish provision and Directive 94/60/EC**

(16) Table 1 shows in detail the differences between the restrictions on the marketing and use of creosote and wood treated with creosote depending on the B[a]P content as laid down in Directive 94/60/EC and the Swedish legal system.

(17) In contrast to the Directive, the Swedish legislation contains no explicit rules with regards to the B[a]P content or other physical parameters of the creosote, which can be used for the treatment of the wood. In their notification, the Swedish authorities claim that all approved products contain less than 50 ppm B[a]P and less than 3% water-soluble phenols.

Table 1

Comparison between Directive 94/60/EC and the Swedish regulations

	Council Directive 94/60/EC	Swedish regulations
B[a]P < 50 ppm	No restrictions on sale or use of creosote or newly treated wood.	Preparations containing creosote for the purpose of wood preservation must be approved individually. Sale to and use by private consumers prohibited. Industrial use only for pressure impregnation. Newly treated wood may only be used for professional purposes as railway sleepers, round timber for transmission line construction and marine installations. Special labelling rules apply to the marketing of treated wood: Written information has to be provided on 1. relevant use restrictions; 2. the installation, in which the wood preservation treatment was carried out; 3. active ingredients of the wood preservative; 4. woodworking procedures for which the wood is suitable and/or is not suitable; 5. health risks during woodworking and other handling of wood; 6. suitable safety precautions; 7. measures for the disposal of waste wood.

	Council Directive 94/60/EC	Swedish regulations
B[a]P < 50 ppm *(cont'd)*		These indications must be attached to each bundle of wood. Where wood treated with preservatives is offered for sale in bulk to customers who fetch it on the spot the information must be displayed at the storage site of the wood. Additionally, a sheet with information is to be made available free of charge for anyone collecting the wood.
B[a]P in range 50 to 500 ppm	Restrictions on sale of creosote: — no sale to private consumers — use only permitted in industrial installations. Minimum drum size 200 l. Special labelling required. Creosoted wood may only be used for professional and industrial applications: — railways — electricity poles — fencing — waterways Explicit restrictions on treated wood. It may not be used: — inside buildings — in contact with foodstuff — for containers for growing purposes — at playgrounds or other sites at risk of skin contact	In principle, as above. In reality, no product containing B[a]P in the range 50 to 500 ppm approved.
B[a]P >500 ppm or water soluble phenols > 3 %	Sale and use of creosote and treated products totally banned	In principle as above. In reality, no product containing more as 500 ppm B[a]P approved.
Old treated wood	Use controlled as for wood with creosote containing B[a]P between 50 and 500 ppm.	If fewer than 30 years have elapsed since impregnation, only permitted for professional use as railway sleepers or for round timber for transmission lines or marine installations. If treatment took place more than 30 years ago wood may also be used for non-professional purposes for certain specified applications: — when the wood is buried in or otherwise in permanent contact with damp soil or water,

	Council Directive 94/60/EC	Swedish regulations
Old treated wood *(cont'd)*		— when the wood is used for the construction of jetties or other marine applications. The same rules apply regarding marketing than for newly treated wood.

(18) The Swedish provisions are more restrictive in the following aspects:

— products containing creosote intended for wood preservation must be individually approved before they can be used. Creosote has been approved for professional use only, not for use by consumers. Wood impregnation has to be performed according to a specific technique;

— the use of treated wood is more restricted: newly treated wood, and wood where treatment took place less than 30 years ago, may only be used for professional applications as railway sleepers or for round timber for transmission lines or marine installations. Wood treated more than 30 years ago may be used by private consumers only when the wood is buried in or otherwise in permanent contact with damp soil or water and when the wood is used for the construction of jetties or other marine applications;

— sale (transfer) of wood is subject to a series of requirements in Sweden regarding the providing of information to consumers.

(19) The Swedish provisions are potentially less restrictive in the following aspects:

— order (1985:836) does not mention a limit in the content of B[a]P as a criterion for approval. On the basis of this Order, the Chemicals Inspectorate could approve the use of a product containing quantities superior to those established in Directive 94/60/EC as a maximum limit.

II. **THE PROCEDURE**

(20) The Order 94/60/EC was adopted on 20 December 1994. The Directive had to be implemented into national law of the Member States no later than one year after its adoption, i.e. 20 December 1995 (Article 2(1), first subparagraph) and the national provisions had to be applied from 20 June 1996 (Article 2(1), second subparagraph).

(21) On 14 December 1995, the Swedish authorities informed the European Commission that Sweden intended to continue applying its present national provisions on creosote and creosote-treated wood, therefore derogating from Directive 94/60/EC concerning creosote, on the basis of health protection, applying the former Article 100a(4), of the EC Treaty.

(22) The Commission invited other Member States to present their observations on the Swedish request by letter of 4 April 1997. As a result of this consultation the Commission received comments from Denmark, Italy, Austria, The Netherlands, Finland, Spain, the United Kingdom, and Greece.

(23) *Denmark* agrees with Sweden that creosote is a dangerous substance to both human beings and the environment, and its use should be restricted as far as possible, or banned completely. Denmark is therefore completely in favour of Sweden being allowed to apply stricter national provisions on creosote. Denmark has informed the Commission that it also wishes to apply more stringent national rules concerning creosote.

(24) *Italy* informs the Commission that it has no substantial objections to the Swedish request. The Italian authorities consider justified the necessity for Sweden to maintain more restrictive rules concerning the use of creosote, taking into account their specific climatic (less sunshine) and geographical conditions (number of lakes). Italy also recalls that the legislation, which Sweden wants to maintain, has been in force for more than 10 years and has not disturbed the market concerning the commercialisation of creosote.

(25) *Austria* points out, that it completely shares the evaluation that sale of creosote to private consumers should be prohibited an that the level of protection of the measures, the cancer risk to consumers from the brush application of B[a]P containing tar-oils for the impregnation of wood is especially high (dermal and inhalatory exposure) and, in addition, this procedure creates environmental and waste problems. Application of creosote should therefore be restricted to cases where no alternative is available. The Swedish provisions concerning prescribed impregnation technologies and

the use of treated wood are justified. In addition, the Swedish regulations do not in any case constitute an arbitrary discrimination or a disguised restriction on trade. The specific climatic and geographic situation in Sweden also supports the recourse to the former Article 100a(4).

(26) *The Netherlands* share the Swedish concern that Directive 94/60/EC does not adequately safeguard the desired level of protection for the environment and human health. The Dutch authorities refer to their own request for derogation and the substantial documentation that they have submitted for justification. The Swedish measures are supported and the Netherlands expresses its confidence that the Commission will carefully examine whether the measures are necessary on grounds of the major needs referred to in the former Article 100a(4) and also meet the conditions for recourse to this provision in other respects.

(27) *Finland* considers that the requirements established in the former Article 100a(4) of the EC Treaty are fulfilled, and the Commission should confirm the Swedish legislation, but it also considers that the maximum concentration limits for B[a]P contents in creosote and for water extractable phenols in accordance with Directive 94/60/EC should be incorporated into Swedish national legislation.

(28) *Greece* informs the Commission that it agrees with the Swedish request. If Sweden maintains its national policy, their will not be particular consequences for Greece.

(29) In contrast, *Spain* understands that the acceptance of Swedish national regulations would provoke barriers to trade, as Directive 94/60/EC would not succeed in its harmonising goal. When Directive 94/60/EC was adopted there were lengthy discussions in the Commission and Council about the limitations, which would be imposed, and the restrictions in point 32 of the Annex were laid down on the basis of the risk of creosote. The Spanish authorities consider that the Swedish request to impose more stringent restrictions than those already applicable should not be admitted.

(30) The same opinion is expressed by the *United Kingdom*. The UK notes that the Swedish authorities do not offer any scientific evidence or data, new or otherwise, to justify their assertion of a health risk. The UK seeks to uphold the principle that all Member States accept the standards imposed by single market measures, unless a Member States has special circumstances which require more stringent provisions to achieve the same level of health, safety or environmental protection. This is not considered to be the case in this instance.

(31) On the 1 May 1999, the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signet at Amsterdam, 2 October 1997, entered into force. By letter of 24 August 1999 the General Secretariat of the Commission informed the Swedish authorities of the fact that their notification regarding the placing on the market and use of creosote would be treated in the framework of the new provisions of the Treaty.

III. **ASSESSMENT**

1. **Applicable Rules**

(32) The Treaty of Amsterdam has amended substantially the provisions of the former Article 100a of the Treaty establishing the European Community, by replacing paragraphs 3, 4, and 5 of this Article with eight new paragraphs numbered 3 to 10. Due to the new numbering of all Articles, the amended Article has become Article 95 of the Treaty establishing the European Community.

(33) The Treaty of Amsterdam does not comprise specific transitional provisions on the rules applicable to the notifications made previously to the time of entry into force of this treaty, like the Swedish notification, which is the subject of this Decision.

(34) In the absence of specific provisions extending their application, the old provisions of Article 100a(4) of the EC Treaty are regarded as repealed from the day of entry into force of the new provisions (1 May 1999). Instead, the new provisions of the Treaty apply immediately from that date to the examination of this notification.

2. **Consideration of admissibility**

(35) The notification submitted by the Swedish authorities intends to obtain the authorisation to maintain national provisions incompatible with Directive 94/60/EC, which constitutes a harmonisation measure adopted on the

basis of former Article 100a (now Article 95) of the EC Treaty.

(36) Article 95(4) of the Treaty reads as the follows: '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 need 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.'

(37) Directive 94/60/EC had to be transposed to the Member States by 20 December 1995 and enforced by 20 June 1996. Sweden notified its national legislation relating to creosote and wood treated with creosote, which had been in place since 1985 and 1992, respectively, on 14 December 1995 and thus before the date foreseen for the application of the national provisions transposing the Directive.

(38) It is therefore well justified to consider that in this case the conditions of Article 95(4) of the Treaty are met, according to which the national provisions notified, for which a Member State wishes to obtain approval for maintaining them after the date of implementation of a Community harmonisation measure, must have been adopted before the adoption of the harmonisation measure.

(39) In the light of what precedes, the Commission considers that the request of the Kingdom of Sweden for derogation from Directive 94/60/EC as notified on 14 December 1995 under the former Article 100a(4) is admissible under Article 95(4) of the EC Treaty.

3. **Assessment of merits**

(40) In accordance with the provisions of Article 95 of the Treaty, the Commission has to assure that all the conditions enabling a Member State to avail of the possibilities of derogation provided for in this Article are met. The Commission has, in particular, to verify whether the provisions notified by the Member State are justified by the major needs of protection referred to in Article 30, or relating to the environment or working environment. In addition, the Commission has to verify, when it considers that these measures are justified, whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States, and whether or not they constitute an obstacle to the operation of the international market (Article 95(6)).

(41) The Swedish authorities have based their request on reasons of protection of human health and the environment. In support of the request, Sweden submitted a brief Memorandum, dated 14 December 1995, explaining the reasons why Sweden deemed it necessary to maintain its stricter national provisions. However, the information contained in this Memorandum was very limited and remained general. It was not possible to examine the merits of the request based on this information alone.

(42) In order to verify whether the Swedish national provisions concerning marketing and use of creosote treated wood, are indeed necessary and proportionate to that end, the Commission mandated a study to an external consultant ([4]). The study tries to assess the risk of cancer arising from the use of creosote and creosote treated wood by consumers, and whether the implementation of Directive 94/60/EC in Sweden would result in unacceptable high creosote exposure of the public, and in unacceptably high creosote exposure of the aquatic environment. In addition, the findings of three further studies ([5]), which were mandated by the Commission in the framework of similar requests from other countries, have been used in the assessment of the request from Sweden.

(43) It has to be noted that, in the light of the time frame established by Article 95(6), which did not exist in the former Article 100a(4) under the regime of which the Swedish request was notified, these substantial efforts of the Commission to find the elements necessary for the justification of the maintenance of the Swedish national provisions cannot constitute a precedent for the future. When examining whether the national measures notified under Article 95(4) are justified by a major need, the Commission has to take as a basis 'the reasons' put forward by the Member State to justify the maintenance of its national provisions. This means that, according to the provisions of the Treaty, the responsibility of proving that these measures are justified, lays on the requesting Member State. Given the procedural framework established by Article 95, 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 justification.

([4]) WS Atkins International Ltd., *Study on the justification in scientific terms of allowing Sweden to retain its national laws on creosote in place of Council Directive 94/60/EC,* Final Report, August 1997.

([5]) G. Grimmer, *Study on the justification in scientific terms of allowing the Netherlands to retain its national laws on creosote in place of Council Directive 94/60/EC.* Final report, Biochemisches Institut für Umweltcarcinogene, Großhansdorf (Germany), December 1995.
Environmental Resources Management, *Scientific evaluation of the German request for derogation from provisions of Council Directive 94/60/EC concerning creosote,* Final Report, 24 April 1996.
Dr. P. M. Sorgo, *Study on the justification in scientific terms of allowing Denmark to retain its national laws on creosote,* Final Report, November 1996.

(44) None of the studies referred to above was completely conclusive with regards to the effects of creosote on human health, in particular concerning its carcinogenic potential, as a specifically designed long-term carcinogenicity study was still ongoing. This study [6] was made available to the Commission at the beginning of 1998. The findings of all these studies are set out in the following. In addition, all studies have been made available to the Scientific Committee on Toxicity, Ecotoxicity, and the Environment, which expressed a first opinion on the cancer risk to consumers from creosote and/or wood treated with such creosote on 27 November 1998. This opinion was revised on 4 March 1999.

3.1. ***Justification on grounds of major needs***

3.1.1. *Creosote — general information*

(45) Creosote is a complex mixture of over 200 chemical compounds, predominantly aromatic hydrocarbons, as well as phenolic and aromatic nitrogen and sulphur compounds. It is a mid-heavy distillate of coal tar (boiling point approximately 200 to 400 °C).

(46) Creosote can contain over 30 different polycyclic aromatic hydrocarbons (PAHs) with a possible total PAH content of 85 %. The most important ones are:

— acenaphthene

— naphthalene

— phenanthrene

— anthracene

— fluorene

— fluoranthene

— chrysene

— triphenylene

— benzo-[a]-anthracene

— benzo-[b]-fluoranthene

— benzo-[k]-fluoranthene

— benzo-[a]-pyrene

(47) Benzo[a]pyrene (B[a]P) is one of the most thoroughly investigated PAHs and the B[a]P content is used as an indicator or marker substance for classification purposes and does not, in itself, reflect the total PAH content of creosote. Depending on the type of creosote concerned, the B[a]P content may vary between 0,003 and 0,3 % by weight (30 to 3 000 ppm). A refined distillation of coal tar and selection of the fractions can lead to lower B[a]P or phenol contents. Different industry standards have been developed by the Western European Institute for Wood Preservation, characterised mainly by different contents of specified distillation fractions and, most important in this context, different contents of B[a]P. Limiting values for classification standards are 500 ppm and 50 ppm.

(48) Modifications to both the physical and chemical properties of creosote are possible if they are required for use or environmental purposes. It is possible to create a lower viscosity product, better suited to brush application, by incorporating components with a lower boiling point, which is sometimes called carbolineum. Directive 94/60/EC does not make a distinction: it covers and treats in an identical way a whole range of different coal tar distillates, all of them specified by their names, Einecs- and CAS numbers.

(49) Creosote is principally and almost exclusively used as a wood preserving agent. Large-scale industrial and professional applications are by far the most important ones: railway sleepers, poles for electricity transport, hydraulic engineering (bank protection), agriculture and fruit production. Creosote and similar products are also used by individual consumers for wood preserving purposes.

(50) The most important properties of creosote are:

— high fungicidal efficacy,

— high insecticidal efficacy,

— long-term persistence,

— resistance to leaching and weathering.

(51) A very small quantity of creosote is used in medicinal products for the treatment of certain skin diseases, e.g. psoriasis.

Toxicity of creosote

Human health effects

(52) Despite the fact that creosote has been used as a wood preservative for over a century, there are only few published data on the effects to humans of sustained exposure to creosote. Many of the studies are rather old and do not always conform to modern standards with regards to documentation.

[6] Fraunhofer Institute of Toxicology and Aerosol Research, *Dermal carcinogenicity study of two coal tar products (CTP) by chronic epicutaneous application in male CD-1 mice (78 weeks)*, Final report, Hannover, October 1997.

(53) Exposure can occur via inhalation, ingestion or skin contact. Creosote is evaluated as mildly to moderately toxic by ingestion. Most effects resulting from animal experiments and all epidemiological studies in humans are linked to dermal exposure.

(54) Skin photosensitivity from coal tars has been described by a number of authors. Irritation symptoms, pitch warts, skin discoloration and dermal tearing have been reported to occur amongst workers exposed to creosote. The most recent study on workers exposed to creosote in Sweden and Norway was published in 1992 ([7]). The study examined workers exposed to creosote between 1950 and 1975. The investigators found a somewhat lower total cancer incidence than expected and an increased risk of cancer of the skin and lip and of non-Hodgkin lymphomas. However, the composition of the creosote was not documented and the authors conclude that the small number of cases did not permit a valid conclusions. The increase could be attributed to exposure both to creosote and to sunlight. One other study ([8]) found an increased risk of mortality from scrotal cancer for brickmakers exposed to creosote during the period 1911 to 1938. Again, neither the B[a]P content of the creosote nor a clear dose response relationship are known.

(55) Mostly based on an animal experiment, where the skin of mice was regularly exposed to B[a]P solutions in acetone during their lifetime ([9]), the International Agency for Research on Cancer (IARC) has classified creosote as a group 2A human carcinogen. IARC estimates that for substances in this class there is sufficient evidence from epidemiological studies to conclude that creosote can be carcinogenic in humans. There is no significant new evidence from more recent investigations, which would affect this conclusion.

(56) For several years, experts from the Member States examined the issue of classification of creosote, other coal tar distillates, and further so-called complex substances in the framework of Council Directive 67/548/EEC of 27 June 1967 relating to the classification, packaging and labelling of dangerous substances ([10]), as last amended by Directive 1999/33/EC ([11]). Drawing largely on the same data as IARC, agreement was reached during the elaboration of Commission Directive 94/69/EC ([12]), the 21st adaptation to technical progress, according to which creosote and some other coal tar distillates are classified as category 2 carcinogens and must be labelled with the risk phrase R 45 'May cause cancer'. However, the classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005 % (= 50 ppm) per weight B[a]P ([13]). This is different from the IARC classification, which applies without any specification of the B[a]P content.

(57) The choice of a limit of 50 ppm to the concentration of B[a]P for classification purposes in Community legislation in order to distinguish carcinogenic from non-carcinogenic coal tar distillates has been accepted by the Member States in the working group for adaptation of Directive 67/548/EEC to technical progress only on the basis of a Joint Declaration by the Commission and the Member States. The declaration states that the situation would be reviewed when the results of the above mentioned scientific study by the Fraunhofer Institute were known, which had been initiated by industry in collaboration with the IARC and was in progress at that time. It has to be recognised that in 1994, there were no experimental data available to prove whether creosote containing less than 50 ppm B[a]P was carcinogenic or not. This situation has changed and the results of the Fraunhofer study will be presented further.

(58) Little is known about the toxicokinetics of creosote in humans or experimental animals. Only very recent studies have investigated quantitative absorption of PAHs through the skin by measuring excreted metabolites of pyrene ([14]): absorption appears to vary between individuals and between different sites within the same individual. In a separate study ([15]), the dermal absorption of different PAH compounds was measured. PAHs of higher molecular weight as pyrene, e.g. B[a]P were absorbed less rapidly. Any estimation of B[a]P uptake based upon the pyrene marker will therefore result in an overestimation and can be considered conservative.

([7]) S. Karlehagen et. al., *Cancer incidence among creosote-exposed workers,* Scand. J. Work. Environ. Health, 1992:18, p. 26.

([8]) IARC, *Monograph on the evaluation of carcinogenic risk to humans, Vol. 35, polynuclear aromatic compounds, Part 4, bitumen, coal tars and derived products, shale soils and soots,* Lyon, 1985.

([9]) J. M. Holland, E. L. Frome, *Advances in modern environmental toxicology, Vol. VI, applied toxicology of petroleum hydrocarbons,* ed. MacFarland and others Princeton Scientific Publishers 1984.

([10]) OJ L 196, 16.8.1967, p. 1.

([11]) OJ L 199, 30.7.1999, p. 57.

([12]) OJ L 381, 31.12.1994, p. 1.

([13]) Nota M of the foreword to Annex I of Council Directive 67/548/EEC is applicable to creosote.

([14]) Van Rooij, J.G.M., et. al., *Absorption of Polycyclic Aromatic Hydrocarbons Through Human Skin: Differences between Anatomical Sites and Individuals,* J. Tox. Environ. Health, 38, 1993, p. 355.

([15]) Van Rooij, J.G.M., *Dermal Exposure to Polycyclic Aromatic Hydrocarbons Among Workers,* Thesis ISBN 90-9007080-X, Nijmwegen 1993.

(59) It has to be noted, that all effects observed in animal experiments or in epidemiological investigations in humans are based on high level chronic exposures. No reports have been found in the literature of examples of cancer of the skin (or any other sites) which could be attributed to exposure to creosote in a non-occupational environmental context.

(60) Exposure of consumers can occur during the use of preparations containing creosote (or carbolineum) for wood preservation by brush application (dermal and inhalatory) or through the use of treated wood (e.g. adults during the construction of fences or other wooden structures for private use, children playing on structures made of treated wood). No measured data are available concerning the exposure of consumers to creosote, either directly through use of the product, or indirectly through contact with wood treated with creosote. Various models and calculations of exposure have been developed in the studies and will be discussed later.

Environment effects

(61) Environmental contamination by creosote has been reported in a number of countries, with old wood treatment facilities often being the source of the contamination. In fact, most information on the fate of creosote in the environment has been obtained from industrial creosote spills and from contamination left from disused creosote plants. Environmental contamination has been traced by an analysis of selected PAH compounds, notably B[a]P.

(62) Creosote is toxic to certain organisms in the soil and highly toxic against aquatic organisms (with 96h LC-50 values often below 1 mg/l). Many of its components are bioaccumulating.

(63) The main characteristics of PAHs in the environment are:

— PAHs bind strongly to soil organic matter;

— the rate of degradation of PAHs in soil and other environmental compartments is usually slow. Creosote residues can persist for many years in the environment (> 20-30 years);

— the main breakdown processes are photodegradation (i.e. under irradiation from the sun) and microbial degradation (i.e. by certain bacteria). Microbial degradation can occur under aerobic and anaerobic conditions. PAHs compounds with four rings and more may be poorly degradable;

— PAHs reaching watercourses are rapidly transferred to sediment;

— in watercourses, most of the lower molecular weight PAHs are removed primarily by microbial degradation and the higher molecular weight compounds by photooxidation and sedimentation. Microbial degradation of the more water soluble PAHs occurs under aerobic and anaerobic conditions. The PAH constituents have been shown to bioaccumulate in aquatic species.

(64) Emissions of PAHs to air, water and soil can occur during the impregnation process and storage at the impregnation site, as well as during use of treated wood. However, PAHs found in the various environmental compartments are originating from a variety of sources (e.g. all combustion processes, traffic, etc.) and it is often difficult to ascribe their levels to any particular source such as creosote treated wood.

(65) A study ([16]) in Sweden has shown that after 40 years in soil, creosote impregnated poles had lost a part of the compounds contained in creosote, especially those with the lowest boiling point (< 270 °C). The part of the poles above the ground lost the larger amount. However, mobility of the leached compounds was very low as they could only be detected in the soil in close contact with the poles. This coherent with the observation that the mobility of PAHs in soil is extremely low due to their strong absorption to organic matter.

(66) The presence of elevated levels of PAH in aquatic environments has often been attributed to the presence of creosote-treated wood. Migration of creosote components from treated wood into water is higher into fresh water than into seawater and has been proven in many studies. Migration seems to be more limited in seawater; in one study, after 10 years in the sea, marine pilings retained 93% of the original composition of creosote compounds ([17]). The pollution of sediments by creosote leaching from waterbank protection has been documented in the Netherlands ([18]) and also in studies on pollution from former impregnation facilities.

(67) As for human exposure, actually measured data on environmental pollution by PAHs originating in creosote are scarce.

([16]) S. Holmroos, *Analys av kreosotstolpar i Simlångsdalen efter 40 års exponering i fält*. Rapport nr. M205-252.092. Älvkarleby: Vattenfall Utveckling. 1994.

([17]) L. L. Ingram and others, *Migration of Creosote and its Components from Treated Piling Sections in a Marine Environment*, Proc. Ann. Meet. Am. Wood Preserv. Assoc. 78, 1982, p. 120. See also footnotes 8 and 18.

([18]) bhk consulting engineers, *Foundation of the appeal against the EC-Directive on creosote*, Final report, Delft, 1 July 1995.

3.1.2. *The Swedish position*

(68) The Swedish authorities hold the opinion that the level of protection of human health guaranteed by Directive 94/60/EC is insufficient. Creosote is a substance resulting from a specific distillation range of coal tar containing some 30 substances/substance groups that are documented as carcinogenic and mutagenic. As proved by the classification through IARC, creosote has properties extremely hazardous to health. Apart from its carcinogenic property it is a strong skin irritant and in combination with sunlight can cause photoallergic reactions such as blistering and serious eczema.

(69) The Swedish authorities underline that there are no data to support the conclusion that creosote with a B[a]P content less than 50 ppm presents an acceptable risk. On the contrary, they assert that, as B[a]P is genotoxic, there is not threshold dose below which exposure presents no health risks. The Swedish authorities recall the Declaration made at the meeting of the Technical Adaptation Committee in 1994 (mentioned above) which according to them shows that there was no satisfactory basis for assessing the carcinogenicity of complex coal-tar based substances containing less than 50 ppm B[a]P.

(70) Creosote has properties detrimental to health and the environment, which means that its use should be limited to applications where long-lasting protection is required. Contact with skin should be avoided as far as possible. Creosote should therefore not be used by consumers who do not have the necessary protective equipment. In the case of industrial pressure impregnation, the workers are informed and protected as far as possible.

(71) Creosote oils have been developed and are already available on the market where certain fractions of the most dangerous substances have been removed. It has not emerged that the B[a]P content in the product has any effect on the impregnation method, the creosote uptake in the wood or the durability of the protection. These products have B[a]P contents of less than 10 ppm. This development may be halted if products with up to 50 ppm are accepted.

(72) With regard to the environmental impact, the Swedish authorities underline that creosote is highly toxic to certain aquatic organisms and that certain components are bioaccumulating. Creosote components leak from treated piles in both fresh and salt water.

(73) Sweden has a special national need because, unlike the situation in other countries of the EU, wood is an extremely important construction material for terraces, bridges and other outdoor constructions in Sweden. Due to the large number of wooden buildings, and the high proportion of its territory covered by surface water (lakes/rivers) where the use of creosote-treated wood might have localised environmental consequences. Increased use of creosote-treated wood by consumers is likely to have negative effects on human health and the environment. The current regulation utilise the substitution principle to ensure that creosote is only used where it is the best alternative.

(74) Furthermore, Sweden claims that it has a special national need due to its geographical location with low annual average temperatures and low annual average insolation levels, leading to reduced degradation of creosote. Photochemical conversion is the main decomposition process for polycyclic aromatic hydrocarbons (PAH), of which creosote is composed. Several types of bacteria can break down creosote. Sweden's geographical situation means that the number of warm, sunny days are fewer there than in most other countries of the Community. The result is lower photochemical and bacterial decomposition of creosote.

(75) In summary, the Swedish authorities underline that there are strong health and environmental objections to amending the Swedish provisions on creosote. The Swedish Government is not intending to ban the use of creosote completely, it wishes to see the continued uses of creosote in applications for which it is considered the best alternative. It is the objective of the approval procedure for each individual product to ensure that this goals are met. The rules of creosote are part of the general Swedish policy of restriction the use of dangerous chemicals.

3.1.3. *Evaluation of the Swedish position*

(76) The issue of health effects of creosote has been examined very carefully in the studies mandated by the Commission. All known findings have already been mentioned in the general information part above.

(77) Experimental data that have become available only recently show that the carcinogenic risk of creosote containing less than 50 ppm B[a]P might be non-negligible. However, it has to be underlined, that all available information was considered in great detail during the deliberations leading to the Community provisions regarding the classification of creosote and the provisions of Directive 94/60/EC. Also, all adverse

health effects of creosote have been observed with high level chronic exposures in animal experiments or under occupational exposure. No reports have been found in the literature of examples of cancer of the skin (or any other sites) which could be attributed to exposure to creosote in any non-occupational contexts.

(78) The analysis carried out by the Swedish authorities during product approval is based upon the principle of seeking to minimise risk wherever possible, both by reducing as far as possible exposure to harmful substances and by substitution of alternative products perceived to be more acceptable. In the case of creosote the alternatives are copper-chronium-arsenic derivatives (CCA). The Swedish position towards the acceptability of a risk linked to the use of a chemical substance is therefore somewhat different than the Community position applied towards the adoption of Directive 94/60/EC.

(79) According the study mandated by the Commission, the Swedish authorities could neither provide documentation regarding the concrete assessments carried out during approval of the four creosote products which are currently allowed for industrial use, nor were documents made available which proved the claim that all four products contain less than 50 ppm B[a]P and 3% water soluble phenols.

(80) There are, however, strong indications to believe that this is the case. According to the study mandated by the Commission, the four products have been authorised under a voluntary agreement between the authorities and the relevant trade association. The letter had undertaken its own research to reduce and eliminate creosote bleeding from treated wood, which leads to increased exposure of the environment and of workers handling or working with treated poles. There has been pressure on the wood impregnation industry to reduce leaching from the principal clients, the electricity and telecommunication companies. The new specifications require the product to be produced from a much narrower distillation range than standard creosotes which eliminates many of the volatile and high boiling components (esp. PAH, including B[a]P). The sample technical approval document obtained by the consultant from a major industrial user and an internal document from the Chemicals Inspectorate also specify that the B[a]P content should be lower than 50 ppm. As a result, all approved products in Sweden are thick, viscous oils consisting of up to 100% of creosote within the specific distillation range for respective oils. The oils are suitable only for use in a specialised, industrial pressure/vacuum impregnation process designed for optimum impregnation of round timber in particular. The technique results in timber containing an average of 135 kg creosote/m^3 and gives a very durable wood (approximately 40 to 50 years).

(81) Regarding the issue of a specific situation in Sweden, the claim that treated wood is an exceptionally important construction material in Sweden is partially corroborated by data on the consumption of creosote treated wood in Europe in 1990:

Table 2

Consumption of creosoted wood in Europe (1990) ([19])

Country	Annual use 1990 (m^3/y)	Annual use/capita (10^{-3} m^3/cap.y)	Annual use/km^2 (m^3 / km^2.y)
Germany	150 000	2,3	0,4
Netherlands	100 000	6,7	2,9
Spain	93 000	2,4	0,2
Italy	74 000	1,3	0,3
United Kingdom	65 000	1,1	0,3
Sweden	57 000	7,1	0,1
France	45 000	0,8	0,08

([19]) *Source:* See footnote 18.

Country	Annual use 1990 (m^3/y)	Annual use/capita (10^{-3} m^3/cap.y)	Annual use/km^2 (m^3 / km^2.y)
Belgium	26 000	2,6	0,8
Norway	20 000	5,0	0,06
Ireland	20 000	5,0	0,3
Finland	13 000	2,6	0,04
Denmark	5 000	1,0	0,1
Europe	1 000 000	2,0	0,2

(82) The use of creosoted wood has remained relatively constant since 1990. In 1995, 74 400 m^3 of wood were treated with creosote (63% poles, the rest railway sleepers), about one quarter was exported.

(83) Table 2 shows that the use of creosote treated wood per capita in Sweden is the highest in Europe, whereas the use per km^2 is among the lowest. The latter figure might be misleading as it can be reasonably assumed that the use of creosote treated wood is more concentrated in the areas of higher population density (e.g. southern Sweden). The high use per capita could lead to a potentially higher exposure of the Swedish population. On the other hand, the low figure of use per surface seems to indicate that the likelihood of contact for an individual of the population is rather low.

Exposure of the environment

(84) For the exposure of the environment, the use of treated wood per surface area is the decisive indicator. It can be seen from Table 1 that this figure is particularly low in Sweden; even a significant increase would not bring it to or above the European average.

(85) It is clear that the construction of jetties will not lead to wooden constructions in water as dense and intense as continuous water bank protection in the Netherlands. Therefore, the surface of treated wood in contact with water is much smaller, the water volume higher. No data were presented by the Swedish authorities to support the statement that local negative effects on aquatic organisms occur in the vicinity of jetties. In contrast, based on measured leaching rates and assuming the presence of sediment, where creosote is strongly absorbed, the study mandated by the Commission concludes that concentrations of creosote in water are least an order of magnitude lower than toxic levels.

(86) The study could identify data regarding the soil around treated posts (some of them having received very high impregnation quantities). Already at distances of 10 to 15 cm from the treated posts, the concentrations of various PAHs were in agreement with normal background concentrations. A second study by Uppsala University indicated that no creosote was found in soil at a distance of 10 cm from creosote treated poles after a 37-year period.

(87) No measured data were available to support the Swedish claims regarding the specific situation for degradation of creosote. Although, the irradiation levels in Sweden are lower than in most other Member States, the study mandated by the Commission points out that photochemical degradation is an important mechanism only in places where light can penetrate, i.e. at the soil surface and the top of the water column. For creosote treated posts in soil, the majority of leached material will not be at the surface as the mobility is very low, in the aqueous environment it will be absorbed to the sediment. Hence, photodegradation will not be important for the overall degradation of creosote. Bio-degradation of creosote is slow in general. No data were provided concerning the effects of temperature on bio-degradation and whether this would have significant effects on the degradation of creosote in Sweden in comparison to other Member States.

(88) Overall, Sweden did not prove, and the study mandated by the Commission could not confirm, that there is a specific situation in Sweden regarding the risks to the environment from creosote in comparison to the other Member States.

Human exposure

(89) If Sweden were to apply the provisions of Directive 94/60/EC, exposure of the public would potentially increase due to the then allowed use of creosote by consumers, increased possibilities to re-use old treated

wood, higher B[a]P content of creosote used industrially for railway sleepers and poles. However, it is rather impossible to estimate how big this increase will be, as the product has not been on the market for over 20 years. The same holds for the question of how much would exposure increase if the rules regarding use of newly treated and old treated wood were changed.

(90) Instead of trying to assess the overall increase in exposure, and similar to the proceeding of the Dutch and German authorities in their respective requests, the study mandated by the Commission proceeds to two exposure assessments under the conditions of Directive 94/60/EC: an adult member of the public construction a private jetty using creosote treated wood and brush application of creosote and children playing on creosote treated wooden play equipment. In both cases the creosote was assumed to contain 50 ppm B[a]P.

(91) Before commenting on the actual evaluations, it has to be noted that this is not specific to Sweden and would apply in a similar manner to other Member States.

(92) The study mandated by the Commission elaborates in great detail on the issue of absorption through the skin trying to use various models as proposed by the EC's technical guidance documents on risk assessment, which, however, were not really applicable. The study therefore carries out a reasonable worst case exposure calculation. Experimental data on the uptake of PAH components through the skin and into the system were used to determine the amount of creosote absorbed rather than relying upon the model calculations. The creosote uptake rate employed was derived experimentally for absorption of PAHs through human skin ([20]).

(93) The worst-case scenario for exposure through dermal contact for the individual constructing a jetty results in 0,43 ng/kg bw/day B[a]P for a creosote containing 50 ppm B[a]P (eight hours exposure per day, 50% covering of open skin, average bodyweight (bw) and skin surface). Assuming that a member of the public spends eight hours a day for two weeks every year using creosote products and creosote treated wood for construction purposes (such as building and maintaining jetties), the permissible daily dose for a probability of cancer in 1 in 100 000 (based on the calculations by the Dutch authorities in their request) is 2,1 ng/kg bw/day. The worst case exposure is thus clearly lower. For a scenario of exposure of six weeks a year it would be 0,7 ng/kg bw/day and thus still higher than the calculated worst case exposure.

(94) The worst-case scenario for exposure through dermal contact for children playing on dry wood treated with creosote (two hours a day, 50% covering of open skin, body weight of 15 kg) amounts to 0,85 ng/kg bw/day. It is interesting to note that the Dutch authorities, in their model calculation, though using a slightly different methodology, have arrived at a daily exposure dose of 2 ng/kg bw/day, which is very close to this result and thus increases confidence. Assuming that a child plays for two hours a day during six months of the year, the permissible daily dose (based on the Dutch assumptions) for a risk of one to 100 000 is 4,8 ng/kg bw/day, and thus higher than the permissible dose is 2,4 ng/kg bw/day and the uptake 1,7 ng/kg bw/day (and thus approaching the limit).

(95) Although there are clearly many uncertain assumptions in these calculations, overall, the results indicate that it can not be excluded that there may be certain individuals who could be exposed at levels approaching the permissible daily doses, but that for the general population this is unlikely to be the case.

3.1.4. *Evaluation of the Scientific Committee for Toxicity, Ecotoxicity, and the Environment*

(96) During elaboration of Directive 94/60/EC, the 21st adaptation to technical progress of Directive 67/548/EEC a B[a]P content of 50 ppm had been accepted as safe by the Member States. However, as was already mentioned, the Commission and the Member States agreed in a Joint Declaration to review the situation in the light of the results of the study concerning the carcinogenic properties of coal tar distillates currently undertaken on initiative of industry and in collaboration with the IARC.

(97) This study ([21]) was made available to the Commission in January 1998. The study tested the carcinogenic effects

([20]) Van Rooij J.G.M., de Roos J.H.C., Bodelier-Bade M.M., Jongeneelen F.J., *Absorption of PAHs through human skin: differences between anatomical sites and individuals*, Journal of Toxicology and Environmental Health, 83 (1993), p. 355.

([21]) See footnote 6.

of two creosote products provided by the sponsoring company (Rüttgers-VfT AG, Germany) containing 10 and 275 ppm B[a]P. Due to the high viscosity of the products, they could not be applied directly to the skin of the mice but had to be diluted in Toluene. Solutions with various concentrations of the product and thus various B[a]P concentrations, as well as pure B[a]P solutions and a control of pure Toluene were applied to groups of 62 mice for a time of 78 weeks (twice a week, 25 µl). Development of tumours was observed during this time and the test animals were carefully examined after termination of the study.

(98) The Commission submitted this study and all other documents containing scientific and exposure information on creosote to the Scientific Committee for Toxicity, Ecotoxicity and the Environment. The SCTEE was asked to evaluate whether there was sufficient scientific evidence to support the opinion that there is a cancer risk to consumers from creosote containing less than 50 ppm B[a]P and/or from wood treated with such creosote, and if such a risk exists, whether its magnitude can be estimated or quantified. The SCTEE adopted its opinion on 27 November 1998.

(99) The SCTEE observes that the Fraunhofer study is well-designed and reaffirms the carcinogenic potential of coal tar preparations. Due to the genotoxic potential of PAHs including B[a]P, there is no threshold concentration determining carcinogenicity. The study indicates clearly a linear dose-response relationship between the B[a]P content of the administered preparations and the number of animals developing tumours. Both preparations have a five-fold higher potency to induce skin tumours than pure B[a]P, presumably due to presence of the other carcinogenic substances in creosote. It can be inferred from the study that creosote containing 50 ppm B[a]P would induce a significant incidence of skin cancer in mice.

(100) Data to fully evaluate the relevance of effects seen in a mouse skin painting study for human exposure situations are insufficient. Extrapolation skin carcinogenicity data from mice to human situation also entails a number of uncertainties leading to difficulties in directly using cancer potency data from mice to assess cancer risk in humans. Species dependent sensitivity of dermal exposure to the carcinogenic actions of creosote will be affected by morphology and physiology of the skin, by metabolic activation and inactivation in the skin and by repair processes. On the basis of all the available information, a scientifically justified assessment of carcinogenic risk, e.g. for the dermal exposure of children playing on wood treated with creosote is therefore difficult.

(101) From the data contained in the Fraunhofer study, the SCTEE calculated a T 25 carcinogenic potency value for pure B[a]P of 13 µg/kg bw/day. The T 25 is the chronic daily dose per kg bodyweight, which induces 25% of the test animals tumours at a specific tissue site within the standard life span of that species. The creosote formulations tested had a five-fold higher overall carcinogenic potency (2,7 µg/kg bw/day).

(102) Should the value of exposure calculated in the study mandated by the Commission apply (0,85 ng B[a]P per kg bw/day (for two hours play time) and 1,7 ng (for four hours play time) approximate the true exposure, this would result in a life-time cancer risk of $8{,}2 \times 10^{-5}$ (respectively $1{,}63 \times 10^{-4}$) for a life long daily exposure, which would give clear concern, a risk of $1{,}16 \times 10^{-5}$ (respectively $2{,}33 \times 10^{-5}$) for a daily exposure during 10 years out of 70 (the Dutch assumption) and $0{,}58 \times 10^{-5}$ (respectively $1{,}16 \times 10^{-5}$) for a daily exposure during five years out of 70 (the German assumption). Using the exposure doses calculated by the Dutch authorities (2 ng/kg bw/day) or the German authorities (2,62 ng/kg bw/day) would increase these risks proportionately.

(103) Based on the most recent study with regards to the dose-response relation for dermal carcinogenicity of creosote as derived by the SCTEE and depending on the selected exposure model, the risk is thus slightly or more clearly above a value of 1×10^{-5}, which proposed as an acceptable risk level for genotoxic carcinogens in drinking water by the World Health Organisation.

(104) The SCTEE also mentions that the figure of 2 ng B[a]P per kg bw/day as a worst-case exposure to B[a]P from playing on the creosote-treated wood has to be compared to estimates for intake of B[a]P via food. Annual intakes of B[a]P from food has been estimated to be in the order of 0,3—1,6 mg, which would result in daily exposures of 12 to 63 ng/kg bw for a person weighing 70 kg (i.e. much higher than the dermal exposure).

(105) Overall the SCTEE concludes:

1. — Given the genotoxiticy of B[a]P and the outcome of the Fraunhofer skin painting study, there is sufficient scientific evidence to support the opinion that there is a cancer risk to consumers from creosote containing less than 50 ppm B[a]P and/or from wood treated with such creosote.

— B[a]P is a good indicator for the carconogenic hazard of the creosote preparation tested, since there was a linear relationship between cancer incidence and B[a]P dose. However, the cancer potency of the creosote preparation was five-fold higher than judged from its B[a]P content.

2. — On the basis of the available information, even taking into account the considerable uncertainties in assessing the risks for children coming into contact with creosote-treated wood, the magnitude of the risk gives clear reason for concern. However, the highest estimated exposure is some six to 30 times lower than the oral exposure of the adult population to B[a]P in food.

— In order to get a better estimate of the exposure situation, one would have to perform a real-life, mass-balance study in exposed children. In addition to being very complicated and resource intensive, to conduct such a study would raise ethical questions.

3.1.5. *Overall evaluation*

(106) The Swedish authorities have not shown, nor could it be demonstrated through further research, that a specific situation exists in Sweden with regards to the general pollution of environment by PAHs, or the exposure of man and the environment to PAHs originating in the use of creosote and creosote treated wood or that this would be the case if Sweden applied the provisions of Directive 94/60/EC.

(107) However, the Commission has received additional information in the framework of similar requests from the Netherlands, Germany, and Denmark for derogation from Directive 94/60/EC under the former Article 100a(4) of the EC Treaty, and new scientific evidence through an extensive study carried out after the adoption of the Community Directive.

(108) Based on these most recent experimental data, the SCTEE has estimated that there is a cancer risk to humans from creosote containing less than 50 ppm B[a]P and wood treated with such creosote, the magnitude of which cannot be estimated with certainty. Taking into consideration the uncertainties concerning exposure, the Commission considers that measures aiming at reducing the probability of prolonged dermal exposure to creosote, either through direct contact with creosote or wood treated with creosote, are justified in the light of the precautionary principle.

(109) However, such measures can only be regarded as justified under the condition of being in conformity with the general principle of proportionality, i.e. the measures do not have to exceed what is suitable and necessary for the pursuit of the legitimate objective. Consequently, the legislation notified to the Commission by the Swedish authorities can be approved only insofar as this legislation sets up an authorisation arrangement for the use of creosote which allows for the possibility to actually obtain such an authorisation, when it is compatible with the needs for the protection of health and the environment.

(110) It has to be noted that the Swedish provisions concerning creosote comprise an approval system without specifying a particular limit of B[a]P content or other physical-chemical parameters of creosote. Article 95(4) only permits the approval of national legislation on grounds of major needs referred to in Article 30, or relating to protection of the environment or working environment. This means that it is not possible to approve national measures that are less protective than those laid down in the Directive. Therefore, the Swedish national legislation can only be approved as its application in practise has shown that no product was approved that was not respecting the limits established by Directive 94/60/EC. A different application of the national Swedish legislation cannot be approved under Article 95(4).

(111) In accordance with Article 95(7) of the Treaty, the Commission is already examining the appropriateness to adapt to technical progress the provisions of Directive 94/60/EC regarding creosote. In addition, the Commission will evaluate the use of creosote under the review programme established in Article 16 of European Parliament and Council Directive 98/8/EC of 16 February 1998 on the placing of biocidal products on the market [22] in a time frame compatible with the general timing of the review programme and taking into account other possible priorities identified when effectively setting up the programme. Furthermore, on ongoing research project under the Fourth Framework Programme for Research and Technological Development is reviewing the production chain and in-service life of poles treated with creosote [23].

3.2. ***The absence of arbitrary discrimination***

(112) Article 95(6) obliges the Commission to verify that the national provisions are not a means of arbitrary

[22] OJ L 123, 24.4.1998, p. 1.

[23] Research Contract FAIR5-CT98-3933 (Fourth Framework Programme for RTD), *Integrating the processes involved in the production of creosoted utility poles*.

discrimination. According to the ruling of the Court of Justice, the absence of discrimination means that no different treatment should be given to similar situations, nor similar treatment to different situations.

(113) The limitation on marketing and use of products containing creosote in the Swedish legislation is general, relating to all products that contain creosote, which are designed to used in the way the Orders specify. The Swedish legislation does not establish special rules for different sorts of products. It does not affect some products in a different manner to others, either national or imported, but applies to all products containing creosote. So there is no evidence that it can be used as a means of arbitrary discrimination between economic operators in the Community.

3.3. *The absence of a disguised restriction on trade*

(114) More restrictive national measures in the area of limitations of marketing and use of products derogating from the provisions of a Community Directive do normally constitute a barrier to trade. Products that can be legally placed on the market in the rest of the Community, cannot be placed on the market in the Member States concerned. The concept enshrined in paragraph 6 of Article 95 is intended to prevent the restrictions based on the criteria of paragraph 4 being applied for inappropriate reasons, and in reality constituting economic measures introduced to impede the import of products from other Member States in order to protect indirectly national production.

(115) The Commission mandated a study ([24]) on the effects of the Swedish legislation on trade and competition. The study undertook in particular to look at the volume and value of trade with other Member States which is affected; the interest, if any, which Sweden may have in using its national rules on creosote-treated wood to promote a national interest in substitutes to creosote-treated wood. Various representatives from the creosote and timber trade were consulted, as well as the relevant Swedish regulators.

(116) There is no producer of creosote in Sweden and the four approved products are all imported from other EU countries. Consequently, the national legislation does not create an advantage for a national production of creosote.

(117) There are three producers of creosote-treated timber in Sweden, operating in five plants. Treated wood is imported from Finland, Norway and the Netherlands. Exports occur to most of the other Member States. Wood for export can only be treated with the products approved in Sweden. Therefore there is not any advantage for Swedish exporters as they have the same limitations in their production than the other European Union producers that want to import into Sweden.

(118) Concerning the alternative products (e.g. chromium-copper-arsenic salts, boron compounds or other organic compounds), it has to be noted that all wood preservation products are classified as pesticides in Sweden and are subject to the same regulations. In addition, Sweden does not produce any wood preservatives and has them all imported. Therefore the limitations on creosote do not hide a protection of an alternative product in the market and are not disguised restrictions on Trade.

(119) As established before, there is a concern with regards to human health, and it appears that the Swedish request for a derogation is motivated by a desire to maintain control on the use of a potentially harmful product rather than to affect trade in that product or in alternatives to it in favour of Swedish producers.

(120) Overall, the Commission considers therefore that there is no evidence of a disguised restriction on trade between Member States provoked by the Swedish legislation concerning creosote.

3.4. *The absence of obstacles to the function of the Internal Market*

(121) This condition, which is established by Article 95(6), first subparagraph, is new in comparison to the text of former Article 100a(4) of the EC Treaty. This condition cannot be interpreted in such a way that it prohibits the approval of any national measure likely to affect the establishment of the internal market. In fact, any national measure derogating from a harmonisation measure aiming at the establishment and operation of the internal market, constitutes in substance a measure that is likely to procedure for derogation provided for by Article 95 of the EC Treaty, the Commission

([24]) Environmental Resources Management, *Effects on Trade and Competition of the Retention by Sweden of its National Rules on Creosote*, Final report, August 1997.

considers that, in the context of the Article 95(6), the concept of obstacle to the operation of the internal market has to be understood as a disproportionate effect in relation to the pursued objective.

(122) According to the study by ERM ([25]), the European creosote-production industry is characterised by the following features:

— creosote is produced as a by-product, not primary product;

— production exceeds consumption to a significant degree;

— there are a small number of creosote producers;

— there is a decline in demand.

(123) Because of this situation, suppliers are generally willing to meet the product specifications required by their customers (if they can do so technically).

(124) Producers of creosote are located in Germany, Austria, Belgium, Denmark, France, the Netherlands, Italy, Spain, and the United Kingdom. 90% of creosote is used for the industrial impregnation of wood by professional wood preservation companies. The remaining 10% of creosote are used by individual consumers, mostly in the United Kingdom and Ireland.

(125) Professional impregnators primarily treat timber for use as telecommunications and power poles and railway sleepers. The composition of creosote varies according to the coal-tar feedstock used, the production method employed and the requirements of the customer. In fact, most of the large-scale users have developed their own detailed specifications in relation to boiling curves and the concentration of specific components in the creosote. Most, but not all, of the producers can produce creosote containing less than 50 ppm B[a]P.

(126) The following Table 3 gives a survey of the situation with regards to producers of creosote, their geographic location, whether they can produce creosote with B[a]P content < 50 ppm and whether they have had trade with Sweden.

Table 3

Production, sales and trade in creosote in Europe ([26])

Country	Number of producers	Possibility to produce creosote with B[a]P < 50 ppm	Sales of creosote (t/year) 1995	Trade with Sweden
Austria	1	No	—	No
Belgium	1	Yes	3 900	No
Danmark	1	Yes	0	Yes
France	1	Yes	6 750	No
Germany	1	Yes	5 000	Yes
Netherlands	1	Yes	5 000	No
Spain	2	Yes/No	13 950	No
United Kingdom	2	Yes	20 000	No
Italy	—	—	11 100	No
Greece	—	—	6 700	No
Ireland	—	—	3 000	No
Sweden	—	—	6 000	—
Finland	—	—	5 000	No

([25]) See footnote 24.

([26]) Source: See footnote 24, and: W. D. Betts, *Study of the effects on trade and competition of the retention by the Netherlands of its national rules in place of the rules to be established by Directive 94/60/EC,* Tar Industries Services, Chesterfield (UK), December 1995.

(127) There are no producers of wood preservatives in Sweden and all products containing creosote or alternatives are imported.

(128) Even were Directive 94/60/EC implemented in Sweden, it is, according to the study, unlikely that the operators of the wood impregnation plants would revert to using creosote formulations with a higher B[a]P content since the approved products are of superior quality and most clients would not purchase poles impregnated with old formulations. The new products are slightly more expensive than the old ones, but the difference in terms of the overall cost of a treated pole is marginal.

(129) Referring to the effect of the Swedish legislation on creosote for the European internal market, the study shows that Swedish exports of creosote-treated timber are slightly greater than imports. But the introduction of the restriction on marketing and use of creosote and creosote-treated timber, in 1985 and 1990, did not have any significant or lasting impact on the market trend at the time, and did not introduce a barrier to trade with the European Member States.

(130) In addition, the fact that the more restrictive rules on the use and marketing on creosote and creosote-treated timber existed in Sweden before it became a member of the European Union, shows that the goal of that more restrictive legislation is not to create obstacles to the function of the internal market.

(131) Taking into account the preceding observations, the Commission considers that there is no evidence that the Swedish provisions subject to this Decision do constitute a disproportionate obstacle to the functioning of the internal market in relation to the pursued objectives.

IV. **CONCLUSION**

(132) In the light of the above considerations, the Commission is of the opinion that the provisions with regards to the use of creosote as notified by the Kingdom of Sweden pursuant to the former Article 100a(4) and examined under the new Article 95(4) and (6) of the EC Treaty:

— fulfil the formal requirements of the said provisions and are to be admitted,

— can be considered justified on grounds of major need of protection of health when applied in conformity with the general principle of proportionality,

— do not constitute either a means of arbitrary discrimination, a disguised restriction on trade between Member States, or a disproportionate obstacle to the functioning of the internal market.

(133) The Commission therefore has reason to consider that the national provisions notified can be approved.

HAS ADOPTED THIS DECISION:

Article 1

The provisions relating to marketing and use of creosote and creosote-treated wood, contained in Order (1985:836) and the National Chemical Inpectorate's regulations KIFS (1990:10) are approved, in so far as they are applied in such a manner

— that the limits for benzo[a]pyrene and water extractable phenols established by Directive 94/60/EC are not exceeded, and

— that the placing on the market and use of creosote are allowed when compatible with the need to protect health and the environment.

Article 2

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 26 October 1999.

For the Commission

Erkki LIIKANEN

Member of the Commission