COMMISSION DECISION

of 26 October 1999

concerning the national provisions notified by the Kingdom of the Netherlands concerning the limitations of the marketing and use of creosote

(notified under document number C(1999) 3424)

(Only the Dutch text is authentic)

(Text with EEA relevance)

(1999/832/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Whereas:

I. FACTS

1. Communtity 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 man and the 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]pyren, in the following 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 or preparations containing 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 %) B[a]P by mass and water extractable phenols up to 30 g/kg for wood treatment in industrial installations. Such products 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 for 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. National provisions: The Control Substances Act and the SIVEB Decision

(4) The Netherlands legal system concerning creosote is established by The Control Substances Act of 1962 [4] and the executing Decision concerning the composition, classification, packaging and labelling of control substances, adopted on 22 February 1980 (hereinafter called the SIVEB Decision) [5] with its subsequent amendments. The legislation provides for a general prohibition combined with an approval system on an individual basis.

(5) The Control Substances Act covers crop control substances (Article 1(1)(f)), which may not be supplied, possessed, kept in stock, marketed, or used in the Netherlands unless approved pursuant to the Act (Article 2 (1)). Article 3(1) defines the general conditions

[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.
[4] As amended by the Act of 15 December 1994, Law Gazette of The Netherlands 1995, No 4.
[5] Official Journal of The Netherlands of 29 February 1980, No 43.

that a control substance has to meet for permission (inter alia, to have no harmful effect on human health, ground water and no unacceptable effects on the environment).

(6) Based on the Controlled Substances Act, the SIVEB-Decision (forming a ministerial regulation), provides for the admissible contents of active agents in control substances. This forms the basis for subsequent approvals (licenses) of the competent Minister to use the control substances falling under the Controlled Substances Act. It is the amendment of 12 March 1992 to the SIVEB Decision ([6]), wich took effect on 18 March 1992, that provides for a maximum content of 50 ppm B[a]P by mass of carbolineum and creosote consisting of one or more coal tar distillates within the meaning of the Directive and the content of water-soluble phenols below 30 g/kg for all uses and applications. In particular, no exemption is given for wood treatment in industrial installations.

(7) The Dutch government notified some examples of individual approvals in the cases of creosote oil and carbolineum, which contain certain exclusions for their use or which determine the only permitted use. These approvals shall have, according to the Dutch government, a legal effect equal to that of a general statutory order, since the same conditions are imposed in all similar cases. For certain uses, like on toys, inside buildings, in contact with foodstuffs, in green- or glasshouses, the use of creosote is totally banned in the approvals. Creosote can be applied only in special industrial installations by using a specified technique (vacuum/pressure).

3. Comparison between the national provisions and Directive 94/60/EC

(8) Table 1 shows in detail the differences between the restrictions on the use of creosote with regard to the B[a]P content imposed by Directive 94/60/EC and the Dutch legal system.

(9) In summary, the Dutch provisions are more restrictive in several aspects:

— the B[a]P content of creosote is not permitted in the range of 50 to 500 ppm for the use in industrial installations

— wood preservation has to be performed according to a specific technique (pressure/vacuum) in special installations

— in certain cases the use of creosote is excluded for wood preservation, even if its B[a]P content is below 50 ppm.

Table 1

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

	Council Directive 94/60/EC	SIVEB Decision
B[a]P < 50 ppm	No restrictions on sale or use of creosote or newly treated wood	Carbolineum: No restrictions on sale. Private use only for treating wood. Explicit restrictions on use of treated wood. It may not be used: — on toys — inside buildings (used by humans or animals) — in spaces for storage of foodstuff — in green- or glasshouses

([6]) Official Journal of The Netherlands of 17 March 1992, No 54.

	Council Directive 94/60/EC	SIVEB Decision
B[a]P < 50 ppm *(cont'd)*		Creosot: Permitted only for industrial use in special installations for treating wood by the vacuum and pressure method for: — railway sleepers — telephone and electricity poles — excavation, road and water works — fencing
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	Sale and use of creosote and treated products totally banned.
B[a]P > 500 ppm	Sale and use of creosote and treated products totally banned	Sale and use of creosote and treated products totally banned
Old treated wood	Use controlled as for wood treated with creosote containing B[a]P between 50 und 500 ppm	No other regulations than for newly treated wood

II. **PROCEDURE**

(10) Directive 94/60/EC was adopted on 20 December 1994. The Netherlands submitted the following declaration to the minutes of the Council: 'The Netherlands is voting against the proposed Directive concerning the 14th amendment of Directive 76/769/EEC, as it fails to comply with regard to "Creosote" with the basic principle enshrined in the EC Treaty that a high level of protection be achieved for the environment and public health. The Netherlands therefore reserves the right, by recourse to Article 100a(4) of the EC Treaty, to adopt national provisions in the filed of creosote that are justified on the important grounds referred to in Article 36 or connected with the protection of working conditions on the environment'.

(11) The Directive had to be implemented into the 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).

(12) By letter of 9 March 1995, the Dutch Permanent Representative informed the Commission that the Netherlands considered it necessary to maintain, in accordance with the former Article 100a(4) of the EC Treaty, the national legal provisions contained in the Control Substances Act of 1962 ([7]) and the 'SIVEB Decision' with its subsequent amendments, which provide for more restrictive measures on the use of creosote offering further protection of public health, the working environment than would be the case on a strict implementation of the Directive.

(13) The Commission consulted the other Member States by letter of 21 June 1995 with regard to the Dutch request to maintain stricter provisions on creosote. Seven Member States replied. Austria, Denmark, Finland, Germany and Sweden support the Dutch request, while Ireland and the United Kingdom are opposed.

(14) *Austria's* assessment of the Dutch position is that the higher level of protection offered by the national provisions is necessary in order to protect the environment in the Netherlands, as creosote-impregnated timber is used in large amounts in shoreline defences and other installations and in ships and ships' hulls. The rate of leaching is particularly high owing to the constant contact with salt water, and accumulation in the sediment poses a considerable hazard to aquatic communities. The massive pollution of Dutch waters and their beds with polycyclic aromatic hydrocarbons (PAHs) can only be remedied by reducing the maximum permissible B[a]P content in creosote to an ecologically acceptable level. Austria takes the view that the stricter provisions cannot in any way be regarded as an arbitrary discrimination or disguised barrier to trade, and that the reference to the former Article 100a(4) is justified.

(15) *Sweden* emphasises the fact that creosote is a mixture of several hundreds of substances including polycyclic aromatic compounds. Many were shown in animal testing to be mutagenic or carcinogenic. Creosote is highly toxic to aquatic organisms and most of the substances contained are bioaccumulating. Creosote strongly irritates the skin and causes, in combination with sunshine, photoallergic reactions as blisters and severe eczema. There is, according to Sweden, at the time being, no scientific evidence to prove that the use of creosote with levels of B[a]P lower than 50 ppm or wood treated with such substances, is safe for consumers or for the environment.

(16) *Denmark* agrees with the Netherlands that creosote is a highly dangerous substance for humans and the environment. Use of the substance should, therefore, be restricted as far as possible, and preferably banned.

(17) In supporting the Dutch views, *Germany* refers to its own request under the former Article 100a(4).

(18) *Finland* expresses the opinion that in this case the conditions contained in the former Article 100(4)a are fulfilled and that the Commission should confirm the Dutch national provisions.

(19) In contrast, *Ireland* considers that the request is not based on new scientific evidence. Ireland therefore sees no reason to move away from the agreed dual standard of 50 ppm and 500 ppm of Directive 94/60/EC nor to introduce controls on the use of wood treated with coal-tar distillates containing less than 50 ppm B[a]P.

(20) The *United Kingdom* argues that the Dutch request does not reflect the sort of risk assessment which is now widely accepted in the evaluation of chemicals in general, and of pesticides in particular. It criticises the Dutch request for only looking at the hazards and that it did not include a summary of toxicological and other data, followed by a risk assessment of permitted uses. The United Kingdom states that the arguments raised by the Netherlands had already been raised and rejected at the Council Working Group stage during the

([7]) As amended by the Act of 15 December 1994, Law Gazette of the Netherlands 1995, No 4.

negotiation of the Directive. The United Kingdom also remarks that a fuller demonstration of the scientific grounds justifying the request would be needed, before the derogation could be accepted. As for the genotoxic mechanism supposedly caused by creosote, the United Kingdom maintains that the Netherlands fail to provide any compelling evidence.

(21) On 1 May 1999, the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signed at Amsterdam on 2 October 1997, entered into force. By letter of 24 August 1999 the General Secretariat of the Commission informed the Dutch 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**

(22) 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.

(23) 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 Dutch notification, which is the subject of this Decision.

(24) 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 the 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**

(25) The notification submitted by the Dutch 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 the former Article 100a (now Article 95) of the EC Treaty.

(26) Article 95(4) of the Treaty reads as 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 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.'

(27) Directive 94/60/EC was adopted on 20 December 1994. The Directive had to be transposed by the Member States by 20 December 1995 and enforced by 20 June 1996. The Netherlands notified the provisions of its national regulations that it intended to maintain on 9 March 1995 and thus before the date foreseen for the application of the national provisions transposing the Directive.

(28) The Dutch provisions in question, namely the relevant amendment of the SIVEB Decision, was adopted on 12 March 1992 and thus before Directive 94/60/EC was adopted (20 December 1994).

(29) 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 that harmonisation measure.

(30) In the light of what precedes, the Commission considers that the request of the Kingdom of the Netherlands for derogation from Directive 94/60/EC as notified on 9 March 1995 under the former Article 100a(4) is admissible under Article 95(4) of the EC Treaty.

3. **Assessment of merits**

(31) 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 functioning of the internal market (Article 95(6)).

(32) The Dutch authorities have based their request on the need of protection of human health and the environment. In order to substantiate its request for derogation of Directive 94/60/EC the Dutch government submitted a study made on behalf of the Ministry of Housing, Spatial Planning and Environment ([8]). The study mainly gives an overview on the use of creosote in The Netherlands and its environmental and health effects. It examines the origin, the pathways and the deposition of polycyclic aromatic hydrocarbons (PAHs), among which B[a]P is the most thoroughly investigated.

(33) The Commission mandated a study to an external consultant to critically review the study submitted by the Dutch authorities and to further assess the situation of environmental contamination and the possible risks to human health by creosote in the Netherlands ([9]). In addition, the findings of three further studies ([10]), 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 the Netherlands.

(34) It has to be noted that, in the light of the time-frame established by Article 95(6), wich did not exist in the former Article 100a(4) under the regime of which the Dutch request was notified, these substantial efforts of the Commission to find additional elements for the justification of the maintenance of the Dutch 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.

(35) None of the studies referred to above was completely conclusive with regards to the effects of creosote an human health, in particular concerning its carcinogenic potential, as a specifically designed long-term carcinogenicity study was still ongoing. This study ([11]) 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*

(36) 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).

(37) 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

— phenathrene

— anthracene

— fluorene

— fluoranthene

— chrysene

— triphenylene

— benzo[a]anthracene

— benzo[b]fluoranthene

— benzo[k]fluoranthene

— benzo[a]pyrene

([8]) bkh consulting engineers, 'Foundation of the appeal against the EC-directive on creosote', Final report, Delft, 1 July 1995.

([9]) 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.

([10]) Environmental Resources Management, 'Scientific Evaluation of the German Request for Derogation from Provisons 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. 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.

([11]) 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, Hanover, October 1997.

(38) Benzo[a]pyrene (B[a]P) is one of the most thoroughly investigated PHAs 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 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.

(39) 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.

(40) 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.

(41) The most important properties of creosote are:

— high fungicidal efficacy,

— high insecticidal efficacy,

— long-term persistence,

— resistance to leaching and weathering.

(42) 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:

(43) 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.

(44) 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.

(45) 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 ([12]). 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 valid conclusions. The increase could be attributed to exposure both to creosote and to sunlight. One other study ([13]) found an increases 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.

(46) Mostly based on an animal experiment, where the skin of mice was regularly exposed to B[a]P solutions in acetone during their lifetime ([14]), 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 that creosote is carcinogenic in animals and certain evidence from epidemiological studies to conclude that creosote can be cacinogenic in humans. There is no significant new evidence from more recent investigations, which would affect this conclusion.

([12]) S. Karlehagen et. al., Cancer Incidence Among Creosote-Exposed Workers, Scand. J. Work Environ. Health, 1992: 18, p. 26.

([13]) 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.

([14]) J.M. Holland, E.L.Frome, Advances in Modern Environmental Toxicology, Vol. VI, Applied Toxicology of Petroleum Hydrocarbons, ed. MacFarland et. al, Princeton Scientific Publishes 1984.

(47) 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 ([15]), as last amended by Directive 1999/33/EC ([16]). Drawing largely on the same data as IARC, agreement was reached during the elaboration of Commission Directive 94/69/EC ([17]) 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 ([18]). This is different from the IARC classification, which applies without any specification of the B[a]P content.

(48) 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, which had been initiated by industry in collaboration with the IARC and was in progress at that time were known. 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 down.

(49) 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 ([19]): absorption appears to vary between individuals and between different sites within the same individual. In a separate study ([20]), the dermal absorption of different PAH compounds was measured. PAHs of higher molecular weight than 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.

(50) 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.

(51) 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:

(52) 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 cantamination left from disused creosote plants. Environmental contamination has been traced by an analysis of selected PAH compounds, notably B[a]P.

(53) 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.

(54) 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 to 30 years).

([15]) OJ 196, 16.8.1967, p. 1..
([16]) OJ L 199, 30.7.1999, p. 57.
([17]) OJ L 381, 31.12.1994, p. 1.
([18]) Nota M of the foreword to Annex I to Council Directive 67/548/EEC is applicable to creosote. 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.
([19]) 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.
([20]) Van Rooij J. G. M., Dermal Exposure to Polycyclic Aromatic Hydrocarbons Among Workers, Thesis ISBN 90-9007080-X, Nijmwegen 1993.

— 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.

(55) 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 originate 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.

(56) A study ([21]) 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 is coherent with the observation that the mobility of PAHs in soil is extremely low due to their strong absorption to organic matter.

(57) 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 wool 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 ([22]). The pollution of sediments by creosote leaching from waterbank protection has been documented in the Netherlands ([23]) and also in studies on pollution from former impregnation facilities.

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

3.1.2. *The positions of The Netherlands*

(59) In the Netherlands, a vigorous policy is in place regarding PAH. In 1993, the Dutch Parliament adopted limit values and target values for individual PAH, related to a maximum permissible concentration (MPC). PAH concentrations have repeatedly exceeded the MPC in certain environmental compartments. As a consequence, considerable emission reductions are required by the National Environment Policy Plan 2. All sources for PAH containing coatings, coal tar varnish, cable burning plants, refineries, sewerages, basic metal industry, chemical industry, wood-burning stoves and traffic.

(60) A number of measures in the form of agreements between the government and various sectors have or will be taken following the Policy Statement Environmental Objectives for the Building Industry 1995 (BMB 1995). The SIVEB decision forms part of a this strict general policy of the Netherlands aiming at a strong reduction of emissions of PAH from all sources. Reduction of emissions from creosoted wood during its production, use, and destruction after use plays an important part in these measures. The major goal is the reduction of the application of creosoted wood where alternatives are available.

Special situation in the Netherlands

(61) In Europe a total of 1 million m^3 of creosoted wood was used in 1990. Table 2 gives an overview of the consumption of creosoted wood in Europe.

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

([22]) L. L. Ingram et. al., '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 13.

([23]) See footnote 8.

Table 2

Consumption of creosoted wood in Europe (1990) ([24])

Country	Annual use 1990 (m^3/y)	Annual use/capita (10^{-3} m^3/cap.y)	Annual use/km^2 (m^3/km^2y)
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
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

(62) In absolute figures, the Netherlands is the second largest user of creosoted wood after Germany. The use per capita is the second highest after Sweden, the consumption per km^2 is by far the highest in the Netherlands and amounts to 15 times the European average. The Netherlands is a water-abundant country, almost 15 % of the surface consists of lakes, rivers canals and other waterways. This is due to the specific geographic situation of the Netherlands being located in the delta of three large rivers: the Rhine, the Meuse, and the Scheldt.

(63) From the Middle Ages onward, areas subject to flooding by the sea and the rivers have been protected by the construction of dikes. In order to adapt the land for habitation and agriculture, the polder system has been developed: the dike protected areas of land are drained by a finely distributed network of artificial water courses. The water so collected is pumped into the rivers and the sea. At present, almost half the surface of the Netherlands consist of polders, the larger part of which is below sea level.

(64) The Netherlands is the most densely populated country in Europe. Moreover, almost 75 % of the population lives or works in the polder areas. The high concentration of population, as well as the extensive industrialisation and agriculture have made the polder areas very sensitive to environmental pollution.

(65) To prevent caving in of the banks of the waterways in the polder areas, most banks are supplied with bank-protective constructions. Approximately 10 000 kilometres of banks are protected with creosoted timber. Due to this necessity, leaching from creosoted wood is one of the major sources of pollution of the aquatic envrionment with PAH, such as B[a]P. Allowing for higher B[a]P contents in creosote (up to 500 ppm instead of 50 ppm) would strongly increase emissions.

(66) The solubility of PAH including B[a]P in water in very limited; however, water serves as a transport medium prior to absorption to suspended particles. In slowly flowing waterways these particles tend to settle down, a process reinforced by high salt concentrations. Both effects are present in the Dutch polder regions leading thus to an accumulation of PAH contaminated sediments. The degradation of accumulated PAH in the sediments is poor due to the prevailing anaerobic conditions.

(67) Sediments polluted with PAH influence the functioning of the aquatic ecosystem. The presence of B[a]P in the sediment of Dutch coastal areas shows a correlation with the occurrence of tumours in the liver of flounders. Earlier species in the food chain also have shown to suffer from sediment contamination. Polluted sediments may cause risks to man in case of fishing, recreation and drinking water supply. A specific danger

([24]) Source: See footnote 8.

occurs in the case of large scale flooding, where parts of the sediment can be distributed over vast areas of land used for agricultural purposes.

(68) As part of the general policy for the protection of the environment, a tolerable limiting value of 0,05 mg B[a]P/kg dry mass of sediment has been established by the Dutch Parliament.

(69) A survey made in 1990 classified sediment samples in four classes, delimited by their B[a]P content. Only sediments in class 1 comply with the limiting value. Results of the survey are show in Table 3.

Table 3

Quality of waterbed sediment (1990) ([25])

Class	Regional waters	Governmental waters
1: < 0,05 mg B[a]P/kg dry mass	14%	22%
2: 0,05 to 0,8 mg/kg	50%	24%
3: 0,8 to 3 mg/kg	26%	35%
4: > 3 mg/kg	10%	10%

class 1: permitted to be distributed as such over land and water

class 2: permitted to be distributed if no threat to the ecosystem exists

class 3: deposition of sludge on adjoining land undesired

class 4: investigation into decontamination necessary

(70) A survey in 1993, consisting of more than 10 000 samples of newly formed sediment, showed that in 95% (90% in regional waters) of the samples the limiting value had been exceeded.

(71) Apparently the situation has not improved in recent years, and it seems that the overwhelming majority of sediments in Dutch waterways is contaminates by B[a]P to an extent beyond the acceptable standards.

(72) Several investigations estimate the total B[a]P emissions in the Netherlands into water as approximately 100 kg/year. Additionally, the rivers flowing into the Netherlands carry more than 1 800 of B[a]P (which would be about 18 times the nationally emitted quantities). These imports form other countries as well as the pollution by shipping (and/or traffic) are limited to the main waterways (= governmental waters in the Dutch terminology). No upward flow of sediment into regional waters occurs. Thus the main source of sediment contamination in the biggest part of the Dutch waterways (regional waters) appears to be leaching from bank protection with creosoted wood.

(73) It has been confirmed by several investigations in different parts of the Netherlands (Fleverwaard (1992), Noordoostpolder (1993), Haarlemmermeerpolder (1989), islands and Wadden Sea (1991), Walcheren (1993), Groenendalse Wetering (1995)) that about 80% of the PAH present in sediments originates form bank protection with creosoted wood (for both newly installed protection and treated wood that had been in place for several years).

(74) A clear quantitative correlation between sediment contamination by PAH and bank protection by creosoted wood has been established by the Fleverwaard water board which has examined the sediment layers of two waterways. One year after placing the new bank protection the sediment was classified in class 2; two years after placing it was already in class 3. The main classification criterion is the content of 3 PAHs: pyrene, fluoroanthene and phenanthrene. Also however B[a]P concentrations alone, amounting to a maximum of 0,5 to 2,3 mg/kg (in dry sediment), largely exceeded the limit value of 0,5 mg/kg (in dry sediment).

(75) The investigation reveals the PAH leach out from creosoted bank protection and are subsequently deposited into the sediment, resulting in an increase of the total PAH concentration by more than a factor of six. A further study in the Groenendalse Wetering has noted an increase of the B[a]P concentration in the sediment after the installation of a bank protection of by creosoted wood from 0,10 to 0,25 mg/kg within a period of half a year.

(76) In view of these results, the Dutch State Council has introduced an additional restriction on the use of creosoted wood for bank protection: a licence under the Surface Water Act is now necessary before creosoted wood can be used.

(77) The study provided by bkh consulting engineers acknowledges that nowhere in the Netherlands the limit value determined by the Dutch Parliament (1 ng/m^3 annually averaged concentration) has been exceeded at the monitoring stations of the national air monitoring net.

([25]) Source: See footnote 8.

(78) About 36% (825 tonnes out of 2 300) of the air pollution by PAH is due to the use of creosote for the conservation of wood. Total emissions to air of B[a]P from creosoted wood during its phase of use are calculated as 212 kg per year (see Table 4).

Table 4

Annual emission of B[a]P from creosoted wood in use in the Netherlands ([26])

Source	Soil (kg/year)	Air (kg/year)	Water (kg/year)
Railways	55	110	—
Waterway engineering	166	33	133
Fruit growing industry	13	26	—
Agriculture	15	30	—
Other fencing	24	47	—
Total	256	212	133

(79) Emissions of B[a]P from carbolineum are estimated at 50 kg/year. Additionally, national emissions of B[a]P into air from creosoted wood during the creosoting process and strorage amounts to 100—150 kg/year.

(80) The study claims that neighbouring residents to creosoting plants have complained about odour nuisance and irritated mucous membranes. Here, emissions can occur during the treatment process and especially during the storage period of the newly impregnated wood. However, only very limited data is available on PAH or B[a]P measured in air in the vicinity of creosoting plants.

3.1.3. *Evaluation of the position of the Netherlands*

(81) From the foregoing the conclusion can be drawn that there are specific requirements in the Netherlands, resulting form a high use of creosote-treated wood and the resulting contamination of sediments in Dutch waterways, that justify the ban on the use of wood treated with creosote containing B[a]P in the range of 50 to 500 ppm and the requirement of specific preservation techniques that reduce leaching out of creosote from treated wood.

([26]) *Source:* See footnote 8.

3.1.4. *Human Health Risks*

(82) Before commenting on the actual evaluations it has to be noted that none of these problems are specific to the Netherlands, and that all of them would apply in a similar manner to other Member States.

(a) The position of the Netherlands

(83) A major part of the Dutch study is concerned with the problem of risk assessments for the exposure of human individuals to B[a]P. In fact, it is this risk evaluation which is presented as the justification for those Dutch provisions that prohibit the use of creosoted wood for certain purposes even if the B[a]P content remains below 50 ppm. Furthermore, the evaluation is supposed to give further support to the Dutch position that a B[a]P content of creosote > 50 ppm is not acceptable in any case.

(84) Risk evaluation has been performed on three groups of the population:

— employees in creosote plants

— neighbouring inhabitants of creosoting plants

— children playing on equipment made of creosoted wood.

(85) The risk evaluation on employees of creosoting plants has been calculated on the basis of their exposure to measured pyrene concentrations, originating form creosote. For inhalation, these have simply been transformed for B[a]P on the assumption that the concentration of B[a]P and pyrene in air are in the same proportion as in liquid creosote. Results indicated that dermal exposure was below effect limit (= maximum concentration deemed acceptable in the Netherlands) for creosote containing B[a]P < 50 ppm and above effect limit for B[a]P content of 500 ppm. Inhalatory exposure was always found to be below effect limit, for B[a]P concentrations based on estimated and measured data. The study made for the Commission supports the Dutch results for dermal exposure. For the inhalatory exposure it states that the Dutch assumptions are reflecting a worst-case scenario. It should also be noted that

regulation of occupational exposure is not an objective of Directive 94/60/EC and is dealt with in other Community and national legislation ([27]).

(86) The exposure of neighbouring residents has been calculated completely on the basis of estimated emission data from creosoting plants. No real data were available. It resulted in the highly theoretical approach that both, dermal and inhalatory exposure, lead to unacceptable risks for creosote containing up to 500 ppm B[a]P and acceptable risks for creosote with B[a]P < 50 ppm.

(87) The risk evaluation on children playing on creosoted wood showed that oral exposure was below effect limit. As no data were available for dermal exposure, it was calculated based on exposure of hands and forearms of employees in assembly plants working with wood treated by creosote 50 ppm of B[a]P. The calculated exposure was above effect limit. However, the study made for the Commission points out an error in the Dutch calculations; the correct result for calculated exposure would be one order of magnitude lower and, therefore, would be rather close to the effect limit.

(88) Table 5 gives a summary of the results of the risk assessments undertaken:

Table 5

Results of risk evaluation performed ([28])

Group	Type of exposure-	B[a]P content of creosote (ppm)	Risk unacceptable
Employees	Skin	500 50	Yes No
	Inhalation	500 50	No No
Neighbours	Inhalation	500 50	Yes No
	Ingestion	500 50	Yes No
Children	Ingestion	50	No
	Skin	50	Yes (?)

([27]) Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1). Council Directive 90/394/EEC on the protection of workers from risks related to exposure to carcinogens at work (OJ L 196, 21.6.1990, p. 1).

([28]) *Source:* See footnote 8.

(89) On the basis of these assessments, the Dutch authorities tried to demonstrate that the protection of human health guaranteed by the Directive is in general insufficient.

(b) Evaluation of the Scientific Committee for Toxicity, Ecotoxicity, and the Environment

(90) During the 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.

(91) This study ([29]) had been scheduled to be completed in December 1996. It was finally made available to the Commission in January 1998. The study tested the carcinogenic effects 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 concentration 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 (two times per week, 25 µl). Development of tumours was observed during this time and the test animals were carefully examined after termination of the study.

(92) The Commission submitted this study and all other documents containing scientific and exposure information on creosote to the Scientific Committee for Toxicity, Ecotoxity 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.

(93) 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

([29]) See footnote 11.

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 the 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.

(94) Data to fully evaluate the relevance of effects seen in a mouse skin-painting study for human exposure situations are insufficient. Extrapolating skin carcinogenicity data from mice to the 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 an wood treated with creosote is therefore difficult.

(95) From the data contained in the Fraunhofer study, the SCTEE calculated a T25 carcinogenic potency value for pure B[a]P of 13 μg/kg bw/day. The T25 is the chronic daily dose kg bodyweight (bw), which give 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).

(96) The SCTEE did not have measured data at its disposal regarding the exposure of the public to creosote. Various values have been calculated in the studies made available to the SCTEE, using different models, assumptions and scenarios. For the most critical exposure, children playing on wood treated with creosote containing 50 ppm B[a]P, the Dutch authorities have arrived at an exposure of two ng B[a]P per kg bw/day (playtime of three hours per day). One of the studies mandated by the Commission, in using a slightly different methodology arrives at exposure doses of 0,85 ng/kg bw/day (playtime of two hours per day) and 1,7 ng/kg bw/day (playtime of four hours per day).

(97) Should the value of exposure estimates for the scenario of children playing on creosote treated wood (two ng B[a]P per kg bw/day) approximate the true exposure, this would result in a life-time cancer risk of $1,92 \times 10^{-4}$ for a life-long daily exposure, which would give clear concern, $2,74 \times 10^{-5}$ for a daily exposure during 10 years out of 70 and $1,37 \times 10^{-5}$ for a daily exposure during five years out of 70. Using the exposure doses calculated in the other study would change the risk proportionately.

(98) 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 exposure model selected, the risk is therefore slightly or more clearly above a value of 1×10^{-5} , which is proposed as an acceptable risk level for genotoxic carcinogens in drinking water by the World Health Organisation.

(99) However, there are many uncertainties regarding exposure. According to the SCTEE, the Dutch calculation is on the one hand an over-estimation (due to an exaggerated exposure model), on the other hand an under-estimation (due to the fact that the five fold higher potency of creosote in comparison to B[a]P was not taken into account). As the SCTEE has taken the latter into account, the result could be an over-estimate as the exaggerated risk model is used.

(100) Also, the SCTEE mentions that the figure of two ng B[a]P per kg bw/day as a worst-case exposure to B[a]P from playing on creosoted-treated wood has to be compared to estimates for intake of B[a]P via food. Annual intakes of B[a]P from food have been estimated to be in the order of 0,3 to 1,6 mg, which would result in daily exposures of 12 to 63 ng/kg bw for a person weighing 70 kg and are thus clearly higher than the doses received form playing an creosote-treated wood.

(101) Overall the SCTEE concludes:

1. — Given the genotoxicity 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 carcinogenic hazard of the creosote preparation tested, since there was a linear relationship betweeen 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 6 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*

(102) The Dutch authorities have demonstrated that the specific geographic situation of the Netherlands, which necessitates extensive bank protection of watercourses, has lead to the highest consumption of creosote-treated wood per surface in the European Union. Leaching of components form creosote into the watercourses has caused the pollution of the major part of sediments with PAH compounds beyond acceptable limits. Measures aiming at an enhanced reduction of the leaching of these compounds into the aquatic environment are therefore justified in the Netherlands.

(103) With regards to the risks posed by creosote to human health, the Commission has received additional information in the framework of similar requests from Germany, Sweden 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.

(104) 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 which 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.

(105) The legislation notified to the Commission by the Dutch authorities takes account of the general principle of proportionality, i.e. the measures do not seem to exceed what suitable and necessary for the pursuit of the legitimate objective, as this legislation provides for the possibility to use creosote-containing products, when compatible with the needs for the protection of health and the environment.

(106) In accordance with Article 95(7) of the Treaty, the Commission is already examining the appropriateness to adapt to technical progress the provision 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 ([30]) 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, an ongoing research project under the Fourth Framework Programme of research and technological development is reviewing the production chain and in-service life of poles treated with creosote ([31]).

3.2. ***Absence of arbitrary discrimination***

(107) Article 95(6) obliges the Commission to verify that the national provisions are not a means of arbitrary discrimination. According to the ruling of Court of Justice, the absence of discrimination means that no different treatment should be given to similar situations, nor similar treatment to different situations.

(108) The maximum content of 50 ppm of B[a]P by mass for the use of carbolineum and creosote for wood-protection provided for by the Dutch regulations (Controlled Substances Act and SIVEB Decision) applies without distinction to all products, whether they are manufactured in the Netherlands or imported (treated wood may be imported according to the communication of the Dutch authorities) from other Member States. Regarding the approval system for individual licences, setting even stricter conditions for the use of carbolineum and creosote, this cannot by nature amount to arbitrary discrimination since the conditions are imposed only on manufacturing uses in the Netherlands. Therfore, there is no evidence that the Dutch regulations have been used as a means of arbitrary discrimination between economic operators in the Community.

([30]) OJ L 123, 24.4.1998, p. 1.

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

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

(109) More restrictive national measures in the area of limitations of marketing and use of products derogating form 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 Article 95(6), is intended to present 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.

(110) The Commission mandated a study ([32]) to analyse the effects on trade and competition of the retention by the Netherlands of its stricter national provisions. The study by TIS undertook to collect information on the annual quantities of creosote used wood preservation and treated wood production in the Member States, the historical development and on how these will change if the Netherlands were to retain its own legislation in place of Directive 94/60/EC. To this end, questionnaires were prepared and distributed to creosote producers, creosote traders and wood impregnators within the EC.

(111) According to the study, there is one producer of creosote in the Netherlands. About three quarters of the total production (5 200 t/year) is exported, whereas about 3 400 t/year are imported (mostly from Germany). Most of the producers in other Member States can comply with the Dutch regulations and those who cannot, have not had business with the Netherlands in the past.

(112) As far as possible substitutes to creosote are concerned, there is no information indicating that the Netherlands has national economic interests in their development, production or export.

(113) It was established before that there is a real concern with regards to human health related to the use of creosote and treated timber, and with regards to the environment due to the specific situation of the Netherlands. Furthermore the national provisions on creosote are a part of a more general policy on PAHs. Therefore, the protection of health and the environment seems to be the real goal of maintaining the national legislation, and not the creation of disguised barriers to trade.

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

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

(115) This condition, which is established by Article 95(6), first subparagraph, is new in comparison to the text of the 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 affect the internal market. Consequently, to preserve the useful character of the procedure for derogation provided for by Article 95 of the EC Treaty, the Commission considers that, in the context of the Article 95(6), the concept of obstacle to the functioning of the internal market has to be understood as a disproportionate effect in relation to the pursued objective.

(116) According to a study by ERM ([33]), 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

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

(118) 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

([32]) 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.

([33]) Environmental Resources Management, Trade and Competition Assessment of the German and Danish Request for Derogations on the Marketing and Use of Creosote, Final Report, June 1996.

wood preservation companies. The remaining 10% of creosote are used by individual consumers, mostly in the United Kingdom and Ireland.

(119) 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 end 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.

(120) The following Table 6 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 the Netherlands.

Table 6

Production, sales and trade in creosote in Europe ([34])

Country	No of producers	Possibility of producing creosote with B[a]P < 50 ppm	Sales of creosote (tonnes/year) 1995	Trade with the Netherlands
Austria	1	No	—	No
Belgium	1	Yes	3 900	No
Denmark	1	Yes	0	No
France	1	Yes	6 750	No
Germany	1	Yes	5 000	Yes
Netherlands	1	Yes	5 000	—
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	No
Finland	—	—	5 000	No

(121) According to the study by TIS ([35]) about three-quarters of the national production of the Netherlands is exported and about the same amount is imported. Imports into the Netherlands come mostly from Germany and concern with a B[a]P content, which already complies with the Dutch regulations. Creosote producers in several other Member States could comply with the Dutch requirements.

(122) Creosote-treated wood in the Netherlands is mainly used in the railway industry (sleepers), hydraulic engineering (protection of waterbanks), agriculture (fencing) and the fruit-growing industry (support of fruit trees). The consumption of creosote-treated wood in the Netherlands has decreased steadily ([36]) from 120 000 m^3 in 1985 to around 78 000 m^3 in 1992 and was expected to decrease to 60 000 m^3 in 1995. This trend seems thus to have started before adoption of the national legislation.

(123) There are three creosote treatment facilities in the Netherlands. The national production of treated round wood and sawn timber has decreased by 40% between 1990 and 1995 (to about 23 000 m^3), and the production of treated railway sleepers by about 50% to 10 000 m^3. The amounts of treated wood used are about twice as high. As part of the treated wood is exported, the Netherlands are also a net importer of treated wood, also with decreasing tendency. Both these trends had already started before the adoption of the

([34]) *Sources:* See footnotes 32 and 33.
([35]) See footnote 32.
([36]) See footnote 8.

national legislative and have continued without Directive 94/60/EC being in place.

(124) The amount of creosote produced and exported has grown steadily over the years from 1990 to 1995, whereas the amount of creosote imported and used has decreased. However, the creosote, which is exported by the Dutch producer, does in general meet the stricter requirements of the Dutch legislation.

(125) Some producers have expressed their concern about the possibility that creosote produced in the Netherlands containing more than 50 and less than 500 ppm B[a]P could be sold in other Member States at a price not reflecting the true costs as the Dutch producer could not market it legally in the Netherlands and would seek to avoid disposal costs. However, there seems to have been only one case which supports this assumption where a consignment of 1 000 tonnes from the Netherlands complying with the requirement of Directive 94/60/EC was sold at a lower price than that of the traditional suppliers. This seems to have been a singular event and does not provide sufficient evidence for the presumption that the internal market would be distorted if the Dutch regulations were approved, as normally the exported creosote also conforms to the stricter national requirements.

(126) Taking into account the preceding observations, the Commission considers that there is no evidence that the Dutch 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**

(127) 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 the Netherlands pursuant to the former Article 100a(4) and examined under 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 human health and, due to a specific situation, on grounds of major need of protection of the environment,

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

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

HAS ADOPTED THIS DECISION:

Article 1

The provisions of the Controlled Substances Act in conjunction with the Decision concerning the composition, classification, packaging and labelling of control substances of 12 March 1992 concerning carbolineum and creosote are approved.

Article 2

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 26 October 1999.

For the Commission
Erkki LIIKANEN
Member of the Commission