COMMISSION DECISION

of 26 October 1999

on the national provisions notified by the Federal Republic of Germany concerning the limitations of the marketing and use of creosote

(notified under document number C(1999) 3425)

(Only the German text is authentic)

(Text with EEA relevance)

(1999/833/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Whereas:

I. FACTS

1. 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 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 among other things 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, in the following B[a]P, and water extractable phenols when used for woodtreatment (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, for example 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 German national provisions

(4) The German legislation uses the term 'tar-oils' to designate the substances subject to the provisions in question. The German Tar-Oil Ordinance (*Teerölverordnung*), which contains the national provisions concerning creosote, was notified to the Commission in 1990, promulgated on 5 June 1991, and entered into force on 1 October 1991. As part of the general reorganisation of the legislation on manufacturing, marketing, and use, the provisions of the Tar-Oil Ordinance where included on 1 November 1993 in two ordinances, the Banned Chemicals Ordinance (*Chemikalien Verbotsverordnung, ChemVerbotsV*) and the Hazardous Substances Ordinance (*Gefahrstoffverordnung,*

[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

GefStoffV) without changing the substantive contents. The provisions of the two ordinances concerning tar-oils were amended by an ordinance of 19 Sepember 1994.

(5) The term 'tar-oils' covers all substances that are produced as liquid by-products of the coking of coal or wood, including those designated by the term 'creosote'.

(6) The legislation with regards to tar-oils in Germany is now comprised of:

— provisions relating to the placing on the market, incorporated into the Banned Chemicals Ordinance in section 17 of the Appendix to paragraph 1,

— provisions relating to special labelling requirements, incorporated into the Hazardous Substances Ordinance in paragraph 12 in conjunction with Appendix III, No 15,

— provisions relating to production and use, incorporated into the Hazardous Substances Ordinance in paragraph 15 in conjunction with Appendix IV, No 13.

(7) In principle, the German regulations place restrictions on the production, marketing and use of substances and preparations containing creosote and wood treated with such substances, depending on various limit values of the B[a]P content: 5 ppm, 50 ppm and 500 ppm.

(8) The German legislation applies to both, creosote and preparations containing creosote, as well as products made of wood, partially or completely, that have been treated with creosote or products containing creosote.

(9) Restrictions on marketing and use of creosote and wood treated with creosote are the following:

1. Sale to private consumers of creosote and preparations containing creosote is completely prohibited, irrespective of their B[a]P content.

2. Creosote with a B[a]P content lower than 5 ppm:

   (a) use is only allowed in closed industrial installations,

   (b) sale of wood treated with such creosote by brushing, spreading, or dipping is prohibited,

   (c) treated wood may not be used inside buildings or as a consumer product within the definitions of the Foodstuffs and consumer products Act (e.g. food packaging, hygiene products, and toys).

3. Creosote with a B[a]P content in the range of 5 to 50 ppm:

   (a) placing on the market is only allowed for use in closed industrial installations by application of certain impregnation techniques:

      — pressure impregnation with final vacuum

      — other impregnation processes for the partial impregnation of wooden posts, which ensure an in-depth protection, especially the dipping in the hot-cold process with final reduction of creosote content at the surface

      — other processes ensuring equal or better protection of man and environment;

   (b) sale of wood treated with such creosote is prohibited if impregnation has not been done according to one of the abovementioned techniques;

   (c) sale of treated wood is completely prohibited for use inside buildings, on children's playgrounds or other purposes with regular human skin contact, or as a consumer product within the definitions of the Foodstuffs and consumer products Act.

4. Creosote with a B[a]P content in the range of 50 to 500 ppm:

   (a) use is permitted only for industrial treatment of railway sleepers and electricity poles in a process of pressure impregnation with final vacuum,

   (b) sale of wood treated with such creosote is prohibited except for use as railway sleepers or electricity poles intended for export to countries where climatic conditions require increased wood protection.

5. In addition, all types of creosote with B[a]P content up to 500 ppm may be placed on the market for

exclusive use in countries, where climatic conditions require increased wood protection.

6. Previously treated railway sleepers, electricity poles and posts may be marketed again as such (even when the indicated limits are exceeded). Such marketing is, however, prohibited if:

— impregnation took place less than 15 years ago

— fresh cut sites have not been permanently sealed or covered

— wood is intended for use inside buildings, in children's playgrounds or other purposes with regular human skin contact

— wood products are intended for private consumers

— the products are consumer products under the Foodstuffs and consumer products Act.

(10) The German national legislation regarding tar-oils was amended for a second time by an ordinance of 12 June 1996. The latter transposed a part of the provisions of Directive 94/60/EC into German law. In their first version, the German regulations did not contain provisions concerning the content of water soluble phenolic compounds in creosote, requirements regarding the minimum drum size of creosote containing 50 to 500 ppm B[a]P or specific labelling requirements of preparations containing such creosote, whereas the Directive establishes a maximum content of 3% phenolic compounds and a specific labelling requirement for creosote containing more than 50 ppm B[a]P. These provisions, being more restrictive than the initial German regulations, have been incorporated in the Banned Chemicals Ordinance and the Hazardous Substances Ordinance by the amending Ordinance in 1996. However the labelling requirement is slightly different from the Community provisions. The German national legislation requires the following wording: 'For exclusive use in the pressure impregnation with final vacuum for railway sleepers and electricity poles'. Furthermore the second amending decree restricted even further the use of old treated wood: in addition to the restrictions mentioned above, previously treated railway sleepers, electricity poles and posts may only be marketed 'as such' again.

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

(11) 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 German legal system in force at the date of adoption of the Directive.

Table 1

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

	Council Directive 94/60/EC	German regulations
B[a]P < 5 ppm	No restrictions on sale or use of creosote or newly treated wood	Sale of creosote to private consumers and for use inside buildings prohibited Industrial use only in closed plants Sale of treated wood prohibited if creosote was applied by brushing, spreading, or dipping, or for use in inside areas or as a consumer product within the definitions of Foodstuffs and consumer products Act

	Council Directive 94/60/EC	German regulations
B[a]P in range 5-50 ppm	No restrictions on sale or use of creosote or newly treated wood	Sale of creosote to private consumers prohibited Industrial use only in closed plants with certain impregnation techniques: — pressure impregnation with final vacuum — other processes with equal protection of man and environment — other impregnation processes for partial impregnation of wooden posts which ensure an in-depth protection, especially dipping in hot-cold process with final reduction of creosote content on the surface Sale of treated wood prohibited if impregnation has not been done with the abovementioned techniques. Sale of treated wood completely prohibited for use inside buildings, on children's playgrounds or other purpose with regular skin contact, or as a consumer product within the definitions of Foodstuffs and consumer products Act.
B[a]P 50-500 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 Treated 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 foodstuffs — for containers for growing purposes — at playgrounds or other sites at risk of skin contact	Sale of creosote to private consumers prohibited. However, all types of creosote with B[a]P content up to 500 ppm may be placed on the market for exclusive use in countries, where climatic conditions require increase wood protection Use permitted only for industrial treatment of railway sleepers and electricity poles in a process of pressure impregnation with final vacuum Sale of treated wood prohibited except for use as railway sleepers or electricity poles intended for export to countries where climatic conditions require increased wood protection.

	Council Directive 94/60/EC	German regulations
B[a]P > 500 ppm or water soluble phenols > 3 %	Sale and use of creosote and treated products totally banned	Sale and use of creosote and treated products totally banned when B[a]P content > 500 ppm (no provisions on water soluble phenols!)
Old treated wood	Use controlled as for wood treated with creosote containing B[a]P between 50 and 500 ppm	Previously treated railway sleepers, electricity poles and posts may be marketed again (even when the limits indicated are exceeded). Such marketing is, however, prohibited if: — impregnation was less than 15 years before — fresh cut sites have not been sealed — wood is intended for use inside buildings, in children's playgrounds or other purpose with regular skin contact — wood products are intended for private consumers — the products are consumer products under the Foodstuffs and consumer products Act

(12) In summary the German provisions are more restrictive in several aspects:

— creosote and preparations containing creosote may not be sold to the private consumer irrespective of their B[a]P content,

— placing on the market of creosote and preparations containing creosote with a B[a]P content up to 500 ppm is only possible for export to countries with climatic conditions requiring enhanced wood preservation and, domestically, for industrial use. Furthermore, specific obligations for the use of creosote and preparations containing creosote with regards to process technology have been established depending on the B[a]P content (5, 5 to 50, and 50 to 500 ppm),

— newly treated wood may not be placed on the market unless certain obligations with regards to the treatment process have been met. Additional restrictions apply for the use of wood treated with creosote containing less than 50 ppm. Wood treated with creosote containing B[a]P in the range 50 to 500 ppm may only be used for two specific applications (railway sleepers, electricity poles for export),

— placing on the market and use of previously treated wood are further restricted in comparison to the EC Directive.

II. **THE PROCEDURE**

(13) Directive 94/60/EC was adopted on 20 December 1994. The Directive had to be transposed into the national law of the Member States no later than one year after its adoption, i.e. by 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).

(14) By letter of 4 July 1995, Germany transmitted a report (dated 19 June 1995) by which they informed the European Commission that on grounds of health protection Germany deemed it necessary to continue to apply the already existing legislation relating to 'tar-oils', and requested a derogation on the basis of the former Article 100a(4) of the EC Treaty from Directive 94/60/EC with regards to creosote. It was also stated that some amendments would be made in order to

incorporate a part of the provisions of the Community Directive into the national legislation. These amendments were notified on 8 July 1996.

(15) By letter of 6 December 1995, the Commission invited the other Member States to present their observations on the German request under the former Article 100a(4). The Commission received comments from Denmark, Sweden, The Netherlands, Austria, and the United Kingdom.

(16) *Denmark* recalls that in its opinion, 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 therefore fully supports the idea that Germany should be given the option to apply more stringent national rules with regards to creosote.

(17) *Sweden* shares the German views regarding the risks posed by creosote and wood treated with creosote and has no objections to the notified more stringent German provisions. Sweden underlines that creosote has adverse environmental impacts as it is highly toxic to certain aquatic organisms and certain components are bioaccumulating. The use of creosote and creosote-treated wood should therefore be limited in order to minimise the risk of damage. Sweden recalls that it had also notified its intention to maintain its national provisions on creosote in view of special circumstances applying in its territory.

(18) *The Netherlands* recall that, they had made a statement in the Council underlining that the level of protection for public health, the workplace, and the environment set by the Directive was insufficient. The Netherland themselves already had notified a request for derogation under the former Article 100a(4). The Netherlands consider that the German measures meet a real need, and cannot be seen as a hidden barrier to trade, and therefore support their confirmation by the Commission.

(19) According to *Austria*, the primary objective of the German provisions is the protection of consumer health, which is the objective of the former Article 100a(3). Austria agrees to the position that the cancer risk to consumers from direct dermal exposure to B[a]P containing tar-oils or wood treated with such tar-oils is considerable as the risks are highest during direct brush application of tar-oils (dermal and inhalatory exposure) and the (unnecessary) use of treated wood inside buildings. Austria therefore considers the continuous application of the national provisions as justified. The German regulations are proportional as they reduce the risk of exposure by addressing specific situations, while the free circulation of goods is only hindered to a very limited extent. Futhermore, the national measures seem to have the greatest effects on German companies. Austria therefore considers that the more stringent measures constitute neither an arbitrary discrimination nor a disguised restriction on trade.

(20) In contrast, the *United Kingdom* objects to the request from Germany. The UK authorities consider that the German request is based on a disagreement with scientific consensus, which was reached at Community level during the adoption of Directive 94/60/EC. Following the UK opinion, all Member States should accept the standards imposed by single market measures, unless there are special circumstances which would lead to an increase of risk in one Member State if similar provisions applied. The UK is not aware of any special circumstances in Germany, which would justify the application of more stringent measures. The UK also points out that the threshold of 50 ppm B[a]P used in the Directive is entirely consistent with the classification criteria used in Directive 67/548/EEC.

(21) 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, signed at Amsterdam, 2 October 1997, entered into force. By letter of 24 August 1999 the General Secretariat of the Commission informed Germany 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 German 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 Germany 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 had to be transposed by the Member States by 20 December 1995 and enforced by 20 June 1996. Germany notified its national legislation relating to 'tar-oils' which it intended to maintain on 4 July 1995 and thus before the date foreseen for application of the national provisions transposing the Directive.

(28) The national provisions for which derogation was sought had entered into force on 1 October 1991 and thus before Directive 94/60/EC was adopted (20 December 1994).

(29) In the notification Germany announced its intention to amend the national legislation in order to transpose those parts of the provisions of Directive 94/60/EC into national law that were more restrictive. By the amending ordinance of 12 June 1996, which was notified to the Commission on 8 August 1996, a maximum permissible content of water soluble phenols, a list of specific substances being covered by the term 'tar-oil', and a minimum drum size and specific labelling requirement for tar-oils containing 50 to 500 ppm B[a]P were included. The existing restrictions for old treated wood were also slightly modified.

(30) In the light of what precedes, the Commission considers that the request of the Federal Republic of Germany for derogation from Directive 94/60/EC as notified on 4 July 1995 under the former Article 100a(4) is admissible under Article 95(4) of the EC Treaty. According to Article 95(4), 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. This Decision therefore exclusively deals with the legislation existing before adoption of Directive 94/60/EC as notified in the request of 4 July 1995. The provisions introduced by the amending Decree of 12 June 1996 (notified on 8 August 1996), for which an approval has not been requested, implement certain provisions of Directive 94/60/EC and are not subject to this Decision.

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 itself 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 internal market (Article 95(6)).

(32) Germany has based its request on the need for protection of human health. In order to substantiate its request for derogation, Germany submitted a brief justification for the more restrictive national measures which was substantiated by three documents: A report from the Senate Commission on the testing of materials injurious to health of the German Research Association (MAK Commission) on the suitability of B[a]P as a marker substance for mixtures of polycyclic aromatic hydrocarbons originating in combustion processes (completed in 1984), a study on the carcinogenic properties of B[a]P [4], and a collection of data on the identity, availability, and application of alternative wood protection agents including their toxicological and ecotoxicological effects. However, it was not possible to examine the merits of the request based exclusively on this information.

(33) In order to verify whether the German national provisions concerning marketing and use of creosote-treated wood, are indeed necessary and

[4] J. M. Holland, E. L. Frome, *Advances in modern environmental toxicology*, Vol. VI, Applied Toxicology of petroleum hydrocarbons, ed. MacFarland et al., Princeton Scientific Publishers 1984.

proportionate to that end, the Commission mandated a study to an external consultant to assess the situation of environmental contamination by creosote in Germany ([5]). In addition, the findings of three further studies ([6]), 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 Germany.

(34) 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 German request was notified, these substantial efforts of the Commission to find the elements necessary for the justification of the maintenance of the German 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 with 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 on human health, in particular concerning its carcinogenic potential, as a specifically designed long-term carcinogenicity study was still ongoing. This study ([7]) was made available to the Commission at the beginning of 1998. The findings of all these studies are set out below. 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.

([5]) 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.

([6]) 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.
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.
W. S. 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.

([7]) 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.

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

— phenanthrene

— anthracene

— fluorene

— fluoranthene

— chrysene

— tripenylene

— benzo[a]anthracene

— benzo[b]fluoranthene

— benzo[k]fluoranthene

— benzo[a]pyrene

(38) 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 phenols 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.

(39) Modification 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, for example 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 is very little published data on the effects on 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 among workers exposed to creosote. The most recent study on workers exposed to creosote in Sweden and Norway was published in 1992 ([8]). 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 ([9]) 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 is known.

(46) Mostly based on an animal experiment, where the skin of mice war regularly exposed to B[a]P solutions in acetone during their life-time ([10]), the International Agency for Research on Cancer (IARC) has classified creosote as a group 2A human carcinogen. The 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 carcinogenic in humans. There is no significant new evidence from more recent investigations, which would affect this conclusion.

(47) For several years, experts from the Member States examined the issue of classification of creosote, other coal tar distillates, and further '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 ([11]), as last amended by Directive 99/33/EC ([12]). Drawing largely on the same data as the IARC, agreement was reached during the elaboration of Commission Directive 94/69/EC ([13]), 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 ([14]). 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 in the concentration of B[a]P for classification purposes in Community

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

([9]) 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.

([10]) See footnote 4.

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

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

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

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

legislation in order to distinguish carcinogenic from non-carcinogenic coal-tar distillates has been accepted by the Member States in the working group for the 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 abovementioned 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 below.

(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 ([15]): absorption appears to vary between individuals and between different sites within the same individual. In a separate study ([16]), the dermal absorption of different PAH compounds was measured. PAHs of higher molecular weight than pyrene, for example B[a]P were absorbed less rapidly. Any estimation of B[a]P uptake based on 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.

([15]) 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.

([16]) Van Rooij, J. G. M., 'Dermal exposure to polycyclic aromatic hydrocarbons among workers', Thesis ISBN 90-9007080-X, Nijmwegen 1993.

Environmental 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 contamination 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)

— 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 ([17]) in Sweden has shown that after 40 years in soil, creosote impregnated poles had lost a part of the compounds contained in creosote, notably 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 in 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 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 ([18]). The pollution of sediments by creosote leaching from waterbank protection has been documented in The Netherlands ([19]) and also in studies on pollution from former impregnation facilities.

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

3.1.2. *The position of Germany*

(59) Germany justifies its request for maintaining the more restrictive national provisions in place of Directive 94/60/EC exclusively on the claim that the level of health protection guaranteed by the Community provisions is in general insufficient, especially with regards to health hazards to consumers. Germany does not share the assessment that hazards related to the use of creosote containing less than 50 ppm B[a]P and wood treated with such creosote are very low, as it has been agreed during the elaboration of Directive 94/69/EC, the 21st adaptation to technical progress of Directive 67/548/EEC, according to which coal-tar distillates containing B[a]P in concentrations lower than the limit value of 50 ppm B[a]P need not be classified as carcinogens. Germany bases its judgment on a study ([20]) published in 1984 presenting the results of carcinogenicity tests with B[a]P.

(60) Germany holds the opinion that the stricter national measures are necessary due to the high carcinogenic potential of tar-oils. A reduction to the level of protection as established by Directive 94/60/EC would lead to an unacceptable additional risk to the population of contracting cancer.

(61) Depending on their origin and on the production process, the carcinogenic potency of tar-oils varies. Individual testing of the carcinogenic effect level of every tar-oil component is impracticable. Nevertheless, in order to be able to take a position on the effect level, the *MAK-Kommission* has carried out an extensive evaluation of the available data and has concluded that:

— B[a]P can be used as a reference substance for estimating the carcinogenic effect of tar-oils

— the carcinogenic effect of tar-oils is greater by a factor of 7 to 20 than the effect due to the B[a]P-content alone.

(62) Therefore, Germany agrees that, for pragmatic reasons, the effect level of tar-oils can be assessed on the basis of their content of certain constituents, for example B[a]P. This, however, cannot lead to fully quantified assessments, since the contents of the different carcinogenic substances in various tar-oils are not identical and not all of the substances have been identified and classified. For many of them, precise effect levels are not known.

(63) According to Germany, the primary aim of the national regulations restricting tar-oils is the protection of the health of the private consumer. In addition, the provisions have the positive effects of protecting workers and the environment. As the determining factor for the broader restrictions was the hazard to the health of the private consumer, Germany does not proceed with any further analysis of the exposure of the professional user or the environment.

(64) In estimating the hazards to the private consumer, the following types of potential exposure have been identified by Germany:

— skin contact during the use of tar-oils (generally through brush application),

— skin contact in the course of installing/carrying out carpentry work on the treated wood,

— skin contact with the installed treated wood,

— inhalation exposure in the course of using the tar-oils,

— inhalation exposure to tar-oil components which escape from the treated wood as gases.

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

([18]) 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.

([19]) See footnote 8.

([20]) See footnote 4.

(65) It is recognised that the level of actual exposure to tar-oils shows a marked dependency on individual behaviour, as is usual in the consumer sector. When considering the exposure provisions, therefore, account must be taken of those situations where the level of exposure is considerably above the average (worst-case scenarios).

(66) Germany considers that according to the data of the only study establishing a dose-response relation for exposure to B[a]P ([21]), a solution containing 50 ppm of B[a]P causes skin tumours in 95 % of the animals. A less concentrated solution, containing 25 ppm of B[a]P, still produces tumours in 44 % of the animals, which proves that also at this concentration B[a]P is a strong dermal carcinogen in mice.

(67) Germany justifies their claim that the level of protection established by Directive 94/60/EC is insufficient, by analysing more thoroughly one of the five exposure scenarios mentioned above: through the calculation of a risk assessment for children playing on wood treated with creosote containing 25 ppm B[a]P. Frequency of contact is assumed to be once a week over five years, transferring 10 µl of tar-oil each time. Assuming a lifetime of 70 years, the cumulative lifetime risk calculated by Germany is 0,02 (2 %).

(68) Germany thus arrives at the conclusion that the cumulative lifetime risk is in the percent range. In contrast, internationally acceptable cancer risks for individual substances are situated in the range of 1×10^{-5} (i.e. 0,001 %). The potential cancer risk of tar-oils containing 25 ppm of B[a]P and of wood treated with such oils, therefore, is not acceptable. Furthermore, the exposure dose is estimated for children playing on treated wood, only taking into account dermal exposure and thus, according to Germany, probably underestimating the actual risk (which could be higher owing to inhalation and oral ingestion).

(69) Germany justifies the other part of their more restrictive national measures, the required impregnation technologies and the restrictions on the marketing and use of treated wood, also by referring to this evaluation according to which the health risks to consumers would otherwise be unacceptable. Only the prescribed impregnation processes ensure a high depth of penetration of the tar-oils and therefore permanent and effective protection of the wood. The reduction of the tar-oil content at the wood surface, which is required following the treatment, is necessary in order to minimise the health hazards. Simple brush application by consumers leads to ineffective impregnation as well as high exposure during application and from elevated surface concentrations. Restrictions on the marketing and use of wood treated with creosote containing B[a]P in the range 50 to 500 ppm are necessary, as despite the reduction in tar-oil content at the surface of wood treated that way, there is still a considerable hazard to health in the case of relatively frequent and even occasional contact. No data, either measured, or estimated are presented to support these assertions.

(70) In what concerns the restrictions on the sale of used wood which was treated previously, they are considered necessary since there is an unacceptable cancer risk from skin contact as in the past tar-oils had higher B[a]P contents, the content of tar-oil at the wood surface, especially under solar exposure, can be considerable even after a number of years, and tar-oils migrate from freshly cut sites of the wood. No data, either measured, or estimated, are presented to support this assertion.

(71) Finally, according to Germany, less hazardous and equally effective substitutes for creosote are available for all applications where the national legislation bans or restricts more severely the use of tar-oils than the EU Directive. In support of this opinion, the German request contains a report on various wood preservation agents, giving the names as well as the health and environmental hazards presented by the substitutes. However, tar-oils are not covered by the report.

3.1.3. *Evaluation of the German position*

Exposure of the environment

(72) The study made by ERM undertook to examine all available information regarding the possible direct exposure of the German population to unusually high doses of creosote through products sold to consumers and by contact with creosote-treated wood, as well as regarding the possible direct exposure of the German aquatic environment to high doses of PAH from creosote-treated wood in order to establish whether there was a specific situation, albeit not invoked by Germany, that could justify maintaining the more restrictive national measures in place of Directive 94/60/EC.

(73) As mentioned in the chapter containing general information on creosote, the application of coal-tar distillates for wood treatment is only one possible source of emissions of B[a]P and other PAHs into the environment. Emissions occur in association with a broad range of human activities, the main sources today being traffic, industrial activities, and energy generation. Table 2, originating from the ERM study gives an overview on estimated emissions of B[a]P in several European countries.

([21]) See footnote 4.

Table 2

Estimated emissions of B[a]P in selected European countries ([22])

Country	Total emissions (t/year)	Source (%)			
		Fuel combustion	Transport	Industry	Others
Denmark	1	57,5	0,0	21,2	21,3
Sweden	6	42,0	2,0	48,2	7,8
Norway	8	14,9	72,6	9,6	2,9
Germany	215	79,9	1,3	17,1	1,7
United Kingdom	49	61,2	0,7	32,8	5,3
France	54	26,2	34,5	34,3	5,0
Netherlands	7	20,0	4,8	67,5	7,7
Europe	1 409	69,3	6,0	23,3	1,8

(74) It is clear from Table 2 that the use of creosote (which would be comprised in category 'others' or 'industry') constitutes only a small contribution to overall B[a]P levels in the German environment.

(75) A recent study ([23]) using the German Environmental Specimen Bank (supported by the German Ministry of Environment) which provides a historical databank of a range of different species from selected locations within Germany, has concluded that PAH concentrations have decreased significantly in the atmospheric and marine environment in the period 1985 to 1994.

(76) Table 3 gives an overview of the consumption of creosoted wood in Europe.

Table 3

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

Country	Annual use in 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
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

([22]) *Source*: van den Hout KD, 1994. 'The impact of atmospheric deposition of non-acidifying pollutants on the quality of European forest soils and the North Sea', main report of the Esquad project, p. 145.

([23]) J. Jakob, G. Grimmer, A. Hildebrandt, 'Trends in environmental pollution by PAH in Germany during the period 1985 to 1995', published in *Polycyclic aromatic compounds* (1996).

([24]) bkh consulting engineers, Foundation of the appeal against the EC of Directive on creosote, Final report, Delft, 1 July 1995, p. 6.

(77) In Europe a total of 1 million m^3 of creosoted wood was used in 1990. In absolute figures, Germany is the largest user of creosoted wood. However, the use per capita is not exceptionally high (rank 8 out of 12), the consumption per km^2 is above average, but far lower than in The Netherlands. It is important to note that the data are from 1990, i.e. before the German regulations on tar-oils entered into force.

(78) It is clear that there are no data supporting the existence of a specific situation in Germany with regards to pollution of the environment by PAH and B[a]P owing to the use of creosote and creosote-treated wood or the overall use of creosote-treated wood, which would necessitate a more restrictive national policy.

Human exposure

(79) Before commenting on the actual evaluations regarding the risks to human health, it has to be noted that none of the problems raised in this chapter are specific to Germany, and that all of them would apply in a similar manner to other Member States.

(80) With regards to the risks to human health, it has to be noted that Germany neither presents new data (i.e. data unknown during the deliberations preparing Directive 94/60/EC) nor data demonstrating a higher exposure to creosote of the general population in Germany in comparison with the other Member States. The claim that the fact that the cancer risk of creosote containing less than 50 ppm B[a]P has been underestimated is sustained by referring to the same study that was used by the IARC for classification and was also discussed as a basis for assessing the carcinogenic potency of B[a]P and tar-oils during the 'Workshop on the carcinogenicity of complex and petroleum derived substances' organised by the EC in Ispra in 1992, which let to the classification rules of Directive 67/548/EEC. This means that the study received due consideration before the adoption of Directive 94/60/EC.

(81) The estimations made by Germany during the risk assessment for children playing on creosote-treated wood rely on a series of assumptions, which need to be compared with similar evaluations made by other assessors, notably those of the Dutch authorities and the study mandated by the Commission in the framework of the Swedish request for derogation under the former Article 100a(4) concerning the same Directive, as well as the Scientific Committee of Toxicity, Ecotoxicity, and the Environment.

(82) The German assessment is fundamentally different from the others in so far as the dose of exposure to B[a]P is simply assumed to be identical to the total quantity of B[a]P transferred on the skin and is not calculated based on measured absorption data. The daily exposure dose to B[a]P according to Germany is 39,3 ng/day (assuming a transfer once a week of 10 µl creosote of a density of 1,1 g/ml containing 25 ppm B[a]P).

(83) In contrast to the other studies, Germany does not take into account the body weight and skin specificities of the exposed individual humans by directly using a dose-response relationship from a study performed on mice. When normalising the calculated exposure to a body weight (bw) of 15 kg (as the other assessors have done), the daily dose amounts to 2,62 ng/kg bw/day. This is somewhat higher but not very different from the results of the Dutch authorities (2 ng/kg bw/day) and the study mandated by the Commission in the framework of the Swedish request (0,85 or 1,7 ng/kg bw/day).

(84) Despite the fact that the daily dose of exposure to B[a]P calculated by Germany (when normalised to the body weight) is thus not very different from the dose estimated by the Dutch authorities (and the study mandated by the Commission for the Swedish request), the results for the calculated risk are, in fact, very different. According to the Dutch authorities, the risk is only slightly above an acceptable level (in the range of 1×10^{-5}) for wood treated with creosote containing 50 ppm B[a]P and daily exposure over 10 years. In contrast, Germany calculates a risk which is orders of magnitude higher (2×10^{-2}) for wood treated with creosote containing only 25 ppm B[a]P with exposure once a week over five years, i.e. a much lower exposure results in a much higher risk. The assumptions made by Germany could thus lead to a clear overestimation of the risks involved.

(85) This interpretation is supported by the ERM study ([25]), which criticises the risk assessment made for children playing on creosote-treated wood presented in the German request as not comprehensive and not quantitative. ERM points out that if the assumptions and calculations made by Germany were applied to exposure data measured for workers in occupational studies, all workers should have contracted skin cancer (risk higher than 300 %) which obviously was not the case.

([25]) See footnote 5.

(86) Nevertheless, based on the assessments carried out by the Dutch authorities, and those contained in the two studies mandated by the Commission in the framework of the German and Swedish requests for derogation under the former Article 100a(4), the result that the likely exposure to B[a]P for children playing on creosote treated wood, which are mentioned above, is such that the claim of Germany that the risk is unacceptable, cannot be totally dismissed. Furthermore, both consultants recommend that the Commission, before taking a decision, awaits the results of the long-term carcinogenicity study that was ongoing at that time ([26]) (received at the beginning of 1998). The findings of this study have been examined by the Scientific Committee for Toxicity, Ecotoxicity, and the Environment and the analysis will be presented below.

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

(87) During the elaboration of Directive 94/69/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.

(88) This study ([27]) was 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. Owing 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 products 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 over a period 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.

(89) 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.

(90) The SCTEE observes that the Fraunhofer study is well-designed and reaffirms the carcinogenic potential of coal-tar preparations. Owing 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 fivefold higher potency to induce skin tumours than pure B[a]P, presumably due to the presence off 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.

(91) Data to fully evaluate the relevance of effects seen during a study on the application on mouse skin 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 the cancer risk in humans. Species dependent sensitivity of dermal exposure to the carcinogenic actions of creosote will be affected by the 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, for example for the dermal exposure of children playing on wood treated with creosote is therefore difficult.

(92) 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 in 25% of the test animals tumours at a specific tissue site within the standard lifespan of that species. The creosote formulations tested had a five-fold higher overall carcinogenic potency (2,7 µg/kg bw/day).

(93) Should the value of exposure estimates for the scenario of children playing on creosote treated wood as calculated by Germany (2,62 ng B[a]P per kg bw/day) approximate the true exposure, this would result in a life-time cancer risk of $2{,}52 \times 10^{-4}$ for a life long daily exposure which gives clear concern, a risk of $3{,}6 \times 10^{-5}$ for a daily exposure over ten years out of 70 (the Dutch

([26]) See footnote 7.
([27]) See footnote 7.

assumption) and $1,8 \times 10^{-5}$ for a daily exposure over five years out of 70 (the German assumption). Using the doses as calculated by the Dutch authorities (2 ng/kg bw/day) or in the study mandated by the Commission for the Swedish case (0,85 or 1,7 ng/kg bw/day), would reduce these risks proportionally.

(94) Based on the most recent study with regards to the dose-response relation for dermal carcinogenicity of creosotes as derived by the SCTEE and the exposure model chosen by Germany, the calculated risk is several orders of magnitude lower than estimated by Germany. Depending on the exposure model selected, the risk is, however, 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.

(95) 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 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 to 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).

(96) Overall the SCTEE concludes:

1. — Given the genotoxicity of B[a]P and the outcome of the Fraunhofer skin-application 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 between cancer incidence and B[a]P dose. However, the cancer potency of the creosote preparation was five times 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*

(97) Germany has neither claimed, nor could it be demonstrated through further research, that a specific situation exists in Germany with regards to the general pollution of the 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 of Germany applied the provisions of Directive 94/60/EC.

(98) However, the Commission has received additional information in the framework of similar requests from The Netherlands, 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.

(99) 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.

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

(101) In accordance with Article 95(7) of the Treaty, the Commission is already examining the appropriateness of

adapting 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 ([28]) 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 for research and technological development is reviewing the production chain and in-service life of poles treated with creosote ([29]).

3.2. *The absence of arbitrary discrimination*

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

(103) The limitations on marketing and use of products containing creosote in the German ordinances is based on their content of B[a]P: 5, 50 or 500 ppm. The restrictions apply without distinction to all products, whether they are manufactured in Germany or imported. The same applies for wood treated with preparations containing creosote. The Commission considers, therefore, that there is no evidence that the German regulations 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*

(104) 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 Article 95(6) 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.

(105) The Commission mandated a study ([30]) to analyse the effects on trade and competition of the retention by Germany of its stricter national provisions. The study undertook to examine all available information regarding the volume and value of trade with other Member States affected, the interest which Germany might have in using its national rules to promote a national interest in substitutes, and the interest which Germany might have in using its national rules to promote alternatives to creosote-treated wood. To this end, interviews took place with regulators in Germany, with industry representatives, and with the relevant industry associations.

(106) According to the study, Germany imports all the creosote for domestic consumption (about 6 000 t). On the other hand, the total production of the only producer of creosote in Germany is exported (30 000 t, mostly to the USA). However, it is to be taken into account that export of creosote containing up to 500 ppm B[a]P is only permitted to countries with specific climatic conditions requiring enhanced wood protection. This means that in practice the same restrictions apply to exports as to the national market. Therefore the national legislation on creosote does not try to protect the national market by creating barriers to imports while allowing unrestricted exports. Germany also seems to import creosote treated timber; exact figures were, however, unavailable.

(107) More recent and higher-value timber treatment biocides (like metal or boron salts) can substitute for creosote. These products are produced and imported in Germany in a similar manner to creosote.

(108) It was established before that there is a real concern with regards to human health related to the use of creosote and treated timber. Therefore, the protection of health seems to be the real goal of maintaining the national legislation, and not the creation of disguised barriers to trade.

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

3.4. *The absence of obstacles to the functioning of the internal market*

(110) This condition, which is established by Article 95(6), first subparagraph, is new in comparison with the text of the former Article 100a(4) of the EC Treaty. This

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

([29]) Research contract FAIR5-CT98-3933 (fourth framework programme for RTD), Integrating the processes involved in the production of creosoted utility poles.

([30]) 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.

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 obstacles to the operation of the internal market has to be understood as a disproportionate effect in relation to the pursued objective.

(111) Germany asserts that the effects of the more restrictive German legislation on the functioning of the internal market can be considered to be small, and this for the following reasons:

— tar-oils are unavoidable byproducts of the coking industry, having a low economic value. Major producers are located in Germany and the United Kingdom,

— the parties most affected by the more stringent national provisions are therefore the German producers, which clearly demonstrates that the national regulations have not been enacted as a means of economic discrimination or disguised restriction on trade.

(112) Germany further affirms that there are no other measures possible which would have a smaller adverse effect on the functioning of the internal market while retaining a comparable level of protection.

(113) According to the study by ERM ([31]), the European creosote-production industry is characterised by the following features:

— creosote is produced as a byproduct, not a primary one,

— production exceeds consumption to a significant degree,

— there are a small number of creosote producers,

— there is a decline in demand.

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

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

(116) 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.

(117) Table 4 gives a survey of the situation with regard 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 Germany.

Table 4

Production, sales and trade in creosote in Europe ([32])

Country	Number of producers	Possibility of producing creosote with B[a]P < 50 ppm	Sales of Creosote (tonnes/year) 1995	Trade with Germany
Austria	1	No	—	Yes
Belgium	1	Yes	3 900	No
Denmark	1	Yes	0	Yes

([31]) See footnote 30.

([32]) *Source*: see footnote 30, 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.

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

(118) Marketing and use of creosote have been regulated in Germany since 1991. The effect of the legislation has been mainly the elimination of the market for brush application (private consumers) and the introduction of restrictions on the professional market (treatment process, use of creosote containing less than 50 ppm B[a]P except for railway sleepers and electricity poles for export).

(119) As a result the German creosote market is restricted to producers who are able to produce creosote with B[a]P level of < 50 ppm, which eliminated the Austrian creosote producer from the German market. Most of the producers in other Member States can comply with the German regulations. In fact, almost all domestically consumed creosote is imported from other Member States. A very small market for creosote containing up to 500 ppm B[a]P still seems to exist (exemption in the national regulations for export) but this market is virtually unknown.

(120) Due to the restrictions, competition has increased and the margins have been lowered in creosote products for marketing and use within Germany. The decline in the market has mainly and disproportionately affected the German producer who had to reduce its creosote output, focus on export markets, re-direct surplus output into lower value products such as carbon black feedstock and electrode pitch. This situation does not seem to have changed after the approval of Directive 94/60/EC.

(121) In what concerns the creosote treated timber, there are some five companies treating wood with creosote (pressure/vacuum impregnation) and it is primarily used for railway sleepers and power/telecommunications poles. Market distortion in trade with treated wood could result from the fact that only wood treated with creosote containing less than 50 ppm B[a]P can be imported, whereas wood treated with creosote containing up to 500 ppm B[a]P can be exported. However, the study states that the quantity of such wood exported seems to be very small.

(122) The market for railway sleepers has declined from a peak of 200 000 sleepers per year during the 1950s to approximately 30 000 sleepers per year in 1995. The main reason is the replacement by concrete as the increased mass of the sleepers is required for modern lines used by high-speed trains. The market for creosote-treated poles is also declining as salt treatment is increasingly used in all applications (power transmission; telecommunication, agriculture). A review on behalf of the Federal Environment Agency into the German market for treated timber in 1992 concluded that about 2 million m^3 of wood is used per year in Germany. 750 000 m^3 is pressure treated with salt, which accounts for 70 to 90 % of the overall market for the treatment of wood.

(123) The market for the treatment of wood with creosote appears to have been declining prior to the implementation of the German legislation, although the legislation appears to have accelerated the trend. Trends to use alternatives for the main applications of treated wood (railway sleepers and poles) had already existed before the implementation of the German regulations and were thus merely reinforced.

(124) In conclusion, the direct volume and value of trade in creosote affected by German regulations is small since the use of creosote has already been effectively reduced. As the national legislation has been in place since 1991,

the maintenance of the national legislation after the approval of Directive 94/60/EC does not change the previously existing situation, which did not seem to have provoked significant distortions of the internal market for treated timber or for creosote.

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

IV. **CONCLUSION**

(126) 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 Federal Republic of Germany 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,

— 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.

(127) 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 tar-oils, contained in the Banned Chemicals Ordinance, section 17 appended to paragraph 1, and the Hazardous Substances Ordinance, paragraph 12 in conjunction with Appendix III, No 15, and paragraph 15 in conjunction with Appendix IV No 13, as notified on 4 July 1995 are approved.

Article 2

This Decision is addressed to The Federal Republic of Germany.

Done at Brussels, 26 October 1999.

For the Commission

Erkki LIIKANEN

Member of the Commission