COMMISSION DECISION

of 26 October 1999

on the national provisions notified by the Kingdom of Denmark concerning the limitation to the placing on the market and use of creosote

(notified under document number C(1999) 3427)

(Only the Danish text is authentic)

(Text with EEA relevance)

(1999/835/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 96/60/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 amongst others the use and marketing of creosote and similar coal tar distillates, as well as preparations containing them, by limiting the content of one specific component, benzo[a]pyrene, 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 not respecting those limits may not be placed on the market.

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

2. The Danish national provisions

(4) Under the Danish legislation, creosote are considered as biocides for which Denmark has had in place an approval regime since 1980, following the adoption of Law 212 of 23 May 1979 on chemical substances and products [4]. The approval scheme was introduced, because Denmark regarded the substances in question as a significant potential threat to health and the environment. Details of the approval scheme are laid down in Chapter 7 of the Law, which is entitled. Approval of chemical substances and products for specific purposes.

(5) All chemical substances or products used for a range of purposes, which are specified in the Annex to the Law, have to be approved by the Minister for the Environment prior to sale, import or use of the substance or product. Among other categories, the

[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] Act on chemical substances and products, notified in the form of the Consolidated Act from the Ministry of the Environment No 583 of 9 July, 1993.

Annex lists the item 'pesticides' which includes chemical substances and products intended for control of:

— plant diseases,

— fungus attacking wood,

— undesired plants,

— algae,

— mucus secreting organisms in pulp,

— and others.

All wood preservatives, including creosote, are covered by the second indent.

(6) Approvals are granted for periods of eight years. For chemical substances and products classified as ,very toxic, or ,toxic, approvals are valid for a period of four years. The Minister may in special cases fix shorter approval periods.

(7) Approvals granted before September 1, 1987, expired on September 1, 1995. For chemical substances and products classified as 'very toxic' and 'toxic', however, approvals expired on September 1, 1991. The Law stipulated that the Minister had to lay down rules for renewal of approvals and on termination of the right to sell or import substances, which cannot be approved.

(8) Applications for approval shall contain information on the purposes for which the substance or product is intended, its composition and possible effects on health or the environment, which its necessary to lay down the approval terms. For approved substances or products, any significant modification or addition to the information submitted has to be notified.

(9) Approval cannot be granted:

— for substances or products which in connection with use or related handling and storage present, on the basis of available investigations or experience are suspected to present particular hazards to health or damage to the environment,

— for substances or products, if other substances, products or methods exist in the same field of application, which present, or on the basis of available investigations or experience are suspected to present, significantly less hazards to health or damage to the environment.

(10) The approval may be granted on the basis of detailed conditions relating to the contents of the substance or product, its quantity, sale, import, packaging, advertising, and labelling prescribing its use and storage etc. Moreover, approval may in special cases be granted on the condition that within a specified time limit further investigation shall be made to clarify such properties of the substance or product, which may be relevant to health or the environment.

(11) Holders of approvals have to pay an annual charge and an additional fee depending on turnover of the sale of the product.

(12) An approval may be repealed if the approval terms are violated or if deemed necessary on the basis of new information. An approval shall be repealed immediately upon demonstration that the chemical substance or product involved presents serious hazards to health or the environment.

(13) To reduce the overall consumption of approvable substances and products, the Minister for the Environment can lay down rules restricting or banning the use of such substances and products in specific areas of land. He can also lay down rules that professional application of pesticides is allowed only by persons holding a certificate or training in environmentally conscious and sound uses of such products.

Application of Chapter 7 of the Law on chemical substances and products to creosote

(14) After a short period of time following the introduction of the Law, a dispensation was granted to allow the continued use of creosote without approval, as it was considered reasonable to give the market more time to meet the greatly increased documentation requirements.

(15) In 1987 and 1989, approval was given for the use of creosote for pressure impregnation of wood in closed systems for railway sleepers and masts only, and the general dispensation was withdrawn. Prior to this, the substance had been used for a great number of products. The approvals expired on 1st January 1991. Since that time there have been no applications for approval of creosote for wood treatment in Denmark.

(16) The national legislation applicable in Denmark was notified, together with the request for derogation under the former Article 100a(4) of the EC Treaty, by letter of 20 December 1995. In that letter, the Danish authorities expressed their determination to completely ban the use of creosote for wood treatment on the basis of existing legislation, i.e. by not approving creosote containing products. In addition Denmark wants to ban completely the current use of treated wood for private application even if the B[a]P content is below 50 ppm and for

industrial application even if the B[a]P is below 500 ppm. However, in their letter, the Danish authorities underlined the fact that the existing approval regime allows for the placing on the market and the use of creosote containing products in Denmark, if it can be documented that their placing on the market or use will not have undesirable consequences for human health or the environment.

(17) However, no specific legislation on creosote was in place. The described system applied to all pesticides, including creosote, for the application as wood preservative.

(18) In Annex to the letter of 20 December 1995, a draft order was notified amending the existing order limiting the sale and use of pentachlorophenol (PCP) by introducing certain specific provisions on creosote. However, the Danish authorities renounced to this draft order, which never came into force.

(19) Instead, by letter of 18 July 1996, Denmark notified an order limiting the sale and use of creosote. Article 2 of this order lays down a total ban on import, sale, or use of creosote except for certain exemptions. These exemptions are, in principle, coherent with the provisions of Directive 94/60/EC, but there is an additional condition: the exemptions have to be approved in accordance with Chapter 7 of the Law on chemical substances and products. The order entered into force on 20 July 1996. According to the Danish authorities, this order should be seen as a temporary measure, which does not affect the communication of 20 December 1995.

(20) Concerning the marketing and use of wood treated with creosote, there are no provisions in the Danish legislation prior to the abovementioned order.

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

(21) Table 1 shows in detail the differences between the restrictions on marketing and use of creosote and wood treated with creosote as laid down in Directive 94/60/EC and the Danish legislation in force at the date of adoption of the Directive.

Table 1

Comparison between Directive 94/60/EC and the Danish legislation

	Council Directive 94/60/EC	Danish legislation
B[a]P < 50 ppm	No restrictions on sale or use of creosote or newly treated wood	Sale and use of creosote are prohibited unless approval according to the Law on chemical substances and products has been obtained No product is approved There are no provisions concerning treated wood
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 Creosoted wood may only be used for professional and industrial applications: — railways — electricity poles — fencing — waterways	As above

	Council Directive 94/60/EC	Danish legislation
B[a]P 50—500 ppm *(cont'd)*	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	
B[a]P > 500 ppm or water soluble phenols > 3 %	Sale and use of creosote and treated products totally banned	As above
Old treated wood	Use controlled as for wood treated with creosote containing B[a]P between 50 and 500 ppm	There are no provisions concerning old treated wood

(22) In summary, the Danish provisions which are the object of this Decision are more restrictive in one aspect:

— products containing creosote intended for wood preservation must be individually approved before they can be used.

(23) However, in contrast to Directive 94/60/EC the Danish legislation existing before entry into force of the Directive, contains no explicit rules with regards to B[a]P content or other physical parameters of creosote which can be used for the treatment of wood and are therefore potentially less restrictive. Furthermore, no restrictions exist regarding the use of treated wood. The Danish authorities could, therefore, approve products that do not respect the limits established by the Community Directive.

II. **THE PROCEDURE**

(24) Directive 94/60/EC was adopted on 20 December 1994. In the Council meeting, Denmark stated that 'a total ban on creosote is the only acceptable solution if health and environmental protection are to be taken into account. Denmark therefore reserves the right to apply stricter national provisions'.

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

(26) On 20 December 1995, the Danish authorities informed the European Commission that Denmark, on grounds of health protection, intended to continue applying its existing national provisions on creosote, therefore derogating from Directive 94/60/EC concerning creosote by applying the former Article 100a(4) of the EC Treaty.

(27) The Commission invited other Member States to present their observations regarding the Danish request by letter of 27 March 1996. As a result of this consultation the Commission received comments from Austria, Germany, and Greece.

(28) *Austria* agrees with Denmark that creosote can be regarded as carcinogenic independent of the content of B[a]P. Austria supports the Danish position with regards to the necessary protection of groundwater, given that this is the main source of drinking water in Denmark and that the degradation of creosote is slow due to the prevailing geographic and climatic conditions, Austria underlines, however, that there is not direct link between the contamination in the close vicinity of a production site and the hazardousness of a substance when it is used. The Austrian authorities consider it justified allowing the continued use of creosote containing up to 500 ppm B[a]P for the impregnation of railway sleepers and poles in industrial installations using pressure-vacuum technology. In contrast, it is

indispensable to ban the sale and use for consumers, who would use the product by brush application which would lead to high inhalatory and dermal exposure and contamination of the environment through spills, dripping, and disposal of left-overs. Overall, Austria supports the Danish request.

(29) *Germany* supports the Danish request and refers to its own notification requesting derogation under the former Article 100a(4) of the EC Treaty concerning Directive 94/60/EC.

(30) *Greece* informs the Commission that it agrees with the Danish request to apply national provisions regarding creosote in accordance with the former Article 100a(4) of the EC Treaty.

(31) 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 Danish authorities of the fact that their notification regarding the placing on the market and use of creosote would be treated in the framework of the new provisions of the Treaty.

III. **ASSESSMENT**

1. **Applicable rules**

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

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

(34) In the absence of specific provisions extending their application, the old provisions of Article 100a(4) of the EC treaty are regarded as repealed from the day of 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**

(35) The notification submitted by the Danish 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.

(36) 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 its 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.'

(37) Directive 94/60/EC was adopted on 20 December 1994. It had to be transposed by the Member States by 20 December 1995 and enforced by 20 June 1996. Denmark notified its national legislation relating to creosote, which had been in place since 1980, on 20 December 1995 and thus before the date foreseen for the application of the national provisions transposing the Directive.

(38) As mentioned before, on 18 July 1996 the Danish authorities notified a new order regulating the marketing and use of creosote and of wood treated with creosote which entered into force on 20 July 1996. This legislation has to be regarded as a temporary implementation of directive 94/60/EC, which is underlined by the Danish authorities in their notification, where they stress that the earlier request for derogation based on the former Article 100a(4) of the EC Treaty concerning the existing legislation is not affected.

(39) It is therefore well justified to consider that in this case the conditions of Article 95(4) of the Treaty are met, according o 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.

(40) In the light of what precedes, the Commission considers that the request of the Kingdom of Denmark for derogation from Directive 94/60/EC as notified on 20 December 1995 is admissible under Article 95(4) of the EC Treaty.

3. **Assessment of merits**

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

(42) The Danish authorities have based their request on the need of protection of human health and the environment. Creosote, as other wood preservatives, is deemed to pose a significant potential threat to health and the environment.

(43) In support of the request, Denmark submitted a brief memorandum, dated 5 December 1995, on the human health and environmental concerns of creosote including an account of measurements of the pollution of soil and groundwater arising from land previously used by creosote treatment companies. However, the information contained in this memorandum was rather limited. It was, therefore, not possible to examine the merits of the request based exclusively on this information.

(44) In order to verify whether the Danish national provisions concerning marketing and use of creosote-treated wood, are indeed necessary and proportionate to that end, the Commission mandated a study to an external consultant [5]. The study tries to assess whether the risk of cancer arising from the use of creosote and creosote-treated wood by consumers has been underestimated, whether the Danish population or the environment are exposed to unusually high doses of creosote through sale and use of the product itself or the use of creosote-treated wood. 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 Denmark.

(45) 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 he regime of which the Danish request was notified, these substantial efforts of the Commission to find the elements necessary for the justification of the maintenance of the Danish national provisions cannot constitute a precedent or 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.

(46) 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 in the following. In addition, all studies have been made available to the Scientific Committee on toxicity, exotoxicity, 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] Dr P. M. Sorgo, *Study on the Justification in Scientific Terms of Allowing Denmark to Retain is National Laws on Creosote*, Final Report, November 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.
Environmental Resources Management, *Scientific Evaluation of the German Request for Derogation from Provisions of Council Directive 94/60/CE Concerning Creosote*, Final Report, 24 April 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.

[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, Hanover, October 1997.

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

3.1.1. *Creosote general information*

(47) 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).

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

— acenaphthene

— naphthalene

— phenanthrene

— anthracene

— fluorene

— fluoranthene

— chrysene

— triphenylene

— benzo[a]anthracene

— benzo[b]fluoranthene

— benzo[k]fluoranthene

— benzo[a]pyrene

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

(50) 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.

(51) 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.

(52) The most important properties of creosote are:

— high fungicidal efficacy,

— high insecticidal efficacy,

— long-term persistence,

— resistance to leaching and weathering.

(53) 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

(54) 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.

(55) 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.

(56) 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 ([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

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

increased risk of cancer of the skin an lip and on 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 are known.

(57) Mostly based on an animal experiment, where the skin of mice was regularly exposed to B[a]P solutions in acetone during their lifetime ([10]), 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 carcinogenic in humans. There is no significant new evidence from more recent investigations, which would affect this conclusion.

(58) 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 ([11]), as last amended by Directive 1999/33/EC ([12]). Drawing largely on the same data as IARC, agreement was reached during the elaboration of Commission Directive 94/69/EC ([13]), EC, 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 an 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.

(59) 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 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 further down.

(60) 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 as pyrene, e.g. B[a]P were absorbed less rapidly. Any estimation of B[a]P uptake based upon the pyrene marker will therefore result in an overestimation and can be considered conservative.

(61) 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 an non-occupational environmental context.

(62) 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.

([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]) 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.

([11]) OJ 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 of Council Directive 67/548/EEC is applicable to creosote.

([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 Polycylic Aromatic Hydrocarbons Among Workers*, Thesis ISBN 90-9007080-X, Nijmwegen 1993.

Environment effects

(63) 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.

(64) 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.

(65) 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 photo-oxidation 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.

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

(67) A study in Sweden ([17]) 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.

(68) 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.

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

3.1.2. *The Danish position*

(70) Denmark regards creosote containing any concentration of B[a]P as carcinogenic, not only if the concentration of B[a]P is higher than 50 ppm, as classified in Directive 94/69/EEC, the 21st adaptation to technical progress of Directive 67/548/EEC. Unlike the classification in the EC, the IARC classification of creosote applies without limit of the B[a]P content. No data are available regarding the carcinogenic properties of creosote containing less than 50 ppm B[a]P.

(71) Creosote is evaluated as mildly to moderately toxic by ingestion and by dermal contact, and as irritant to the

([17]) S. Holmroos, *Analys av kreosotstolpar i Simlångsdalen efter 40 års exponering i fält*. Rapport nr. M205-252.092. Älvkarleby: 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 18.

([19]) Bkh consulting engineers, *Foundation of the appeal against the EC Directive on creosote*, Final Report, Delft, 1 July 1995.

skin and eyes. It induces phototoxicity of the skin and has been demonstrated to be a skin carcinogen in animals. Presence of co-carcinogens can be important in the development of skin cancer. It also induces phototoxic eczema after dermal exposure in connection with sunlight.

(72) Denmark considers that occupational exposure to coal tar creosote increases the incidence of skin cancer among workers. This claim is substandiated by reference to the abovementioned study among workers in Scandinavian creosote impregnation plants ([20]).

(73) In addition to dermal contact with creosote or treated products, occupational exposure to PAHs occurs via inhalation of contaminated workplace air. Impregnation of wood by creosote contributes to atmospheric PAH pollution. Denmark has a limit value of 200 μ/m^3 for the workplace measured in the benzene-soluble particulate fraction. The Danish memorandum contains one example of measurements in one American plant (made before 1985) where results in the range 0,05 to 650 $\mu g/m^3$ had been found. In some investigations the concentration of B[a]P has been measured separately. Especially when the treated wood is heated as in manual metal-arch welding the concentration of B[a]P is significant (0,39 to 0,89 $\mu g/m^3$). Metabolites of creosote compounds could be found in the urine of creosote workers after inhalation and dermal exposure.

(74) Non-occupational exposure (of consumers) occurs through treated wood, e.g. old railroad sleepers are used in Denmark in gardens and playgrounds. Dermal exposure can occur during outdoor activities, especially in summer when high temperatures lead to increased creosote concentrations at the wood surface and people expose more unprotected skin for contact. Wood samples from the surface of old railroad sleepers used in playgrounds showed a high concentration of B[a]P (no concrete figures are provided).

(75) Non-occupational exposure can also occur if impregnated wood is used for construction work and in connection with surface treatment with creosote paints.

(76) Open burning of creosote-treated railway sleepers results in high concentrations of PAHs. If lifetime accumulated doses are used as the best indicator risk, one time acute exposure at sufficient separation distance probably results in an insignificant risk, whereas multiple exposures may present unacceptable risks (no concrete data are given for any of this in the Danish memorandum).

(77) The Danish authorities also mention that creosote also has ecotoxic effects in both soil and water. Creosote and sediment polluted with creosote show a high acute toxicity against aquatic organisms. Many of the substances in creosote can bioaccumulate in nature. The high acute toxicity against aquatic organisms and the lipophilic properties of creosote and many of its components, which enable them to bioaccumulate, makes it an undesirable substance in the environment.

(78) PAHs evaporate from creosote-treated wood and the composition changes in time. Some of the PAH compounds at the soil surface can be degraded by solar irradiation. Microbial degradation can also contribute to the removal of PAHs. Microbial degradation can occur under aerobic and anaerobic conditions. PAHs compounds with four rings and more may be poorly degradable. The degradation is not complete and studies have been conducted at water temperatures above 20 °C whereas the temperature in Danish groundwater is below 10 °C. As the temperature and solar irradiation are lower in Denmark compared to other countries in the Community, the photochemical and microbial degradation of creosote are reduced.

(79) Resuming the use of creosote in Denmark would add to the pollution by PAHs, which already exists, and is very slowly degradable due to Denmark's geographical position and climatic conditions. Combustion of creosote treated wood can release high concentrations of PAH compounds. If the treated wood is burned in fireplaces in private homes the concentrations will increase the risks of effects on human health.

(80) Creosote also contains substances other than B[a]P which are harmful to health and which would threaten the quality of drinking water in Denmark if they were to seep into the groundwater. Phenols, naphthalene and benzopyrenes are some of the substances in creosote that can reach the groundwater. The concentration exceeds the Danish quality criteria. Denmark uses unpurified groundwater as drinking water.

3.1.3. *Evaluation of the Danish position*

(81) The positions of the Danish authorities have to be evaluated in comparison to the information on the

([20]) See footnote 8.

toxicity end ecotoxicity of creosote. In addition, it has to be noted that all the information on health and environmental concerns with regards to creosote, which is put forward by the Danish authorities, was old and had already been known at the time of preparation of Directive 94/60/EC. Especially the available data regarding carcinogenicity had been discussed in great depth during the preparation of the Directive concerning the classification of creosote.

(82) All findings of the various studies have been mentioned in the general information part above. Only very recently, experimental data have become available that show that the carcinogenic risk of creosote containing less than 50 ppm B[a]P might be non-negligible.

(83) With regards to the exposure of workers via inhalation, it is doubtful whether the data measured a considerable time ago in one American plant are of relevance in the Danish context, where relevant standards exist, ensuring a high protection of workers. Furthermore the Dutch authorities in their request for application of the former Article 100a(4) of the EC Treaty concerning the same Directive have also examined the risks to workers from inhalatatory exposure and have concluded that the risks involved are acceptable.

(84) The study, on which the Danish authorities base their claim that creosote exposure leads to higher incidence of skin cancer, has already been mentioned above ([21]). In fact, the conclusions of the authors themselves are far less clear than those of the Danish authorities ('no valid conclusions'); so are those of other epidemiological studies.

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

(86) In Denmark wood preservation with creosote had taken place for more than 100 years. Three impregnation facilities were operating in 1987, when the approval system was applied. The individual licenses approved the use of creosote only for treating wood in closed industrial installations. Use of treated wood was restricted to railway sleepers and poles. The last approval expired in January 1991. No approvals have been granted since. Table 2 shows the use of creosote treated wood in Europe in 1990, i.e. before the last approval for the use of creosote in Denmark expired.

(87) Already in 1990, Denmark hat the second lowest use of creosote-treated wood-per capita and one of the lowest per surface. A decline in the use of creosote-treated wood started already in the early 70s to the benefit of other impregnation substances such as copper chromium arsenic complexes (CCA).

(88) In Denmark, there is no epidemiological evidence, no reports of adverse incidents, and no data or estimates for creosote intake from various exposures available. It is therefore not possible to make direct estimates of the amount of creosote taken in by or affecting the members of the Danish population. But given the low use per capita and surface, exposure is probably lower. If Directive 94/60/EC was applied, there would probably be an increase but it is not possible to make quantitative estimates. However, even a significant increase would not lead to exposure values higher than in other European countries.

Table 2

Consumption of creosoted wood in Europe (1999) ([22])

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

([21]) See footnote 8.
([22]) *Source:* see footnote 19, p. 6.

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

(89) Denmark mentions the emission of PAHs from treated wood, if this is burnt by consumers. No data are presented on the quantities of wood that are so disposed of; furthermore, it has to be noted that the burning of wood (treated or not) always produces a certain amount of PAHs. The concern of the Danish authorities with regards to the disposal of old and disused railway sleepers is not different from the situation in other countries with a second hand market of creosote-treated wood and cannot be a proof of a specific situation.

(90) Contamination of the environment by creosote-related sources can include emissions to air and water from Creosote impregnation plants, seepage and run-off from disused plants and the dissemination of creosote constituents from treated wood into soil and water. As a consequence it is possible that constituents such as PAHs will contaminate terrestrial and aquatic organisms. However, PAHs found in environmental compartments are originating from a variety of sources. It is often difficult to ascribe their levels to any particular source such as creosote.

(91) In Denmark, creosote compounds were only found in soil and groundwater near closed down wood impregnation facilities. Denmark has established guideline limit values for some organic substances in soil and groundwater. Total PAH compounds should be below 1 mg/kg dry weight to avoid ecotoxicological effects. For B[a]P alone, the limit value is 0,1 mg/kg. The water quality criterion in groundwater is 0,2 µg/1 for the sum of six PAH compounds (including B[a]P. At some polluted sites (closed down impregnation facilities), concentrations of B[a]P up to 320 mg/kg were found in soil and up to 3 µg/1 in some water samples. However, no data were provided for the normal or general situation.

(92) With regards to the specific situation of Denmark, which was evoked in the request, the following analysis applies: Denmark claims to have a specific problem, because in general, drinking water is being generated directly from unpurified groundwater, which therefore needs special protection. The use of treated wood could lead to the contamination of groundwater through the leaching of creosote compounds from the treated wood in contact with soil. At present there are three sites of closed down creosote impregnation plants in Denmark, where elevated levels of PAHs in groundwater were found and where the adjacent groundwater is excluded as a source of drinking water. This contamination is, however, due to the operating practices of the impregnation sites and cannot be generalised for creosote-treated wood used as sleepers or poles. As has been shown above, leakage of PAHs from creosote-treated wood into soil and or ground water is unlikely to be significant since they remain mostly within a very short distance of the poles and posts from which they originate, even after years of contact. PAHs are strongly adsorbed on the soil's organic matter and the possibility of reaching groundwater is minimal. The argument of a general protection of groundwater from creosote originating in treated wood is thus not applicable.

(93) No data could be found with regards to the concentration of creosote constituents in Danish waters and sediments. From the available information, it would seem that apart from localised contamination from three disused wood impregnation sites, the Danish

aquatic environment is not unduly contaminated with creosote or its PAH constituents.

(94) If Denmark were to apply the provisions of Directive 94/60/EC, exposure of the public would potentially increase due to the then allowed use of creosote by consumers, increased use of treated wood, and higher B[a]P content of creosote used industrially for railway sleepers and poles. It is rather impossible to estimate how big this increase will be, as the product has not been on the market for many years.

(95) A particular concern expressed by the Dutch and German authorities in their requests for derogation from Directive 94/60/EC under the former Article 100a(4) of the EC Treaty lies with creosote-treated wooden playground equipment. As in these other cases, no data are available for Denmark, but calculations and estimates would probably result in figures comparable to those contained in the studies made in the framework of the Dutch, German, and Swedish requests, as the scenario of children playing on creosote-treated playground equipment is not country specific. Therefore the exposure assessments made in relation to these requests are also applicable. Results were as follows:

(96) The exposure through dermal contact for children playing on dry wood treated with creosote calculated in the study mandated by the Commission in the framework of the Swedish request was 0,85 ng/kg bw/day for the scenario of 2 hours a day, 50% coverage of open skin, body weight (bw) of 15 kg and 1,7 ng/kg bw/day for an exposure time of four hours a day. The Dutch authorities, in their model calculation, though using a slightly different methodology, have arrived at daily exposure dose of 2 ng/kg bw/day, which is very close to this result and thus increases confidence. Exposure in Denmark would normally be similar.

(97) The magnitude of the risks due to such a level of exposure are deemed to be unacceptable by the Dutch authorities. Furthermore, the various studies recommended that the Commission, before taking a decision, awaits the results of the long-term carcinogenicity study that was ongoing at that time [23] (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 in the following.

3.1.4. *Evaluation of the Scientific Committee for toxicity, ecotoxicity, and the environment*

(98) 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 in recital 59, 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.

(99) This study [24] 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. Due to the high viscosity of the products, they could not be applied directly to the skin of the mice but had to be diluted in toluene, Solutions with various concentrations of the product and thus various B[a]P concentrations, as well as pure B[a]P solutions and a control of pure toluene were applied to groups of 62 mice for a time of 78 weeks (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.

(100) The Commission submitted this study and all other documents containing scientific and exposure information on creosote to the Scientific Committee for toxicity, ecotoxicity and 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. This opinion was revised on 4 March 1999.

(101) The SCTEE observes that the Fraunhofer study is well-designed and reaffirms the carcinogenic potential of coal tar preparations. Due to the genotoxic potential of PAHs including B[a]P, there is no threshold concentration determining carcinogenicity. The study indicates clearly a linear dose-response relationship between the B[a]P content of the administered preparations and the number of animal 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

[23] See footnote 7.

[24] See footnote 7.

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.

(102) 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 o 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 o carcinogenic risk, e.g. for the dermal exposure of children playing on wood treated with creosote is therefore difficult.

(103) 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 per kg bodyweight, which induces in 25 % of the test animals tumours at a specific tissue site within the standard life span of the species. The creosote formulations tested had a five-fold higher overall carcinogenic potency (2,7 µg/kg bw/day).

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

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

(106) 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 62 ng/kg bw for a person weighing 70 kg (i.e. much higher than the dermal exposure).

(107) 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 between cancer incidence and B[a]P dose. However, the cancer potency of the creosote preparation was five-fold higher than judged from its B[a]P content.

2. On the basis of the available information, even taking into account the considerable uncertainties in assessing he 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*

(108) The Danish authorities have not shown, nor could it be demonstrated through further research, that a specific situation exists in Denmark 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 if Denmark applied the provisions of Directive 94/60/EC.

(109) However, the Commission has received additional information in the framework of similar requests from the Netherlands, Germany, and Sweden 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.

(110) Based on these most recent experimental data, the SCTEE has estimated that here 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, he 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.

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

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

(113) Although the Danish authorities, in their notification of 20 December 1995 under the former Article 100a(4) of the EC Treaty have expressed their intention to ban the existing uses of wood treated with creosote, the national legislation notified by the Danish authorities in that request does not contain provisions concerning treated wood. Such measures, as they have not been formally notified to the Commission, cannot be approved in this Decision.

(114) In accordance with Article 95(7) of the Treaty, the Commission is already examining the appropriateness to adapt to technical progress the provisions of Directive 94/60/EC regarding creosote. In addition, the Commission will evaluate the use of creosote under the review programme established in Article 16 of European Parliament and Council Directive 98/8/EC of 16 February 1998 on the placing of biocidal products on the market [25] 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 [26].

3.2. *The absence of arbitrary discrimination*

(115) 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.

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

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

[26] 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***

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

(118) The Commission mandated a study ([27]) to examine the implications of maintaining the national provisions in Denmark on the functioning of the internal market. The study undertook to collect all available information regarding the volume and value of trade with other Member States affected, the interest which Denmark might have in using its national rules to promote a national interest in substitutes, and the interest which Denmark might have in using its national rules to promote alternatives to creosote-treated wood. To this end, interviews took place with regulators in Denmark, with industry representatives, and with the relevant industry associations.

(119) In the general framework of its legislation on wood preservatives, the Danish Ministry of the Environment has restricted, or is in the process of trying to restrict the use of a number of products. Inorganic metal salts (CCA) were used as the primary alternative to creosote in Denmark until the use of such treated wood was banned by order No 1042 of 17 December 1997.

(120) There are four producers of 'organic' wood preservatives in Denmark producing tin-based and azole-based preservatives. Competitors from outside Denmark have expressed their concern that one of the effects of the Danish policy on wood preservatives would be the exclusive possibility to use products manufactured in Denmark for the treatment of wood to be sold in Denmark, while the existing producers of other preservatives in Denmark would continue to export to other countries. However, as the use and import of wood treated with creosote are not regulated, the national legislation does not have the alleged effect on the sale of treated wood in Denmark.

([27]) 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.

(121) Concerning he import of wood preservatives there are no special rules for imported products that are not applicable to domestically produces products. Although there is the possibility that the producers of certain alternative wood preservatives in Denmark would benefit from the overall Danish policy regarding wood preservatives, it is also to the detriment of the domestic producers of preservatives currently used.

(122) The Danish authorities should take into consideration that the possibility to export creosote, while its use and thus import are prohibited in Denmark, could constitute a disguised restriction on trade to the benefit of the Danish producer of creosote.

(123) However, as was established before, there is a real concern with regards to human health, which justifies the more restrictive national legislation as it has been found for other Member States. The primary objective of the national legislation is thus the protection of human health and not the preference of domestic production.

(124) Overall, the Commission considers that there is no evidence of a disguised restriction on trade between Member States provoked by the Danish provisions concerning the use of creosote.

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

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

(126) 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.

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

(128) According to ERM ([28]), 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 are used by individual consumers, mostly in the United Kingdom and Ireland.

(129) 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.

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

(131) Denmark is an exclusive exporter of creosote. There is one producer of creosote in Denmark, with a production of approximately 14 000 tonnes per year. Production of creosote accounts for about 4,5 % of overall output of coal tar derived products (pitch, carbon black etc.). The complete production of creosote is being exported, mostly to Sweden, Norway and Germany. The quantities of creosote sold in Denmark were 630 tonnes in 1987, 552 tonnes in 1988, 434 tonnes in 1989 and 0 tonnes in 1990. A very small quantity of creosote is imported as part of medicinal preparations and in creosote-derived carbolineum paint preparations.

Table 3

Production, sales and trade in creosote in Europe ([29])

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

([28]) See footnote 27.

([29]) *Source:* See footnote 27, 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.

(132) Since January 1991 there have been no applications for approval of creosote to be used in wood impregnation facilities in Denmark. The last impregnation facility using creosote closed down already in 1989. There is still a limited damand for creosote-treated railway sleepers and poles, which are imported: 1 365 tonnes in 1992 and 770 tonnes in 1995 (about 7 500 m^3). No creosote-treated timber is exported from Denmark.

(133) The market for the treatment of wood with creosote appears to have been declining already prior to the expiration of the last approval for the use of creosote in Denmark, although the legislation does appear to have accelerated the trend. Trends to use alternatives for the main applications of treated wood (railway sleepers and poles) had already existed before, because creosote-treated railway sleepers were replaced by concrete sleepers, the demand for telephone poles declined as more and more lines were put underground, and creosote-treated timber pilings were replaced with concrete/steel pilings.

(134) Overall, the Danish wood preservation industry produces about 220 000 m^3 of treated wood per year. According to data from Eurostat, in 1995, 69 500 tonnes of treated timber (all types) were imported into Denmark (about twice the quantity of 1994), and 2 700 tonnes exported. Denmark is thus a net importer of treated timber.

(135) Taking into account the preceding observations, the Commission considers hat there is no evidence that he Danish 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**

(136) 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 Denmark pursuant to the former Article 100a(4) and examined under the new Article 95(4) and (6) of the EC Treaty:

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

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

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

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

HAS ADOPTED THIS DECISION:

Article 1

The provisions applicable to the marketing and use of creosote, as contained in Chapter 7 of Law No 212 of 23 May 1979 are approved, in so far as they are applied in such a manner:

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

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

Article 2

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 26 October 1999.

For the Commission

Erkki LIIKANEN

Member of the Commission