

Official Journal

of the European Communities

ISSN 0378-6978

L 329

Volume 42

22 December 1999

English edition

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COMMISSION

COMMISSION DECISION

of 26 October 1999

on the national provisions notified by the Kingdom of Denmark concerning the use of sulphites, nitrites and nitrates in foodstuffs

(notified under document number C(1999) 3416)

(Only the Danish text is authentic)

(Text with EEA relevance)

(1999/830/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Whereas:

THE FACTS

1. Community legislation

- (1) Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption was adopted on 21 December 1988⁽¹⁾. Article 3(2) of this Directive provides that the Council shall, acting on a proposal from the Commission under the procedure laid down in former Article 100a of the EC Treaty, adopt a list of additives the use of which is authorised to the exclusion of all others and the list of foodstuffs to which these additives may be added, the conditions under which they may be added and, where appropriate, a limit on the technological purpose of their use.
- (2) Pursuant to the above provision, the Commission presented three proposals for specific directives, the first on sweeteners, the second on colours and the third on

additives other than colours and sweeteners. These proposals were prepared in accordance with the requirements of Article 6 of Directive 89/107/EEC after consultation with the Scientific Committee for Food (SCF) which had been asked earlier by the Commission to evaluate the safety of additives. The opinions of the SCF, on which the Commission based its proposals for directives, were constantly taken into consideration throughout the discussions on these proposals in the European Parliament and the Council, right up to the adoption of the directives themselves. Three specific directives constituting stages in the comprehensive directive referred to in Article 3 of Directive 89/107/EEC were thus adopted⁽²⁾. Only the third of these three Directives is concerned with this Decision, i.e. European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.

2. National provisions

- (3) Before the entry into force of Directive 95/2/EC, the Danish legislation consisted of a positive list drawn up in October 1988 determining the conditions of use in foodstuffs of additives, including nitrates, nitrites and sulphites, and Order No 242 of 17 April 1991. Member States were required to bring into force the laws, regulations and administrative provisions necessary to

⁽¹⁾ OJ L 40, 11.2.1989, p. 27. Directive 89/107/EEC as last amended by Directive 94/34/EC (OJ L 237, 10.9.1994, p. 1).

⁽²⁾ Directive 94/35/EC on sweeteners (OJ L 237, 10.9.1994, p. 3). Directive 94/35/EC as last amended by Directive 96/83/EC (OJ L 48, 19.2.1997, p. 16). Directive 94/36/EC on colours (OJ L 237, 10.9.1994, p. 13). Directive 95/2/EC (OJ L 61, 18.3.1995, p. 1). Directive 95/2/EC as last amended by Directive 98/72/EC (OJ L 295, 4.11.1998, p. 18).

comply with the directive before 25 September 1996. Directive 95/2/EC was transposed in Denmark by Order No 1055 of 18 December 1995⁽³⁾. This Order of 18 December 1995 was supplemented by a positive list⁽⁴⁾ determining the conditions of use of additives in foodstuffs. By letter of 15 July 1996, the Danish Government forwarded to the Commission a copy of these national measures transposing Directive 95/2/EC, pointing out, however, that these measures did not concern sulphites, nitrites and nitrates and that it intended, with regard to those additives, to enact national provisions derogating from Directive 95/2/EC in accordance with Article 100a(4) of the EC Treaty. On 23 September 1996, namely two days before the time limit for transposing Directive 95/2/EC, Order No 834 was adopted, supplementing the previous Order No 1055 and the positive list as concerned specifically sulphites, nitrites and nitrates⁽⁵⁾.

3. Sulphites

- (4) Directive 95/2/EC on food additives other than colours and sweeteners determines the conditions of use of a certain number of additives belonging to several categories such as preservatives and antioxidants. Article 1(3) of Directive 95/2/EC defines preservatives as 'substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by micro-organisms' and antioxidants as 'substances which prolong the shelf-life of foodstuffs by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes'. For this category of additive, Article 2(1) of the Directive provides that only substances listed in Annex III may be used in foodstuffs for the purposes mentioned in Article 1(3). Article 2(4) provides that the additives listed in Annex III may only be used in the foodstuffs referred to in that Annex and under the conditions specified therein. Annex III, Part B specifies, in the form of a table, the conditions of use for sulphur dioxide (E 220) and sulphites⁽⁶⁾: sodium sulphite (E 221), sodium hydrogen sulphite (E 222), sodium metabisulphite (E 223), potassium metabisulphite (E 224), calcium sulphite (E 226), calcium hydrogen sulphite (E 227), and potassium hydrogen sulphite (E 228)⁽⁷⁾:

⁽³⁾ Sundhedsministeriets bekendtgørelse nr. 1055 af 18 December 1995 om tilsætningsstoffer til levnedsmidler. Sundhedsmin., j.nr. 95-3400-24. Levnedsmiddelstyrelsen, j.nr. 100-0066. Lovtidende A hæfte 198 udgivet den 30 December 1995 s. 5571. GBEK.

⁽⁴⁾ Fortegnelse over tilsætningsstoffer til levnedsmidler-Positivlisten (Levnedsmiddelstyrelsen Sundhedsministeriet). Publikation nr. 231, December 1995.

⁽⁵⁾ Lovtidende A 1996 hæfte 145 udgivet den 23 September 1996 s. 5089. GBEK.

⁽⁶⁾ The term 'sulphite agents' comprises both sulphur dioxide and sulphites. In the present Decision, the term 'sulphites' will be used to describe 'sulphite agents'.

⁽⁷⁾ These extracts from the Directive are reproduced for information purposes. They do not create any right or obligation other than those deriving from the text of the Directive as published in its entirety in the *Official Journal of the European Communities*. Only the latter text is authentic.

Foodstuff	Maximum level in relation to the quantity available (mg/kg or mg/l, as appropriate) expressed as SO ₂
Burger meat with a minimum vegetable and/or cereal content of 4 %	450
Breakfast sausages	450
<i>Longaniza fresca</i> and <i>butifarra fresca</i>	450
Dried salted fish of the <i>Gadidae</i> species	200
Crustaceans and cephalopods: — fresh, frozen and deep-frozen Crustaceans, <i>penaeidae solencerides</i> , <i>Aristeidae</i> family: — up to 80 units — between 80 and 120 units — over 120 units — cooked	 150 200 300 50
Dry biscuits	50
Starches (excluding starches for weaning foods, follow-on formulae and infant formulae)	50
Sago	30
Pearl barley	30
Dehydrated granulated potatoes	400
Cereal- and potato-based snacks	50
Peeled potatoes	50
Processed potatoes (including frozen and deep-frozen potatoes)	100
Potato dough	100
White vegetables, dried	400
White vegetables, processed (including frozen and deep-frozen white vegetables)	50
Dried ginger	150
Dried tomatoes	200

Foodstuff	Maximum level in relation to the quantity available (mg/kg or mg/l, as appropriate) expressed as SO ₂
Horseradish pulp	800
Onion, garlic and shallot pulp	300
Vegetables and fruits in vinegar, oil or brine (except olives and golden peppers in brine)	100
Golden peppers in brine	500
Processed mushrooms (including frozen mushrooms)	50
Dried mushrooms	100
Dried fruits	
— apricots, peaches, grapes, plums and figs	2 000
— bananas	1 000
— apples and pears	600
— other (including nuts in shell)	500
Dried coconut	50
Candied, crystallised or Glico fruit, vegetables, angelica and citrus peel	100
Jam, jelly and marmalade as defined in Directive 79/693/EEC (except extra jam and extra jelly) and other similar fruit spreads including low-calorie products	50
Jams, jellies and marmalades made with sulphated fruit	100
Fruit-based pie fillings	100
Citrus-juice based seasonings	200
Concentrated grape juice for home wine-making	2 000
<i>Mostarda di frutta</i>	100
Jellying fruit extract, liquid pectin for sale to the final consumer	800
Bottled whiteheart cherries, rehydrated dried fruit and lychees	100

Foodstuff	Maximum level in relation to the quantity available (mg/kg or mg/l, as appropriate) expressed as SO ₂
Bottled, sliced lemon	250
Sugars as defined in directive 73/437/EEC, except glucose syrup, whether or not dehydrated	15
Glucose syrup, whether or not dehydrated	20
Treacle and molasses	70
Other sugars	40
Toppings (syrups for pancakes, flavoured syrups for milkshakes and ice cream; similar products)	40
Orange, grapefruit, apple and pineapple juice for bulk dispensing in catering establishments	50
Lime and lemon juice	350
Concentrates based on fruit juice and containing not less than 2,5 % barley (barley water)	350
Other concentrates based on fruit juice or comminuted fruit; <i>capilé groselha</i>	250
Non-alcoholic flavoured drinks containing fruit juice	20 (carry-over from concentrates only)
Non-alcoholic flavoured drinks containing at least 235 g/l glucose syrup	50
Grape juice, unfermented, for sacramental use	70
Glucose-syrup-based confectionery	50 (carry-over from the glucose syrup only)
Beer, including low-alcohol and alcohol-free beer	20
Beer, with a second fermentation in the cask	50

Foodstuff	Maximum level in relation to the quantity available (mg/kg or mg/l, as appropriate) expressed as SO ₂
Wine	In accordance with Council Regulations (EEC) No 822/87, (EEC) No 4252/88, (EEC) No 2332/92 and (EEC) No 1873/84 and their implementing Regulations.
Alcohol-free wine	200
Made wine	260
Cider, perry, fruit wine, sparkling fruit wine (including alcohol-free products)	200
Mead	200
Fermentation vinegar	170
Mustard, excluding Dijon mustard	250
Dijon mustard	500
Gelatin	50
Vegetable- and cereal-protein-based meat, fish and crustacean analogues	200

- (5) The Danish Order of 23 September 1996 introduces an Annex, Annex No 9, into the Order of 18 December 1995, specifying in the form of a table the conditions of use of sulphites other than those covered by Community Regulations on wine⁽⁸⁾:

Foodstuff	Maximum quantity added (mg/kg or mg/l, as appropriate) expressed as SO ₂
Garlic pulp	300
Horseradish pulp	600
Apricots	1 000

⁽⁸⁾ These extracts from the Danish legislation are reproduced for information purposes. They do not create any right or obligation other than those deriving from legal texts that have been adopted in law and published in the official Danish publications. Only the latter texts are authentic.

Foodstuff	Maximum quantity added (mg/kg or mg/l, as appropriate) expressed as SO ₂
Granulated potatoes	100
Jams, jellies, marmalades and chestnut puree (covered by Directive 79/693/EEC)	50
Other jams	50
Glucose-syrup-based confectionery	50
Dry biscuits	150
Deep-water fresh lobster	30
Frozen crustaceans	30
Cooked crustaceans	30
Sugar products (covered by Directive 73/437/EEC)	15
Glucose syrup	20
Vinegar with an acid content of 8 %	100
Lime juice	100
Lemon juice	300
Flavoured drinks based on concentrated fruit juice	20
Beer	20
Cider and perry	50
Fruit wine	300

4. Nitrites and nitrates

- (6) Article 1(3) of Directive 95/2/EC on food additives other than colours and sweeteners provides a definition of preservatives and antioxidants⁽⁹⁾. For this category of additives, Article 2(1) provides that only substances listed in Annex III may be used in foodstuffs for the purposes

⁽⁹⁾ See recital 4 of this Decision.

mentioned in Article 1(3). Article 2(4) provides that the additives listed in Annex III may only be used in the foodstuffs referred to in that Annex and under the conditions specified therein. Annex III, Part C specifies, in the form of a table, the conditions of use for potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252)⁽¹⁰⁾:

Potassium nitrite (E 249) and sodium nitrite (E 250)

Foodstuff	Indicative ingoing amount (mg/kg)	Residual amount (mg/kg)
Non-heat-treated, cured, dried meat products	150	50
Other cured meat products and canned meat products <i>Foie gras, foie gras entier, blocs de foie gras</i>	150	100
Cured bacon		175

Sodium nitrate (E 251) and potassium nitrate (E 252)

Foodstuff	Indicative ingoing amount (mg/kg)	Residual amount (mg/kg)
Cured meat products	300	250
Canned meat products		
Hard, semi-hard and semi-soft cheese		50
Dairy-based cheese analogue		
Pickled herring and sprats		200

Potassium nitrite (E 249) and sodium nitrite (E 250)

Foodstuff	Quantity added (mg/kg)
Non-heat-treated meat-based products derived from whole pieces of meat, including slices of products	60
Bacon of the Wiltshire type and related cuts, including saltcured ham	150
Heat-treated meat-based products derived from whole pieces of meat, including slices of products	60
<i>Rullepølse</i> (rolled meat sausage)	100
Entirely preserved or semi-preserved heat-treated meat-based products derived from whole pieces of meat, including slices of products	150
Bacon and related cuts of the Wiltshire type, including saltcured ham	150
Non-heat-treated meat-based products derived from minced meat	60
Fermented Danish salami	100
Entirely preserved or semi-preserved non-heat-treated meat-based products derived from minced meat	150
Heat-treated meat-based products derived from minced meat	60
Meatballs or liver paté	150
Entirely preserved or semi-preserved heat-treated meat-based products derived from minced meat	150

Sodium nitrate (E 251) and potassium nitrate (E 252)

Foodstuff	Quantity added (mg/kg)
Bacon of the Wiltshire type and related cuts, including saltcured ham	300
Bacon of the Wiltshire type and related cuts, including saltcured ham	300

- (7) The conditions of use for nitrates and nitrites in foodstuffs other than meat products feature in the positive list⁽¹¹⁾, to which the Order of 18 December 1995 refers in its paragraph 11. The Commission has examined these provisions and has decided that they comply with the corresponding provisions of Directive 95/2/EC. The Danish Order of 23 September 1996 introduces an Annex 8 into the Order of 18 December 1995, specifying, in the form of a table, the conditions of use of nitrites and nitrates in meat products⁽¹²⁾:

⁽¹⁰⁾ See footnote 7 of this Decision.

⁽¹¹⁾ See footnote 4 of this Decision.

⁽¹²⁾ See footnote 8 of this Decision.

THE PROCEDURE

- (8) When the Council adopted Directive 95/2/EC on 15 December 1994 as an A item, the Danish delegation asked to make a voting declaration, as follows: 'The Danish delegation votes against the adoption of the European Parliament and Council Directive on food additives other than colours and sweeteners. With regard to the use of nitrites/nitrates, sulphites and sodium aluminium phosphates, the Directive does not respond satisfactorily to health requirements, to which the Danish delegation ascribes a crucial importance in provisions regulating food additives. [...] In addition, the Danish Government remains firmly convinced that the Scientific Committee for Food ought, in accordance with the declarations put forward by the Commission, to deliver an opinion on nitrites/nitrates and sulphites as soon as possible. The Government will welcome the conclusions of the Scientific Committee and reserves the right to maintain national provisions needed to safeguard human life and health in accordance with Article 100a(4) of the Treaty'. Directive 95/2/EC was signed by the Presidents of the European Parliament and of the Council on 20 February 1995. The Directive provides that Member States are required to bring into force national measures implementing the Directive by 25 September 1996.
- (9) The Permanent Representation of Denmark to the European Union addressed a letter to the Secretariat-General of the Commission on 15 July 1996. By means of this letter, the Danish authorities forwarded to the Commission a copy of their national measures to implement Directive 95/2/EC⁽¹³⁾. The Danish authorities pointed out, however, that 'Denmark has not transposed the provisions in Directive 95/2/EC concerning nitrates and nitrites in meat products and concerning sulphites (see comparative table). Reference should be made to the voting declaration made by Denmark when the Directive was adopted. Pursuant to former Article 100a(4) of the Treaty, concerning these substances, the Danish Government intends to apply its national measures, which are justified by the major needs referred to in Article 36. Please refer to the enclosed scientific report'⁽¹⁴⁾. Given the incomplete character of the file at this stage, the Commission departments did not consider that this letter was a formal notification within the meaning of Article 100a(4). In parallel with this communication, correspondence was exchanged between the competent Danish Minister and the competent Member of the European Commission. The Minister confirmed the Danish position as expressed in the voting declaration. The Commission Member took note of Denmark's intention to ask for a derogation from the Directive under Article 100a(4), adding that the Commission departments would examine this request as soon as they had received the complete, official notification.
- (10) The Commission departments were made aware of Order No 834 of 23 September 1996 through a complaint introduced in November 1996. In a letter requesting information addressed to the Danish authorities on 20 January 1997 to follow up this complaint, Commission officials considered that the intention expressed by the Danish authorities in July 1996 to derogate from Directive 95/2/EC had been followed by the later adoption of the Order which was the subject of the complaint. Following informal contacts, the Danish authorities provided a detailed reply on 20 May 1997 to the Commission letter asking for more information. An examination of all the various items of correspondence led Commission officials to regard the letter dated 15 July 1996 from the Danish authorities, when read together with their detailed letter of 20 May 1997, as being equivalent to notifying their legislation on nitrites, nitrates and sulphites, pursuant to Article 100a(4) of the EC Treaty. At the same time, other complaints were reaching the Commission denouncing obstacles to the marketing in Denmark of foodstuffs containing sulphites and meat products containing nitrites and/or nitrates. Further informal talks were held between Commission officials and the Danish authorities in order to discuss the scientific and technical aspects of this dossier. These contacts did not make it possible to reach a common position. The only agreement reached was that the Danish authorities would forward further information to the Commission to bolster the justifications needed to support their request for a derogation. This additional information was addressed to the Commission on 14 July 1998.
- (11) The notification file, comprising the memorandum attached to the letter of 15 July 1996 and the additional information last forwarded by the Danish authorities, was then forwarded to the other Member States for their opinions. The Commission received opinions from Germany, France, the Netherlands, Portugal, Finland, Sweden and the United Kingdom.
- Germany points out that the conditions of use of sulphites, nitrites and nitrates in foodstuffs were determined taking account of the evaluations of the SCF. Germany nevertheless feels that it would be useful to invite the SCF to examine the documentation forwarded by the Danish authorities,
- France thinks that, on some points, the Danish legislation appears discriminatory. France recognises that it would be useful to re-examine at Community level the conditions of use of sulphites, nitrites and

⁽¹³⁾ See recital 3 of this Decision.

⁽¹⁴⁾ 'Memorandum' on the evaluation of safety and of other aspects of using nitrates and sulphites in 'foodstuffs', hereinafter referred to as 'the memorandum'

nitrites, and believes that it would be preferable to await the results of studies on the consumption of food additives carried out by the Member States before undertaking this re-examination,

- The Netherlands does not support the Danish derogation request, since it thinks that the Danish authorities have not demonstrated that their restrictive measures are particularly justified on account of the eating habits of the Danish population,
 - Portugal recalls that the reasons invoked by the Danish authorities in their request for a derogation had already been put forward during the discussions preceding the adoption of Directive 95/2/EC, but had not been accepted by the Council. Portugal recommends waiting for the results of the studies on the consumption of food additives to see whether the conditions of use of additives as provided for in the Directive should be changed,
 - Finland understands the concern of the Danish authorities to see the conditions of use of nitrites, nitrites and sulphites in foodstuffs tightened up. Finland points out that Directive 95/2/EC ought to be reviewed on these points, depending on the assessments of the levels of consumption of additives in the Member States, which should be available at the end of 1999,
 - Sweden believes that it has no reason to oppose the Danish rules, considering that it will be necessary to review the conditions of use of the additives in question in the Community, and stating that the application of the Danish rules does not appear to hamper trade,
 - The United Kingdom affirms that the Danish authorities have not supplied proof that the risk is greater for Danish consumers than for those in the other Member States.
- (12) 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. The Treaty of Amsterdam amended substantially the provisions of Article 100a of the Treaty establishing the European Community, replacing paragraphs 3, 4 and 5 of this Article by eight new paragraphs, numbered from 3 to 10. The Article amended in this way became, due to the new numbering of the Articles, Article 95 of the Treaty establishing the European Community. By letter dated 29 July 1999, the Secretariat-General of the Commission informed the Danish authorities that their notification on the use of sulphites, nitrites and nitrites in foodstuffs had been taken into account within the framework of the new provisions of the Treaty.

LEGAL ASSESSMENT

1. Applicable rules

- (13) The Treaty of Amsterdam does not contain any specific transitional provisions concerning the rules applicable to notifications made before the date of entry into force of this Treaty, such as the Danish notification which is the subject of this Decision. In the absence of specific provisions extending their application, the former provisions of Article 100a(4) of the EC Treaty are considered abrogated from the day of the entry into force of the new provisions (1 May 1999).
- (14) The Commission has informed the Kingdom of Denmark that the notification which it submitted under the provisions of the former Article 100a(4) of the EC Treaty has been regarded as maintained within the framework of the new provisions of this Treaty. Indeed, a comparison of the form of the provisions of Article 100a(4) of the EC Treaty and the new provisions of Article 95(4) and (6) of the said Treaty, reveals that these are comparable, where not identical. These new provisions of the Treaty, which have replaced the old provisions of Article 100a(4) since 1 May 1999, thus constitute the law which is applicable when examining this notification.

2. Consideration of admissibility

- (15) The notification presented by the Danish authorities seeks to obtain authorisation to maintain certain national provisions which are incompatible with Directive 95/2/EC, which constitutes a harmonisation measure adopted on the basis of the former Article 100a (which has since become Article 95) of the EC Treaty. Indeed, although the letters dated 15 July 1996 and 20 May 1997 from the Danish authorities refer to national provisions which postdate the adoption of Directive 95/2/EC, it is necessary to note, as indicated in recital 3, that the national provisions substantially reproduce national rules which existed before its adoption. It must therefore be considered that, in the case in point, the condition provided for in Article 95(4) of the Treaty has been fulfilled, according to which rules notified under this provision are those which a Member State wishes to 'maintain' following the adoption of a harmonisation measure.
- (16) In addition, the Commission was informed by the Kingdom of Denmark of its intention to maintain national measures which were incompatible with Directive 95/2/EC before the date on which this Directive was to be implemented. Indeed, with their letter of 15 July 1996, the Danish authorities informed the Commission of their intention to maintain their national provisions derogating from Directive 95/2/EC. This initial letter, supplemented by later communications which clarified its exact meaning, did indeed include a description of the derogating national provisions. In the case in point, therefore, the Commission was aware of the Danish derogation measures as from July 1996, which is before the time limit for the implementation of measures to transpose the Directive.

- (17) In the light of the above considerations, the Commission believes that the notification made by the Kingdom of Denmark is admissible under Article 95(4) of the EC Treaty.

3. Assessment of the merits

- (18) In accordance with the key provisions of Article 95(4) of the EC Treaty, the Commission must ascertain that the national provisions notified are justified by the major needs referred to in Article 30 of the EC Treaty (formerly Article 36 of the Treaty) or which concern the protection of the environment or the working environment. In their letter of notification, the Danish authorities invoke the objective of safeguarding public health. The Commission must therefore verify whether these measures are necessary and proportionate to the objective pursued. When the Commission has concluded that the national notified provisions are justified, it must then verify, pursuant to Article 95(6) EC, whether these measures constitute or not a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market. In addition, it should be pointed out that, from now on, Article 95(4) of the Treaty expressly compels Member States to prove that these conditions are fulfilled in order for a derogation to be authorised.

(a) *Justification with regard to the major need to protect public health*

(i) *Sulphites*

- (19) In their memorandum, the Danish authorities base their argument on framework Directive 89/107/EEC concerning additives to justify their request for a derogation. Annex II of this Directive sets out general criteria for the use of food additives. The Danish authorities criticise the Community legislators for not having followed these criteria to establish the conditions of use of sulphites in foodstuffs when Directive 95/2/EC was adopted.
- (20) However, the elements put forward by the Danish authorities with regard to two of the criteria defining the conditions of use of additives, namely technological need and the risk of misleading consumers, have nothing to do with the objective of public health protection as mentioned in Article 30 of the EC Treaty, neither do they refer to the other objectives listed in Article 95(4) of this Treaty. These elements are not in any case pertinent, therefore, if they are compared with the limited cases for justification that have been listed in the abovementioned Article 95(4), and the Commission believes, moreover, that the arguments put forward are not founded.
- (21) As far as the technological need is concerned, the Danish authorities insist on the need for a strict framework for the conditions of use of sulphites in foodstuffs and stress the fact that, since the introduction in 1988 in Denmark of a restrictive legislation regarding the use of these additives, several of the foodstuffs mentioned in Directive 95/2/EC have been marketed in Denmark without the addition of sulphites and with no problem for food safety. The Danish authorities quote the example of peeled potatoes, mustard, dried fruits and canned fruits and vegetables. The Commission affirms that Community legislation took proper account of the need for a strict framework for the conditions of use of sulphites in foodstuffs. It specifies, however, that sulphites are authorised as preservatives and/or antioxidants⁽¹⁵⁾ by Directive 95/2/EC, and that these additives thus perform a technological function and correspond to a technological need which cannot be satisfied by other economically and technologically usable methods. The Commission believes, moreover, that this argument cannot be invoked for the purposes of public health protection, since it is up to the Danish authorities to establish that the presence of sulphites constitutes a risk to public health.
- (22) Turning to the risk of misleading consumers, the Danish authorities question once again the justification for using sulphites established by Directive 95/2/EC, believing that these additives have a bleaching effect on fruit and vegetables, which could possibly be regarded as misleading consumers. The Commission recalls that sulphites are authorised by Directive 95/2/EC as preservatives and/or antioxidants, but not as bleaching agents. The function of antioxidants is to 'protect [foodstuffs] against deterioration caused by oxidation, such as [...] colour changes'⁽¹⁶⁾. The Commission believes that a function of this kind cannot lead a consumer to be misled as to the nature of the product, given that the product labelling mentions the presence of the additive in question. What is more, this argument could not constitute a justification with regard to the objective of public health protection.
- (23) The specific community directives on additives were adopted on the basis of a rigorous safety assessment of all the additives carried out by the SCF so that only those additives whose use in foods was judged risk-free would feature in the specific directives and could hence be used in the Community. Annex II to Directive 89/107/EEC provides that 'to assess the possible harmful effects of a food additive or derivatives thereof, it must be subjected to appropriate toxicological testing and evaluation. The evaluation should also take into account, for example, any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the body'. On several occasions the SCF has been called on to carry out a toxicological evaluation of sulphites, the last being in an opinion

⁽¹⁵⁾ See the definitions of preservatives and antioxidants in recital 4.

⁽¹⁶⁾ Article 1(3)(b) of Directive 95/2/EC.

delivered on 25 February 1994⁽¹⁷⁾. The Danish authorities are using this opinion as a basis for their argument to condemn the risks of exceeding the acceptable daily intake (ADI) and the risks of allergies connected with the consumption of sulphites.

may be used. Thus, the Danish Order of 23 September 1996 retains only 16 categories of foodstuffs in which sulphites may be used out of the 61 categories which are included in Directive 95/2/EC.

(24) The evaluation of the safety of an additive may highlight the need to establish an ADI to safeguard public health. This ADI represents the quantity which can be safely ingested on average every day throughout a lifetime. The ADI, which comprises a habitual safety factor of 100, which may be as high as 500, is expressed in milligrams per kilogram of body weight (mg/kg bw). The approval of any food additive and the determination of its conditions of use must therefore take into account the technological need for this additive (the quantity needed to reach the desired effect) while simultaneously taking account of the probable daily intake of the additive in all food products, in order to check that the authorised use does not risk leading to the ADI that has been established for the additive in question being exceeded.

(25) In its opinion of 25 February 1994, the SCF established an ADI of 0,7 mg/kg bw per day for sulphites⁽¹⁸⁾, corresponding to 49 mg/day for an adult (0,7 mg/kg × 70 kg) and 21 mg/day for a child (0,7 mg/kg × 30 kg). This value is based on a quantity which has no effect on the gastrointestinal system. The conditions of use of sulphites defined in Directive 95/2/EC may, according to the Danish authorities, lead to the ADI being exceeded. The Danish authorities quote the example of wine, in which sulphites are authorised up to 160 mg/l⁽¹⁹⁾. The consumption of two glasses of wine represents an intake of 40 mg of sulphites (25 cl × 160 mg/l) which is not far from the daily admissible intake for an adult. The Danish authorities believe that any additional authorisation of sulphite use will lead to the ADI being exceeded or will increase the risk of its being exceeded.

(26) The Danish authorities are not however seeking to tighten up the conditions of the use of sulphites in wine, but their conditions of use in other foodstuffs, such as those defined in Directive 95/2/EC. To tighten up the conditions of use of sulphites, the Danish authorities have reduced the number of foodstuffs in which sulphites

(27) The Commission notes that the Danish authorities have not justified the choice which they have made. This choice may appear arbitrary to the extent that the Danish authorities have not indicated how technological need has been demonstrated in some cases and not in others. For example, the Danish authorities prohibit the use of sulphites in mustard, without having provided information on the levels of consumption of mustard in Denmark, which would show the importance of this foodstuff in the eating habits of the population and hence the need to outlaw the use of sulphites in this product in order to reduce the sulphite intake in the diet as a whole. To tighten up the conditions of use of sulphites in some foodstuffs the Danish authorities have lowered the levels of use of sulphites⁽²⁰⁾. The Danish Order of 23 September 1996 determines the added quantity, which is the opposite of Directive 95/2/EC, which determines the maximum quantity available in the finished product⁽²¹⁾. For example, the use of sulphites in dehydrated potato granules is authorised up to a level of 100 mg/kg in Denmark, while Directive 95/2/EC authorises a total available quantity of 400 mg/kg of sulphites. The Danish authorities have not justified this measure and, more specifically, have not taken account of the fact that the use of sulphites is authorised by Directive 95/2/EC in a certain number of foodstuffs, including dehydrated potato granules, which can only be consumed after cooking or reconstitution. It is precisely these treatments which reduce substantially the sulphite content in foodstuffs when they are consumed. The Commission is therefore inclined to question the choice made by the Danish authorities of the foodstuffs in which sulphites may be used.

(28) The Commission points out that the Community provisions on sulphites are still likely to be the subject of a review. The safeguard clause provided for in Article 4 of Directive 89/107/EEC may lead to the changing of the positive list. Article 7 of Directive 95/2/EC, which imposes on the Member States and on the Commission the tasks of monitoring additive consumption trends, should permit a re-examination of the conditions of use of the additives provided for in the Directive and lead to its adaptation.

⁽¹⁷⁾ Reports of the SCF, 35th series.

⁽¹⁸⁾ In its previous opinion on sulphites delivered in 1981, the SCF considered that it was not necessary to set an ADI.

⁽¹⁹⁾ Directive 95/2/EC in fact refers back to Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organisation of the market in wine (OJ L 84, 27.3.1987, p. 1), last modified by Council Regulation (EC) No 1627/98 of 20 July 1998 (OJ L 210, 28.7.1998, p. 8). In its Article 65, this Regulation provides that the total sulphur dioxide content of still wines 'may not exceed [...] 160 mg/litre for red wine, 210 mg/litre for white and rosé wine'.

⁽²⁰⁾ It is not feasible to lower generally the levels of use of sulphites in foodstuffs. The levels of use which feature in the Directive were calculated to produce the effects which are the intrinsic technological function of these additives; below such levels, the desired effects are not produced.

⁽²¹⁾ See the first footnote of Annex III, Part B, to Directive 95/2/EC. For dry biscuits, for instance, the quantity allowed in the Danish Order is as a result higher than that which features in Directive 95/2/EC. Nevertheless, the Danish authorities do not specify that the maximum level in the finished product is not higher than that set by the Community text.

- (29) Apart from the question of exceeding the ADI, the Danish authorities stressed the risk of allergic reactions caused by sulphites which may occur in certain predisposed individuals at low levels of exposure. The Danish authorities refer here directly to the opinion of the SCF of 25 February 1994 to insist on the need to limit the use of sulphites to as small a number of products as possible and to provide information for consumers on the presence of sulphites in foodstuffs.
- (30) The Commission acknowledges that sulphites, like a certain number of other additives, may provoke allergic reactions in certain individuals and points out that these risks of allergies have been taken into account in the Community legislation. The Commission believes that the Community legislation provides an appropriate response to the problem of food allergies in general. The Community legislator admits that it is perfectly legitimate to avoid, in so far as it is possible, subjecting such individuals to the risks of allergic reactions. The Community legislator did not nevertheless deem it necessary to outlaw generally the use of these allergenic ingredients, among which additives such as sulphites feature. The solution opted for at Community level is based on informing consumers: individuals who suffer from an allergy attributable to certain ingredients should have the possibility of choosing to consume foodstuffs which do not contain these ingredients. Council Directive 79/112/EEC of 18 December 1978 on the labelling of foodstuffs⁽²²⁾ offers them this possibility since it provides for the compulsory listing of ingredients on the labelling of foodstuffs. In particular, pursuant to Article 6 of Directive 79/112/EEC, all additives which serve a technological function must of necessity be mentioned on the labelling. Thus sulphites appear in the list of ingredients. The Commission believes, therefore, that existing Community legislation gives consumers or, when such consumers are children, gives their parents or members of their entourage, such as officials in schools, a guarantee of sufficiently clear and detailed information as regards the presence of sulphites in foodstuffs.
- (31) The Commission acknowledges that the labelling does not always indicate the presence of sulphites in certain circumstances. This is the case of sulphites which, having been used in the preparation of foodstuffs, remain present in the finished product without at that stage serving any technological function⁽²³⁾. This is also the case of sulphites which are present in a large number of foodstuffs without having been voluntarily added⁽²⁴⁾. These two examples correspond to very low levels of sulphites which may nevertheless cause allergies in some individuals. The Commission notes that the regulation applicable in Denmark does not solve this problem of a lack of labelling of sulphites with such low content levels. Work is in progress at community level to make it systematically compulsory to label allergenic ingredients such as the sulphites quoted in the examples above. Information for consumers on the presence of sulphites could also be incomplete as regards foodstuffs offered for sale which have not been prepackaged. The Commission would point out that Article 12 of Directive 79/112/EEC allows Member States to decide on the manner of labelling such foodstuffs, such as the obligation of affixing descriptions to accompany products sold loose (without prepackaging) and containing certain particulars regarding these products. In order to inform all consumers fully about the content of some foodstuffs, Member States may thus oblige restaurant owners to record on the menu the list of ingredients of the dishes that they offer. The Danish authorities also evoke the case of alcoholic beverages, in whose labelling the list of ingredients does not necessarily appear. The Commission would stress that, pursuant to Article 6(3) of Directive 79/112/EEC, it presented a proposal for a European Parliament and Council Directive amending Directive 79/112/EEC, aimed at making the labelling of ingredients in alcoholic drinks⁽²⁵⁾ compulsory. This proposal for a Directive follows other proposals formulated by the Commission in the past but which led to no tangible result. That is why the Commission did not propose the adoption by some Member States of national legislations making the indication of ingredients compulsory in the labelling of certain alcoholic beverages.
- (32) In the light of the information supplied by Denmark, the Commission also examined whether sulphites constituted a particular health problem for the Danish population as compared with the populations of the other Member States. In their memorandum, the Danish authorities did not refer to any epidemiological study, did not offer any data on the prevalence of food allergies nor of allergies to additives nor, more specifically, of allergies to sulphites which would have made it possible to make comparisons with the averages for the European or world population with a view to establishing whether the Danish population is in a specific situation with regard to the prevalence of allergies to sulphites. The Commission has no knowledge of any such studies concerning Denmark or any other Member State or any third country. The Commission also tried to analyse the situation in greater detail by referring to a report issued by the SCF on 22 September 1995 concerning adverse reactions to foodstuffs and the ingredients of

⁽²²⁾ OJ L 33, 8.2.1979, p. 1. Directive as last amended by Directive 97/4/EC of 27 January 1997 (OJ L 43, 14.2.1997, p. 2).

⁽²³⁾ Article 6(4)(c)(ii) of Directive 79/112/EEC. Apart from the foodstuffs to which the provisions of Directive 95/2/EC are applicable with respect to sulphites, sulphites may legally be transferred to a certain number of other foodstuffs in accordance with Article 3(1) of this Directive through the application of the carryover principle.

⁽²⁴⁾ The second footnote of Annex III, Part B to Directive 95/2/EC specifies for this reason that sulphites whose content does not exceed 10 mg/kg are not considered to be present in the finished product.

⁽²⁵⁾ Proposal for a Directive published in OJ C 106, 4.4.1997, p. 5.

foodstuffs⁽²⁶⁾. In this report, the SCF indicates that, according to the available studies carried out throughout the world, 'the prevalence of food allergy is clearly less than 1% in the adult population and may be slightly higher in the case of children'. The SCF mentions several studies which reveal that this prevalence when related more specifically to food additives is less than 0,1% for the population. But it mentions a further crucial element in its report, namely that genetic and environmental factors as well as eating habits may increase the prevalence of food allergies. The SCF quotes the example of regions where allergens are present in the environment. It also quotes the case of regions where allergens are widely consumed. Consequently, the SCF concludes that 'the prevalence of food allergy depends greatly on the geographical region'. The Commission therefore felt bound to check whether the Danish authorities had actually supplied proof of the existence and importance of such factors, linked to genetics, the environment or eating habits. The Commission has not detected anything in the memorandum which throws the existence of any of these factors into relief. Consequently, the information available to the Commission has not made it possible to conclude that the Danish population is in a specific situation compared with the populations of other Member States, notably its immediate neighbours, as regards this question of allergies related to sulphites.

- (33) What is more, the Commission finds that the Danish measures as notified are inconsistent with the declared objective of protecting public health. Indeed, the restrictive measures refer only to sulphites. Sulphites, however, are not the only additives which present allergy risks. We may also quote the example, based on the already quoted report by the SCF of 22 September 1995, of benzoates and certain colourings such as azo dyes. The Commission observes that these various sources of allergies have not been subject to the same sort of restrictions as those applicable to sulphites in Denmark.
- (34) In the light of these facts, the Commission is led to conclude that the Danish measures, though based on public health considerations, are still not justified by the need to protect public health.

(ii) *Nitrites and nitrates*

- (35) The Danish authorities want to maintain their restrictive provisions regarding the use of nitrites and nitrates in meat products. The conditions of use for these additives in cheese and in fish as laid down in Directive 95/2/EC have not been questioned. The Danish Order of 23 September 1996 authorises the use of nitrites in the meat products referred to in Directive 95/2/EC within limits lower, on average, than half those provided for by the Directive, except for bacon of the Wiltshire type and

rolled meat sausage (rullepølse), in which levels of nitrites used may be comparable to those provided for by the Directive. The use of nitrates is not authorised by the Order of 23 September 1996 in any of the products referred to in the Directive, except in bacon of the Wiltshire type, at levels close to those provided for in the Directive. The Danish authorities are keen to apply their restrictive measures since they believe that the use of nitrites and nitrates in meat products in the conditions set out in Directive 95/2/EC is not necessary from the technological viewpoint and that these additives present a danger to health⁽²⁷⁾.

- (36) Nitrites and nitrates are used in meat products as preservatives⁽²⁸⁾ to inhibit or halt the growth of undesirable micro-organisms such as *Clostridium botulinum*, the bacterium responsible for botulism, or *Staphylococcus aureus*. The Danish authorities do not contest that nitrites and nitrates perform such a technological function, but consider that the levels of use of these additives set out in Directive 95/2/EC exceed what is required to satisfy this technological need. It is all the more important to limit the conditions of use of nitrites and nitrates to what is strictly necessary given that there are particular health risks which are connected with these additives⁽²⁹⁾. The Danish authorities refer to reports by the Danish National Food Agency showing that restrictive conditions of use of nitrites and nitrates in force in Denmark since the adoption of Directive 95/2/EC have not led to cases of botulism among the population. Experiments carried out in Denmark during the production phase and based, in particular, on the application of the HACCP⁽³⁰⁾ system regarding hygiene show that the levels of nitrites and nitrates in meat products provided for in the Danish regulation are sufficient from the technological standpoint.
- (37) The Commission does not share the Danish authorities' view and considers that the conditions of use of nitrites and nitrates in meat products defined in Directive 95/2/EC correspond to what is required from the technological viewpoint in order to achieve the desired effects. The Commission observes that the Danish Order of 23 September 1996 authorises the use of nitrites and nitrates in conditions comparable to those of Directive 95/2/EC in two types of meat product: bacon of the

⁽²⁷⁾ This would mean that the first two of the three cumulative conditions for the authorisation of additives set out in Directive 89/107/EEC would not be fulfilled.

⁽²⁸⁾ The technological function of these additives is to extend the shelf life of foodstuffs by protecting them from deterioration due to micro-organisms, in accordance with the definition of preservatives given in Article 1(3)(a) of Directive 95/2/EC. The use of nitrites and nitrates also has direct consequences on the determination of the final date for the consumption of a product in that they make it possible to retain the water which the meat product contains naturally in order to preserve its organoleptic qualities, particularly its aromas, colour and texture.

⁽²⁹⁾ These risks are described in recitals 35 et seq. of this Decision.

⁽³⁰⁾ HACCP denotes the 'Hazard analysis and critical control points' system. See Article 3 of Council Directive 93/43/EEC on the hygiene of foodstuffs (OJ L 175, 19.7.1993, p. 1). The Directive does not however deal with meat products during the stages preceding their sale to the final consumer.

⁽²⁶⁾ SCF reports, 37th series.

Wiltshire type and rolled meat sausage (rullepølse). The Danish authorities have not explained why these products, which are, moreover, traditional Danish products, require higher levels of nitrites and nitrates than other meat products. The Commission does not see that there are any substantial differences between these categories of products which could justify discriminatory treatment of this kind.

(38) The Commission confirms that the conditions of use of nitrites and nitrates in meat products do not exceed what is required for these additives to perform their technological function. Nitrites and nitrates used in meat products tend to inhibit or halt the growth of undesirable micro-organisms such as *Clostridium botulinum*. Contamination of meat products by this bacterium is likely to occur throughout the food production process, particularly at the carcasse-cutting stage, during the production process, up to and including the consumption stage⁽³¹⁾. The levels of nitrites and nitrates must therefore be calculated so that these additives fulfil their role as preservatives right up to the last stage of the food production and consumption process. But from the moment that they have been incorporated into meat products, the quantities of nitrites and nitrates diminish considerably over a period of time and transform themselves into nitrosamines. That is why Directive 95/2/EC determines both the indicative ingoing amount and the residual amount. The Danish Order of 23 September 1996 is more restrictive than Directive 95/2/EC: it determines only the quantities of nitrites and nitrates added and these quantities are generally lower than the indicative ingoing amounts defined in the Directive. The Order does not therefore guarantee that the presence of additives in products at the end of the food production process is sufficient to perform their technological function, which is to guarantee the microbiological safety of products.

(39) The Danish authorities base their arguments on the opinions of the SCF of 19 October 1990⁽³²⁾ and 22 September 1995⁽³³⁾ to denounce the serious health risks connected with nitrites and nitrates. The Danish authorities refer in particular to the latter opinion of the SCF which, having been formulated after the adoption of Directive 95/2/EC, might have contained new elements capable of bringing certain aspects of this Directive into question. In this opinion of 22 September 1995, having recalled that, after their addition to a meat product, nitrates transform themselves into nitrites and these nitrites lead to the formation of nitrosamines, the SCF specified that 'there is an obvious correlation between the addition of nitrites for the curing of meat and the formation of volatile nitrosamines'. Nitrosamines are genotoxic, carcinogenic substances. For this type of

substance, there is no threshold below which the formation of cancerous cells and tumours can be excluded. It is therefore vital to reduce the exposure to preformed nitrosamines present in foodstuffs by using appropriate technological methods to arrive at the minimum needed to obtain the desired preservative effect and to guarantee microbiological safety.

(40) The Danish authorities are of the opinion that the Community legislation does not meet this health protection objective in that it uses an inappropriate methodology. The Danish authorities point out that there is no relation between the quantity of nitrites and nitrates added and the residues which may be detected in the food product ready for consumption, but that there is an 'obvious correlation' between the quantity added and the formation of nitrosamines. According to the Danish authorities, legislation justified by health reasons ought to be based on limiting the quantity added, and not on limiting the residual amount. But Directive 95/2/EC in fact determines the ingoing amounts only indicatively. If there is a need to establish a limit for the residual amount, there is a simultaneous need to establish a limit for the added quantity. The Danish authorities consider that, quite apart from the methodology followed, the figures for the maximum levels of nitrites and nitrates given in the Directive are too high compared with the minimum needed to obtain the desired preservative effect and to guarantee microbiological safety. The Danish authorities are therefore led to evoke the possibility that the ADI is being exceeded. They do not however give any details, but quote the SCF, which, in its opinion of 22 September 1995, stated that 'if the levels of nitrite residues were as high as those authorised by Directive 95/2/EC, the ADI could be exceeded'.

(41) The Commission notes in the first place that the Danish measures do not appear consistent with the declared objective of health protection in that they do not in any way prevent nitrosamines from forming in products which are widely consumed in Denmark, such as bacon of the Wiltshire type, rolled meat sausage and fermented Danish salami, since the use of nitrites and nitrates is authorised in these products by the Danish Order of 23 September 1996 in conditions which are comparable with those provided for in the Community legislation.

(42) The Commission then examined with particular attention the fundamental questions raised by the Danish authorities. In its opinion of 1990, the SCF had already evoked the connection between nitrites and nitrosamines and had recommended reducing the levels of nitrites and nitrates in foodstuffs as much as possible in order to limit exposure by consumers to preformed nitrosamines. The SCF reported a lack of scientific data concerning the formation of nitrosamines, especially as regards

⁽³¹⁾ Infection caused by a consumer when handling the product.

⁽³²⁾ Reports of the SCF, 26th series.

⁽³³⁾ Reports of the SCF, 38th series.

endogenous nitrosamines, the main source of which is the nitrites naturally present in saliva. Directive 95/2/EC was adopted taking into account all these questions raised by the SCF. In its opinion of 1995, the SCF upheld its opinion of 1990. If the memorandum of the Danish authorities had contained new elements which would help evaluations to progress, the SCF would have been informed at once of the dossier. But the Commission is forced to acknowledge that such is not the case of the information communicated by the Danish authorities. The Commission wishes to insist on the responsibility incumbent on a legislator, whether Community or national, with regard to risk management. The Community legislator did fix the levels of nitrites and nitrates in meat products, precisely in order to achieve the desired technological aim and at the same time to attain the objective of public health protection. Since nitrites and nitrates greatly inhibit the proliferation of *Clostridium botulinum*, they do effectively contribute to avoiding cases of botulism. This technological need, which the Danish authorities are not questioning for some meat products, such as bacon of the Wiltshire type, is, in the Commission's view, crucial from the health point of view. The levels of use of these additives have been calculated in order to attain this health objective. It is not however excluded that, in the future, these levels of use could be lowered in Community regulations to take account of possible developments in the HACCP approach with respect to the hygiene of meat products⁽³⁴⁾.

- (43) As regards the exceeding of the ADI, the Commission would point out that the SCF has established an ADI of 5 mg/kg bw, expressed as sodium nitrate, for nitrites and an ADI of 0,1 mg/kg bw, expressed as sodium nitrite, for nitrites. The daily admissible intake for an adult is 350 mg (5 mg/kg x 70 kg) in the first case and 7 mg (0,1 mg/kg x 70 kg) in the other. To reach the level of this admissible daily intake, it would be necessary to consume approximately 1 400 g of prepared meat products (350 mg/kg/250 mg/kg) every day in the first case and 40 g of bacon (7 mg/kg/175 mg/kg) in the other. The figures for the nitrates exclude a priori any risk of exceeding the ADI⁽³⁵⁾. As far as nitrites are concerned, the Danish authorities put forward no data on the levels of consumption of meat products containing nitrites in Denmark. Such data might have justified the restrictive measures and even led to the adaptation of Community legislation on this point. But the Danish authorities have not mentioned any study in their memorandum enabling them to make comparisons with average data concerning the European or world population, with a view to determining whether the Danish population is in a specific situation with regard to the danger which the use of nitrites and nitrates could represent. In this context the Commission would point out that the review of Directive 95/2/EC could be

initiated in several ways. The safeguard clause provided for in Article 4 of Directive 89/107/EEC might lead to the amendment of the positive list. Article 7 of Directive 95/2/EC, which makes it compulsory for Member States and the Commission to monitor trends in the consumption of additives ought to permit a reexamination of the conditions of use of the additives provided for in the Directive. Directive 95/2/EC could be reviewed as a result of any new information provided, such as a precise study on the levels of consumption of foodstuffs likely to contain nitrites and nitrates and on the possible need to impose further restrictions on the conditions of use of nitrites in order for consumers not to exceed the ADI. This is not however the case of the information communicated by Denmark to support its request for a derogation. What is more, so far no other Member State has forwarded any such new information to the Commission.

- (44) The Commission therefore considers that, while the Danish measures are aimed at protecting public health, they are excessive in relation to this aim.

(b) Absence of arbitrary discrimination

- (45) Since the measures in question are not justified by the need to protect public health, the Commission does not have to verify whether this condition is satisfied.

(c) Absence of a disguised restriction on trade between Member States

- (46) Since the measures in question are not justified by the need to protect public health, the Commission does not have to verify whether this condition is satisfied.

(d) Absence of an obstacle to the functioning of the internal market

- (47) Since the measures in question are not justified by the need to protect public health, the Commission does not have to verify whether this condition is satisfied.

CONCLUSION

- (48) In the light of the above considerations, the Commission concludes that the national provisions notified by the Kingdom of Denmark pursuant to the former Article 100a(4) of the EC Treaty, concerning the conditions of

⁽³⁴⁾ See note 33 of this Decision. Work is in progress at Community level to examine the possibility of developing the HACCP approach with regard to foodstuffs of animal origin which are not covered by Directive 93/43/EEC.

⁽³⁵⁾ The conditions of use of nitrates were determined taking account of the fact that their use as additives in foodstuffs contributes only a small proportion of the total intake, most of which comes from vegetables and water.

use of sulphites, nitrites and nitrates in foodstuffs, though pursuing the objective of protecting public health, which is one of the major needs referred to in Article 30 of the EC Treaty (formerly Article 36 of the Treaty), are not justified since they are not strictly necessary for achieving that objective. The Commission therefore has reason to consider that the national provisions notified cannot be approved,

EC Treaty and examined by the Commission pursuant to Article 95(4) and (6) are not approved.

Article 2

This Decision is addressed to the Kingdom of Denmark.

HAS ADOPTED THIS DECISION:

Done at Brussels, 26 October 1999.

Article 1

The Danish national provisions derogating from Directive 95/2/EC notified pursuant to the former Article 100a(4) of the

For the Commission

Erkki LIIKANEN

Member of the Commission

COMMISSION DECISION

of 26 October 1999

concerning the national provisions notified by the Kingdom of the Netherlands concerning the limitations of the marketing and use of pentachlorophenol (PCP)

(notified under document number C(1999) 3419)

(Only the Dutch text is authentic)

(Text with EEA relevance)

(1999/831/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 91/173/EEC

- (1) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations⁽¹⁾, as last amended by Commission Directive 1999/77/EC⁽²⁾, provides for the prohibition and restriction of the use of certain dangerous substances and preparations. Directive 76/769/EEC is regularly amended to include in its Annex additional substances which are dangerous to man or the environment.
- (2) Council Directive 91/173/EEC⁽³⁾, which amends Directive 76/769/EEC for the ninth time, harmonises the placing on the market and use of pentachlorophenol (in the following: PCP) and its salts and esters. Directive 91/173/EEC prohibits the marketing and use of PCP and its salts and esters in substances or preparations in a concentration equal to or greater than 0,1 % by mass.
- (3) However, four exceptions are granted. The use of PCP and its compounds in industrial installations is permitted:

- (a) for the treatment of wood. However, treated wood may not be used inside buildings and not for the manufacture of containers intended for growing purposes or packaging which may come into contact with products intended for human and/or animal consumption;
- (b) for the impregnation of fibres and heavy-duty textiles not intended for clothing or for decorative furnishings;
- (c) as a synthesising and/or processing agent in industrial processes;
- (d) for the *in situ* treatment of buildings of cultural and historic interest (subject to individual authorisation by the Member State concerned) as a remedial treatment of timber and masonry infected by dry rot fungus and cubic rot fungi.

In any event, PCP as such or as a constituent of preparations used on the basis of the exceptions referred to above must have a total hexachlorodibenzo-paradioxine (H6CDD) content of less than four parts per million. The substances and preparations concerned may not be placed on the market except in packages of 20 litres or more, may not be sold to the general public and must, in addition to the labelling required by other Community provisions, be labelled with the sentence 'Reserved for industrial and professional use'.

- (4) The Directive provided that these exceptions had to be reconsidered in the light of changes in knowledge and technology no later than three years after the implementation of the Directive. The first review of the Directive was carried out in the course of 1995. Discussions within the working group on limitations of the marketing and use of dangerous substances and preparations led to the conclusion not to amend Directive 76/769/EEC as far as PCP is concerned, as the group held the opinion that the assessment of possible substitutes had not led to acceptable results and needed further examination.

⁽¹⁾ OJ L 262, 27.9.1976, p. 201.

⁽²⁾ OJ L 207, 6.8.1999, p. 18.

⁽³⁾ OJ L 85, 5.4.1991, p. 34.

- (5) This examination was concluded in the course of 1998 when a second review led to the adoption of Commission Directive 1999/51/EC⁽⁴⁾, which among others, adapts to technical progress the provisions concerning PCP and its salts and esters. According to the amended provisions, PCP and its salts and esters may not be placed on the market and used in substances or preparations in a concentration equal to or greater than 0,1% by mass. This amounts to a ban on the use of substances and preparations to which PCP and its salts and esters have been added intentionally. The new provisions are to be applied as of 1 September 2000. By way of derogation, France, Ireland, Portugal, Spain, and the United Kingdom may continue to apply the former legislation until 31 December 2008.

2. National provisions

- (6) The legal system of the Netherlands concerning PCP is established by four different pieces of legislation: the Controlled Substances Act (also referred to as Pesticides Law) of 1962⁽⁵⁾, Chapter IX 'Wood and Cork' of the Regulation on packaging and consumer products from 1980⁽⁶⁾, the Order of 18 August 1992 pursuant to Article 24 of the Law on environmentally hazardous substances from 1992⁽⁷⁾, and the Regulation on pentachlorophenol under the commodities Act from 11 February 1994⁽⁸⁾.
- (7) The legislation established by the Controlled Substances Act of 1962 and the executing Decision concerning the composition, classification, packaging and labelling of control substances, adopted on 22 February 1980 (hereinafter called the SIVEB Decision)⁽⁹⁾ with its subsequent amendments provides for a general prohibition of the substances concerned combined with an approval system on an individual basis. The Controlled Substances Act covers crop control substances or non-agricultural control substances (Article 1(1)(f)), which may not be supplied, possessed, kept in stock, marketed, or used in the Netherlands unless approved pursuant to the Act (Article 2(1)). Article 3(1) defines the general conditions that a control substance has to meet for permission (*inter alia*, to have no harmful effect on human health, ground water and no unacceptable effects on the environment).
- (8) Based on the Controlled Substance Act, the SIVEB Decision (forming a ministerial regulation), provides for

the admissible contents of active agents in control substances. This forms the basis for subsequent approvals (licenses) of the competent Minister to use the control substances falling under the Controlled Substances Act. In the case of PCP, the SIVEB Decision provides for a maximum content of certain impurities: hexachlorobenzene 1 g/kg, hexachlorodibenzoparadioxines 10 mg/kg (= 10 ppm), heptachlorodibenzoparadioxines (100 mg/kg), trichlorophenol (1 g/kg), chlorinated dibenzofuranes (500 mg/kg). All approvals granted for the treatment of wood with PCP containing products had expired in 1989. The last remaining approval for the treatment of textiles expired in 1992.

- (9) The Regulation on packaging and consumer products of 1980 establishes among others, that wood and cork used as packaging and consumer products must be manufactured by using substances that are specified in the Annex to the Decision on packaging and consumer products⁽¹⁰⁾. Raw materials and adjuvants may not be used in any way other than specified in the Annex. PCP and its salts and esters are not listed as permitted wood preservatives and therefore cannot be used.
- (10) The Order on the basis of Article 24 of the Law on environmentally hazardous substances from 1992 prohibits in general the marketing and use of PCP and its salts and esters for any purpose if their concentration exceeds 0,1%. Exemptions are given for the use as intermediates in closed industrial processes under the condition that there are no emissions and that the content of hexachlorodibenzoparadioxine is below 4 ppm, and for purposes of laboratory research. The Order further establishes a complete ban on the sale to private consumers, a minimum drum size of 20 litres, and a labelling requirement 'Reserved for industrial and professional use'.
- (11) The Regulation under the commodities Act on PCP from 1994 stipulates that goods treated with PCP may not be placed on the market in the Netherlands if they contain more than 5 mg/kg PCP.

3. Comparison between the national provisions and Directive 91/173/EEC

- (12) When comparing the Community legislation and the Netherlands provisions, it emerges that the national measures are more restrictive in one essential aspect: the placing on the market and use of substances or preparations containing PCP and its salts and esters for the treatment of wood and the impregnation of fibres

⁽⁴⁾ OJ L 142, 5.6.1999, p. 22.

⁽⁵⁾ Law Gazette of the Netherlands 1962, No 288, as amended by the Act of 25 December 1994, Law Gazette of the Netherlands 1995, No 4.

⁽⁶⁾ Law Gazette of the Netherlands 1980, No 18.

⁽⁷⁾ Law Gazette of the Netherlands 1992, No 455.

⁽⁸⁾ Law Gazette of the Netherlands 1994, No 35.

⁽⁹⁾ Law Gazette of the Netherlands 1980, No 43.

⁽¹⁰⁾ Law Gazette of the Netherlands 1979, No 558.

and heavy-duty textiles, which are allowed by the Community Directive, are not permitted in the Netherlands.

- (13) On the other hand, the Netherlands provisions are potentially less restrictive than the Community Directive, as the Controlled Substances Act of 1962 does not clearly limit the areas of use for which approvals could be granted. This is done in the individual approvals. The Netherlands authorities could, therefore, approve the use of PCP for applications not allowed by Directive 91/173/EEC. Furthermore the limit value of hexachlorodibenzoparadioxine in PCP (that could theoretically be approved for use) is 10 ppm and thus higher than the limit value of 4 ppm established by the Community Directive.
- (14) As already indicated, the provisions of Directive 76/769/EEC regarding PCP have been amended by Directive 1999/51/EC, and shall be applied by the Netherlands as from 1 September 2000. The Dutch legislation, for which approval according to the former Article 100a(4) has been requested, is in line with the new Community provisions.

II. PROCEDURE

- (15) Directive 91/173/EEC was adopted on 21 March 1991. Member States had to bring into force the national provisions necessary to comply with the Directive before 1 July 1992 (Article 2(2)).
- (16) By letter of 21 January 1992, the Netherlands Permanent Representative informed the Commission that the Netherlands considered it necessary to maintain or adopt, in accordance with the former Article 100a(4) of the EC Treaty, national legal provisions, which provide for more restrictive measures on the use of PCP in the treatment of wood and the impregnation of fibres and heavy-duty textiles (sub-points (a) and (b) of point 23 of the Annex of Directive 91/173/EEC) in order to protect the environment and also public health. By letter of 30 March 1992 the Netherlands Permanent Representative notified a draft regulation on PCP under the Commodities Act prohibiting the marketing and use of goods treated with PCP, and requested a confirmation under the former Article 100a(4) to adopt this legislation.
- (17) The Commission consulted the other Member States by letter of 27 April 1992, supplemented by a letter of 26 June 1992, with regard to the Netherlands request to apply stricter national provisions on PCP. Seven Member States replied: Ireland, Denmark and Germany support the Netherlands request, whilst France, Spain, Greece and Portugal are opposed.
- (18) *Ireland* informs the Commission that it has no objections to the request presented by the Netherlands authorities.
- (19) *Denmark* supports the Netherlands' request and agrees with the Netherlands assessment of the danger of PCP to human life and the environment. A total ban on PCP is the only acceptable solution to Denmark. Denmark also reserves the right to apply stricter national rules.
- (20) In supporting the Netherlands views, *Germany* refers to its own request under the former Article 100a(4).
- (21) *France* contests the Netherlands request. According to the evaluation of the French authorities, the justification submitted by the Netherlands authorities is insufficient, the national provisions do not respect the rule of proportionality, and the economic consequences for the functioning of the internal market and trade with third countries are important.
- (22) *Spain* holds the opinion that the restrictions imposed by Directive 91/173/EEC are sufficient to ensure the protection of the environment and consumer health. A positive decision on the Netherlands request would create an imbalance detrimental to the completion of the Internal Market. Spain favours an overall revision of the Directive as the most sensible solution to the problem.
- (23) *Greece* considers that Directive 91/173/EEC ought to be implemented correctly by all Member States, as the effects of national measures on the Internal Market would be important. National measures are only justified if it can be shown that environmental or consumer protection as provided for by the Directive are not adequate.
- (24) *Portugal* doubts that the Netherlands national measures are in conformity with the principle of proportionality, as the exemptions in the Directive had been deemed necessary due to the non-existence of safer and equally efficient alternatives. Portugal is opposed to a derogation for the Netherlands as the Netherlands authorities have failed to produce any justification that was not known at the moment when the Directive was adopted.
- (25) By letter of 23 September 1993, the Commission informed the Netherlands authorities that in its opinion the draft Regulation on PCP under the Commodities Act as notified by the Netherlands on 30 March 1992 was outside the area of harmonisation established by the provisions of Directive 91/173/EEC. The draft Regulation concerned exclusively goods treated with PCP. The

Netherlands expressed their opposition to this interpretation by letter of 4 March 1994. However, the Court supported the position of the Commission in its judgement of 1 October 1998, according to which, 'Article 1(1) of Directive 76/769/EEC, as amended by Directive 91/173/EEC, does not apply to products treated with PCP, its salts and esters or with a preparation produced from that substance, with the result that the Member States remain in principle free to fix limit values for such products independently' ⁽¹¹⁾.

(26) By letter of 8 November 1995, the Commission informed the Netherlands authorities that with regards to the notification of 21 January 1992, the Commission was intending to carry out an assessment of the risks to man and the environment of PCP and its substitutes. The assessment was expected to be finalised in 1998 and could, if found necessary, lead to an adaptation of the Community Directive. Under these circumstances, the Commission did not see it opportune to take a final decision on the notification presented by the Netherlands.

(27) The review process was concluded in 1998 and led to an adaptation of the provisions of Directive 76/769/EEC regarding PCP through Directive 1999/51/EC (see Chapter I above). The amending Directive did eliminate in principle the derogation for wood and textile treatment originally included in the Community Directive.

(28) 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 22 September 1999 the General Secretariat of the Commission informed the Netherlands authorities of the fact that their notification regarding the placing on the market and use of PCP would be treated in the framework of the new provisions of the Treaty.

III. ASSESSMENT

1. Applicable rules

(29) 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.

(30) 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 Netherlands notification, which is the subject of this Decision.

(31) 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

(32) The notification submitted by the Netherlands authorities on 21 January 1992 intends to obtain the authorisation to maintain national provisions incompatible with Directive 91/173/EEC, which constitutes a harmonisation measure adopted on the basis of the former Article 100a (now Article 95) of the EC Treaty.

(33) 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.'

(34) Directive 91/173/EEC was adopted on 21 March 1991. Member States had to bring into force the national provisions necessary to comply with the Directive before 1 July 1992. The Netherlands notified the provisions of its national regulations that it intended to maintain on 21 January 1992 and thus before the date foreseen for the application of the national provisions transposing the Directive.

(35) The Netherlands provisions in question, namely the Control Substances Act was adopted in 1962. All approvals for application of PCP for wood treatment had expired before 1989. It had been decided on 26 May 1989 that the last approval for the treatment of textiles with a PCP ester was to expire on 1 July 1992. In conclusion, the more restrictive legislation regarding the use of PCP for the treatment of wood and textiles had thus been adopted before Directive 91/173/EEC was adopted (21 March 1991).

⁽¹¹⁾ Case C-127/97, point 31.

- (36) It is therefore well justified to consider that in this case the conditions of Article 95(4) of the Treaty are met, according to which the national provisions notified, for which a Member State wishes to obtain approval for maintaining them after the date of implementation of a Community harmonisation measure, must have been adopted before the adoption of that harmonisation measure.
- (37) In addition, the Netherlands Authorities notified on 30 March 1992 a draft regulation on PCP under the Commodities Act and requested the authorisation for approval of this draft under the former Article 100a(4). The Regulation was finally adopted on 11 February 1994. However, it has been explained in the previous chapter that the provisions of this national regulation are outside the scope of harmonisation of Directive 91/173/EEC and are therefore not subject to this Decision.
- (38) In the light of what precedes, the Commission considers that the request of the Kingdom of the Netherlands for derogation from Directive 91/173/EEC as notified on 21 January 1992 under the former Article 100a(4) is admissible under Article 95(4) of the EC Treaty.

3. Assessment of merits

- (39) In accordance with the provisions of Article 95 of the Treaty, the Commission has to assure that all the conditions enabling a Member State to avail of the possibilities of derogation provided for in this article are met. The Commission has, in particular, to verify whether the provisions notified by the Member State are justified by the major needs of protection referred to in Article 30, or relating to the environment or working environment. In addition, the Commission has to verify, when it considers that these measures are justified, whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States, and whether or not they constitute an obstacle to the functioning of the internal market (Article 95(6)).
- (40) The Netherlands authorities have based their request on the need of protection of the environment and also human health. In support of their request of 21 January 1992 they submitted a brief analysis on the health and environmental effects of PCP, short summaries in the form of explanatory notes to existing or draft national legislation, as well as the texts of some parliamentary questions and replies concerning the marketing and use of PCP. After numerous contacts with the Commission services and in order to further substantiate its request for derogation from Directive 91/173/EEC the

Netherlands Government submitted five additional studies⁽¹²⁾ by a letter of 26 April 1994.

- (41) The Commission mandated a study to an external consultant to examine the situation in the Netherlands concerning the pollution with dioxines and furanes and the use of PCP⁽¹³⁾. Further studies, which were mandated by the Commission in the framework of similar requests from Germany and Denmark, have also been used. In addition, in the course of the review process of the provisions of Directive 91/173/EEC, the Commission prepared a report on the operation of the Directive and on the substitutability of PCP⁽¹⁴⁾, and mandated further studies to external consultants on the risks posed by PCP⁽¹⁵⁾ and possible substitutes for the treatment of wood and textiles⁽¹⁶⁾. The Commission consulted the Scientific Committee for Toxicity, Ecotoxicity, and the Environment on the basis of the last study on the risks posed by PCP. The Committee adopted its opinion on 27 November 1998.
- (42) 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 Netherlands request was notified, these substantial efforts of the Commission to find additional elements for the justification of the maintenance of the Netherlands national provisions cannot constitute a precedent for the future. When examining whether the national measures notified under Article 95(4) are justified by a major need, the Commission has to take as a basis 'the reasons' put forward by the Member State to justify the maintenance of its national provisions. This means that, according to the provisions of the Treaty, the responsibility of proving that these measures are justified, lays on the requesting

⁽¹²⁾ *Integrated criteria document chlorophenols*. RIVM report No 710401013, August 1991.

Assessment of the integrated criteria document chlorophenols. Advisor report by the Committee on Risk Assessment of Substances of the Health Council of the Netherlands.

Basisdocument dioxinen. RIVM report No 710401024, February 1993.

Emissies van dioxinen in Nederland. RIVM and TNO report No 770501003, April 1993.

Besluit luchtmissies afvalverbranding. A General Administrative Order including Explanatory Note.

⁽¹³⁾ C. Rappe, *Concerning Pentachlorophenol and dioxins*. Final report, Institute of Environmental Chemistry, Umea University, Umea, December 1994.

⁽¹⁴⁾ Report to the Commission on Pentachlorophenol (PCP), Brussels, 14 December 1994. The report was established after consultation of all Member States and other interested stakeholders who had been informed through a note published in the OJ C 315, 12.11.1994, p. 4. Three studies prepared by external consultants have also been taken into account.

⁽¹⁵⁾ Environmental Resources Management, *Assessment of the Risks Posed by Pentachlorophenol (PCP) through the Exposure of Man and the Environment to Dioxins*, Final Report, London, December 1997.

⁽¹⁶⁾ The Consultant 'Cabinet Paracelse' has prepared hazard assessments and reports on the suitability as substitutes to PCP in wood and textile treatment for five substances. The Final reports were submitted in September 1998.

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.

3.1. *Justification on grounds of major needs*

3.1.1. *PCP — general information*

- (43) PCP is a synthetically manufactured chemical substance, which is recognised as being dangerous for both man and the environment. The classification and labelling of PCP are harmonised at Community level in accordance with Council Directive 67/548/EEC of 27 June 1967 relating to the classification, packaging and labelling of dangerous substances⁽¹⁷⁾, as last amended by Directive 99/33/EC⁽¹⁸⁾, PCP is:

- classified as a category 3 carcinogen, i.e. a substance of concern to man because of a possible carcinogenic effect which, however, cannot be satisfactorily assessed given the information available. Evidence is available from appropriate studies on animals but it is not sufficient to place the substance in the group of category 2 carcinogens. Such a substance is labelled with the risk phrase 'R 40: Possible risk of irreversible effects',
- classified as very toxic by inhalation and labelled 'R 26: Very toxic by inhalation',
- classified as toxic in contact with skin and if swallowed and labelled 'R 24/25: Toxic in contact with skin and if swallowed',
- classified as irritating to eyes, the respiratory system and skin and labelled 'R 36/37/38: Irritating to eyes, respiratory system and skin',
- classified as dangerous for the environment and labelled 'R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment'.

- (44) As an organohalogen compound, PCP is included in List I of Council Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community⁽¹⁹⁾, as amended by Directive 91/692/EEC⁽²⁰⁾. This list contains substances that are selected mainly on the basis of their toxicity, persistence and bioaccumulation.

- (45) With the aim of eliminating pollution of the various parts of the aquatic environment, which could be affected by discharges of PCP, limit values were fixed by Council Directive 86/280/EEC of 12 June 1986⁽²¹⁾ on limit values and quality objectives for discharges of certain dangerous substances included in List I of the Annex to Directive 76/464/EEC.

- (46) PCP contains dangerous impurities including up to 0,1% of polychlorodibenzodioxins and 1 to 5% of polychlorinated phenoxyphenols. PCP alone and these impurities are contributing to the daily emission of dioxins into the environment. Dioxins are emitted when products treated with PCP are exposed to the sun and when they are incinerated at the end of their useful life. PCP in sewage sludge is also a source of dioxins.

- (47) PCP is used as:

- wood preservative (fungicide and anti-blueing agent),
- agent for the impregnation of industrial textiles (fungicide),
- bactericide in tanning and the paper pulp industry,
- molluscicide in the treatment of industrial water, in particular cooling water, and sometimes as
- sterilising agent.

- (48) Because of its toxicity, PCP has been made subject to various restrictions in more than thirty countries.

3.1.2. *The position of the Netherlands*

- (49) In their notification of 21 January 1992, the Netherlands authorities base the more stringent national measures on major needs relating to the protection of the environment and human health.

- (50) According to the Netherlands authorities, PCP (including its esters and salts) is scarcely degradable in the environment and is toxic to man and organisms in the aquatic environment. PCP is relatively mobile and dispersed through all environmental media.

- (51) PCP accumulates in fat tissue and thus in the food chain. Its esters and salts break down in PCP and thus have similar effects. PCP and its salts and esters are contaminated with chlorinated dibenzodioxins and dibenzofuranes. These compounds are also formed when PCP is incinerated in waste. Consequently, uses of PCP constitute a significant source of environmental contamination with chlorinated dibenzodioxins and dibenzofuranes.

⁽¹⁷⁾ OJ 196, 16.8.1967, p. 1.

⁽¹⁸⁾ OJ L 199, 30.7.1999, p. 57.

⁽¹⁹⁾ OJ L 129, 18.5.1976, p. 23.

⁽²⁰⁾ OJ L 377, 31.12.1991, p. 48.

⁽²¹⁾ OJ L 181, 4.7.1986, p. 16.

- (52) The Netherlands authorities recall that the dangers of PCP for the aquatic environment were already acknowledged on European level in 1976: Directive 76/464/EEC provides that the best available technology must be used to prevent emissions of PCP to surface waters.
- (53) Paragraph c of Annex 1B to the final declaration of the third North Sea Conference lists PCP as a substance, the use of which in pesticides should be strictly limited or terminated.
- (54) The Netherlands authorities also point out that, with regard to drinking water production, the presence of PCP in ground and surface water in concentrations greater than 0,1 pg/l is not acceptable. In this context they refer to the pollution of the Rhine and Meuse, which are also used for the production of drinking water in the Netherlands. Therefore, measurable emissions of this substance to water, soil and air should be avoided through replacement in all cases by other substances.
- (55) In 1992, the major emissions of PCP occurred to the atmosphere (48 tonnes per year), mostly originating from treated wood. Approximately 14 tonnes of PCP per year were deposited on soil and water from air, 11,5 tonnes originating from PCP contained in treated wood.
- (56) The major use of PCP was as wood preservative. This was banned in 1989, when the necessary approvals were not renewed. Already before that date, in the time period from 1984 to 1987, consumption had declined from 300 tonnes a year to 0,2 tonnes. PCP was used to a smaller extent in glues, textiles, leather, colour, paper, and cooling fluids. PCP was never produced in the Netherlands.
- (57) In a letter of 6 February 1995, the Netherlands authorities communicated calculations on the emission of dioxines to the Commission, which showed that in the year 2000 the use of PCP in the past will form the major source of dioxine emissions (20 g out of 58 g from all sources, including waster incineration), assuming the continuation of the existing ban on use. If the use of PCP was to be allowed again, this situation would become worse.
- which would necessitate the more restrictive national measures.
- (59) The study mandated by the Commission to an external consultant⁽²²⁾ confirms this by concluding that contrary to the situation in Germany, no special circumstances exist in the Netherlands. The Netherlands national measures could not be justified by a specific need to protect human health as the exposure to PCP in the Netherlands was well below acceptable daily doses. This emerged also from the additional documentation submitted by the Netherlands authorities.
- (60) The study also contests the arguments used by the Dutch authorities about the protection of the environment: PCP undergoes volatilisation, photochemical degradation and biodegradation and is thus not persistent⁽²³⁾. PCP is excreted in urine and faeces by all animals and thus does not accumulate in fatty tissue and in the food chain. The study also states that the pollution levels of the aquatic environment, as documented in the Dutch documents⁽²⁴⁾ are well below acceptable limit levels. The study could not detect either a correlation between the concentrations of dioxines and furanes in the environment or in breast milk and the use of PCP in the Netherlands. Nor was there a problem in more general terms (no history of PCP manufacture; very little use).
- (61) However, the provisions of Directive 91/173/EEC contain a requirement to re-examine the exemptions from the general ban on the use of PCP and its salts and esters in the light of developments in knowledge and techniques. The Community Directive provided for exemptions from the ban only in those areas where suitable or safer alternatives could not easily be identified at the time of adoption. Overall, the risks to man and the environment of PCP had thus clearly been recognised and addressed in the light of the available knowledge.
- (62) Already as early as 1994, the Commission started a review programme dealing with the evaluation of the risks linked to the use of substitutes for PCP, with the aim of tightening the restrictions adopted in Directive 91/173/EEC in the direction of a total ban⁽²⁵⁾. This programme was concluded in 1998 and did result in the

3.1.3. Evaluation of the position of the Netherlands

- (58) It can be seen from the arguments brought forward in the preceding chapter that the Netherlands authorities base their request for derogation exclusively on arguments concerning the general effects of PCP and the impurities contained in it on health and environment. They do not claim that there is a specific situation in the Netherlands in comparison to the other Member States,

⁽²²⁾ See footnote 13.

⁽²³⁾ This is also confirmed by the WHO *Environmental health criteria document 71, pentachlorophenol*, WHO, Geneva 1987.

⁽²⁴⁾ See footnote 12.

⁽²⁵⁾ This was announced in the Commission Decision 94/783/EC concerning the prohibition of PCP notified by the Federal Republic of Germany (OJ L 316, 9.12.1994, p. 43) and in the notice published in the OJ C 315, 12.11.1994 for consulting the stakeholders before the establishment of the report on PCP.

conclusion that in fact less dangerous alternatives were available.

- (63) In addition, the Scientific Committee, in its opinion of 27 November 1998 and based on a large amount of information available in the public domain and the study by ERM⁽²⁶⁾, concluded that in some areas, human exposure continued even where PCP use had ceased. No adequate clean-up treatment has yet been found to remedy contaminated soil. Risks for the aquatic environment from PCP and associated chemicals may occur, at least in 'hot spot' areas, involving local PCP release to the environment.
- (64) In the light of the comprehensive review and evaluation of alternatives carried out in the time period from 1994 to 1998, the Commission and the Member States, in their endeavour to reach a high level of protection of health and environment, have considered it necessary to adopt in Directive 1999/51/EC measures for the Community, which are equivalent to the Netherlands provisions. Member States will adopt these Community provisions as from January 2000.
- (65) The restrictions of the use of PCP in the Netherlands legislation are considered proportionate in relation to the pursued objective, as the exceptions to the ban of PCP established in Directive 91/173/EEC are no longer deemed to be acceptable if a sufficiently high level of health and environment protection is to be guaranteed. Therefore, it can be concluded that, although there are no specific circumstances in the Netherlands in comparison to the other Member States, the more stringent national measures can be regarded as justified.

3.2. *Absence of arbitrary discrimination*

- (66) Article 95(6) obliges the Commission to verify that the national provisions are not a means of arbitrary discrimination. According to the jurisprudence 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.
- (67) The Netherlands regulations apply without distinction to all products, whether they are manufactured in the Netherlands or imported from other Member States. Therefore, there is no evidence that the Netherlands regulations have been used as a means of arbitrary discrimination between economic operators in the Community.

⁽²⁶⁾ See footnote 15.

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

- (68) 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.
- (69) The Commission mandated a study⁽²⁷⁾ to analyse the effects on trade and competition of the retention by the Netherlands of its stricter national provisions. The study undertook to collect information on the volume and trade with other Member States which are affected, the interest, if any, which the Netherlands may have in using the national rules to promote a national interest in substitutes to PCP, the interest, if any, which the Netherlands might have in using the national rules to promote a national interest in substitutes to PCP-containing products.
- (70) According to the study, neither PCP nor its derivatives are manufactured in any of the Member States of the European Community. Substitutes for the treatment of wood or textiles must be approved according to the same legislation as PCP, whether they are produced in the Netherlands or in other Member States. There is no direct advantage from the national legislation on PCP to the producers of substitutes in the Netherlands.
- (71) It was established before that there is a real concern with regards to human health and the environment related to the use of PCP and treated timber. Furthermore the national provisions on PCP are a part of a more general policy on dioxines and furanes. Therefore, there is no evidence that the protection of health and the environment is not the real goal of maintaining the national legislation.
- (72) Overall, the Commission considers therefore that there is no evidence of a disguised restriction on trade between Member States provoked by the Netherlands legislation concerning PCP.

⁽²⁷⁾ S. J. Davis, *The effects of the retention by the Netherlands of its national rules on pentachlorophenol in place of the rules established by Directive 91/173/EEC*, London (UK), May 1995.

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

(73) 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 requirement cannot be interpreted in such a way that it prohibits the approval of any national measure likely to affect the establishment of the internal market. In fact, any national measure derogating from a harmonisation measure aiming at the establishment and operation of the internal market, constitutes in substance a measure that is likely to affect the internal market. Consequently, to preserve the useful character of the procedure for derogation provided for by Article 95 of the EC Treaty, the Commission considers that, in the context of the Article 95(6), the concept of obstacle to the functioning of the Internal Market has to be understood as a disproportionate effect in relation to the pursued objective.

(74) There have been no producers of PCP in the Community after the last manufacturer closed down in France in 1992. Producers in Germany, who started production in 1978 stopped already in 1985. Due to the restrictions in European and national levels, considerable amounts of PCP for wood treatment are used in three Member States only, and a small quantity for textile treatment for a very limited use in the military area. Use in the EC has decreased from 8 000 tonnes in 1986 to 2 000 tonnes in 1994.

(75) The world-wide production of PCP has decreased from 26 000 tonnes in 1986 to 11 000 tonnes in 1994. Producers are located in the US, India and China.

(76) Imports into the Netherlands had already decreased to around two to four tonnes for wood treatment in 1987, and thus before the expiration of the last approval, and 37,5 of PCP laureate for textile treatment. This represented already a very small part of the overall market in the EC. The study mandated by the Commission⁽²⁸⁾ did conclude that the effect of the Netherlands legislation on the market was practically negligible.

(77) Furthermore, although the Netherlands authorities have continued to apply the national legislation since 1 July 1992 instead of the Community legislation, there has never been a complaint from an economic operator from within or from outside the Netherlands. As in the meantime the Community legislation has been adapted to

technical progress and there will be no differences between the Netherlands legislation and the Community legislation from 1 September 2000, the overall effects on the functioning of the internal market are judged to be small.

(78) Taking into account the preceding observations, the Commission considers that there is no evidence that the Netherlands 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

(79) In the light of the above considerations, the Commission is of the opinion that the provisions with regards to the use of pentachlorophenol as notified by the Kingdom of the Netherlands pursuant to the former Article 100a(4) on 21 January 1992 and examined under Article 95(4) and (6) of the EC Treaty:

- fulfil the formal requirements of the said provisions and are to be admitted,
- can be considered justified on grounds of major need of protection of human health and the environment,
- 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.

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

(81) It has to be noted that the Netherlands provisions concerning PCP comprise an approval system without limiting clearly the areas of possible use. Furthermore, the limit for the impurity hexachlorodibenzo-paradioxines as laid down in the SIVEB Decision of 1980 is higher than in the Community Directive. 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 Netherlands national legislation can only be approved as its application in practice has shown that no product containing PCP was approved for applications not permitted by the Community Directive or containing more hexachlorodibenzo-paradioxine than 4 ppm. A

⁽²⁸⁾ See footnote 27.

different application of the Netherlands national legislation cannot be approved under Article 95(4).

Act are granted, which go beyond the provisions of Directive 91/173/EEC with regard to exceptions to the ban on the use of PCP or the content of hexachlorodibenzoparadioxin.

- (82) This Decision is without prejudice to the implementation by the Kingdom of the Netherlands of the provisions of Directive 1999/51/EC,

Article 2

HAS ADOPTED THIS DECISION:

This Decision is addressed to the Kingdom of the Netherlands.

Article 1

Done at Brussels, 26 October 1999.

The provisions of the Controlled Substances Act of 1962 are approved in so far as they are applied in such a way that no approvals pursuant to Article 2 of the Controlled Substances

For the Commission

Erkki LIIKANEN

Member of the Commission

COMMISSION DECISION

of 26 October 1999

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

(notified under document number C(1999) 3424)

(Only the Dutch text is authentic)

(Text with EEA relevance)

(1999/832/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

preparations containing creosote not respecting those limits may not be placed on the market.

Having regard of 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 Commission Directive 1999/77/EC⁽²⁾, provides for the prohibition and restriction of the use of certain dangerous substances and preparations. Directive 76/769/EEC is regularly amended to include in its Annex additional substances which are dangerous to man and the environment.
- (2) European Parliament and Council Directive 94/60/EC⁽³⁾ which amends Directive 76/769/EEC for the 14th time, harmonises amongst others the use and marketing of creosote and similar coal tar distillates, as well as preparations containing them, by limiting the content of one specific component, benzo[a]pyren, in the following B[a]P and water extractable phenols when used for wood-treatment (point 32 in the Annex to Directive 94/60/EC). The limit for B[a]P is fixed at a maximum of 50 ppm (= 0,005%) by mass and the limit for water extractable phenols is fixed at a maximum of 3% (= 30 g/kg) by mass. Wood treated with creosote or

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

2. National provisions: The Control Substances Act and the SIVEB Decision

- (4) The Netherlands legal system concerning creosote is established by The Control Substances Act of 1962⁽⁴⁾ and the executing Decision concerning the composition, classification, packaging and labelling of control substances, adopted on 22 February 1980 (hereinafter called the SIVEB Decision)⁽⁵⁾ with its subsequent amendments. The legislation provides for a general prohibition combined with an approval system on an individual basis.
- (5) The Control Substances Act covers crop control substances (Article 1(1)(f)), which may not be supplied, possessed, kept in stock, marketed, or used in the Netherlands unless approved pursuant to the Act (Article 2 (1)). Article 3(1) defines the general conditions

⁽¹⁾ OJ L 262, 27.9.1976, p. 201.

⁽²⁾ OJ L 207, 6.8.1999, p. 18.

⁽³⁾ OJ L 365, 31.12.1994, p. 1.

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

⁽⁵⁾ Official Journal of The Netherlands of 29 February 1980, No 43.

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

glasshouses, the use of creosote is totally banned in the approvals. Creosote can be applied only in special industrial installations by using a specified technique (vacuum/pressure).

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

(7) The Dutch government notified some examples of individual approvals in the cases of creosote oil and carbolineum, which contain certain exclusions for their use or which determine the only permitted use. These approvals shall have, according to the Dutch government, a legal effect equal to that of a general statutory order, since the same conditions are imposed in all similar cases. For certain uses, like on toys, inside buildings, in contact with foodstuffs, in green- or

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

- (8) Table 1 shows in detail the differences between the restrictions on the use of creosote with regard to the B[a]P content imposed by Directive 94/60/EC and the Dutch legal system.
- (9) In summary, the Dutch provisions are more restrictive in several aspects:
- the B[a]P content of creosote is not permitted in the range of 50 to 500 ppm for the use in industrial installations
 - wood preservation has to be performed according to a specific technique (pressure/vacuum) in special installations
 - in certain cases the use of creosote is excluded for wood preservation, even if its B[a]P content is below 50 ppm.

Table 1

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

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

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

	Council Directive 94/60/EC	SIVEB Decision
B[a]P < 50 ppm (cont'd)		Creosot: Permitted only for industrial use in special installations for treating wood by the vacuum and pressure method for: — railway sleepers — telephone and electricity poles — excavation, road and water works — fencing
B[a]P in range 50 to 500 ppm	Restrictions on sale of creosote: — no sale to private consumers — use only permitted in industrial installations — Minimum drum size 200 l; Special labelling required. Creosoted wood may only be used for professional and industrial applications: — railways — electricity poles — fencing — waterways Explicit restrictions on treated wood. It may not be used: — inside buildings — in contact with foodstuff — for containers for growing purposes — at playgrounds or other sites at risk of skin contact	Sale and use of creosote and treated products totally banned.
B[a]P > 500 ppm	Sale and use of creosote and treated products totally banned	Sale and use of creosote and treated products totally banned
Old treated wood	Use controlled as for wood treated with creosote containing B[a]P between 50 and 500 ppm	No other regulations than for newly treated wood

II. PROCEDURE

- (10) Directive 94/60/EC was adopted on 20 December 1994. The Netherlands submitted the following declaration to the minutes of the Council: 'The Netherlands is voting against the proposed Directive concerning the 14th amendment of Directive 76/769/EEC, as it fails to comply with regard to "Creosote" with the basic principle enshrined in the EC Treaty that a high level of protection be achieved for the environment and public health. The Netherlands therefore reserves the right, by recourse to Article 100a(4) of the EC Treaty, to adopt national provisions in the field of creosote that are justified on the important grounds referred to in Article 36 or connected with the protection of working conditions on the environment'.
- (11) The Directive had to be implemented into the national law of the Member States no later than one year after its adoption, i.e. 20 December 1995 (Article 2(1), first subparagraph) and the national provisions had to be applied from 20 June 1996 (Article 2(1), second subparagraph).
- (12) By letter of 9 March 1995, the Dutch Permanent Representative informed the Commission that the Netherlands considered it necessary to maintain, in accordance with the former Article 100a(4) of the EC Treaty, the national legal provisions contained in the Control Substances Act of 1962⁽⁷⁾ and the 'SIVB Decision' with its subsequent amendments, which provide for more restrictive measures on the use of creosote offering further protection of public health, the working environment than would be the case on a strict implementation of the Directive.
- (13) The Commission consulted the other Member States by letter of 21 June 1995 with regard to the Dutch request to maintain stricter provisions on creosote. Seven Member States replied. Austria, Denmark, Finland, Germany and Sweden support the Dutch request, while Ireland and the United Kingdom are opposed.
- (14) Austria's assessment of the Dutch position is that the higher level of protection offered by the national provisions is necessary in order to protect the environment in the Netherlands, as creosote-impregnated timber is used in large amounts in shoreline defences and other installations and in ships and ships' hulls. The rate of leaching is particularly high owing to the constant contact with salt water, and accumulation in the sediment poses a considerable hazard to aquatic communities. The massive pollution of Dutch waters and their beds with polycyclic aromatic hydrocarbons (PAHs) can only be remedied by reducing the maximum permissible B[a]P content in creosote to an ecologically acceptable level. Austria takes the view that the stricter provisions cannot in any way be regarded as an arbitrary discrimination or disguised barrier to trade, and that the reference to the former Article 100a(4) is justified.
- (15) Sweden emphasises the fact that creosote is a mixture of several hundreds of substances including polycyclic aromatic compounds. Many were shown in animal testing to be mutagenic or carcinogenic. Creosote is highly toxic to aquatic organisms and most of the substances contained are bioaccumulating. Creosote strongly irritates the skin and causes, in combination with sunshine, photoallergic reactions as blisters and severe eczema. There is, according to Sweden, at the time being, no scientific evidence to prove that the use of creosote with levels of B[a]P lower than 50 ppm or wood treated with such substances, is safe for consumers or for the environment.
- (16) Denmark agrees with the Netherlands that creosote is a highly dangerous substance for humans and the environment. Use of the substance should, therefore, be restricted as far as possible, and preferably banned.
- (17) In supporting the Dutch views, Germany refers to its own request under the former Article 100a(4).
- (18) Finland expresses the opinion that in this case the conditions contained in the former Article 100(4)a are fulfilled and that the Commission should confirm the Dutch national provisions.
- (19) In contrast, Ireland considers that the request is not based on new scientific evidence. Ireland therefore sees no reason to move away from the agreed dual standard of 50 ppm and 500 ppm of Directive 94/60/EC nor to introduce controls on the use of wood treated with coal-tar distillates containing less than 50 ppm B[a]P.
- (20) The United Kingdom argues that the Dutch request does not reflect the sort of risk assessment which is now widely accepted in the evaluation of chemicals in general, and of pesticides in particular. It criticises the Dutch request for only looking at the hazards and that it did not include a summary of toxicological and other data, followed by a risk assessment of permitted uses. The United Kingdom states that the arguments raised by the Netherlands had already been raised and rejected at the Council Working Group stage during the

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

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

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

III. ASSESSMENT

1. Applicable rules

- (22) The Treaty of Amsterdam has amended substantially the provisions of the former Article 100a of the Treaty establishing the European Community, by replacing paragraphs 3, 4, and 5 of this article with eight new paragraphs numbered 3 to 10. Due to the new numbering of all articles, the amended article has become Article 95 of the Treaty establishing the European Community.
- (23) The Treaty of Amsterdam does not comprise specific transitional provisions on the rules applicable to the notifications made previously to the time of entry into force of this treaty, like the Dutch notification, which is the subject of this Decision.
- (24) In the absence of specific provisions extending their application, the old provisions of Article 100a(4) of the EC Treaty are regarded as repealed from the day of the entry into force of the new provisions (1 May 1999). Instead, the new provisions of the Treaty apply immediately from that date to the examination of this notification.

2. Consideration of admissibility

- (25) The notification submitted by the Dutch authorities intends to obtain the authorisation to maintain national provisions incompatible with Directive 94/60/EC, which

constitutes a harmonisation measure adopted on the basis of the former Article 100a (now Article 95) of the EC Treaty.

- (26) Article 95(4) of the Treaty reads as follows: 'If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.'
- (27) Directive 94/60/EC was adopted on 20 December 1994. The Directive had to be transposed by the Member States by 20 December 1995 and enforced by 20 June 1996. The Netherlands notified the provisions of its national regulations that it intended to maintain on 9 March 1995 and thus before the date foreseen for the application of the national provisions transposing the Directive.
- (28) The Dutch provisions in question, namely the relevant amendment of the SIVB Decision, was adopted on 12 March 1992 and thus before Directive 94/60/EC was adopted (20 December 1994).
- (29) It is therefore well justified to consider that in this case the conditions of Article 95(4) of the Treaty are met, according to which the national provisions notified, for which a Member State wishes to obtain approval for maintaining them after the date of implementation of a Community harmonisation measure, must have been adopted before the adoption of that harmonisation measure.
- (30) In the light of what precedes, the Commission considers that the request of the Kingdom of the Netherlands for derogation from Directive 94/60/EC as notified on 9 March 1995 under the former Article 100a(4) is admissible under Article 95(4) of the EC Treaty.

3. Assessment of merits

- (31) In accordance with the provisions of Article 95 of the Treaty, the Commission has to assure that all the conditions enabling a Member State to avail of the possibilities of derogation provided for in this article are met. The Commission has, in particular, to verify whether the provisions notified by the Member State are justified by the major needs of protection referred to in Article 30, or relating to the environment or working environment. In addition, the Commission has to verify, when it considers that these measures are justified,

whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States, and whether or not they constitute an obstacle to the functioning of the internal market (Article 95(6)).

- (32) The Dutch authorities have based their request on the need of protection of human health and the environment. In order to substantiate its request for derogation of Directive 94/60/EC the Dutch government submitted a study made on behalf of the Ministry of Housing, Spatial Planning and Environment⁽⁸⁾. The study mainly gives an overview on the use of creosote in The Netherlands and its environmental and health effects. It examines the origin, the pathways and the deposition of polycyclic aromatic hydrocarbons (PAHs), among which B[a]P is the most thoroughly investigated.
- (33) The Commission mandated a study to an external consultant to critically review the study submitted by the Dutch authorities and to further assess the situation of environmental contamination and the possible risks to human health by creosote in the Netherlands⁽⁹⁾. In addition, the findings of three further studies⁽¹⁰⁾, which were mandated by the Commission in the framework of similar requests from other countries, have been used in the assessment of the request from the Netherlands.
- (34) It has to be noted that, in the light of the time-frame established by Article 95(6), which did not exist in the former Article 100a(4) under the regime of which the Dutch request was notified, these substantial efforts of the Commission to find additional elements for the justification of the maintenance of the Dutch national provisions cannot constitute a precedent for the future. When examining whether the national measures notified under Article 95(4) are justified by a major need, the Commission has to take as a basis 'the reasons' put forward by the Member State to justify the maintenance of its national provisions. This means that, according to the provisions of the Treaty, the responsibility of proving that these measures are justified, lays on the requesting Member State. Given the procedural framework established by Article 95, the Commission normally has to limit itself to examining the relevance

of the elements which are submitted by the requesting Member State, without having to seek itself possible reasons of justification.

- (35) None of the studies referred to above was completely conclusive with regards to the effects of creosote on human health, in particular concerning its carcinogenic potential, as a specifically designed long-term carcinogenicity study was still ongoing. This study⁽¹¹⁾ was made available to the Commission at the beginning of 1998. The findings of all these studies are set out in the following. In addition, all studies have been made available to the Scientific Committee on Toxicity, Ecotoxicity, and the Environment, which expressed a first opinion on the cancer risk to consumers from creosote and/or wood treated with such creosote on 27 November 1998. This opinion was revised on 4 March 1999.

3.1. *Justification on grounds of major needs*

3.1.1. *Creosote — general information*

- (36) Creosote is a complex mixture of over 200 chemical compounds, predominantly aromatic hydrocarbons, as well as phenolic and aromatic nitrogen and sulphur compounds. It is a mid-heavy distillate of coal tar (boiling point approximately 200 to 400°C).
- (37) Creosote can contain over 30 different polycyclic aromatic hydrocarbons (PAHs) with a possible total PAH content of 85%. The most important ones are:
- acenaphthene
 - naphthalene
 - phenanthrene
 - anthracene
 - fluorene
 - fluoranthene
 - chrysene
 - triphenylene
 - benzo[a]anthracene
 - benzo[b]fluoranthene
 - benzo[k]fluoranthene
 - benzo[a]pyrene

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

⁽⁹⁾ G. Grimmer, 'Study on the Justification in Scientific Terms of Allowing The Netherlands to retain its National Laws on Creosote in Place of Council Directive 94/60/EC.' Final report, Biochemisches Institut für Umweltcarcinogene, Großhansdorf (Germany), December 1995.

⁽¹⁰⁾ Environmental Resources Management, 'Scientific Evaluation of the German Request for Derogation from Provisions of Council Directive 94/60/EC Concerning Creosote', Final Report, 24 April 1996. Dr. P.M. Sorgo, 'Study on the Justification in Scientific Terms of Allowing Denmark to Retain its National Laws on Creosote', Final Report, November 1996. WS Atkins International Ltd., 'Study on the Justification in Scientific Terms of Allowing Sweden to Retain its National Laws on Creosote in Place of Council Directive 94/60/EC', Final Report August 1997.

⁽¹¹⁾ Fraunhofer Institute of Toxicology and Aerosol Research, 'Dermal Carcinogenicity Study of two Coal Tar Products (CTP) by Chronic Epicutaneous Application in Male CD-1 Mice (78 Weeks)', Final Report, Hanover, October 1997.

- (38) Benzo[a]pyrene (B[a]P) is one of the most thoroughly investigated PHAs and the B[a]P content is used as an indicator or marker substance for classification purposes and does not, in itself, reflect the total PAH content of creosote. Depending on the type of creosote concerned, the B[a]P content may vary between 0,003 and 0,3 % by weight (30 to 3 000 ppm). A refined distillation of coal tar and selection of the fractions can lead to lower B[a]P or phenol contents. Different industry standards have been developed by the Western European Institute for Wood Preservation, characterised mainly by different contents specified distillation fractions and, most important in this context, different contents of B[a]P. Limiting values for classification standards are 500 ppm and 50 ppm.
- (39) Modifications to both the physical and chemical properties of creosote are possible if they are required for use or environmental purposes. It is possible to create a lower viscosity product, better suited to brush application, by incorporating components with a lower boiling point, which is sometimes called *carbolineum*. Directive 94/60/EC does not make a distinction: it covers and treats in an identical way a whole range of different coal tar distillates, all of them specified by their names, EINECS, and CAS numbers.
- (40) Creosote is principally and almost exclusively used as a wood preserving agent. Large-scale industrial and professional applications are by far the most important ones: railway sleepers, poles for electricity transport, hydraulic engineering (bank protection), agriculture and fruit production. Creosote and similar products are also used by individual consumers for wood preserving purposes.
- (41) The most important properties of creosote are:
- high fungicidal efficacy,
 - high insecticidal efficacy,
 - long-term persistence,
 - resistance to leaching and weathering.
- (42) A very small quantity of creosote is used in medicinal products for the treatment of certain skin diseases, e.g. psoriasis.
- Toxicity of creosote:
- Human health effects:
- (43) Despite the fact that creosote has been used as a wood preservative for over a century, there are only few published data on the effects to humans of sustained exposure to creosote. Many of the studies are rather old and do not always conform to modern standards with regards to documentation.
- (44) Exposure can occur via inhalation, ingestion, or skin contact. Creosote is evaluated as mildly to moderately toxic by ingestion. Most effects resulting from animal experiments and all epidemiological studies in humans are linked to dermal exposure.
- (45) Skin photosensitivity from coal tars has been described by a number of authors. Irritation symptoms, pitch warts, skin discoloration and dermal tearing have been reported to occur amongst workers exposed to creosote. The most recent study on workers exposed to creosote in Sweden and Norway was published in 1992⁽¹²⁾. The study examined workers exposed to creosote between 1950 and 1975. The investigators found a somewhat lower total cancer incidence than expected and an increased risk of cancer of the skin and lip and of non-Hodgkin lymphomas. However, the composition of the creosote was not documented and the authors conclude that the small number of cases did not permit valid conclusions. The increase could be attributed to exposure both to creosote and to sunlight. One other study⁽¹³⁾ found an increase in risk of mortality from scrotal cancer for brickmakers exposed to creosote during the period 1911 to 1938. Again, neither the B[a]P content of the creosote nor a clear dose response relationship are known.
- (46) Mostly based on an animal experiment, where the skin of mice was regularly exposed to B[a]P solutions in acetone during their lifetime⁽¹⁴⁾, the International Agency for Research on Cancer (IARC) has classified creosote as a group 2A human carcinogen. IARC estimates that for substances in this class there is sufficient evidence that creosote is carcinogenic in animals and certain evidence from epidemiological studies to conclude that creosote can be carcinogenic in humans. There is no significant new evidence from more recent investigations, which would affect this conclusion.
- ⁽¹²⁾ S. Karlehagen et. al., Cancer Incidence Among Creosote-Exposed Workers, Scand. J. Work Environ. Health, 1992: 18, p. 26.
- ⁽¹³⁾ IARC, Monograph on the Evaluation of Carcinogenic Risk to Humans, Vol. 35, Polynuclear Aromatic Compounds, Part 4, Bitumen, Coal Tars and Derived products, Shale Soils and Soots, Lyon, 1985.
- ⁽¹⁴⁾ J.M. Holland, E.L. Frome, Advances in Modern Environmental Toxicology, Vol. VI, Applied Toxicology of Petroleum Hydrocarbons, ed. MacFarland et. al, Princeton Scientific Publishers 1984.

(47) For several years, experts from the Member States examined the issue of classification of creosote, other coal-tar distillates, and further so-called complex substances in the framework of Council Directive 67/548/EEC of 27 June 1967 relating to the classification, packaging and labelling of dangerous substances⁽¹⁵⁾, as last amended by Directive 1999/33/EC⁽¹⁶⁾. Drawing largely on the same data as IARC, agreement was reached during the elaboration of Commission Directive 94/69/EC⁽¹⁷⁾ the 21st adaptation to technical progress, according to which creosote and some other coal tar distillates are classified as category 2 carcinogens and must be labelled with the risk phrase R 45 'May cause cancer'. However, the classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005% (= 50 ppm) per weight B[a]P⁽¹⁸⁾. This is different from the IARC classification, which applies without any specification of the B[a]P content.

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

(49) Little is known about the toxicokinetics of creosote in humans or experimental animals. Only very recent studies have investigated quantitative absorption of PAHs through the skin by measuring excreted metabolites of pyrene⁽¹⁹⁾: absorption appears to vary between individuals and between different sites within the same individual. In a separate study⁽²⁰⁾, the dermal absorption of different PAH compounds was measured. PAHs of higher molecular weight than pyrene, e.g. B[a]P

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

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

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

Environment effects:

(52) Environmental contamination by creosote has been reported in a number of countries, with old wood treatment facilities often being the source of the contamination. In fact, most information on the fate of creosote in the environment has been obtained from industrial creosote spills and from 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).

⁽¹⁵⁾ OJ 196, 16.8.1967, p. 1..

⁽¹⁶⁾ OJ L 199, 30.7.1999, p. 57.

⁽¹⁷⁾ OJ L 381, 31.12.1994, p. 1.

⁽¹⁸⁾ Nota M of the foreword to Annex I to Council Directive 67/548/EEC is applicable to creosote. Van Rooij J.G.M., et al., Absorption of Polycyclic Aromatic Hydrocarbons Through Human Skin: differences between Anatomical Sites and Individuals, J. Tox. Environ. Health, 38, 1993, p. 355.

⁽¹⁹⁾ Van Rooij J. G. M., et. al., Absorption of Polycyclic Aromatic Hydrocarbons Through Human Skin: Differences between Anatomical Sites and Individuals, J. Tox. Environ. Health, 38, 1993, p. 355.

⁽²⁰⁾ Van Rooij J. G. M., Dermal Exposure to Polycyclic Aromatic Hydrocarbons Among Workers, Thesis ISBN 90-9007080-X, Nijmegen 1993.

- The main breakdown processes are photodegradation (i.e. under irradiation from the sun) and microbial degradation (i.e. by certain bacteria). Microbial degradation can occur under aerobic and anaerobic conditions. PAHs compounds with four rings and more may be poorly degradable.
 - PAHs reaching watercourses are rapidly transferred to sediment.
 - In watercourses, most of the lower molecular weight PAHs are removed primarily by microbial degradation and the higher molecular weight compounds by photooxidation and sedimentation. Microbial degradation of the more water-soluble PAHs occurs under aerobic and anaerobic conditions. The PAH constituents have been shown to bioaccumulate in aquatic species.
- (55) Emissions of PAHs to air, water and soil can occur during the impregnation process and storage at the impregnation site, as well as during use of treated wood. However PAHs found in the various environmental compartments originate from a variety of sources (e.g. all combustion processes, traffic etc.) and it is often difficult to ascribe their levels to any particular source such as creosote-treated wood.
- (56) A study⁽²¹⁾ in Sweden has shown that after 40 years in soil, creosote impregnated poles had lost a part of the compounds contained in creosote, especially those with the lowest boiling point (< 270 °C). The part of the poles above the ground lost the larger amount. However, mobility of the leached compounds was very low as they could only be detected in the soil in close contact with the poles. This is coherent with the observation that the mobility of PAHs in soil is extremely low due to their strong absorption to organic matter.
- (57) The presence of elevated levels of PAH in aquatic environments has often been attributed to the presence of creosote-treated wood. Migration of creosote components from treated 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⁽²²⁾. The pollution of sediments by creosote leaching from waterbank protection has been documented in the Netherlands⁽²³⁾ and also in studies on pollution from former impregnation facilities.
- (58) As for human exposure, actually measured data on environmental pollution by PAHs originating in creosote are scarce.
- ### 3.1.2. *The positions of The Netherlands*
- (59) In the Netherlands, a vigorous policy is in place regarding PAH. In 1993, the Dutch Parliament adopted limit values and target values for individual PAH, related to a maximum permissible concentration (MPC). PAH concentrations have repeatedly exceeded the MPC in certain environmental compartments. As a consequence, considerable emission reductions are required by the National Environment Policy Plan 2. All sources for PAH containing coatings, coal tar varnish, cable burning plants, refineries, sewerages, basic metal industry, chemical industry, wood-burning stoves and traffic.
- (60) A number of measures in the form of agreements between the government and various sectors have or will be taken following the Policy Statement Environmental Objectives for the Building Industry 1995 (BMB 1995). The SIVEB decision forms part of a this strict general policy of the Netherlands aiming at a strong reduction of emissions of PAH from all sources. Reduction of emissions from creosoted wood during its production, use, and destruction after use plays an important part in these measures. The major goal is the reduction of the application of creosoted wood where alternatives are available.
- ### Special situation in the Netherlands
- (61) In Europe a total of 1 million m³ of creosoted wood was used in 1990. Table 2 gives an overview of the consumption of creosoted wood in Europe.

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

⁽²²⁾ L. L. Ingram et. al., 'Migration of Creosote and Its Components from Treated Piling Sections in a Marine Environment', Proc. Ann. Meet. Am. Wood Preserv. Assoc. 78, 1982, p. 120. See also footnotes 8 and 13.

⁽²³⁾ See footnote 8.

Table 2

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

Country	Annual use 1990 (m ³ /y)	Annual use/capita (10 ⁻³ m ³ /cap.y)	Annual use/km ² (m ³ /km 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

(62) In absolute figures, the Netherlands is the second largest user of creosoted wood after Germany. The use per capita is the second highest after Sweden, the consumption per km² is by far the highest in the Netherlands and amounts to 15 times the European average. The Netherlands is a water-abundant country, almost 15 % of the surface consists of lakes, rivers canals and other waterways. This is due to the specific geographic situation of the Netherlands being located in the delta of three large rivers: the Rhine, the Meuse, and the Scheldt.

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

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

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

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

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

⁽²⁴⁾ Source: See footnote 8.

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

- (68) As part of the general policy for the protection of the environment, a tolerable limiting value of 0,05 mg B[a]P/kg dry mass of sediment has been established by the Dutch Parliament.
- (69) A survey made in 1990 classified sediment samples in four classes, delimited by their B[a]P content. Only sediments in class 1 comply with the limiting value. Results of the survey are shown in Table 3.

Table 3

Quality of waterbed sediment (1990) ⁽²⁵⁾

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

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

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

class 3: deposition of sludge on adjoining land undesired

class 4: investigation into decontamination necessary

- (70) A survey in 1993, consisting of more than 10 000 samples of newly formed sediment, showed that in 95% (90% in regional waters) of the samples the limiting value had been exceeded.
- (71) Apparently the situation has not improved in recent years, and it seems that the overwhelming majority of sediments in Dutch waterways is contaminated by B[a]P to an extent beyond the acceptable standards.
- (72) Several investigations estimate the total B[a]P emissions in the Netherlands into water as approximately 100 kg/year. Additionally, the rivers flowing into the Netherlands carry more than 1 800 of B[a]P (which would be about 18 times the nationally emitted

quantities). These imports from other countries as well as the pollution by shipping (and/or traffic) are limited to the main waterways (= governmental waters in the Dutch terminology). No upward flow of sediment into regional waters occurs. Thus the main source of sediment contamination in the biggest part of the Dutch waterways (regional waters) appears to be leaching from bank protection with creosoted wood.

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

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

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

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

- (77) The study provided by bkh consulting engineers acknowledges that nowhere in the Netherlands the limit value determined by the Dutch Parliament (1 ng/m³ annually averaged concentration) has been exceeded at the monitoring stations of the national air monitoring net.

⁽²⁵⁾ Source: See footnote 8.

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

Table 4

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

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

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

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

3.1.3. Evaluation of the position of the Netherlands

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

3.1.4. Human Health Risks

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

(a) The position of the Netherlands

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

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

— employees in creosote plants

— neighbouring inhabitants of creosoting plants

— children playing on equipment made of creosoted wood.

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

⁽²⁶⁾ Source: See footnote 8.

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

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

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

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

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

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

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

(91) This study⁽²⁹⁾ had been scheduled to be completed in December 1996. It was finally made available to the Commission in January 1998. The study tested the carcinogenic effects of two creosote products provided by the sponsoring company (Rüttgers-VfT AG, Germany) containing 10 and 275 ppm B[a]P. Due to the high viscosity of the products, they could not be applied directly to the skin of the mice but had to be diluted in Toluene. Solutions with various concentration of the product and thus various B[a]P concentrations, as well as pure B[a]P solutions and a control of pure Toluene were applied to groups of 62 mice for a time of 78 weeks (two times per week, 25 µl). Development of tumours was observed during this time and the test animals were carefully examined after termination of the study.

Table 5

Results of risk evaluation performed⁽²⁸⁾

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

(92) 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.

(93) The SCTEE observes that the Fraunhofer study is well-designed and reaffirms the carcinogenic potential of coal tar preparations. Due to the genotoxic potential of

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

⁽²⁸⁾ Source: See footnote 8.

⁽²⁹⁾ See footnote 11.

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

- (94) Data to fully evaluate the relevance of effects seen in a mouse skin-painting study for human exposure situations are insufficient. Extrapolating skin carcinogenicity data from mice to the human situation also entails a number of uncertainties leading to difficulties in directly using cancer potency data from mice to assess cancer risk in humans. Species-dependent sensitivity of dermal exposure to the carcinogenic actions of creosote will be affected by morphology and physiology of the skin, by metabolic activation and inactivation in the skin and by repair processes. On the basis of all the available information; a scientifically justified assessment of carcinogenic risk, e.g. for the dermal exposure of children playing on wood treated with creosote is therefore difficult.
- (95) From the data contained in the Fraunhofer study, the SCTEE calculated a T25 carcinogenic potency value for pure B[a]P of 13 µg/kg bw/day. The T25 is the chronic daily dose kg bodyweight (bw), which give 25% of the test animals tumours at a specific tissue site within the standard life span of that species. The creosote formulations tested had a five-fold higher overall carcinogenic potency (2,7 µg/kg bw/day).
- (96) The SCTEE did not have measured data at its disposal regarding the exposure of the public to creosote. Various values have been calculated in the studies made available to the SCTEE, using different models, assumptions and scenarios. For the most critical exposure, children playing on wood treated with creosote containing 50 ppm B[a]P, the Dutch authorities have arrived at an exposure of two ng B[a]P per kg bw/day (playtime of three hours per day). One of the studies mandated by the Commission, in using a slightly different methodology arrives at exposure doses of 0,85 ng/kg bw/day (playtime of two hours per day) and 1,7 ng/kg bw/day (playtime of four hours per day).
- (97) Should the value of exposure estimates for the scenario of children playing on creosote treated wood (two ng B[a]P per kg bw/day) approximate the true exposure, this would result in a life-time cancer risk of $1,92 \times 10^{-4}$
- for a life-long daily exposure, which would give clear concern, $2,74 \times 10^{-5}$ for a daily exposure during 10 years out of 70 and $1,37 \times 10^{-5}$ for a daily exposure during five years out of 70. Using the exposure doses calculated in the other study would change the risk proportionately.
- (98) Based on the most recent study with regards to the dose-response relation for dermal carcinogenicity of creosote, as derived by the SCTEE, and depending on the exposure model selected, the risk is therefore slightly or more clearly above a value of 1×10^{-5} , which is proposed as an acceptable risk level for genotoxic carcinogens in drinking water by the World Health Organisation.
- (99) However, there are many uncertainties regarding exposure. According to the SCTEE, the Dutch calculation is on the one hand an over-estimation (due to an exaggerated exposure model), on the other hand an under-estimation (due to the fact that the five fold higher potency of creosote in comparison to B[a]P was not taken into account). As the SCTEE has taken the latter into account, the result could be an over-estimate as the exaggerated risk model is used.
- (100) Also, the SCTEE mentions that the figure of two ng B[a]P per kg bw/day as a worst-case exposure to B[a]P from playing on creosoted-treated wood has to be compared to estimates for intake of B[a]P via food. Annual intakes of B[a]P from food have been estimated to be in the order of 0,3 to 1,6 mg, which would result in daily exposures of 12 to 63 ng/kg bw for a person weighing 70 kg and are thus clearly higher than the doses received from playing on creosote-treated wood.
- (101) Overall the SCTEE concludes:
1. — Given the genotoxicity of B[a]P and the outcome of the Fraunhofer skin-painting study, there is sufficient scientific evidence to support the opinion that there is a cancer risk to consumers from creosote containing less than 50 ppm B[a]P and/or from wood treated with such creosote.
 - B[a]P is a good indicator for the carcinogenic hazard of the creosote preparation tested, since there was a linear relationship between cancer incidence and B[a]P dose. However, the cancer potency of the creosote preparation was five-fold higher than judged from its B[a]P content.

2. — On the basis of the available information, even taking into account the considerable uncertainties in assessing the risks for children coming into contact with creosote-treated wood, the magnitude of the risk gives clear reason for concern. However, the highest estimated exposure is some 6 to 30 times lower than the oral exposure of the adult population to B[a]P in food.

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

3.1.5. Overall Evaluation

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

(103) With regards to the risks posed by creosote to human health, the Commission has received additional information in the framework of similar requests from Germany, Sweden and Denmark for derogation from Directive 94/60/EC under the former Article 100a(4) of the EC Treaty, and new scientific evidence through an extensive study carried out after the adoption of the Community Directive.

(104) Based on these most recent experimental data, the SCTEE has estimated that there is a cancer risk to humans from creosote containing less than 50 ppm B[a]P and wood treated 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.

(105) The legislation notified to the Commission by the Dutch authorities takes account of the general principle of proportionality, i.e. the measures do not seem to exceed what suitable and necessary for the pursuit of the

legitimate objective, as this legislation provides for the possibility to use creosote-containing products, when compatible with the needs for the protection of health and the environment.

(106) In accordance with Article 95(7) of the Treaty, the Commission is already examining the appropriateness to adapt to technical progress the provision of Directive 94/60/EC regarding creosote. In addition, the Commission will evaluate the use of creosote under the review programme established in Article 16 of European Parliament and Council Directive 98/8/EC of 16 February 1998 on the placing of biocidal products on the market⁽³⁰⁾ in a time-frame compatible with the general timing of the review programme and taking into account other possible priorities identified when effectively setting up the programme. Furthermore, an ongoing research project under the Fourth Framework Programme of research and technological development is reviewing the production chain and in-service life of poles treated with creosote⁽³¹⁾.

3.2. Absence of arbitrary discrimination

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

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

⁽³⁰⁾ OJ L 123, 24.4.1998, p. 1.

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

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

- (109) More restrictive national measures in the area of limitations of marketing and use of products derogating 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 present the restrictions based on the criteria of paragraph 4 being applied for inappropriate reasons, and in reality constituting economic measures introduced to impede the import of products from other Member States in order to protect indirectly national production.
- (110) The Commission mandated a study⁽³²⁾ to analyse the effects on trade and competition of the retention by the Netherlands of its stricter national provisions. The study by TIS undertook to collect information on the annual quantities of creosote used wood preservation and treated wood production in the Member States, the historical development and on how these will change if the Netherlands were to retain its own legislation in place of Directive 94/60/EC. To this end, questionnaires were prepared and distributed to creosote producers, creosote traders and wood impregnators within the EC.
- (111) According to the study, there is one producer of creosote in the Netherlands. About three quarters of the total production (5 200 t/year) is exported, whereas about 3 400 t/year are imported (mostly from Germany). Most of the producers in other Member States can comply with the Dutch regulations and those who cannot, have not had business with the Netherlands in the past.
- (112) As far as possible substitutes to creosote are concerned, there is no information indicating that the Netherlands has national economic interests in their development, production or export.
- (113) It was established before that there is a real concern with regards to human health related to the use of creosote and treated timber, and with regards to the environment due to the specific situation of the Netherlands. Furthermore the national provisions on creosote are a part of a more general policy on PAHs. Therefore, the protection of health and the environment

seems to be the real goal of maintaining the national legislation, and not the creation of disguised barriers to trade.

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

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

- (115) This condition, which is established by Article 95(6), first subparagraph, is new in comparison to the text of the former Article 100a(4) of the EC Treaty. This condition cannot be interpreted in such a way that it prohibits the approval of any national measure likely to affect the establishment of the internal market. In fact, any national measure derogating from a harmonisation measure aiming at the establishment and operation of the internal market, constitutes in substance a measure that is likely to affect the internal market. Consequently, to preserve the useful character of the procedure for derogation provided for by Article 95 of the EC Treaty, the Commission considers that, in the context of the Article 95(6), the concept of obstacle to the functioning of the internal market has to be understood as a disproportionate effect in relation to the pursued objective.
- (116) According to a study by ERM⁽³³⁾, the European creosote-production industry is characterised by the following features:
- creosote is produced as a by-product, not primary product
 - production exceeds consumption to a significant degree
 - there are a small number of creosote producers
 - there is a decline in demand
- (117) Because of this situation, suppliers are generally willing to meet the product specifications required by their customers (if they can do so technically).
- (118) Producers of creosote are located in Germany, Austria, Belgium, Denmark, France, the Netherlands, Italy, Spain and the United Kingdom. 90 % of creosote is used for the industrial impregnation of wood by professional

⁽³²⁾ W. D. Betts, Study of the Effects on Trade and Competition of the Retention by The Netherlands of its National Rules in Place of the Rules to be Established by Directive 94/60/EC. Tar Industries Services, Chesterfield (UK), December 1995.

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

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

- (119) Professional impregnators primarily treat timber for use as telecommunications and power poles and railway sleepers. The composition of creosote varies according to the coal tar feedstock used, the production method employed and the requirements of the customer. In fact, most of the large-scale users have developed their own

detailed specifications in relation to boiling curves 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.

- (120) The following Table 6 gives a survey of the situation with regards to producers of creosote, their geographic location, whether they can produce creosote with B[a]P content < 50 ppm and whether they have had trade with the Netherlands.

Table 6

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

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

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

Netherlands has decreased steadily ⁽³⁶⁾ from 120 000 m³ in 1985 to around 78 000 m³ in 1992 and was expected to decrease to 60 000 m³ in 1995. This trend seems thus to have started before adoption of the national legislation.

- (122) Creosote-treated wood in the Netherlands is mainly used in the railway industry (sleepers), hydraulic engineering (protection of waterbanks), agriculture (fencing) and the fruit-growing industry (support of fruit trees). The consumption of creosote-treated wood in the

- (123) There are three creosote treatment facilities in the Netherlands. The national production of treated round wood and sawn timber has decreased by 40% between 1990 and 1995 (to about 23 000 m³), and the production of treated railway sleepers by about 50% to 10 000 m³. The amounts of treated wood used are about twice as high. As part of the treated wood is exported, the Netherlands are also a net importer of treated wood, also with decreasing tendency. Both these trends had already started before the adoption of the

⁽³⁴⁾ Sources: See footnotes 32 and 33.

⁽³⁵⁾ See footnote 32.

⁽³⁶⁾ See footnote 8.

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

- (124) The amount of creosote produced and exported has grown steadily over the years from 1990 to 1995, whereas the amount of creosote imported and used has decreased. However, the creosote, which is exported by the Dutch producer, does in general meet the stricter requirements of the Dutch legislation.
- (125) Some producers have expressed their concern about the possibility that creosote produced in the Netherlands containing more than 50 and less than 500 ppm B[a]P could be sold in other Member States at a price not reflecting the true costs as the Dutch producer could not market it legally in the Netherlands and would seek to avoid disposal costs. However, there seems to have been only one case which supports this assumption where a consignment of 1 000 tonnes from the Netherlands complying with the requirement of Directive 94/60/EC was sold at a lower price than that of the traditional suppliers. This seems to have been a singular event and does not provide sufficient evidence for the presumption that the internal market would be distorted if the Dutch regulations were approved, as normally the exported creosote also conforms to the stricter national requirements.
- (126) Taking into account the preceding observations, the Commission considers that there is no evidence that the Dutch provisions subject to this Decision do constitute a disproportionate obstacle to the functioning of the internal market in relation to the pursued objectives.

IV. CONCLUSION

- (127) In the light of the above considerations, the Commission is of the opinion that the provisions with regards to the use of creosote as notified by the Kingdom of the Netherlands pursuant to the former

Article 100a(4) and examined under Article 95(4) and (6) of the EC Treaty:

- fulfil the formal requirements of the said provisions and are to be admitted,
 - can be considered justified on grounds of major need of protection of human health and, due to a specific situation, on grounds of major need of protection of the environment,
 - do not constitute either a means of arbitrary disguised restriction on trade between Member States, or a disproportionate obstacle to the functioning of the internal market.
- (128) The Commission therefore has reason to consider that the national provisions notified can be approved,

HAS ADOPTED THIS DECISION:

Article 1

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

Article 2

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 26 October 1999.

For the Commission

Erkki LIIKANEN

Member of the Commission

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,

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.

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) 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 were included on 1 November 1993 in two ordinances, the Banned Chemicals Ordinance (*Chemikalien Verbotverordnung*, *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 September 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 Netherlands 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. Furthermore, 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. Sörgo, 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
- triphenylene
- 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 was 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

⁽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.

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

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, Nijmegen 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.
- (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.

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.
- (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. 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 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 m³ 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 km² 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 of the other carcinogenic substances in creosote. It can be inferred from the study that creosote containing 50 ppm B[a]P would induce a significant incidence of skin cancer in mice.

(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 m³ of wood is used per year in Germany. 750 000 m³ 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

COMMISSION DECISION

of 26 October 1999

on The National Provisions Notified By The Kingdom Of Sweden Concerning The Limitation To The Placing On The Market And Use Of Creosote*(notified under document number C(1999) 3426)***(Only the Swedish text is authentic)****(Text with EEA relevance)**

(1999/834/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

respecting those limits may not be placed on the market.

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

Whereas:

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

I. THE FACTS**1. Community legislation: Directive 94/60/EC**

- (1) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations⁽¹⁾, as last amended by Commission Directive 1999/77/EC⁽²⁾, provides for the prohibition and restriction of the use of certain dangerous substances and preparations. Directive 76/769/EEC is regularly amended to include in its Annex additional substances, which are dangerous to health and environment.
- (2) European Parliament and Council Directive 94/60/EC⁽³⁾, which amends Directive 76/769/EEC for the 14th time, harmonises amongst others the use and marketing of creosote and similar coal tar distillates, as well as preparations containing them, by limiting the content of one specific component, Benzo[a]pyrene (hereinafter B[a]P), and water extractable phenols when used for wood-treatment (point 32 in the Annex to Directive 94/60/EC). The limit for B[a]P is fixed at a maximum of 50 ppm (= 0,005 %) by mass and the limit for water extractable phenols is fixed at a maximum of 3 % (= 30 g/kg) by mass. Wood treated with creosote not

2. The Swedish national provisions

- (4) Under the Swedish legislation, creosote and preparations containing creosote are considered as pesticides.
- (5) The Swedish provisions concerning the marketing and use of creosote and wood treated with creosote are included in two different legal instruments:
1. Order (1985:836) on pesticides, issued on 7 November 1985 and last amended by order (1995:208) establishing general provisions on the marketing and use of pesticides
 2. National Chemicals Inspectorate regulation KIFS 1990:10 on wood treated with preservatives, especially sections 7—11, concerning wood treated with preservatives containing creosote.

⁽¹⁾ OJ L 262, 27.9.1976, p. 201.

⁽²⁾ OJ L 207, 6.8.1999, p. 18.

⁽³⁾ OJ L 365, 31.12.1994, p. 1.

- (6) Section 3 of Order (1985:836) stipulates that the Chemicals Inspectorate must approve pesticides before they can be sold, transferred or used. The same applies to the import of pesticides from countries that are not members of the European Union. Section 5 states the basic requirements for approval: The substance must pass an assessment with regards to health and environment protection and it must be shown that it is required for the purposes in the intended area of application. An approval is limited in time (five years) and may be subject to conditions. On approval of a pesticide, the Chemicals Inspectorate establishes the requirements with regards to labelling and other product information, handling, and other special conditions to prevent harm.
- (7) On the basis of assessment concerning health and environment, the pesticide is attributed to one of three classes:
- Class 1: Products for professional use by persons with a special licence only
- Class 2: Products for professional use only
- Class 3: Products for general use
- (8) The rules on labelling and other product information, handling of the pesticide and other special conditions to prevent harm are notified together with the approval (section 7).
- (9) The order also establishes that a fee must be paid in order to obtain an approval, and that any new information on health and environmental effects must be notified.
- (10) Application of these rules has resulted in wood preservatives containing creosote being approved in Sweden only for use in industrial installations for pressure impregnation. Such installations are subject to special competence requirements. A series of earlier approvals for general use were revoked with effect from 1 January 1986 based on the classification of creosote as potential human carcinogen by the International Agency for Research on Cancer (IARC).
- (11) Four individual products are approved for exclusive industrial use in Sweden. The decisions on approval did not specify a particular limit for B[a]P content, but according to the information submitted by the Swedish authorities, the approved products all have B[a]P contents of less than 50 ppm, in some cases less than 10 ppm. The phenol content in all products is less than 3%.
- (12) For treated wood, section 7 (in conjunction with section 6) of the Chemical Inspectorate's regulations KIFS 1990:10 establishes the following restrictions on its use, which entered into force on 1 January 1992.
- (13) If fewer than 30 years have elapsed since impregnation with creosote, the timber is permitted for professional use only as railway sleepers or for round timber for transmission lines (e.g. power lines) or marine installations. Thereafter, the timber may also be used for non-professional purposes for certain specified applications: when the wood is buried in or otherwise in permanent contact with damp soil or water, when the wood is used for the construction of jetties or other marine applications. These rules apply irrespective of the B[a]P content in the wood preservative used for treatment.
- (14) Section 8 prohibits the professional marketing, sale and transfer of timber for the purposes that are prohibited under the regulations. Section 9 lays down rules for the marketing of treated wood: anyone who, in the course of business activities, transfers wood treated with preservatives has to provide written information on the following:
1. relevant restrictions on use according to sections 5 to 7;
 2. the installation, in which the wood preservation treatment was carried out;
 3. active ingredients of the wood preservative;
 4. woodworking procedures for which the wood is suitable and/or is not suitable;
 5. health risks during woodworking and other handling of the wood;
 6. suitable safety precautions;
 7. measures for the disposal of waste wood.
- (15) According to section 10, these indications must be attached to each bundle of wood placed on the market. Where wood treated with preservatives is offered for sale in bulk to customers, who fetch it on the spot, the information must be displayed at the storage site of the wood. Additionally, a sheet with information is to be made available free of charge for anyone collecting the

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

wood treated with creosote depending on the B[a]P content as laid down in Directive 94/60/EC and the Swedish legal system.

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

(16) Table 1 shows in detail the differences between the restrictions on the marketing and use of creosote and

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

Table 1

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

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

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

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

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

- products containing creosote intended for wood preservation must be individually approved before they can be used. Creosote has been approved for professional use only, not for use by consumers. Wood impregnation has to be performed according to a specific technique;
- the use of treated wood is more restricted: newly treated wood, and wood where treatment took place less than 30 years ago, may only be used for professional applications as railway sleepers or for round timber for transmission lines or marine installations. Wood treated more than 30 years ago may be used by private consumers only when the wood is buried in or otherwise in permanent contact with damp soil or water and when the wood is used for the construction of jetties or other marine applications;
- sale (transfer) of wood is subject to a series of requirements in Sweden regarding the providing of information to consumers.

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

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

II. THE PROCEDURE

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

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

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

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

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

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

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

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

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

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

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

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

health, safety or environmental protection. This is not considered to be the case in this instance.

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

III. ASSESSMENT

1. Applicable Rules

- (32) The Treaty of Amsterdam has amended substantially the provisions of the former Article 100a of the Treaty establishing the European Community, by replacing paragraphs 3, 4, and 5 of this Article with eight new paragraphs numbered 3 to 10. Due to the new numbering of all Articles, the amended Article has become Article 95 of the Treaty establishing the European Community.
- (33) The Treaty of Amsterdam does not comprise specific transitional provisions on the rules applicable to the notifications made previously to the time of entry into force of this treaty, like the Swedish notification, which is the subject of this Decision.
- (34) In the absence of specific provisions extending their application, the old provisions of Article 100a(4) of the EC Treaty are regarded as repealed from the day of entry into force of the new provisions (1 May 1999). Instead, the new provisions of the Treaty apply immediately from that date to the examination of this notification.

2. Consideration of admissibility

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

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

- (36) Article 95(4) of the Treaty reads as follows: 'If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major need referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.'
- (37) Directive 94/60/EC had to be transposed to the Member States by 20 December 1995 and enforced by 20 June 1996. Sweden notified its national legislation relating to creosote and wood treated with creosote, which had been in place since 1985 and 1992, respectively, on 14 December 1995 and thus before the date foreseen for the application of the national provisions transposing the Directive.
- (38) It is therefore well justified to consider that in this case the conditions of Article 95(4) of the Treaty are met, according to which the national provisions notified, for which a Member State wishes to obtain approval for maintaining them after the date of implementation of a Community harmonisation measure, must have been adopted before the adoption of the harmonisation measure.
- (39) In the light of what precedes, the Commission considers that the request of the Kingdom of Sweden for derogation from Directive 94/60/EC as notified on 14 December 1995 under the former Article 100a(4) is admissible under Article 95(4) of the EC Treaty.

3. Assessment of merits

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

- (41) The Swedish authorities have based their request on reasons of protection of human health and the environment. In support of the request, Sweden submitted a brief Memorandum, dated 14 December 1995, explaining the reasons why Sweden deemed it necessary to maintain its stricter national provisions. However, the information contained in this Memorandum was very limited and remained general. It was not possible to examine the merits of the request based on this information alone.
- (42) In order to verify whether the Swedish national provisions concerning marketing and use of creosote treated wood, are indeed necessary and proportionate to that end, the Commission mandated a study to an external consultant⁽⁴⁾. The study tries to assess the risk of cancer arising from the use of creosote and creosote treated wood by consumers, and whether the implementation of Directive 94/60/EC in Sweden would result in unacceptable high creosote exposure of the public, and in unacceptably high creosote exposure of the aquatic environment. In addition, the findings of three further studies⁽⁵⁾, which were mandated by the Commission in the framework of similar requests from other countries, have been used in the assessment of the request from Sweden.
- (43) It has to be noted that, in the light of the time frame established by Article 95(6), which did not exist in the former Article 100a(4) under the regime of which the Swedish request was notified, these substantial efforts of the Commission to find the elements necessary for the justification of the maintenance of the Swedish national provisions cannot constitute a precedent for the future. When examining whether the national measures notified under Article 95(4) are justified by a major need, the Commission has to take as a basis 'the reasons' put forward by the Member State to justify the maintenance of its national provisions. This means that, according to the provisions of the Treaty, the responsibility of proving that these measures are justified, lays on the requesting Member State. Given the procedural framework established by Article 95, the Commission normally has to limit itself to examining the relevance of the elements which are submitted by the requesting Member State, without having to seek itself possible reasons of justification.

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

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

Dr. P. M. Sorgo, *Study on the justification in scientific terms of allowing Denmark to retain its national laws on creosote*, Final Report, November 1996.

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

3.1. Justification on grounds of major needs

3.1.1. Creosote — general information

- (45) Creosote is a complex mixture of over 200 chemical compounds, predominantly aromatic hydrocarbons, as well as phenolic and aromatic nitrogen and sulphur compounds. It is a mid-heavy distillate of coal tar (boiling point approximately 200 to 400°C).
- (46) Creosote can contain over 30 different polycyclic aromatic hydrocarbons (PAHs) with a possible total PAH content of 85 %. The most important ones are:
- acenaphthene
 - naphthalene
 - phenanthrene
 - anthracene
 - fluorene
 - fluoranthene
 - chrysene
 - triphenylene
 - benzo-[a]-anthracene
 - benzo-[b]-fluoranthene
 - benzo-[k]-fluoranthene
 - benzo-[a]-pyrene
- (47) Benzo[a]pyrene (B[a]P) is one of the most thoroughly investigated PAHs and the B[a]P content is used as an
- indicator or marker substance for classification purposes and does not, in itself, reflect the total PAH content of creosote. Depending on the type of creosote concerned, the B[a]P content may vary between 0,003 and 0,3 % by weight (30 to 3 000 ppm). A refined distillation of coal tar and selection of the fractions can lead to lower B[a]P or phenol contents. Different industry standards have been developed by the Western European Institute for Wood Preservation, characterised mainly by different contents of specified distillation fractions and, most important in this context, different contents of B[a]P. Limiting values for classification standards are 500 ppm and 50 ppm.
- (48) Modifications to both the physical and chemical properties of creosote are possible if they are required for use or environmental purposes. It is possible to create a lower viscosity product, better suited to brush application, by incorporating components with a lower boiling point, which is sometimes called carbolineum. Directive 94/60/EC does not make a distinction: it covers and treats in an identical way a whole range of different coal tar distillates, all of them specified by their names, EINECS- and CAS numbers.
- (49) Creosote is principally and almost exclusively used as a wood preserving agent. Large-scale industrial and professional applications are by far the most important ones: railway sleepers, poles for electricity transport, hydraulic engineering (bank protection), agriculture and fruit production. Creosote and similar products are also used by individual consumers for wood preserving purposes.
- (50) The most important properties of creosote are:
- high fungicidal efficacy,
 - high insecticidal efficacy,
 - long-term persistence,
 - resistance to leaching and weathering.
- (51) A very small quantity of creosote is used in medicinal products for the treatment of certain skin diseases, e.g. psoriasis.

Toxicity of creosote

Human health effects

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

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

- (53) Exposure can occur via inhalation, ingestion or skin contact. Creosote is evaluated as mildly to moderately toxic by ingestion. Most effects resulting from animal experiments and all epidemiological studies in humans are linked to dermal exposure.
- (54) Skin photosensitivity from coal tars has been described by a number of authors. Irritation symptoms, pitch warts, skin discoloration and dermal tearing have been reported to occur amongst workers exposed to creosote. The most recent study on workers exposed to creosote in Sweden and Norway was published in 1992⁽⁷⁾. The study examined workers exposed to creosote between 1950 and 1975. The investigators found a somewhat lower total cancer incidence than expected and an increased risk of cancer of the skin and lip and of non-Hodgkin lymphomas. However, the composition of the creosote was not documented and the authors conclude that the small number of cases did not permit a valid conclusion. The increase could be attributed to exposure both to creosote and to sunlight. One other study⁽⁸⁾ found an increased risk of mortality from scrotal cancer for brickmakers exposed to creosote during the period 1911 to 1938. Again, neither the B[a]P content of the creosote nor a clear dose response relationship are known.
- (55) Mostly based on an animal experiment, where the skin of mice was regularly exposed to B[a]P solutions in acetone during their lifetime⁽⁹⁾, the International Agency for Research on Cancer (IARC) has classified creosote as a group 2A human carcinogen. IARC estimates that for substances in this class there is sufficient evidence from epidemiological studies to conclude that creosote can be carcinogenic in humans. There is no significant new evidence from more recent investigations, which would affect this conclusion.
- (56) For several years, experts from the Member States examined the issue of classification of creosote, other coal tar distillates, and further so-called complex substances in the framework of Council Directive 67/548/EEC of 27 June 1967 relating to the classification, packaging and labelling of dangerous substances⁽¹⁰⁾, as last amended by Directive 1999/33/EC⁽¹¹⁾. Drawing largely on the same data as IARC, agreement was reached during the elaboration of Commission Directive 94/69/EC⁽¹²⁾, the 21st adaptation to technical progress, according to which creosote and some other coal tar distillates are classified as category 2 carcinogens and must be labelled with the risk phrase R 45 'May cause cancer'. However, the classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005 % (= 50 ppm) per weight B[a]P⁽¹³⁾. This is different from the IARC classification, which applies without any specification of the B[a]P content.
- (57) The choice of a limit of 50 ppm to the concentration of B[a]P for classification purposes in Community legislation in order to distinguish carcinogenic from non-carcinogenic coal tar distillates has been accepted by the Member States in the working group for adaptation of Directive 67/548/EEC to technical progress only on the basis of a Joint Declaration by the Commission and the Member States. The declaration states that the situation would be reviewed when the results of the above mentioned scientific study by the Fraunhofer Institute were known, which had been initiated by industry in collaboration with the IARC and was in progress at that time. It has to be recognised that in 1994, there were no experimental data available to prove whether creosote containing less than 50 ppm B[a]P was carcinogenic or not. This situation has changed and the results of the Fraunhofer study will be presented further.
- (58) Little is known about the toxicokinetics of creosote in humans or experimental animals. Only very recent studies have investigated quantitative absorption of PAHs through the skin by measuring excreted metabolites of pyrene⁽¹⁴⁾: absorption appears to vary between individuals and between different sites within the same individual. In a separate study⁽¹⁵⁾, the dermal absorption of different PAH compounds was measured. PAHs of higher molecular weight as pyrene, e.g. B[a]P were absorbed less rapidly. Any estimation of B[a]P uptake based upon the pyrene marker will therefore result in an overestimation and can be considered conservative.
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- ⁽⁷⁾ S. Karlehagen et. al., *Cancer incidence among creosote-exposed workers*, Scand. J. Work. Environ. Health, 1992:18, p. 26.
- ⁽⁸⁾ IARC, *Monograph on the evaluation of carcinogenic risk to humans*, Vol. 35, polynuclear aromatic compounds, Part 4, bitumen, coal tars and derived products, shale soils and soots, Lyon, 1985.
- ⁽⁹⁾ J. M. Holland, E. L. Frome, *Advances in modern environmental toxicology*, Vol. VI, applied toxicology of petroleum hydrocarbons, ed. MacFarland and others Princeton Scientific Publishers 1984.
- ⁽¹⁰⁾ OJ L 196, 16.8.1967, p. 1.
- ⁽¹¹⁾ OJ L 199, 30.7.1999, p. 57.
- ⁽¹²⁾ OJ L 381, 31.12.1994, p. 1.
- ⁽¹³⁾ Nota M of the foreword to Annex I of Council Directive 67/548/EEC is applicable to creosote.
- ⁽¹⁴⁾ Van Rooij, J.G.M., et. al., *Absorption of Polycyclic Aromatic Hydrocarbons Through Human Skin: Differences between Anatomical Sites and Individuals*, J. Tox. Environ. Health, 38, 1993, p. 355.
- ⁽¹⁵⁾ Van Rooij, J.G.M., *Dermal Exposure to Polycyclic Aromatic Hydrocarbons Among Workers*, Thesis ISBN 90-9007080-X, Nijmegen 1993.

- (59) It has to be noted, that all effects observed in animal experiments or in epidemiological investigations in humans are based on high level chronic exposures. No reports have been found in the literature of examples of cancer of the skin (or any other sites) which could be attributed to exposure to creosote in a non-occupational environmental context.
- (60) Exposure of consumers can occur during the use of preparations containing creosote (or carbolineum) for wood preservation by brush application (dermal and inhalatory) or through the use of treated wood (e.g. adults during the construction of fences or other wooden structures for private use, children playing on structures made of treated wood). No measured data are available concerning the exposure of consumers to creosote, either directly through use of the product, or indirectly through contact with wood treated with creosote. Various models and calculations of exposure have been developed in the studies and will be discussed later.
- PAHs reaching watercourses are rapidly transferred to sediment;
 - in watercourses, most of the lower molecular weight PAHs are removed primarily by microbial degradation and the higher molecular weight compounds by photooxidation and sedimentation. Microbial degradation of the more water soluble PAHs occurs under aerobic and anaerobic conditions. The PAH constituents have been shown to bioaccumulate in aquatic species.
- (64) Emissions of PAHs to air, water and soil can occur during the impregnation process and storage at the impregnation site, as well as during use of treated wood. However, PAHs found in the various environmental compartments are originating from a variety of sources (e.g. all combustion processes, traffic, etc.) and it is often difficult to ascribe their levels to any particular source such as creosote treated wood.

Environment effects

- (61) Environmental contamination by creosote has been reported in a number of countries, with old wood treatment facilities often being the source of the contamination. In fact, most information on the fate of creosote in the environment has been obtained from industrial creosote spills and from contamination left from disused creosote plants. Environmental contamination has been traced by an analysis of selected PAH compounds, notably B[a]P.
- (62) Creosote is toxic to certain organisms in the soil and highly toxic against aquatic organisms (with 96h LC-50 values often below 1 mg/l). Many of its components are bioaccumulating.
- (63) The main characteristics of PAHs in the environment are:
- PAHs bind strongly to soil organic matter;
 - the rate of degradation of PAHs in soil and other environmental compartments is usually slow. Creosote residues can persist for many years in the environment (> 20-30 years);
 - the main breakdown processes are photodegradation (i.e. under irradiation from the sun) and microbial degradation (i.e. by certain bacteria). Microbial degradation can occur under aerobic and anaerobic conditions. PAHs compounds with four rings and more may be poorly degradable;
- (65) A study⁽¹⁶⁾ in Sweden has shown that after 40 years in soil, creosote impregnated poles had lost a part of the compounds contained in creosote, especially those with the lowest boiling point (< 270°C). The part of the poles above the ground lost the larger amount. However, mobility of the leached compounds was very low as they could only be detected in the soil in close contact with the poles. This coherent with the observation that the mobility of PAHs in soil is extremely low due to their strong absorption to organic matter.
- (66) The presence of elevated levels of PAH in aquatic environments has often been attributed to the presence of creosote-treated wood. Migration of creosote components from treated wood into water is higher into fresh water than into seawater and has been proven in many studies. Migration seems to be more limited in seawater; in one study, after 10 years in the sea, marine pilings retained 93% of the original composition of creosote compounds⁽¹⁷⁾. The pollution of sediments by creosote leaching from waterbank protection has been documented in the Netherlands⁽¹⁸⁾ and also in studies on pollution from former impregnation facilities.
- (67) As for human exposure, actually measured data on environmental pollution by PAHs originating in creosote are scarce.

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

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

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

3.1.2. *The Swedish position*

- (68) The Swedish authorities hold the opinion that the level of protection of human health guaranteed by Directive 94/60/EC is insufficient. Creosote is a substance resulting from a specific distillation range of coal tar containing some 30 substances/substance groups that are documented as carcinogenic and mutagenic. As proved by the classification through IARC, creosote has properties extremely hazardous to health. Apart from its carcinogenic property it is a strong skin irritant and in combination with sunlight can cause photoallergic reactions such as blistering and serious eczema.
- (69) The Swedish authorities underline that there are no data to support the conclusion that creosote with a B[a]P content less than 50 ppm presents an acceptable risk. On the contrary, they assert that, as B[a]P is genotoxic, there is not threshold dose below which exposure presents no health risks. The Swedish authorities recall the Declaration made at the meeting of the Technical Adaptation Committee in 1994 (mentioned above) which according to them shows that there was no satisfactory basis for assessing the carcinogenicity of complex coal-tar based substances containing less than 50 ppm B[a]P.
- (70) Creosote has properties detrimental to health and the environment, which means that its use should be limited to applications where long-lasting protection is required. Contact with skin should be avoided as far as possible. Creosote should therefore not be used by consumers who do not have the necessary protective equipment. In the case of industrial pressure impregnation, the workers are informed and protected as far as possible.
- (71) Creosote oils have been developed and are already available on the market where certain fractions of the most dangerous substances have been removed. It has not emerged that the B[a]P content in the product has any effect on the impregnation method, the creosote uptake in the wood or the durability of the protection. These products have B[a]P contents of less than 10 ppm. This development may be halted if products with up to 50 ppm are accepted.
- (72) With regard to the environmental impact, the Swedish authorities underline that creosote is highly toxic to certain aquatic organisms and that certain components are bioaccumulating. Creosote components leak from treated piles in both fresh and salt water.
- (73) Sweden has a special national need because, unlike the situation in other countries of the EU, wood is an

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

- (74) Furthermore, Sweden claims that it has a special national need due to its geographical location with low annual average temperatures and low annual average insolation levels, leading to reduced degradation of creosote. Photochemical conversion is the main decomposition process for polycyclic aromatic hydrocarbons (PAH), of which creosote is composed. Several types of bacteria can break down creosote. Sweden's geographical situation means that the number of warm, sunny days are fewer there than in most other countries of the Community. The result is lower photochemical and bacterial decomposition of creosote.
- (75) In summary, the Swedish authorities underline that there are strong health and environmental objections to amending the Swedish provisions on creosote. The Swedish Government is not intending to ban the use of creosote completely, it wishes to see the continued uses of creosote in applications for which it is considered the best alternative. It is the objective of the approval procedure for each individual product to ensure that this goals are met. The rules of creosote are part of the general Swedish policy of restriction the use of dangerous chemicals.

3.1.3. *Evaluation of the Swedish position*

- (76) The issue of health effects of creosote has been examined very carefully in the studies mandated by the Commission. All known findings have already been mentioned in the general information part above.
- (77) Experimental data that have become available only recently show that the carcinogenic risk of creosote containing less than 50 ppm B[a]P might be non-negligible. However, it has to be underlined, that all available information was considered in great detail during the deliberations leading to the Community provisions regarding the classification of creosote and the provisions of Directive 94/60/EC. Also, all adverse

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

- (78) The analysis carried out by the Swedish authorities during product approval is based upon the principle of seeking to minimise risk wherever possible, both by reducing as far as possible exposure to harmful substances and by substitution of alternative products perceived to be more acceptable. In the case of creosote the alternatives are copper-chromium-arsenic derivatives (CCA). The Swedish position towards the acceptability of a risk linked to the use of a chemical substance is therefore somewhat different than the Community position applied towards the adoption of Directive 94/60/EC.
- (79) According to the study mandated by the Commission, the Swedish authorities could neither provide documentation regarding the concrete assessments carried out during approval of the four creosote products which are currently allowed for industrial use, nor were documents made available which proved the claim that all four products contain less than 50 ppm B[a]P and 3 % water soluble phenols.
- (80) There are, however, strong indications to believe that this is the case. According to the study mandated by the

Commission, the four products have been authorised under a voluntary agreement between the authorities and the relevant trade association. The latter had undertaken its own research to reduce and eliminate creosote bleeding from treated wood, which leads to increased exposure of the environment and of workers handling or working with treated poles. There has been pressure on the wood impregnation industry to reduce leaching from the principal clients, the electricity and telecommunication companies. The new specifications require the product to be produced from a much narrower distillation range than standard creosotes which eliminates many of the volatile and high boiling components (esp. PAH, including B[a]P). The sample technical approval document obtained by the consultant from a major industrial user and an internal document from the Chemicals Inspectorate also specify that the B[a]P content should be lower than 50 ppm. As a result, all approved products in Sweden are thick, viscous oils consisting of up to 100 % of creosote within the specific distillation range for respective oils. The oils are suitable only for use in a specialised, industrial pressure/vacuum impregnation process designed for optimum impregnation of round timber in particular. The technique results in timber containing an average of 135 kg creosote/m³ and gives a very durable wood (approximately 40 to 50 years).

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

Table 2

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

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

⁽¹⁹⁾ Source: See footnote 18.

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

(82) The use of creosoted wood has remained relatively constant since 1990. In 1995, 74 400 m³ of wood were treated with creosote (63% poles, the rest railway sleepers), about one quarter was exported.

(83) Table 2 shows that the use of creosote treated wood per capita in Sweden is the highest in Europe, whereas the use per km² is among the lowest. The latter figure might be misleading as it can be reasonably assumed that the use of creosote treated wood is more concentrated in the areas of higher population density (e.g. southern Sweden). The high use per capita could lead to a potentially higher exposure of the Swedish population. On the other hand, the low figure of use per surface seems to indicate that the likelihood of contact for an individual of the population is rather low.

Exposure of the environment

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

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

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

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

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

Human exposure

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

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

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

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

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

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

the Dutch authorities in their request) is 2,1 ng/kg bw/day. The worst case exposure is thus clearly lower. For a scenario of exposure of six weeks a year it would be 0,7 ng/kg bw/day and thus still higher than the calculated worst case exposure.

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

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

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

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

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

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

⁽²¹⁾ See footnote 6.

- of two creosote products provided by the sponsoring company (Rüttgers-VfT AG, Germany) containing 10 and 275 ppm B[a]P. Due to the high viscosity of the products, they could not be applied directly to the skin of the mice but had to be diluted in Toluene. Solutions with various concentrations of the product and thus various B[a]P concentrations, as well as pure B[a]P solutions and a control of pure Toluene were applied to groups of 62 mice for a time of 78 weeks (twice a week, 25 µl). Development of tumours was observed during this time and the test animals were carefully examined after termination of the study.
- (98) The Commission submitted this study and all other documents containing scientific and exposure information on creosote to the Scientific Committee for Toxicity, Ecotoxicity and the Environment. The SCTEE was asked to evaluate whether there was sufficient scientific evidence to support the opinion that there is a cancer risk to consumers from creosote containing less than 50 ppm B[a]P and/or from wood treated with such creosote, and if such a risk exists, whether its magnitude can be estimated or quantified. The SCTEE adopted its opinion on 27 November 1998.
- (99) The SCTEE observes that the Fraunhofer study is well-designed and reaffirms the carcinogenic potential of coal tar preparations. Due to the genotoxic potential of PAHs including B[a]P, there is no threshold concentration determining carcinogenicity. The study indicates clearly a linear dose-response relationship between the B[a]P content of the administered preparations and the number of animals developing tumours. Both preparations have a five-fold higher potency to induce skin tumours than pure B[a]P, presumably due to presence of the other carcinogenic substances in creosote. It can be inferred from the study that creosote containing 50 ppm B[a]P would induce a significant incidence of skin cancer in mice.
- (100) Data to fully evaluate the relevance of effects seen in a mouse skin painting study for human exposure situations are insufficient. Extrapolation skin carcinogenicity data from mice to human situation also entails a number of uncertainties leading to difficulties in directly using cancer potency data from mice to assess cancer risk in humans. Species dependent sensitivity of dermal exposure to the carcinogenic actions of creosote will be affected by morphology and physiology of the skin, by metabolic activation and inactivation in the skin and by repair processes. On the basis of all the available information, a scientifically justified assessment of carcinogenic risk, e.g. for the dermal exposure of children playing on wood treated with creosote is therefore difficult.
- (101) From the data contained in the Fraunhofer study, the SCTEE calculated a T 25 carcinogenic potency value for pure B[a]P of 13 µg/kg bw/day. The T 25 is the chronic daily dose per kg bodyweight, which induces 25% of the test animals tumours at a specific tissue site within the standard life span of that species. The creosote formulations tested had a five-fold higher overall carcinogenic potency (2,7 µg/kg bw/day).
- (102) Should the value of exposure calculated in the study mandated by the Commission apply (0,85 ng B[a]P per kg bw/day (for two hours play time) and 1,7 ng (for four hours play time) approximate the true exposure, this would result in a life-time cancer risk of $8,2 \times 10^{-5}$ (respectively $1,63 \times 10^{-4}$) for a life long daily exposure, which would give clear concern, a risk of $1,16 \times 10^{-5}$ (respectively $2,33 \times 10^{-5}$) for a daily exposure during 10 years out of 70 (the Dutch assumption) and $0,58 \times 10^{-5}$ (respectively $1,16 \times 10^{-5}$) for a daily exposure during five years out of 70 (the German assumption). Using the exposure doses calculated by the Dutch authorities (2 ng/kg bw/day) or the German authorities (2,62 ng/kg bw/day) would increase these risks proportionately.
- (103) Based on the most recent study with regards to the dose-response relation for dermal carcinogenicity of creosote as derived by the SCTEE and depending on the selected exposure model, the risk is thus slightly or more clearly above a value of 1×10^{-5} , which proposed as an acceptable risk level for genotoxic carcinogens in drinking water by the World Health Organisation.
- (104) The SCTEE also mentions that the figure of 2 ng B[a]P per kg bw/day as a worst-case exposure to B[a]P from playing on the creosote-treated wood has to be compared to estimates for intake of B[a]P via food. Annual intakes of B[a]P from food has been estimated to be in the order of 0,3—1,6 mg, which would result in daily exposures of 12 to 63 ng/kg bw for a person weighing 70 kg (i.e. much higher than the dermal exposure).
- (105) Overall the SCTEE concludes:
1. — Given the 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 the risks for children coming into contact with creosote-treated wood, the magnitude of the risk gives clear reason for concern. However, the highest estimated exposure is some six to 30 times lower than the oral exposure of the adult population to B[a]P in food.
- In order to get a better estimate of the exposure situation, one would have to perform a real-life, mass-balance study in exposed children. In addition to being very complicated and resource intensive, to conduct such a study would raise ethical questions.

3.1.5. Overall evaluation

- (106) The Swedish authorities have not shown, nor could it be demonstrated through further research, that a specific situation exists in Sweden with regards to the general pollution of environment by PAHs, or the exposure of man and the environment to PAHs originating in the use of creosote and creosote treated wood or that this would be the case if Sweden applied the provisions of Directive 94/60/EC.
- (107) However, the Commission has received additional information in the framework of similar requests from the Netherlands, Germany, and Denmark for derogation from Directive 94/60/EC under the former Article 100a(4) of the EC Treaty, and new scientific evidence through an extensive study carried out after the adoption of the Community Directive.
- (108) Based on these most recent experimental data, the SCTEE has estimated that there is a cancer risk to humans from creosote containing less than 50 ppm B[a]P and wood treated with such creosote, the magnitude of which cannot be estimated with certainty. Taking into consideration the uncertainties concerning exposure, the Commission considers that measures aiming at reducing the probability of prolonged dermal exposure to creosote, either through direct contact with creosote or wood treated with creosote, are justified in the light of the precautionary principle.
- (109) However, such measures can only be regarded as justified under the condition of being in conformity with the general principle of proportionality, i.e. the measures do not have to exceed what is suitable and necessary for the pursuit of the legitimate objective. Consequently, the legislation notified to the Commission by the Swedish authorities can be approved only insofar as this legislation sets up an authorisation arrangement for the use of creosote which allows for the possibility to actually obtain such an authorisation, when it is compatible with the needs for the protection of health and the environment.
- (110) It has to be noted that the Swedish provisions concerning creosote comprise an approval system without specifying a particular limit of B[a]P content or other physical-chemical parameters of creosote. Article 95(4) only permits the approval of national legislation on grounds of major needs referred to in Article 30, or relating to protection of the environment or working environment. This means that it is not possible to approve national measures that are less protective than those laid down in the Directive. Therefore, the Swedish national legislation can only be approved as its application in practice has shown that no product was approved that was not respecting the limits established by Directive 94/60/EC. A different application of the national Swedish legislation cannot be approved under Article 95(4).
- (111) In accordance with Article 95(7) of the Treaty, the Commission is already examining the appropriateness to adapt to technical progress the provisions of Directive 94/60/EC regarding creosote. In addition, the Commission will evaluate the use of creosote under the review programme established in Article 16 of European Parliament and Council Directive 98/8/EC of 16 February 1998 on the placing of biocidal products on the market⁽²²⁾ in a time frame compatible with the general timing of the review programme and taking into account other possible priorities identified when effectively setting up the programme. Furthermore, on ongoing research project under the Fourth Framework Programme for Research and Technological Development is reviewing the production chain and in-service life of poles treated with creosote⁽²³⁾.

3.2. The absence of arbitrary discrimination

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

⁽²²⁾ OJ L 123, 24.4.1998, p. 1.

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

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

not create an advantage for a national production of creosote.

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

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

- (114) More restrictive national measures in the area of limitations of marketing and use of products derogating from the provisions of a Community Directive do normally constitute a barrier to trade. Products that can be legally placed on the market in the rest of the Community, cannot be placed on the market in the Member States concerned. The concept enshrined in paragraph 6 of Article 95 is intended to prevent the restrictions based on the criteria of paragraph 4 being applied for inappropriate reasons, and in reality constituting economic measures introduced to impede the import of products from other Member States in order to protect indirectly national production.
- (115) The Commission mandated a study⁽²⁴⁾ on the effects of the Swedish legislation on trade and competition. The study undertook in particular to look at the volume and value of trade with other Member States which is affected; the interest, if any, which Sweden may have in using its national rules on creosote-treated wood to promote a national interest in substitutes to creosote-treated wood. Various representatives from the creosote and timber trade were consulted, as well as the relevant Swedish regulators.
- (116) There is no producer of creosote in Sweden and the four approved products are all imported from other EU countries. Consequently, the national legislation does

- (117) There are three producers of creosote-treated timber in Sweden, operating in five plants. Treated wood is imported from Finland, Norway and the Netherlands. Exports occur to most of the other Member States. Wood for export can only be treated with the products approved in Sweden. Therefore there is not any advantage for Swedish exporters as they have the same limitations in their production than the other European Union producers that want to import into Sweden.
- (118) Concerning the alternative products (e.g. chromium-copper-arsenic salts, boron compounds or other organic compounds), it has to be noted that all wood preservation products are classified as pesticides in Sweden and are subject to the same regulations. In addition, Sweden does not produce any wood preservatives and has them all imported. Therefore the limitations on creosote do not hide a protection of an alternative product in the market and are not disguised restrictions on Trade.
- (119) As established before, there is a concern with regards to human health, and it appears that the Swedish request for a derogation is motivated by a desire to maintain control on the use of a potentially harmful product rather than to affect trade in that product or in alternatives to it in favour of Swedish producers.
- (120) Overall, the Commission considers therefore that there is no evidence of a disguised restriction on trade between Member States provoked by the Swedish legislation concerning creosote.

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

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

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

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

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

- creosote is produced as a by-product, not primary product;
- production exceeds consumption to a significant degree;
- there are a small number of creosote producers;
- there is a decline in demand.

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

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

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

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

Table 3

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

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

⁽²⁵⁾ See footnote 24.

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

- (127) There are no producers of wood preservatives in Sweden and all products containing creosote or alternatives are imported.
- (128) Even were Directive 94/60/EC implemented in Sweden, it is, according to the study, unlikely that the operators of the wood impregnation plants would revert to using creosote formulations with a higher B[a]P content since the approved products are of superior quality and most clients would not purchase poles impregnated with old formulations. The new products are slightly more expensive than the old ones, but the difference in terms of the overall cost of a treated pole is marginal.
- (129) Referring to the effect of the Swedish legislation on creosote for the European internal market, the study shows that Swedish exports of creosote-treated timber are slightly greater than imports. But the introduction of the restriction on marketing and use of creosote and creosote-treated timber, in 1985 and 1990, did not have any significant or lasting impact on the market trend at the time, and did not introduce a barrier to trade with the European Member States.
- (130) In addition, the fact that the more restrictive rules on the use and marketing on creosote and creosote-treated timber existed in Sweden before it became a member of the European Union, shows that the goal of that more restrictive legislation is not to create obstacles to the function of the internal market.
- (131) Taking into account the preceding observations, the Commission considers that there is no evidence that the Swedish provisions subject to this Decision do constitute a disproportionate obstacle to the functioning of the internal market in relation to the pursued objectives.
- can be considered justified on grounds of major need of protection of health when applied in conformity with the general principle of proportionality,
- do not constitute either a means of arbitrary discrimination, a disguised restriction on trade between Member States, or a disproportionate obstacle to the functioning of the internal market.
- (133) The Commission therefore has reason to consider that the national provisions notified can be approved.

HAS ADOPTED THIS DECISION:

Article 1

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

- that the limits for benzo[a]pyrene and water extractable phenols established by Directive 94/60/EC are not exceeded, and
- that the placing on the market and use of creosote are allowed when compatible with the need to protect health and the environment.

Article 2

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 26 October 1999.

IV. CONCLUSION

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

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

For the Commission

Erkki LIIKANEN

Member of the Commission

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 (<i>cont'd</i>)	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 to which the national provisions notified, for which a Member State wishes to obtain approval for maintaining them after the date of implementation of a Community harmonisation measure, must have been adopted before the adoption of that harmonisation measure.

- (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 the 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.

⁽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.

⁽⁵⁾ Dr P. M. Sörgo, *Study on the Justification in Scientific Terms of Allowing Denmark to Retain its National Laws on Creosote*, Final Report, November 1996.

3.1. *Justification on grounds of major needs*

different coal tar distillates, all of them specified by their names, EINECS and CAS numbers.

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

(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 on 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.

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.

(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.

(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.

(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.

(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 a non-occupational environmental context.

(59) The choice of a limit of 50 ppm to the concentration of B[a]P for classification purposes in Community

(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 Polycyclic Aromatic Hydrocarbons Among Workers*, Thesis ISBN 90-9007080-X, Nijmegen 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.

concrete data are given for any of this in the Danish memorandum).

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

(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.

(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 µg/m³ 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 µg/m³ 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 µg/m³). Metabolites of creosote compounds could be found in the urine of creosote workers after inhalation and dermal exposure.

(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.

(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).

(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.

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

(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.

(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

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 and 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 inhalatory 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 had 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/l 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/l 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.

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

- (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.
- (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.

acceptable risk level for genotoxic carcinogens in drinking water by the World Health Organisation.

(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 to the human situation also entails a number of uncertainties leading to difficulties in directly using cancer potency data from mice to assess cancer risk in humans. Species dependent sensitivity of dermal exposure to the carcinogenic actions of creosote will be affected by morphology and physiology of the skin, by metabolic activation and inactivation in the skin and by repair processes. On the basis of all the available information, a scientifically justified assessment of carcinogenic risk, e.g. for the dermal exposure of children playing 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

(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 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

(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, 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.
- (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 the pursuit of the 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.

⁽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.
- (121) Concerning the import of wood preservatives there are no special rules for imported products that are not applicable to domestically produced 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 at the establishment and operation of the Internal Market, constitutes in substance a measure that is likely to affect the internal market. Consequently, to preserve the useful character of the procedure for derogation provided for by Article 95 of the EC Treaty, the Commission considers that, in the context of the Article 95(6), the concept of obstacle to the 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:

⁽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.

— 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 demand for creosote-treated railway sleepers and poles, which are imported: 1 365 tonnes in 1992 and 770 tonnes in 1995 (about 7 500 m³). 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 m³ 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 that there is no evidence that the 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

COMMISSION DECISION

of 26 October 1999

on the national provisions concerning mineral wool notified by Germany derogating from Directive 97/69/EC adapting to technical progress for the 23rd time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(notified under document number C(1999) 3490)

(Only the German text is authentic)

(Text with EEA relevance)

(1999/836/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Whereas:

classification, packaging and labelling of dangerous substances⁽³⁾ was adopted on 5 December 1997. The latest date for Member States to comply with this was 16 December 1998. *Inter alia*, the 23rd adaptation introduced:

- a general entry on mineral wool into the list of dangerous substances in Annex I,
- a specific Note Q relating to mineral wool into the foreword to Annex I.

I. THE FACTS

1. Community legislation

- (1) Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽¹⁾, as last amended by Directive 1999/33/EC of the European Parliament and the Council⁽²⁾, contains a list of dangerous substances displaying the harmonised classification and labelling that apply to such substances. All manufacturers, importers or distributors are required to use the harmonised classification and labelling when placing a dangerous substance on the Community market. The list is regularly updated to take account of the continuous increase in scientific and technical knowledge. This is done by revising specific entries in the list and by adding new entries to the list.

The foreword to Annex I describes particular aspects of the list of dangerous substances such as the interpretation of notes that may be added to specific entries. The foreword is also updated when necessary.

Updates of Annex I are adopted by adaptations to technical progress in accordance with Article 28 of Directive 67/548/EEC.

- (2) Commission Directive 97/69/EC of 5 December 1997 adapting to technical progress for the 23rd time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the

The draft for the 23rd adaptation was discussed for more than seven years among the Commission, Member State experts such as the Commission Working Group on Classification and Labelling — Health Effects, and experts from the industry involved. The results of these in-depth discussions were taken into account when drafting the draft. Member States delivered a favourable opinion when voting on the draft, with the exception of Germany who voted against.

- (3) The general entry on mineral wool defines mineral wool as consisting of man-made vitreous (silicate) fibres with random orientation with an alkaline oxide and an alkaline earth oxide content greater than 18% by weight. All mineral wools are classified as:

- carcinogenic, category 3, risk phrase R 40; and irritant; symbol Xi, R 38,
- or labelled with the symbol Xn, R 38-40, safety phrases S (2-)36/37.

An exception to this general entry would be a specific wool which was given an individual entry in Annex I. The general entry exempts any such possible individual entries by using the descriptor 'with the exception of those specified elsewhere in this Annex'.

⁽¹⁾ OJ 196, 16.8.1967, p. 1.

⁽²⁾ OJ L 199, 30.7.1999, p. 57.

⁽³⁾ OJ L 343, 13.12.1997, p. 19.

Directive 97/69/EC further provides for the addition of a Note Q to the foreword to Annex I. According to Note Q, the classification of a specific mineral wool as carcinogenic, category 3, need not apply if the result of an animal test with the wool is 'negative'. Note Q offers the option of four such tests. If a mineral wool were to meet this requirement it would not have to be labelled as carcinogenic. However, the classification and labelling as 'irritant' would remain.

2. National provisions

- (4) The national provisions at issue consist of a proposal by Germany that the Note Q referred to in Article 1(1)(c) of Directive 97/69/EC, and the classification of mineral wools set out in the Annex to that Directive, should be incorporated into its national laws, amending these as follows (see item I in that request):

Note Q₁:

The classification as category 2, carcinogenic, need not apply if it can be established that the substance meets one of the following conditions:

- an appropriate test involving intraperitoneal injection of a dose of 1×10^9 WHO fibres, in the size distribution of a typical workplace has shown no evidence of excess carcinogenicity,
- the chemical composition of the substances is such that the algebraic sum of the percentages of weight of the oxides $\text{Na}_2\text{O} + \text{K}_2\text{O} + \text{CaO} + \text{MgO} + \text{BaO} + \text{B}_2\text{O}_3 - 2\text{Al}_2\text{O}_3$ is greater than 30.

Note Q₂:

The classification as a category 3 carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:

- an appropriate intraperitoneal test at a dose of 5×10^9 WHO fibres, in the size distribution of a typical workplace, has shown no evidence of excess carcinogenicity,
- the half life after intra-tracheal instillation of 2 mg of a fine suspension for fibres with a length of 5 μm , a diameter of less than 3 μm and a length-to-diameter ratio of more than 3:1 (WHO fibres) is not more than 40 days, or
- the chemical composition of the substance is such that the algebraic sum of the percentages of weight of the oxides $\text{Na}_2\text{O} + \text{K}_2\text{O} + \text{CaO} + \text{MgO} + \text{BaO} + \text{B}_2\text{O}_3 - 2\text{Al}_2\text{O}_3$ is greater than 40.

ANNEX

CAS No	EC No	No 650-016-00-2
		Note A
		Note Q ₁
		Note R

Mineral wool, unless specified elsewhere in this Annex:

[Man-made vitreous (silicate) fibres with random orientation and an alkaline oxide and an alkaline earth oxide content ($\text{Na}_2\text{O} + \text{K}_2\text{O} + \text{CaO} + \text{MgO} + \text{BaO}$) greater than 18 % by weight]

Classification

Carc. Cat 2; R 49

Labelling

T	
	R: 49 S: 53/45

CAS No	EC No	No 650-016-00-2
		Note A
		Note Q ₂
		Note R

Mineral wool, unless otherwise specified in this Annex:

[Man-made vitreous (silicate) fibres with random orientation and an alkaline oxide and an alkaline earth oxide content ($\text{Na}_2\text{O} + \text{K}_2\text{O} + \text{CaO} + \text{MgO} + \text{BaO}$) greater than 18 % by weight]

Classification

Carc. Cat 3; R 40

Labelling

Xn	
	R: 40 S: (2-)22'

3. Comparing the national provisions with Community legislation

- (5) The communication from Germany is in line with Directive 97/69/EC in that mineral wool consists of man-made vitreous (silicate) fibres with random orientation and an alkaline oxide and alkaline earth oxide content greater than 18 % by weight.

However, the communication considers that mineral wools need to be divided into two categories. The first of these should be:

- classified as carcinogenic, category 2, R 49, and be
- labelled with symbol T, R 49, S 53-45.

Inter alia Note Q₁ should exempt these mineral wools from the classification as carcinogenic, category 2 on condition that either:

- the result of an animal test has been 'negative', or
- the carcinogenicity index 'KI' which is a number calculated from the chemical composition of the wool, exceeds 30.

It can be assumed that such wools should then be classified as carcinogenic, category 3.

The second category of mineral wools should be

- classified as carcinogenic, category 3, R 40, and be
- labelled with symbol Xn, R 40, S (2-)22.

Inter alia Note Q₂ should exempt these mineral wools from the classification as carcinogenic, category 3 on condition that either:

- the result of an animal test has been 'negative' and the communication offers the option of two such tests, or
- the KI exceeds 40.

Such wools should then not be classified and labelled at all, not even as irritant, R 38.

II. PROCEDURE

- (6) On 11 December 1998, the Office of the Permanent Representative of the Federal Republic of Germany to the European Communities informed the Secretariat-General of the European Commission, by fax, of a request based on former Article 100a(4) of the Treaty establishing the European Community that the Commission should confirm the proposal made by the Federal Government to incorporate the Note Q referred to in Article 1(1)(c) of Directive 97/69/EC and the classification of mineral wool in the Annex to that Directive into its national laws in an amended form (see above). Germany feels that the intended national provisions are justified by 'the major requirements referred to in Article 36, namely the protection of health and of human and animal lives, and

the protection of the working environment' (see Item II of the request and the amplifications therein).

On 17 December 1998, the Office of the Permanent Representative of the Federal Republic of Germany to the European Communities sent that request to the Secretariat-General of the European Commission in an official letter that was received on 21 December 1998.

- (7) The German request was passed on to the other Member States for comment. No comment was received from the Member States with regard to the content of the notification transmitted to them.

III. ASSESSMENT

1. Rules applying

- (8) The Treaty of Amsterdam has substantially amended the provisions of former Article 100a of the Treaty establishing the European Community by replacing paragraphs 3, 4 and 5 of that Article with eight new paragraphs numbered 3 to 10. Owing to the renumbering of all of the Articles the amended Article has now become Article 95 of the Treaty establishing the European Community.

The Treaty of Amsterdam does not contain any specific transitional provisions on the rules applying to the earlier notifications concerning the time of entry into force of this Treaty, such as the German notification, which is the subject of this Decision.

In the absence of specific provisions extending their scope, the former provisions of Article 100a(4) of the EC Treaty are to be regarded as repealed from the date of entry into force of the new provisions (1 May 1999). Instead the new provisions of the Treaty apply to the examination of this notification with immediate effect from that date.

- (9) It emerges from Germany's notification that this is aimed at approval by the Commission of provisions which Germany is intending to introduce after Directive 97/69/EC has been adopted. However, those provisions are not compatible with that Directive. The Commission should therefore examine that notification in the light of Article 95(5) EC that apply if this were the case. Moreover, the Commission must, where appropriate, carry out the checks provided for by Article 95(6) EC. The provisions of Article 95(4) EC cannot be applied in this instance since they solely relate to a situation where a Member State wishes to receive approval to maintain national provisions already adopted before the harmonisation measure concerned has been adopted, this not being the case in this instance.

- (10) It must be stressed that, on the date Germany sent its notification, the Treaty rules applying did not make any provision that this notification had to be based on new scientific proof relating to the protection of the environment or workplace because a specific problem in that Member State had arisen after the harmonisation measure had been adopted. This notification must be examined in the light of that specific situation.

2. Conditions attached to acceptability

- (11) The notification of Germany is intended to obtain an authorisation to introduce national provisions that are incompatible with Commission Directive 97/69/EC. That Directive constitutes one of the harmonisation measures referred to in Article 95(5) EC, the scope of which deliberately includes harmonisation measures that have been adopted by the Commission.

As required by Article 95(5) EC, Germany notified the Commission of the actual wording of the provisions that they were intending to introduce, accompanying their request by an explanation of the reasons which, they felt, justified the introduction of those provisions.

In view of the above, the Commission feels that the notification prepared by Germany in order to obtain approval for the introduction of national provisions that were incompatible with Directive 97/69/EC, on the basis of the provisions of former Article 100a(4) of the EC Treaty, can be acceptable pursuant to Article 95(5) EC.

3. Assessment of merits

- (12) It emerges from Article 95 of the Treaty that the Commission must satisfy itself that all of the conditions enabling a Member State to avail itself of the scope for divergence offered by that Article are met.

The Commission must therefore assess whether the conditions provided for by Article 95(5) EC are met. This requires (a) 'new scientific proof with regard to the protection of the environment and workplace', (b) which causes the applicant Member State to consider the introduction of national provisions to be necessary 'as a result of a problem that is specific to that Member State', (c) where the problem concerned arose 'after the harmonisation measure had been adopted'.

In addition, pursuant to Article 95(6) EC, where it feels that the introduction of such national provisions is justified the Commission must check whether those national provisions are, or are not a means of arbitrary discrimination or a hidden restriction of trade between the Member States and whether they do, or do not, constitute 'an impediment to the functioning of the internal market'.

3.1 *New scientific evidence concerning the protection of the environment or workplace following a specific problem in the Member State concerned arising after the harmonisation measure has been adopted*

- (13) Germany is basing its request on the 'major requirements referred to in Article 36, namely the protection of health and of human and animal life, and the protection of the workplace'.

The national provisions that Germany intends to apply to the classification and labelling of mineral wool are in conformity with Directive 97/69/EC with regard to the chemical composition that such a wool must have. Furthermore, those provisions are in conformity with Notes A and R, which are attached to the classification of mineral wool both in the German provisions and in Directive 97/69/EC.

However, the German draft provisions provide for two classes of mineral wool which, with reference to carcinogenicity, are classified as category 2 (stronger carcinogen) and category 3 (weaker carcinogen), whereas Directive 97/69/EC only classifies mineral wool in category 3. It is therefore not possible to evaluate the criteria for exemption from category 2 in the notification from Germany as compared with the exemption criteria in Directive 97/69/EC.

For mineral wool classified as 'category 3, carcinogenic' the German notification places the exemption criteria in a Note Q₂, whereas Directive 97/69/EC places such criteria in Note Q.

The first exemption criterion in Note Q₂ gives more details concerning an intra-peritoneal test than Note Q in Directive 97/69/EC, which simply requires an 'appropriate intra-peritoneal test'. The criteria in both notes could be considered as equivalent, at least in certain cases.

The second criterion in Note Q₂ describes a test with intra-tracheal instillation in detail. Again, the description of the intra-tracheal instillation test in Note Q in Directive 97/69/EC is less detailed. A notable difference is, however, that Note Q₂ also includes relatively short mineral wool fibres, whereas Note Q in Directive 97/69/EC concentrates on longer fibres.

The third criterion in Note Q₂ refers to the chemical composition of a wool required for exemption from the classification as carcinogenic. This is an application of the KI (CI) index which, according to the opinion⁽⁴⁾ adopted by the Scientific Committee for Toxicology, Ecotoxicology and the Environment (CSTEE) by written procedure on 10 September 1999, has 'not been extensively tested to confirm that the chemical composition of a fibre is informative with regard to its carcinogenicity'. There is no equivalent to the KI (CI) index in Note Q in Directive 97/69/EC.

Finally, Note Q in Directive 97/69/EC also lists a short-term biopersistence test by inhalation and a long term inhalation test as criteria for exempting mineral wool from classification as carcinogenic. Neither of these two tests is referred to in Note Q₂ in the notification from the German authorities.

This being the case it follows that the criteria for exempting mineral wool from the classification as a carcinogen proposed in the German notification differ to a considerable extent from the criteria laid down in Directive 97/69/EC. One of the proposed criteria, namely the use of the chemical composition has, in the opinion of the CSTEE, not been extensively tested and therefore does not appear to be acceptable.

- (14) In order to address the scientific/technical reasons put forward in the notification from Germany for applying national provisions which diverge from the requirements of Directive 97/69/EC, the Commission called on experts in the field of classification and labelling to draw up a technical report. In short the arguments from Germany can be summarised as:

- the classification of mineral wool as laid down in Directive 97/69/EC conflicts with the provisions of Directive 67/548/EEC and is not toxicologically sound,
- the exemption criteria in Note Q in Directive 97/69/EC contradict scientific knowledge,
- the planned national provisions tie in with the principles laid down at Community level for avoiding unnecessary animal experiments.

The technical report refuted each individual argument presented. This included reference to the year long, in depth scientific/technical discussions that had taken place during the preparation of Directive 97/69/EC: 'The Communication from the Federal Government is not

considered to contain any evidence that has not previously been considered by the Commission and other Member States in the meetings leading to the development and adoption of Directive 97/69/EC'.

Thus, with regard to the scientific arguments presented by Germany, the situation is the same as before the adoption of Directive 97/69/EC. These arguments had not convinced the experts from the other Member States during the preparatory scientific discussions.

It can therefore be concluded that the scientific/technical arguments put forward in the German notification cannot be considered a better basis for the classification of mineral wool than the provisions in Directive 97/69/EC.

The technical report was forwarded to the CSTEE for assessment as to whether it correctly addressed the reasons put forward in the notification from Germany. In its opinion of 10 September 1999 the CSTEE considered in a general comment that 'A scientific evaluation of either document (the German communication and the technical report) is made difficult by the lack of references to the scientific literature. The text of both documents (particularly that of the technical report) mixes allusions to scientific findings and to their potential normative consequences, without drawing a clear distinction between the two'.

Furthermore, in evaluating the scientific basis for the classification of mineral wool the CSTEE opinion refers, among other things, to scientific findings that were dismissed in both the notification from Germany and also the technical report.

Thus, the scientific arguments in the German notification are considered incomplete and cannot serve as a sound basis for the classification of mineral wool. Similarly the technical report is of unsatisfactory quality. It can therefore be concluded that the scientific developments in the field of man-made mineral fibres need further evaluation.

- (15) In addition, in the light of the requirements laid down in Article 95(5) the Commission asked the CSTEE whether the reasons put forward by Germany in its communication:

- (a) represented or contained new scientific evidence which had arisen after 5 December 1997 (the date of adoption of Directive 97/69/EC);
- (b) related to the protection of the environment or the workplace;

⁽⁴⁾ http://europa.eu.int/comm/dg24/health/sc/sct/out48_en.html

- (c) constituted a justification based on a problem which was specific to the Federal Republic of Germany.

constitute an impairment of the functioning of the internal market'.

The CSTE included its response in its abovementioned opinion of 10 September 1999.

- (a) with regard to the first requirement of Article 95(5) mentioned above, the opinion of the CSTE was that the reasons put forward in the notification from the German authorities did not specifically allude to any scientific evidence which had arisen after 5 December 1997.

The Commission therefore considers that the requirement concerning new scientific evidence in Article 95(5) is not fulfilled.

- (b) With regard to the second requirement of Article 95(5) mentioned above, the opinion of the CSTE stated that the scientific evidence provided by Germany did indeed relate to the protection of the workplace.

Consequently, the second requirement of Article 95(5) can be considered as fulfilled.

- (c) With regard to the third requirement of Article 95(5) mentioned above, the opinion of the CSTE was that the problem of protecting the workplace which Germany intend to tackle with its notification is not specific to Germany.

The Commission therefore considers that the third requirement of Article 95(5) is likewise not fulfilled.

In view of the opinion of the CSTE, the Commission feels that the basic conditions set out in Article 95(5) are not met in this particular instance.

3.2. *Arbitrary means of discrimination/hidden restriction of trade between the Member States/impairment of the functioning of the internal market*

- (16) Under Article 95(6), the Commission will either approve or reject any given national provisions 'after having checked whether these are or are not a means of arbitrary discrimination or a hidden barrier to trade between Member States and if they either do or do not

- (17) Since the request made by Germany is not justified in the light of the basic conditions set out in Article 95(5) (see point 3.1), the Commission is not obliged to check whether the national provisions referred to are, or are not, a means of arbitrary discrimination or a hidden barrier to trade between Member States and if they either do or do not constitute an impairment of the functioning of the internal market.

IV. CONCLUSION

- (18) In view of the above factors, the Commission feels that the request made by Germany:

— is acceptable,

— but is not justified.

The Commission therefore concludes by rejecting that request in accordance with Article 95(6) of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions concerning mineral wool, of which the Commission was notified by Germany by fax on 11 December and by a letter dated 17 December 1998, and which diverge from Directive 97/69/EC are hereby rejected.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 26 October 1999.

For the Commission

Margot WALLSTRÖM

Member of the Commission