# COMMISSION DECISION

## of 13 July 2001

## on draft national provisions notified by the Federal Republic of Germany on limitations on the marketing and use of organostannic compounds

*(notified under document number C(2001) 1912)*

**(Only the German text is authentic)**

**(Text with EEA relevance)**

(2001/570/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

(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 89/677/EEC [3] amended Directive 76/769/EEC to harmonise amongst other things the placing on the market and use of organostannic compounds in certain areas. The provisions concerning organostannic compounds were modified by Commission Directive 1999/51/EC of 26 May 1999 adapting to technical progress for the fifth time Annex I to Council Directive 76/769/EEC 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 (tin, PCP and Cadmium) [4].

(3) Directive 1999/51/EC amends Directive 76/769/EEC to prohibit the marketing and use of organostannic compounds as substances and constituents of preparations when acting as biocides in free association antifouling paint.

(4) Directive 1999/51/EC also serves to prohibit the use of organostannic compounds as substances and constituents of preparations when acting as biocides to prevent the fouling by mircro-organisms, plants or animals of:

(a) the hulls of:

— boats of an overall length, as defined by ISO 8666, of less than 25 m,

— vessels of any length for use predominantly on inland waterways and lakes;

(b) cages, floats, net and any other appliances or equipment used for fish or shellfish farming;

(c) any totally or partly submerged appliance or equipment.

Such substances and preparations:

— may be placed on the market only in packages of a capacity equal to or greater than 20 l,

— may not be sold to the general public but only to professional users.

(5) Without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of such preparations must be legible and indelibly marked as follows:

'Not to be used on boats of an overall length of less than 25 m, or on vessels of any length for use predominantly on inland waterways and lakes, or any appliances or equipment used in fish or shellfish farming.

Restricted to professional users.'

(6) The provisions referred to under recital 4(a) and the special labelling provisions are applicable to Sweden and Austria from 1 January 2003 and will be reviewed by the Commission in cooperation with Member States and stakeholders before that date.

(7) Furthermore organostannic compounds may not be used as substances and constituents of preparations intended for the use in the treatment of industrial waters.

[1] OJ L 262, 27.9.1976, p. 201.
[2] OJ L 207, 6.8.1999, p. 18.
[3] OJ L 398, 30.12.1989, p. 19.
[4] OJ L 142, 5.6.1999, p. 22.

(8) It also follows from Directive 1999/51/EC that the remaining allowed uses are to be reviewed before 1 January 2003. In recital 2, specific reference is made to the developments in the International Maritime Organisation (IMO), which has recognised the risks posed by organostannic compounds to the marine environment. The Marine Environment Protection Committee (MEPC) of the IMO has called for a global prohibition of the application of organostannic compounds which act as biocides in antifouling systems on ships by 1 January 2003.

(9) The MEPC met on 23 to 27 April 2001 and prepared a legally binding instrument (International Convention on the Control of Harmful Antifouling Systems) to be adopted at a diplomatic conference scheduled for 1 to 5 October 2001. The Council of the European Union had adopted conclusions for the negotiations in April, which, among others, underline its intention to contribute to the conclusion of a legally binding instrument to prohibit the use of organostannic compounds as of 1 January 2003. They also urged the Commission to take as soon as possible any additional steps deemed necessary in relation to relevant Community legislation.

## 2. **National provisions**

(10) Germany intends to adopt new national provisions going beyond the measures provided for under Directive 1999/51/EC by amending:

— the Annex to paragraph 1 of the Chemicals Prohibition Order (Chemikalienverbotsverordnung) regarding organostannic compounds in the version published on 19 July 1996 and last amended by Article 2 of the Order of 26 June 2000, and

— Annex IV to the Dangerous Substances Order (Gefahrstoffverordnung) in the version published on 15 November 1999 and last amended by Article 3 of the Order of 26 June 2000.

(11) The draft amendment of the Chemicals Prohibition Order modifies the existing section 11 (entitled 'Organostannic compounds') and seeks to ban the placing on the market of organostannic compounds and preparations containing organostannic compound for the following purposes:

1. as antifouling paints,

2. for water treatment in the industrial, commercial, and municipal sectors, regardless of use,

3. for wood preservation,

4. for the biocidal impregnation of heavy industrial textiles and their constituent yarns, and

5. for the biocidal treatment of consumer articles within the meaning of paragraph 5(1) No 6 of the Foodstuffs and Consumer Products Law.

(12) In addition, the following products may not be placed on the market if they have a mass content of triorgano-tin compounds of more than 1 mg tin/kg:

1. heavy industrial textiles, and

2. products within the meaning of paragraph 5(1) No 6 of the Foodstuffs and Consumer Products Law.

(13) By way of derogation, the restriction referred to in recital 11(1) will not apply until 31 December 2002 to the placing on the market of antifouling paints containing chemically bound organostannic compounds for ships with an overall length of more than 25 m that are essentially intended for operation outside inland waterways and lakes, if sold for professional purposes in minimum quantities of 20 l. The prohibitions referred to in recital 12 will not apply to products which were placed on the market for the first time before the first day of the calendar month following promulgation of the draft national legislation.

(14) The draft amendment to Annex IV (Restrictions on production and use) to the Dangerous Substances Order, seeks to modify points (entitled 'Antifouling Paints') and 8 (entitled 'Organostannic Compounds').

(15) Point 5(1) already contains a general ban on the use of organostannic compounds in antifouling paints, but, in line with the provisions of Directive 1999/51/EC, the current paragraph 2 provides for a derogation for 'chemically-bound organostannic antifouling paints for ships more than 25 m in total length that are essentially intended to operate outside inland waterways and lakes if sold for professional purposes in minimum quantities of 20 l.' The draft amendment seeks to limit the duration of the derogation by adding 'until 31 December 2002'.

(16) The draft amendment of point 8 (Organostannic compounds) intends to replace the current text by:

'Dangerous substances containing organostannic compounds shall not be used:

1. for the treatment if water in the industrial, commercial and municipal sectors, regardless of its use;

2. for wood preservation;

3. for the biocidal impregnation of heavy industrial textiles and their constituent yarns, and

4. for the biocidal treatment of products within the meaning of paragraph 5(1) No 6 of the Foodstuffs and Consumer Products Law ([5]).'

([5]) According to paragraph 5(1) No 6 of that law these are: Objects, that are intended to be in contact with the human body in a non-transitory way, such as clothes, bedlinen, masks, wigs, hair pieces, artificial eyelashes, bracelets, spectacle frames.

II. **PROCEDURE**

(17) Directive 1999/51/EC was adopted on 26 May 1999. Member States had to bring into force the national provisions necessary to comply with it before 29 February 2000 and to apply them from 1 September 2000. Germany correctly transposed the Community provisions through an amendment of the Dangerous Substances Order (Order of 26 June 2000, Federal Law Gazette I 2000, p. 932).

(18) By letter of 22 January 2001, the German Permanent Representation informed the Commission that Germany, in accordance with Article 95(5) of the Treaty, intended to apply stricter measures regarding organostannic compounds than those contained in Directive 1999/51/EC. Germany considered it necessary to introduce such national measures which are justified in accordance with Article 30 of the Treaty to protect the environment and human health against the harmful effects of organostannic compounds used as components in biocidal preparations. The letter was received on 25 January 2001.

(19) By letter of 22 February 2001, the Commission informed the German authorities that it had received the notification under Article 95(5) and that the six month period for its examination according to Article 95(6) started on 26 January 2001, the day following the one when the notification was received.

(20) By letter of 17 April 2001, the Commission informed the other Member States about the request received from Germany and invited them to submit comments, if deemed necessary, within one month. The Commission also published a notice regarding the request in the *Official Journal of the European Communities* ([6]) in order to inform other interested parties of the draft national measures that Germany intends to adopt.

III. **ASSESSMENT**

1. **Consideration of admissibility**

(21) The notification submitted by the German authorities on 25 January 2001 intends to obtain approval to introduce national provisions incompatible with Directive 1999/51/EC, which constitutes a harmonisation measure adopted on the basis of Article 95 of the Treaty.

(22) Article 95(5) 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 introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.'

(23) Annex I to Directive 76/769/EEC as amended by Directive 1999/51/EC deals with three different situations in which organostannic compounds are marketed or used. These three situations are all concerned with the aquatic environment, or more precisely they involve applications in water or on objects partially or totally submerged in water:

— point 21.1 currently prohibits the marketing of organostannic compounds for use as substances and constituents of preparations when acting as biocides in free association antifouling paints ([7]). Other types of preparations are allowed to be placed on the market,

— point 21.2 restricts the use of organostannic compounds as substances and constituents of preparations when acting as biocides to prevent the fouling by micro-organisms, plants or animals of the hulls of boats of an overall length of less than 25 m, of vessels of any length for use predominantly on inland waterways and lakes, any equipment used for fish or shellfish farming, and any totally or partly submerged appliance or equipment,

— in addition, point 21.4 prohibits the use of organostannic compounds in the treatment of industrial waters irrespective of their use.

(24) When comparing the current Community legislation and the draft national provisions which Germany intends to apply, it emerges that the national measures go beyond the Community legislation, as they amount to:

— a ban on the marketing and use of organostannic compounds in all kinds of antifouling products as of 1 January 2003,

— a ban on the use of organostannic compounds for a range of other uses: wood preservation, impregnation of heavy industrial textiles and their constituent yarns, and treatment of consumer articles.

(25) In addition, the draft national measures intend to limit the maximum content of triorganic-tin compounds for a number of products such as heavy industrial textiles and consumer products.

(26) The draft national provisions notified by Germany concern the use of organostannic compounds in antifouling paints, which is within the harmonised area created by Directive 1999/51/EC. The draft national provisions also seek to ban the use of organostannic compounds for the treatment of wood, textiles, and consumer articles. Here, two cases have to be distinguished: if the treated products are intended for uses where they are partly or totally submerged in water (i.e.

([6]) OJ C 120, 24.4.2001, p. 9.

([7]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 describes in Annex V, antifouling products (product-type 21) as 'products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water'.

use in the aquatic environment) or intended for equipment or appliances for fish or shellfish farming, they are within the harmonised area and Directive 1999/51/EC already bans the use of organostannic compounds for this purpose. Treatment of wood, heavy industrial textiles and consumer products, which are intended for other purposes is not regulated by the Directive.

(27) As required by Article 95(5) of the Treaty, Germany notified the Commission of the actual wording of the provisions that are intended to be introduced, accompanying the request by an explanation of the reasons, which, in its opinion, justify the introduction of those provisions. However, only a part of the draft national measures is within the area of harmonisation created by Directive 1999/51/EC.

(28) The notification submitted by Germany on 25 January 2001 in order to obtain approval for the introduction of national provisions regarding the use of organostannic compounds in antifouling products which derogate from the provisions of Directive 1999/51/EC may therefore be held admissible under Article 95(5) of the Treaty. The notification of the draft national measures concerning other uses of organostannic compounds, which are outside the area of harmonisation created by Directive 1999/51/EC, is inadmissible.

(29) Consequently, this Decision will only refer to the draft national provisions regarding antifouling products intended for use in the aquatic environment, for which derogation is sought. The draft national measures for the other uses are not concerned by this Decision and will have to be notified and evaluated according to the procedures established by Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations ([8]), as amended by Directive 1998/48/EC ([9]).

## 2. **Assessment of merits**

(30) In accordance with Article 95 of the Treaty, the Commission has to ensure that all the conditions enabling a Member State to avail itself of the possibilities of derogation provided for in that Article are fulfilled.

(31) The Commission must therefore assess whether the conditions provided for by Article 95(5) are met. This requires (a) 'new scientific evidence with regard to the protection of the environment or the working environment', (b) which causes the applicant Member State to consider the introduction of national provisions to be necessary 'on grounds of a problem specific to that Member State', (c) where the problem concerned arose 'after the adoption of the harmonisation measure'.

(32) In addition, pursuant to Article 95(6), where it considers that the introduction of such national provisions is justified, the Commission must check whether or not those national provisions are 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.

### 2.1. *The nature of organostannic compounds*

(33) Organostannic compounds are a group of substances, which are composed of tin and a variable number of organic groups, which are directly bound to the tin atom. Organostannic compounds are very effective antifouling agents for ships, the most important and effective compounds being tributyltin, TBT, and Bis(tributyltin)oxide TBTO.

(34) Tribuyltin compounds are classified according to 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 99/33/EC ([11]), as:

— harmful in contact with skin,

— toxic if swallowed,

— irritating to eyes and skin,

— toxic: danger of serious damage to health by prolonged exposure through inhalation and if swallowed,

— very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

(35) For an antifoulant to be effective, the active substance must be bioavailable, and hence constantly released to the surrounding environment. As a result of this release to the aquatic environment and the high acute and chronic toxicity of organostannic compounds, damage can result to exposed ecosystems.

(36) TBTO is strongly absorbed to sediment. The principal degradation pathway of TBT is biodegradation to dibutyltin and monobutyltin and eventually tin oxide. The speed of the degradation is strongly influenced by the surrounding matrix, with half lives in water of two weeks, biota two months, sediment 0,5 to 20 years. TBT shows some bioaccumulation within the environment.

(37) TBT interferes with the metabolism of exposed organisms (inhibition of enzymes and denaturing of proteins), and the endocrine system of certain snails (imposing the development of male sexual characteristics in females; a phenomenon called imposex).

([8]) OJ L 204, 21.7.1998, p. 37.
([9]) OJ L 217, 5.8.1998, p. 18.
([10]) OJ L 196, 16.8.1967, p. 1.
([11]) OJ L 199, 30.7.1999, p. 57.

(38) Risks to the aquatic environment from TBT are well recognised and even in 1989, the first Community measures (Directive 89/677/EEC) had been taken to reduce the risks from the use of organostannic compounds in antifouling paints by restricting their use to professional users for ships of a length of more than 25 m.

(39) A thorough reevaluation carried out by the Commission in cooperation with the Member States, led to the adoption of Directive 1999/51/EC, which strengthens these protective measures considerably. That Directive bans completely the use of those types of antifouling paints, which are liable to higher and uncontrolled release of organostannic compounds, and the use on boats of any size predominantly employed on inland waterways and lakes. In the course of the review process, the Commission had commissioned a study on the matter by an external consultant ([12]) and, based on that study, requested the opinion of the Scientific Committee of Toxicity, Ecotoxicity, and the Environment (SCTEE), which was adopted on 27 November 1998.

2.2. *The position of Germany*

(40) A description is given of all the arguments behind the notified provisions, including those relating to areas which have been considered as falling outside of the scope of Directive 1999/51/EC.

(41) Germany takes the view that the knowledge both of the ecotoxicological effects and possible health damage justifies a more comprehensive ban on the use of organostannic compounds as biocidal agents than is provided for in Directive 1999/51/EC.

(42) In the interests of health and environment protection, Germany considers it necessary to transpose into national law IMO Resolution A.895(21), which was adopted on 25 November 1999, and to lay down further requirements prohibiting the use of organostannic compound as biocidal agents in certain consumer products.

(43) Germany believes that the national provisions set out in the draft measures are necessary and justified for reasons of protection of human and animal health and life pursuant to Article 30 of the Treaty. In its view, only these measures can ensure adequate protection of the abovementioned legal rights.

(44) Germany recalls that in the context of a 'concerted action' at the 45th MEPC meeting, the parties to the OSPAR Convention (including Germany and the European Commission emphasised that the proposed date for the entry into force of the ban on organostannic compounds as antifouling agents in ships' paint (1 January 2003) must be regarded as definitive and that it was extremely important for the proposed globally binding instrument to take effect on time (MEPC document 45/4/8 of 9 August 2000).

(45) Accordingly, the draft national measures intend to eliminate the existing exemption on the marketing of chemically-bound organostannic antifouling paints for ships of more than 25 m in total length that are essentially intended to operate outside inland waterways and lakes as of 1 January 2003.

(46) In addition, Germany thinks that as yet, Directive 76/769/EEC does not cover the use of organostannic compounds as biocidal agents in heavy textiles and consumer products. In view of the need for action to protect the environment and human health, the existing prohibitions on the marketing and use of organostannic compounds and preparations containing these substances will be extended. Their use will be prohibited for the biocidal impregnation of heavy industrial textiles and their constituent yarns, the biocidal treatment of certain consumer products and as wood preservatives.

(47) Wood preservatives containing biocidal organostannic compounds have not been used in Germany for several years. More ecologically acceptable alternatives for the biocidal treatment of heavy textiles are also available. The particular objective of the ban is to prevent the diffusion of triorgano-tin compounds in the environment. Since high concentrations of organostannic compounds are necessary to achieve biocidal effects, the biocidal treatment of consumer products, which have prolonged contact with the human body must also be prohibited because of the toxic properties of these substances.

(48) Germany claims that there is new scientific evidence, which was discussed on 14 March 2000, when the Federal Environmental Office and the Federal Institute for Consumer Protection and Veterinary Medicine on behalf of the Federal Ministry of the Environment, organised a panel hearing in Berlin on the 'Production and use of organotin compounds in Germany'. The report

([12]) WS Atkins International Ltd, 'Assessment of the risks to health and to the environment of tin organic compounds and of arsenic in certain biocidal products and of the effects of further restrictions on their marketing and use', final report, April 1998.Opinion of the SCTEE on the report by WS Atkins International Ltd. Expressed at the sixth SCTEE plenary meeting, Brussels, 27 November 1998.

(which was annexed to the request), outlines recent findings on use, environmental concentrations and toxicology. According to Germany, a number of the results were obtained only after the preparation of Directive 1999/51/EC, and reflect the environmental damage caused by organostannic compounds in Germany and thus justify the tighter restrictions contained in the draft measures.

(49) In the case of sediment, a distinction should be drawn between 'normal' concentrations and concentrations in the vicinity of 'hot spots' (ports, production. facilities of organostannic compounds). As expected, concentrations of organostannic compounds in suspended matter and sediments also generally correlate with the percentage of municipal waste waters in the examined water.

(50) In the course of various measurement programmes, maximum concentrations of 10-77 µg Tributyltin (TBT)/kg were recorded in the suspended matter of water taken from the rivers Rhine, Main, Fulda, Lahn and Nidda, with typical values lying between 5 and 20 µg TBT/kg dry matter (DM). Comparable values were also recorded for mono- and di-butyltin.

(51) Maximum values in sediments are very much higher. Thus, the 'Elbe Association' reported levels ranging from 1 000 to 5 000 µg organostannic compounds/kg DM in the rivers Elbe and Mulde. Greenpeace identified similarly high values in the vicinity of shipyards in 1999 and reported measuring 4 978 µg organostannic compounds/kg close to the Neptune shipyard floating dock. The area around the largest German ship repair yard (Norderwerft) is the most contaminated, with 103 795 µg TBT/kg being recorded.

(52) The particularly high contamination with organostannic compounds of the German Bay is essentially due to the fact that it encompasses the estuaries and lower reaches not only of the Elbe but also of the Weser and Ems, which have some of the busiest shipping lanes in the Community. This problem is aggravated by the proximity of these routes to the Wadden Sea, a particularly vulnerable area enjoying special protection as a national park. Since TBT degrades much more slowly in sediment than in water, high sedimentary concentrations create a special problem for countries having mudflats that warrant protection.

(53) That extreme contamination of the marine environment leads to high accumulation of organostannic compounds in marine animals. The Institute for Environmental Chemistry and Ecotoxicology of the Fraunhofer-Gesellschaft, Schmallenberg, completed a research project on the 'Monitoring of environmental pollution caused by alkyl phenols, bisphenol A and organostannic compounds in representative samples' in 1999. The study identified up to 459 µg TBT/kg in bream musculature and 940 µg TBT/kg in *dreissenidae* mussels.

(54) Consumption of fish, and particularly mussels, can account for a significant proportion of consumer exposure. The consumption of 200 g of highly polluted fish containing 100 µg organostannic compounds/kg would result in the ingestion of 20 µg, corresponding to 0,33 µg/kg bodyweight (60 kg). This would be slightly in excess of the TBTO admissible daily intake (ADI). Values exceeding that level by an even greater margin can be expected in fish taken from problem waters, for example in the vicinity of ports, dense shipping lanes and shipyards.

(55) Organostannic compounds were also detected in consumer products. Thus, the current textiles resources catalogue (2000) offers anti-microbial agents, which, according to their chemical composition, contain organostannic compounds. These are TBT compounds. Maximum values of 130 mg TBT/kg were detected in textile clothing samples examined in 1999 and 2000 (cycling-shorts padding). Assuming a resorption rate of 1 % whenever such garments are worn and a 20 % resorption quota, the uptake will come close to the WHO ADI value.

(56) TBT is not only used as an antifouling paint but is also employed, as indicated above, for the biocidal impregnation of heavy textiles (i.e. heavy industrial textiles such as awnings and tarpaulins of Lorries) and articles of clothing. When washed out of textiles, TBT is released to the environment. Sludge concentrations, particularly from municipal areas, are an appropriate indicator of current wastewater contamination by hydrophobic substances having a generally diffuse emission spectrum.

(57) The concentrations of organostannic compounds measured in municipal sludge vary considerably. Starting at approximately 10 µg/kg DM, they increase to the several mg/kg DM range. TBT is almost totally (97,5 %) sludge-bound. An average concentration of 0,3 mg/kg TBT in dry sludge mass (median value of 53 samples from German treatment plant) and the generation of 2,95 million t of sludge per annum, gives a national annual value of 885 kg. The fact that 40 % of this sludge is used in agriculture means that approximately 350 kg of TBT is spread on farmland each year.

(58) The harmful effect of TBT on the metabolism of exposed organisms (enzyme inhibition and protein denaturation) and the hormone system of certain snails (appearance of male sexual characteristics in females; imposex) together with the associated threat to the aquatic environment are sufficiently well known and generally recognised.

(59) Recent scientific studies of human cell cultures, the results of which were published after the entry into force of Directive 1999/51/EC, confirm that TBT also inhibits the enzyme system responsible for female sex hormone development. It therefore seems possible that TBT, even in small concentrations, could damage human health.

(60) Germany does not believe that the proposed new regulations will hamper the operation of the internal market.

(61) As regards implementation of the IMO Resolution, the industry concerned is already preparing for the complete worldwide ban on the use of antifouling ships' paint containing organostannic compounds, which is due to come into force on 1 January 2003. The draft Order has also adopted this reference date for its proposed ban on use.

(62) One company based in Germany is the market leader in TBT production, accounting for approximately 80 % of worldwide output. This proves that the proposed restrictions are neither a means of arbitrary discrimination against foreign producers nor a hidden barrier to intra-Community trade. Since they primarily affect TBT producers and shipyards in Germany, they do not obstruct the operation of the internal market.

(63) The most recent scientific findings with regard to the toxicological properties of organostannic compounds and current German exposure data justify a complete ban, in line with the IMO Resolution, on the aquatic discharge of TBT ships' paint and the imposition of further restrictions on organostannic compounds. This is the only way of ensuring adequate human and environment protection against the harmful effects of these substances.

(64) In conclusion, Germany points out that it would have preferred to see the adoption of the proposed measures for the whole of the Community. To that extent, it regrets that the Commission was unable to comply with the request made in its memorandum of 20 September 2000 concerning the presentation of a corresponding draft directive.

2.3. *Evaluation of the position of Germany*

2.3.1. The burden of proof

(65) It has to be noted that, in the light of the time frame established by Article 95(6) of the Treaty, the Commission, when examining whether the draft national measures notified under Article 95(5) are justified, has to take as a basis 'the grounds' put forward by the Member State. This means that, under the Treaty, the responsibility of proving that these measures are justified, lies with the requesting Member State. Given the procedural framework established by Article 95, including in particular a strict six-month deadline for a Decision to be adopted, 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 justifications.

(66) If the elements submitted by the requesting Member State are not sufficient to enable the Commission to assess whether the conditions of Article 95(5) are fulfilled and the Commission therefore rejects the draft national measures, the Member State is not precluded from notifying its request again and substantiating it with all additional and/or new elements, which are necessary to establish whether or not the conditions of Article 95(5) are fulfilled.

2.3.2. New scientific evidence concerning the protection of the environment or the working environment regarding a problem specific to the Member State arising after the adoption of the harmonisation measure

(67) Germany has submitted a number of documents in support of its request for application of Article 95(5). However, only a part of the information contained in both, the request and these documents, relates to the use of organostannic compounds in antifouling paints. In the following the statements and positions of Germany regarding this area of application will be evaluated in the light of the criteria established in that Article.

(68) The arguments put forward by Germany to justify the draft national provisions regarding the use of organostannic compounds in antifouling paints relate to the protection of the environment, but in part also to human health.

(69) Germany makes extensive reference to the work of the IMO, and in particular its Resolution A.895(21), which was adopted on 25 November 1999. However, the subject of this resolution and in particular the preparatory work of the MEPC were already well known at the time when Directive 1999/51/EC was adopted and are specifically mentioned in it. The second recital states that the development of the work and the decisions taken in the IMO will be fully taken into account during the revision of provisions on TBT, which will be carried out before 1 January 2003.

(70) Germany mentions a number of data regarding TBT concentrations in river sediments (Rhine, Main, Fulda, Lahn and Nidda). However, these data are of no relevance for the justification of measures going beyond the restrictions of Directive 1999/51/EC, as the Directive already prohibits completely the use of organostannic compounds for antifouling paints for boats that are predominantly used in inland waterways.

(71) Germany mentions particularly high concentrations of TBT in sediments in the vicinity of hotspots (ports, organotin production facilities, dockyards) and give as example measurements from the river Elbe and Mulde (1 000 to 5 000 µg/kg dry mass), 4 978 µg/kg around the Neptune shipyard dock, and up to 103 795 µg/kg around the Norderwerft ship repair yard. These data are from a Greenpeace study published in July and September 1999 and thus after the adoption of Directive 1999/51/EC. However, Germany does not indicate when the data were measured nor is the full text of the study available.

(72) Germany also refers to a particular high contamination of the German Bight by the rivers Elbe, Weser and Ems, which all are very busy shipping lanes leading to major ports. According to Germany, this problem is aggravated by the proximity of these routes to the Wadden Sea (mudflats), a particulary vulnerable area enjoying special protection as a national park. No data are provided to support these claims and Germany itself states that the latter problem is specific for all countries having mudflats that warrant protection.

(73) Although it is likely that the data referred to in recital 71 were indeed measured at a time, when Directive 1999/51/EC was already adopted, they do not *per se* constitute new information. The effect that there are specifically high releases of biocides (including TBT) from fresh antifouling paint was already well known when Directive 1999/51/EC was prepared and is specifically documented in the study mandated by the Commission ([13]) in the course of the preparatory work. Furthermore the argument is applicable to any port in the world where drydock work involving antifouling painting is carried out.

(74) The data regarding the TBT concentrations in the sediments of busy shipping lanes are not new either. The study mandated by the Commission in the review of the Community legislation gives examples of various ports around the world (Hong Kong, France, New Zealand, the Netherlands), dating from 1989 to 1995 showing TBT concentrations in harbour sediments from 10 to 2 100 µg/kg. This clearly shows that the levels of TBT found in sediments in the river Elbe (close to the port of Hamburg) are of a kind that was already known when Directive 1999/51/EC was drawn up, and that they are not unique for Germany. The problem seems, however, to be specific for Member States, where busy ports are located ([14]).

(75) Given that no data are provided concerning the pollution of the Wadden Sea, it is not possible to comment on their potential relevance for the justification of the draft national measures.

(76) Germany also mentions high concentrations of organostannic compounds found in seafood, fish, and mussels in a study published in 1999. This could lead to an exposure of humans consuming such polluted fish and seafood slightly in excess of recommended admissible daily intake (ADI), or even higher from seafood coming from problematic areas (vicinity of ports, dense shipping lanes, and shipyards). However, these observations are not specific for Germany, and only human health arguments related to the working environment are relevant in the framework of the evaluation procedure under Article 95(5) of the Treaty. It has to be noted that the implications for consumer health from the accumulation of organostannic compounds in food products are undergoing assessment by the Scientific Committee on Food. The outcome of this assessment and the need for future legislation to protect consumers from these compounds in food will be considered.

(77) All other information and data provided by Germany relate to the use of organostannic compounds in areas of application that are not harmonised by Directive 1999/51/EC and therefore need not be evaluated here.

(78) Overall it can be seen that the data and justification submitted by Germany in support of its request under Article 95(5) do not establish that the draft national measures regarding the use of organostannic compounds in antifouling paints are based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to Germany arising after the adoption of the harmonisation measure. The conditions for the application of Article 95(5), are, therefore, not fulfilled.

([13]) See footnote 12.

([14]) Similar arguments were raised by the Belgian authorities and examined by the Commission in the framework of a request by Belgium according to Article 95(5) to introduce draft national measures regarding organostannic compounds as of 1 January 2003. The Commission adopted a Decision rejecting the draft national measures on 25 July 2000 (Decision 2000/509/EC; OJ L 205, 12.8.2000, p. 7).

(79) In view of that analysis of the material submitted, there are no grounds for consulting the other Member States or interested groups or for requesting a new opinion of the SCTEE.

2.4. *Absence of any arbitrary discrimination, any disguised restriction of trade or any obstacle to the functioning of the internal market*

(80) Under Article 95(6) the Commission is either to approve or reject the draft national provisions notified 'after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market'.

(81) Since the request made by Germany does not fulfil the basic conditions set out in Article 95(5) (see section 2.3 of this Decision), the Commission is not obliged to verify whether or not the draft national provisions are a means of arbitrary discrimination or disguised restriction on trade between Member States, and whether or not they constitute an obstacle to the functioning of the internal market.

## IV. **CONCLUSION**

(82) In the light of the foregoing, it should be concluded that the request by Germany for introducing national legislation going beyond Directive 1999/51/EC as submitted on 25 January 2001:

— is admissible in so far as it refers to antifouling products intended for use in water (i.e. in the aquatic environment) but is inadmissible as regards the rest,

— to the extent it is admissible, does not fulfil the conditions established by Article 95(5) of the Treaty.

(83) That request should, therefore, be rejected in accordance with Article 95(6) of the Treaty.

(84) However, developments in the IMO should be followed very closely and taken into account when Directive 76/769/EEC has to be reviewed, before 1 January 2003. In addition, the necessary conclusions will be drawn from the outcome of the ongoing assessment on the implications for consumer health from the accumulation of organostannic compounds in food products, including the need for future legislation to protect consumers from these compounds,

HAS ADOPTED THIS DECISION:

*Article 1*

The draft national provisions concerning organostannic compounds, which the Federal Republic of Germany notified to the Commission by letter dated 22 January 2001, and which seek to derogate from Directive 1999/51/EC as of 1 January 2003 regarding the use of organostannic compounds in antifouling products intended for use in the aquatic environments are rejected.

*Article 2*

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 13 July 2001.

*For the Commission*

Erkki LIIKANEN

*Member of the Commission*