II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 25 July 2000

concerning the draft national provisions notified by the Kingdom of Belgium concerning the limitations of the marketing and use of organostannic compounds

(notified under document number C(2000) 2016)

(Only the French and Dutch texts are authentic)

(Text with EEA relevance)

(2000/509/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 1999/51/EC

(1) Council Directive 76/769/EEC [1] 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, as last amended by Commission Directive 1999/77/EC [2] of 26 July 1999, 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] of 21 December 1989, which amends for the eighth time Directive 76/769/EEC, harmonises amongst others the placing on the market and use of organostannic compounds. The provisions concerning organostannic compounds were modified by Commission Directive 1999/51/EC [4] 26 May 1999, which adapts to technical progress for the fifth time Annex I to Directive 76/769/EEC.

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

(4) The Directive also prohibits the use of organostannic compounds as substances and constituents of preparations when acting as biocides to prevent the fouling by mircroorganisms, plants or animals of

(a) the hulls of:

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

— 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 litres,

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

[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.

(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 shall be legible and indelibly marked as follows:

'Not to be used on boats of an overall length of less than 25 metres, 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 under point 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 this 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.

(8) The Directive thus establishes that organostannic compounds may only be used in antifouling products providing for controlled release of active ingredients for ships of a length of more than 25 m that are not predominately used on inland waterways and lakes. Austria and Sweden are authorised to maintain their existing stricter legislation in view of the specific needs to protect the especially sensitive environments of the Baltic Sea and inland waterways.

(9) The Directive also establishes that the remaining allowed uses are to be reviewed before 1 January 2003. In the second whereas clause, specific reference is made to the developments in the International Maritime Organisation (IMO), which has recognised the risks posed by organostannic compounds. The Marine Environment Protection Committee of the IMP 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.

2. **National provisions**

(10) Belgium intends to transpose the provisions of Directive 1999/51/EC concerning organostannic compounds by modifying the Royal Decree of 25 February 1996 placing restrictions on the marketing and use of certain dangerous substances and preparations. The existing Article 1(2) will be replaced by a new text containing exactly the same provisions as adopted in the Community Directive.

(11) Belgium also intends, after the implementation of the Directive, to replace as from 1 January 2003 the said Article 1(2) of the Royal Decree of 25 February 1996 by the following provision:

'Organostannic compounds may not be placed on the market for use as substances and constituents of preparations when acting as biocides in antifouling paints.'

3. **Comparison between the draft national provisions and Directive 1999/51/EC**

(12) When comparing the current Community legislation and the draft national provisions which Belgium intends to apply as of 1 January 2003, it emerges that the national measures are more restrictive, as they amount to a total ban on the marketing and use of organostannic compounds in antifouling products.

II. **PROCEDURE**

(13) Directive 1999/51/EC was adopted on 26 May 1999. Member States had to bring into force the national provisions necessary to comply with the Directive before 29 February 2000 and to apply them from 1 September 2000.

(14) By letter of 21 February 2000, the Belgian Permanent Representative informed the Commission that Belgium would correctly transpose the provisions of Directive 1999/51/EC, but that in accordance with Article 95(5) of the EC Treaty, it was intended to apply stricter measures as of 1 January 2003. Belgium considers it necessary to introduce such national measures to protect the environment against the harmful effects of antifouling paints based on organostannic compounds, on the basis of new scientific evidence. The letter was received on 23 February 2000.

(15) By letter of 23 March 2000, the Commission informed the Belgian authorities that it had received the notification under Article 95(5) and that the six months period for its examination according to Article 95(6) started on 24 February 2000, the day following the one when the notification was received.

III. **ASSESSMENT**

1. **Consideration of admissibility**

(16) The notification submitted by the Belgian authorities on 21 February 2000 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 EC Treaty.

(17) 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.'

(18) As required by Article 95(5) of the EC Treaty, Belgium notified the Commission of the actual wording of the provisions that are intended to be introduced as of 1 January 2003, accompanying the request by an explanation of the reasons, which, in its opinion, justify the introduction of those provisions.

(19) The Commission, therefore, is of the opinion that the notification submitted by Belgium on 21 February 2000 in order to obtain approval for the introduction of national provisions derogating from the provisions of Directive 1999/51/EC is admissible under Article 95(5) of the EC Treaty.

2. **Assessment of merits**

(20) In accordance with the provisions of Article 95 of the EC 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 this article are fulfilled.

(21) The Commission must therefore assess whether the conditions provided for by Article 95(5) of the EC Treaty 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'.

(22) In addition, pursuant to Article 95(6) of the EC Treaty, where it feels 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. ***Organostannic compounds - general information***

(23) 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 ([5]) for ships, the most important and effective compounds being tributyltin, TBT, and Bis(tributyltin)oxide TBTO.

(24) Tributyltin compounds are classified according to Council Directive 67/548/EEC of 27 June 1967 relating to the classification, packaging and labelling of dangerous substances ([6]) as last amended by Directive 99/33/EC ([7]) 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.

(25) 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.

(26) 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.

(27) TBT is interfering 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).

(28) Risks to the aquatic environment from TBT are well recognised and already in 1989, the first Community measures (Directive 89/677/EEC) were 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 metres.

(29) A thorough re-evaluation 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. The 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 mandated a study on the matter to an external consultant ([8]) 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.

([5]) Fouling denotes the effect that a wide range of organisms are susceptible to colonise on ships' hulls and constructions in water. The presence of fouling organisms on the surface of ship hulls can have a very significant effect on the performance of a ship, leading to reduced handling and increased fuel consumption.

([6]) OJ 196, 16.8.1967, p. 1.
([7]) OJ L 199, 30.7.1999, p. 57.
([8]) 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.

2.2. ***The position of Belgium***

(30) The Belgian authorities take the view that the proposed measure is designed to protect the health of humans and animals as well as the environment, a fact supported by a number of facts, which add to the underlying reasons for Directive 1999/51/EC.

(31) According to them, it was already shown at the time of preparation of Directive 1999/51/EC that the concentration of TBT from antifouling paint used to treat the hulls of boats, on busy shipping lanes and in port areas, reaches a level that is harmful to oysters and dogwhelk, and causes shell thickening and imposex in those organisms. These effects and others illustrate the endocrine-destructive capacity of TBT for some animal species at very low concentrations.

(32) The Belgian authorities acknowledge that because of economic considerations, i.e. the possible consequences of a unilateral European TBT ban for European shipyards with relocation of activities and circumvention of a ban imposed by the European Community, at European level the option for a restricted ban on TBT paint was taken and that, as far as a total ban on TBT was concerned, reference was made to an IMO Decision and the prospect of 1 January 2003.

(33) In their request, the Belgian authorities state that a recent study shows that exposure to TBT in flatfish reduces resistance to infection. These fish live on the seabed and are exposed to relatively high concentrations of TBT.

(34) TBT can also damage the immune system of mammals, such as sea otters, which feed on shellfish which live in an environment contaminated with TBT. The effect on immunity on humans is also a possible consequence of exposure to TBT, which is one of the reasons for the low value of the admissible daily intake (ADI) of 0,25µg/kg/day regarded as possible by the SCTEE. Data on the presence of organostannic compounds in fish, shellfish and crustaceans are limited. The data that are available, however, show that exceeding the ADI of TBT may be the case in people whose eating habits contain a sizeable proportion of fish and shellfish contaminated with TBT, such as mussels. In support of these arguments, the Belgian authorities make reference to a study ([9]) of June 1999.

(35) It is stated further that an analysis of dredging spoil from Belgian ports showed that the concentration of TBT is over 7 µg/kg, the limit for the marine environment. Samples taken in June 1999 provided readings of more than double this limit.

([9]) A.C. Belfoid, M. Puperhart and F. Ariese, *Organotin levels in seafood in relation to the tolerable daily intake (TDI) for humans*, Institute for Environmental Studies, Vrije Universiteit Amsterdam, June 1999.

(36) According to the Belgian authorities, the scientific information available indicates that within two weeks of applying a fresh coating of paint TBT release averages 110 µg TBT/cm²/day, with peaks of up to 1 128 µg TBT/cm²/day. The treatment with antifouling paints carried out in Belgian ports is likely to increase the contamination in the port area and the nearby shipping lanes, which helps to explain the high TBT levels in the dredging spoil.

(37) The Belgian authorities also point out that imposex is not limited to dogwhelk but has been noted world-wide in 72 species of marine snails.

(38) It is underlined that at its 43rd meeting from 28 June to 2 July 1999 the Marine Environment Protection Committee of the IMO took further steps to enable the IMO Diplomatic Conference in 2001 to take the decision to ban the use of organostannic compounds in antifouling paint on sea-going vessels from 1 January 2003.

(39) The Belgian authorities also claim that antifouling paints without organostannic compounds and of equal duration and effectiveness are already available. Their cost price, which at present is still considerably higher than the price of paints containing TBT, is expected to drop when production is on a larger scale, as was the case years ago for paint containing TBT.

(40) As the abovementioned damaging effects of TBT contamination of the marine environment were established at a time when TBT had already been banned for some time on boats of less than 25 metres, the Belgian authorities assume that further measures, namely, a total ban on antifouling paints based on organostannic compounds, will be needed in order to counter any further detrimental effects for the environment.

(41) Being close to the ports and one of the busiest shipping lanes, the marine environment off the Belgian coast is particularly exposed to the consequences of TBT production from sea-going vessels. The abundant sediment in that area forms a reservoir from which, protected against rapid degradation, TBT will pose a threat to the aquatic environment many years after the use of TBT has been stopped.

(42) To prevent dredging spoil contaminated with TBT from damaging the environment, it will have to be specially treated, which will mean very high costs for the community. These costs will increase the longer the use of paints based on organostannic compounds continues. In view of these costs economic justification for delaying the total ban of TBT is no longer tenable for Belgium.

(43) The Belgian Government therefore takes the view that the use of antifouling paints should be stopped from 1 January 2003 onwards, the date proposed by the Marine Environment Protection Committee of the IMO.

2.3. ***Evaluation of the position of Belgium***

(44) The material and data submitted by the Belgian authorities in support of their request for application of Article 95(5) is rather limited. In the following their statements and positions will be evaluated in the light of the criteria established in that article.

2.3.1. *The burden of proof*

(45) It has to be noted that, in the light of the time frame established by Article 95(6), 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, 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, including in particular a strict six months 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 reasons of justification.

(46) 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*

(47) The arguments put forward by the Belgian authorities do relate to the protection of the environment. However, the Belgian authorities acknowledge themselves that a very large amount of information on the environmental effects of TBT and other organostannic compounds was already known and taken into account in the preparation of Directive 1999/51/EC. This applies particularly to the work of the IMO, which is specifically mentioned in the second recital of Directive 1999/51/EC. In fact, it is clearly stipulated there that the development of the work and the decisions taken in the IMO will be fully taken into account during the revision of the Directive which will be made before 1 January 2003.

(48) The Belgian authorities claim that a recent study has shown that exposure to TBT in flatfish reduces resistance to infection. No further information is provided, neither the text of the study, nor a reference. It is therefore not possible to verify whether this information did indeed occur or become known only after the adoption of Directive 1999/51/EC.

(49) Effects on human health, specifically due to exposure in the working environment, have been assessed both in the study mandated by the Commission and the opinion of the SCTEE during the preparation of Directive 1999/51/EC. It is therefore unclear whether the information provided by the Belgian authorities based on a study from June 1999 ([10]) to which reference is made (but the text is not provided) constitutes new evidence in the sense of Article 95(5). In particular, the information relates to daily intake of TBT through food, and therefore is not linked to the protection of humans in the working environment.

(50) The Belgian authorities claim that samples of dredging spoil taken from Belgian ports in June 1999 showed that the concentration of TBT was more than twice the level of 7µg/kg. No further details are provided. Although these data were measured at a time, when Directive 1999/51/EC was already adopted, they do not *per se* constitute new information. In fact, 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 neither the levels of TBT found in sediments in Belgian ports are of a kind not already known when the Directive was prepared, nor are they unique for Belgium. The problem seems, however, to be specific for Member States, where busy ports are located.

(51) The Belgian authorities point out that after application of TBT paint in dockyards (which is done in Belgian ports), there are specifically high releases of TBT from the fresh paint, which is one of the reasons why the levels of TBT in harbour sediments are elevated. No specific data for Belgium, nor the timing when the data became available are provided. On the other hand, 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 ([11]). Furthermore the argument is applicable to any port in the world where drydock work involving antifouling painting is carried out.

(52) The remaining arguments from the Belgian authorities (see above) give rise to the following comments. The study mandated by the Commission does already acknowledge that imposex is not limited to dogwhelk and occurs in a number of other marine snails. However, the dogwhelk is the most sensitive species. The objective of the actions taken by the Marine Environment Protection Committee of the IMO at its meeting from 28 June to 2 July 1999, namely to enable the IMO Diplomatic Conference to ban the use of organostannic compounds in antifouling paints on sea-going vessels

([10]) See footnote No 9.
([11]) See footnote No 8, page 1-7.

from 1 January 2003, was already known at the time when Directive 1999/51/EC was adopted and is specifically mentioned in the recitals. The fact that alternative paints without organostannic compounds are available and will become less expensive is not relevant in the justification of the Belgian request.

(53) Lastly the Belgian authorities state that being close to the ports and one of the biggest shipping lanes, the marine environment off the Belgian coast is particularly exposed to the consequences of TBT production from sea-going vessels. To prevent damage to the environment, the sediments will have to be dredged and decontaminated, which will entail high economic costs. No further data, neither on the actual contamination along the Belgian coastline, nor on the economic costs of decontamination are provided. The study mandated by the Commission is well aware of the fact that coast-lines close to major ports and busy shipping lanes are environments at high risk. The example of the Netherlands' coast line is presented in detail. However, the data from the Netherlands indicate that the contamination of the coast line is more due to the effluents and dumping of dredged spoil from busy ports than from the fact that busy shipping lanes are close by.

(54) Overall it can be seen that the data and justification submitted by the Belgian authorities in support of their request for Article 95(5) do not allow to conclude that the draft national measures are based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to Belgium arising after the adoption of the harmonisation measure. The conditions of Article 95(5), therefore are not fulfilled.

(55) Given these results of the analysis of the submitted material, there is no basis to consult the other Member States, interested groups or request a new opinion of the SCTEE.

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

(56) Under Article 95(6), the Commission will either 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'.

(57) Since the request made by Belgium does not fulfill the basic conditions set out in Article 95(5) (see point 2.3), 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**

(58) In the light of the above considerations, the Commission is of the opinion that the request by Belgium for introducing national legislation derogating from the provisions of Directive 1999/51/EC with regards to organostannic compounds as submitted on 21 February 2000:

— is admissible,

— but does not fulfill the conditions established by Article 95(5).

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

HAS ADOPTED THIS DECISION:

Article 1

The draft national provisions concerning organostannic compounds, which the Kingdom of Belgium notified to the Commission by letter dated 21 February 2000, and which intend to derogate from Directive 1999/51/EC as of 1 January 2003, are hereby rejected.

Article 2

This Decision is addressed to the Kingdom of Belgium.

Done at Brussels, 25 July 2000.

For the Commission

Erkki LIIKANEN

Member of the Commission