JUDGMENT OF THE COURT (First Chamber)

15 July 2004 *

In Case C-443/02,

REFERENCE to the Court under Article 234 EC by the Tribunale di Pordenone (Italy) for a preliminary ruling in the criminal proceedings before that court against

Nicolas Schreiber

on the interpretation of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ 1998 L 123, p. 1), and Article 28 EC,

THE COURT (First Chamber),

composed of: P. Jann (Rapporteur), President of the Chamber, A. Rosas, S. von Bahr, R. Silva de Lapuerta and K. Lenaerts, Judges,

Advocate General: D. Ruiz-Jarabo Colomer,
Registrar: L. Hewlett, Principal Administrator,

* Language of the case: Italian.

after considering the written observations submitted on behalf of:

— Mr Schreiber, by M. Casini and F. Capelli, avvocati,

— the Belgian Government, by A. Snoecx, acting as Agent,

— the Commission of the European Communities, by L. Ström, acting as Agent, and M. Moretto, avocat,

having regard to the Report for the Hearing,

after hearing the oral observations of Mr Schreiber and the Commission at the hearing on 8 January 2004,

after hearing the Opinion of the Advocate General at the sitting on 12 February 2004,

gives the following

Judgment

1 By order of 20 November 2002, received at the Court on 6 December 2002, the Tribunale di Pordenone (Pordenone District Court) referred to the Court for a preliminary ruling under Article 234 EC five questions on the interpretation of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ 1998 L 123, p. 1), and Article 28 EC.

2 Those questions were raised in criminal proceedings against Mr Schreiber following an infringement of national rules requiring authorisation for the placing on the market of blocks of red cedar wood having natural anti-moth properties.

Legal background

Community rules

Definitions

3 According to Article 2(1)(a) of Directive 98/8, 'biocidal products' means 'active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means'.

4 Pursuant to Article 2(1)(b) of Directive 98/8, 'low-risk biocidal product[s]' are defined as 'biocidal product[s] which [contain] as active substance(s) only one or more of those listed in Annex IA and which [do] not contain any substance(s) of concern'.

5 According to Article 2(1)(c) of Directive 98/8, 'basic substance' means 'a substance which is listed in Annex IB, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use'.

6 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ, English Special Edition 1967 (I), p. 234), as amended by Council Directive 92/32/EEC of 30 April 1992 (OJ 1992 L 154, p. 1), to which Directive 98/8 refers, defines 'substances' as 'chemical elements and their compounds in the natural state or obtained by any production process ...'.

Substantive rules

7 According to the first, third and eighth recitals in the preamble, Directive 98/8 is intended to introduce a Community system for the placing on the market of non-agricultural pesticides (biocides) so as to take account of the public health concerns underpinning the different restrictions imposed by the Member States in that regard.

8 To that end, Articles 3(1) and (2) of the directive provide:

'1. Member States shall prescribe that a biocidal product shall not be placed on the market and used in their territory unless it has been authorised in accordance with this directive.

2. By way of derogation from paragraph 1:

(i) Member States shall, subject to registration, allow the placing on the market and use of a low-risk biocidal product, provided that a dossier in accordance with Article 8(3) has been submitted and verified by the competent authorities.

Unless otherwise specified, all provisions relating to authorisation under this directive shall also apply to registration.

(ii) Member States shall allow the placing on the market and use of [basic substances] for biocidal purposes once they have been entered in Annex IB.'

9 The first sentence of Article 4(1) of the directive provides, with regard to the 'mutual recognition of authorisations', that 'without prejudice to Article 12, a biocidal product that has already been authorised or registered in one Member State shall be authorised or registered in another Member State within 120 days, or 60 days respectively, of an application being received by the other Member State, provided

that the active substance of the biocidal product is included in Annex I or IA and conforms to the requirements thereof'.

10 Thus, Annex I must list the active substances agreed at Community level for inclusion in biocidal products, Annex IA must list those for inclusion in low-risk biocidal products and Annex IB the basic substances.

11 Article 16 of Directive 98/8 lays down a transitional period of 10 years. Inter alia, Annexes I, IA and IB are to be drawn up within that period.

National law

Definitions

12 The terms 'biocidal product', 'low-risk biocidal product' and 'basic substance' are defined in Article 2 of Legislative Decree No 174 of 25 February 2000 (ordinary supplement to GURI No 149 of 28 June 2000, 'the biocides decree').

Substantive rules

13 The biocides decree implemented Directive 98/8.

14 Articles 3 and 4 of the decree require authorisation for the placing on the market of biocidal products and the registration of low-risk biocidal products. Article 5 provides that products which contain only a basic substance may be placed on the market and used without authorisation or registration provided that they are included in the corresponding list drawn up at Community level.

15 Article 17(1) of the biocides decree provides that, during the transitional period laid down by Article 16 of Directive 98/8, the Ministero della Sanità (Minister for Health) is empowered to apply the rules in force concerning the placing on the market of biocidal products set out in Decree No 392 of the President of the Republic of 6 October 1998 on the production and placing on the market of medico-surgical instruments (GURI No 266 of 13 November 1998, 'the medico-surgical instruments decree').

16 Article 1 of the decree requires that there be prior authorisation for the placing on the market of insect repellents.

The main proceedings and the questions referred

17 The Italian authorities commenced criminal proceedings against Mr Schreiber in his capacity as managing director of LIDL-ITALIA Srl, alleging that, in March 2001, without having obtained the authorisation necessary under Italian law, that company had placed on the market 20 packages of blocks of red cedar wood having natural anti-moth properties originating in Germany, which are considered to be 'medico-surgical instruments' within the meaning of the medico-surgical instruments decree.

18 Mr Schreiber submits that those blocks are a product containing only a 'basic substance' within the meaning of Directive 98/8 and that, according to Article 3(2)(ii) of the directive, that product should be allowed to be placed on the market without authorisation or registration. In the alternative, he submits that the national rules infringe Article 28 EC.

19 In those circumstances the Tribunale di Pordenone decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'1. Must Article 2(1)(a) and (b) of Directive 98/8/EC be construed, in the light of the general rules which that directive introduces into the Community legal order, as meaning that the terms "biocidal products" and "low-risk biocidal product" refer solely to products whose biocidal function depends on active substances added to those products by chemical or biological means through processes expressly designed to add such substances in order to confer on those products a biocidal function?

2. Must Article 2(1)(c) of Directive 98/8/EC be construed, in the light of the general rules which that directive introduces into the Community legal order, as meaning that the term "basic substance" refers to substances which are not added to a product in order to enable it to perform an intended biocidal function but whose biocidal function is performed in addition to the function normally performed by that product during its use ...?

3. May a piece of red cedar wood be classed, simply by virtue of the fact that it is marketed as being "anti-moth", as a "biocidal product", as a "low-risk biocidal product" or as a "basic substance", bearing in mind that: (a) the wood in question has in no way been treated chemically or biologically; (b) the substance

on which the effects attributed to the wood may depend is naturally present in the product; (c) the product is substantially marketed as found in its natural state?

4. Must Article 2(1)(c) of Directive 98/8/EC be construed as meaning that it is only if a "basic substance" is included on the list referred to in Annex IB that that substance may be exempted from the authorisation and registration provided for for the marketing in the Member States of products covered by Article 2, with such inclusion on the list referred to in Annex IB thus acquiring constitutive effectiveness for all purposes?

5. Must Article 4 of Directive 98/8/EC be construed, by reference to Articles 28 EC and 30 EC, as meaning that a product such as that described in Question 3, placed lawfully on the market in a Member State without any need for authorisation or registration in that Member State, may be made subject to authorisation or registration in another Member State in which it is subsequently marketed by reason of the fact that the product in question is not included on the list referred to in Annex IB to Directive 98/8/EC?'

The questions referred

Preliminary observations

20 It should be noted that, at the time of the facts alleged in the main proceedings, the harmonisation provided for by Directive 98/8 had not been completed in that Annexes I, IA and IB to the directive, listing the active substances whose use is authorised in biocidal products, low-risk biocidal products and products containing only basic substances, were still being compiled at Community level. Indeed, the

evaluation of the active substances notified for possible inclusion in those annexes will only be completed between 2006 and 2010.

21 It is, however, clear from Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16 (2) of Directive 98/8, and amending Regulation (EC) No 1896/2000 (OJ 2003 L 307, p. 1), that the Commission has drawn up an interim list of active substances which will not be included in those annexes, either because no notification has been accepted by the Commission or because no Member State has expressed an interest in respect of those substances. It follows from Article 4(2) of that regulation, read together with Annex III thereto, that with effect from 1 September 2006 certain biocidal products containing active substances which are natural oils, such as cedarwood oil and cedar oil, will no longer be allowed to be placed on the market in the Member States.

22 In the light of the wording of the questions referred by the national court there is, however, no need for the Court to consider whether the complete prohibition on the marketing of biocidal products containing those natural oils is proportionate to the objectives pursued by the Community rules.

The first four questions: the obligation on the Member States to allow the placing on the market of products containing only 'basic substances'

23 By its first four questions, which it is convenient to examine together, the national court asks essentially whether Article 3(2)(ii) of Directive 98/8 precludes a Member State from requiring prior authorisation for the marketing of blocks of cedar wood

such as those in issue in the main proceedings ('the system of prior authorisation in issue in the main proceedings').

In that context, the referring court wishes to know whether such blocks may be classified as a product containing only a 'basic substance' so that, pursuant to Article 3(2)(ii) of the directive, they may be placed on the market in Italy without prior authorisation or registration, or whether they should be classified as a 'biocidal product' or a 'low-risk biocidal product' within the meaning of Directive 98/8.

24 It should be noted in this regard that Article 3(2)(ii) of the directive requires the Member States to allow the placing on the market without prior authorisation or registration of products containing only basic substances if they have been entered in Annex IB.

25 According to the definition in Article 2(1)(c) of Directive 98/8, in order to be classified as a 'basic substance', a substance must satisfy three conditions: (i) it must be entered in Annex IB; (ii) its major use must be non-pesticidal but it must have some minor use as a biocide, and (iii) it must not be directly marketed for a biocidal use.

26 By contrast, according to the definition in Article 2(1)(a), 'biocidal products' are active substances put up in the form in which they are supplied to the user and which are intended to destroy, deter or render harmless harmful organisms by chemical or biological means. An exhaustive list of the types of biocidal products is given in Annex V to Directive 98/8.

27 Lastly, Article 2(1)(b) defines a 'low-risk biocidal product' as a biocidal product which contains as active substances only one or more of the substances listed in Annex IA and which does not contain any substance of concern.

28 In the main proceedings, it is not in dispute that the blocks of cedar wood in issue were sold as an anti-moth product, that they contained cedar oil, an active substance which, upon evaporation, repels insects and, lastly, that they were included in one of the types of product listed in Annex V to Directive 98/8. By contrast, at the time of the facts alleged in the main proceedings, it could not be argued that the active substance contained in those blocks, namely cedar oil, was listed in Annexes IA or IB to that directive since those annexes had not been completed.

29 In those circumstances, those blocks cannot be classified as a product containing only a 'basic substance' or as a 'low-risk biocidal product' within the meaning of Directive 98/8. They should, by contrast, be regarded as a 'biocidal product' within the meaning of the directive.

30 It should be added in that context that it matters little whether the repellent effect of an active substance is natural or whether it is the result of chemical or biological manipulation. The mere fact that a substance is natural cannot preclude the existence of a risk for humans, animals or the environment. Furthermore, the effect of the reference in Article 2(2)(a) of the directive to the definitions in Article 2 of Directive 67/548 is that 'substances' are defined as chemical elements and their compounds in the natural state or obtained by any production process.

31 Moreover, it is now certain that blocks of cedar wood such as those in issue are neither a product containing only a 'basic substance' nor a 'low-risk biocidal product' within the meaning of Directive 98/8, as Annex III to Regulation No 2032/2003 makes it clear that cedar oil will not be listed in Annexes IA or IB to the directive. Notwithstanding its classification as an 'existing active substance' within the meaning of Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8 (OJ 2000 L 228, p. 6), the Commission has not accepted any notification and no Member State has indicated an interest in respect of cedar oil.

32 Consequently, the answer to the first four questions must be that Article 3(2)(ii) of Directive 98/8 does not preclude a Member State from requiring prior authorisation for the marketing of blocks of cedar wood such as those in issue in the main proceedings.

33 Such blocks cannot be classified as a product containing only a 'basic substance' such that they may be placed on the market in Italy without prior authorisation or registration, but must be classified as a 'biocidal product' within the meaning of Directive 98/8.

The first part of the fifth question: the obligation on Member States to recognise authorisation and registration granted by another Member State

34 By the first part of its fifth question, the referring court asks essentially whether Article 4(1) of Directive 98/8 precludes a Member State from requiring prior authorisation for the marketing of blocks of cedar wood such as those in issue in the

main proceedings, which have been lawfully placed on the market in another Member State in which there is no requirement of authorisation or registration.

35 It should be noted in that regard that that paragraph imposes an obligation on the Member States to recognise authorisation and registration granted by another Member State provided that the active substance is included in Annexes I or IA.

36 In the main proceedings, it is clear that the blocks of cedar wood in question have not been authorised to be placed on the market or registered in another Member State.

37 Moreover, at the time of the facts alleged in the main proceedings, it was not possible to foresee whether cedar oil would be included in Annexes I or IA to that directive.

38 Annex III to Regulation No 2032/2003 makes it clear in any event that cedar oil will not be included in Annexes I or IA to the directive.

39 Consequently, the answer to the first part of the fifth question must be that Article 4 (1) of Directive 98/8 does not preclude a Member State from requiring prior authorisation for the marketing of blocks of cedar wood such as those in issue in the main proceedings, which have been lawfully placed on the market in another Member State in which there is no requirement of authorisation or registration.

The second part of the fifth question: the right of free movement of goods

40 By the second part of the fifth question, the national court asks essentially whether Article 28 EC precludes a Member State from requiring prior authorisation for the marketing of blocks of cedar wood such as those in issue in the main proceedings, which have been lawfully placed on the market in another Member State in which there is no requirement of authorisation or registration.

41 According to settled case-law, all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are measures having an effect equivalent to quantitative restrictions within the meaning of Article 28 EC and are therefore in principle prohibited (Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5, and Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 66).

42 However, in the absence of Community harmonising measures, the free movement of a good may be restricted by national rules justified either on one of the grounds laid down by Article 30 EC or by mandatory requirements (Case 120/78 *Rewe-Zentral* ('*Cassis de Dijon*') [1979] ECR 649, paragraph 8).

43 In adopting national measures to protect public health within the meaning of Article 30 EC, it is for the Member States to decide what degree of protection they intend to assure thereto (see, to that effect, Case 272/80 *Frans-Nederlandse Maatschappij*

voor Belgische Producten [1981] ECR 3277, paragraph 12, Case C-293/94 *Brandsma* [1996] ECR I-3159, paragraph 11, and Case C-400/96 *Harpegnies* [1998] ECR I-5121, paragraph 33). However, those national rules must be proportionate to the objectives pursued (Case 174/82 *Sandoz* [1983] ECR 2445, paragraph 18, and *Harpegnies*, paragraph 34).

44 In the present case, it is necessary to examine in turn four points: (i) whether there is a restriction within the meaning of Article 28 EC; (ii) whether there are Community harmonising measures on the matter; (iii) whether the system of prior authorisation at issue in the main proceedings may be justified on the basis of Article 30 EC, and (iv) whether that system is proportionate.

45 First, it should be noted that a scheme prohibiting the placing on the market of biocidal products without prior authorisation constitutes a restriction on the free movement of goods within the meaning of Article 28 EC (see, to that effect, *Brandsma*, paragraph 6, and *Harpegnies*, paragraph 30).

46 Second, at the time of the facts alleged, the placing on the market of blocks of cedar wood such as those at issue in the main proceedings had not been fully harmonised at Community level in that Annexes I, IA and IB to Directive 98/8 had not been completed and no other system had been established for that product. However, at that time, Directive 98/8 had already harmonised the definition of 'biocidal product'.

47 Third, a system of prior authorisation such as that in issue in the main proceedings pursues an objective for the protection of public health within the meaning of

Article 30 EC. Since blocks of cedar wood such as those in issue in the main proceedings must be considered to be 'biocidal products' within the meaning of Directive 98/8 and, according to the third recital in the preamble to that directive, biocidal products can pose risks to humans, animals and the environment in a variety of ways due to their intrinsic properties and associated use patterns, a system requiring prior authorisation for their marketing satisfies the objective of protecting public health.

48 Fourth, the system of prior authorisation at issue in the main proceedings is proportionate to the legitimate objective pursued. Whilst it is true that blocks of cedar wood such as those at issue in the main proceedings may be placed on the market in Germany without prior authorisation or registration, the fact that one Member State imposes less strict rules than another Member State does not mean that the latter's rules are disproportionate (see, to that effect, Case C-384/93 *Alpine Investments* [1995] ECR I-1141, paragraph 51).

49 In those circumstances, a system requiring prior authorisation for the placing on the market of blocks of red cedar wood having natural anti-moth properties must be classed as a measure having equivalent effect contrary to Article 28 EC. However, since such a system corresponds to the level of protection of public health that the Member State concerned intends to assure, in that it concerns the placing on the market of all biocidal products and is not disproportionate to that objective, it may be regarded as justified under Article 30 EC.

50 Consequently, the answer to the second part of the fifth question must be that the fact that a Member State requires prior authorisation for the marketing of blocks of cedar wood such as those in issue in the main proceedings, which have been lawfully placed on the market in another Member State in which there is no requirement of authorisation or registration, constitutes a measure having equivalent effect contrary

to Article 28 EC, which may nevertheless be regarded as justified on grounds of the protection of public health under Article 30 EC.

Costs

51 The costs incurred by the Belgian Government and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main action, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (First Chamber),

in answer to the questions referred to it by the Tribunale di Pordenone by order of 20 November 2002, hereby rules:

1. **Article 3(2)(ii) of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market does not preclude a Member State from requiring prior authorisation for the marketing of blocks of red cedar wood having natural anti-moth properties.**

Such blocks cannot be classed as a product containing only a 'basic substance' such that they may be placed on the market in Italy without prior authorisation or registration, but must be classed as a 'biocidal product' within the meaning of Directive 98/8.

2. **Article 4(1) of Directive 98/8 does not preclude a Member State from requiring prior authorisation for the marketing of blocks of red cedar wood having natural anti-moth properties, which have been lawfully placed on the market in another Member State in which there is no requirement of authorisation or registration.**

3. **The fact that a Member State requires prior authorisation for the marketing of blocks of red cedar wood having natural anti-moth properties, which have been lawfully placed on the market in another Member State in which there is no requirement of authorisation or registration, constitutes a measure having equivalent effect contrary to Article 28 EC, which may nevertheless be regarded as justified on grounds of the protection of public health under Article 30 EC.**

Jann Rosas von Bahr

Silva de Lapuerta Lenaerts

Delivered in open court in Luxembourg on 15 July 2004.

R. Grass P. Jann

Registrar President of the First Chamber