JUDGMENT OF THE COURT (Grand Chamber)

14 December 2004 *

In Case C-210/03,

REFERENCE for a preliminary ruling under Article 234 EC from the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), made by decision of 17 April 2003, received at the Court on 15 May 2003, in the proceedings

The Queen, on the application of:

Swedish Match AB,

Swedish Match UK Ltd

V

Secretary of State for Health,

* Language of the case: English.

THE COURT (Grand Chamber),

composed of: V. Skouris, President, P. Jann, C.W.A. Timmermans and K. Lenaerts, Presidents of Chambers, C. Gulmann, J.-P. Puissochet, N. Colneric, S. von Bahr and J.N. Cunha Rodrigues (Rapporteur), Judges,

Advocate General: L.A. Geelhoed,

Registrar: H. von Holstein, Deputy Registrar, and subsequently M.-F. Contet, Principal Administrator,

having regard to the written procedure and further to the hearing on 8 June 2004,

after considering the observations submitted on behalf of:

— Swedish Match AB and Swedish Match UK Ltd, by G. Barling QC and M. Lester, Barrister, instructed by S. Kon, D. Roy and S. Turnbull, Solicitors,

— the United Kingdom Government, by C. Jackson, acting as Agent, and N. Paines QC and T. Ward, Barrister,

— the French Government, by G. de Bergues and R. Loosli-Surrans, acting as Agents,

— the Irish Government, by D.J. O'Hagan, acting as Agent,

— the Finnish Government, by T. Pynnä, acting as Agent,

— the Swedish Government, by A. Kruse, acting as Agent,

— the European Parliament, by J.L. Rufas Quintana and M. Moore, acting as Agents,

— the Council of the European Union, by E. Karlsson and J.-P. Hix, acting as Agents,

— the Commission of the European Communities, by I. Martínez del Peral and N. Yerrell, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 7 September 2004,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the validity of Article 8 of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ 2001 L 194, p. 26), the interpretation of Articles 28 EC to 30 EC, and the compatibility with those provisions and with the general principles of Community law of national legislation prohibiting the placing on the market of tobacco products for oral use.

2 The reference was made in the course of proceedings between Swedish Match AB and Swedish Match UK Ltd (hereinafter referred to together as 'Swedish Match') and the Secretary of State for Health concerning the prohibition of the marketing in the United Kingdom of tobacco products for oral use.

Legal background

Community legislation

3 Article 8a of Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the labelling of tobacco products (OJ 1989 L 359, p. 1), as amended by Council Directive 92/41/EEC of 15 May 1992 (OJ 1992 L 158, p. 30),

('Directive 89/622') provides that the Member States are to prohibit the placing on the market of tobacco for oral use, defined in Article 2(4) of that directive as 'all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or particulate form or in any combination of these forms — particularly those presented in sachet portions or porous sachets — or in a form resembling a food product'.

4 The 11th recital in the preamble to Directive 92/41 states that 'it has been proved that smokeless tobacco products are a major risk factor as regards cancer and ... they should therefore carry a specific warning of that risk'. According to the 12th recital in that preamble, 'scientific experts are of the opinion that the addiction caused by tobacco consumption constitutes a danger meriting a specific warning on every tobacco product'.

5 According to the 13th recital in the preamble to Directive 92/41:

'... new tobacco products for oral use which have appeared on the market in certain Member States are particularly attractive to young people and ... the Member States most exposed to this problem have already placed total bans on these new tobacco products or intend so to do'.

6 The 14th recital in that preamble states:

'... regarding such products, there are differences between the laws, regulations and administrative provisions of the Member States and ... these products therefore need to be made subject to common rules'.

7 According to the 15th recital in the preamble:

'... there is a real risk that the new products for oral use will be used above all by young people, thus leading to nicotine addiction, unless restrictive measures are taken in time'.

8 According to the 16th recital in the preamble:

'... in accordance with the conclusions of the studies conducted by the International Agency for Research on Cancer, tobacco for oral use contains particularly large quantities of carcinogenic substances; ... these new products cause cancer of the mouth in particular'.

9 According to the 17th recital in the preamble to that directive:

'... the sales bans on such tobacco already adopted by three Member States have a direct impact on the establishment and operation of the internal market; ... it is therefore necessary to approximate Member States' laws, regulations and administrative provisions in this area, taking as a base a high level of health protection; ... the only appropriate measure is a total ban; ... however, such a ban should not affect traditional tobacco products for oral use, which will remain subject to the provisions of Directive 89/622/EEC, as amended by this Directive, applicable to smokeless tobacco products'.

10 Article 151(1) of the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21, and OJ 1995 L 1, p. 1, 'the Act of Accession') provides:

'The Acts listed in Annex XV to this Act shall apply in respect of the new Member States under the conditions laid down in that Annex.'

11 Chapter X, 'Miscellaneous', of Annex XV establishing the list provided for in Article 151 of the Act of Accession, provides:

'(a) The prohibition in Article 8a of Directive 89/622/EEC, as amended ..., concerning the placing on the market of the product defined in Article 2(4) of [the] Directive ... shall not apply [in the Kingdom of Sweden ...], with the exception of the prohibition to place this product on the market in a form resembling a food product.

(b) [The Kingdom of Sweden] shall take all measures necessary to ensure that the product referred to in paragraph (a) is not placed on the market in the Member States for which Directives 89/622/EEC and 92/41/EEC are fully applicable.

...'

12 Directive 2001/37 was adopted on the basis of Articles 95 EC and 133 EC and recasts Directive 89/622 and Council Directive 90/239/EEC of 17 May 1990 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the maximum tar yield of cigarettes (OJ 1990 L 137, p. 36).

13 According to the 28th recital in the preamble to Directive 2001/37:

'Directive 89/622/EEC prohibited the sale in the Member States of certain types of tobacco for oral use. Article 151 of the Act of Accession ... grants the Kingdom of Sweden a derogation from the provisions of that Directive in this regard.'

14 Article 2 of Directive 2001/37, headed 'Definitions', provides:

'For the purposes of this Directive:

1. "tobacco products" means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not;

...

4. "tobacco for oral use" means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product;

...'

15 According to Article 5(4) of that directive:

'Tobacco products for oral use, where their marketing is permitted under Article 8, and smokeless tobacco products shall carry the following warning: "This tobacco product can damage your health and is addictive".

...'

16 Article 8 of the directive, 'Tobacco for oral use', provides:

'Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession ...'

17 Under Article 13(1) of the directive:

'Member States may not, for considerations relating to the limitation of the tar, nicotine or carbon monoxide yields of cigarettes, to health warnings and other indications or to other requirements of this Directive, prohibit or restrict the import, sale or consumption of tobacco products which comply with this Directive, with the exception of measures taken for the purposes of verifying the data provided under Article 4.'

18 Article 15 of the directive provides inter alia that Directive 89/622 is repealed and that references to it are to be construed as references to Directive 2001/37.

National legislation

19 In the United Kingdom, the prohibition provided for in Article 8a of Directive 89/622 was transposed into domestic law by the Tobacco for Oral Use (Safety) Regulations 1992 ('the 1992 Regulations').

The main proceedings and the questions referred for a preliminary ruling

20 Swedish Match wished to market in the United Kingdom 'snus', which is finely ground or cut tobacco sold loose or in small sachet portions and intended to be consumed by placing between the gum and the lip.

21 Swedish Match wrote to the United Kingdom Department of Health on 18 March 2002, setting out the reasons why it considered that the prohibition of the placing on the market of tobacco products for oral use laid down by the 1992 Regulations was unlawful. In its reply of 24 April 2002, that department stated that it considered the prohibition to be lawful. Swedish Match brought proceedings for judicial review on 8 May 2002, submitting that the prohibition infringed various provisions of Community law. The High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'1. Are Articles 28 EC to 30 EC, applied compatibly with the general principles of proportionality, non-discrimination and fundamental rights (in particular the right to property), to be interpreted as precluding national legislation which prohibits any person from supplying, offering or agreeing to supply, exposing for supply or possessing for supply any product made wholly or partly of tobacco which is either in powder or particulate form or any combination of those forms or is presented in a form resembling a food product and is intended for oral use other than smoking or chewing?

2. Is Article 8 of Directive 2001/37/EC invalid in whole or in part by reason of:

(a) infringement of the principle of non-discrimination;

(b) infringement of Article 28 EC and/or 29 EC;

(c) infringement of the principle of proportionality;

(d) the inadequacy of Article 95 EC and/or Article 133 EC as a legal basis;

(e) infringement of Article 95(3) EC;

(f) misuse of powers;

(g) infringement of Article 253 EC and/or the duty to give reasons;

(h) infringement of the fundamental right to property?

3. In circumstances where:

(a) a national measure implementing Article 8a of Directive 89/622/EEC was adopted in 1992;

(b) the said national measure was adopted pursuant to powers in domestic law which do not depend on the existence of an obligation to implement the directive;

(c) Directive 89/622/EEC (as subsequently amended by the Act of Accession ...) is repealed and replaced by Directive 2001/37/EC, Article 8 of which re-enacts Article 8a of Directive 89/622/EEC; and

(d) Article 8 of Directive 2001/37/EC is invalid by reason of the principles referred to in questions 2(a), 2(c) or 2(h),

are those principles to be interpreted as also prohibiting the national measure in question?'

The applications for leave to submit observations in reply to the Opinion of the Advocate General and, in the alternative, for reopening of the oral procedure

22 By act lodged at the Court Registry on 4 October 2004, Swedish Match requested the Court:

— to grant it leave to submit written observations following the Opinion of the Advocate General;

— in the alternative, to order the oral procedure to be reopened, pursuant to Article 61 of the Rules of Procedure.

23 Swedish Match wishes to comment on the Advocate General's suggestions relating to the possibility of maintaining the effects of Directive 2001/37 in the event that the Court declares it invalid.

24 On this point, it must be recalled that the Statute of the Court of Justice and its Rules of Procedure make no provision for the parties to submit observations in response to the Advocate General's Opinion (see the order in Case C-17/98 *Emesa Sugar* [2000] ECR I-665, paragraph 2). The application for leave to submit written observations in reply to the Advocate General's Opinion is therefore dismissed.

25 The Court may also, of its own motion, on a proposal from the Advocate General, or at the request of the parties, order the reopening of the oral procedure, in accordance with Article 61 of the Rules of Procedure, if it considers that it lacks sufficient information or that the case should be decided on the basis of an argument which has not been debated between the parties (see Case C-309/99 *Wouters and Others* [2002] ECR I-1577, paragraph 42, and Case C-470/00 P *Parliament* v *Ripa di Meana and Others* [2004] ECR I-4167, paragraph 33). In the present case, however, the Court, after hearing the Advocate General, considers that it has all the information necessary for it to answer the questions referred for a preliminary ruling. The application for the oral procedure to be reopened must therefore be dismissed.

The questions referred for a preliminary ruling

Question 2

26 By its second question, which should be examined first, the national court asks whether Article 8 of Directive 2001/37 is invalid in whole or in part by reason of infringement of the EC Treaty or of general principles of Community law, or by reason of misuse of powers.

The choice of Articles 95 EC and 133 EC as legal bases

27 The question is aimed at determining whether Article 95 EC constitutes an appropriate legal basis for Article 8 of Directive 2001/37, and if so whether recourse to Article 133 EC as a second legal basis for that provision is necessary or possible in this case.

28 Article 95(1) EC provides that the Council is to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

29 In this respect, it should be recalled that, while a mere finding of disparities between national rules is not sufficient to justify having recourse to Article 95 EC (see, to that effect, Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-8419, paragraph 84), it is otherwise where there are differences between the laws, regulations or administrative provisions of the Member States which are such as to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market (see, to that effect, *Germany* v *Parliament and Council*, paragraph 95, and Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 60).

30 It also follows from the Court's case-law that, while recourse to Article 95 EC as a legal basis is possible if the aim is to prevent future obstacles to trade resulting from the heterogeneous development of national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them (see, to that effect, Case C-350/92 *Spain* v *Council* [1995] ECR I-1985, paragraph 35,

Germany v *Parliament and Council*, paragraph 86, Case C-377/98 *Netherlands* v *Parliament and Council* [2001] ECR I-7079, paragraph 15, and *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 61).

31 The Court has also held that, where the conditions for recourse to Article 95 EC as a legal basis are fulfilled, the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 62).

32 It should also be noted that the first subparagraph of Article 152(1) EC provides that a high level of protection of human health is to be ensured in the definition and implementation of all Community policies and activities, and that Article 95(3) EC expressly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 62).

33 It follows from the foregoing that, where there are obstacles to trade or it is likely that such obstacles will emerge in future because the Member States have taken or are about to take divergent measures with respect to a product or a class of products such as to ensure different levels of protection and thereby prevent the product or products concerned from moving freely within the Community, Article 95 EC authorises the Community legislature to intervene by adopting appropriate measures, in compliance with Article 95(3) EC and with the legal principles mentioned in the Treaty or identified in the case-law, in particular the principle of proportionality.

34 Depending on the circumstances, those appropriate measures may consist in requiring all the Member States to authorise the marketing of the product or products concerned, subjecting such an obligation of authorisation to certain conditions, or even provisionally or definitively prohibiting the marketing of a product or products (see, in the context of Council Directive 92/59/EEC of 29 June 1992 on general product safety (OJ 1992 L 228, p. 24), Case C-359/92 *Germany* v *Council* [1994] ECR I-3681, paragraphs 4 and 33).

35 It is in the light of those principles that the Court must ascertain whether the conditions for recourse to Article 95 EC as legal basis were satisfied in the case of Article 8 of Directive 2001/37.

36 It must be pointed out, to begin with, that Article 8 does no more than reproduce the provisions of Article 8a of Directive 89/622 under which the Member States are to prohibit the placing on the market of tobacco for oral use. That tobacco is defined in Directive 2001/37, and in Directive 89/622, as 'all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product'.

37 It is common ground that for those products, as indicated in the 14th recital in the preamble to Directive 92/41, there were differences, at the time of adoption of that directive, between the laws, regulations and administrative provisions of the Member States. Two of them had already prohibited the marketing of such products and a third had adopted provisions which, while not yet in force, had the same object. Those provisions were intended, according to their authors, to stop the expansion of consumption of products harmful to health which were new to the markets of the Member States and were thought to be especially attractive to young people.

38 As the market in tobacco products is one in which trade between Member States represents a relatively large part (see *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 64), those prohibitions of marketing contributed to a heterogeneous development of that market and were therefore such as to constitute obstacles to the free movement of goods.

39 Having regard also to the public's growing awareness of the dangers to health of the consumption of tobacco products, it was likely that obstacles to the free movement of those products would arise by reason of the adoption by the Member States of new rules reflecting that development and intended more effectively to discourage consumption of those products (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 67).

40 Article 8 of Directive 2001/37 was adopted in a context which, from the point of view of obstacles to the free movement of goods existing in the market for tobacco products as a result of the heterogeneous development of conditions of marketing of tobacco products for oral use in the various Member States, was no different from that which existed when Article 8a of Directive 89/622 was adopted. It should be added that the Act of Accession cannot have any bearing on the assessment of that context. That Act not only excluded the Kingdom of Sweden from the scope of Article 8a, it also required that Member State to take all necessary measures to ensure that tobacco products for oral use were not placed on the market in the other Member States.

41 Action by the Community legislature on the basis of Article 95 EC was therefore justified with respect to tobacco products for oral use.

42 It follows from the foregoing that the prohibition in Article 8 of Directive 2001/37 could be adopted on the basis of Article 95 EC. It will have to be examined below whether the adoption of that measure complied with Article 95(3) EC and the legal principles referred to in the national court's questions.

43 As regards the question whether recourse to Article 133 EC as a second legal basis of Article 8 was necessary or possible in the present case, it suffices to recall that in paragraph 97 of *British American Tobacco (Investments) and Imperial Tobacco* the Court considered that Article 95 EC constituted the only appropriate legal basis for Directive 2001/37 and that it was incorrect for it to cite Article 133 EC as well.

44 However, that incorrect reference to Article 133 EC as a second legal basis for that directive does not of itself mean that the directive is invalid (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 98). Such an error in the citations of a Community act is no more than a purely formal defect, unless it gave rise to irregularity in the procedure applicable to the adoption of that act (see, to that effect, Case 165/87 *Commission* v *Council* [1988] ECR 5545, paragraph 19, and Joined Cases C-184/02 and C-223/02 *Spain and Finland* v *Parliament and Council* [2004] ECR I-7789, paragraph 44). The Court went on to hold, in paragraph 111 of *British American Tobacco (Investments) and Imperial Tobacco*, that recourse to the twofold legal basis of Articles 95 EC and 133 EC did not give rise to irregularity in the procedure for adopting the directive and that the directive was not invalid on that account.

45 Accordingly, Article 8 of Directive 2001/37 is not invalid on account of lack of an appropriate legal basis.

Article 95(3) EC and the principle of proportionality

46 Article 95(3) EC provides that both the Commission and also the Parliament and the Council are to take as a base a high level of protection of human health, taking account in particular of any new development based on scientific facts.

47 It should also be borne in mind that the principle of proportionality, which is one of the general principles of Community law, requires that measures implemented through Community provisions are appropriate for attaining the objective pursued and must not go beyond what is necessary to achieve it (see, inter alia, Case 137/85 *Maizena* [1987] ECR 4587, paragraph 15; Case C-339/92 *ADM Ölmühlen* [1993] ECR I-6473, paragraph 15; and Case C-210/00 *Käserei Champignon Hofmeister* [2002] ECR I-6453, paragraph 59).

48 With regard to judicial review of the conditions referred to in the previous paragraph, the Community legislature must be allowed a broad discretion in an area such as that concerned in the present case, which involves political, economic and social choices on its part, and in which it is called on to undertake complex assessments. Only if a measure adopted in this field is manifestly inappropriate in relation to the objective which the competent institutions are seeking to pursue can the lawfulness of such a measure be affected (see, to that effect, Case C-84/94 *United Kingdom* v *Council* [1996] ECR I-5755, paragraph 58; Case C-233/94 *Germany* v *Parliament and Council* [1997] ECR I-2405, paragraphs 55 and 56; Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 61; and *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 123).

49 With regard to Article 8a inserted in Directive 89/622 by Directive 92/41, it is apparent from the preamble to the latter directive that the prohibition of the marketing of tobacco products for oral use was the only measure that appeared appropriate to cope with the real danger that those new products would be used by young people, thus leading to nicotine addiction, with those products causing cancer of the mouth in particular.

50 Swedish Match essentially submits that, having regard to the state of the scientific information available to the Community legislature in 2001, when Article 8 of Directive 2001/37 was adopted, on which it moreover relied in amending the rules governing the warning referred to in Article 5(4) of that directive, maintenance of the prohibition of marketing tobacco products for oral use was disproportionate in relation to the objective pursued and did not take account of the development of that scientific information.

51 The answer to that argument must be that, while some experts could from 1999 call into question the assertion that, as the 16th recital in the preamble to Directive 92/41 puts it, 'these new products cause cancer of the mouth in particular', all controversy on that point was not eliminated at the time of adoption of Directive 2001/37. Moreover, while part of the scientific community accepted that tobacco products for oral use could be used as substitute products for cigarettes, another part challenged the correctness of such a position. From that situation it must be inferred that the scientific information which could have been available to the Community legislature in 2001 did not allow the conclusion that consumption of the products in question presented no danger to human health.

52 Moreover, like all other tobacco products, those for oral use contain nicotine, which causes addiction and whose toxicity is not disputed.

53 Now, first, it had not been shown at the time of adoption of Directive 2001/37 that the harmful effects of those products were lesser in that regard than those of other tobacco products. Second, it had been shown that they presented serious risks to health, which the Community legislature had to take into account.

54 In those circumstances, it cannot be maintained that, contrary to the provisions of Article 95(3) EC, the prohibition which follows from Article 8 of Directive 2001/37 was laid down without account being taken of the development of scientific information.

55 Moreover, nothing that has been submitted to the Court allows the view to be taken that tobacco products for oral use were not products new to the market of the Member States as it existed at the time of adoption of Directive 92/41.

56 To satisfy its obligation to take as a base a high level of protection in health matters, in accordance with Article 95(3) EC, the Community legislature was thus able, without exceeding the limits of its discretion in the matter, to consider that a prohibition of the marketing of tobacco products for oral use was necessary, and in particular that there was no alternative measure which allowed that objective to be achieved as effectively.

57 As the Advocate General observes in points 116 to 119 of his Opinion, no other measures aimed at imposing technical standards on manufacturers in order to reduce the harmful effects of the product, or at regulating the labelling of packagings of the product and its conditions of sale, in particular to minors, would have the same preventive effect in terms of the protection of health, inasmuch as they would let a product which is in any event harmful gain a place in the market.

58 It follows from the above considerations that, with respect both to the objective of ensuring a high level of protection of human health given to the Community legislature by Article 95(3) EC and to its obligation to comply with the principle of proportionality, the contested prohibition cannot be regarded as manifestly inappropriate.

Article 28 EC and/or Article 29 EC

59 It is settled case-law that the prohibition of quantitative restrictions and measures having equivalent effect laid down by Articles 28 EC and 29 EC applies not only to national measures but also to measures adopted by the Community institutions (see in particular, to that effect, Case 15/83 *Denkavit Nederland* [1984] ECR 2171, paragraph 15; Case C-51/93 *Meyhui* [1994] ECR I-3879, paragraph 11; and Case C-114/96 *Kieffer and Thill* [1997] ECR I-3629, paragraph 27).

60 Nevertheless, as Article 30 EC provides, the provisions of Articles 28 EC and 29 EC do not preclude prohibitions or restrictions on imports, exports or goods in transit justified inter alia on grounds of protection of the health and life of humans.

61 While the prohibition of marketing tobacco products for oral use under Article 8 of Directive 2001/37 constitutes one of the restrictions referred to in Articles 28 EC and 29 EC, it is nevertheless justified, as indicated in paragraph 58 above, on grounds of the protection of human health. It cannot therefore, in any event, be regarded as having been adopted in breach of the provisions of Articles 28 EC and 29 EC.

62 Moreover, the prohibition imposed on the Kingdom of Sweden on placing tobacco products for oral use on the markets of the other Member States derives from the provisions of point (b) of Chapter X of Annex XV to the Act of Accession, not those of Directive 2001/37.

Article 253 EC

63 It must be borne in mind that, while the statement of reasons required by Article 253 EC must show clearly and unequivocally the reasoning of the Community authority which adopted the contested measure, so as to enable the persons concerned to ascertain the reasons for it and to enable the Court to exercise judicial review, it is not required to go into every relevant point of fact and law (see, inter alia, Case C-122/94 *Commission* v *Council* [1996] ECR I-881, paragraph 29).

64 Furthermore, the question whether a statement of reasons satisfies the requirements must be assessed with reference not only to the wording of the measure but also to its context and to the whole body of legal rules governing the matter in question. If the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for each of the technical choices made by the institution (see, in particular, Case C-100/99 *Italy* v *Council and Commission* [2001] ECR I-5217, paragraph 64, and, to that effect, *Spain and Finland* v *Parliament and Council*, paragraph 79).

65 The recitals in the preamble to Directive 92/41 set out clearly the reasons why a measure prohibiting the marketing of tobacco products for oral use was to be introduced in Directive 89/622. In particular, after recalling that scientific experts were of the opinion that all tobacco products entail dangers to health and that it had been proved that smokeless tobacco products were a major risk factor as regards cancer, the preamble further stated that new tobacco products for oral use appearing on the market in certain Member States were particularly attractive to young people,

with the risk of their developing an addiction to nicotine if restrictive measures were not taken in time. It was also observed that the Member States most exposed to that problem had already placed total bans on those new products or intended to do so.

66 It should also be stated that the prohibition of marketing tobacco products for oral use laid down in Article 8 of Directive 2001/37 is confined, in the context of the recasting of earlier provisions which constitutes one of the objects of that directive, to confirming the identical measure adopted in 1992. The different treatment reserved in 1992 for those products as opposed to other smokeless tobacco products was the result of circumstances relating to the novelty on the internal market at the time of the products affected by the prohibition, their attraction for young people, and the existence of national prohibitive measures in certain Member States.

67 Those circumstances remained the same in 2001. Admittedly, it is common ground that the marketing of tobacco products for oral use has a long tradition in Sweden and that those products could not be regarded as new to the market corresponding to the territory of that Member State on its accession in 1995. However, since Article 151 of the Act of Accession precisely excluded the Kingdom of Sweden from the scope of the prohibition adopted in 1992, the territory of that State cannot be taken into account for the determination of the market referred to in Article 8 of Directive 2001/37 or, consequently, for the assessment with respect to that market of the novelty of the products whose marketing is prohibited there in accordance with that article.

68 Since Directive 2001/37 specifies, in the 28th recital in its preamble, that Directive 89/622 prohibited the sale in the Member States of certain types of tobacco for oral use and that Article 151 of the Act of Accession granted the Kingdom of Sweden a

derogation from the provisions of the latter directive, it does not appear that the confirmation of that prohibition in Article 8 of Directive 2001/37 required that directive to specify other relevant points of fact and law in order to satisfy the obligation to state reasons under Article 253 EC.

69 Accordingly, Article 8 of Directive 2001/37 complies with the obligation to state reasons set out in Article 253 EC.

The principle of non-discrimination

70 It is settled case-law that the principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (see, to that effect, Case C-304/01 *Spain* v *Commission* [2004] ECR I-7655, paragraph 31).

71 Although tobacco products for oral use, as defined in Article 2 of Directive 2001/37, are not fundamentally different in their composition or indeed their intended use from tobacco products intended to be chewed, they were not in the same situation as those products. The tobacco products for oral use which are the subject of the prohibition laid down in Article 8a of Directive 89/622 and repeated in Article 8 of Directive 2001/37 were new to the markets of the Member States referred to in that measure. That particular situation thus authorised a difference in treatment, and it cannot validly be argued that there was a breach of the principle of non-discrimination.

The principle of freedom to pursue a trade or profession and the right to property

72 According to the case-law of the Court, the freedom to pursue a trade or profession, like the right to property, is one of the general principles of Community law. Those principles are not absolute rights, however, but must be considered in relation to their social function. Consequently, restrictions may be imposed on the exercise of the freedom to pursue a trade or profession, as on the exercise of the right to property, provided that the restrictions in fact correspond to objectives of general interest and do not constitute, in relation to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed (see, inter alia, Case 265/87 *Schräder* [1989] ECR 2237, paragraph 15; Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 78; Case C-293/97 *Standley and Others* [1999] ECR I-2603, paragraph 54; Joined Cases C-37/02 and C-38/02 *Di Lenardo and Dilexport* [2004] ECR I-6911, paragraph 82, and *Spain and Finland* v *Parliament and Council*, paragraph 52).

73 The prohibition on the marketing of tobacco products for oral use laid down in Article 8 of Directive 2001/37 is indeed capable of restricting the freedom of manufacturers of such products to pursue their trade or profession, assuming that they have envisaged such marketing in the geographical region concerned by that prohibition. However, the operators' right to property is not called into question by the introduction of such a measure. No economic operator can claim a right to property in a market share, even if he held it at a time before the introduction of a measure affecting that market, since such a market share constitutes only a momentary economic position exposed to the risks of changing circumstances (Case C-280/93 *Germany* v *Council*, paragraph 79). Nor can an economic operator claim an acquired right or even a legitimate expectation that an existing situation which is capable of being altered by decisions taken by the Community institutions within the limits of their discretionary power will be maintained (see Case 52/81 *Faust* v *Commission* [1982] ECR 3745, paragraph 27).

74 As stated above, Directive 2001/37 pursues an objective in the general interest by ensuring a high level of protection of health in the context of the harmonisation of the provisions applicable to the placing on the market of tobacco products. It does not appear, as indicated in paragraph 58 above, that the prohibition laid down in Article 8 of that directive is inappropriate to that objective. In those circumstances, the obstacle to the freedom to pursue an economic activity constituted by a measure of such a kind cannot be regarded, in relation to the aim pursued, as a disproportionate interference with the exercise of that freedom or with the right to property.

Alleged misuse of powers

75 As the Court has repeatedly held, a measure is vitiated by misuse of powers only if it appears on the basis of objective, relevant and consistent evidence to have been taken with the exclusive or main purpose of achieving an end other than that stated or evading a procedure specifically prescribed by the Treaty for dealing with the circumstances of the case (see Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 24, and Case C-110/97 *Netherlands* v *Council* [2001] ECR I-8763, paragraph 137).

76 With regard in particular to the express exclusion of any harmonisation of the laws and regulations of the Member States designed to protect and improve human health laid down in the first indent of Article 129(4) of the EC Treaty (now, after amendment, the first subparagraph of Article 152(4) EC), the Court has held that other articles of the Treaty may not be used as a legal basis in order to circumvent that exclusion (Case C-376/98 *Germany* v *Parliament and Council*, paragraph 79). The Court has, however, stated that, provided that the conditions for recourse to Article 95(1) EC as a legal basis are fulfilled, the Community legislature cannot be prevented from relying on that legal basis on the ground that the protection of public health is a decisive factor in the choices to be made (Case C-376/98 *Germany* v *Parliament and Council*, paragraph 88, and *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 190).

77 First, the conditions for recourse to Article 95 EC were fulfilled in the case of Article 8 of Directive 2001/37 and, second, it has not been shown that that provision was adopted with the exclusive or main purpose of achieving an objective other than that of eliminating the barriers to trade connected with the heterogeneous development of national laws on tobacco products for oral use.

78 Accordingly, Article 8 of Directive 2001/37 is not invalid by reason of misuse of powers.

The answer to Question 2 taken as a whole

79 The answer to Question 2, taken as a whole, must be that consideration of that question has not disclosed any factor of such a kind as to affect the validity of Article 8 of Directive 2001/37.

Question 1

80 By its first question, the national court essentially asks whether Articles 28 EC and 29 EC must be interpreted as precluding national legislation such as that at issue in the main proceedings.

81 It should be borne in mind that, in a field which has been exhaustively harmonised at Community level, a national measure must be assessed in the light of the provisions of that harmonising measure and not of those of primary law (see Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, paragraph 9, and Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, paragraph 32).

82 Since the marketing of tobacco products for oral use is a question that is regulated in a harmonised manner at Community level, the national legislation at issue in the main proceedings which, duly transposing the Community legislation, prohibits the marketing of those products may thus be assessed with regard only to the provisions of that Community legislation, not to those of Articles 28 EC and 29 EC.

83 In the light of the above considerations, the answer to Question 1 must be that, where a national measure prohibits the marketing of tobacco products for oral use in accordance with the provisions of Article 8 of Directive 2001/37, there is no need to ascertain separately whether that national measure complies with Articles 28 EC and 29 EC.

Question 3

84 By its third question, the national court essentially asks whether, in the event that Article 8 of Directive 2001/37 is invalid, the principles of non-discrimination, proportionality and the protection of the right to property should be interpreted as precluding a national measure prohibiting tobacco products for oral use.

85 There is no need to answer this question, since, as stated in paragraph 79 above, consideration of Question 2 has not disclosed any factor of such a kind as to affect the validity of Article 8 of Directive 2001/37.

Costs

86 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) rules as follows:

1. **Consideration of the second question has not disclosed any factor of such a kind as to affect the validity of Article 8 of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.**

2. **Where a national measure prohibits the marketing of tobacco products for oral use in accordance with the provisions of Article 8 of Directive 2001/37, there is no need to ascertain separately whether that national measure complies with Articles 28 EC and 29 EC.**

Signatures.