Case C-491/01

The Queen
v
Secretary of State for Health,
ex parte British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd

(Reference for a preliminary ruling from the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court))

«(Directive 2001/37/EC – Manufacture, presentation and sale of tobacco products – Validity – Legal basis – Articles 95 EC and 133 EC – Interpretation – Applicability to tobacco products packaged in the Community and intended for export to non-member countries)»

Summary of the Judgment

1..

Approximation of laws – Directive 2001/37 concerning the manufacture, presentation and sale of tobacco products – Legal basis – Article 95 EC – Improvement of the conditions for the functioning of the internal market – Protection of public health a decisive factor in the choices involved in the harmonising measures – Not relevant
(Art. 95 EC; Directive 2001/37 of the European Parliament and of the Council)

2..

Approximation of laws – Directive 2001/37 concerning the manufacture, presentation and sale of tobacco products – Legal basis – Article 95 EC – Improvement of the conditions for the functioning of the internal market – Prohibition of manufacture intended to prevent the circumvention of the marketing rules in the internal market – Included
(Art. 95 EC; Directive 2001/37 of the European Parliament and of the Council, Art. 3(1))

3..

Acts of the institutions – Directive 2001/37 concerning the manufacture, presentation and sale of tobacco products – Choice of legal basis – Criteria – Community measure pursuing a twofold basis or having a twofold component – Reference to the main or predominant purpose or component – Incorrect reference to Article 133 EC as a second legal basis – Not relevant to the validity of the directive
(Arts 95 EC and 133 EC; Directive 2001/37 of the European Parliament and of the Council)

4..

Approximation of laws – Directive 2001/37 concerning the manufacture, presentation and sale of tobacco products – Harmonising measures – No breach of the principle of proportionality
(Directive 2001/37 of the European Parliament and of the Council, Arts 3, 5 and 7)

5..

Approximation of laws – Directive 2001/37 concerning the manufacture, presentation and sale of tobacco products – Respect of the right to property – Trade mark – Proportionate restrictions not impairing the very substance of that right
(Directive 2001/37 of the European Parliament and of the Council, Arts 5 and 7)

6..

Community law – Principles – Principle of subsidiarity – Application to acts adopted for the purpose of establishing the

internal market – Review of observance of the principle of subsidiarity – Criteria
(Art. 95 EC)

7..

Approximation of laws – Directive 2001/37 concerning the manufacture, presentation and sale of tobacco products – Article 7 – Prohibition of the use of descriptors likely to mislead consumers – Applicable only to tobacco products marketed within the Community
(Art. 95 EC; Directive 2001/37 of the European Parliament and of the Council, Arts 3, 5 and 7)

1.

Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products genuinely has as its object the improvement of the conditions for the functioning of the internal market and it was, therefore, possible for it to be adopted on the basis of Article 95 EC, and it is no bar that the protection of public health was a decisive factor in the choices involved in the harmonising measures which it defines. The market for tobacco products, especially cigarettes, in the Community is one in which trade between Member States represents a relatively large part. Moreover, national rules laying down the requirements to be met by products, in particular those relating to their designation, composition or packaging, are in themselves liable, in the absence of harmonisation at Community level, to constitute obstacles to the free movement of goods. The Community harmonisation measures already adopted in this sphere, namely, Directive 89/622 concerning the labelling of tobacco products and Directive 90/239 concerning the maximum tar yield of cigarettes, containing only limited requirements concerning the manufacture and labelling of tobacco products, the Member States were free to adopt national rules in respect of those aspects not covered by those directives. Having regard to the fact that the public is increasingly conscious of the dangers to health posed by consuming tobacco products, it is likely that obstacles to the free movement of those products would arise by reason of the adoption by the Member States of such national rules reflecting that development and intended more effectively to discourage consumption of those products by means of warnings and information appearing on their packaging or to reduce the harmful effects of tobacco products by introducing new rules governing their composition. Certain of the Member States had, moreover, already adopted provisions to that effect. In that context, a new harmonising directive makes it possible to prevent the appearance of impediments to the free movement of tobacco products within the Community, which would be caused by the adoption of national rules fixing differing requirements concerning the manufacture, presentation and sale of tobacco products. see paras 64-75

2.

Article 3(1) of Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products lays down a prohibition on manufacturing, within the Community, cigarettes that do not comply with the maximum tar, nicotine and carbon monoxide levels fixed by that article. Although the prohibition of manufacture at issue is not a provision aimed directly at improving the conditions for the functioning of the internal market, the fact remains that a measure adopted on the basis of Article 95 EC may incorporate such a provision so long as its purpose is to ensure that certain prohibitions concerning the internal market and imposed in pursuit of that object are not circumvented, such as the prohibitions of placing cigarettes which do not comply with the requirements of Article 3(1) in free circulation or of marketing them in the Member States. see paras 82, 90

3.

In the context of the organisation of the powers of the Community the choice of a legal basis for a measure must rest on objective factors which are amenable to judicial review. Those factors include in particular the aim and the content of the measure. If examination of a Community act shows that it has a twofold purpose or twofold component and if one of these is identifiable as main or predominant, whereas the other is merely incidental, the act must be founded on a sole legal basis, that is, the one required by the main or predominant purpose or component. The objective linked to the implementation of the common commercial policy under Article 133 EC is, in relation to the aim and content of Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products as a whole, merely secondary to the principal objective pursued by the directive, which is the improvement of the conditions for the functioning of the internal market. Article 95 EC therefore constitutes the only appropriate legal basis for the Directive and it is incorrect for the Directive to cite Article 133 EC also as a legal basis. However, that incorrect reference to Article 133 EC as a second legal basis for the Directive does not of itself mean that the latter is invalid. Such an error in the legal basis relied on for a Community measure 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 paras 93-98

4.

Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, the objective of which is to eliminate the barriers raised by differences which still exist between those provisions and impede the functioning of the internal markets, is not invalid by reason of infringement of the principle of proportionality. The prohibition laid down in Article 3 of the Directive on

releasing for free circulation or marketing within the Community cigarettes that do not comply with the maximum levels of tar, nicotine and carbon monoxide, together with the obligation imposed on the Member States to authorise the import, sale and consumption of cigarettes which do comply with those levels, in accordance with Article 13(1) of the Directive, is a measure appropriate for the purpose of attaining the objective pursued by the Directive and one which, having regard to the duty of the Community legislature to ensure a high level of health protection, does not go beyond what is necessary to attain that objective. The prohibition, also laid down in Article 3 of the Directive, on manufacturing cigarettes which do not comply with the maximum levels fixed by the Directive is especially appropriate for preventing at source deflections in trade affecting cigarettes manufactured in the Community for export to non-member countries. Such deflections amount to a form of fraud which it is not possible to combat as efficiently by means of an alternative measure such as reinforcing controls on the Community's frontiers. In addition, the requirements laid down in Article 5 of the Directive to show information on cigarette packets as to the levels of harmful substances and warnings concerning the risks to health are appropriate measures for attaining a high level of health protection when the barriers raised by national laws on labelling are removed, in relation to which the Community legislature has not overstepped the bounds of the discretion which it enjoys in this area. The ban, laid down in Article 7 of the Directive, on the use on tobacco product packaging of certain texts, such as low-tar, light, ultra-light, mild, and certain names, pictures and figurative or other signs likely to mislead consumers, is appropriate for attaining a high level of health protection. That provision has the purpose of ensuring that consumers are given objective information concerning the toxicity of tobacco products. It is also necessary, having regard in particular to the fact that it is not clear that merely regulating the use of those descriptors would have ensured that consumers received objective information, having regard to the fact that those descriptors are in any event likely, by their very nature, to encourage smoking. see paras 124-141

5.

The right to property forms part of the general principles of Community law. Its exercise may be restricted, provided that those restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed. Article 5 of Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products requires cigarette packets to carry indications of the levels of harmful substances and warnings concerning the risks to health. The only effect produced by Article 5 is to restrict the right of manufacturers of tobacco products to use the space on some sides of cigarette packets or using packets of tobacco products to show their trade marks, without prejudicing the substance of their trade mark rights, the purpose being to ensure a high level of health protection when the obstacles created by national laws on labelling are eliminated. In the light of this analysis, this article constitutes a proportionate restriction on the use of the right to property compatible with the protection afforded that right by Community law. Article 7 of the Directive is intended to ensure, in a manner in keeping with the principle of proportionality, a high level of health protection on the harmonisation of the provisions applicable to the description of tobacco products. While that article entails prohibition, in relation only to the packaging of tobacco products, on using a trade mark incorporating one of the descriptors referred to in that provision, the fact remains that a manufacturer of tobacco products may continue, notwithstanding the removal of that description from the packaging, to distinguish its product by using other distinctive signs. The restrictions on the trade mark right which may be caused by Article 7 do in fact correspond to an objective of general interest pursued by the Community and do not constitute a disproportionate and intolerable interference, impairing the very substance of that right. see paras 149-153

6.

The principle of subsidiarity applies where the Community legislature makes use of Article 95 EC, inasmuch as that provision does not give it exclusive competence to regulate economic activity on the internal market. In this respect, there are two levels to the review of observance of the principle of subsidiarity. It must first be considered whether the objective of the proposed action can be better achieved at Community level, and second, whether the intensity of the action undertaken does not go beyond what is necessary to achieve the objective pursued. see paras 179-184

7.

Article 7 of Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, which prohibits the use on the packaging of tobacco products of descriptors liable to mislead consumers as to their toxicity, is to be construed as applying only to tobacco products marketed within the European Community. The chief objective of the Directive being to improve the conditions for the functioning of the internal market in the tobacco products sector while ensuring a high level of health protection, the Directive in principle concerns only tobacco products which are to be placed on the internal market. Admittedly, with regard to Article 3 of the Directive, fixing maximum levels of harmful substances in cigarettes, the risk of adverse effects for the internal market may justify the adoption, on the basis of Article 95 EC, of a provision relating to goods exported to non-member countries, as a measure intended to prevent the circumvention of the internal market provisions. Nevertheless, in that case the Community legislature expressly provided for Article 3 to apply to tobacco products for export to non-member countries, having regard to its evaluation of the risks that the Directive's provisions on maximum yields of harmful substances in cigarettes might be circumvented, by reason of illicit reimports into the Community or

deflections of trade within it. By contrast, Article 7, like Article 5, concerns the presentation of tobacco products and not their composition. The risks of adverse consequences for the internal market posed by the illicit marketing of, on the one hand, cigarettes that do not comply with the Directive's requirements concerning maximum yields of harmful substances or, on the other, of tobacco products that do not comply with its requirements concerning labelling and the information appearing on packaging, are not necessarily of the same severity or of the same kind and do not necessarily entail the adoption of the same measures. Accordingly, in the absence of any indication to that effect in Directive 2001/37, there is no reason to suppose that the Community legislature intended to supplement the prohibition on marketing tobacco products that do not comply with the requirements of Article 7 of the Directive within the Community with a similar prohibition concerning tobacco products packaged in the Community and intended to be marketed in non-member countries. see paras 211-217, operative part 2

JUDGMENT OF THE COURT
10 December 2002 (1)

((Directive 2001/37/EC – Manufacture, presentation and sale of tobacco products – Validity – Legal basis – Articles 95 EC and 133 EC – Interpretation – Applicability to tobacco products manufactured in the Community and intended for export to non-member countries))

In Case C-491/01,

REFERENCE to the Court under Article 234 EC by the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), for a preliminary ruling in the proceedings pending before that court between

The Queen

and

Secretary of State for Health, ex parte: British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd, supported by Japan Tobacco Inc. and JT International SA,

on the validity and interpretation 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 COURT,,

composed of: G.C. Rodríguez Iglesias, President, J.-P. Puissochet, M. Wathelet, R. Schintgen and C.W.A. Timmermans (Presidents of Chambers), D.A.O. Edward, A. La Pergola (Rapporteur), P. Jann, V. Skouris, F. Macken, N. Colneric, S. von Bahr and J.N. Cunha Rodrigues, Judges,

Advocate General: L.A. Geelhoed,
Registrar: L. Hewlett, Principal Administrator, and M.-F. Contet, Administrator,

after considering the written observations submitted on behalf of:

– British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd, by D. Wyatt QC and D. Anderson QC, and by J. Stratford, Barrister, instructed by Lovells, Solicitors,

– Japan Tobacco Inc. and JT International SA, par O.W. Brouwer, advocaat, and N.P. Lomas, Solicitor, both of Freshfields Bruckhaus Deringer, Solicitors,

– the United Kingdom Government, by P. Ormond, acting as Agent, and by N. Paine QC, and T. Ward, Barrister,

– the Belgian Government, by A. Snoecx, acting as Agent, assisted by E. Gillet and G. Vandersanden, avocats,

– the German Government, by W.-D. Plessing, acting as Agent, assisted by J. Sedemund, Rechtsanwalt,

– the Greek Government, by V. Kontolaimos and S. Charitakis, acting as Agents,

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

– the Italian Government, by U. Leanza, acting as Agent, and O. Fiumara, avvocato dello Stato,

– the Luxembourg Government, by J. Faltz, acting as Agent, assisted by P. Kinsch, avocat,

– the Netherlands Government, by H.G. Sevenster, acting as Agent,

– the Finnish Government, by E. Bygglin, acting as Agent,

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

– the European Parliament, by C. Pennera 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. Martinez del Peral and K. Fitch, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd, represented by D. Wyatt and D. Anderson, and by J. Stratford; of Japan Tobacco Inc. and JT International SA, represented by O.W. Brouwer and N.P. Lomas; of the United Kingdom Government, represented by J.E. Collins, acting as Agent, and N. Paine and T. Ward; of the Belgian Government, represented by G. Vandersanden; of the German Government, represented by M. Lumma, acting as Agent, assisted by J. Sedemund; of the Greek Government, represented by V. Kontolaimos and S. Charitakis; of the French Government, represented by R. Loosli-Surrans; of the Irish Government, represented by J. Buttimore BL; of the Italian Government, represented by O. Fiumara; of the Luxembourg Government, represented by N. Mackel, acting as Agent, assisted by P. Kinsch; of the Netherlands Government, represented by J. van Bakel, acting as Agent; of the Finnish Government, represented by E. Bygglin; of the Parliament, represented by C. Pennera and M. Moore; of the Council, represented by E. Karlsson and J.-P. Hix, and of the Commission, represented by I. Martinez del Peral and K. Fitch, at the hearing on 2 July 2002,

after hearing the Opinion of the Advocate General at the sitting on 10 September 2002,

gives the following

Judgment

1

By order of 6 December 2001, received at the Court on 10 December 2001, the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) referred to the Court for a preliminary ruling under Article 234 EC two questions on the validity and interpretation 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 Directive).

2

Those questions were raised in connection with the proceedings brought on 3 September 2001 by British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd, seeking permission to apply for judicial review of the intention and/or obligation of the United Kingdom Government to transpose the Directive into national law.

The relevant provisions

Directive 89/622/EEC

3

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 and the prohibition of the marketing of certain types of tobacco for oral use (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), adopted on the basis of Article 100a of the EC Treaty (now, after amendment, Article 95 EC), established *inter alia*

a general warning to be carried on the unit packaging of all tobacco products, together with additional warnings exclusively for cigarettes and, from 1992, extended the requirement for additional warnings to other tobacco products.

Directive 90/239/EEC

4

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), adopted on the basis of Article 100a of the Treaty, set the maximum limits for the tar yield of cigarettes marketed in the Member States at 15 milligrams per cigarette with effect from 31 December 1992 and at 12 milligrams per cigarette from 31 December 1997.

The Directive

5

The Directive was adopted on the basis of Articles 95 EC and 133 EC and is aimed at recasting Directives 89/622 and 90/239 by amending and adding to their provisions.

6

According to the second and third recitals in the preamble to the Directive, there are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation, and sale of tobacco products which impede the functioning of the internal market, and those barriers ought to be eliminated by approximating the rules applicable in that area.

7

In the words of the fourth recital in the preamble to the Directive: In accordance with Article 95(3) of the Treaty, a high level of protection in terms of health, safety, environmental protection and consumer protection should be taken as a basis, regard being had, in particular, to any new developments based on scientific facts; in view of the particularly harmful effects of tobacco, health protection should be given priority in this context.

8

The fifth recital in the preamble to the Directive provides that: Directive 90/239/EEC established maximum limits for the tar yield of cigarettes marketed in the Member States with effect from 31 December 1992. The carcinogenic nature of tar makes it necessary to reduce further the levels of tar in cigarettes.

9

The seventh recital in the preamble to the Directive is worded as follows: Several Member States have indicated that, if measures establishing maximum carbon monoxide yields for cigarettes are not adopted at Community level, they will adopt such measures at national level. Differences in rules concerning carbon monoxide are likely to constitute barriers to trade and to impede the smooth operation of the internal market. ... .

10

According to the ninth recital in the preamble to the Directive: There are differences between the laws, regulations and administrative provisions of the Member States on the limitation of the maximum nicotine yield of cigarettes. Such differences are liable to constitute barriers to trade and to impede the smooth operation of the internal market. ...

11

The 11th recital in the preamble to the Directive states: This Directive will also have consequences for tobacco products which are exported from the European Community. The export regime is part of the common commercial policy. Health requirements are, pursuant to Article 152(1) of the Treaty and the case law of the Court of Justice of the European Communities, to form a constituent part of the Community's other policies. Rules should be adopted in order to ensure that the internal market provisions are not undermined.

12

According to the 19th recital in the preamble to the Directive: The presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated. It is necessary to that end that the existing legislation be strengthened and clarified, while ensuring a high level of health protection.

13

According to the 27th recital in the preamble to the Directive: The use on tobacco product packaging of certain texts, such as low-tar, light, ultra-light, mild, names, pictures and figurative or other signs, may mislead the consumer into the belief that such products are less harmful and give rise to changes in consumption. Smoking behaviour and addiction, and not only the content of certain substances contained in the product before consumption, also determine the level of inhaled substances. This fact is not reflected in the use of such terms and so may undermine the labelling requirements set in this Directive. In order to ensure the proper functioning of the internal market, and given the development of proposed international rules, the prohibition of such use should be provided for at Community level, giving sufficient time for introduction of this rule.

14

Under Article 1 of the Directive, headed Aim: The aim of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning the maximum tar, nicotine and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products, taking as a basis a high level of health protection.

15

Article 3(1) and (2) of the Directive provides:

1.

From 1 January 2004, the yield of cigarettes released for free circulation, marketed or manufactured in the Member States shall not be greater than:

– 10 mg per cigarette for tar,

– 1 mg per cigarette for nicotine,

– 10 mg per cigarette for carbon monoxide.

2.

By way of derogation from the date referred to in paragraph 1, as regards cigarettes manufactured

within, but exported from, the European Community, Member States may apply the yield limits laid down in this Article as from 1 January 2005 but shall in any event do so by 1 January 2007 at the latest.

16

Under Article 4(1) of the Directive, the tar, nicotine and carbon monoxide yields of cigarettes are to be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide. Article 4(3) authorises Member States to require tobacco manufacturers or importers to carry out any other tests as may be laid down by the competent national authorities in order to assess the yield of other substances produced by their products, and in order to assess the effects of those other substances on health. In accordance with Article 4(4), the results of the tests are to be submitted to the relevant national authorities, which are to ensure that they are disseminated with a view to informing consumers and, pursuant to Article 4(5), to be communicated to the Commission, which is to take account of them when drawing up the report referred to in Article 11.

17

Article 5 of the Directive lays down labelling requirements, including in particular the requirement that the product packaging must show the tar, nicotine and carbon monoxide yields in such a way as to cover certain percentages of its surface, and that the packaging must carry warnings concerning the risks to health posed by tobacco products, except tobacco for oral use and other smokeless tobacco products. In particular, Article 5(6)(e) of the Directive provides that the text of the warnings and indications of yields must be printed in the official language or languages of the Member State where the product is placed on the market.

18

In accordance with Article 6 of the Directive, the Member States are to require manufacturers and importers of tobacco products to submit to them a list of all ingredients, and quantities thereof, used in the manufacture of those tobacco products by brand name and type. The Member States are to ensure the dissemination of that information by any appropriate means, with a view to informing consumers, and communicate it annually to the Commission.

19

Article 7 of the Directive, entitled Product descriptions, is worded as follows: With effect from 30 September 2003, and without prejudice to Article 5(1), texts, names, trade marks and figurative or other signs suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products.

20

In accordance with Article 12 of the Directive, the Commission is invited to submit, on the basis of the information provided under Article 6, at the latest by 31 December 2004, and with a view to the proper functioning of the internal market, a proposal providing for a common list of ingredients authorised for tobacco products, taking into account, *inter alia* , their addictiveness.

21

Article 13 of the Directive provides:

1.

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.

2.

This Directive shall not affect the right of Member States to keep or introduce, in accordance with the Treaty, more stringent rules concerning the manufacture, import, sale and consumption of tobacco products which they deem necessary in order to protect public health, in so far as such rules do not prejudice the rules laid down in this Directive.

3.

In particular, Member States may provide for the prohibition, pending the establishment of the common list of ingredients referred to in Article 12, of the use of ingredients which have the effect of increasing the addictive properties of tobacco products.

22

In accordance with the first subparagraph of Article 14(1) of the Directive, the Member States are to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive by 30 September 2002 at the latest and to inform the Commission thereof forthwith.

23

The first paragraph of Article 15 of the Directive repeals Directives 89/622 and 90/239.

The dispute in the main proceedings and the questions referred for a preliminary ruling

24

The claimants in the main proceedings are tobacco manufacturers established in the United Kingdom. They have brought proceedings before the court making the reference seeking permission to apply for judicial review of the intention and/or obligation of the United Kingdom Government to transpose the Directive into national law, raising seven pleas in law contesting the validity of that measure.

25

The High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) granted that permission and decided to stay proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

1.

Is Directive 2001/37/EC invalid, in whole or in part, by reason of:

(a)

the inadequacy of Articles 95 EC and/or 133 EC as a legal basis;

(b)

the use of Articles 95 EC and 133 EC as a dual legal basis;

(c)

infringement of the principle of proportionality;

(d)

infringement of Article 295 EC, the fundamental right to property and/or Article 20 of TRIPs;

(e)

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

(f)

infringement of the principle of subsidiarity;

(g)
misuse of powers?

2.
If it is valid, does Article 7 of Directive 2001/37/EC of the Parliament and Council apply only to tobacco products marketed within the European Community, or does it apply also to tobacco products packaged within the European Community for export to third countries?

26
By order of 26 February 2002 the High Court granted Japan Tobacco Inc. and JT International SA (together Japan Tobacco) permission to intervene in the main proceedings, in order to enable them to submit written observations to the Court concerning the validity of Article 7 of the Directive.

27
Japan Tobacco Inc. is the trade mark owner and JT International SA is the exclusive licensee of the Mild Seven trade mark for cigarettes. Japan Tobacco submits that Article 7 of the Directive, in so far as it is to be interpreted as applying to established trade marks, will preclude Japan Tobacco from having the benefit of or using, within the Community, the intellectual property in the Mild Seven trade mark, which, when that provision enters into force, will cause severe damage to the value of the brand worldwide.

Admissibility of the order for reference

Observations submitted to the Court

28
The French Government and the Commission maintain that the request for a preliminary ruling is inadmissible.

29
In their view, the request is inadmissible, first, because the decision to make the reference was adopted before 30 September 2002, the date on which the time-limit set for implementation of the Directive expired and, second, because when the order for reference was made national legislation transposing the Directive in the United Kingdom had not yet been adopted. According to the French Government and the Commission, in such a situation it would be contrary to the nature of directives and to the system of judicial review of the lawfulness of Community acts if questions concerning the validity and interpretation of a directive could properly be referred to the Court.

30
The French Government and the Commission observe in this connection that the Court has held that a directive can be relied on by individuals before national courts only after the expiry of the time-limit laid down for its transposition into national law and that its provisions cannot before that date create rights for individuals which the national courts must protect (Case C-316/93 *Vaneetveld* [1994] ECR I-763, paragraphs 16 and 19).

31
In addition, they argue that to permit an individual to challenge the validity of a directive before a national court before the expiry of the period prescribed for its implementation and when no measures have been adopted to transpose it into national law could constitute a means of circumventing Article 230 EC, which would be contrary to the system of legal remedies established by the Treaty.

Findings of the Court

32 Under Article 234 EC the Court has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the Community institutions, regardless of whether they are directly applicable (see, to that effect, Case 111/75 *Mazzalai* [1976] ECR 657, paragraph 7, and Case C-373/95 *Maso and Others* [1997] ECR I-4051, paragraph 28).

33 A directive therefore constitutes an act covered by Article 234 EC even though the period for its implementation has not yet expired, and a question concerning it may validly be referred to the Court provided that that reference also satisfies the conditions for admissibility laid down in the Court's case-law.

34 In that regard, it is to be remembered that when a question on the validity of a measure adopted by the Community institutions is raised before a national court, it is for that court to decide whether a decision on the matter is necessary to enable it to give judgment and consequently whether it should request the Court to rule on that question. Accordingly, where the national court's questions relate to the validity of a provision of Community law, the Court is obliged in principle to give a ruling (Case C-408/95 *Eurotunnel and Others* [1997] ECR I-6315, paragraph 19).

35 Nevertheless, the Court has held that it cannot give a preliminary ruling on a question submitted by a national court where, *inter alia* , it is quite obvious that the ruling sought by that court on the interpretation or validity of Community law bears no relation to the actual facts of the main action or its purpose or where the problem is hypothetical (see, in particular, Joined Cases C-430/99 and C-431/99 *Sea-Land Service and Nedlloyd Lijnen* [2002] ECR I-5235, paragraph 46).

36 With regard, first of all, to the actual facts of the dispute in the main proceedings, it is clear from the order for reference that, pursuant to the permission granted to them for that purpose by the High Court, the claimants in the main proceedings may make an application for judicial review of the legality of the intention and/or obligation of the United Kingdom Government to implement the Directive even though, when that application was made, the period prescribed for implementation of the Directive had not yet expired and that Government had adopted no national implementation measures. There is, moreover, some disagreement between the claimants and the Secretary of State for Health as to whether or not the abovementioned application is well founded.

37 With regard, next, to the relevance of the questions referred to the outcome of the dispute in the main proceedings, it is first to be observed that, should the Directive be held to be invalid, that would indeed influence the outcome. The claimants in the main proceedings maintain that implementation by the United Kingdom Government of a directive by means of regulations adopted on the basis of Article 2(2) of the European Communities Act 1972 is subject to the condition that the directive should be valid, with the result that its invalidity would prevent its being implemented by means of regulations under that legislation. Second, it must be stated that interpretation of the provisions of the Directive may also influence the outcome of the dispute in the main proceedings.

38 It is therefore not obvious that the assessment of the Directive's validity or its interpretation, requested by the national court, bear no relation to the actual facts of the main action or its purpose or raise a purely hypothetical question.

39

As for the argument that to accept the admissibility of the order for reference seeking a decision on validity in a situation such as that in the main proceedings could be tantamount to circumventing the requirements of Article 230 EC, it must be stated that, in the complete system of legal remedies and procedures established by the EC Treaty with a view to ensuring judicial review of the legality of acts of the institutions, where natural or legal persons cannot, by reason of the conditions for admissibility laid down in the fourth paragraph of that article, directly challenge Community measures of general application, they are able, depending on the case, either indirectly to plead the invalidity of such acts before the Community judicature under Article 241 EC or to do so before the national courts and ask them, since they have no jurisdiction themselves to declare those measures invalid, to make a reference to the Court of Justice for a preliminary ruling on validity (Case C-50/00 P *Unión de Pequeños Agricultores* v *Council* [2002] ECR I-6677, paragraph 40).

40

The opportunity open to individuals to plead the invalidity of a Community act of general application before national courts is not conditional upon that act's actually having been the subject of implementing measures adopted pursuant to national law. In that respect, it is sufficient if the national court is called upon to hear a genuine dispute in which the question of the validity of such an act is raised indirectly. That condition is amply fulfilled in the circumstances of the case in the main proceedings, as is apparent from paragraphs 36 and 37 above.

41

It follows from all the foregoing considerations that the questions referred by the national court are admissible.

The first question

Question 1(a)

42

By Question 1(a) the national court asks whether the Directive is invalid in whole or in part by reason of the fact that Articles 95 EC and/or 133 EC do not furnish an appropriate legal basis. Observations submitted to the Court

43

The claimants in the main proceedings argue that under Article 152(4)(c) EC the Community does not have the power to harmonise national rules in the domain of public health as such and that it has the power to adopt a harmonising measure under Article 95 EC only on condition that the measure genuinely has as its object the improvement of the conditions for the establishment and functioning of the internal market and actually contributes to eliminating obstacles to the free movement of goods or to the freedom to provide services, or to removing distortions of competition (see, to that effect, Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-2247, in particular, paragraphs 84 and 95, the tobacco advertising judgment). In their submission, the Directive, notwithstanding the statements made in its recitals, is not intended to ensure the free movement of tobacco products but rather to ensure the protection of public health.

44

The claimants in the main proceedings also argue that since Directive 90/239 established a fully harmonised regime applicable to the tar yields of cigarettes, there can be no further legislation pursuing objectives which concern the attainment of the internal market in order to reduce tar yields which have already been defined. Even if it were to be conceded that the Community legislature had the power to legislate afresh on the basis of considerations of health in an area which it has already harmonised for

reasons appertaining to the internal market, such legislation must at least be based on new developments based on scientific facts.

45

Furthermore, according to the claimants in the main proceedings, Article 133 EC cannot constitute an appropriate legal basis for the Directive either, since Article 3 of the latter, in so far as it lays down requirements concerning the manufacture of cigarettes within the Community, does not aim at establishing a common commercial policy in respect of the export regime for those products, since those manufacturing requirements do not specifically concern international trade, but affect intra-Community trade just as much.

46

According to Japan Tobacco, Article 7 of the Directive cannot find a legal basis in Article 95 EC or Article 133 EC, in particular because there is no evidence that obstacles to trade or distortions of competition could have emerged if Article 7 had not been adopted.

47

The German Government submits that Article 3(1) of the Directive not only prohibits the marketing of cigarettes that do not comply with the maximum yields fixed by that provision, but also prohibits their manufacture. Article 3(2) imposes different rules, depending on whether the products are manufactured for the purposes of being marketed within the Community or for export to non-member countries. According to that Government, the prohibition on manufacture contained in Article 3(2) of the Directive is, in relation to non-member countries, in the nature of a ban on exports.

48

Furthermore, according to the German Government, the last sentence of the 11th recital in the preamble to the Directive makes it clear that the intention is to prevent the export to non-member countries of cigarettes which do not meet the requirements of the Directive in respect of tar, nicotine and carbon monoxide levels in order to prevent their being marketed within the Community after illegal reimportation, which would undermine the internal market provisions.

49

According to that Government, the prohibition of exports in question cannot actually contribute to the smooth operation of the internal market since, to its knowledge, cigarettes illegally imported into the Community are in any event almost exclusively manufactured in non-member countries and not within the Community.

50

Furthermore, the German Government maintains that illegal imports of cigarettes constitute first and foremost an evasion of customs duty and taxes on tobacco products and must be combated by more effective controls on the Community's borders.

51

Nor, according to the German Government, can Article 133 EC constitute an appropriate legal basis for the export ban in question, since that provision's sphere of application is restricted to measures aimed primarily at influencing the volume or channels of trade with non-member countries, which is not the case here, since the prohibition of exports is intended only to prevent illegal reimports of cigarettes into the Community in order to protect the health of Community citizens.

52

The Greek Government submits that, inasmuch as Articles 3 and 7 of the Directive apply to products manufactured or packaged within the Community but intended to be consumed outside the Community,

they are not aimed at facilitating the movement of tobacco products within the internal market or preventing the circumvention of the relevant rules within the Community, so those articles cannot be based on Article 95 EC.

53

Furthermore, according to the Greek Government, Article 133 EC cannot supply an appropriate legal basis for the provisions of the Directive at issue either, since they have an adverse effect on exports of Community products to non-member countries.

54

The Luxembourg Government submits, first, that in so far as it concerns products placed on the market outside the Community, the Directive cannot be based on either Article 95 EC or Article 133 EC and, second and more generally, that its real object is simply the protection of public health, a sphere in respect of which Article 152 EC excludes harmonisation of the provisions laid down by the laws and regulations of the Member States.

55

The Luxembourg Government observes, in particular, that the application of Article 3 of the Directive to tobacco products intended for export to non-member countries is based on the idea that products which do not comply with the provisions of the Directive might be unlawfully reimported into the Community. In its submission, that is a mere theory contradicted by the facts. Most of the cigarettes illegally imported into the Community are manufactured in non-member countries. Moreover, a measure which does not relate specifically to international trade and which affects internal trade just as much, if not more, cannot be based on Article 133 EC.

56

The United Kingdom, Belgian, French, Irish, Italian, Netherlands and Swedish Governments, and the Parliament, the Council and the Commission, maintain that Articles 95 EC and 133 EC constitute the appropriate legal basis for the Directive. With regard to recourse to Article 95 EC, they point out *inter alia* that the object of the Directive is to improve the conditions for the functioning of the internal market in the tobacco products sector and that, in accordance with Article 95(3) EC, the Directive is intended to attain, in the context of the harmonisation it is to bring about, the objective of a high level of protection of public health. With regard to recourse to Article 133 EC as the second legal basis for the Directive, the Parliament and the Council, in particular, submit that it is justified by the fact that Article 3 of the Directive, which makes clear that cigarettes which do not comply with the requirements of that provision may not be manufactured in the Community for export to non-member countries, pursues at one and the same time an objective of protecting the internal market from reimports into the Community of cigarettes which do not comply with those requirements and an objective of regulating exports to non-member countries which is connected to the implementation of the common commercial policy.

57

The Finnish Government maintains that Article 95 EC is the correct legal basis for the Directive, whereas recourse to Article 133 EC as a second legal basis is not necessary. It submits in this connection that the principal purpose of the Directive is to approximate national provisions in order to establish the internal market in the area of tobacco products. Protection of public health and regulation of trade with non-member countries are ancillary objectives in comparison with that primary purpose.
Findings of the Court

58

It is necessary to consider here whether Article 95 EC is an appropriate legal basis for the Directive and, if it is, to establish whether recourse to Article 133 EC as a second legal basis is either necessary or possible in the circumstances.

59

As a preliminary point, the case-law concerning Article 100a(1) of the EC Treaty (now, after amendment, Article 95(1) EC) must be borne in mind.

60

First of all, it is clear from paragraphs 83, 84 and 95 of the tobacco advertising judgment that the measures referred to in that provision are intended to improve the conditions for the establishment and functioning of the internal market and must genuinely have that object, actually contributing to the elimination of obstacles to the free movement of goods or to the freedom to provide services, or to the removal of distortions of competition.

61

Also, it follows from that case-law that while recourse to Article 95 EC as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious 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; the tobacco advertising judgment, paragraph 86, and Case C-377/98 *Netherlands* v *Parliament and Council* [2001] ECR I-7079, paragraph 15).

62

Finally, provided that 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 (see, to that effect, the tobacco advertising judgment, paragraph 88). Moreover, the first subparagraph of Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities, and Article 95(3) EC explicitly requires that, in achieving harmonisation, a high level of protection of human health should be guaranteed.

63

It is to be determined, in light of those principles, whether the conditions for recourse to Article 95 EC as a legal basis have, in the case of the Directive, been satisfied.

64

The following considerations ought to be noted at the outset. First, as the Advocate General observed in paragraph 61 of his Opinion, the market for tobacco products, especially cigarettes, in the Community is one in which trade between Member States represents a relatively large part. Second, national rules laying down the requirements to be met by products, in particular those relating to their designation, composition or packaging, are in themselves liable, in the absence of harmonisation at Community level, to constitute obstacles to the free movement of goods (see, to that effect, Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraph 15).

65

Notwithstanding the Community harmonisation measures already adopted, namely, Directive 89/622 concerning the labelling of tobacco products and Directive 90/239 concerning the maximum tar yield of cigarettes, differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco products, which create obstacles to trade, had already emerged, or were likely to emerge, by the time the Directive was adopted.

66

On the one hand, some provisions contained in the Community harmonisation measures already adopted merely laid down minimal requirements, leaving the Member States a degree of discretion to

adapt them (see Case C-222/91 *Philip Morris Belgium and Others* [1993] ECR I-3469, paragraphs 11 and 17, and also Case C-11/92 *Gallaher and Others* [1993] ECR I-3545, paragraphs 14 and 20). On the other hand, Directives 89/622 and 90/239 covered only certain aspects of the conditions for manufacture, presentation and sale of tobacco products, the Member States being free to adopt national rules in respect of those aspects not thereby covered.

67

In that context, having regard to the fact that the public is increasingly conscious of the dangers to health posed by consuming tobacco products, it is 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 by means of warnings and information appearing on their packaging or to reduce the harmful effects of tobacco products by introducing new rules governing their composition.

68

That analysis is confirmed by the content of the recitals in the preamble to the Directive and by the observations submitted during the procedure.

69

It is apparent from the seventh recital in the preamble to the Directive that several Member States were contemplating adopting measures establishing maximum carbon monoxide yields for cigarettes if such measures were not taken at Community level.

70

Similarly, the ninth recital in the preamble to the Directive states that differences had emerged between the laws of the Member States on the limitation of the maximum nicotine yield of cigarettes. Observations submitted during the procedure show that three Member States had already introduced such limitations and that several others were thinking of doing so. Even if it is accepted that, having regard to the levels at which they were set and to the biochemical link between tar and nicotine, those limitations did not in practice form an obstacle to the marketing of cigarettes which complied with the requirements relating to the maximum tar yield permitted under Community law, the fact nevertheless remains that for Member States to set specific maximum yields for nicotine creates a risk that the subsequent lowering of those maximum yields may entail the creation of obstacles to trade.

71

Furthermore, the 13th recital in the preamble to the Directive mentions negotiations for the drafting of a World Health Organisation Framework Convention on Tobacco Control, including the definition of internationally applicable standards for tobacco products.

72

In addition, the 19th and 22nd recitals in the preamble to the Directive refer to the fact that different Member States have different laws with regard to the presentation of warnings and indications of yields of harmful substances on the one hand and the ingredients and additives used in the manufacture of tobacco products on the other.

73

Lastly, the written procedure reveals that one Member State had adopted provisions regulating the use of certain of the descriptive terms mentioned in the 27th recital in the preamble to the Directive and referred to in Article 7.

74

It must be added that, unlike the directive at issue in the case giving rise to the tobacco advertising

judgment, the Directive contains a provision, Article 13(1), which guarantees the free movement of products which comply with its requirements. By forbidding the Member States to prevent, on grounds relating to the matters harmonised by the Directive, the import, sale or consumption of tobacco products which do comply, that provision gives the Directive its full effect in relation to its object of improving the conditions for the functioning of the internal market.

75

It follows that the Directive genuinely has as its object the improvement of the conditions for the functioning of the internal market and that it was, therefore, possible for it to be adopted on the basis of Article 95 EC, and it is no bar that the protection of public health was a decisive factor in the choices involved in the harmonising measures which it defines.

76

That conclusion is not called into question by the argument that, since the Community legislature had established a fully harmonised regime applicable to the tar yields of cigarettes, it could not legislate afresh on the basis of Article 95 EC in order to settle that matter or, in any event, could do so only on the basis of new scientific facts.

77

The fact is that since the Community legislature made exhaustive provision in Directive 90/239 over the question of fixing the maximum tar yield of cigarettes, the Member States no longer had the power to enact individual rules in that area. As the Advocate General has observed in paragraph 124 of his Opinion, the Community legislature can properly carry out its task of safeguarding the general interests recognised by the Treaty, such as public health, only if it has the freedom to amend the relevant Community legislation so as to take account of any change in perceptions or circumstances.

78

It follows that, even where a provision of Community law guarantees the removal of all obstacles to trade in the area it harmonises, that fact cannot make it impossible for the Community legislature to adapt that provision in step with other considerations.

79

With regard in particular to the protection of public health, it follows from Article 95(3) EC that the Community legislature, in harmonising the legislation, must guarantee a high level of protection, taking particular account of any new development based on scientific facts.

80

Progress in scientific knowledge is not, however, the only ground on which the Community legislature can decide to adapt Community legislation since it must, in exercising the discretion it possesses in that area, also take into account other considerations, such as the increased importance given to the social and political aspects of the anti-smoking campaign.

81

Nor is the conclusion that Article 95 EC constitutes an appropriate legal basis for the adoption of the Directive undermined by the argument that the prohibition on the manufacture within the Community, for export to non-member countries, of cigarettes which do not comply with the requirements of Article 3(1) of the Directive does not actually contribute to improving the conditions for the functioning of the internal market.

82

Although the prohibition of manufacture at issue is not a provision aimed directly at improving the conditions for the functioning of the internal market, the fact remains that a measure adopted on the

basis of Article 95 EC may incorporate such a provision so long as its purpose is to ensure that certain prohibitions concerning the internal market and imposed in pursuit of that object are not circumvented (see, to that effect, the tobacco advertising judgment, paragraph 100).

83 It is to be noted that the Court has accepted that the risks of unlawful reimports or deflections of trade liable to jeopardise the effectiveness of a Community measure adopted in the sphere of the common agricultural policy justified a prohibition of exports to non-member countries (Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraphs 62 and 109).

84 In this instance, the 11th recital in the preamble to the Directive, concerning the consequences of the Directive for tobacco products exported from the Community, makes it clear that the rules which that measure lays down in that regard were adopted in order to ensure that its internal market provisions should not be undermined.

85 It is apparent from the observations submitted during the procedure that in the circumstances the Community legislature intended to prevent the undermining of the internal market provisions in the tobacco products sector which might be caused by unlawful reimports into the Community or by deflections of trade within the Community affecting products which do not comply with the requirements of Article 3(1) of the Directive in respect of maximum yields of certain substances applicable to cigarettes.

86 It is true that the information supplied by the claimants in the main proceedings, the Member States and the institutions which submitted observations in the course of these proceedings, mentioned in paragraph 64 of the Advocate General's Opinion, does not make it possible to evaluate with precision the volume of unlawful trade in cigarettes manufactured in the Community and disposed of illicitly on that market after being reimported from non-member countries or placed directly on that market when they were intended for export to non-member countries. It is also true, as the German Government maintains, that the cause of the unlawful trade in cigarettes is essentially the profit made because those goods avoid the payment of tax and customs duties to which they would ordinarily be subject, the circumvention of the provisions relating to the composition of the cigarettes not being a crucial factor in this area.

87 It is however unarguable that the cigarette market particularly lends itself to the development of unlawful trade and that if the manufacture within the Community itself of cigarettes which could not legally be put into circulation or on the market in the Community were to be allowed, that would be likely to increase the risks of fraud.

88 In addition, the danger that the effectiveness of the measures defined by the Directive might be jeopardised must be assessed not only in relation to the situation as it was before the Directive was adopted, but also taking into consideration the foreseeable effects of its provisions on the nature and volume of the illegal trade in cigarettes.

89 In that regard it may reasonably be thought that lowering the maximum permitted yield of tar per cigarette and introducing maximum yields for nicotine and carbon monoxide, making it impossible for consumers lawfully to buy products which do not comply with those maximum yields, but which they

were accustomed to consume before those new requirements were brought in, is liable to encourage them to buy those products illicitly.

90

In those circumstances, the ban on manufacture provided for by Article 3(1) of the Directive may be regarded as a measure intended to prevent the circumvention of the prohibitions, also laid down by that provision, of placing cigarettes which do not comply with the requirements of that provision in free circulation or of marketing them in the Member States.

91

It follows that it was possible for the Directive, including the provision prohibiting the manufacture in the Community for export to non-member countries of cigarettes which do not comply with the requirements of Article 3(1) of the Directive, to be adopted on the basis of Article 95 EC.

92

The question whether recourse to Article 133 EC as a second legal basis for the Directive was necessary or possible in the circumstances must be answered as follows.

93

As a preliminary point, it must be borne in mind that, according to settled case-law, in the context of the organisation of the powers of the Community the choice of a legal basis for a measure must rest on objective factors which are amenable to judicial review. Those factors include in particular the aim and the content of the measure (see, in particular, Case C-269/97 *Commission* v *Council* [2000] ECR I-2257, paragraph 43, and Case C-36/98 *Spain* v *Council* [2001] ECR I-779, paragraph 58).

94

If examination of a Community act shows that it has a twofold purpose or twofold component and if one of these is identifiable as main or predominant, whereas the other is merely incidental, the act must be founded on a sole legal basis, that is, the one required by the main or predominant purpose or component (see, *inter alia* , Case C-42/97 *Parliament* v *Council* [1999] ECR I-869, paragraphs 39 and 40, and Case C-36/98 *Spain* v *Council* , cited above, paragraph 59). Exceptionally, if it is established that the act simultaneously pursues a number of objectives, indissociably linked, without one being secondary and indirect in relation to the other, such an act may be founded on the various corresponding legal bases (Opinion 2/00 [2001] ECR I-9713, paragraph 23).

95

In light of the principles set out in the two paragraphs above and having regard to the conclusion in paragraph 91 above, it must be concluded that the Directive could not simultaneously have Articles 95 EC and 133 EC for a legal basis.

96

Without there being any need to consider whether, in its provisions affecting tobacco products exported to non-member countries, the Directive also pursued an objective linked to the implementation of the common commercial policy under Article 133 EC, that objective is in any event secondary in relation to the aim and content of the Directive as a whole, which is primarily designed to improve the conditions for the functioning of the internal market.

97

It follows that Article 95 EC constitutes the only appropriate legal basis for the Directive and that it is incorrect for it to cite Article 133 EC also as a legal basis.

98

However, that incorrect reference to Article 133 EC as a second legal basis for the Directive does not of itself mean that the latter is invalid. Such an error in the legal basis relied on for a Community measure 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), a matter which, in the case of the Directive, is the subject of Question 1(b), considered in paragraphs 100 to 111 below.

99

It follows from the foregoing considerations concerning Question 1(a) that the Directive is not invalid for lack of an appropriate legal basis. *Question 1(b)*

100

By Question 1(b) the national court essentially asks whether recourse to the twofold legal basis of Articles 95 EC and 133 EC vitiates the procedure in adopting the Directive by reason of the application of two legislative procedures incompatible one with the other, and whether that renders the Directive invalid. Observations submitted to the Court

101

The claimants in the main proceedings maintain that the legislative procedures which the Community must follow in adopting legislation under Articles 95 EC and 133 EC respectively are different from and inconsistent with one another, so that recourse to such a dual legal basis is not permissible (see, in particular, Case C-300/89 *Commission* v *Council* (*Titanium dioxide*) [1991] ECR I-2867, paragraphs 17 to 21). Article 95 EC requires the Council to act jointly with the Parliament in accordance with the co-decision procedure laid down in Article 251 EC, whereas Article 133 EC lays down a procedure in which the Parliament does not participate and the Council acts by a qualified majority. Application of the co-decision procedure to the adoption of a measure relating to the common commercial policy, when Article 133 EC does not even provide for the Parliament to be consulted, would run counter to the separation of powers between institutions intended by the Treaty.

102

The United Kingdom, French, Italian, Netherlands, Finnish and Swedish Governments, and the Parliament, the Council and the Commission submit that Articles 95 EC and 133 EC do not constitute two legal bases incompatible one with the other. They argue in essence that although those two Treaty articles involve the application of different legislative procedures those are not, unlike the procedures at issue in *Titanium dioxide* , cited above, incompatible one with another since they can be cumulated without affecting the scope of the Parliament's participation in the legislative procedure.

Findings of the Court

103

As stated in paragraph 97 above, Article 95 EC constitutes the only appropriate legal basis for the Directive. Accordingly, in order to answer Question 1(b) it must be established whether the legislative procedure which was actually followed when the Directive was adopted, on the bases of Articles 95 EC and 133 EC, satisfies the requirements of the legislative procedure applicable when a Community act is adopted on the basis of Article 95 EC alone.

104

Article 95(1) EC provides that measures enacted on its basis are to be adopted in accordance with the co-decision procedure referred to in Article 251 EC and after consulting the Economic and Social Committee.

105

It is common ground that that procedure was followed in the instant case when the Directive was adopted.

106

Furthermore, adding Article 133 EC to Article 95 EC as a second legal basis for the Directive did not prejudice the substance of the co-decision procedure followed in this case.

107

Article 133(4) EC provides that, in exercising the powers conferred upon it by that provision, the Council is to act by a qualified majority.

108

Accordingly, the fact that the procedure laid down for the adoption of acts on that second legal basis was followed did not entail an obligation on the part of the Council to act unanimously in any event, it being borne in mind that in the co-decision procedure laid down in Article 251 EC, it is in principle to act by qualified majority, except where it approves the amendments to the common position which have been made by the Parliament and on which the Commission has delivered a negative opinion, in which case it must act unanimously.

109

In those circumstances, unlike the situation concerned in the case giving rise to the *Titanium dioxide* judgment, cited above, the distinction between those cases in which the Council acts by qualified majority and those in which it must act unanimously, which forms the essential point of the legislative procedure, has not in the circumstances of the case been in any way compromised by the simultaneous reference to the two legal bases mentioned in the Directive.

110

The argument that application of the co-decision procedure in the adoption of a measure concerning the common commercial policy is contrary to the separation of powers between institutions intended by the Treaty is in any event without any bearing in the circumstances since, as paragraph 97 above makes clear, the Directive is not an act which must be adopted on the basis of Article 133 EC.

111

It follows from the foregoing considerations relating to Question 1(b) that recourse to the twofold legal basis of Articles 95 EC and 133 EC has not vitiated the procedure for adopting the Directive and that the latter is not invalid on that account. *Question 1(c)*

112

By Question 1(c) the national court asks whether the Directive is invalid in whole or in part by reason of infringement of the principle of proportionality.

Observations submitted to the Court

113

The claimants in the main proceedings argue that, even if it were to be conceded that the Directive may genuinely have as its object the attainment of the internal market or the establishment of a common commercial policy, it seeks to achieve those objects in a disproportionate manner, which applies more particularly to Articles 5 and 7 and to its application to cigarettes intended for export to non-member countries.

114

They maintain in particular, with regard to Article 7 of the Directive, that the ban on descriptors referring

to lower levels of harmful substances is inconsistent with the stated aim of Article 3(1) of the Directive further to reduce tar yields on public health grounds. They also claim that Article 7 constitutes much greater interference with their rights than is necessary to pursue the legitimate objective which the provision is claimed to have. In that respect, they submit that the relevant Spanish legislation, which simply contains provisions governing the use of descriptors, provides a good example of legislation resulting in less interference with the rights of manufacturers of tobacco products while protecting public health.

115

The claimants in the main proceedings also argue that the ban on manufacture for export to non-member countries of cigarettes which do not comply with the requirements of Article 3(1) of the Directive is not an appropriate method of preventing circumvention of the new limits fixed by that provision, particularly since the overwhelming majority of cigarettes unlawfully imported into the Community are manufactured outside the Community.

116

According to Japan Tobacco, Article 7 of the Directive infringes the principle of proportionality in so far as it applies to established trade marks. It is argued that that provision is not the least restrictive means by which to attain the objectives of the Directive. That provision, read in the light of the 27th recital in the preamble to the Directive, is based on the premiss that consumers are unaware that the levels of tar and nicotine which they inhale may be influenced by their smoking behaviour; a message to that effect on the packaging would therefore have been sufficient instead of prohibiting the use of descriptors. Furthermore, a clause relating to established rights could have been included in the Directive, so that Article 7 would not apply to trade marks already registered, such as Mild Seven.

117

The German, Greek and Luxembourg Governments submit that the ban on manufacture for export, laid down in Article 3 of the Directive, and the ban on the use of certain descriptors laid down in Article 7 thereof, infringe the principle of proportionality inasmuch as they are inappropriate and do excessive damage to the economic interests of the manufacturers of tobacco products. In particular, they argue that Article 3 does not make it possible to ensure effective protection against the risk that cigarettes will be imported illegally into the Community, given the negligible volume of cigarettes reimported into the Community, and that that risk could be better avoided by reinforcing import controls. With regard to Article 7 of the Directive, those governments observe *inter alia* that, in contrast to the absolute prohibition of the use of descriptors laid down in that provision, regulation of their use, such as provided for in the Spanish legislation, on the basis of classifying products according to their tar and nicotine levels, would make it possible to give objective information to consumers without excessively affecting the economic interests of the manufacturers of tobacco products.

118

The Belgian, French and Swedish Governments, and the Council and Commission, maintain that the Directive is in keeping with the principle of proportionality inasmuch as its provisions go no further than is necessary to safeguard the smooth operation of the internal market in the tobacco products sector and to ensure, at the same time, a high level of public health protection.

119

With more particular regard to Article 7 of the Directive, the French Government observes that that provision does not prohibit all indications or presentations of cigarettes which could attract smokers and encourage brand loyalty, but only those which suggest that one particular tobacco product is less harmful than others.

120

According to the Swedish Government, since the use of tobacco products is associated with serious health risks, it is especially important that consumers should not be misled with regard to the risks of that use and it is hard to envisage any alternative to the prohibition under Article 7 which would achieve the same result as that prohibition but with a less severe impact on trade mark proprietors.

121

The Commission submits that Article 7 is not incompatible with the objective set out in Article 3(1) of the Directive, which is to reduce tar yields. Since descriptors were not regulated at Community level, they could be used by manufacturers of tobacco products to indicate other attributes of a cigarette, such as taste, which have no connection with its tar yield, which could mislead consumers. The Commission adds that, even if light cigarettes do have a lower level of tar, many smokers are misled because they receive the inaccurate impression that those products are in fact safe, which is not true, in particular because cigarette smoke also contains other toxic products which are not regulated by the Directive.

Findings of the Court

122

As a preliminary point, it ought to 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 should be 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).

123

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 involved in the present case, which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue (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, and Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 61).

124

With regard to the Directive, the first, second and third recitals in the preamble thereto make it clear that its objective is, by approximating the rules applicable in this area, to eliminate the barriers raised by differences which, notwithstanding the harmonisation measures already adopted, still exist between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco products and impede the functioning of the internal market. In addition, it is apparent from the fourth recital that, in the attaining of that objective, the Directive takes as a basis a high level of health protection, in accordance with Article 95(3) of the Treaty.

125

During the procedure various arguments have been put forward in order to challenge the compatibility of the Directive with the principle of proportionality, particularly so far as Articles 3, 5 and 7 are concerned.

126

It must first be stated that the prohibition laid down in Article 3 of the Directive on releasing for free

circulation or marketing within the Community cigarettes that do not comply with the maximum levels of tar, nicotine and carbon monoxide, together with the obligation imposed on the Member States to authorise the import, sale and consumption of cigarettes which do comply with those levels, in accordance with Article 13(1) of the Directive, is a measure appropriate for the purpose of attaining the objective pursued by the Directive and one which, having regard to the duty of the Community legislature to ensure a high level of health protection, does not go beyond what is necessary to attain that objective.

127

Secondly, as pointed out in paragraph 85 above, the purpose of the prohibition, also laid down in Article 3 of the Directive, on manufacturing cigarettes which do not comply with the maximum levels fixed by that provision is to avoid the undermining of the internal market provisions in the tobacco products sector which might be caused by illicit reimports into the Community or by deflections of trade within the Community affecting products which do not comply with the requirements of Article 3(1).

128

The proportionality of that ban on manufacture has been called into question on the ground that it is not a measure for the purpose of attaining its objective and that it goes beyond what is necessary to attain it since, in particular, an alternative measure, such as reinforcing inspections of imports from non-member countries, would have been sufficient.

129

It must here be stated that, while the prohibition at issue does not of itself make it possible to prevent the development of the illegal trade in cigarettes in the Community, having particular regard to the fact that cigarettes which do not comply with the requirements of Article 3(1) of the Directive may also be placed illegally on the Community market after being manufactured in non-member countries, the Community legislature did not overstep the bounds of its discretion when it considered that such a prohibition nevertheless constitutes a measure likely to make an effective contribution to limiting the risk of growth in the illegal trafficking of cigarettes and to preventing the consequent undermining of the internal market.

130

Nor has it been established that reinforcing controls would in the circumstances be enough to attain the objective pursued by the contested provision. It must be observed that the prohibition on manufacture at issue is especially appropriate for preventing at source deflections in trade affecting cigarettes manufactured in the Community for export to non-member countries, deflections which amount to a form of fraud which, *ex hypothesi* , it is not possible to combat as efficiently by means of an alternative measure such as reinforcing controls on the Community's frontiers.

131

As regards Article 5 of the Directive, the obligation to show information on cigarette packets as to the tar, nicotine and carbon monoxide levels and to print on the unit packets of tobacco products warnings concerning the risks to health posed by those products are appropriate measures for attaining a high level of health protection when the barriers raised by national laws on labelling are removed. Those obligations in fact constitute a recognised means of encouraging consumers to reduce their consumption of tobacco products or of guiding them towards such of those products as pose less risk to health.

132

Accordingly, by requiring in Article 5 of the Directive an increase in the percentage of the surface area on certain sides of the unit packet of tobacco products to be given over to those indications and warnings, in a proportion which leaves sufficient space for the manufacturers of those products to be

able to affix other material, in particular concerning their trade marks, the Community legislature has not overstepped the bounds of the discretion which it enjoys in this area.

133

Article 7 of the Directive calls for the following observations.

134

The purpose of that provision is explained in the 27th recital in the preamble to the Directive, which makes it clear that the reason for the ban on the use on tobacco product packaging of certain texts, such as low-tar, light, ultra-light, mild, names, pictures and figurative or other signs is the fear that consumers may be misled into the belief that such products are less harmful, giving rise to changes in consumption. That recital states in this connection that the level of inhaled substances is determined not only by the quantities of certain substances contained in the product before consumption, but also by smoking behaviour and addiction, which fact is not reflected in the use of such terms and so may undermine the labelling requirements set out in the Directive.

135

Read in the light of the 27th recital in the preamble, Article 7 of the Directive has the purpose therefore of ensuring that consumers are given objective information concerning the toxicity of tobacco products.

136

Such a requirement to supply information is appropriate for attaining a high level of health protection on the harmonisation of the provisions applicable to the description of tobacco products.

137

It was possible for the Community legislature to take the view, without overstepping the bounds of its discretion, that stating those tar, nicotine and carbon monoxide levels in accordance with Article 5(1) of the Directive ensured that consumers would be given objective information concerning the toxicity of tobacco products connected to those substances, whereas the use of descriptors such as those referred to in Article 7 of the Directive did not ensure that consumers would be given objective information.

138

As the Advocate General has pointed out in paragraphs 241 to 248 of his Opinion, those descriptors are liable to mislead consumers. In the first place, they might, like the word mild, for example, indicate a sensation of taste, without any connection with the product's level of noxious substances. In the second place, terms such as low-tar, light, ultra-light, do not, in the absence of rules governing the use of those terms, refer to specific quantitative limits. In the third place, even if the product in question is lower in tar, nicotine and carbon monoxide than other products, the fact remains that the amount of those substances actually inhaled by consumers depends on their manner of smoking and that that product may contain other harmful substances. In the fourth place, the use of descriptions which suggest that consumption of a certain tobacco product is beneficial to health, compared with other tobacco products, is liable to encourage smoking.

139

Furthermore, it was possible for the Community legislature to take the view, without going beyond the bounds of the discretion which it enjoys in this area, that the prohibition laid down in Article 7 of the Directive was necessary in order to ensure that consumers be given objective information concerning the toxicity of tobacco products and that, specifically, there was no alternative measure which could have attained that objective as efficiently while being less restrictive of the rights of the manufacturers of tobacco products.

140

It is not clear that merely regulating the use of the descriptions referred to in Article 7, as proposed by the claimants in the main proceedings and by the German, Greek and Luxembourg Governments, or saying on the tobacco products' packaging, as proposed by Japan Tobacco, that the amounts of noxious substances inhaled depend also on the user's smoking behaviour would have ensured that consumers received objective information, having regard to the fact that those descriptions are in any event likely, by their very nature, to encourage smoking.

141

It follows from the preceding considerations concerning Question 1(c) that the Directive is not invalid by reason of infringement of the principle of proportionality. *Question 1(d)*

142

By Question 1(d) the national court asks whether the Directive is invalid in whole or in part by reason of infringement of Article 295 EC, the fundamental right to property and/or Article 20 of the Agreement on the Trade-related Aspects of Intellectual Property Rights (the TRIPs Agreement), as set out in Annex 1 C to the Agreement establishing the World Trade Organisation (the WTO Agreement), approved on behalf of the European Community, as regards matters within its competence, by Council Decision 94/800/EC of 22 December 1994 (OJ 1994 L 336, p. 1).

Observations submitted to the Court

143

The claimants in the main proceedings maintain that Articles 5 and 7 of the Directive infringe Article 295 EC, the fundamental right to property and/or Article 20 of the TRIPs Agreement, which provides that use of a trade mark in the course of trade is not to be unjustifiably encumbered by special requirements such as its use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. They claim that the very large size of the new health warnings required by Article 5 of the Directive constitutes a serious infringement of their intellectual property rights. Those warnings will dominate the overall appearance of tobacco product packaging and so curtail or even prevent the use of their trade marks by the manufacturers of those products. Likewise, they claim that the absolute prohibition on using the descriptive terms referred to in Article 7 of the Directive will deprive them of a number of their trade marks because they will no longer be permitted to use them.

144

According to Japan Tobacco, Article 7 of the Directive prohibits it from exercising its intellectual property rights by preventing it from using its trade mark Mild Seven in the Community and by depriving it of the economic benefit of its exclusive licences for that trade mark. Such a result entails infringement of the right to property, which is recognised to be a fundamental human right in the Community legal order, protected by the first subparagraph of Article 1 of the First Protocol to the European Convention on Human Rights (ECHR) and enshrined in Article 17 of the Charter of Fundamental Rights of the European Union.

145

The Greek and Luxembourg Governments submit that Article 7 of the Directive interferes with the intellectual property rights of the manufacturers of tobacco products and causes damage to their financial results since, by prohibiting absolutely the use of certain descriptive terms, its effect is purely and simply to prohibit certain trade marks duly registered by those manufacturers.

146

The United Kingdom, Belgian, French, Netherlands and Swedish Governments, and the Parliament,

Council and Commission observe first of all that the provisions of the Directive have no effect on the rules governing the system of property ownership in the Member States within the meaning of Article 295 EC. Then they argue that the fundamental right to property is not an absolute right, but one that may be restricted on grounds of the general interest such as, in the case in the main proceedings, the protection of public health. Lastly, they submit that the TRIPs Agreement does not have direct effect and, in any event, the provisions of the Directive are not contrary to Article 20 of that Agreement, since the latter does not forbid every cigarette manufacturer to continue to use its trade mark by distinguishing it from others by means of words, signs, colours and drawings which are particular to it and which it could present on the available surfaces of the tobacco products' packaging.

Findings of the Court

147

With regard, first of all, to Article 295 EC, it must be borne in mind that according to that provision the Treaty shall in no way prejudice the rules in Member States governing the system of property ownership. That provision merely recognises the power of Member States to define the rules governing the system of property ownership and does not exclude any influence whatever of Community law on the exercise of national property rights (see, to that effect, Joined Cases 56/64 and 58/64 *Consten and Grundig* v *Commission* [1966] ECR 299, p. 345).

148

It must be stated that in the circumstances of the present case the Directive does not impinge in any way on the rules governing the system of property ownership in the Member States within the meaning of Article 295 EC which is irrelevant in relation to any effect produced by the Directive on the exercise by the manufacturers of tobacco products of their trademark rights over those products.

149

As regards the validity of the Directive in respect of the right to property, the Court has consistently held that, while that right forms part of the general principles of Community law, it is not an absolute right and must be viewed in relation to its social function. Consequently, its exercise may be restricted, provided that those restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed (see, in particular, Case 265/87 *Schräder* [1989] ECR 2237, paragraph 15; Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 78, and Case C-293/97 *Standley and Others* [1999] ECR I-2603, paragraph 54).

150

As paragraphs 131 and 132 above make clear, the only effect produced by Article 5 of the Directive is to restrict the right of manufacturers of tobacco products to use the space on some sides of cigarette packets or unit packets of tobacco products to show their trade marks, without prejudicing the substance of their trade mark rights, the purpose being to ensure a high level of health protection when the obstacles created by national laws on labelling are eliminated. In the light of this analysis, Article 5 constitutes a proportionate restriction on the use of the right to property compatible with the protection afforded that right by Community law.

151

It is made clear in paragraphs 134 to 141 above that Article 7 of the Directive is intended to ensure, in a manner in keeping with the principle of proportionality, a high level of health protection on the harmonisation of the provisions applicable to the description of tobacco products.

152

While that article entails prohibition, in relation only to the packaging of tobacco products, on using a

trade mark incorporating one of the descriptors referred to in that provision, the fact remains that a manufacturer of tobacco products may continue, notwithstanding the removal of that description from the packaging, to distinguish its product by using other distinctive signs. In addition, the Directive provides for a sufficient period of time between its adoption and the entry into force of the prohibition under Article 7.

153

In light of the foregoing, it must be held that the restrictions on the trade mark right which may be caused by Article 7 of the Directive do in fact correspond to objectives of general interest pursued by the Community and do not constitute a disproportionate and intolerable interference, impairing the very substance of that right.

154

With regard, finally, to the validity of the Directive in the light of Article 20 of the TRIPs Agreement, the Court has consistently held that the lawfulness of a Community measure cannot be assessed in the light of instruments of international law which, like the WTO Agreement and the TRIPs Agreement which is part of it, are not in principle, having regard to their nature and structure, among the rules in the light of which the Court is to review the lawfulness of measures adopted by the Community institutions (Case C-149/96 *Portugal* v *Council* [1999] ECR I-8395, paragraph 47; Case C-377/98 *Netherlands* v *Parliament and Council* , cited above, paragraph 52; Case C-301/97 *Netherlands* v *Council* [2001] ECR I-8853, paragraph 53, and Joined Cases C-27/00 and C-122/00 *Omega Air and Others* [2002] ECR I-2569, paragraph 93).

155

It is also clear from that case-law that it is only where the Community intended to implement a particular obligation assumed in the context of the WTO, or where the Community measure refers expressly to the precise provisions of the WTO agreements, that it is for the Court to review the legality of the Community measure in question in the light of the WTO rules (see the judgments cited above, *Portugal* v *Council* , paragraph 49; *Netherlands* v *Council* , paragraph 54, and *Omega Air and Others* , paragraph 94).

156

Those conditions are not satisfied in the case of the Directive, with the result that there is no need to examine its validity in the light of Article 20 of the TRIPs Agreement.

157

It follows from the foregoing considerations concerning Question 1(d) that the Directive is not invalid by reason of infringement of Article 295 EC or the fundamental right to property. *Question 1(e)*

158

By Question 1(e) the referring court asks in essence whether the Directive is invalid in whole or in part by reason of infringement of the obligation to give reasons laid down in Article 253 EC.

Observations submitted to the Court

159

The claimants in the main proceedings argue *inter alia* that, even if it were to be conceded that the Community legislature has the power to legislate afresh in respect of tar yields and labelling on the basis of Article 95 EC, when those matters have already been harmonised at Community level, such legislation must at the very least be based on new developments based on scientific facts, within the meaning of Article 95(3) EC. Accordingly, the fact that the Directive nowhere refers to any scientific facts in relation to the new provisions on tar yields and labelling in Articles 3 and 5 is, in their

submission, contrary to Article 253 EC.

160

According to Japan Tobacco, the Directive does not satisfy the requirements of Article 253 EC because it does not explain the reasons of fact and law that led the Community legislature to conclude that the prohibition of the use of certain descriptors laid down in Article 7 was necessary.

161

The German Government maintains that Article 3(1) and (2) of the Directive is invalid in so far as it prohibits the manufacture for export to non-member countries of cigarettes that do not comply with the requirements relating to maximum levels of toxic substances, while the recitals in the preamble do not set out the reasons why health protection in the Community is significantly affected by illegal reimports of tobacco products manufactured in the Community.

162

The Greek Government observes in particular that the mere reference in the 11th recital in the preamble to the Directive to the need for rules to be adopted to ensure that the internal market provisions are not undermined does not satisfy the requirement to state reasons laid down in Article 253 EC, since that recital does not give a general description of the highly likely present or future danger referred to therein.

163

The Luxembourg Government submits that the Directive is vitiated by failure to give reasons since, in particular, the recitals in the preamble merely repeat the same reference to the smooth operation of the internal market, without explaining how that operation would have been jeopardised if the Directive had not been adopted.

164

According to the United Kingdom, Belgian, French, Italian and Netherlands Governments, and the Parliament and the Council, the Directive contains sufficient reasoning in the light of the requirements of Article 253 EC. In this connection they particularly observe that the Community legislature is not required to provide a specific statement of reasons for each of the technical choices made.

Findings of the Court

165

It must be borne in mind that, whilst the reasoning 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, the authority 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).

166

Furthermore, the question whether a statement of reasons satisfies the requirements must be assessed with reference not only to the wording of the impugned measure but also to its context and to the whole body of legal rules governing the matter in question. Consequently, 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).

167

The recitals in the preamble to the Directive clearly show that the measures introduced by the latter are

intended, by approximating the rules applicable in this area, to eliminate the barriers raised by differences which, notwithstanding the harmonisation measures already adopted, still exist between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco products and impede the functioning of the internal market.

168

Such is the case in respect of the first three recitals in the preamble to the Directive, which make it plain that the object of the Directive is to recast Directives 89/622 and 90/239, amending and adding to their provisions with a view to improving the functioning of the internal market in the tobacco products sector.

169

Such is also the case in respect of the fifth, seventh, ninth, 11th, 14th, 19th and 27th recitals in the preamble to the Directive, which specify the main areas in which the Community legislature considered it necessary to strengthen harmonisation measures already in existence or to introduce new harmonisation measures in relation, respectively, to the maximum tar, carbon monoxide and nicotine yields permitted in cigarettes, to the consequences of the Directive for tobacco products exported from the Community, to standards for the measurement of tar, nicotine and carbon monoxide yields of cigarettes, to the presentation of health warnings and the indication of those yields on unit packets of tobacco products, and to the ban on using certain descriptive terms on tobacco product packaging.

170

The argument that the Directive ought to have referred to scientific facts to justify the new provisions it incorporates in relation to the Community measures previously adopted cannot be accepted. Paragraph 80 above clearly shows that Article 95 EC does not require developments in scientific knowledge to be invoked if the Community legislature is to be able to adopt measures on the basis of that provision.

171

The argument that the Directive was inaccurate in its statement of reasons in that it prohibits the manufacture of cigarettes for export to non-member countries cannot be accepted either, since sufficient reasoning is supplied by the statement in the 11th recital in the preamble to the Directive to the effect that, in respect of those products, rules ought to be adopted in order to ensure that the internal market provisions are not undermined.

172

It follows from the foregoing considerations concerning Question 1(e) that the Directive is not invalid by reason of infringement of the duty to state reasons laid down in Article 253 EC. *Question 1(f)*

173

By Question 1(f) the national court asks whether the Directive is invalid in whole or in part by reason of infringement of the principle of subsidiarity.

Observations submitted to the Court

174

The claimants in the main proceedings maintain that the principle of subsidiarity is applicable to measures relating to the internal market such as the Directive and that, when the latter was adopted, the Community legislature left that principle wholly out of account or, in any event, failed to take it properly into account. If it had done so, it would have had to reach the conclusion that there was no need to adopt the Directive, since harmonised rules had already been established by Directives 89/622 and 90/239 for the purpose of eliminating barriers to trade in tobacco products. Furthermore, they

argue that no evidence has been adduced to show that the Member States could not adopt the measures of public health protection they considered necessary.

175

The Belgian Government and the Parliament maintain that the principle of subsidiarity does not apply to the Directive, inasmuch as that principle is applicable only in those areas in which the Community does not have exclusive competence, whereas the Directive, being adopted for the purpose of attaining the internal market, comes within one of those areas of exclusive competence. In any event, even if it were accepted that that principle applied to the Directive, it was complied with in the circumstances, since the action undertaken could not have been satisfactorily achieved at Member State level.

176

The United Kingdom, French, Netherlands and Swedish Governments, and the Council and Commission, submit that the principle of subsidiarity is applicable in the present case and was complied with by the Directive. The United Kingdom and French Governments and the Commission observe in particular that the considerations set out in paragraphs 30 to 34 of *Netherlands* v *Parliament and Council* , cited above, may be applied to the circumstances of this case and prompt the conclusion that the Directive is valid with regard to the principle of subsidiarity. According to the Netherlands Government and the Commission, where the conditions for the use of Article 95 EC have been satisfied, the conditions for Community action under the second paragraph of Article 5 EC are also satisfied, since it is clear that no Member State acting alone can take the necessary measures to prevent any divergence between the laws of the Member States having an impact on trade.

Findings of the Court

177

The principle of subsidiarity is set out in the second paragraph of Article 5 EC, according to which, in areas which do not fall within its exclusive competence, the Community is to take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved at Community level.

178

Article 3 of the protocol on the application of the principles of subsidiarity and proportionality, annexed to the Treaty establishing the European Community, states that the principle of subsidiarity does not call into question the powers conferred on the Community by the Treaty as interpreted by the Court.

179

It is to be noted, as a preliminary, that the principle of subsidiarity applies where the Community legislature makes use of Article 95 EC, inasmuch as that provision does not give it exclusive competence to regulate economic activity on the internal market, but only a certain competence for the purpose of improving the conditions for its establishment and functioning, by eliminating barriers to the free movement of goods and the freedom to provide services or by removing distortions of competition (see, to that effect, the tobacco advertising judgment, paragraphs 83 and 95).

180

As regards the question whether the Directive was adopted in keeping with the principle of subsidiarity, it must first be considered whether the objective of the proposed action could be better achieved at Community level.

181

As the Court has stated in paragraph 124 above, the Directive's objective is to eliminate the barriers

raised by the differences which still exist between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco products, while ensuring a high level of health protection, in accordance with Article 95(3) EC.

182

Such an objective cannot be sufficiently achieved by the Member States individually and calls for action at Community level, as demonstrated by the multifarious development of national laws in this case (see paragraph 61 above).

183

It follows that, in the case of the Directive, the objective of the proposed action could be better achieved at Community level.

184

Second, the intensity of the action undertaken by the Community in this instance was also in keeping with the requirements of the principle of subsidiarity in that, as paragraphs 122 to 141 above make clear, it did not go beyond what was necessary to achieve the objective pursued.

185

It follows from the foregoing conclusions concerning Question 1(f) that the Directive is not invalid by reason of infringement of the principle of subsidiarity. *Question 1(g)*

186

By Question 1(g) the national court asks whether the Directive is invalid in whole or in part by reason of misuse of powers.

Observations submitted to the Court

187

The claimants in the main proceedings and the Greek Government maintain that the Directive amounts to a misuse of powers, in that its sole objective is the protection of public health and not the development of the internal market or the development of the common commercial policy. They allege, in particular, that the ban on the manufacture of cigarettes for export was introduced with the sole aim of protecting the health of persons living in non-member countries.

188

According to the United Kingdom, Belgian, French, Netherlands and Swedish Governments, and the Parliament and the Council, the allegation of misuse of powers is based on the incorrect claim that the Directive is a public health measure in disguise.

Findings of the Court

189

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 (Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 24; Case C-156/93 *Parliament* v *Commission* [1995] ECR I-2019, paragraph 31; and Case C-48/96 P *Windpark Groothusen* v *Commission* [1998] ECR I-2873, paragraph 52, and Case C-110/97 *Netherlands* v *Council* [2001] ECR I-8763, paragraph 137).

190

With particular regard 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 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 (the tobacco advertising judgment, paragraph 79). The Court has, however, stated that, provided that the conditions for recourse to Articles 100a, 57(2) of the EC Treaty (now, after amendment, Article 47(2) EC) and 66 of the EC Treaty (now Article 55 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 (the tobacco advertising judgment, paragraph 88).

191

As has been stated in paragraph 91 above, the conditions for recourse to Article 95 EC were satisfied in the case of the Directive, and it has not in any way been established that it was adopted with the exclusive, or at least decisive, purpose of achieving an end other than that of improving the conditions for the functioning of the internal market in the tobacco products sector.

192

It is apparent from the foregoing considerations concerning Question 1(g) that the Directive is not invalid by reason of a misuse of powers.

The answer to be given to the first question, taken as a whole

193

The answer to be given to the first question, taken as a whole, is that consideration of that question has not disclosed any factor of such a kind as to affect the validity of the Directive.

The second question

194

By its second question the national court seeks to ascertain whether Article 7 of the Directive is to be construed as applying only to tobacco products marketed within the Community or also to tobacco products packaged within the Community for export to non-member countries.

Observations submitted to the Court

195

According to the claimants in the main proceedings, the Greek, Irish, Luxembourg, Netherlands and Swedish Governments, and the Parliament, Council and Commission, Article 7 of the Directive must be construed as not applying to tobacco products packaged in the Community for export to non-member countries, but only to tobacco products marketed within the Community.

196

First of all, they argue that it is not apparent from the wording of Article 7 of the Directive or the recitals in the preamble, in particular the 27th recital, that the Community legislature intended the prohibition laid down in Article 7 to apply also to products for export to non-member countries.

197

They then submit that, taking account of the adverse consequences of the prohibition laid down by that provision for manufacturers of tobacco products, its scope must be interpreted restrictively.

198

Last, they maintain that, as is apparent from the 27th recital in the preamble to the Directive, the objective of Article 7 is to ensure that the labelling requirements under Article 5 of the Directive are not

rendered meaningless. The two provisions must be understood to have the same field of application. Article 5(1) of the Directive lays down specific linguistic rules for the purposes of that act, determined by reference to the official languages of the Member States, and therefore applies only to tobacco products marketed within the Community.

199

According to the United Kingdom, Belgian, French, Italian and Finnish Governments, Article 7 of the Directive is to be interpreted as applying also to tobacco products packaged in the Community for export to non-member countries.

200

First of all, they submit that where Article 7 provides that certain descriptions may not be used on the packaging of tobacco products, the scope of that prohibition is not restricted by reference to the place of ultimate consumption of those products.

201

Next, they maintain that Article 152(1) EC requires that a high level of human health protection should be ensured in the definition and implementation of all Community policies and activities. This obligation extends to the common commercial policy, which again suggests that if the Community legislature had intended to exclude exports to non-member countries from the scope of Article 7, it would have said so expressly.

202

Finally, they observe that the descriptive information which must appear on tobacco product packaging must be identical, whatever the destination of those products, having regard to the risks of reintroduction into the Community of goods intended for export to non-member countries.

Findings of the Court

203

The Court has consistently held that, in interpreting a provision of Community law, it is necessary to consider not only its wording but also the context in which it occurs and the objects of the rules of which it forms part (Case C-223/98 *Adidas* [1999] ECR I-7081, paragraph 23; Case C-301/98 *KVS International* [2000] ECR I-3583, paragraph 21; Case C-156/98 *Germany* v *Commission* [2000] ECR I-6857, paragraph 50, and Case C-191/99 *Kvaerner* [2001] ECR I-4447, paragraph 30).

204

The wording of Article 7 does not of itself allow it to be determined whether the prohibition which it lays down applies only to tobacco products marketed in the Community or whether it does not also concern tobacco products packaged in the Community for export to non-member countries.

205

On that point Article 7 of the Directive can be distinguished from Article 3, which clearly states that its provisions relating to the maximum yields of harmful substances of cigarettes also apply to those manufactured in the Community and exported from it. Unlike Article 7, Article 3(2) of the Directive provides in particular for an additional period for the implementation of Article 3(1) concerning cigarettes for export to non-member countries.

206

In order to interpret the scope of Article 7 of the Directive it is necessary to take into consideration the context formed by the Directive's other provisions.

207

It is apparent from the 27th recital in the preamble that the particular aim of Article 7 of the Directive is to prevent the labelling requirements defined in Article 5 of that measure from being rendered meaningless.

208

In the scheme of the Directive, Articles 5 and 7 are complementary provisions since Article 5(1) provides that cigarette packets are to display the yields of harmful substances, thus ensuring that consumers receive objective information as to the toxicity of tobacco products connected to those substances, while Article 7 prohibits the use of descriptions liable to mislead consumers in that respect.

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It is clear from Article 5 of the Directive that the only requirements that it lays down in relation to tobacco product labelling are those imposed on products which are to be marketed within the Community.

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Such an interpretation follows in particular from the fact that Article 5(6)(e) of the Directive provides that the text of the warnings and yield indications required by that provision is to be printed in the official language or languages of the Member State where the product is placed on the market.

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As regards the objectives pursued by the Directive, it must be recalled that the chief objective is to improve the conditions for the functioning of the internal market in the tobacco products sector while ensuring a high level of health protection.

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The provisions of the Directive must therefore be considered in principle to concern only tobacco products which are to be placed on the internal market.

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Admittedly, with regard to Article 3 of the Directive, the Court has accepted in paragraphs 82 to 91 above that the risk of adverse effects for the internal market may justify the adoption, on the basis of Article 95 EC, of a provision relating to goods exported to non-member countries, as a measure intended to prevent the circumvention of the internal market provisions.

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Nevertheless, in that case the Community legislature expressly provided for Article 3 of the Directive to apply to tobacco products for export to non-member countries, having regard to its evaluation of the risks that the Directive's provisions on maximum yields of harmful substances in cigarettes might be circumvented, by reason of illicit reimports into the Community or deflections of trade within it.

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By contrast, Article 7, like Article 5, concerns the presentation of tobacco products and not their composition. The risks of adverse consequences for the internal market posed by the illicit marketing of, on the one hand, cigarettes that do not comply with the Directive's requirements concerning maximum yields of harmful substances or, on the other, of tobacco products that do not comply with its requirements concerning labelling and the information appearing on packaging, are not necessarily of the same severity or of the same kind and do not necessarily entail the adoption of the same measures.

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Accordingly, in the absence of any indication to that effect in the Directive, there is no reason to suppose that the Community legislature intended to supplement the prohibition on marketing tobacco products that do not comply with the requirements of Article 7 of the Directive within the Community with a similar prohibition concerning tobacco products packaged in the Community and intended to be marketed in non-member countries.

217 In light of all the foregoing considerations, the answer to the second question must be that Article 7 of the Directive is to be construed as applying only to tobacco products marketed within the Community.

Costs

218 The costs incurred by the United Kingdom, Belgian, German, Greek, French, Irish, Italian, Luxembourg, Netherlands, Finnish and Swedish Governments, and by the Parliament, the Council and the Commission, which have submitted observations to the Court, are not recoverable. 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.

On those grounds,

THE COURT,

in answer to the questions referred to it by the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) by order of 6 December 2001, hereby rules:

1. Consideration of the first question has not disclosed any factor of such a kind as to affect the validity 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. Article 7 of Directive 2001/37 is to be construed as applying only to tobacco products marketed within the European Community.

Rodríguez Iglesias	Puissochet	Wathelet
Schintgen	Timmermans	Edward
La Pergola	Jann	Skouris
Macken	Colneric	von Bahr
Cunha Rodrigues		

Delivered in open court in Luxembourg on 10 December 2002.

R. Grass	G.C. Rodríguez Iglesias
Registrar	President

1 – Language of the case: English.