OPINION OF ADVOCATE GENERAL GEELHOED

delivered on 10 September 2002 [1]

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1 — Original language: Dutch.

I — Introduction

1. This request by the High Court of Justice (Administrative Court) for a preliminary ruling concerns 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 (hereinafter: 'the Directive').[2]

2. The Directive can be distinguished in one significant respect from other EC directives laying down product-related requirements. The Directive (at any rate, Article 3 thereof) is applicable not only to tobacco products placed on the market within the European Union itself but also to tobacco products manufactured in the European Union and exported to non-member countries.

3. Central to this case is the question whether Article 95 EC could serve as the legal basis for the Directive and whether Article 133 EC could be used as a legal basis for regulating exports of cigarettes. The High Court of Justice (Administrative Court) also asks whether the Directive may be invalid on the ground that it infringes certain legal principles or the right to property. The High Court submits, finally, a question on the interpretation of Article 7 of the Directive.

4. The present case is related to Case C-376/98 *Germany* v *Parliament and Council*[3] (hereinafter: 'the *tobacco advertising* judgment'), in which the Court

2 — OJ 2001 L 194, p. 26.

3 — Judgment of 5 October 2000 in Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-8419.

annulled a separate directive relating to tobacco products. The directive there in issue was Directive 98/43/EC of the European Parliament and of the Council of 6 July 1998 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (hereinafter: 'Directive 98/43'). [4]

5. So far as the Directive in the present case is concerned, the German Government has also challenged its validity before the Court. [5] By order of 17 May 2002 the Court dismissed that application as being inadmissible on the ground that it had been lodged out of time.

6. The present case provides an opportunity to examine in general the powers of the Community legislature under Article 95 EC. That article confers the power to adopt rules which have as their object the establishment and functioning of the internal market. In particular, two questions are central to the present case:

— does that power also encompass the possibility to adopt rules intended primarily to protect public health, and

— to what extent can this legal basis be used to adopt rules for products that are manufactured within the EC but are not intended to be placed on the internal market?

Also in issue generally within the present context is the power under Article 133 EC, specifically the extent to which the Community legislature is authorised to impose restrictions on exports of certain products to non-member countries in the context of the risks to public health which those products present.

II — The legal framework

A — The operative provisions of the Directive

7. Articles 3 to 7 of the Directive set out the obligations imposed on manufacturers of and dealers in tobacco products. These articles are reproduced *in extenso* below.

4 — OJ 1998 L 213, p. 9.
5 — Case C-406/01, ECR I-4561.

8. Articles 3 to 7 provide as follows:

'*Article 3*

Cigarettes: maximum tar, nicotine and carbon monoxide yields

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.

3. For Greece, as a temporary derogation, the date of application of the maximum tar yield of cigarettes manufactured and marketed within its territory, as referred to in paragraph 1, shall be 1 January 2007.

Article 4

Measurement methods

1. The tar, nicotine and carbon monoxide yields of cigarettes shall be measured on the basis of ISO standards 4387 for tar, 10315 for nicotine, and 8454 for carbon monoxide.

The accuracy of the tar and nicotine indications on packets shall be verified in accordance with ISO standard 8243.

2. The tests referred to in paragraph 1 shall be carried out or verified by testing laboratories which are approved and monitored by the competent authorities of the Member States.

Member States shall send the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, by 30 September 2002, and whenever any change is made.

3. Member States may also 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 tobacco products on a brand-name-by-brand-name basis and type-by-type-basis and in order to assess the effects of those other substances on health, taking into account, *inter alia*, their addictiveness. Member States may also require that such tests be carried out or verified in approved testing laboratories as laid down in paragraph 2.

4. The results of tests carried out in accordance with paragraph 3 shall be submitted to the relevant national authorities on an annual basis. Member States may provide for less frequent disclosure of test results in cases where the product specifications have not varied. Member States shall be informed of changes in such product specifications.

Member States shall ensure the dissemination, by any appropriate means, of information submitted in accordance with this Article with a view to informing consumers and in so doing shall take account, where appropriate, of any information which constitutes a trade secret.

5. Each year Member States shall communicate all data and information submitted pursuant to this Article to the Commission, which shall take account thereof when drawing up the report referred to in Article 11.

Article 5

Labelling

1. The tar, nicotine and carbon monoxide yields of cigarettes measured in accordance with Article 4 shall be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10% of the corresponding surface is covered.

That percentage shall be raised to 12% for Member States with two official languages and to 15% for Member States with three official languages.

2. Each unit packet of tobacco products, except for tobacco for oral use and other smokeless tobacco products, must carry the following warnings:

(a) general warnings:

1. "Smoking kills/Smoking can kill", or

2. "Smoking seriously harms you and others around you".

The general warnings indicated above shall be rotated in such a way as to guarantee their regular appearance. The warning shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product; and

(b) an additional warning taken from the list set out in Annex I.

The additional warnings referred to above shall be rotated in such a way as to guarantee their regular appearance.

That warning shall be printed on the other most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

Member States may determine the positioning of the warnings on those surfaces in order to accommodate language requirements.

3. The Commission shall, as soon as practicable and in any event not later than 31 December 2002, in accordance with the procedure laid down in Article 10(2), adopt rules for the use of colour photographs or other illustrations to depict and explain the health consequences of smoking, with a view to ensuring that internal market provisions are not undermined.

Where Member States require additional warnings in the form of colour photographs or other illustrations, these shall be in accordance with the abovementioned rules.

4. Tobacco products for oral use, where their marketing is permitted under Article 8, and smokeless tobacco products

shall carry the following warning: "This tobacco product can damage your health and is addictive".

This warning shall be printed on the most visible surface of the unit packet and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

Member States may determine the positioning of the warning on that surface in order to accommodate language requirements.

5. The general warning required pursuant to paragraph 2(a) and the warning for smokeless and oral tobacco products referred to in paragraph 4 shall cover not less than 30% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 32% for Member States with two official languages and 35% for Member States with three official languages. The additional warning required pursuant to paragraph 2(b) shall cover not less than 40% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. That proportion shall be increased to 45% for Member States with two official languages and 50% for Member States with three official languages.

However, in the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm^2, the warnings referred to in paragraph 2 shall cover an area of at least 22.5 cm^2 on each surface. That area shall be increased to 24 cm^2 for Member States with two official languages and 26.25 cm^2 for Member States with three official languages.

6. The text of warnings and yield indications required under this Article shall be:

(a) printed in black Helvetica bold type on a white background. In order to accommodate language requirements, Member States shall have the right to determine the point size of the font, provided that the font size specified in their legislation is such as to occupy the greatest possible proportion of the area set aside for the text required;

(b) in lower-case type, except for the first letter of the message and where required by grammar usage;

(c) centred in the area in which the text is required to be printed, parallel to the top edge of the packet;

(d) for products other than those referred to in paragraph 4, surrounded by a black border not less than 3 mm and not more than 4 mm in width which in no way interferes with the text of the warning or information given;

(e) in the official language or languages of the Member State where the product is placed on the market.

7. The printing of the texts required by this Article on the tax stamps of unit packets shall be prohibited. The texts shall be irremovably printed, indelible and shall in no way be hidden, obscured or interrupted by other written or pictorial matter or by the opening of the packet. In the case of tobacco products other than cigarettes, the texts may be affixed by means of stickers, provided that such stickers are irremovable.

8. Member States may stipulate that the warnings referred to in paragraphs 2 and 4 are to be accompanied by a reference, outside the box for warnings, to the issuing authority.

9. To ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined.

The technical measures to apply this provision shall be adopted in accordance with the procedure laid down in Article 10(2).

Article 6

Further product information

1. Member States shall 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.

This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products. It shall indicate their function and category. The list shall also be accompanied by the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to

their effects on health and taking into account, *inter alia*, any addictive effects. The list shall be established in descending order of the weight of each ingredient included in the product.

The information referred to in the first subparagraph shall be provided on a yearly basis and for the first time by 31 December 2002 at the latest.

2. Member States shall ensure the dissemination of the information provided in accordance with this Article by any appropriate means, with a view to informing consumers. Due account shall nevertheless be taken of protection of any information on specific product formulae which constitutes a trade secret.

3. Member States shall ensure that the list of ingredients for each product, indicating tar, nicotine and carbon monoxide yields, is made public.

4. Each year Member States shall communicate all data and information submitted pursuant to this Article to the Commission, which shall take account thereof when drawing up the report referred to in Article 11.

Article 7

Product descriptions

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.'

9. Article 13 of the Directive sets out the powers and obligations which apply once the Directive has come into force. It provides as follows:

'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.'

B — *The legal basis of and the preamble to the Directive*

10. Articles 95 EC and 133 EC were chosen as the legal basis of the Directive. It should be noted in this connection that Article 133 EC was added at a late stage in the adoption procedure by the European Parliament. The Commission proposal contained only one legal basis, namely Article 95 EC.

11. In the preamble Article 95 EC, or at least the removal of obstacles to the operation of the internal market, is given central prominence as the legal basis. The second and third recitals state that 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. Those barriers must be eliminated. The fourth recital goes on to state that, in accordance with Article 95(3) EC, priority must be given to public health in view of the particularly harmful effects of tobacco.

12. Reference is also made in numerous other recitals to (potential) obstacles to the internal market. In particular, I would mention:

— the first sentence of the seventh recital: '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.';

— the first and second sentences of the ninth recital: '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.'

13. Only the 11th recital in the preamble to the Directive relates to exports, and thus also to Article 133 EC. That recital provides: '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.'

14. The reasons for maximum yields of specified harmful products (Article 3 of the Directive) are set out in the fifth, seventh and ninth recitals. With regard to tar, Directive 90/239 (hereinafter: 'Directive 90/239') [6] lays down the maximum amounts for tar yields of cigarettes marketed in the Member States. A further reduction follows from the carcinogenic nature of tar. Regarding carbon monoxide, 'cigarettes have been shown to produce amounts of carbon monoxide which are hazardous to human health and capable of contributing to heart disease and other ailments'. Nicotine, according to the ninth recital, raises specific public-health problems.

15. The 19th recital sets out grounds for Article 5 of the Directive, stating that: '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.'

16. In connection with the interpretation of Article 7 of the Directive — the second question posed by the referring court — the 27th recital is relevant: 'The use on

6 — OJ 1990 L 137, p. 36.

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.'

C — *The judgment in Case C-376/98 on tobacco advertising*

17. In the examination of the present case, the *tobacco advertising* judgment of 5 October 2000 in Case C-376/98, which resulted in the annulment of Directive 98/43, plays a significant role. The question arises as to what bearing that judgment of the Court has on the present Directive, which also seeks to reduce tobacco consumption and is — at least in the main — based on Article 95 EC. For that reason I shall set out here, as part of the legal framework, the main findings in that judgment.

18. It its judgment the Court laid down the conditions under which Article 95 EC can serve as a legal basis for the harmonisation of product requirements. [7] In summary form these conditions are as follows:

— The measures must improve the conditions for the establishment and functioning of the internal market. Article 95 EC does not confer any general power to regulate the internal market.

— The measures must have as their object the removal of obstacles to the exercise of fundamental freedoms or the removal of distortions of competition.

— There must be a serious risk. Article 95 EC may be used to prevent the emergence of future obstacles to trade resulting from multifarious deve-

7 — See paragraphs 83, 84, 86, 88 and 100 of the judgment.

lopment of national laws. However, the emergence of such obstacles must be probable and the measure in question must be designed to prevent them.

— A directive may incorporate provisions which contribute only indirectly to the removal of obstacles. These are provisions which are necessary to prevent the circumvention of prohibitions directly involving the removal of obstacles.

— Distortions of competition are, according to established case-law, relevant only if they are appreciable.

— The Court regards as a distortion of competition any restriction of forms of competition applicable to all market participants in a Member State, for instance through the fact that a particular course of action is prohibited. Such a distortion does not by itself justify Article 95 EC as a legal basis for the general application to the entire European Union of a stringent prohibition existing in one Member State.

19. If the conditions governing the use of Article 95 EC are met, the protection of public health may be a decisive factor in the choices to be made.

20. Regarding the measure adopted, it must be ascertained whether this makes a meaningful contribution to the elimination of obstacles to free movement and of distortions of competition.

21. The examination in regard to free movement provided the following results. The Court took the view that the advertising rules for printed media are authorised under Article 95 EC, while the prohibition of advertising on, *inter alia*, posters, parasols and ashtrays, and the prohibition of advertising spots in cinemas have no effect on free movement. The Court apparently proceeded on the assumption that these latter cases involve more or less local markets, which, in my view, considering the international nature of the market in tobacco, of which the production of and trade in advertising hoardings form part, is hardly self-evident. The Court attached importance to the fact that the conditions governing advertising hoardings are minimum conditions; the Member States may impose more stringent requirements. There was no provision relating to free movement. Consequently — as I understand the view taken by the Court — the Directive could not make any actual contribution to the elimination of obstacles to free movement.

22. The examination in the area of competition resulted in the following conclusion: Article 95 EC is not appropriate to eliminate a distortion of competition by restricting even further competition within the whole Community.

23. A final point of importance is that the Court did not in that case consider that it had the power to annul the directive in part, in view of the general nature of the prohibition laid down by the directive.

III — Facts and procedure

A — *The main proceedings*

24. The claimants in the main proceedings, British American Tobacco (Investments) Ltd and Imperial Tobacco Ltd ('the claimants'), manufacture tobacco products in the United Kingdom. They are among the largest manufacturers of tobacco products in the world. They operate in 180 countries and have a global market share of 15.1%. They have more than 80 factories in over 64 countries and manufacture 800 billion cigarettes annually. The claimants employ 80 000 people worldwide. Their most prestigious international brands are Lucky Strike, Kent, Dunhill and Pall Mall. Other major brands include Rothmans, Peter Stuyvesant, Benson & Hedges and John Player Gold Leaf. [8] Implementation of the Directive, so the claimants argue, will have considerable impact on their activities and those of their subsidiaries.

25. On 3 September 2001 the claimants brought proceedings before the High Court of Justice in which they sought leave to apply for judicial review of the intention and/or obligation of the United Kingdom Government to transpose the Directive into national law. During the hearing before the Court the question arose in this connection as to the meaning of section 2(2) of the European Communities Act. The claimants submitted that that provision empowers the United Kingdom Government to give effect to its Community obligations. The claimants sought a declaration from the national court that the exercise by the United Kingdom Government of its powers under the European Communities Act was *ultra vires* inasmuch as the Directive is *per se* invalid. The United Kingdom Government was for that reason under no Community-law obligation such as could justify the exercise of those powers.

26. By order of 26 February 2002 the High Court of Justice granted leave to Japan Tobacco Inc. and JT International SA to intervene in the main proceedings.

8 — Information obtained from the claimants' website.

27. Japan Tobacco Inc. states that its submissions relate to Article 7 of the Directive and in particular to the pleas in law put forward by the claimants in the main proceedings.

28. Japan Tobacco Inc. is one of the largest cigarette manufacturers in the world. JT International SA is a subsidiary of Japan Tobacco Inc. JT International SA manufactures cigarettes in its factory in Germany and distributes the cigarettes to the 15 Community Member States. Japan Tobacco Inc. is also the owner of the Mild Seven trademark. It claims that Mild Seven is the second largest cigarette brand in the world. JT International SA holds the exclusive licence for that trademark. Sales of Mild Seven represent more than 40% of the total sales of Japan Tobacco Inc. [9]

29. The claimants put forward seven grounds for the invalidity of Directive 2001/37/EC and these are set out in the seven sections of the first question submitted for preliminary ruling.

9 — Japan Tobacco Inc. and JT International SA shall henceforth be referred to in this Opinion as 'Japan Tobacco'.

B — *The questions submitted for preliminary ruling*

30. By order of 6 December 2001, received at the Court Registry on 19 December 2001, the High Court of Justice (Administrative Court) accordingly referred the following questions 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 and/or 133 EC as a legal basis;

(b) the use of Articles 95 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?'

C — *Procedure before the Court*

31. Pursuant to Article 20 of the Protocol on the EC Statute of the Court of Justice, written observations were submitted by: the claimants, Japan Tobacco, the European Parliament, the Council and Commission, and by the Governments of Belgium, Germany, Finland, France, Greece, Italy, Luxembourg, the Netherlands, the United Kingdom and Sweden. At the hearing before the Court on 2 July 2002 the claimants, Japan Tobacco, the European Parliament, the Council and Commission, and the Governments of Belgium, Germany, Finland, France, Greece, Ireland, Italy, Luxembourg, the Netherlands and the United Kingdom presented oral argument in support of the forms of order respectively sought.

D — *Preliminary point*

32. The Parliament notes that the claimants in the main proceedings have contended that their argument finds support in confidential advice regarding the draft Directive provided by the Parliament's Legal Service. Two separate opinions from the Legal Service were also annexed to the witness statements of the claimants in the main proceedings. The claimants further reinforce their viewpoint with an opinion from the Parliament's Legal Committee.

33. The Parliament requests the Court not to take any account of these opinions or of the documents in which those opinions are cited or referred to. The Parliament refers in this connection to the Opinion of Advocate General Jacobs in *Spain* v *Council*, [10] in which he found that, in the absence of express authorisation by a Community

10 — Opinion in Case C-350/92 *Spain* v *Council* [1995] ECR I-1985. Advocate General Jacobs also takes the view that the same principle applies where no documents of the Legal Service have been produced but the pleadings merely contain references to the position which the Legal Service is alleged to have taken.

institution, an opinion of the Legal Service of that institution cannot be invoked before the Court either directly or indirectly. To do so would be prejudicial to the public interest in the provision of independent legal advice. The Parliament also refers to the order of the President of the Court of First Instance in *Carlsen*, [11] which makes it clear that the diffusion of opinions given by the Legal Service may generate uncertainty with regard to the legality of Community measures and may impact negatively on the operation of Community institutions. The stability of the Community order and the proper functioning of the institutions — general interests, compliance with which must be positively guaranteed — would be adversely affected by such diffusion.

34. I take the view that legal opinions delivered in the course of the adoption of Community legislation need not remain secret in all cases. Divulgation of such opinions also has an important advantage in that it increases the transparency of the process governing the adoption of Community legislation. This, however, does not mean that all opinions and advice must be made public. I draw a distinction in this regard between, on the one hand, internal advice proffered by legal services, which must be capable of being given freely for the purpose of determining the internal standpoint of an institution and, on the other hand, more formal, external advice such as that given in certain Member States by a Council of State. In the case of this latter type of advice, I see no reason whatever for maintaining secrecy. However, in the case of internal advice also, such advice may also be rendered public, for whatever reason. Parties in proceedings such as the present would of course then be free to make use of the arguments set out in opinions of that kind. This does not, however, mean that an institution can be bound by the internal views expressed by its Legal Service.

35. In the present case, the documents in question need not be taken into account for the purpose of ascertaining the intention of the Community legislature. I further propose that the Court take note, when examining this case, of the fact that these opinions do not represent the viewpoint of the European Parliament. The request made by the European Parliament does not require further consideration.

IV — The particular character of the proceedings and the issue of admissibility

36. The present case is particular in character inasmuch as the Court is being called on for the first time to rule on the admissibility of preliminary questions concerning the validity of a directive which have been raised, during the implementation phase, by affected parties in proceed-

11 — Order in Case T-610/97 R *Carlsen and Others* v *Council* [1998] ECR II-485. See also Case T-44/97 *Ghignone* v *Council* [2000] ECR-SC I-A-223 and II-1023.

ings before a national court. The situation here in issue also arose in the case of *Imperial Tobacco and Others*;[12] in that case, however, the Court did not have to rule on admissibility as the case no longer served any purpose after the directive in issue had been declared invalid by the judgment of 5 October 2000.[13] In its judgment in *SMW Winzersekt*[14] the Court replied to a somewhat similar question. That case involved a provision in a regulation that was applicable only once a transitional period had expired. The applicant in the main proceedings in that case was not, the Court ruled, obliged to wait until the expiry of the transitional period before being able to argue before the national courts that the provision in question was not applicable.

37. The French Government and the Commission contest the admissibility of the present case. The French Government points out that a directive cannot by itself impose obligations on individuals. It refers specifically to the judgment in *Salamander and Others* v *Parliament and Council*,[15] in which the Court of First Instance ruled that a directive which requires Member States to impose obligations on economic operators is not of itself, before the adoption of national transposing measures and independently of them, such as to affect directly the legal position of those economic operators. Any harm incurred by individuals during the implementation period thus has a bearing only on their factual situation and is not based on Community law. The Commission also takes the view that it is not necessary to rule on the validity and interpretation of a directive before the period for its implementation has expired. Further: if an individual was able, before the expiry of the implementation period, to challenge the validity of a directive before national courts, that could be considered as constituting a circumvention of Article 230 EC and a failure to follow the proper avenues of legal redress laid down in the EC Treaty.

38. In my opinion the Court's established case-law on the admissibility of questions referred for preliminary ruling provides the answer in the present case with regard to questions concerning the validity of a directive which were submitted during the period set for implementation of that directive.

39. Essentially, the established case-law of the Court states that, where questions referred by the national court or tribunal concern the interpretation of a provision of Community law, the Court is, in principle, obliged to reply to those questions. A reference by a national court or tribunal may be rejected only if it appears that the procedure laid down by Article 234 EC has

12 — Case C-74/99 *Imperial Tobacco and Others* [2000] ECR I-8599.

13 — Case C-376/98, cited in footnote 3.

14 — Case C-306/93 *SMW Winzersekt* [1994] ECR I-5555.

15 — Joined Cases T-172/98, T-175/98, T-176/98 and T-177/98 *Salamander and Others* v *Parliament and Council* [2000] ECR II-2487, paragraph 54.

been misused, either in order to elicit a ruling from the Court by means of a contrived dispute or where it is obvious that Community law cannot apply, either directly or indirectly, to the circumstances of the case. [16]

40. The Court thus construes broadly its obligation to reply to a question submitted for preliminary ruling, referring consistently to the fact that the Article 234 EC procedure is an instrument of cooperation between the Court and national judicial bodies. Consequently, so the Court holds, it is exclusively for the national court or tribunal which is seised of a case and is responsible for the decision to be given to decide, in the light of the special features of the specific case, whether a preliminary ruling is necessary to enable it to give a decision, and to decide on the legal relevance of the questions which it submits to the Court.

41. In other words, it is the national court — and thus not the Court of Justice — which decides whether it is appropriate to refer questions for a preliminary ruling. The only conditions are that the dispute must not be contrived and the questions must concern the application of Community law.

42. In my view, these points are beyond any doubt. First, there is under national law a genuine dispute concerning the authority of the United Kingdom Government to apply section 2(2) of the European Communities Act. Second, the questions concern the application of Community law. The dispute, indeed, does not relate to draft Community legislation but rather to a directive which has been adopted and which, in accordance with its Article 16, entered into force on the day of its publication. The content of the Directive and the obligations rising under it on expiry of the implementation period are thus fixed and ascertained.

43. This finding — as the Commission points out — is not affected by the Court's judgment in *Vaneetveld*. [17] The Court there held that individuals can invoke a directive before national courts only after the period laid down for its transposition into national law has expired. Before that period has expired, a directive cannot create rights for an individual which national courts must protect. No obligations whatever can arise under a directive for an individual during that period. It is only on the Member States that clearly defined obligations devolve at that time. They must transpose the directive into national law and must also refrain from taking measures liable seriously to compromise the result prescribed by the directive. [18]

16 — See, for example, Case C-130/95 *Giloy* [1997] ECR I-4291, paragraph 20 et seq.

17 — Case C-316/93 *Vaneetveld* [1994] ECR I-763.

18 — Case C-129/96 *Inter-Environnement Wallonie* [1997] ECR I-7411.

44. This, however, does not mean that there is no objective need [19] for an answer to the questions submitted for preliminary ruling and that one can thus speak of a contrived dispute, in which case the Court would not be required to reply.

45. Furthermore, there can be no doubt that the claimants have an interest in securing a response to the questions submitted. That interest lies on the fact that they require certainty as regards the rights and obligations fundamental to the operation of their business which will be devolving on them in the near future. In addition, it may be presumed that they will need to adopt certain measures for operational purposes even before the expiry of the period set for implementation. The Court need not evaluate the content or scope of that requirement; under the preliminary reference procedure, that evaluation is reserved to the national courts. This is precisely the difference between the preliminary reference procedure and direct actions brought before the Community Courts under Article 230 EC. [20] Merely for the sake of completeness, I would also point out that there is also no doubt but that the claimants' interest is significant. Likewise, I take issue with the French Government's argument that the claimants' interest is factual in nature and is not based on Community law. That argument strikes me as being not only incorrect [21] but also as being of no relevance to the Court inasmuch as the assessment of that interest is a matter for the national court.

46. I accordingly conclude that the Court must answer the questions which the High Court has referred to it for a preliminary ruling. I would point out that this conclusion is in line with that chosen by the Court in the somewhat analogous case of *SMW Winzersekt*. [22]

47. It ought, however, to be pointed out that a different conclusion — leading to inadmissibility — would mean that the Community legal order does not provide effective safeguards for the claimants' rights. As a result, no account would be taken of this important general principle of law that has been consistently recognised by the Court [23] as underlying the constitutional traditions common to the Member States. This principle of law is laid down in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms ('the ECHR') and is expressed for the European Union in Article 47 of the Charter of Fundamental Rights.

19 — The Court deals with this criterion in its judgment in Case C-415/93 *Bosman* [1995] ECR I-4921, paragraph 65.

20 — See also, in this connection, paragraph 32 of the Opinion of Advocate General Fennelly in Case C-74/99 *Imperial Tobacco and Others*, cited in footnote 12.

21 — See paragraph 37 of the present Opinion.

22 — See paragraph 36 of the present Opinion.

23 — See, for example, Case 222/84 *Johnston* [1986] ECR 1651.

48. In connection with the requirement of effective legal remedies, I would first of all refer to the following: the preliminary reference procedure forms part of a corpus of provisions designed to offer the necessary legal protection to individuals. In addition to the preliminary reference procedure, provision is made for direct actions which every natural or legal person may, under specified conditions, bring before the Court of First Instance.

49. However, under Article 230 EC the validity of a directive can be examined only in a direct action brought by a Member State, the Council or the Commission.[24] Natural and legal persons have no right under that article to bring an action before the Court concerning the validity of a directive. The fourth paragraph of Article 230 EC refers only to decisions and — in one specific circumstance — regulations.

50. It must be inferred from the fact that the fourth paragraph of Article 230 EC sets out unequivocally the cases in which natural and legal persons have a right of action that the Community legislature expressly chose not to confer any direct right of access to the Community Courts in a case such as the present. This is also in line with the Court's case-law, in which the Court imposes stringent requirements as to the particular interest that individuals must have in order to be able to institute proceedings before the Community Courts.[25] Persons concerned have *locus standi* to bring an action only if a 'decision affects them by reason of certain attributes which are peculiar to them, or by reason of factual circumstances which differentiate them from all other persons and thereby distinguish them individually in the same way as the person addressed'.[26] According to this case-law, the claimants in the main proceedings have no right of action in that they are not differentiated from other manufacturers of tobacco products affected by the Directive. In brief, therefore, even if the fourth paragraph of Article 230 EC had referred to directives, the claimants would still not have any right of action under that article.

51. The Court's restrictive interpretation is based on, *inter alia*, the argument that an individual can bring a matter before the national courts, which can then submit questions for a preliminary ruling. The entitlement of individuals to have their rights vindicated effectively can be guaranteed through the preliminary reference procedure.[27] However, Community law must also of course not close off the

24 — And, in special cases, by the European Parliament, the Court of Auditors or the ECB.

25 — For a review of this case-law, see the Opinion of Advocate General Jacobs in Case C-50/00 P *Unión de Pequeños Agricultores (UPA)* [2002] ECR I-6677.

26 — Case C-321/95 P *Greenpeace Council and Others* v *Commission* [1998] ECR I-1651, paragraph 7, recently confirmed in the judgment in Case C-50/00 P *Unión de Pequeños Agricultores (UPA)*, cited in footnote 25, paragraph 44.

27 — For the reasoning of the Court, see in particular the judgment in Case C-50/00 P *Unión de Pequeños Agricultores (UPA)*, cited in footnote 25, paragraph 38 et seq. In this the Court thus takes a diametrically opposite approach to the Commission, which argued that making the preliminary reference procedure available actually interferes with the system of legal redress in the EC Treaty.

preliminary reference avenue and thereby create a juridical vacuum. I consider this separately from the issue whether this restrictive interpretation by the Court of the fourth paragraph of Article 230 EC satisfies in full the fundamental entitlement of individuals to access to the courts. In this connection, Advocate General Jacobs, in his Opinion in *UPA*,[28] has, correctly in my view, raised serious doubts.

52. Second, I consider that the principle of legal certainty also has a role to play. In a properly functioning legal system an affected party should have as much certainty as possible regarding the rights and obligations applicable in its regard. This is *a fortiori* the case in regard to obligations which may have a significant bearing on that party's conduct of its business. I attach no significance to the fact that the case involves rights and obligations which are not yet in force at a given moment but which will certainly be entering into force shortly after.

53. It is settled that, under the EC Treaty in preliminary ruling proceedings, the legal validity of a directive may be brought for decision before the Court in connection with proceedings instituted before a national court by an affected party harbouring well-founded doubts as to its validity in law. In my view, it would be contrary to the principle of legal certainty if Community law were to be construed as meaning that an affected party must wait until the expiry of the implementation period before being entitled to use this avenue of legal redress.

54. Third, a finding of inadmissibility in the present case could result in the parties concerned suffering damage, given that they must already take measures to adapt their production, should it later transpire that the Directive is invalid. The parties affected would then have to attempt to recover compensation for any resulting damage from the Member State which adopted the implementing legislation, or directly from the European Community. The second paragraph of Article 288 EC offers a possibility in this regard.

55. According to established case-law, the Court imposes stringent conditions on the award of compensation on grounds of unlawful legislation. I need not here address in detail the question of what prospects of success such an action for compensation against the European Community might have. I do not consider this to be excluded, certainly not if the invalidity arises from the fact that the Community legislature has adopted a measure which, under the EC Treaty, it has no power to adopt by reason of the absence of a legal basis.

28 — See footnote 25. In its judgment of 3 May 2002 in Case T-177/01 *Jégo-Quéré* v *Commission* [2002] ECR II-2365, the Court of First Instance has also already given a broader interpretation.

56. It is more significant if a ruling of inadmissibility, followed by a subsequent declaration, in new proceedings, that the Directive is invalid were to result in damage for the parties concerned that is outwith their control. The issue of whether — before invalidity has been determined — the necessary measures have been taken to meet the requirements of the Directive is not based on the choice made by an undertaking, but on a legal obligation.

57. A system of legal remedies should be established in such a way that it makes provision to prevent, so far as possible, damage arising or at least to limit the extent of the damage. To put it in other words: it cannot be correct to construe the provisions of the EC Treaty guaranteeing judicial access in such a way as to exclude the possibility for individuals to limit such damage.

V — Contextual factors

A — *General*

58. This case does not stand by itself. The decision in this case will be determined to a significant degree by the context of the case. First of all there is the factual context in which the manufacture, marketing and consumption of tobacco products take place. It was this factual context which formed the basis on which the Directive was drawn up. The drafting of the Directive comes under this as the second point for examination. The third point which I consider to be relevant is represented by the substantive changes resulting from the Directive. The composition and labelling of tobacco products has, indeed, for a long time been the subject of intervention by the Community legislature.

B — *The factual context*

59. A great deal of information has been provided to the Court in these proceedings regarding the risks associated with tobacco consumption, in the form, *inter alia*, of extensive medical and scientific reports and photographs of victims. I do not consider it to be the Court's function to form an in-depth view on the precise consequences of smoking. Suffice it here to confirm that the grave nature of those consequences is really no longer a matter of dispute and that social views on tobacco consumption have altered significantly. Both of these developments follow on from the increase in scientific knowledge of the harmful consequences of smoking. Many people, particularly young people, continue none the less to smoke.[29]

29 — The communication from the Commission to the Council and the European Parliament on the present and proposed Community role in combating tobacco consumption (COM/96/0609 Final) of 18 December 1996 is based on the fact that — in 1996 — more than 40% of the adult population of the European Union still smoked.

60. Policy both at the European Union level and in several Member States is at present based on two pillars. The first pillar comprises measures designed to discourage smoking as much as possible, with particular emphasis on young people, while the second concerns measures to limit as much as possible the deleterious effects which smoking can have. The labelling obligation in the Directive provides an example of the policy being pursued in the first pillar, while the obligation as to composition gives expression to the second pillar. The Commission further points out that a more far-reaching measure — a total ban on tobacco products — might well be justified by the dangers represented by smoking but would not be feasible on practical grounds and for fiscal and political reasons.

61. That brings me to the market for tobacco products, particularly cigarettes. This market is becoming ever increasingly transnational. [30] Local preferences play an ever decreasing role; a limited number of major cigarette brands dominate the market. The concentration with regard to the tobacco industry is even greater: [31] the major players frequently market several brands. The transnational nature of the cigarette market does not mean that a single market has been created with a level playing field. On the contrary, the market is regulated to a significant degree by national authorities. National excise duties, *inter alia*, have resulted in considerable price differences and the rules governing advertising also vary considerably.

62. The significant price differences have resulted in this market becoming susceptible to illegal commerce and smuggling. A report compiled by the World Bank in 1999 [32] estimated that 30% of cigarettes exported internationally, that is to say, approximately 355 billion cigarettes, are lost to smuggling.

63. In trade between Member States of the European Union and non-member countries, illegal commerce and smuggling also constitute a major activity, a fact not disputed in the present proceedings. Views do, however, diverge as to the extent of smuggling of cigarettes that are manufactured within the European Union and

30 — According to Eurostat figures for 1999, inter-State commerce within the European Union has significant proportions (export value within the EU: ECU 3 626 419 070), set against the total value of cigarettes sold in the European Union, which comes to ECU 14 275 426 293. Exports from the European Union to non-member countries also have a relatively high value of ECU 1 667 025 670. However, imports to the European Union from non-member countries are significantly limited (ECU 10 627 240). See ep16va, Annual value data (NACE 16: Manufacture of tobacco products), Eurostat, 1999.

31 — Eurostat figures also show that in 2000 46 manufacturing units were established within the European Union. Of these, 4 were established in Belgium, 7 in Germany, 6 in Greece, 6 in Spain, 3 in Ireland, 1 in Luxembourg, 4 in the Netherlands, 3 in Portugal and 4 in the United Kingdom.

32 — Curbing the Epidemic, Governments and the Economics of Tobacco Control, Washington D.C., 1999, p. 63.

consequently (whether or not after exportation and re-importation) placed illegally on the European market, or of cigarettes originating in non-member countries.

64. Thus, the Luxembourg Government states that 97% of cigarettes illicitly imported into the European Union come from non-member countries, the German Government cites the same percentage for clandestine imports into Germany, and the claimants in the main proceedings aver that 85% of cigarettes illegally in Europe come from non-member countries. The Commission, on the other hand, states that, of the illegal cigarettes to be found in the European Union, the percentage of those manufactured within the European Union is significantly greater than 15%.

65. Cigarette smuggling is for all Member States and many non-member countries a problem giving rise to serious losses for the Community and national budgets, according to the most recent report of activities of OLAF. [33] Fraudulent operators in the cigarette sector are active world-wide and have considerable funds and a highly sophisticated infrastructure at their disposal. Cigarette fraud generally occurs in practice along the same lines: most cases involve false declarations, circumvention of rules and pure smuggling. If more stringent checks on the origin of cigarettes are introduced in one Member State or non-member country, fraudulent operators will transfer their activities to another Member State or non-member country. Because enormous profits stand to be made, criminals are prepared to store or transport cigarettes over considerable periods in the hope that the attention of the investigation services will slacken before they fraudulently import the cigarettes into the Community. [34] The report also states that, in the case of cigarette smuggling, the cigarettes are first stored in the European Union before being exported to non-member countries (or declared as being exported).

66. In these proceedings, attention must also be paid to the economic importance of the tobacco sector in the European Union, with particular reference to the cultivation of tobacco — which occurs mainly in a number of southern Member States — and its industrial processing. The Directive may impact adversely on this sector. According to the claimants, if the Directive is applicable to exports, this will result in the loss of 1 800 to 3 000 jobs within their own undertakings alone.

33 — Report of the European Anti-Fraud Office, Activities Report for the period from 1 June 2000 to 31 May 2001, pages 26 and 27.

34 — According to the annual report for 1998, Andorra has since 1996 been the major country for the smuggling of cigarettes into the European Union. See *Protecting the Communities' financial interests and the fight against fraud*, Annual Report 1998, p. 19.

C — *The background to the Directive*

67. The Directive has a long prior history. The most important measures in the Directive (Articles 3 to 7 inclusive) were already mentioned as options in the Commission's communication of 18 December 1996.[35] In that communication, the Commission proposed a series of measures to intensify efforts designed to prevent smoking within the Community.

68. That communication was followed by, *inter alia*, a Parliament resolution[36] in which the Parliament recommended careful monitoring of developments in the display of nicotine levels on packets throughout the Community. The Commission was also requested to evaluate the effectiveness of the health warning on packages. The Parliament further condemned the European Union's export to non-member countries of poor quality tobacco not meeting European standards, thereby contributing to health problems in countries which already have a low level of public health.

69. Subsequent to the comments of the European Parliament and the Council, the Commission, in October 1999, submitted a report[37] on the follow-up to its 1996 communication. That report contains an analysis of Member States' policy and practices in regard to a series of measures designed to counter tobacco consumption.

70. In its conclusions on combating tobacco consumption,[38] the Council underlined the need to develop an overall strategy comprising an effective system to monitor tobacco consumption, tobacco policies and their effects throughout the Community as well as the implementation of Community legislation. A number of the measures proposed in those conclusions have been developed in greater detail in a recent Commission proposal[39] on combating tobacco consumption. In particular, individual initiatives have been taken to protect minors, including legislation on conditions of sale and sales through electronic means and vending machines.

71. The efforts exerted by the European Community in the fight against smoking date back much further. As far back as 1985, the European Council, meeting in Milan, stressed the need to launch a programme of action against cancer. The

35 — See footnote 29.

36 — Resolution on the Commission communication to the Council and the European Parliament on the present and proposed Community role in combating tobacco consumption (OJ 1998 C 14, p. 197).

37 — Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions — Progress achieved in relation to public health protection from the harmful effects of tobacco consumption (COM(1999) 407 final).

38 — Council conclusions of 18 November 1999 on combating tobacco consumption (OJ 2000 C 86, p. 4).

39 — Proposal for a Council recommendation on the prevention of smoking and on initiatives to improve tobacco control (COM(2002) 303 final).

programme of action came into being on 7 July 1986[40] with the objective of contributing to an improvement of the health and quality of life of Community citizens by reducing the incidence of cancer. This programme of action stated that priority should be given to combating smoking. It was in order to give effect to this programme of action that the first harmonising directives with regard to tobacco consumption were adopted.

72. The background to the adoption of the Directive must also be considered in the light of developments at international level. A number of western countries outside the European Union have considerably tightened up their legislation over the last number of years. Canada is frequently cited as an example in this process, its health warnings being significantly stricter than the provisions proposed in the Directive.

73. Discussions are also ongoing within the World Health Organisation in regard to a framework convention on tobacco control.[41] Both the Commission and the Member States are taking part in these discussions. It is evident from the minutes of the negotiations[42] that the tobacco industry is being kept informed of the discussions on a framework convention and is in a position to set out its views on that convention.

74. In summary, the restrictions which the Directive imposes on the composition, labelling and designation of tobacco products have not been totally unexpected. They have an extensive prior history in which the tobacco industry has been closely involved. All of this means that the manufacturers of tobacco products in the European Union — as well as the importers of tobacco products — have had the opportunity to adopt in good time the measures needed to limit any potential harm to their interests resulting from the Directive.

D — *What substantial changes result from the Directive?*

75. Commerce in tobacco products is already the subject of Community provisions linked to the health risks posed by smoking. Those provisions are to be found in the following directives:

— Council Directive 89/622/EEC of 13 November 1989 on the approximation of the laws, regulations and

40 — OJ 1986 C 184, p. 19.

41 — Extensive material relating to this issue is available on the WHO's website at www.who.int.

42 — These can be found on the WHO's website.

administrative provisions of the Member States concerning the labelling of tobacco products (hereinafter 'Directive 89/622');[43]

— 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;

— The directive on television without borders[44] bans television advertising of tobacco products.

Also in force was Directive 98/43 on advertising and sponsoring for tobacco products. As stated above, this directive has now been annulled by the Court.

76. This existing Community legislation is rendered more stringent by the present Directive. That is the case both with regard to the provisions on labelling — the seriousness of the warnings for smokers has been increased — and to the provisions on composition. In addition to lower maximum tar yields, maximum levels are now also in force for nicotine and carbon monoxide yields. Furthermore — and this is an entirely new feature in the legislation — the maximum yields now also apply to cigarettes manufactured in the Community for export to non-member countries.

77. The Directive also imposes two obligations which must be regarded as novel. Article 6 provides for publication of product composition via the authorities of the Member States. Article 7 prohibits the use of certain designations which may have a suggestive effect, such as 'mild', 'light' or 'ultra-light'. This prohibition applies even if the designation concerned has been registered as a trademark or as part of a trademark.

VI — Examination of the first question: the legal basis chosen

A — *Introduction and approach*

78. The first question submitted by the national court is central to the present proceedings. The High Court mentions in

43 — OJ 1989 L 359, p. 1. This directive was extensively amended by Directive 92/41/EEC (OJ 1992 L 158, p. 30).

44 — Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities (OJ 1989 L 298, p. 23), as amended by Directive 97/36/EC.

its question a series of factors which may cast doubt on the legal validity of the Directive.

79. The Governments of the United Kingdom, Belgium, Finland, France, Ireland, Italy, the Netherlands and Sweden, together with the Parliament, the Council and the Commission, take the view that the Directive is valid. In contrast, the claimants in the main proceedings and the Governments of Greece and Luxembourg consider that the Directive is invalid in its entirety. The claimants argue that the purpose of the Directive is not to improve the conditions for the establishment and functioning of the internal market. Nor, in so far as Article 133 EC has been employed as a legal basis, does the Directive serve the objective of introducing a common commercial policy. The Luxembourg Government argues that the Directive's sole purpose is to safeguard public health. Harmonisation cannot be authorised for that reason. The Greek Government calls the validity of the Directive into question with regard to the exportation of cigarettes. In the opinion of Japan Tobacco, Article 7 of the Directive is invalid. While not expressing any views on the validity of other provisions of the Directive, the German Government submits that the provisions of Article 3(1) and (2) are invalid on the ground that this article prohibits the manufacture of cigarettes intended for export.

80. To begin my examination of the first question, I shall address the issue of the legal basis, as set out in points (a) and (b) of the question. Are the European Parliament and the Council authorised to harmonise product norms in such a way as envisaged by the Directive? The question whether, by virtue of its content, the Directive may infringe certain principles of law will be addressed in section VII of this Opinion.

81. In this approach I shall follow the order in which the question has been posed by the High Court. A significant portion of the proceedings relates not so much to the Directive as a whole as to the legal validity of the various obligations laid down in Articles 3 to 7 inclusive. The approach chosen means that some of these obligations will be addressed at more than one point. Essentially, however, I shall draw a distinction between, on the one hand, the requirements governing composition (Article 3 in conjunction with Article 4 of the Directive), in which the legal basis chosen is a matter for discussion and, ancillary thereto, *inter alia*, proportionality, and, on the other, the obligations relating to labelling and the provision of information (Articles 5 to 7 inclusive), with regard to which the discussion will concentrate on proportionality and the right to property.

82. By extension from this, I would impose a further restriction. The Court does not, in my opinion, have to look separately at Articles 4 and 6 of the Directive.

83. With regard to Article 4: the determination of measurement methods follows necessarily from the requirement governing composition in Article 3. If measurement methods were not determined, there would be no sense in laying down maximum yields for tar, nicotine and carbon monoxide in cigarettes. This is not altered by the fact that Article 4(3) allows Member States further scope for prescribing measurements for other substances. Contrary to what appears to be the thrust of the claimants' argument, Article 4(3) does not constitute a separate barrier to trade. That provision merely confirms the policy scope available to the Member States in regard to a component that has not been harmonised by the Directive.

84. The reason for not paying separate attention to Article 6 of the Directive is of a different nature. No specific heads of complaint have been directed against Article 6 in the course of the proceedings. The claimants' argument that this article does not have any internal market objective but is designed rather to safeguard public health [45] is adequately addressed in section VI — C, separately from the provisions of Article 6 of the Directive.

45 — The claimants also refer to the 22nd recital in the preamble, which refers to transparency as being an objective.

B — *A preliminary comment on the legal basis*

85. In its adopted form the Directive is based on both Article 95 EC and Article 133 EC. Both of those legal bases cannot be regarded in the present case as being equivalent. The starting point for the Community legislature was Article 95 EC. Given that the Community legislature was not certain that Article 95 EC could also serve as a legal basis for regulating cigarettes intended for export from the European Union, Article 133 EC was added as a legal basis for this one particular aspect of the Directive.

86. The reasons given by the legislature for applicability of the Directive to exports can be found in the 11th recital in the preamble to the Directive. Of the provisions contained in that recital, only the final sentence is appropriate to form the basis for a rule. That final sentence refers to the desire to ensure that the internal market provisions are not undermined. At the hearing the Council and Parliament provided additional reasons. They argue that applicability to exports serves two objectives which are inextricably linked one to the other. The first objective, which justifies the legal basis of Article 95 EC, relates to the desirability of combating illegal trade and thereby protecting the internal market. The second objective concerns the exportation of cigarettes *in se*. Article 133 EC constitutes the legal basis for this. I proceed on the basis that the first objective alone has its origin in the recital.

87. When examining the propriety of the legal basis chosen, the Court ought to take account of the lack of equivalence between the two legal bases and of the grounds selected by the Community legislature. First of all, it is necessary to examine whether the Directive as a whole could have been based on Article 95 EC. Two questions are central to this examination:

— Can a measure which is (also) intended to safeguard public health be based on Article 95 EC?

— Can a measure which is based on Article 95 EC also relate to the manufacture of products intended for export to non-member countries?

A negative reply to the first question will result in the invalidity of the Directive; a reply in the negative to the second question will not *per se* have that result. The question will then arise as to whether Article 133 EC can serve as a supplementary legal basis for exports to non-member countries. However, even if the second question is answered in the affirmative, the Court will still have to examine Article 133 EC. Separate from the question whether the Community legislature required Article 133 EC as a supplementary legal basis, the fact remains that it did use that article as such.

88. The examination of the use made of Article 133 EC as a legal basis covers the following questions:

— In this case, is a dual legal basis, with Article 133 EC being used to supplement Article 95 EC, permissible in itself?

— Can Article 133 EC be used here as a legal basis for rules relating to the manufacture of products intended for export to non-member countries? In this connection, the Court must in any event bear in mind the content of the 11th recital in the preamble to the Directive.

— What consequences in law flow from the incorrect use of Article 133 EC, assuming that Article 95 EC can provide a legal basis for the entire Directive?

C — *Article 95 and the protection of public health*

1. Arguments submitted

89. The claimants argue that the Community legislature does not have the power to establish harmonisation measures in the domain of public health. Article 152(1) EC provides that a high level of human health protection must be ensured in the definition and implementation of all Community policies and activities. Article 152 EC goes on to set out in greater detail what the Community, in conjunction with the Member States and complementary to their action, may do within the area of public health. Article 152(4)(c) excludes measures of harmonisation. The Luxembourg Government shares this view taken by the claimants.

90. According to the claimants, the legal basis provided by Article 95 EC may be used only for the purpose of improving the establishment and functioning of the internal market. In this context, they regard the objectives mentioned in Article 95 EC as constituting means for promoting trade, not for restricting it. They point out that Directive 98/43 was annulled notwithstanding the fact that the preamble to that directive mentions preoccupations in the area of public health. The claimants contend essentially that the present Directive is a disguised public-health measure inspired by the same thinking as the draft version of the framework convention on tobacco control drawn up by the World Health Organisation, which is referred to in the 13th recital in the preamble to the Directive.

91. Realisation of the internal market cannot, in the claimants' view, be used in any way whatever as an argument in favour of the requirements which the Directive imposes in respect of tar. Indeed, Directive 90/239 harmonised in full the rules governing maximum tar yields. No further barriers to trade are permissible and there is therefore no power to reduce maximum tar yields even further with a view to realising the internal market. To this the claimants add the following. Even if the Community legislature were empowered to fix new rules on tar yields on health grounds, such rules would at least have to be supported by new developments based on scientific data.

92. The claimants submit that there is also no power in regard to maximum yields of nicotine and carbon monoxide in view of the fact that no concrete threat of barriers to trade can result from unilateral measures taken by Member States. In this connection, the ninth recital in the preamble,

which refers to differences in statutorily prescribed maximum nicotine yields, is factually incorrect.

93. This argument of the claimants concerning the power of the Community legislature to adopt, on the basis of Article 95 EC, harmonisation measures in connection with the protection of public health finds no support among the many other intervening parties in these proceedings. Those arguments have been contradicted in very large measure. This is the case with regard to both the arguments on competence in general and those which relate specifically to the Directive. There are, however, divergent views on the issue of what is the main objective of the Directive, and whether that main objective is the realisation of the internal market, the protection of public health, or, as the Irish Government submitted at the hearing, both of these together.

2. The case-law

94. In its judgment in *Netherlands* v *European Parliament and Council* (hereinafter: 'the *Biotechnology* judgment'), [46] the Court construed broadly the possibility of using Article 95 EC as a legal basis in a case where a measure is designed not merely to remove obstacles to the internal market. I quote: 'The legal basis on which an act must be adopted should be determined according to its main object... Whilst it is common ground, in that regard, that the aim of the Directive is to promote research and development in the field of genetic engineering in the European Community, the way in which it does so is to remove the legal obstacles within the single market that are brought about by differences in national legislation and case-law and are likely to impede and disrupt research and development activity in that field. Approximation of the legislation of the Member States is therefore not an incidental or subsidiary objective of the Directive but is its essential purpose. The fact that it also pursues an objective falling within Articles 130 and 130f of the Treaty [47] is not, therefore, such as to make it inappropriate to use Article 100a of the Treaty [48] as the legal basis of the Directive.'

95. In the case where the purpose of a measure is to protect public health, the power of the Community legislature to adopt rules under Article 95 EC is at least equally extensive. This power, however, is not unlimited, as is clear from the *tobacco advertising* judgment. Even if they do not have the removal of barriers to free movement as their objective, the measures must

46 — Case C-377/98 *Netherlands* v *Parliament and Council* [2001] ECR I-7079, paragraphs 27 and 28.

47 — Now Articles 157 EC and 163 EC respectively.

48 — Now Article 95 EC.

at any rate contribute significantly to their removal. Although these barriers may be in the future, it must never the less be probable that such barriers will arise.

96. In this connection, the Court appears to attach more importance to the content (subject-matter) of the measure that to the objective pursued by the legislature. To illustrate this point I refer to the placing in perspective of the distinction between objective and subject-matter which Advocate General Tesauro provided in his Opinion in the *titanium dioxide* case.[49] He considers the distinction to be ultimately one of only terminological significance. However, in determining the subject-matter the purpose served by a measure is also taken into consideration, while, on the other hand, the purpose served by a measure can be understood only by reference to its content and effects, simply in order to avoid the danger (and the blame) that the assessment is based on a subjective criterion (that is to say, the view of an institution regarding the objectives pursued by a measure).

3. General appraisal

97. Many of the observations submitted deal with the primary purpose of the Directive. Does that purpose relate to the single market or is the intention, rather, to safeguard public health? My view tends *prima facie* to the latter, certainly when one bears in mind the fact that the Directive forms part of a Community package of measures to combat tobacco consumption.[50] I find that less importance attaches in this connection to the fact that the recitals in the preamble refer extensively to the single market: those references are included precisely in order to justify the use of Article 95 EC and not so much in connection with the real purpose of the Directive. My submissions in what follows on the legal basis offered by Article 95 must therefore be considered in that light.

98. From the observations submitted to the Court in the course of these proceedings and from the case-law, I infer that the doubts which may arise as to the power of the Community legislature to adopt a directive such as the present are expressed essentially in the following question: does the requirement in Article 95 EC that a measure must have as its object the establishment and functioning of the internal market mean that the primary purpose of a measure must relate to the internal market? Or does the argument put forward by the United Kingdom Government, with reference to the *tobacco advertising* judgment, hold true, namely that Article 95 EC can also be relied on where the emphasis of a measure falls, not on the promotion of the internal market, but on the protection of public health?

49 — Opinion in Case C-300/89 *Commission* v *Council* [1991] ECR I-2867.

50 — See paragraphs 67 to 77.

99. In order to answer these questions I shall now examine in general the powers which Article 95 EC confers on the Community legislature.

100. The issue boils down to the following: if a (potential) barrier to trade arises, the Community must be in a position to act. Such action must, as I construe the *biotechnology* judgment, [51] consist in the removal of those barriers. Article 95 EC creates the power to do so. No conclusive significance attaches in this connection to the issue whether the barrier to trade also constitutes the principal reason for action on the part of the Community legislature. The fact that there are specific powers under the Treaty for the Community legislature to act within defined areas of policy, as in the area of public health under Article 152 EC, also has no bearing on this finding.

101. This power, however, is not unlimited. Even in a case where it has been determined that a measure concerns a barrier to trade, a court may, in a specific case, assess whether the Community legislature has exercised the powers conferred on it in accordance with Community law. This assessment will in every case involve the question of the extent to which the measure is in fact intended to safeguard a public interest recognised by Community law. The court will accordingly examine whether the intervention of the legislature in a given case is genuinely appropriate for contributing to the removal of the barrier to trade. Possible misuse of the powers conferred by the Treaty may also be addressed, as can the other principles of law mentioned by the High Court in the questions which it has submitted. The principles of law are dealt with below in the present Opinion. [52]

4. Appraisal of the essential aspects of the powers conferred

102. I shall now develop these premisses, beginning with the essential aspects of the powers conferred by Article 95 EC.

103. Article 95 EC does not contain any general power for the Community legislature to harmonise national provisions. It sets out only the power to adopt harmonisation measures having as their object the establishment of the internal market. [53] The internal market is established, as Article 3(1)(c) EC states, through the abolition, as between Member States, of

51 — Cited in footnote 46.

52 — See paragraph 223 et seq.

53 — Article 95 EC also mentions the functioning of the internal market. I shall examine this aspect of Article 95 EC only at a later stage in the present Opinion (from paragraph 133 on) in connection with the power under Article 95 EC to adopt rules also relating to the manufacture of cigarettes.

obstacles to the free movement of goods, persons, services and capital. To abolish those obstacles, the EC Treaty provides for two instruments which are complementary in their operation. If I confine myself to the free movement of goods, the first instrument consists of the prohibition in Articles 28 EC and 29 EC of quantitative restrictions on imports and exports and of measures having equivalent effect, including the exceptions thereto recognised in Article 30 EC and in the Court's case-law. The second instrument is the Community legislature's power under Article 95 EC to remove the obstacles which remain — or which are created — by virtue of the fact that the national legislature applies one of the derogations from the Article 28 EC and Article 29 EC prohibitions. National statutory measures to protect specific recognised public interests such as public health constitute a prime example of measures which generate barriers to trade.

104. According to the Court's case-law, the power of the Community legislature arises only once actual barriers have come about, or at least once future barriers are likely to be created.

105. With specific reference to the present case: a national measure which imposes restrictions on the composition or designation of tobacco products constitutes, as such, a quantitative restriction on exports within the meaning of Article 29 EC. Article 30 EC, however, offers a ground for justification of such a national measure if that measure is intended to protect public health. According to the Court's case-law, the national measure must satisfy a number of ancillary conditions, *inter alia* with regard to proportionality. In the present case, where the intention is to counter smoking, such a national measure would be easily acceptable.

106. Proceeding on the assumption that a national measure such as that outlined in the preceding paragraph is justified by Article 30 EC, this will already mean that the barrier to trade exists. In order to set aside this barrier to trade, the Community legislature is entitled to adopt measures by which it takes over from the national legislature the protection of the matter of public interest (*in casu*, public health). In other words, the realisation of the internal market may mean that a particular public interest — such as here public health — is dealt with at the level of the European Union. In this the interest of the internal market is not yet the principal objective of a Community measure. The realisation of the internal market simply determines the level at which another public interest is safeguarded.

107. A power of this kind vested in the Community legislature is essential for inte-

gration within the EC context. I refer in this connection to Article 2 EU, in which the creation of an area without internal frontiers is described as being a principal objective of the European Union, as well as to Article 2 EC, pursuant to which the common market was established. In an area without internal frontiers, or in a common market, it is not appropriate that inter-State trade should be subject to restrictive conditions. Were the Community legislature unable to act in such a situation, a significant means by which to set aside those conditions would be lacking. I would even go so far as to say that the Treaty places an obligation on the Community legislature itself to take the measures necessary with regard to the establishment and functioning of the internal market.

108. As has already been stated, the purpose of the action is not important. In this connection the Community's power is comparable to that enjoyed by the federal authorities in the United States in regard to inter-State trade. As the US Supreme Court has ruled, 'It makes no difference if the extraneous objective [in our case: public health] is the principal or dominant objective of the federal measure [in our case: the EC Directive] — so long as a legitimate objective [in our case: the internal market] is sufficiently served.' [54] I regard the power of the Community legislature as a functional power necessary for realising the internal market.

109. Briefly, in order to reply to the question whether the EC is empowered to adopt a specific measure having as its object the establishment of the internal market, the Court must examine whether that measure is directly connected to a barrier to inter-State trade. On this point I refer to paragraph 84 et seq. of the *tobacco advertising* judgment.

110. The claimants in the main proceedings draw a link with the specific power which the EC has within the domain of public health. They note in particular that Article 152(4)(c) EC excludes harmonisation of national legislation. If harmonisation of legislation could none the less be effected on the basis of Article 95 EC, so they argue, this would involve circumvention of the provision laid down in Article 152(4)(c) EC.

111. This construction of Article 152 is wide of the mark. During the drafting of the Maastricht Treaty, through which the title on public health was incorporated in the EC Treaty, it was specifically intended that the Community legislature should be given power in areas where it was hitherto lacking. This related, in particular, to measures in the area of public health which are not directly connected to the functioning of the internal market.

54 — *Oklahoma, ex rel. Phillips* v *Guy F. Atkinson Co*, 313 U.S. 508, 533-34 (1941), as quoted in David E. Engdahl, Constitutional Federalism, St. Paul, Minnesota, 1987.

112. The inclusion of this new power in the Treaty can, of course, never have the consequence of depriving the European Community of a prior existing legislative instrument by which public health could also be effectively protected. That consequence not only would be at variance with the Article 152 objective of conferring on (rather than depriving) the Community specific powers in the area of public health but would also adversely affect the principle set out in Article 152(1) EC that all Community policies must ensure a high level of human health protection.

113. Moreover, if it were not possible to use the power under Article 95 EC in order to harmonise standards in the area of public health, an important instrument in the realisation of the internal market would thereby be rendered ineffective. As I have already pointed out, it frequently turns out to be precisely the justified national measures of public-health protection that create barriers to trade. [55]

114. Stated briefly, Article 152 complements the already existing EC Treaty powers such as Article 95. The exception in Article 152(4)(c) means simply that Article 152 EC cannot provide a legal basis for harmonisation, but it makes no reference to legal bases included elsewhere in the Treaty. Article 152(4)(c) does not limit, *ratione materiae*, the power to harmonise national measures within the area of public health. [56]

5. Appraisal of the exercise of the powers conferred

115. Under this point I address the exercise by the Community legislature of the powers conferred on it.

116. The following must be stated by way of preliminary comment. I have already mentioned that the EC Treaty imposes on the Community legislature the duty to adopt the measures necessary for the establishment and functioning of the internal market. In performing that duty the Community legislature enjoys the necessary margin of discretion. It determines for itself in which cases it considers it appropriate to adopt Community harmonisation measures. That evaluation includes the determination as to whether the instrument selected is the most effective for ensuring

55 — See also, along these lines, paragraph 23 of the *titanium dioxide* judgment, in which the Court alludes to the effects on the internal market which might result from national provisions prompted by health and environmental considerations.

56 — I am also basing myself here on the line of reasoning followed by Advocate General Fennelly in his Opinion in the *tobacco advertising* case, cited in footnote 3, at paragraph 78.

protection of a particular public interest and the determination as to the desired level of protection. The Court does not intervene in these legislative evaluations, examining rather whether the Community legislature has overstepped the bounds of its discretion.

117. The first limit concerns the effect which a measure is expected to have. According to the Court's case-law, a measure adopted pursuant to Article 95 EC must contribute practically to the establishment of the internal market. [57] With specific regard to the present case, the issue is whether a measure is likely to contribute to the abolition of existing or at least probable barriers to trade. I would point out that Directive 98/43 was annulled in the *tobacco advertising* judgment on the ground that not all of the provisions of that directive satisfied that criterion. The Court held that not all the provisions were concerned with inter-State trade. The position is different in the present case: apart from the product ban in issue here, all of the measures relate to inter-State trade in products.

118. The second limit is connected with the (principal) objective of the action pursued on the basis of Article 95 EC, in this case the protection of public health. By using Article 95 EC the Community legislature has removed the protection of this matter of public interest from the powers of the national legislative bodies. [58] The removal of the protection of a matter of public interest which is also recognised by the EC Treaty, such as public health in the present case, [59] from the power of the national legislative bodies cannot, however, have the result that that interest is accorded a lower level of protection on the ground that the Community legislature has regard for market-related interests alone.

119. Essentially, the Community legislature is faced with the same evaluation as the national legislatures which it is replacing. That evaluation must lead to certain prior conditions being attached to the economic freedom of market participants, under which equal account is taken of the freedom of market participants and of the need to protect specific public interests.

120. In carrying out that evaluation the Community legislature enjoys a broad degree of latitude, at any rate where health protection is in issue. In this the Community legislature does not therefore differ from the national legislature which utilises the scope conferred on it by Article 30 EC. In this appraisal by the legislature, a multitude of aspects enter into play. The need for

57 — See, *inter alia*, paragraph 23 of the *titanium dioxide* judgment, cited in footnote 49.

58 — In paragraph 65 of his Opinion in the *tobacco advertising* case, Advocate General Fennelly speaks of substitution in this regard. Cited in footnote 3.

59 — See, *inter alia*, Articles 3 (1) (p) EC and 152 EC.

protective measures depends not only on the scientific understanding of specific health risks but also on the social and political evaluation of those risks. The same holds true with regard to the choice of measure. The Community legislature (and these are the only substantive minimum conditions which follow from the EC Treaty) must have regard for the precautionary principle and take as its base a high level of protection (Article 95(3) EC). It must in any event take account of scientific developments.

121. The third limit is constituted by the principles of law, in particular the principle of proportionality, which I shall discuss in section VII — A.

122. To summarise, then: the Community legislature derives its powers from the realisation of the internal market. Those powers can, none the less, be exercised with a view to protecting a matter of public interest, such as public health in the present case. The measures adopted must in fact be appropriate for abolishing existing or at least probable obstacles to free movement. In exercising its powers the Community legislature is faced with the same evaluation as the national legislature when it intends, for the protection of a matter of public interest, to impose prior conditions on the economic freedom of market participants.

6. Appraisal of the tightening of product norms that have already been harmonised

123. The claimants in the main proceedings dispute the power of the Community legislature to increase, pursuant to Article 95, the strictness of product norms that have already been harmonised. In their view, the existing product norms already guarantee market unity and making them even stricter has therefore nothing to do with the internal market. Considered in itself, the claimants' submission is not incorrect: there is indeed no further risk that legislation in the Member States will diverge. That said, the Court's case-law provides no support for their view. Nor can there be any such support in view of my foregoing explanation.

124. Following harmonisation, the protection of public health has become a task for the Community legislature. Indeed, national legislatures are no longer empowered to act in that regard. The Community legislature, however, can carry out this task properly only if it has the freedom to amend legislation so as to take account of changes in perceptions or circumstances. In short, the performance by the Community legislature of its tasks is not static but dynamic in character.

125. This dynamic character is also taken into consideration in the Treaty. Article 95(3) EC requires the institutions to take account of scientific developments. [60] Contrary to what the claimants contend, Article 95 does not require that there must be a new scientific development. Article 95 provides only that account must be taken of any scientific development. I have already referred to this in paragraph 120.

126. In more general terms, it is true that legislation is a dynamic activity. It is not solely the task of the legislature to draft legislation but also to amend that legislation to take account of changes in social circumstances. Should it fail to do so, the result will be overdue maintenance and the legislation will no longer meet the requirements which may be imposed on it.

127. In the proceedings before the Court, the option under which the Community legislature may act only once was referred to, in particular by the United Kingdom Government, as 'fossilisation'. This term in itself demonstrates that what the claimants are arguing would have absurd consequences in practice.

60 — A good example in the Community's secondary legislation is provided by the rules on dangerous substances in the context of Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1976 L 262, p. 201). These rules provide, *inter alia*, for compulsory periodic and systematic assessment of certain dangerous substances and preparations and consequently for a simplified procedure for the adaptation of the rules to the level of technical development.

7. The Directive specifically in issue in the present case

128. Judicial appraisal in the present case ought to be confined to the issue of whether the Community legislature could reasonably have reached the conclusion in question. I need not here examine the requirements imposed with regard to production.

129. First, I will mention the context of the Directive. Counteracting tobacco consumption is in many Member States a matter to which considerable political and policy-related importance is attached. While a certain consensus appears — as one of the results of increased knowledge of the harm caused by smoking — to have emerged in the Member States in regard to imposing ever stricter rules on the use of tobacco, this still does not mean that there is also consensus on the specific manner of tackling this issue. This is equally apparent from the divergent views expressed by the Member States in these proceedings before the Court. Those views appear to indicate a great diversity, dependent on time and place. This creates a specific risk that national provisions may diverge, *inter alia* in regard to authorised yields of the harmful constituents of cigarettes.

130. A positive response in regard to the Community legislature's balancing of interests is thus also in my view evident. First, competence exists, and the measure relates

to inter-State trade in products. Second, a public interest is being protected which is recognised by EC law; as the requirements relating to composition and designations of cigarettes are being made considerably more stringent, there can be no doubt as to the high level of protection. Third, it may be assumed that there were — or that there was at least a specific threat of — differences between the statutory and administrative provisions of the Member States. The seventh recital in the preamble states that several Member States had indicated that, if measures were not adopted at Community level, they would themselves adopt measures at national level.

131. The seventh recital otherwise merits particular attention. This recital appears to be based on a questionnaire completed by the Member States at the Commission's request. A perusal of the results of this questionnaire[61] does not lead directly to the conviction that concrete plans for national legislation exist. None of the Member States indicates an intention to amend existing national legislation. That notwithstanding, I see no reason to cast doubt on the powers of the Community legislature under Article 95 EC. The situation is namely as follows:

— According to the questionnaire, a number of Member States — France, Italy, the Netherlands, the United Kingdom and Sweden — expressly support the desire to make the product rules governing tobacco products more stringent. In this connection, however, they give preference to regulation at European level.

— There is no doubt as to this attitude of the Member States. The priority being given to measures to counter the use of tobacco is as great as is the extent of the political and social importance attached to this issue.

If the Community legislature defaults in such a situation, it is entirely credible that Member States will choose the alternative which is for them the most attractive, namely tightening of the norms at national level. To this I would add one point linked to the possible consequences of an opposite view. Preference on the part of Member

61 — See the Report from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions — Progress achieved in relation to public health protection from the harmful effects of tobacco consumption, COM/99/407 final, p. 22 et seq.

States for regulation at Community level — and thus renunciation of national measures in restraint of trade — would then result in the Community legislature not having any power precisely because of the absence of national measures in restraint of trade.

132. For the sake of completeness I would also point out that when the Directive was being drafted maximum nicotine yields were already laid down in national legislation in Belgium, Spain and Portugal. The claimants also refer to this, but submit in this connection that such national legislation has no practical effect given that the maximum yields laid down in that legislation cannot be exceeded because of the biochemical connection between the tar and nicotine yields. These existing statutory rules cannot therefore result in barriers to trade. I regard this view of the claimants — which has also not been challenged on factual grounds — as being plausible. The reasons given in the first two sentences of the ninth recital in the preamble would then also be unable to support the harmonisation measure. This defect, however, remains without effect in the present case given that there is a sufficient presumption of potential barriers to trade.

D — *Article 95 and manufacture for export to non-member countries*

1. Arguments submitted

133. The central objection expressed in these proceedings [62] against the production ban, whereby (part of) the Directive is applicable to cigarettes destined for non-member countries, is as follows: this prohibition does not in any way contribute to the removal of obstacles to the free movement of goods or provide a guarantee that the rules governing the internal market will not be circumvented. The Greek Government also refers in this connection to Article 14 EC. The German Government adds that a ban on production will, as a rule, be acceptable only if the product itself constitutes a danger. In the present case, however, the ban is in the interest of neither the internal market nor public health within the European Union.

134. Other intervening parties, in contrast, construe favourably the production ban in the light of what they consider to be the serious risk that cigarettes intended for non-member countries may none the less come onto the market in the European Union, whether through illegal re-import-

62 — By the claimants and the Governments of Germany, Greece and Luxembourg.

ation or because they never leave the European Union. In essence, the arguments presented to the Court have focused in large measure on expectations concerning the rise of illegal trade and the appropriateness of the production ban as a means of countering that trade.

135. If I abstract from the many and frequently inconsistent figures adduced in these proceedings and relating to both legal and illegal trade in cigarettes, the objections to the production ban boil down essentially to the following points:

— the measure is not appropriate, in view of the fact that by far the greater part of the cigarettes unlawfully smoked in the European Union come from non-member countries;

— in so far as there is an illegal trade in cigarettes, this takes place solely in order to avoid high excise duties. Illegal trade has no connection with the composition or labelling of cigarettes;

— illegal trade can be combated by means of intensive monitoring.

136. Against these are ranged the arguments which support a production ban:

— the Council in particular has stated that, although the percentage of cigarettes which are the subject of illegal trade is small, this does not mean that the dimensions of the illegal trade are also small in absolute terms;

— the report of activities of OLAF[63] substantiates the serious nature of cigarette smuggling;

— an increase in vigilance by Member States is not an appropriate alternative within the open area of the European Union.

2. Approach

137. The question here for examination is whether the Community legislature is empowered in this case under Article 95 EC to adopt rules on the manu-

63 — See paragraph 65 of this Opinion.

facture of cigarettes even where such manufacture takes place for the purpose of exporting cigarettes from the European Union. The subject of the measure thus concerns products which never enter the internal market commercially or are at least not intended to do so.

138. I shall adopt the following approach in answering this question. I shall first outline how the Community legislature has used Article 95 EC — and the similar Article 94 EC — in previous cases for the purpose of establishing rules for the production stage. This outline leads to an analysis of the powers which Article 95 EC has conferred on the Community legislature in regard to rules which do not directly concern inter-State trade. This analysis is necessary to enable me to determine that Article 95 confers broad, but certainly not unlimited, powers to effect harmonisation. In conclusion I shall determine whether the exercise of those powers by the Community legislature in the present case remains within the bounds conferred on it.

3. Articles 94 EC and 95 EC and requirements at the production stage: a brief outline

139. Requirements applying at the production stage of goods may be intended both to influence the characteristics of the products themselves and the circumstances under which they are manufactured, for example in connection with the environment or the workplace.

140. Actual production requirements which also apply at the production stage constitute an exception in Community legislation. Most of the legislation which is based on Article 95 EC relates only to the placing of products on the internal market and does not affect the production stage, even where health-sensitive products are concerned. By way of example I refer to the authorisation systems as they apply in the case of medicinal products, veterinary products and plant protection products. [64] The legislature evidently took the view that it was not necessary for these products that the authorisation systems be applied to production and thereby to those products intended for export from the European Union. Product requirements do, however, arise at the production stage. Thus, Euro-

64 — See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1), and Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1). However, I am also thinking of product legislation relating to quite different types of products, such as — just to take one example at random — Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (OJ 1988 L 187, p. 1), which concerns solely the placing of products on the Community market.

pean foodstuffs legislation applies to all stages in the food production chain. [65] This broad scope of application follows from the fact that all stages of the production chain may ultimately have a bearing on the safety of the foodstuff itself. [66]

141. I now turn to the requirements which apply to production. As the first, I shall mention the *titanium dioxide* directive. [67] This directive was adopted after the earlier *titanium dioxide* directive had been annulled by the Court on the ground that an incorrect legal basis had been chosen. [68] The Commission sets out as follows the reasons for its decision to base the proposal for a replacement directive on Article 95 EC: although the existing national rules were introduced with a view to protecting the environment, the harmonisation requirement follows from the need to eliminate distortions of competition. [69] The directive imposes, *inter alia*, rules on the production process, in particular the processing of waste.

142. Earlier environmental directives adopted prior to the Single European Act, in which, among other things, a specific environment title was incorporated in the Treaty, provide an insight into the possibilities of imposing requirements on the production process pursuant to Articles 94 EC and 95 EC. [70] In these the Community legislature has consistently taken the view that differences in national legislation in regard to, for instance, authorised discharges into water or the air may result in unequal conditions of competition and thereby directly affect the functioning of the common market. Article 94 EC was able to serve as a legal basis in this regard. On the other hand, it was, according to the legislature, necessary also to employ Article 308 EC for the reason that the EC Treaty did not make provision for powers in respect of environmental protection. The limit with which the Community legislature was here dealing was not entirely clear and was also not reasoned.

65 — See Article 4 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1).

66 — I refer also in this connection to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption (OJ 1989 L 40, p. 27). While the directive does not impose any requirements on actual production (whether of additives or of the foodstuffs in which those additives are used), it does indirectly impose requirements on the manufacture of foodstuffs.

67 — Council Directive 92/112/EEC of 15 December 1992 on procedures for harmonising the programmes for the reduction and eventual elimination of pollution caused by waste from the titanium dioxide industry (OJ 1992 L 409, p. 11).

68 — Judgment of 11 June 1991 (cited in footnote 49).

69 — COM(91) 358 final.

70 — See, for example, Council Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (OJ 1976 L 129, p. 23), Council Directive 85/203/EEC of 7 March 1985 on air quality standards for nitrogen dioxide (OJ 1985 L 87, p. 1), and Council Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos (OJ 1987 L 85, p. 40).

143. With regard to the working environment, Article 94 EC appeared to provide authority for a Community directive to protect employees against the risks of exposure to chemical, physical and biological agents. [71] According to the legislature, this involves measures which directly affect the functioning of the common market.

144. Following the establishment of a specific environment title and the specific powers under Article 137 EC in the area of the working environment, the Community legislature now has less need of Articles 94 EC or 95 EC in order to be able to adopt provisions governing production. This, however, does not mean that there should no longer be any powers under Article 95 EC. [72]

145. To summarise, then: it is primarily within the context of distortions of competition that the Community legislature has exercised its powers to adopt rules at the production stage. The Directive at issue in the present case involves product requirements which apply even before the products enter the commercial chain. It will be clear from this brief outline that the Directive marks a novel departure inasmuch as a production ban is introduced to prevent the regulation of the internal market from being undermined.

4. The powers of the Community legislature: the requirement that a distortion must be appreciable

146. Article 95 EC provides in the first place for the power to adopt measures having as their object the establishment of the internal market: measures may also be adopted under Article 95 which directly remove barriers to inter-State trade. Confining myself to product legislation, what is in issue is the harmonisation of national rules on trade in products on the internal market. Together with Articles 28 EC, 29 EC to 30 EC, this power of the Community legislature constitutes an elaboration of Article 3(1)(c) EC. I have already addressed this matter in more detail in paragraph 103 of the present Opinion. In order to abolish these barriers, the EC Treaty thus provides for two instruments which complement each other in their operation.

147. It is through the complementary application of Article 95 EC, on the one hand, and of Articles 28 EC to 30 EC, on the other, that an internal market is estab-

71 — Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work (OJ 1980 L 327, p. 8).

72 — By way of further illustration I refer to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 1). This regulates not only the placing on the internal market within the Community of genetically modified organisms as a product or contained in products but also the deliberate release of such organisms into the environment for purposes other than placing them on the market within the EU. The objective of this addition is evident: protection of the environment within the EU. Article 95 EC none the less provides the legal basis here.

lished. This, however, still does not provide any guarantee that the market thus established can also function as a common market. Additional harmonisation measures will frequently be needed for that end. The Community legislature has acknowledged this problem and has provided a second component to the competence under Article 95 EC: the power based on Article 95 EC extends *ratione materiae* to harmonisation measures concerning, not the establishment, but the functioning of the internal market. [73] This is an elaboration of Article 3(h) of the EC Treaty providing as follows: the approximation of national laws to the extent required for the functioning of the internal market.

148. To this I would add the following. With the advancement of the establishment of the internal market, as evidenced by decreasing frequency of obstacles in the way of cross-border trade between Member States — attributable to, *inter alia*, the harmonisation of product legislation — the emphasis will be increasingly placed on the functioning of the internal market. Genuine market unity requires more than simply the abolition of obstacles at borders. I would point out in this connection that the Community has, pursuant to Article 95 EC, adopted a series of measures designed precisely to strengthen the functioning of the internal market. The directives cited in paragraphs 141, 142 and 143 provide good examples in this regard.

149. We are here in an area in which the power to adopt rules is in principle vested in the Member States. There is no general prohibitory provision comparable to Article 28 EC. In issue are measures which — were they to be adopted by the national legislature — would not impose quantitative restrictions on imports or exports. These are measures which regulate the conditions governing production and which are not requirements for the products on the common market itself. For these reasons the Community must have a qualified interest in order to be entitled to breach this competence of the Member States. Or, to use the words of the Court when dealing with distortions of competition: the operation of the market must be appreciably distorted. [74]

150. This requirement that any distortion must be appreciable also means that Article 95 EC does not confer a general unlimited power to effect harmonisation. That would be the case if every — even a very minor — disruption to the functioning of the common market could lead to harmonisation. Briefly, as we are here in an area where Member States have an auton-

73 — In practice, though, the Community legislature tends not to draw a very clear distinction between establishment and functioning. The removal of barriers to trade is referred to in the preambles to many instruments of Community legislation as 'functioning' of the market. This is also the case in regard to the Directive under present consideration.

74 — See, *inter alia*, the *tobacco advertising* judgment, cited in footnote 3, paragraph 106.

omous legislative power which is also not limited by any general prohibitory provision, the Community legislature can intervene only if there is an appreciable distortion. It is presumably also for this reason that the Community legislature included Article 308 EC as a joint basis for the environmental directives mentioned in paragraph 142 above.

151. This requirement of an appreciable distortion thus also forms a constitutive component of the Community legislature in so far as rules adopted on the basis of Article 95 EC for the production stage are concerned. The question now is as to when a case involves an appreciable distortion. Two forms of distortion may, in my opinion, be relevant here.

152. The first distortion relates to the risk that the rules which directly govern trade on the internal market might easily be undermined. The Community legislature will then be able to adopt supplementary rules for the production stage which are designed to obviate this effect. If the Community legislature is unable to adopt these rules, an internal market will still be established but will simply not be able to function effectively. In more specific terms, these will be rules which are designed to contribute to the effectiveness of the rules relating to trade on the internal market. The implementation and enforcement of these rules may be adversely affected if a measure provides a possibility of evasion. This is the reason which the Community legislature in the present case adduces in the 11th recital in the preamble to the Directive.

153. The second distortion which may constitute the basis for rules at the production stage concerns an inequivalence in relations of competition. This situation will arise if the disparity between the conditions in the various Member States governing participation in the common market becomes too great as a result of the lack of concordance of national conditions imposed on the manufacture of particular goods. A harmonisation measure based on Article 95 EC can remove this disparity.

154. The *titanium dioxide* judgment is relevant in this regard. There the Court argued as follows: national provisions — motivated in that case by health and environmental considerations — may be a burden on the undertakings to which they apply.[75] If there is no harmonisation of national provisions there will be a danger of serious distortion of competition. A measure to harmonise national rules on the conditions governing production within a particular industrial sector which is intended to put an end to distortions of

75 — Cited in paragraph 49; see in particular paragraph 23 of the judgment.

competition within that sector thus contributes to the realisation of the internal market and consequently falls within the scope of Article 95 EC. The *titanium dioxide* case involved legislation on the processing of waste. The Court recognised in this context that national rules applying equally to all market participants in a sector may distort competition.

5. The tobacco Directive

155. I now come to the question whether, in adopting the tobacco Directive, the Community legislature has removed an appreciable distortion of the functioning of the internal market.

156. In the proceedings before the Court, the Community legislature, in support of its contention that the Directive applies to the manufacture of cigarettes intended for export, stated that the regulation of the internal market is not undermined. It is clear from the manner in which the case has been dealt with before the Court that the legislature [76] is concerned about the illegal re-importation of cigarettes which do not meet the norms imposed by the Directive and also wishes to prevent cigarettes from being directly placed illegally on the market within the European Union. This relates therefore to the first form of distortion of the internal market, as I have described it in paragraph 152.

157. In my view, the Community legislature is authorised in such a situation to take action subject to the following conditions:

— The damage which circumvention may have on the effect of the measure must be serious. This requirement that the damage be serious is the manifestation in factual terms of the above requirement that the distortion must be appreciable.

— The damage can reasonably be avoided only if there is a guarantee that all Member States are acting in uniformity. In other words, if there is divergence of national implementing provisions and practices, or at least a real risk that national provisions will diverge, it will not be sufficiently certain that genuinely effective action can also be taken against circumvention.

76 — The Council in particular followed this line of argument at the hearing before the Court.

— The lack of supplementary rules results in disproportionately heavy charges for implementation and enforcement.

158. Assessing the degree of seriousness of potential damage involves an analysis of the evaluation of the risk that an illegal market may be created. In my view, the following constitutes the determining factor. Cigarettes are a stimulant and have for that reason an element of excitement for smokers. This is certainly the case with young smokers, to whom the anti-smoking policy is in large measure addressed. In such a situation it is entirely reasonable to assume that an illegal market will be established in cigarettes that are banned within the European Union but which can be obtained outside it. The illegal nature may in itself mean that the product concerned will find a market. The assertion that at present illegal trade is engaged in solely for the purpose of evading excise duty is, in my view, not conclusive in this regard. The establishment of an illegal market requires in the first instance legislation that creates the illegality. Further, the more stringent the provisions, the greater the susceptibility to evasion will be. It is thus the present Directive that has first made the establishment of an illegal market possible — and therefore perhaps attractive.

159. The second condition relates to the need for Community action. A unilateral national ban on production for the purpose of countering illegal re-importation will not be effective in view of the fact that controls have to be carried out along the common market's external borders. Should differences arise in legislation as between Member States — and thus also differences in the controls carried out at the various external borders — the illegal flow of business will simply transfer to an external border where the ban in question does not apply. Action at Community level is for that reason necessary. However, even if the cigarettes do not leave the European Union a national measure cannot be effective on account of the establishment of an open internal market. Within that market, a Member State cannot take effective action against cigarettes being marketed (illegally) within its territory which have come from another Member State in which the production ban does not apply.

160. I shall now consider the third condition. Given that re-importation does take place illegally and that it is frequently individual travellers who re-import the products into the European Union, controls are not really practicable. The least that can be said is that such controls give rise to disproportionate burdens in regard to implementation. The position is no different with regard to illegal trade within the European Union.

161. On this point my conclusion is that the Community legislature has in this case removed an appreciable distortion in the functioning of the internal market. That said, I consider that the production ban may also possibly be based on another foundation. The real risk of an appreciable

distortion of competition, which is the second type of disruption to the functioning of the internal market, can in my opinion form the basis for the EC provisions.

162. I am in no doubt that the provisions applying to the composition of cigarettes — and the expectations regarding the evolution of those provisions — exercise a significant influence on the investment decisions of tobacco product manufacturers who manufacture (also) for export to non-member countries. Manufacturers will prefer to invest in countries which have the most flexible legislation. One of the factors taken into account in this regard is the fact that they will have to compete, in those non-member countries, with manufacturers from outside the European Union which are also not subject to strict requirements as regards composition. In short, the expectation is that divergent national provisions could result in the transfer of investments within the European Union and for that reason lead to an appreciable distortion of the common market. The claimants' assertion that they may transfer their production as a result of the Directive confirms my view.

163. A unilateral national ban on production would thus be not merely ineffective but also scarcely conceivable. A Member State cannot unilaterally prohibit the manufacture of cigarettes in order to guarantee the enforceability of the ban on trade within the internal market. In such a case, the effect at least will be that a cigarette manufacturer will transfer production to a Member State in which no production ban is in force. A unilateral measure of this kind would thus have no effect whatever with regard to enforcement and would result solely in economic damage for the Member State concerned.

164. In this respect the Directive — through harmonisation of the product norms governing tobacco products manufactured in the European Union irrespective of destination — contributes to the prevention of serious disparities in the conditions governing market participation by manufacturers of tobacco products in the different Member States.

165. For the sake of completeness I would point out that the Directive requires to be distinguished in this regard from Directive 98/43. In the case of the latter directive, so the Court ruled, unequal conditions of competition as between Member States could not constitute a basis for a harmonising measure in view of the fact that this would eliminate competition throughout the Community or would at least extensively restrict it. In my view, this finding of the Court must be considered in the light of

the specific context of Directive 98/43. That directive imposed a very extensive restriction on advertising for tobacco products and thereby pre-eminently deprived manufacturers of tobacco products of an instrument of competition. They had in any event, as a result of that directive, less opportunity to present their product to consumers. The Directive in the present case, in contrast, does not have any such particular effect on competition.

166. To recapitulate, then, Article 95 EC can form the legal basis for a measure which imposes conditions on the manufacture of tobacco products irrespective of the intended destination for which they were manufactured.

E — *Is a dual legal basis permissible?*

167. The issue here is essentially the following. First, the substantive test: under what circumstances can a measure be based on more than one legal basis? Does this require that the legal bases must, in view of the objective which the measure seeks to attain, be equivalent in character? Second, is it open to the Community legislature when wishing to regulate several matters — which cannot be brought under one single legal basis — to incorporate those different matters in one single measure? Third, the adoption procedure: are the procedures laid down in Articles 95 EC and 133 EC compatible?

168. In determining the first point Community law provides plenty of scope to go on. A Community measure, such as the Directive, must, as follows from the first paragraph of Article 5 EC, rest on a specific legal basis. The Court's established case-law is set out in its opinion on the Cartagena Protocol: [77]

'It is settled case-law that the choice of the legal basis for a measure... does not follow from its author's conviction alone, but 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 measure reveals that it pursues a twofold purpose or that it has a twofold component and if one is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the measure must be founded on a single legal basis, namely that required by the main or predominant purpose or component... By way of exception, if it is established that the measure simultaneously pursues several objectives which

77 — Opinion 2/00, [2001] ECR I-9713, paragraphs 22 and 23.

are inseparably linked without one being secondary and indirect in relation to the other, the measure may be founded on the corresponding legal bases.'

169. If there are several objectives of more or less equal importance, the principal rule from the judgment in the *Commission* v *Council* case on the goods nomenclature [78] must apply, to the effect that 'where an institution's power is based on two provisions of the Treaty, it is bound to adopt the relevant measures on the basis of the two relevant provisions'.

170. This case-law confers the necessary competence on the Community legislature to base legislation on more than one article of the EC Treaty. This is subject to the condition that use of a legal basis is genuine. Considerations of an ancillary nature are not sufficient to justify the use of a legal basis. For purposes of clarification, I would refer at this point to Advocate General Fennelly's Opinion in the *tobacco advertising* case. [79] In paragraph 68 of his Opinion he submits — and in this I share his view — that the notion of the 'centre of gravity' of a measure is meaningful only where a cumulation of legal bases is excluded on the ground that the adoption procedures set out for both legal bases are incompatible.

171. If it proceeds on the basis that this particular situation does not obtain here — I shall return to this point below — the Court will not need to attach any significance to the inequivalence of the two legal bases used in this case. It is sufficient if Article 133 EC forms the real basis for a part of the Directive — no matter how small that part may be. More particularly, it is necessary to determine whether, in declaring that the Directive also applies to exports of cigarettes from the European Union, the Community legislature has sought to attain an objective that falls within the common commercial policy.

172. The second point which I touched on above arises from the submissions of the claimants and the German Government. Referring to the legislation on infant food, [80] they argue that the Community legislature ought to have adopted the measure governing cigarette exports in separate legislation.

173. The case-law confirms the legislative practice under which several legal bases are frequently used for one measure of Community legislation. [81] Legislation frequently contains several sections — or components, to use the term employed by the Court in the abovementioned opinion —

78 — Case 165/87 *Commission* v *Council* [1988] ECR 5545.

79 — Cited in footnote 3.

80 — See paragraph 191 et seq. of the present Opinion.

81 — A good example in this connection is provided by Regulation (EC) No 178/2002, cited in footnote 65. This regulation is based on Articles 39 EC, 95 EC, 133 EC and 152(4)(b) EC.

and is intended to serve several purposes at the same time. This is also desirable from the point of view of legislative economy. There is little sense in distinguishing the rules laid down for a particular type of product according to the purpose or the series of purposes intended to be achieved thereby. Better integrated rules will be more comprehensible to the persons to whom they apply, while unnecessary divergence in interpretation or implementation can also be avoided. [82] In this connection I consider to be far from satisfactory the solution chosen, for instance, for the rules relating to infant food, where two directives were adopted whose application depended on the intended destination of the product.

174. The third point relates to the compatibility of the adoption procedures.

175. As is clear from the *titanium dioxide* judgment, [83] there is an exception to the main rule that a dual legal basis is permissible in Community law. That exception applies where the provisions of the EC Treaty used lay down separate and incompatible adoption procedures.

176. The Parliament, the Commission and the Council, together with a number of the intervening Governments, submit that cumulative use of Articles 95 EC and 133 EC is possible in view of the fact that such use differs fundamentally from that in the *titanium dioxide* case. The claimants, in contrast, argue that the legislative procedures which the Community legislature must follow under Articles 95 EC and 133 EC respectively are mutually incompatible. The German Government also takes the view that the two legal bases are incompatible. The fact that the present Directive was adopted in accordance with the co-decision procedure, whereas the Council alone decides under Article 133(4) EC, jeopardises, in its opinion, the institutional balance. [84]

177. For purposes of appraisal, I will first refer to the grounds of the *titanium dioxide* judgment dealing with this point: [85] '... Article 100a requires recourse to the cooperation procedure provided for in Article 149(2) of the Treaty, whereas... Article 130s requires the Council to act unanimously after merely consulting the European Parliament.... Under the cooperation procedure, the Council [as a general rule] [86] acts by a qualified majority... That

82 — Such a choice also complies better with the provisions laid down in the Interinstitutional Agreement of 22 December 1998 on common guidelines for the quality of drafting of Community legislation (OJ 1999 C 73, p. 1).

83 — Cited in footnote 49, paragraph 17 et seq.

84 — Somewhat similar is the claimants' argument relating to Article 300(3) EC. They point out that this provision envisages merely a consultative role for the Parliament. It would be constitutionally inappropriate to increase the Parliament's role in decision-making. I need not address this argument in view of the fact that the provision in question concerns solely the conclusion of international agreements.

85 — Cited in footnote 49; paragraphs 18 to 20 of the judgment.

86 — Inserted by the present writer.

essential element of the cooperation procedure would be undermined if, as a result of simultaneous reference to Articles 100a and 130s, the Council were required, in any event, to act unanimously. The very purpose of the cooperation procedure, which is to increase the involvement of the European Parliament in the legislative process of the Community, would thus be jeopardised. As the Court stated... that participation reflects a fundamental democratic principle that the peoples should take part in the exercise of power through the intermediary of a representative assembly.'

178. Two fundamental elements are here in issue, namely the possibility of taking decisions (in some cases) by qualified majority and the prerogatives of the European Parliament. Neither of these elements has a role to play in the present case. Although Article 95 EC refers to the co-decision procedure and Article 133 EC does not, this does not mean that the two legal bases cannot be used at the same time. My reading of the *titanium dioxide* judgment suggests that the co-decision procedure must indeed be applied. The prerogatives of the European Parliament would otherwise be infringed. [87]

179. I would comment as follows on the German Government's submission concerning institutional balance. This submission, in my opinion, is based on a misconstruction of the *titanium dioxide* judgment. Institutional balance plays an important role in the decisions of the Court. In this, however, the Court establishes a direct link with the prerogatives of the European Parliament and the democratic principles underlying them.

180. I fail to see what interest is adversely affected by use of the co-decision procedure in the present case. On the contrary, the most stringent adoption procedure was chosen by which account may be taken of as many interests as possible. Considered from the aspect of institutional balance: if there is any procedure in Community law which is designed to achieve an optimum balance between different authorities, that would appear to me to be the co-decision procedure. Those who drafted the Treaty confirmed their preference for this procedure. In the most recent Treaty amendments introduced in Amsterdam and Nice the choice was also made to apply this procedure to an increasing number of cases.

181. In conclusion, I would point out as follows. Even if there is an adverse effect on the recognised interest of the Council in being able to take decisions alone, it was the choice of the Community legislature itself — and thus also that of the Council — to leave that interest out of account. Indeed, the Community legislature could have applied the same technique as with the

87 — And the position would then become comparable to that in the *titanium dioxide* case. The provisions of the EC Treaty here cited have either been amended (in particular Article 130s; now Article 175 EC) or repealed (Article 149(2)).

legislation on infant food and adopted a separate measure to cover exports. The fact that this is not my preference has no bearing on the matter.

182. To summarise then, and with specific regard to the present case: the Court's case-law does not in principle oppose the use of Article 133 EC as a legal basis in addition to Article 95 EC, given that the adoption procedures provided in both articles are mutually compatible. The answer to the question whether the addition of Article 133 EC in this case is also really possible or necessary will depend on the objective which the Community legislature was seeking to attain.

F — *Article 133 EC and exports of products to non-member countries*

183. I have already found above that Article 95 EC may serve as a legal basis for the applicability of the Directive to the manufacture of cigarettes regardless of their intended destination. The entire Directive can thus be based on Article 95. However, in view of the fact that the Directive further uses Article 133 EC as a legal basis, it is also necessary to decide whether that article can constitute the legal basis for restricting exports of cigarettes from the European Union. I must point out that it was only in the present proceedings — that is to say, after the event — that the Community legislature indicated its intention also in fact to regulate such exports. At the end of this section I shall address the question whether an *ex post facto* statement of reasons can support a measure. Otherwise, I shall adopt an approach similar to that in VI — D: I begin with a brief outline of the existing Community legislation before going on to analyse what I consider to be the broad legislative powers of the Community legislature and addressing the question whether the latter remained within the confines of the powers conferred on it.

1. Arguments submitted

184. At the hearing before the Court, the Parliament and Council argued, as I have already mentioned, that the Directive is also intended to regulate exports. For that reason Article 133 EC was, in their opinion, correctly added as a legal basis. That view is supported by the Commission and several of the intervening Governments. Individual arguments were adduced in this connection which are material to the assessment:

— The United Kingdom Government argues that Article 133 EC is justified as a legal basis in view of the fact that

Articles 3 and 7 of the Directive establish unambiguous principles of common commercial policy. Article 95 EC constitutes no more than a secondary legal basis for the manufacture of cigarettes intended for export to non-member countries.

— The Netherlands Government refers to the 11th recital in the preamble to the Directive, which states that the export regime forms part of the common commercial policy. The fact that the Directive also seeks to attain (or does attain, although not intending to do so) objectives not relating to commercial policy has no bearing on this. [88]

— In the Commission's view, the application of quality standards to the exportation of products must be regarded as a matter of commercial concern to the European Union as it prevents products of inferior quality being dumped on the world market. For that reason alone Article 133 EC can serve as a legal basis.

88 — Case 62/88 *Greece* v *Council* [1990] ECR I-1527, paragraphs 17 to 20.

185. The main objections to the use of Article 133 EC are the following:

— According to the claimants, the Community's powers in the area of the common commercial policy have as their main objective to ensure that trade between the Member States and non-member countries does not lead to distortions in intra-Community trade.

— The claimants point out that the purpose of the Directive is to protect health. For that reason the Directive cannot be based on Article 133 EC. Article 133 EC confers power to promote, not restrict, trade. The Greek Government sets out a similar argument.

— Following on from this, the German Government submits that measures based on Article 133 EC must have the objective of influencing currents of trade with non-member countries. The liberalisation, and not the restriction, of trade must be to the fore. While restrictive measures are permitted on

the basis of Article 133 EC, they must constitute a component of a measure designed to bring about liberalisation.

— Both the German and the Luxembourg Governments draw attention to the protection of public health in non-member countries, which is a consequence of the Directive. The Directive thereby has extra-territorial effect, even though — in the absence of any international standard — it is a matter for the country of importation itself to establish health norms.

2. Article 133 EC and exports of products to non-member countries: a brief outline

186. Community legislation concerning products for export and based on Article 133 EC is to be found in many areas and with a variety objectives. International agreements frequently form the basis of such legislation. By way of example I cite the legislation on sanctions [89] and regulations to counter the exportation of drugs and counterfeit goods. [90] On occasions such legislation is unilateral Community legislation, as is the case with the tobacco Directive. A recent example is provided by the framework regulation for legislation on foodstuffs, [91] which is discussed below in paragraph 190.

187. For the rest, measures governing products intended for export also fall outside the scope of Article 133 EC. An example within the agricultural sector is provided by the Commission decision [92] in which, by means of emergency measures to combat BSE, a ban was introduced on exports of British cattle and beef. This measure also applied to exports to non-member countries. This is remarkable given that the underlying Council regulations related only to internal trade. The justifi-

89 — See, for example, Council Regulation (EEC) No 990/93 of 26 April 1993 concerning trade between the European Economic Community and the Federal Republic of Yugoslavia (Serbia and Montenegro) (OJ 1993 L 102, p. 14), which was examined by the Court in the *Bosphorus* case (Case C-84/95 *Bosphorus* [1996] ECR I-3953).

90 — Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances (OJ 1990 L 357, p. 1). Although the products regulated in this legislation are, as regards their effects, somewhat similar to tobacco products, the rules are substantially quite distinct from those in the Directive in this case. See also Council Regulation (EC) No 3295/94 of 22 December 1994 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods (OJ 1994 L 341, p. 8). Under this regulation counterfeit or pirated goods may not be brought into free circulation, exported or re-exported.

91 — Regulation No 178/2002, cited in footnote 65. This regulation has as its legal basis Articles 37 EC, 95 EC, 133 EC and 152(4)(b) EC.

92 — Commission Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy (OJ 1996 L 78, p. 47).

cation for the measure lay in the risk of re-importation. [93]

188. Three measures merit special attention in the examination of the present case.

189. The basic rules for the application of Article 133 EC to exports are laid down in Regulation (EEC) No 2603/69 of the Council of 20 December 1969 establishing common rules for exports. [94] The main rule in Article 1 states that exports may not in principle be subject to any quantitative restriction. Article 11 provides Member States with the possibility of adopting national restrictions on exports in order to safeguard one of the interests mentioned in Article 30 EC.

190. Article 133 EC forms the legal basis for Community product requirements relating to exports in the — broad — framework regulation on foodstuff legislation. [95] Central to this regulation is the protection of the health and safety of EC nationals and nationals of non-member countries. Foodstuffs intended for export to a non-member country and placed on the market in that country must satisfy the relevant provisions of foodstuffs legislation which apply to products intended for domestic consumption. Furthermore, they must not be injurious to health or, in the case of animal feedstuffs, unsafe.

191. It was precisely for the purpose of regulating exports that Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries was adopted. [96] This directive, which is based on Article 133 EC, supplements earlier directives which contain (similar) product requirements for infant formulae and follow-on formulae intended for the internal market. [97] The purpose of this directive is to safeguard the health of infants in non-member countries. The product requirements in question must be in accordance with the EC legislation applicable to the

93 — In Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, the Court dismissed an application for the annulment of this decision. See also paragraph 234 of the present Opinion. See also the legislation on the environment pursuant to Article 175 EC, such as Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals (OJ 1992 L 251, p. 13). That regulation seeks to guarantee the protection of humans and the environment both within the Community and in non-member countries. The provisions result in part from cooperation with international organisations such as the United Nations Environmental Programme (UNEP) and the Food and Agriculture Organisation (FAO).

94 — OJ, English Special Edition 1969 (II), p. 590.

95 — See footnote 65.

96 — OJ 1992 L 179, p. 129.

97 — Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ 1989 L 186, p. 27) and Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae (OJ 1991 L 175, p. 35).

internal market or with the internationally applicable norms adopted within the framework of the Codex Alimentarius. [98]

192. To summarise, then, rules are adopted on the basis of Article 133 EC and applied to products for export with a view to a variety of objectives. These certainly do not relate solely to commercial policy in the strict sense of promoting trade but also to measures which restrict exports of specific products by dint of other objectives of general concern.

3. Appraisal of the powers under Article 133 EC

193. The first question craving reply is whether Article 133 EC can serve as the legal basis for a measure that is primarily intended to protect public health. This question does not differ in its essentials from that relating to Article 95 EC. In other words, the question is whether Article 133 EC is also to be regarded as comprising a functional competence which the Community legislature requires in order to adopt measures having external effect.

194. According to the case-law, the competence of the Community legislature must be construed broadly. I refer back to Opinion 1/78 of the Court: 'it is therefore not possible to lay down, for Article 113 of the EEC Treaty, an interpretation the effect of which would be to restrict the common commercial policy to the use of instruments intended to have an effect only on the traditional aspects of external trade'. The Court added that 'the enumeration in Article 113 of the subjects covered by commercial policy... is conceived as a non-exhaustive enumeration'. [99] While it might have been thought that 'at the time when the Treaty was drafted liberalisation of trade was the dominant idea', other objectives, such as issues relating to development, have gradually assumed a role also. [100]

195. This opinion of the Court makes it clear that Article 133 EC does not by itself suffice to promote trade between the European Union and non-member countries.

98 — The Community legislature has applied a similar technique in the legislation on radioactive contamination of foodstuffs and animal feedingstuffs. Council Regulation (EEC) No 2219/89 of 18 July 1989 on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ 1989 L 211, p. 4), which is based on Article 133 EC, prohibits the exportation of foodstuffs and animal feedingstuffs in which the level of radioactive contamination exceeds the maxima applicable for products intended for domestic consumption. The maximum permissible levels of radioactive contamination for foodstuffs and animal feedingstuffs are set out in Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (OJ 1987 L 371, p. 11), as amended by Council Regulation (Euratom) No 2218/89 (OJ 1989 L 211, p. 1).

99 — Opinion 1/78 [1979] ECR 2871, paragraphs 44 and 45.

100 — See also in this connection Case 45/86 *Commission* v *Council* [1987] ECR 1493.

Even where Article 133 EC is applied, other public interests may play a role, in regard to which the Community legislature may impose prior qualitative conditions on trade. The Court's case-law hereby confirms the broad construction placed on the concept of the common commercial policy, as evidenced in practice by Community legislation.

196. The power to confer a role on other important areas of public interest can also be derived from Regulation No 2603/69. That regulation authorises Member States to restrict exports in order to safeguard the areas of public interest mentioned in Article 30 EC. The existence of this power on the part of the Member States means in itself that the promotion of these interests may also be the subject of Community action. Indeed, unilateral action by Member States may interfere with the common commercial policy — an area in which the European Community enjoys exclusive competence. The Community legislature must therefore be able, in the interests of trade, to replace these unilateral national measures by Community action. On the other hand, such action by the Community also may not lead to a situation in which other public interests are afforded less protection. So far as the protection of public health is concerned, the obligation under Article 152(1) EC is significant, requiring as it does all Community activities to ensure a high level of protection. Here too the comparison with internal trade is evident. It is precisely because Article 30 EC gives rise to the possibility of barriers to trade that the Community must — on the basis of Article 95 EC — be able to act.

197. In brief, the competence of the European Community to act externally on the basis of Article 133 EC is in large measure similar to the competence of the Community legislature under Article 95 EC to act internally. [101] What is here in issue is also a functional competence.

198. I should also point out in this connection that Article XX of the GATT Agreement provides for exceptions with a view to specific areas of public interest such as the protection of public health. That is also logical. The promotion of free trade implies that prior conditions may also be imposed on such trade. It is incorrect to confuse those prior conditions with barriers to trade, as the claimants appear to be doing.

199. The German and Luxembourg Governments raise for discussion the issue of the extraterritorial effect of the Directive, in that the requirements governing exports of cigarettes amount essentially to the protection of public health in non-member

101 — To illustrate this point, I refer to the Opinion of Advocate General Jacobs in Case C-70/94 *Werner* [1995] ECR I-3189, in which he stated that Article 11 of Regulation No 2603/69 must in large measure be given the same construction as Article 30 EC.

countries. I share those Governments' view that this protection — which in any event is primary — is a matter for the Governments of the countries of importation. The question, however, is whether this means that no further requirements may be imposed on exports.

200. This question is situated within the delicate area of extraterritorial protection measures. Significant differences exist in the views on the permissibility of measures of this kind, depending on the interpretation of what constitutes commercial policy. The Court has not so far set out its views in express terms on whether such measures are permissible. Nor does any clear picture emerge within the framework of the World Trade Organisation, at least not in regard to measures concerning exports. [102]

201. My reply to this question is as follows. Requirements imposed on products intended for export may be divided into three categories. The first of these concerns those requirements arising under international agreements, while the second consists of unilateral Community requirements for the internal market which also apply to exports and the third category comprises requirements imposed exclusively on exports.

202. In my opinion, those requirements that belong to the first and second categories are in general permissible, in view of the broad construction placed on the concept of the common commercial policy in both the Court's case-law and legislative practice.

203. With regard to the first category: extraterritorial protection measures cannot in any case be criticised if they are based on international standards. Article 133 EC provides the instrument by which the Community can give effect to international agreements concerning trade. Standards of this kind form the basis of the export rules governing infant foods.

204. I come now to the second category of requirements, among which the requirements in the tobacco Directive may be included. The Community legislature may ban the exportation of inferior products that have also been refused access to the internal market. The reason for this is that it is important for the credibility of trade that inferior products are not placed on the market. With regard to the internal market, the Court has recognised this ground in its judgment in *Alpine Investments*. [103] It is in this connection immaterial whether the

102 — It is true that in two cases involving tuna a GATT panel did rule that imports may not be banned in the cause of the protection of the environment in another country. See www.wto.int, Committee on Trade and Environment, GATT/WTO Dispute Settlement Practice relating to Article XX, Paragraphs (b), (d) and (g) of GATT, document symbol WT/CTE/W/53.

103 — Case C-384/93 *Alpine Investments* [1995] ECR I-1141. In paragraph 43 the Court stated that although the protection of consumers in other Member States is not, as such, a matter for a Member State, the nature and extent of that protection do none the less have a direct effect on good commercial reputation.

case relates to defective or dangerous products or — as in the present case — products that constitute a health risk. In this sense I agree with the Commission's argument referred to in paragraph 184 above. This ground forms the basis for the ban on exports of harmful foodstuffs.

205. In specific terms, my view means that the question whether extraterritorial protection measures are permissible requires only to be answered for unilateral measures taken by the European Community (or by a Member State) which relate exclusively to exports and not also to the internal market. Having regard to the content of the tobacco Directive, that question need not be addressed in the present case.

4. The limits of competence

206. In its opinion on the Cartagena Protocol, [104] the Court pointed out that a broad interpretation by the Community legislature cannot have the result of rendering the specific Treaty provisions concerning — in that case — environmental protection policy largely nugatory by virtue of the fact that Article 133 EC would be applicable as soon as it was established that Community action was liable to have repercussions on trade. This opinion of the Court is, moreover, relevant only in those cases in which a choice of legal basis is necessary in view of differences in procedures. [105] In those cases it is necessary to consider within what area a measure principally falls. Frequently, however, a cumulation of legal bases will be possible.

207. Opinion 2/00 dealt with the demarcation between the common commercial policy and the Community's powers with regard to special areas of public interest. A second line of demarcation also needs to be drawn, namely that between the common commercial policy (understood as meaning trade with non-member countries) and the internal market.

208. According to the Court, the mere fact that a measure also concerns imports into the Community does not suffice to make Article 133 EC applicable. [106] The case in point involved uniform rules on trade in specified meat products. The only reason why imports were also affected was that the measure did not distinguish between products originating in non-member countries and products originating in the European Union. That which applies to imports also applies, in my opinion, to exports. The mere fact that a product-related provision

104 — Cited in footnote 77; paragraph 40.

105 — In this sense, Opinion 2/00 follows on from the *titanium dioxide* judgment, cited in footnote 49.

106 — Case 131/87 *Commission* v *Council* [1989] ECR 3743, paragraph 28.

in force for the internal market applies to products that are manufactured for export to non-member countries does not automatically mean that Article 133 EC may be used as a legal basis.

209. The regulation which governed imports of agricultural products into the EU in the wake of the Chernobyl disaster was, in contrast, quite capable of being based on Article 133 EC.[107] The Court based itself primarily on the purpose served by the regulation. The Community rules were intended to safeguard the health of consumers, maintain the unified nature of the market and prevent deflections of trade, without imposing unnecessary barriers on trade between the Community and non-member countries.

210. In its opinion of 15 November 1994,[108] the Court was requested to rule on the competence of the EC to conclude the TRIPs Agreement.[109] The Court stated that intellectual property rights are not specifically linked to external trade, but are also not specifically linked to the internal market. Article 133 EC therefore did not constitute an appropriate legal basis in that case.

211. I shall now sum up. The demarcation of Article 133 EC has two dimensions. The first line of demarcation is broad: Article 133 EC can be used for the benefit of public interests other than the interest of international trade *per se*. Exercise of this competence, however, may not be at variance with special areas of competence that are recognised as vested in the Community institutions. The second demarcation line is narrower. If a measure is primarily intended to regulate internal trade, Article 133 EC will not be applicable, even though both imported and exported products are affected thereby.

212. That said, I consider the powers under Articles 95 EC and 133 EC to be comparable and complementary. Article 133 EC represents for the external market what Article 95 EC represents for the internal market. Article 133 EC can serve as a legal basis only for measures having a real connection with the external market and under which the consequences for external trade are more than merely ancillary.

5. Appraisal of the Directive

213. Taking as my basis the reasons put forward by the Parliament and the Council at the hearing — and thus *ex post facto* — I come to the view that Article 133 EC can

107 — *Greece* v *Council* (cited in footnote 88), paragraphs 14 to 16.

108 — Opinion 1/94 [1994] ECR I-5267, paragraph 57.

109 — This agreement is attached as Annex 1 C to the Agreement establishing the World Trade Organisation and approved on behalf of the European Community by Council Decision 94/800/EC of 22 December 1994 (OJ 1994 L 336, p. 1).

serve as a legal basis for external effect. I consider the subject-matter of the measure to be conclusive in this regard. Specifically, the Community legislature intends by the ban on manufacture to impose real conditions on exports of cigarettes to non-member countries.

214. This view rests on the following factors:

— Article 133 EC constitutes a functional competence which can be used to impose prior qualitative conditions on the exportation of products;

— the extraterritorial effect of the protective measures is justified by their content, namely that the ban applies only to exports of inferior quality cigarettes which are not permitted on the internal market;

— cumulation of the legal bases of Article 95 EC and Article 133 EC is in principle possible;

— the measure does in fact relate to the internal market. External effects are more than ancillary effects.

215. I would also confirm in this connection that the present Directive is comparable, so far as external effect is concerned, to other product legislation in which health protection for nationals of non-member countries forms the subject of regulation. I have already cited the framework regulation on foodstuffs and the legislation on infant foods. [110]

216. That said, I consider that I am bound by the reasoning which the Community legislature has set out in the 11th recital in the preamble. According to settled case-law on Article 253 EC, the statement of reasons provided by the Community legislature must set out the reasoning clearly and unequivocally so as to inform the persons concerned of the justification for the measure adopted and to enable the Court to exercise its powers of review. [111] Regard being had to this function of the duty to state reasons, it is insufficient if reasons are given subsequently when an issue happens to be raised before the Court. A statement of reasons may, it is true, be clarified by the Community legislature in proceedings before the Court; that, however, does not mean that an entirely new ground of justification can be submitted.

217. As already mentioned in paragraph 86, the 11th recital in the preamble states that the application to exports is to ensure that the internal market provisions are not

110 — See paragraphs 190 and 191.

111 — See, for example, Case C-228/99 *Silos e Mangimi Martini* [2001] ECR I-8401, paragraph 27.

undermined. In this the consequences which the Directive has for external trade are no more than ancillary effects. These effects follow from the measures relating to the internal market and for that reason alone Article 133 EC cannot serve as a legal basis.

218. The purpose of the measure is, according to the recital, not to impose restrictions on trade in cigarettes with non-member countries. Nor can it be regarded as forming part of the common commercial policy. The fact that it does indeed have consequences for trade with non-member countries has no bearing on this. I refer on this point to the formulation used by the Court in the *biotechnology* judgment. [112] In brief: applicability to cigarettes intended for export is an ancillary or subordinate objective of the Directive and does not coincide with its *raison d'être*.

219. All of this leads me to the conclusion that Article 133 EC was incorrectly included as a legal basis for the Directive. Even the rules relating to exports could, and should, have been based on Article 95 EC.

112 — Cited in footnote 46.

G — *The legal consequence of incorrect use of Article 133 EC*

220. The question then arises as to the legal consequence of this formal defect: will this formal defect lead to the annulment of the Directive? My answer to that question is in the negative. Even after Article 133 EC falls as a legal basis, a sufficient legal basis still subsists in the form of Article 95 EC. Also, if one considers the legislative history of the Directive, there is justification for the view that Article 133 EC was, as it were, unnecessarily added as a legal basis. Once this superfluous legal basis has fallen, the original legal basis continues to stand.

221. In addition, this formal defect means only that the Directive is incorrectly reasoned. An inaccuracy in the preamble to a directive cannot be placed on a par with an inaccuracy in its substantive regulatory part. An inaccuracy in the substantive regulatory part means that the provision in question may not be applied. In such a case, the Court is obliged to annul a directive in whole or in part. An inaccuracy in the preamble means only that the recital or legal basis in question cannot support the measure. The Court must consequently rule whether there remains an adequate statement of reasons without that recital or legal basis.

222. I never the less take the view that letting a directive such as the present stand notwithstanding a defect in the reasoning need not constitute an incitement for the

Community legislature to provide as broad a statement of reasons as possible. Every statement of reasons remains in any case subject to review by the Court. In this the Court naturally proceeds on the basis of a fundamental feature of Community law, namely that the EC Treaty confers an exhaustive number of areas of competence on the Community legislature. That attribution lies at the heart of the division of powers between the Community and the Member States. Proper use of these powers demands sensitivity and is subject to review by the Community Courts. It is not for nothing that Article 7 EC provides, as a principle of EC law, that an institution must act within the limits of the powers conferred on it.

VII — Examination of the first question: possible infringement of legal principles

223. Even if it is clear that the correct legal basis has been chosen, the validity of the Directive will not yet have been established. There may be other reasons for invalidity, such as infringement of legal principles. The High Court directs its queries in this direction in parts (c) to (g) inclusive of its first question. I attach greatest significance in the present case to the possibility of an infringement of the principle of proportionality, given that it is only in connection with this legal principle that serious doubt can arise as to validity. In the case of the other legal principles in issue, it is clear that they cannot — at least not by themselves — have this consequence in law. This applies also with regard to the right to property, notwithstanding the more extensive discussion which I will be devoting to that issue.

A — *The principle of proportionality*

224. In what follows, I shall first of all consider the significance of the principle of proportionality for the Directive as a whole. I shall then consider in more detail the proportionality of the rules applying to the exportation of cigarettes before finally examining the proportionality of Article 7 of the Directive.

1. General appraisal

225. Assessment of the principle of proportionality in the present case consists of a variety of elements. The primary element is as follows: the task of the Community legislature to offer adequate protection for matters of public interest is not disputed in regard to the protection of public health. In this the Community legislature is no different from national legislative bodies. As the Commission has also stated in these proceedings, the scope of judicial review is limited. Examination may be made only as to whether the Community legislature did

or did not exceed the limits of its competence. The principle of proportionality constitutes one of those limits. I refer to paragraphs 120 and 121 of this Opinion.

226. In my Opinion in *Hahn* [113] I referred to the Court's settled case-law which states that human health and life are foremost among the goods and interests protected in Article 30 EC. In the absence of exhaustive harmonisation, it is for the Member States to decide on the extent to which they wish to safeguard the protection of the health and life of individuals. Although they have a broad discretion in this regard, they must still take proper account of the requirements imposed by the free movement of goods. In particular, a national measure or commercial practice will not come under the derogation in Article 30 EC if public health can be accorded equally effective protection by measures having a less restrictive effect on intra-Community trade.

227. The particular nature of public health protection also finds expression in Article 152(1) EC, which provides that the requirements relating to public health protection are to form a constituent part of Community policy in other areas. The Court has stressed the importance of this provision, *inter alia* in connection with the common agricultural policy. [114]

228. In my Opinion in *Hahn* I discussed the precautionary principle. The precautionary principle and the principle of preventive action are set out in the EC Treaty Title dealing with the environment but are also recognised by the Court as being principles which can form the basis of measures to protect public health. The Court thus accepted these principles as the basis for legislative measures affording protection against BSE. [115]

229. In brief, the protection of public health is a matter of public interest which the legislature must be able to protect in full. The value of this public interest is so great that, in the legislature's assessment other matters of interest, such as the freedom of market participants, must be made subsidiary to it. This holds true both for national legislative bodies and for the Community legislature in so far as the latter has taken over public health protection from national legislative bodies. [116]

113 — Opinion of 13 December 2001 in Case C-121/00 *Hahn*, ECR [2002] I-9193, I-9195, paragraph 34. The view here expressed dates back to the judgment in Case 104/75 *De Peijper* [1976] ECR 613.

114 — Case C-180/96 *United Kingdom* v *Commission*, cited in footnote 93, paragraph 120. The Treaty also makes similar provision for environmental protection (Article 6 EC).

115 — See the judgment mentioned in the previous footnote. The Court reasons in this connection that under Article 174(1) EC the protection of public health constitutes part of the policy on the environment and that consequently this principle of environmental policy also applies in regard to health protection.

116 — See also paragraph 118 et seq. of this Opinion.

230. It is in this light that I also consider the operation of the principle of proportionality. This principle does not provide that two matters of interest have to be weighed one against the other but focuses only on the choice of measure which has been or is being adopted to protect public health. Is this measure appropriate and is any other — less intrusive — measure available which would provide equally good protection for public health? The Community Courts exercise a limited appraisal of these issues.

231. It is clear to me that the obligations which the present Directive imposes satisfy these criteria. Further, the provisions concerned strike me as being particularly well suited to contributing to the intended purpose of public health protection. In measures intended to restrict (the consequences of) smoking, the legislature seeks to achieve a balance between measures which, on the one hand, are substantial and which may in any event be expected to be effective and, on the other, take account of the fact that tobacco consumption also cannot be banned entirely, or at any rate that such a ban would give rise to an extensive illegal economy. The Community legislature appears in the present case to have succeeded in achieving that balance. I am unable to identify any less intrusive measure which would provide equally good protection for public health.

2. Appraisal in regard to applicability to exports

232. More particularly, the Court must examine the proportionality of having (Article 3 of) the Directive apply to cigarettes destined for export from the European Union. Above (paragraph 213 et seq.) I have found that this ban is primarily intended to counter the illicit trade in cigarettes within the European Union. The question now is whether this objective could equally well have been attained by measures less restrictive of trade. The claimants argue that the ban which Article 3 of the Directive imposes on the manufacture, and thus on the exportation, of cigarettes manufactured in the Community otherwise than in accordance with the maximum yields indicated is contrary to the principle of proportionality.

233. The proportionality of this measure is not a matter of established fact from the outset. There is a lack of symmetry between the substance and the effect of this measure, on the one hand, and, on the other, the objective which that measure seeks to attain. Indeed, we may assume that cigarettes are normally exported for the purpose of sale, and also end use, in non-member countries and that it is there that the end use actually takes place in most cases. These exports are now subjected in their entirety to restraints intended to prevent an ancillary consequence, namely the illegal trade in those cigarettes within the European Union itself.

234. To begin, both the claimants and the German Government cast doubt on the appropriateness of the measure. They draw a comparison with the ban on exports of cattle from the United Kingdom in the context of BSE infection, which the Court upheld in its judgment in *United Kingdom* v *Commission*. [117] They argue that the ban in that case was indeed appropriate to achieve the intended purpose as the source of the health risk which the legislation sought to counter was to be found in the United Kingdom, whereas in the present case the source is in large measure to be found outside the European Union. The Council comments as follows on this line of argument: the measure in issue in the BSE case also went considerably further than the tobacco Directive. In other words, as the tobacco Directive is not appropriate for doing away effectively and entirely with the health risk, the Community legislature confines itself here to a more limited measure.

235. The claimants and the German Government have, in my view, chosen an incorrect basis for their appraisal of the appropriateness of the measure. If the objective is to ban the illegal consumption of cigarettes which fail to meet Community requirements, that measure will not be appropriate in view of the fact that a large proportion of those cigarettes originate outside the European Union. However, the measure has a more limited objective, namely that of preventing the internal market rules from being undermined by cigarettes that are manufactured in the European Union but may not be marketed there and which none the less come on to that market. In the light of that limited objective it can be established that the measure is appropriate in nature.

236. The question whether, in that case, a less intrusive measure might not have been available is, in my view, more difficult to answer. On this point the Council's marginal remark is material. I am not entirely in agreement with that remark: the measure is not limited in its scope. As already stated, the measure results in a total ban on exports of cigarettes that fail to satisfy the requirements. On the other hand — and this is what I consider to be more important — the significance of the ban should also not be overestimated: a number of importing countries have themselves imposed similar — or even stricter — requirements on cigarettes, international norms covering cigarettes are at present being drafted and, furthermore, the fact that the European Union guarantees that no inferior cigarettes will be placed on the world market can also increase the confidence which consumers in non-member countries vest in European cigarettes.

237. It is clear to me that a ban on production is required in order to attain

117 — Cited in footnote 93.

the objective sought by the measure. I refer once again to the following points: [118]

— there is a plausible risk that an illegal market will develop, whether through re-importation or through the fact that products are brought directly on to the illegal market;

— action at Community level is required to counter this. Unilateral national measures are ineffective for purposes of control;

— unilateral national measures also lead to a significant distortion of the internal market.

238. I fail to see how any measure less drastic than a ban on production could offer the same protection. As less drastic measures, one might, for example, envisage obligations to separate production flows, possibly supplemented by more extensive provision of proof by manufacturers that cigarettes have indeed been exported. Whatever might be the effectiveness of such measures in themselves, they will never be able entirely to counteract the establishment of an illegal economy. Part of that illegal economy does indeed originate in re-importation. Assuming that, in the case of easily enforceable Community legislation, the situation is arrived at in which all — or nearly all — cigarettes intended for export are in fact exported, the attractiveness of illegal re-importation will simply increase.

118 — See paragraphs 159 to 163 of this Opinion.

3. Appraisal in regard to Article 7

239. The claimants in the main proceedings, Japan Tobacco and the Greek Government dispute the proportionality of Article 7 of the Directive, as explained in the 27th recital in the preamble. The arguments which they put forward amount to a submission, first, that the measure is not appropriate for the protection of health and, second, that there is a less onerous alternative.

240. The central argument relating to the appropriateness of Article 7 is that this article is at variance with Articles 3 and 5 of the Directive. It is essentially as follows: whereas Articles 3 and 5 contain measures that seek to ensure that smokers will choose lighter cigarettes, Article 7 has precisely the effect of impeding them in making that choice. Japan Tobacco submits in this connection that the indications which Article 7 prohibits — also referred

to as 'descriptors' — serve a useful purpose: they provide consumers with information on the tar and nicotine yields of the tobacco product. It is precisely such information that consumers are deprived of by the fact that Article 7 prohibits the use of descriptors.

241. All of this has the result that this measure is not appropriate for protecting public health. These arguments are in particular rebutted by the submission that the indications which Article 7 prohibits do not contain objective information but rather mislead smokers by suggesting that a particular tobacco product is less harmful than other products.

242. Underlying this discussion is, *inter alia*, a controversy regarding the extent to which cigarettes with a lower tar yield are less harmful than those with a higher yield. The arguments presented and evidence adduced in the present proceedings cannot resolve this controversy. On the one hand, it strikes me as sufficiently obvious that a cigarette with a lower tar yield is *per se* less harmful than a cigarette that has a higher tar yield. This is also a starting point for the Community legislature. For that reason the maximum tar yield has been reduced in Article 3 of the Directive. The fifth recital in the preamble also stresses the connection between this reduction and carcinogenicity. On the other hand, the Commission, among others, has argued in these proceedings that cigarettes with a low tar yield none the less contain a high level of other harmful substances and will therefore still be harmful. Moreover, it is not implausible that a smoker will smoke more cigarettes if these have a lower tar yield. I quote from the 27th recital in the preamble: '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.' In brief, there are grounds for doubting whether the fact that smokers switch from heavier to lighter cigarettes consistently represents a significant health advantage.

243. In this connection there is a second point of controversy: the effect which the measure is expected to have on public health. The views concerning expectations in this regard are divergent, as is evident from the submissions made by the various intervening parties to these proceedings. Nor does it surprise me that no uniform pattern of expectations emerges. The question here is one of the extent to which a consumer who smokes will adapt his behaviour as a result of the disappearance of indications such as 'light' and 'mild'.

244. These two aspects of the controversy determine the context of this measure. In

order to give a meaningful answer to the question of the appropriateness of a measure for the protection of public health, I shall now examine in more detail the content of the measure itself.

245. In the first place, the possibility of providing objective information on the composition of tobacco products is not restricted. Second — and this is a point which the French Government, among others, has raised — Article 7 of the Directive does not prohibit all presentations and designations of cigarettes capable of tempting consumers and gaining their trust, prohibiting as it does only those references which suggest that a particular tobacco product is less harmful than others. *Alteris verbis*, the ban applies to suggestive designations liable to confuse consumers. These descriptors are used to emphasise various characteristics of cigarettes, sometimes without any connection whatever with the tar yield of a cigarette. Thus, as the Netherlands Government pointed out at the hearing, 'mild' can also be used to indicate a taste sensation. I would mention a second potential cause of confusion: even 'lighter' cigarettes contain tar. Smokers may be misled inasmuch as they are given the erroneous impression that such cigarettes are innocuous, which is not the case, particularly as cigarettes contain other noxious substances that are not regulated by the Directive.

246. In brief, the provision in issue is one which bans a limited number of common designations which may cause confusion among consumers, particularly in regard to the harmfulness of the product. A provision of this kind strikes me as being, in the general sense, an appropriate means by which to protect public health.

247. This instrument is certainly appropriate given the serious doubt as to whether a change by consumers to cigarettes having a lower tar yield is beneficial in health terms. The Community legislature was able for those reasons to conclude that the use of descriptors should be banned, given that these implicitly encourage the smoking of cigarettes with lower tar yields.

248. However, even if I were to assume that cigarettes with a lower tar yield are less injurious to public health, the Community legislature could still reasonably have concluded that use of these descriptors must be countered. They are, after all, still euphemistic indicators intended to encourage use by consumers, even though it is common ground that cigarettes with a lower tar yield are also — albeit to a lesser degree — harmful to public health. Further, and this is more important, the use of these indicators is in no wise linked to objective data such as tar yield. In this respect also these descriptors differ from

the notification of tar, nicotine and carbon monoxide yields which Article 5(1) of the Directive requires to be displayed on the packet. Whereas these yields simply provide objective information for consumers, the descriptors, as already mentioned, amount to euphemistic indications and are thereby not limited to providing objective information.

249. I have already touched above — as the second point of controversy — on the anticipated effect of Article 7 of the Directive. The effect, namely a change in smoking habits, is difficult to demonstrate. However, the Community legislature is also, in my view, not required to prove such an effect. The Community legislature enjoys a broad measure of discretion in choosing the instruments for protecting public health, in the exercise of which it is bound by the precautionary principle, and the measure, moreover, forms part of the Community policy of discouraging people from smoking. In addition, this policy of dissuasion would be thwarted if indicators were permitted which are liable precisely to encourage individuals to smoke.

250. In brief, I consider Article 7 to be appropriate for protecting public health. The next question is whether any other measure would protect public health just as well. The system in force in the Kingdom of Spain has been cited as such a measure in this case: under that system, the use of indicators such as 'light' and 'ultralight' are allowed only for cigarettes with specified low or, as the case may be, very low tar yields. The Greek Government, in particular, has argued that the use of the descriptors — as authorised under Spanish legislation — contributes precisely to providing direct and objective information to consumers without any serious adverse effect on the economic interests of manufacturers.

251. In my view, the Court need not examine in detail whether such a measure, which undeniably has a less obstructive impact on trade, provides equally good protection for public health. The Community legislature enjoys a freedom of appraisal in choosing the most appropriate instrument. The Court rules simply on whether the Community legislature could reasonably have come to the conclusion that the Spanish version does not provide equivalent protection for public health. This is in my view established in the light of what I have stated above regarding the euphemistic character of the descriptors. Even if the use of the descriptors were to be made objective by being linked to specific tar yields, they would still remain designations liable to encourage smoking.

4. Summary

252. The Directive satisfies the principle of proportionality. This holds true for all sections of the Directive.

B — *Restriction of (intellectual) property rights*

1. Demarcation

253. The claimants argue that Articles 5 and 7 of the Directive are contrary to Article 295 EC, which provides that the Treaty may not prejudice the rules in Member States governing the system of property ownership. They further claim that these provisions of the Directive are at variance with the right to property, as laid down in, *inter alia*, the ECHR and/or Article 20 of the TRIPs Agreement. [119]

254. More specifically, the claimants regard Articles 5 and 7 as constituting a serious infringement of their intellectual property rights by reason of the dimensions of the health warnings on cigarette packaging. Their contention is that the Directive thereby makes the proper exercise of those rights impossible and reduces the goodwill that the trademarks have acquired. Japan Tobacco also states that, due to the prohibition in Article 7, cigarette manufacturers will no longer be able to exercise their rights under a number of registered trademarks. Japan Tobacco considers that Article 7 of the Directive prohibits it from exercising its intellectual property rights inasmuch as it is no longer able to use the brand 'Mild Seven' as a trademark within the Community. [120] It claims that it is thereby deprived of the economic advantage of the exclusive licences for that mark. At the hearing Japan Tobacco added that the rules under Article 7 will deprive it of one of its most important assets. The Greek Government shares the view that the ban infringes the intellectual property rights of cigarette manufacturers.

255. In what follows I shall examine the substantive aspects of the potential infringement of the right to (intellectual) property. Before doing so, I would state that two legal rules have been invoked that are not relevant to the present case. This relates to Article 295 EC and the TRIPs Agreement.

256. As far as Article 295 EC is concerned, the Governments of the United Kingdom, France and Belgium correctly point out that the provisions of the Directive bear no

119 — See footnote 109.

120 — Japan Tobacco stated at the hearing that the term 'mild' in Mild Seven was deemed in a recent decision by the Netherlands advertising authority not to give rise to confusion.

relation to the systems of property ownership in the Member States within the meaning of Article 295 EC. The Directive does no more than impose a restriction on the exercise of specified property rights by cigarette manufacturers. Article 295 EC cannot be invoked in order to set aside a restriction on the exercise of property rights which results from the application of Community provisions. [121]

257. In relation to the TRIPs Agreement, I will comment as follows. The Court has ruled on more than one occasion that, having regard to their nature and structure, the WTO agreements are not in principle among the rules in the light of which the Court may review the legality of measures adopted by the Community institutions. [122] While it recognises that there are individual exceptions to this principle — what it refers to as 'particular obligations' assumed in the context of the WTO — the Court held in its judgment in *Dior* [123] that the TRIPs Agreement is not such as to create rights upon which individuals may rely directly before the courts by virtue of Community law.

258. The Court did, however, recognise in the *Dior* judgment that the TRIPs Agreement may have some significance in proceedings before national courts. [124] In this connection I refer to the TRIPs Agreement itself. It is not contrary to that Agreement for a party to it to restrict the use of a trademark for imperative reasons of public interest. The assessment which, pursuant to the TRIPs Agreement, must consequently be carried out before the national courts adds nothing, however, to the assessment which must in any event be made pursuant to the EC Treaty. In brief, the TRIPs Agreement, precisely for those reasons, plays no role in assessing whether the interference with the right to property was lawful.

2. The right to property in Community law

259. The right to property is not a right recognised as such by the EC or EU Treaties. Article 17 of the Charter of Fundamental Rights [125] does, it is true, recognise the right to property (and the protection of intellectual property). With regard to the present legal position, however, I attach more importance to Article 6 EU. That article requires the European Union to respect fundamental rights, as guaranteed by, *inter alia*, the ECHR, as general principles of Community law. One of those fundamental rights is the

121 — See in this connection Case 182/83 *Fearon* [1984] ECR 3677, paragraph 7. The Court there ruled that the entitlement of Member States to regulate property rights is circumscribed by restrictions resulting from the principle of non-discrimination as protected by the EC Treaty.

122 — *Inter alia*, Case C-149/96 *Portugal* v *Council* [1999] ECR I-8395, paragraph 47.

123 — Joined Cases C-300/98 and C-392/98 *Parfums Christian Dior and Others* [2000] ECR I-11307, paragraph 44.

124 — See in particular paragraphs 47 and 48 of the judgment, cited in the previous footnote.

125 — Charter of fundamental rights of the European Union, OJ 2000 C 364, p. 1.

right to property, as referred to in Article 1, First Protocol, of the ECHR.

260. The Court has also on several occasions expressly recognised the right to property in the Community legal order. [126] According to its settled case-law, the exercise of this right to property may be made subject to restrictions, provided that such restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute, with regard to the aim pursued, disproportionate and unreasonable interference undermining the very substance of that right. [127]

261. There cannot in this case be any question but that the restrictions on the right to property have been introduced by virtue of a matter of public interest. In replying to the question whether this situation can be described as one of disproportionate and unreasonable interference, the following matters, in my view, are relevant. First of all it is necessary to determine whether interference, in view of its scope, is in itself legitimate. Next, if the interference is in itself legitimate, the question needs to be addressed as to whether the case none the less involves an infringement of the principle of legal certainty or, as the case may, the principle of legitimate expectations.

126 — See, *inter alia*, Case 44/79 *Hauer* [1979] ECR 3727, paragraph 17.

127 — This case-law has been developed in the context of the common agricultural policy. See Case 5/88 *Wachauf* [1989] ECR 2609, paragraph 18, and, more recently, Case C-292/97 *Karlsson and Others* [2000] ECR I-2737, paragraph 45.

262. I shall begin by considering the scope of the interference. To what extent is the enjoyment of the property curtailed and the very substance of the right thereby undermined? Without going into this point in detail (I need not yet address the matter of the possible infringement of trademarks): the enjoyment is not curtailed in any particular way or undermined in its very substance. There is no curtailment of the enjoyment of the property of any cigarette-manufacturing unit. Even after the Directive has been implemented, it still remains possible for such a unit to be operated and for cigarettes to be manufactured there. Only the composition and the labelling of those cigarettes must be adapted. Nor is there any curtailment of the enjoyment of the property in the products themselves: as is frequently the case with product legislation, the party entitled must adapt the composition and labelling of its product and is given a transitional period for that purpose, enabling it to dispose of existing stocks. The new tobacco products which it is to manufacture and market must meet specified requirements as to composition and labelling. Those requirements have nothing to do with a restriction of the property right in products.

263. To state it briefly: regard being had to the objective, the measures referred to are nowhere close to constituting a disproportionate and unreasonable interference with the right to property. It is for that reason unnecessary to give any opinion on possible infringement of the principles of legal certainty or, as the case may, of legitimate expectations.

3. The right to intellectual property

264. I shall now concentrate this argument on the right to intellectual property, or more particularly trademark rights. Interference with the enjoyment of trademark rights, following on from the Directive's entry into force, may be substantial. As a result of Article 7 of the Directive, certain trademarks may, in their entirety, no longer be usable, while at the same time the dimensions of the health warnings under Article 5 may also have the result that the distinctiveness of the trademark on a cigarette packet is significantly reduced. Each of these reduces the possibility of recouping the investment made in building up the trademark and can thus result in significant loss.

265. It is also the case in regard to trademark rights that their exercise may be made subject to restrictions on grounds of general interest, [128] but the very substance of the rights themselves may not be undermined.

266. I fail to see how the obligations resulting from Article 5 can be regarded as undermining the very substance of the trademark right. The trademark can normally be displayed on the packaging. Only part of the packaging — which itself amounts to even less than 50% — must be reserved for the statements and warnings prescribed in Article 5. Furthermore, the essential substance of a trademark right does not consist in an entitlement as against the authorities to use a trademark unimpeded by provisions of public law. On the contrary, a trademark right is essentially a right enforceable against other individuals if they infringe the use made by the holder. It is only if normal usage is no longer possible as a result of provisions of public law that a situation can arise in which the substance of the right is affected by reason of those provisions.

267. The situation is more complicated with regard to the ban laid down in Article 7. Article 7, indeed, prohibits the use on tobacco products of certain trademarks, such as the Mild Seven trademark used by Japan Tobacco, or parts of trademarks, such as the word 'light' when used as a component part of a trademark. In the case of the trademark Mild Seven, as Japan Tobacco also submits, the trademark cannot be adapted by dispensing with the additional word 'mild'. I would, however, point out [129] that it is precisely the word 'mild' forming part of the trademark Mild Seven that may be misleading for consumers. The reason for this is that, in the course of the present proceedings, it emerged that cigarettes with widely differing tar yields are marketed under the Mild Seven trademark.

128 — As I stated in paragraph 261, this area of interest does not require to be discussed here.

129 — As the Commission also submitted at the hearing.

268. I take the view that Article 7 is none the less not at variance with the right of (intellectual) property. In reaching this view I do not base myself on an assessment as to whether the very substance of the use of the trademark right is being undermined in this case, but rather reason on the basis of the trademark right itself. That right is not inviolable *in se*. Community legislation on trademark rights already provides for a number of individual grounds of invalidity.

269. In this case, particular significance attaches to Article 3(1)(g) of Directive 89/104 on trademarks. [130] Under that provision, trademarks which are of such a nature as to deceive the public are liable to be declared invalid. In the case of the Community trademark, provision is made for this possibility of invalidity under Article 51(1)(a), in conjunction with Article 7(1)(g), of Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trademark. [131]

270. Article 7 of the Directive, which, moreover, refers expressly to commercial trademarks, bans specific indications with a suggestive meaning. These, in short, are indications liable to mislead the public. Article 7 thereby does no more than prohibit the exercise of a trademark right in a situation in which that right is not in itself inviolable.

271. There cannot, in such a case, be any question of unlawful interference with the essential aspects of the right. Nor do I need to carry out any appraisal of the extent of the interference with regard to its potentially disproportionate or unreasonable nature.

272. To this I would add the following. Both of the above items of Community legislation on trademark rights provide for yet another ground of invalidity, namely conflict with public policy or accepted principles of morality. A trademark coming under the public-law ban on designations in Article 7 of the Directive for the protection of public health is, in my view, invalid as being contrary to public policy.

273. For the sake of completeness, I should also point out that I am not convinced that the scope of the interference is disproportionate or unreasonable. The Council refers in this connection to the judgment in *Estée Lauder*, [132] which involved a cosmetic product the title of which contained the word 'lifting'. The Court in that case upheld national rules which prohibited the

130 — First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trademarks (OJ 1989 L 40, p. 1).

131 — OJ 1994 L 11, p. 1.

132 — Case C-220/98 *Estée Lauder* [2000] ECR I-117. This case did not otherwise involve any trademark right.

importation and marketing of that cosmetic product. As in *Estée Lauder*, the present case also concerns the prohibition of the use of specific designations which have a particular import. The interference with the trademark right is merely an ancillary effect of a measure if the designation forms part of a trademark. This effect does not for that reason render the measure unlawful. According to established case-law, the end objective must also be taken into account. That objective provides justification in the present case for more extensive interference. In conclusion, I also attach importance to the fact that the present Directive provides, in respect of Article 7, for a transitional period which is to expire on 30 September 2003. This provides undertakings with the opportunity to invest in new trademarks.

274. Can one none the less speak — in the case of lawful interference as outlined above — of an infringement of the principle of legal certainty, and more particularly of the principle of legitimate expectations? An entrepreneur must generally be able to rely on the version of legislation in force when he takes a commercial decision. The principle of legitimate expectations, as I stated in my Opinion in the *Silos* case, [133] manifests itself in two forms of confidence which may require protection. First, this involves protection against interference with existing rights. This right, as I held in that Opinion, is not absolute. Second, the principle of legitimate expectations is connected to the protection of expectations that are justified.

275. If we apply the principle of legitimate expectations to the case at present before the Court, the following question will require a reply. To what extent may a cigarette manufacturer remain confident, in the context of its commercial decisions, that the legislation governing the composition and labelling of cigarettes will remain unchanged?

276. This question is almost rhetorical in tone. A manufacturer of no matter what product will always have to bear in mind the fact that the product norms to which it is subject will not remain unchanged indefinitely. Such — technical — norms, indeed, are by their very nature time- and place-specific. This is *a fortiori* the case with regard to the norms governing cigarettes. Scientific insights into the harmfulness of smoking and social views on smoking are undergoing rapid development. It is thus no more than logical that the establishment of standards should be subject to equally rapid change. The tobacco industry is aware of this like no other.

133 — Opinion of 3 April 2001 in Case C-228/99 *Silos*, cited in footnote 111, paragraph 46 et seq.

277. In relation to trademark rights also, there can be no question of infringement of the principles of legal certainty or legitimate expectations. In the first place, the Directive — and more particularly the Article 7 ban — was not totally unexpected. The principal measures contained in the Directive, including Article 7, had already been set out in the Commission's communication of 18 December 1996.[134] A prudent manufacturer would thus have been able to change its market strategy and select a mark to which less risk attached. Second, by choosing a mark which suggests that the product concerned is not harmful, the manufacturer was already assuming a certain risk, even if that manufacturer did not itself consciously create that suggestion. Indeed, under the protection which Community law affords to trademark rights, the right to use a trademark is not in itself inviolable if that trademark is liable to mislead the public. I have already dealt with this issue in paragraph 268 et seq.

278. By way of illustration I would also refer to the position of Japan Tobacco, which it seems would have been most unlikely to have been taken aback by Article 7 of the Directive. It was stated at the hearing, without being contradicted, that, when the Directive was adopted, the Mild Seven brand had only a very short time previously been introduced into the European Union, in any event well after the Commission's communication of 18 December 1996. Further, the brand was still at that time available in only one Member State. In such a situation, there can be no question whatever of an infringement of the principles of legal certainty or legitimate expectations.

134 — See paragraph 67 of this Opinion.

C — *Other principles of law*

279. The High Court mentions a further three principles of law which may be relevant to the validity of the Directive: these are the principle that reasons must be given, the principle of subsidiarity, and the principle that powers must not be misused.

1. The principle that reasons must be given

280. The arguments submitted regarding a possible breach of the duty to state reasons are of two types. The first type of argument relates to the factual and scientific basis underlying the Directive. I mention the claimants' submission that new legislation must be based on new developments, which in turn must be based on scientific data. The preamble to the Directive, however, does not make any reference to scientific data. The second type of argument concerns the reasons set out in the 11th recital in the preamble. The Greek Government

points out, *inter alia*, that the reference to Article 133 EC does not indicate which aspect of the common commercial policy is being realised by the ban on export-geared production. In the opinion of the German Government, the recital fails to indicate why health protection within the Community would be affected by illegal re-importation of tobacco products manufactured in the Community.

281. Against this, it has been argued in particular that the Community legislature is not obligated to provide reasons for every individual choice. Nor is it required to refer to scientific data.

282. The principle that reasons must be given was raised earlier at an important point in this Opinion. It constituted for me the reason why Article 133 EC cannot serve as a legal basis for the Directive. Justice has thus been done to the Greek Government's argument.

283. Further, the statement of reasons in the 11th recital was more generally addressed in the discussion on the production ban (see VI — D). The reasoning — albeit summary — contained in the recital was able to support that production ban. Indeed, according to the Court's settled case-law not all data need be specified. I note in this connection that the recital does not allude to the risk of distortions of competition as a basis for the Directive. For that reason what I have stated in paragraph 161 et seq. is in the nature of a superfluous submission.

284. For the rest, the recital provides a detailed statement of the reasons which led to the adoption of the Directive. It is not necessary in this connection to refer to scientific data, certainly in so far as measures to counter smoking are involved. Relevant also in this connection is the fact that the legislature may take into account not only scientific data but also social opinion.

2. The principle of subsidiarity

285. The issue of subsidiarity may, in my view, be easily disposed of. Just as in the *biotechnology* judgment, [135] the Court can, without going into unduly detailed reasoning, confirm that the principle of subsidiarity has not been infringed. To begin with, the principle of subsidiarity is a dynamic concept which leaves the necessary scope to the appraisal of the European legislature,

135 — Cited in footnote 46, paragraph 30 et seq. of the judgment.

second, the need for Community intervention is thoroughly reasoned,[136] while finally the Directive complies with the guidelines enunciated in the subsidiarity protocol.[137] As I have concluded in this case that action by the Community legislature under Article 95 EC was necessary, no further significance attaches to the appraisal of subsidiarity. In connection with this Directive I wish in particular to refer to:

— paragraph 130 of this Opinion, in which I concluded that the measure has its basis in — at least the specific threat of — differences between the legislation of the Member States liable to give rise to barriers to trade;

— paragraphs 159 to 163 inclusive of this Opinion, in which I concluded that a national ban on production would be neither effective nor conceivable.

3. Misuse of powers

286. Finally, we come to the issue of misuse of powers. The Court's case-law states that a measure may constitute a misuse of powers only if it appears, on the basis of objective, relevant and consistent factors, to have been taken with the exclusive purpose, or at any rate the main purpose, of achieving an end other than that stated or of evading a procedure specifically prescribed by the Treaty for dealing with the circumstances of the case.

287. If I apply that case-law to the present case, I must conclude that in a case such as that here, where the legal basis of a Community measure is under discussion, no separate significance need be attached to the principle that powers must not be misused. The Court can rule that the correct legal basis was chosen, whereby it will be settled that the Community legislature made proper use of the powers conferred on it. There could therefore be no question of misuse of powers. The Court can also rule that the correct legal basis was not chosen and for that reason annul the Directive. There would then also be no need for the Court to examine the question whether powers had been misused.

VIII — Examination of the second question

A — *Arguments submitted*

288. According to the complainants, Japan Tobacco, and the Governments of Greece, Ireland, Luxembourg, the Netherlands and

136 — See the recitals in the preamble, in particular the 33rd recital.

137 — Protocol on the application of the principles of subsidiarity and proportionality, annexed to the Treaty of Amsterdam.

Sweden, as well as the Parliament, the Council and the Commission, Article 7 of the Directive applies only to tobacco products that are marketed within the European Community. In contrast, the Governments of the United Kingdom, Belgium, France, Italy and Finland take the view that Article 7 also covers tobacco products manufactured in the Community and destined for exportation to non-member countries.

289. The main arguments put forward by the first group of intervening parties in favour of a restricted interpretation run as follows:

— It is not clear from the wording of Article 7 that it was intended to have extraterritorial effect, and thus the prohibition also cannot have such an effect. The Council, however, recognises in this connection that Article 7 also does not expressly limit the territorial effect.

— An extension of the prohibition to tobacco products intended for export is inappropriate for the purpose of preventing undermining of the internal market provisions.

— Article 7 cannot be considered in isolation from Article 5 in view of the fact that Article 7 is designed to prevent the labelling requirements of Article 5 from being undermined. This ought to mean that the territorial scope of Article 7 is equivalent to that of Article 5. Article 5 can, in view of its linguistic requirements, apply only to tobacco products within the internal market.

290. The principal arguments adduced by the second group of intervening parties in favour of a broad construction are as follows:

— It is not evident from the wording of Article 7, which provides that certain designations may no longer be used on the packaging of tobacco products, that this article is limited to cigarettes destined for the internal market.

— Application of Article 7 to exports is justified because of the real danger of illicit trade.

— Article 7 constitutes a necessary supplement to Articles 3 and 5. The effect of these latter articles would be undermined without Article 7. For that reason Article 7 has the same scope of application as do Articles 3 and 5.

— Article 152(1) EC requires that a high level of human health protection be ensured in the Community's activities and policies. This obligation also covers the common commercial policy. This, in the view of the United Kingdom Government, means that, if the Community legislature had intended to make an exception for exports to non-member countries, that would have been expressly set out in Article 7 of the Directive.

B — *Appraisal*

291. The main significance in my view attaches to the fact that the text of the Directive provides no indication as to whether Article 7 is also applicable to cigarettes intended for export to non-member countries. The text is not unambiguous, as illustrated by the fact that both those who argue for and those who argue against an external effect invoke the wording of the Directive. In such circumstances the Community Courts may avail of a variety of methods of interpretation.

292. My view is that the systematic legislative interpretation is here the most effective. Such an interpretation can be made on the basis of the two most important obligations which, apart from Article 7, are derived from the Directive. These are the obligation as to composition set out in Article 3 and the labelling obligation laid down in Article 5. Article 3 equally concerns production for purposes of exportation and also states so in express terms. The wording of Article 5 is silent as to its scope of application. Careful reading, however, will indicate that Article 5 cannot also be intended to cover exports to non-member countries. This is because the warnings to be placed on cigarette packets pursuant to Article 5 must appear in an official language of a Member State. This linguistic requirement, which is an essential element of the obligation pursuant to Article 5, would be meaningless if it related to exports to non-member countries.

293. Article 7 is just as silent as Article 5, but in contrast to Article 3 it is silent as to its scope and for that reason alone can be construed better by analogy to Article 5. In addition, Article 7 is, *qua* content, more similar to Article 5 than to Article 3. Indeed, Article 7 concerns the designations, not the composition, of tobacco products. Even more significant, in my opinion, is the fact that Articles 5 and 7 are substantively also closely related to one another. As the Belgian Government also pointed out during the hearing, Articles 5 and 7 can be treated as complementary provisions. Article 5 imposes an obligation as to the

inclusion on packaging of objective data on, *inter alia*, tar yields, and Article 7 prohibits the inclusion of suggestive designations which may adversely affect the value which consumers attach to the objective data notified pursuant to Article 5. I am also in agreement with the view that the effect of Article 5 could be undermined without Article 7.

294. In brief, the systematic legislative interpretation leads to the conclusion that Article 7 does not apply to cigarettes intended for export.

295. Nor does the teleological method of interpretation lead to any different conclusion. First, Article 7 imposes a very extensive obligation on certain market participants. In such a case it is not the function of the courts to construe the scope of application as broadly as possible when the provision itself is ambiguous. A limitation on the freedom of market participants must be based on an express choice by the legislature.

296. Article 152(1) EC has no role to play in this regard. Article 152(1) EC contains a guiding principle for the Community legislature but is not a source for the interpretation of Community law where the legislature has elected to remain silent. In addition, as is clear from my conclusion, and in contrast to the position which I mentioned in the fourth indent of paragraph 290, the Directive has nothing to do with the common commercial policy.

297. In conclusion, I shall consider — as the third method of interpretation — the nature and content of Article 7 of the Directive. Here too I conclude that this article has nothing to do with exports from the European Union. Article 7 concerns the designation and consequently the labelling of cigarettes. The labelling of cigarettes will vary according to the country of destination, having regard also to the warnings which, under Article 3, must be included on the packaging. Given that the packaging of cigarettes, unlike their composition, will differ in its nature depending on the country for which the cigarettes are destined, I see no reason to place a construction on Article 7 that does not draw such a distinction. I refer once again to the arguments concerning the risk of illicit trade. I concur with the argument that an extension of the Article 7 ban to tobacco products intended for export is not appropriate for ensuring that the provisions of the internal market are not undermined. As already stated, the labelling of cigarettes by definition differs according to the country of destination.

IX — Conclusion

298. On the basis of the foregoing considerations, I propose that the Court reply as follows to the questions submitted by the High Court of Justice (Administrative Court):

(1) 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 is valid.

(2) Article 7 of Directive 2001/37/EC does not apply to tobacco products that are not marketed within the European Community.