OPINION OF ADVOCATE GENERAL GEELHOED

delivered on 4 July 2002 [1]

I — Introduction

1. The cases covered by these combined Opinions essentially concern the question whether a national rule containing a general prohibition on health-related information appearing on foodstuffs unless prior authorisation has been granted is compatible with the provisions of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (hereinafter 'Directive 79/112') [2] and with Articles 28 and 30 EC relating to the free movement of goods. In particular, the Court is required to rule on the provisions of Directive 79/112 concerning the prohibition of disease-related information and misleading labelling (Article 2) and the right of Member States to prohibit the sale of foodstuffs which comply with the directive by applying non-harmonised national labelling provisions (Article 15).

2. Case C-221/00 concerns an action brought against the Republic of Austria by the Commission under Article 226 EC. The Commission received complaints that foodstuffs which had been lawfully manufactured and put on the market in other Member States could not be sold in Austria because the health-related information affixed thereto was not authorised by the authorities. Such information included, for example, the statements 'for a cholesterol-conscious diet' on the labelling of salmon-oil capsules; 'a contribution to healthy intestinal bacteria and healthy cells' on the labelling of bread, and 'dietary fibre and bulking agent for sufferers of constipation caused by diet' on the labelling of linseed.

3. After the Commission brought the action, a number of courts in Austria referred questions to the Court of Justice for a preliminary ruling on the compatibility of the same national rules with Community law. The main proceedings concern *inter alia* the statements 'a good name for healthy enjoyment' on the labelling of pâté (Case C-421/00) and the information 'for the protection of the cell membrane against

1 — Original language: Dutch.

2 — OJ 1979 L 33, p. 1. The directive has been amended several times. On 20 March 2000 a consolidated text (Directive 2000/13/EC, OJ 2000 L 109, p. 29; hereinafter 'Directive 2000/13') was adopted by the Council and the European Parliament.

free radicals', 'important for the functioning of many enzymes', 'important as a building block for bones and teeth' and 'regulation of the fluid balance (bladder function)' in the leaflet accompanying pumpkin seed capsules (Case C-16/01).

4. The Austrian prohibition on health-related information, subject to authorisation, applies not only to foodstuffs, but also to cosmetic products. The Court has already given a ruling on that subject in 1999, in its judgment in *Unilever*. [3]

II — Legal framework

A — *Community law*

5. Article 28 EC prohibits quantitative restrictions on imports and all measures having equivalent effect between Member States. Article 30 EC provides that Article 28 EC does not preclude prohibitions or restrictions on imports or goods in transit justified on grounds of *inter alia* the protection of health and life of humans. Such prohibitions or restrictions must not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

6. According to the recitals in the preamble to Directive 79/112, the purpose of the directive is to approximate the provisions of the Member States on labelling in order thus to facilitate the free circulation of foodstuffs. To that end it lays down a number of rules of a general nature applicable horizontally to all foodstuffs put on the market.

7. Article 2 of Directive 79/112 (now Article 2 of Directive 2000/13), which establishes the principles which must form the basis of any rules in the field of labelling and advertising, is worded as follows:

'1. The labelling and methods used must not:

(a) be such as could mislead the purchaser to a material degree, particularly:

(i) as to the characteristics of the foodstuff and, in particular, as to

3 — Case C-77/97 [1999] ECR I-431. With regard to the rules for cosmetic products, see the pending Case C-99/01 *Linhart* [2002] ECR I-9375, in which I delivered my Opinion on 7 March 2002.

its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production;

(ii) by attributing to the foodstuff effects or properties which it does not possess;

(iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;

(b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties.

2. The Council, in accordance with the procedure laid down in Article 95 of the Treaty, shall draw up a non-exhaustive list of the claims within the meaning of paragraph 1, the use of which must at all events be prohibited or restricted. [4]

3. The prohibitions or restrictions referred to in paragraphs 1 and 2 shall also apply to:

(a) the presentation of foodstuffs, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.'

8. Article 15 of Directive 79/112 (now Article 18 of Directive 2000/13) provides:

'1. Member States may not forbid trade in foodstuffs which comply with the rules laid

4 — For the sake of completeness, I would point out that, as early as 1981, the Commission submitted, pursuant to Article 2(2) of Directive 79/112, a proposal for a Council directive providing for the harmonisation of prohibited misleading claims (OJ 1981 C 198, p. 4). The purpose of the draft directive was to establish a non-exhaustive list of claims relating to the characteristics, effects or properties referred to in Article 2(1)(a) of Directive 79/112. However, the proposal was withdrawn in 1985.

down in this Directive by the application of non-harmonised national provisions governing the labelling and presentation of certain foodstuffs or of foodstuffs in general.

2. Paragraph 1 shall not apply to non-harmonised national provisions justified on grounds of:

— protection of public health,

— prevention of fraud, unless such provisions are liable to impede the application of the definitions and rules laid down by this Directive,

— protection of industrial and commercial property rights, indications of provenance, registered designations of origin and prevention of unfair competition.'

9. Under Article 4 of Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (hereinafter 'Directive 84/450'),[5] Member States are to ensure that 'adequate and effective means exist for the control of misleading advertising in the interests of consumers as well as competitors and the general public'. Article 7 provides that Directive 84/450 does not preclude Member States from retaining or adopting provisions with a view to ensuring more extensive protection for the persons concerned.

B — *National law*

10. The Bundesgesetz über den Verkehr mit Lebensmitteln, Verzehrprodukten, Zusatzstoffen, kosmetischen Mitteln und Gebrauchsgegenständen (Federal Law on trade in foodstuffs, products intended for human consumption, additives, cosmetic products and consumer goods) of 23 February 1975 (the Lebensmittelgesetz 1975, hereinafter 'the LMG')[6] contains *inter alia* a number of description rules.

11. Under Paragraph 9(1) of the LMG, it is forbidden, in marketing foodstuffs, products intended for human consumption or additives,

5 — OJ 1984 L 250, p. 17, as amended by Directive 97/55/EC of the European Parliament and of the Council of 6 October 1997, which extended its scope to include comparative advertising (OJ 1997 L 290, p. 18).

6 — BGBl. 86.

'(a) to refer to the prevention, relief or cure of illnesses or symptoms of illness, or to physiological or pharmacological effects, in particular effects which prolong youthfulness, slow down the symptoms of ageing, lead to weight loss or preserve health or to create the impression of any such effect;

(b) to refer to case histories, recommendations by doctors or expert medical opinions;

(c) to use health-related pictorial or stylised representations of organs of the human body, depictions of members of the health-care professions or of sanatoria or other pictures or illustrations referring to health-care activities.'

12. Under Paragraph 9(3) of the LMG, the minister must, upon request and by decree, authorise the provision of health-related information in respect of certain foodstuffs or products intended for human consumption where that is consistent with protecting consumers against being misled.

13. According to Paragraph 74(1) of the LMG, anyone who *inter alia* falsely describes foodstuffs or markets foodstuffs which are falsely described is guilty of an administrative offence (*Verwaltungsübertretung*).

III — Facts and procedure

A — *The infringement proceedings*

14. In the infringement proceedings, the Commission claims that the Court should:

'(1) declare that, by interpreting and applying Paragraph 9(1) of the Lebensmittelgesetz ("the LMG") as meaning that health-related information on foodstuffs intended for human consumption is prohibited in a general and absolute manner, and by subjecting the affixing of such information to a prior authorisation procedure (Paragraph 9(3) of the LMG)), the Republic of Austria has failed to fulfil its obligations under

Articles 2(1)(b) and 15(1) and (2) of Directive 79/112 and under Article 28 EC (ex Article 30 of the EC Treaty);

(2) order the defendant to pay the costs.'

15. The Republic of Austria contends that the action should be dismissed and that the Commission should be ordered to pay the costs.

16. The President of the Court gave the Kingdom of Denmark leave to intervene in support of the Republic of Austria. A hearing took place on 2 May 2002.

B — *The proceedings for preliminary rulings (Cases C-421/00, C-426/00 and C-16/01)*

17. In the main proceedings in Case C-421/00, R. Sterbenz is charged with having put on the market the foodstuffs 'Tartex veget. Pastete Champignon' and 'Tartex veget. Pastete Kräuter' [7] even though those products were falsely described in that they bore the health-related information 'ein guter Name für gesunden Genuss' ('a good name for healthy enjoyment') and it is forbidden, in marketing foodstuffs, consumer products or additives, to refer to the prevention, relief or cure of illnesses or symptoms of illness, or to physiological or pharmacological effects, or to create the impression of any such effect. She therefore acted in contravention of the provisions of Paragraph 9(1)(a) of the LMG and was ordered *inter alia* to pay fines pursuant to Paragraph 74(1) of the LMG.

18. Ms Sterbenz appealed against that sentence before the Unabhängiger Verwaltungssenat für Kärnten (Independent Administrative Chamber for Carinthia). The defendant requested that the administrative penalty proceedings be stayed, referring principally to the action brought by the European Commission against the Republic of Austria, which was pending under case number C-221/00, and to the fact that the decision to be given by the Court of Justice would serve as a precedent for the disposal of the appeal. Under the Verwaltungsstrafgesetz (Law on Administrative Penalties, 'the VStG') 1991, a reference for a preliminary ruling appears to be the only instrument capable of interrupting the decision period within the meaning of Paragraph 51(7) of the VStG. [8] By order of 8 November 2000, the Unabhängiger Ver-

7 — Clearly a mushroom pâté and a herb pâté respectively, intended for spreading on bread.

8 — Paragraph 51(7) of the VStG states: 'Where in proceedings in which only the defendant has a right of appeal 15 months have elapsed since lodgement of an appeal against a penalty, the penalty shall cease by operation of law to have effect; the proceedings shall be discontinued. Time taken by proceedings before the Verfassungsgerichtshof (Federal Constitutional Court) or the Court of Justice of the European Communities shall not be included in that period.'

waltungssenat therefore referred the following question for a preliminary ruling:

'Are Article 28 (ex Article 30) of the EC Treaty as amended by the Treaty of Amsterdam and Articles 2(1)(b) and 15(1) and (2) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (OJ 1979 L 33, p. 1) in the applicable version to be interpreted as precluding national legislation prohibiting any health-related information from appearing on the labelling and presentation of foodstuffs, products intended for human consumption and additives for general consumption, save if expressly authorised? (Paragraph 9(1)(a), (b) and (c) and (3) of the LMG 1975, BGBl. No 1975/86 in the applicable version)?'

19. In the main proceedings in Case C-426/00, P.D. Haug was ordered by the city council of Vienna to pay fines for contravening the foodstuffs legislation. In an order for reference of 15 November 2000, which otherwise provides no insight into the factual background to the case in the main proceedings, the Unabhängiger Verwaltungssenat Wien (Independent Administrative Chamber, Vienna) requests the Court of Justice to give a ruling on the following questions:

'(1) Does Paragraph 9 of the LMG constitute an appropriate transposition of Article 2(1)(b) of Council Directive 79/112/EEC of 18 December 1978?

(2) Does Article 2(1)(b) of Directive 79/112/EEC make exhaustive provision concerning unlawful labelling, or does that provision provide for a minimum level of regulation which may be supplemented by national provisions?

(3) Is Article 2(1)(b) of Directive 79/112/EEC to be construed to mean that a restriction on labelling (such as that in Paragraph 9(1) of the LMG in regard to health-related information) is only permissible where a prohibition appears to be an unavoidable necessity in order to prevent consumers from being misled?

(4) Can Paragraph 9(1) of the LMG be interpreted so as to comply with the directive and the restriction on labelling mentioned therein be deemed to be

in conformity with Article 2(1)(b) of Directive 79/112/EEC? This would be possible inasmuch as an intention to mislead is not required by Article 2(1)[(b)] as a whole but is a second criterion of the unlawfulness of a label.'

20. Finally, in the main proceedings in Case C-16/01, by judgment of the Unabhängiger Verwaltungssenat Wien of 12 October 1999, P.D. Haug was found guilty, as the manager with general commercial power of representation of Renatura Naturheilmittel Ges.mb.H., of having been responsible for the company's supplying to DM-Zentrale in Enns, and thus putting on the market, the product 'Renatura Kürbiskernkapseln mit Vitamin E Blase und Prostata' purchased from Renatura Naturheilmittel Ges.m.b.H in Germany. Under the LMG, that consumer product was falsely described inasmuch as the accompanying leaflet contained the following health-related information in contravention of Paragraph 9(1) of the LMG: 'for protection of the cell membrane from free radicals'; 'important for the functioning of many enzymes'; 'important as a building block for bones and teeth'; 'regulation of the fluid balance (bladder functioning)'.

That information was given in the following context: 'Styrian oil pumpkin seeds are ideal for enhancing the nutritional level of the daily food intake because they contain: a high level of linoleic acid, important as a constituent of the cell membrane; tocopherols and carotenoids, important in protecting the cell membrane against free radicals; the trace elements iron, copper, manganese, zinc and selenium, which are important for the functioning of many enzymes; the minerals calcium, magnesium and phosphate, which are important for building bones and teeth; a high level of potassium, important in regulating the fluid balance (bladder functioning). Oil pumpkin seed capsules from Renatura not only contain the valuable nutrients of Styrian oil pumpkin seeds, but are also enriched with added Vitamin E. They can therefore be especially recommended as a daily food supplement.'

21. In its case-law, the Verwaltungsgerichtshof has hitherto construed Paragraph 9(1) of the LMG as not distinguishing between health-related and disease-related information, but as prohibiting generally all health-related information. In considering whether a specific piece of information is health-related, the Verwaltungsgerichtshof has always based its assessment on the generally prevailing view. Under the case-law of the Verwaltungsgerichtshof, the decisive factor is whether, in the case of the average consumer, a description is likely at first glance to convey the impression that consumption of the foodstuff so described has a favourable effect on health (that is to say, at least the effect of

maintaining health). [9] The Verwaltungsgerichtshof has also taken the view hitherto in its decisions that Paragraph 9(1) of the LMG with its general prohibition on health-related information is not contrary to Article 2(1)(b) of Directive 79/112. [10]

22. The information forming the subject of the charge against the appellant P.D. Haug was also deemed to be prohibited health-related information. He questions the validity of the existing national rules and in his appeal before the Verwaltungsgerichtshof submits that the information classified by the Unabhängiger Verwaltungssenat as health-related information prohibited by the LMG is not prohibited under Article 2(1)(b) of Directive 79/112. In his view, it is not prohibited disease-related information, but permitted health-related information, which is not misleading and should therefore not be subject to an authorisation procedure under Paragraph 9(3) of the LMG either.

23. By order of 18 December 2000, the Verwaltungsgerichtshof therefore requested the Court, pursuant to Article 234 EC, to give a ruling on the following questions:

'1. Does Article 2(1)(b) of Council Directive 79/112/EEC..., under which — subject to Community provisions applicable to natural mineral waters and to foodstuffs for particular nutritional uses — the labelling and methods used may not attribute to any foodstuff the property of preventing, treating or curing a human disease, or suggest that it possesses such properties, preclude national legislation which makes it an offence when marketing foodstuffs:

(a) to refer to physiological or pharmacological effects, in particular those which preserve youthfulness, inhibit signs of ageing, promote slimming or maintain health, or to create the impression of any such effect;

(b) to refer to case-histories, recommendations made by doctors or medical experts' reports;

9 — The referring court cites as examples of descriptions which have been classified as prohibited health-related information: 'the healthy alternative'; 'only approx. 105kcal/100g — makes you fit, not fat'; 'Linusit Gold supplies roughage and bulking agent for constipation caused by diet'; and 'improves bladder function'.

10 — It is worth mentioning that the referring court states that it does not share the view expressed by the Austrian Government in the reply in Case C-221/00, and discussed further on in this Opinion, that Paragraph 9(1) of the LMG goes beyond the terms of Article 2(1)(b) of Directive 79/112.

(c) to use health-related pictorial or stylised representations of organs of the human body, pictures of members of the health-care professions or of sanatoria or other pictures or illustrations referring to health-care activities?

2. Do Directive 79/112/EEC or Articles 28 and 30 EC preclude a national provision which, on the placing into circulation of foodstuffs, permits health-related information such as that described in Question 1 to be affixed thereto only after prior authorisation by the competent federal minister, whereby a condition of authorisation is that the health-related information is consistent with protecting the consumer from being misled?'

24. The President of the Court ordered that Cases C-421/00, C-426/00 and C-16/01 be joined. [11] Written observations were submitted by Sterbenz (in Case C-421/00), the Austrian Government and the Commission. No hearing took place in the preliminary ruling cases.

11 — It may be noted in passing that the other proceedings for preliminary rulings, in which Austrian courts have referred similar questions, have been stayed (Cases C-66/01, C-74/01, C-339/01, C-343/01 and C-357/01).

IV — Pleas in law and main arguments of the parties

A — *Infringement proceedings (Case C-221/00)*

25. In its application, the Commission makes a distinction between the prohibition of health-related information appearing on foodstuffs (Paragraph 9(1) of the LMG) and the requirement of prior authorisation for health-related information to appear on foodstuffs (Paragraph 9(3) of the LMG).

26. It argues that the prohibition of health-related statements appearing on foodstuffs is incompatible with Article 2(1)(b) and Article 15(1) and (2) of Directive 79/112. Article 2(1)(b) of that directive only authorises the Member States to prohibit disease-related information. A prohibition on health-related statements exceeds the scope of that provision and must therefore be assessed under Article 15(1) and (2) of Directive 79/112. Article 15(2) lists exhaustively the grounds on which the application of non-harmonised national provisions prohibiting trade in foodstuffs which comply with the directive may be justified. [12] In the Commission's view, the defence of con-

12 — Case C-241/89 *SARPP* [1990] ECR I-4695, paragraph 15.

sumer protection relied on by the Austrian Government does not justify a general prohibition of health-related information since statements which are true and not likely to confuse the average consumer are also caught by the prohibition. [13] In that connection, the Commission points out that the law of a Member State must not cement given consumer habits with a view to preserving an advantage acquired by a domestic industry engaged in meeting the consumer demand when other measures are available to protect consumers against the risk of being misled. [14] The Court's case-law confirms that it is not permitted to base national rules for the protection of public health and consumers only on the circumstances prevailing in the Member State concerned. According to the Commission, the view that a general prohibition such as the one at issue finds no justification in Article 15(2) of Directive 79/112 is borne out by the judgment in *Unilever* which concerned the same Austrian rules in so far as they relate to cosmetic products. [15]

27. The Commission assesses the condition of prior authorisation in the light of the Treaty provisions concerning the free movement of goods (Articles 28 and 30 EC). The fact that authorisation must be applied for under Paragraph 9(3) of the LMG, even though such authorisation may be granted if the information in question is truthful and not misleading — as the Austrian Government claims —, constitutes a measure having equivalent effect within the meaning of Article 28 EC. Under the Court's settled case-law, obstacles to movement within the Community resulting from disparities between national laws are accepted in so far as those provisions are necessary for reasons relating to the public interest, such as consumer protection, provided that they are proportionate to the intended purpose and that purpose cannot be achieved by measures less restrictive of free trade. [16] However, since the Commission considers that the general prohibition of health-related information is not justified on grounds of consumer protection, the same conclusion applies with regard to the requirement of prior authorisation connected with that prohibition. Moreover, consumer protection can be ensured by measures having a less restrictive effect on the free movement of goods. Thus, for example, targeted checks on the market could take place in order to identify products bearing descriptions likely to mislead the consumer, as the Court has already held in *Unilever*. [17] The Commission further argues that the Austrian Government has failed to show why the procedure of prior examination is the least restrictive and most appropriate means of protecting the consumer against the risk of being misled. Moreover, the case-law under which the marketing of foodstuffs may be made subject to prior authorisation is not relevant in the present case. [18]

13 — By analogy with Case C-383/97 *Van der Laan* [1999] ECR I-731, paragraph 37 et seq.

14 — With reference to Case 178/84 *Commission* v *Germany* [1987] ECR 1227, paragraph 32 ('*Beer Purity*').

15 — Case C-77/97, cited in footnote 3, paragraphs 33 and 34.

16 — Case 120/78 *Rewe-Zentral* [1979] ECR 649 ('*Cassis de Dijon*').

17 — Cited in footnote 3, paragraphs 34 and 35.

18 — Case 304/84 *Muller and Others* [1986] ECR 1511 and the *Beer Purity* case, cited in footnote 16.

28. The Austrian Government acknowledges that the prohibition on health-related information exceeds the scope of Article 2(1)(b) of Directive 79/112 but argues that it is covered by Article 15(2) of that directive for reasons connected with the protection of public health and the consumer. Any application for authorisation to use a health-related description is granted if that description is truthful and consistent with the requirement that the consumer must be protected against the risk of being misled. That must not be left to the subjective judgement of a trader but must be verified on the basis of an objective criterion. A misleading description which attributes to a product a property which it does not possess (for example, 'beneficial to your health') may have adverse effects on a patient's condition, in particular where an effective treatment for a disease and its symptoms is disregarded because patients rely on the 'effect' of the product. The Austrian Government is not convinced by the judgments cited by the Commission and in its opinion the examples of health-related descriptions mentioned in the application [19] are not relevant. Those descriptions have either already been authorised or, as medicinal claims, fall under Article 2(1)(b) of Directive 79/112, or they are misleading and therefore prohibited in any case.

29. With regard to the requirement of prior authorisation laid down by Paragraph 9(3) of the LMG, the Austrian Government then adds the following further points to those arguments. It argues that Directive 79/112 does not make exhaustive provision. Article 2 deals with the prohibition of misleading and disease-related descriptions, but is silent on the permissibility of health-related information and advertising which are not misleading. For those reasons, the Austrian Government — in contrast to the Commission — takes the view that in this case account must also be taken of Directive 84/450, as amended by Directive 97/55. Article 2 of Directive 84/450, which also applies to foodstuffs, starts from a broad concept of deceptive advertising. That directive therefore also applies to advertising on a product, the deceptive character of which stems from the wording on the packaging. The Austrian Government infers from the recitals in the preamble to Directive 84/450, and from the right of Member States, enshrined in Article 7, to adopt measures which afford consumers more extensive protection against misleading advertising, that a requirement of prior authorisation for foodstuffs carrying health-related information is not contrary to Community law. The purpose of Paragraph 9(3) of the LMG is not to protect the consumer from truthful information which cannot mislead the consumer, but from information which is untrue and therefore likely to mislead the consumer, possibly inducing him to risk acts or omissions harmful to his health. As far as the Austrian Government is concerned, a system of *ex post* control of foodstuffs which have already been placed on the market is not sufficient to ensure the necessary protection of the consumer, as is confirmed by negative experiences in the United States. In that connection, it also points out that the legal framework resulting from the *Unilever* judgment, which relates to cosmetic products, is different

19 — Cited in point 2 of this Opinion.

from that in this case, since foodstuffs are intended to be consumed, justifying a higher level of protection. [20]

30. The Danish Government argues in its intervention *inter alia* that Article 2(1)(b) of Directive 79/112 applies to all health-related descriptions in the context of foodstuffs labelling. Paragraph 9 of the LMG complies with that provision, with the result that there is no need for any assessment under Article 15(2) of Directive 79/112.

B — *The proceedings for preliminary rulings (Cases C-421/00, C-426/00 and C-16/01)*

31. The Austrian Government repeats in essence in its written observations the arguments which it had already put forward in Case C-221/00. The Commission also starts from the position already adopted by it in Case C-221/00. In addition, it submits specific observations on each of the preliminary-ruling cases, which I shall consider, together with the observations of Sterbenz in Case C-421/00, in the assessment below.

20 — Cited in footnote 3.

V — Assessment

A — *Introductory observations*

32. In the last few decades a growing demand for 'health products' has arisen in the Member States. This has encouraged the marketing of a great variety of new products to which specific health characteristics are ascribed. Connected with that development, there has been an increase in the use of health information on the labelling of, and in advertisements for, foodstuffs. The descriptions or claims involved vary in type. They may stress the maintenance of health ('increases your natural resistance'), warn against risky ingredients in food ('saturated fats raise the blood cholesterol level'), indicate that a particular ingredient is good for one's health ('rich in vitamin C'), relate to the composition of products ('more than 50% linoleic acid') or simply refer to health in general ('tasty can also be healthy'). [21]

33. The Austrian provisions contained in Paragraph 9(1) of the LMG, as extensively interpreted in the national case-law, prohibit any health-related information from

21 — Examples borrowed from Kabel, J., *Uw bakker, uw dokter! Gezondheidsclaims bij levensmiddelen*, Universiteit van Amsterdam, 1996, pp. 30 to 31.

appearing on foodstuffs, even if the description in itself is true. Under the case-law of the Verwaltungsgerichtshof, the decisive factor for classifying a description as 'health-related information' is whether, it is likely at a glance to convey to the mind of an average consumer the impression that consumption of the foodstuff so described has a beneficial effect on health. However, the prohibition on such information is not absolute. Under Paragraph 9(3) of the LMG, a trader may apply for prior authorisation to show health-related information on foodstuffs. The minister responsible must grant authorisation if the claims are truthful and do not mislead the consumer.

34. The scope of that national legislation is not essentially in dispute in the present proceedings. The point at issue is the extent to which Community law permits a national prohibition on health-related information appearing on foodstuffs, subject to the possibility of prior authorisation. Basically, the questions which arise in particular are the extent to which health-related claims are in fact likely to mislead consumers and endanger their health and whether the national system in question is consistent with the principle of proportionality. Before those questions can be answered, it is necessary to examine how labelling with 'health-related information' is positioned within the scheme of Directive 79/112. That analysis is technical and legal in nature. Nevertheless, a number of questions of principle arise in this regard, which are relevant to the further development of law in the field of information about, and labelling of, foodstuffs.

35. I shall examine below, first, the Commission's application in Case C-221/00. The assessment of that case will then provide the basis for answering the questions referred by the Austrian courts. Where appropriate, submissions made in connection with the proceedings for preliminary rulings will be assessed in the course of considering the infringement proceedings.

B — *Subject-matter of the proceedings and applicable legal framework in Case C-221/00*

36. To begin with, I take the view that the distinction made by the Commission between the general prohibition of health-related information, which is examined in the light of Article 2(1)(b) and Article 15(1)

and (2) of Directive 79/112,[22] and the requirement of prior authorisation, which the Commission examines under Articles 28 and 30 EC, is not tenable. That separate assessment of the provisions of Paragraph 9(1) and Paragraph 9(3) of the LMG is functionally illogical. It is also inconsistent with the scheme of Directive 79/112.

37. First, there is an obvious and indissoluble connection between the general prohibition in Paragraph 9(1) of the LMG and the authorisation requirement in Paragraph 9(3) of the LMG. The Austrian Government has rightly pointed out that the system of authorisation in Paragraph 9(3) of the LMG presupposes the general prohibition in Paragraph 9(1) of the LMG. Without such a prohibition, the system of authorisation could not work. By means of the functional correlation between them, the two provisions are designed to ensure effective control of health-related information.

38. Second, the scheme of Directive 79/112 precludes decoupling the two national provisions. That follows from the central position of Article 15 within the scheme of Directive 79/112. Article 15(1) contains a market access clause: Member States may not forbid trade in foodstuffs which comply with the provisions of the directive by applying national foodstuffs legislation in so far as such legislation consists of 'non-harmonised national provisions'. If a national provision is harmonised, it must be assessed on the basis of the corresponding provision of the directive.[23] If a national provision is not harmonised, but falls within the material scope of Directive 79/112, it may be justified only by virtue of Article 15(2). Under that provision, Article 15(1) does not apply to 'non-harmonised national provisions' justified on grounds of *inter alia* the protection of public health and the prevention of fraud and unfair competition. In *SARPP*, the Court held that the limits of the power of the Member States to maintain or adopt rules in addition to those laid down by the directive are 'set by the directive itself in so far as it lists exhaustively, in Article 15(2), the grounds on which the application of non-harmonised national provisions... may be justified.'[24]

39. The directive thus takes as its starting point harmonised and non-harmonised

22 — At the hearing, the representative of the Austrian Government pointed out that the Commission's application is dated 31 May 2000, whereas Directive 2000/13 had already entered into force on 26 May 2000. The provisions of Directive 79/112 at issue are substantively identical to those of Directive 2000/13, and the transposition requirements are therefore also identical. For that reason, the Commission's omission should not, in my opinion, affect the admissibility of its application.

23 — See to that effect, for example, Case C-123/00 *Bellamy and English Shop Wholesale* [2001] ECR I-2795 and Case C-465/98 *Darbo* [2000] ECR I-2297.

24 — Cited in footnote 12, paragraph 15. The distinction between 'harmonised' and 'non-harmonised' matters is also the subject of Case C-229/01 (*Muller*), currently pending.

national laws and attaches different legal consequences to them. However, there is yet a third possibility. If a national provision is not harmonised, but also falls outside the scope of the directive, the provision in question must, where appropriate, be examined in the light of the general provisions of the Treaty. Thus, according to the Court in the judgment in *SARPP*, Directive 79/112 makes a distinction between the rules for labelling and advertising. As far as labelling is concerned, the limit of the powers of the Member States is set by the directive itself. That also applies to national rules which lay down conditions which, as such, are not covered by the directive. On the other hand, national rules which make advertising subject to conditions in addition to those laid down by the directive must be considered in the light, in particular, of the provisions of the Treaty on the free movement of goods and especially Articles 28 and 30 EC. [25]

40. Advertising has thus been partially harmonised, [26] but labelling of foodstuffs has been fully harmonised, although it is assumed in the scheme of Directive 79/112 that not all national labelling requirements are fully covered by the directive. Thus, for example, there are no specific provisions on health-related descriptions and the matter of authorisation requirements is not covered. Moreover, the directive allows the Member States to adopt certain derogating measures in the field of labelling. Nevertheless, national labelling rules pertaining to areas harmonised by the directive must be assessed within the scheme of the directive — namely, Article 15(2) — and not in the light of Articles 28 and 30 EC. [27] With regard to the legislation on labelling, the system of the directive is conclusive. [28]

41. In the present proceedings, the Commission argues in the reply, in my view therefore wrongly, that a general prior authorisation procedure does not fall within the scope of the directive. Although it is true that Directive 79/112 does not contemplate any specific procedures for the prior authorisation of labelling, it seems to

25 — Cited in footnote 12, paragraph 15. The distinction in question is important. Article 15(2) contains an exhaustive list of matters of public interest which may justify a breach of the prohibition laid down in Article 15(1). On the other hand, in *Cassis de Dijon*, cited in footnote 16, the Court takes as its starting point a non-exhaustive list of matters of public interest which may be invoked to justify obstacles to imports. I would point out that the Council adopted Directive 79/112 on 18 December 1978 and the *Cassis de Dijon* judgment was delivered over two months later.

26 — See, as another example of partial harmonisation, where the Court examines national provisions which are not (any longer) harmonised in the light of Article 28 EC, Case C-3/99 *Ruwet* [2000] ECR I-8749, paragraphs 44 et seq.

27 — If, for example, a Member State adopts a measure in respect of environmental labelling on foodstuffs, that national measure must, in my view, be examined in the light of the primary provisions of the Treaty or any other appropriate secondary Community legislation, since environmental matters are not regulated by Directive 79/112.

28 — See, for example, the three recent judgments concerning Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ 1985 L 210, p. 29). With regard to the degree of harmonisation achieved in respect of product liability, the Court observes in those judgments that 'the directive seeks to achieve, *in the matters regulated by it*, complete harmonisation of the laws, regulations and administrative provisions of the Member States' (Case C-154/00 *Commission* v *Greece* [2002] ECR I-3879, paragraph 20, Case C-52/00 *Commission* v *France* [2002] ECR I-3827, paragraph 24, and Case C-183/00 *González Sánchez* [2002] ECR I-3901, paragraph 32; italics added).

me that the authorisation requirement under Paragraph 9(3) of the LMG must be regarded as a 'non-harmonised' national provision which nevertheless falls within the scope of the directive. The prohibition and its associated prior authorisation procedure in Paragraph 9 of the LMG must therefore, in my opinion, be assessed together in the light of Article 15 of Directive 79/112.

42. A number of supplementary arguments must also be put forward in support of that view. As to whether a national provision falls within the material scope of the directive, it must be examined whether the wording, purpose and context of the Community provision and the national provision correspond. Leaving aside the objective of free circulation, the purpose of Directive 79/112 — the creation of a general framework for the regulation of foodstuffs labelling in order to approximate the conditions of competition with due regard for the protection of the health and economic interests of the consumer — also forms the basis of the Austrian provision in question.

43. An authorisation procedure is, moreover, pre-eminently suited to inclusion within the scope of the prohibition laid down in Article 15(1) of Directive 79/112. That provision prohibits restrictions on the marketing of foodstuffs in so far as they comply with the provisions of the directive, including, in this case, the requirements of Article 2. In other words, if health-related information is not in any way connected with the prevention or cure of diseases, is not misleading, and does not otherwise infringe the labelling provisions of Directive 79/112, a Member State may not restrict trade in foodstuffs for reasons connected with the information shown on the label unless such a restriction can be justified on the basis of Article 15(2). As far as the scope of Directive 79/112 is concerned, it is not relevant, in my opinion, whether a Member State opts, for example, for a statutory prohibition on health-related information, under which certain categories of claims are nevertheless allowed, or for a general statutory prohibition with the possibility of individual exemption by means of authorisation.

44. It is conceivable that the Commission chose the dual track of Directive 79/112 and Articles 28 and 30 EC because the Court's existing case-law is not wholly consistent. Although the judgment in *SARPP*[29] offers support for the view that the authorisation requirement should be assessed in the light of Article 15(2) of Directive 79/112, it is clear to me that the case-law concerning the relationship between Article 15 of Directive 79/112,

29 — Cited in footnote 12.

the remaining provisions of the directive, and Articles 28 and 30 EC is not notable for its high degree of consistency. In a number of judgments, alleged infringements of specific provisions of the directive are assessed solely in the light of the relevant provisions of the directive, without reference to primary Community law on the free movement of goods. In another part of the case-law, the Court takes as its basis both the directive and Articles 28 and 30 EC. [30] On no occasion does the Court state any clear criteria on the basis of which it makes such a distinction. [31]

45. I think it is preferable, where a particular matter has been made subject to fully harmonised rules at Community level, to assess the relevant national provisions covered by the directive in question in the light of that secondary Community legislation and not in the light of the provisions of primary Community law. [32] Only where a national rule must unquestionably be regarded as falling outside the scope of the directive can there be any justification for assessing it under the provisions of the

30 — Here are a few examples. In the *Smanor* judgment (Case 298/87 [1988] ECR 4489), the Court examined national rules regarding the trade description of deep-frozen yoghurt both under Article 28 EC and under the provisions of Directive 79/112, in particular the specific rules on names under which foodstuffs are sold in Article 5(1), but also Article 15 of that directive. In infringement proceedings against Germany, the Court gave judgment on national rules under which foodstuffs containing an ingredient which is not in conformity with the traditional national recipe must carry a trade description with an additional statement indicating that the substance in question has been used, even if that substance is already included in the list of ingredients. The Commission had based its complaints both on Article 5 of Directive 79/112 and on Article 28 EC. The Court held as follows in that regard: 'In that connection, it is sufficient to note that the requirement laid down in Article 5(1) of the Directive to the effect that any additional particulars accompanying the trade description must be necessary for the information of consumers also follows from Article [28 EC] *and that, consequently, this point cannot constitute a separate ground of challenge*' (Case C-51/94 *Commission* v *Germany* [1995] ECR I-3599, paragraph 40, italics added). In the *Bellamy and English Shop Wholesale* case, a Belgian court sought to ascertain whether Article 28 EC precludes a national rule which prohibits giving the impression that a branded product possesses particular qualities when in fact all similar foodstuffs display the same qualities and, if so, whether such a rule may be justified under Article 30 EC. The Court held that the national provision in question correctly transposed Article 2(1)(a)(iii) of Directive 79/112 and thus did not constitute an obstacle to free movement contrary to Article 28 EC (cited in footnote 23, paragraph 21). It is remarkable that the Court implicitly gave judgment by reference to primary Community law, whereas in fact the case concerned the transposition of a provision of a directive. In *Darbo*, cited in footnote 23, the Court was asked whether Article 2(1)(a)(i) of Directive 79/112 precludes use of the words 'naturally pure' to describe a strawberry jam which contains the gelling agent pectin and traces or residues of lead, cadmium and pesticides in specific quantities. The Court confined itself to an assessment under the directive.

31 — An illustrative example of this is the case-law concerning language requirements which a Member State may impose in the field of labelling. In the judgment in *Piageme I*, the Court declared that a national rule requiring the exclusive use of a specific language for the labelling of foodstuffs, without allowing for alternative methods of informing the purchaser, was contrary to Article 28 EC and to the rules on the use of languages under Article 14 of Directive 79/112, which were applicable at that time (Case C-369/89 [1991] ECR I-2971). In *Piageme II*, on the other hand, a question concerning the same national rule was disposed of solely on the basis of Article 14 (Case C-85/94 [1995] ECR I-2955). Similarly, in the judgment in the related *Goerres* case, there is no reference to Article 28 EC, perhaps because the national court had not mentioned that provision in its questions (Case C-385/96 [1998] ECR I-4431). In the recent judgment in *Geffroy*, however, the Court assesses national rules, which on the one hand provide that labelling must not mislead the purchaser, particularly as to the characteristics of the foodstuff, and on the other hand require the use of a specific language for the labelling of foodstuffs, both in the light of the directive and in the light of Article 28 EC. That twofold examination occurs only by virtue of a reference to the abovementioned three judgments in *Piageme I*, *Piageme II* and *Goerres* (Case C-366/98 [2000] ECR I-6579, paragraphs 24 to 28).

32 — As recently held in Case C-324/99 *DaimlerChrysler* [2001] ECR I-9897, paragraph 32. See also in this respect, as regards the exhaustive Community rules laid down by Directive 76/768/EEC on cosmetic products, my Opinion in the *Linhart* case, cited in footnote 3, points 27 and 28.

Treaty. In my opinion, no such possibility arises in this case.

46. However, that does not alter the fact that the provisions of Directive 79/112 must, as must any provisions of secondary law, be interpreted in the light of the provisions of the Treaty relating to the free movement of goods. [33] That applies *a fortiori* in the present case, where the scope of Article 15(2) of Directive 79/112 displays features in common with the grounds of justification under Article 30 EC (protection of public health) and the *Cassis de Dijon* case-law (consumer protection and fair trade). [34] A consequence of that affinity is that the principle of proportionality also applies when examining national rules in the light of Article 15 of Directive 79/112. [35] Viewed thus, those considerations do not affect the issues in these proceedings. The Commission's action seeks a declaration that the national rules in question are in any event contrary to Article 15(1) and (2) of the directive. In so far as the Commission's action also seeks a finding of infringement of Articles 28 and 30 EC, that complaint no longer has any independent significance.

47. Finally, the Austrian Government's argument that, in addition to Directive 79/112, Directive 84/450 (as amended) is also relevant for the purpose of assessing the authorisation requirement laid down by Paragraph 9(3) of the LMG must also be examined.

48. Even assuming that Directive 84/450 covers the labelling of foodstuffs, that directive cannot be relied on successfully in the present proceedings. In so far as the issue in the labelling of foodstuffs is that the consumer may be misled, Directive 79/112 lays down specific provisions in Articles 2 and 15. Here the principle *lex specialis derogat legi generali* applies, so that that directive takes precedence over a set of general rules such as Directive 84/450. In view of the exhaustive nature of the harmonisation of national labelling provisions, Member States may not derogate from the requirements laid down in those rules. That applies in particular to Article 7 of Directive 84/450, which allows more extensive protection for consumers against misleading advertising. [36]

C — *The scope of Article 2(1)(b) of Directive 79/112*

49. Article 2(1)(b) of Directive 79/112 prohibits references to the prevention, treatment or cure of a human disease. With

33 — I confine myself to a reference to the judgment in Case C-315/92 *Verband Sozialer Wettbewerb* [1994] ECR I-317 ('*Clinique*'), paragraph 11.

34 — Cited in footnote 16.

35 — See *SARPP*, cited in footnote 12.

36 — See also my Opinion in *Linhart*, cited in footnote 3, point 29.

regard to the object and scope of that provision, there are two opposing views in the present proceedings.

50. The Commission points out in its application that the recitals in the preamble to the directive (now recital 14) state that the rules on labelling should also prohibit the use of information that would 'attribute medicinal properties to foodstuffs'. It adds that that function is reserved to medicinal products within the meaning of Directive 65/65. [37]

51. That narrow view is disputed by the Danish Government. According to the latter, health-related statements are also covered by Article 2(1)(b) of Directive 79/112. The Verwaltungsgerichtshof, which is the referring court in Case C-16/01, likewise points out that that provision makes no distinction between health-related and disease-related information. A workable criterion for distinguishing between health-related and disease-related information cannot be found, and the consumer would also be unable to make a distinction between health-related and disease-related information. In the view of the Verwaltungsgerichtshof, all information which is in any way related to health must in principle be covered by the prohibition laid down by Article 2(1)(b) of the directive. According to that court, the overall impression is decisive in this respect, and in particular the subjective impression which the labelling makes on the responsible and informed consumer.

52. The Commission concedes, in its written observations in Case C-16/01, that Article 2(1)(b) does not make an express distinction between health-related and disease-related information. In its opinion, the directive seeks to keep the consumer, when ill or in order to prevent disease, from resorting to foodstuffs which are not intended for that purpose. Under the definition in Directive 65/65, a medicinal product has the property of restoring, correcting or modifying physiological functions in human beings. If, on the other hand, a product is merely 'healthy', such properties cannot be ascribed to it. A distinction between the two kinds of information must therefore be made, even though the dividing line is sometimes difficult to draw.

53. I agree with the view that a distinction must certainly be made here, a view which was in any case not contradicted by the Austrian Government in the main proceedings. Article 2(1)(b) states unequivocally that the prohibition relates to labelling which is directly or indirectly connected with a human *disease*. Disease is a condition in which a person's organs and vital processes do not function properly and normally. Disease is contrasted with a

37 — Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 24). It has since been replaced by 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). The definition of 'medicinal product' has remained unchanged.

healthy condition in which a person has no physical or, as the case may be, mental infirmities. For that reason there is a fundamental difference between statements relating to the prevention, treatment or cure of a disease, and statements connected with the promotion of human well-being. In the case of disease-related claims, the emphasis is on treating or curing an existing disease or on preventing disease. In the case of health-related claims, they are premised on a positive basic idea, namely the maintenance or promotion of health. It may indeed be difficult in marginal cases to maintain a strict division between health-related claims and disease-related claims, since certain health-related claims may give the consumer the impression that the product has a curative effect. For example, by explicitly suggesting that a particular foodstuff 'keeps you healthy', the impression is implicitly given that the product can prevent diseases. However, that does not detract from the fundamental distinction between the two categories of claims. The nature of the information in question will need to be determined on a case-to-case basis.

54. The prohibition laid down by Article 2(1)(b) of Directive 79/112 is absolute, which means that what are described as disease-related claims are by definition prohibited regardless of whether they are accurate or whether they mislead the consumer. That provision requires Member States to prohibit disease-related information, but by contrary inference is not concerned with health-related information, which is thus not prohibited by virtue of that prohibition. If a statement on a foodstuff has any of the characteristics of a disease-related claim, while also making claims relating to health, it is covered by the prohibition laid down in Article 2(1)(b) by reason of the particular dangers to public health which are associated with disease-related claims. [38] Those particular dangers imply that a Member State may, in my opinion, start from a wide interpretation of the scope of that provision, but may not undermine the fundamental distinction, as described above, between disease-related claims and health-related claims.

55. A prohibition subject to prior authorisation on health-related information, as laid down in Paragraph 9 of the LMG, thus goes further than Article 2(1)(b) of Directive 79/112 allows.

D — *Assessment under Article 15 of Directive 79/112*

56. It should be pointed out from the outset that Article 15(1) precludes the application

38 — By analogy with the way in which the Court regards products possessing properties of both medicinal products and, for example, cosmetic products as subject to the more rigorous Community rules applicable to medicinal products (see Case C-369/88 *Delattre* [1991] ECR I-1487, paragraphs 20 to 22).

of Paragraph 9(1) and (3) of the LMG in so far as those provisions are wider in scope than the prohibitions laid down by Article 2(1)(a) or Article 2(1)(b) of Directive 79/112. With regard to foodstuffs which in other respects satisfy the labelling requirements of Directive 79/112 and have been marketed lawfully in another Member State, both requirements amount *de facto* to a prohibition of trade in Austria.

57. I shall now assess whether both national provisions can be justified under Article 15(2) of Directive 79/112. This requires an examination in two stages. First it must be shown that the national measure is suitable for the purpose of achieving one of the objectives of protection referred to in that provision. Then the proportionality of the measure must be examined, that is to say, that the measure must not go beyond what is strictly necessary and, more specifically, that it must not be possible to achieve the desired objective by genuine alternative means that are less restrictive of trade.

58. In order to justify the prohibition on health-related information in Paragraph 9(1) of the LMG, as well as the requirement of prior authorisation under Paragraph 9(3) of the LMG, the Austrian Government relies on consumer protection and the protection of public health. Both interests are mentioned in Article 15(2) of Directive 79/112.

59. There is a difference between the circumstances in which those two interests can be invoked by a Member State. That difference arises from the Treaty and from the Court's case-law on foodstuffs which is relevant in this case. Protection of the consumer means that the consumer is afforded guarantees to safeguard his economic interests. In particular, he is entitled to be protected from misleading information shown on the products which he wishes to purchase, or on their packaging. [39] Applied to this case, that would mean that the purchaser must not be confused as to the health properties of the product by health-related information, either when purchasing the product or even at the time of consuming it. The protection of health of humans, on the other hand, as mentioned in Article 30 EC and, more particularly, as referred to in Article 15(2) of the directive, relates to human physical or mental well-being. The health of the consumer may be at risk if, in consuming the foodstuff, he wrongly assumes, as a consequence of health-related information, that the product has a therapeutic effect, as a result of which he may, for example,

39 — See, in particular, Case C-303/97 *Sektkellerei Kessler* [1999] ECR I-513, paragraph 33.

neglect to change his dietary habits or to seek medical help.

60. In the light of the foregoing, the scheme of the directive makes it impossible, in my view, for Austria to rely, as justification for the prohibition at issue, on protection of the consumer against confusion as referred to in Article 15(2) of Directive 79/112. Article 2(1)(a) of Directive 79/112 already prohibits all labelling which misleads or could mislead the consumer. A general prohibition on misleading health-related information cannot be justified on the basis of Article 15(2) of Directive 79/112 since the interest in question — consumer protection — is already covered by Article 2(1)(a) of Directive 79/112.

61. However, the prohibition laid down by Paragraph 9(1) of the LMG applies to all health-related information, regardless of whether it is misleading.[40] A general prohibition which, in addition to disease-related claims as harmonised by Article 2(1)(b) of Directive 79/112, also applies to non-misleading health-related information may, in principle, be justified on the ground of protection of public health.

62. In infringement proceedings it is for the Member State to prove that a general prohibition on non-misleading health-related information is necessary for the protection of public health. The Austrian Government argues that such information may endanger the health of consumers since they may wrongly rely on the effect of a health-related statement. The Commission counters that by submitting that nothing is gained by prohibiting the description 'healthy', since foodstuffs harmful to health may not lawfully be marketed.

63. Although, in my opinion, the Austrian Government has not provided a great deal of evidence to support its claim that health-related information endangers the physical and mental well-being of the consumer, I am prepared to accept that in a given context certain health-related information may affect the state of health of the consumer. That is even possible where the information as such is true and does not mislead the average purchaser. The instrument of a general prohibition on health-related information with the possibility of

40 — It should be borne in mind in this context that a 'true statement' is not automatically a 'non-misleading' statement. Even true information can mislead a purchaser. If, for example, the label of a foodstuff states that the product does not contain certain additives which are in any case prohibited by law, that is ascribing to that foodstuff special characteristics which all similar foodstuffs possess. Article 2(1)(a)(iii) of Directive 79/112 prohibits such claims since they are misleading.

exemption is then appropriate, in principle, in order to eliminate or limit that risk. Whether such a measure, which is effective in principle, misses its target and therefore infringes the principle of proportionality is another question, which must be examined in more detail.

64. It is not easy to state precisely the circumstances in which the health of a consumer may be endangered. The only example which the Austrian Government has given, the claim 'good for your health', is difficult to assess without knowing the context of those words. If that information occurs on the labelling of a bag of apples, I really do not see how even a vulnerable consumer could suppose that a visit to the doctor can be postponed simply by eating apples. If the claim appears on the packaging of a food supplement which may be marketed as a foodstuff, such an effect can more readily be envisaged. However, even in that situation health will only be at risk if consumption of such supplements is at the expense of a balanced diet.

65. It will therefore be necessary to determine, taking into account all the relevant circumstances of the case, whether a particular statement constitutes a genuine risk to public health.

66. In the absence of specific Community rules, Community law allows the Member States a relatively wide margin of discretion where public health is at stake. [41] Nevertheless, even then the principle of proportionality requires that the objective should not be achievable by less restrictive means. In view of the general application of the prohibition laid down by Paragraph 9(1) of the LMG, the abovementioned case-by-case approach can be adopted only in the context of the authorisation procedure under Paragraph 9(3) of the LMG. According to the Austrian Government, that procedure is necessary since only the public authorities are capable of acting reliably in a supervisory capacity.

67. The combination of a far-reaching general prohibition of any health-related information and an onerous authorisation procedure is not, in my view, proportionate to the desired objective. I would point out in this connection that the risks to public health to be prevented are residual risks. Article 2(1)(a) and (b) of Directive 79/112 already prohibits incorrect or misleading information on health effects and any disease-related information. Moreover, as the Commission has rightly stated, it must be borne in mind that the foodstuffs in question may on no account constitute a

41 — See, for example, the case-law on additives, as set out in *Müller and Others* and *Beer Purity*, cited in footnotes 24 and 14 respectively.

danger to public health. That requirement is laid down in other general and specific Community legislation.[42] In so far as a product possesses particular characteristics which may give rise to health problems for certain categories of consumers, that risk is catered for by the compulsory listing of ingredients on the labelling. The Court assumes that the list of ingredients, the display of which is required by Article 6 of Directive 79/112, will be read by the consumer.[43]

68. Since inherently correct information on health effects may result in health risks only in a stated context and with regard to specific cases or products, the rules contained in Paragraph 9(1) and (3) of the LMG are disproportionate. They go beyond that which is permitted by Article 15(2) of Directive 79/112. Less restrictive solutions for the prevention of such residual risks do exist.

69. It would seem to me to be more logical to introduce a system which — in accordance with Article 2 of Directive 79/112 — simply prohibits misleading information and disease-related claims. In such a system, a claim such as 'good for your health', for example, can be examined critically in relation to the characteristics of the product and all other relevant factors and, where appropriate, prohibited. Thus, the controls exercised by the national authorities could take the form, *inter alia*, of an obligation requiring the manufacturer or distributor of the product in question, in the event of any uncertainty, to furnish evidence of the accuracy of the factual claims appearing on the labelling.[44] The *ex ante* prohibition of all health-related statements on foodstuffs renders superfluous from the outset the distinction drawn in the directive between information which is responsible and thus, in principle, in conformity with the directive, and information which is irresponsible and not in conformity with the directive.

70. I would further point out in this connection that traders who place products on the market bearing health-related statements which could not in any way endanger public health are nevertheless caught by the prohibition and made subject to an authorisation requirement which is unnecessary for their products. If a Member State finds it necessary, in a specific context, to adopt special rules

42 — See, as an example of a general provision, Article 3 of Council Directive 92/59/EEC of 29 June 1992 on general product safety (OJ 1992 L 228, p. 24). On 15 January 1994 that directive was replaced by Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 (OJ 2002 L 11, p. 4). Article 14 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) enters into force on 1 January 2005. Paragraph 1 of that provision prohibits in general terms the placing on the market of food if it is unsafe, and will apply in addition to existing specific Community provisions on food safety.

43 — *Darbo*, cited in footnote 23, paragraph 22.

44 — In the manner provided for by Article 6(a) of Directive 84/450, as held by the Court in *Unilever*, cited in footnote 3, paragraphs 34 and 35. That provision requires Member States to confer upon the courts or administrative authorities powers enabling them in proceedings concerning misleading advertising to require the advertiser to prove the accuracy of factual claims in advertising.

concerning certain health-related information on foodstuffs, a less restrictive method is to establish objective and transparent criteria with which such health claims must comply and on the basis of which *ex post* control of the market can then be exercised. Such enforcement does not necessarily have to be exercised exclusively by the public authorities, but can also be entrusted to competing traders and, for example, consumer organisations. [45]

71. The Court's case-law cited by the Austrian Government, according to which prior authorisation may be required for the marketing of additives, does not apply in this case. The Court has also, in that case-law, laid down conditions for the introduction of a system of authorisation which are based on the principle of proportionality. Moreover, because of their inherent characteristics, additives in foodstuffs may constitute a danger to public health. That warrants stricter measures than are needed to control 'dubious' health-related information, where the safety of the foodstuff as such is not in issue.

72. In my opinion, neither a general prohibition on health-related information appearing on the labelling of foodstuffs nor a requirement of prior authorisation can therefore be justified by reference to Article 15(2) of Directive 79/112. That view accords *mutatis mutandis* with the case-law concerning statements appearing on cosmetic products, in which the Court has specifically criticised the authorisation requirement under the LMG. [46] The Austrian Government's argument that foodstuffs must be distinguished from cosmetic products cannot be accepted. The nature of the interests to be protected — consumer protection and public health — and therefore the objective of the LMG, is identical in both cases. In this connection, as the Commission has rightly pointed out, the Court's case-law also allows no differentiation according to product category. In protecting the consumer against being misled, the basic yardstick, in the case of both foodstuffs and cosmetic products, is the model of the average consumer. [47] Moreover, the damage to health caused

45 — The argument put forward by the Austrian Government, that there has been negative experience of this form of self-regulation in the United States, is not substantiated in any way by it.

46 — See *Unilever*, cited in footnote 3. In the pending *Linhart* case, cited in footnote 3, the Court has before it a reference from the Verwaltungsgerichtshof for a ruling on the compatibility with Community law of a prohibition on the statement 'dermatologically tested' appearing on soaps and shampoos.

47 — Aptly cited in Case C-220/98 *Estée Lauder* [2000] ECR I-117 which, like *Unilever* (cited in footnote 3), relates to cosmetic products and where the Court refers, in paragraph 27, to the judgment in *Gut Springenheide and Tusky*, which concerns foodstuffs (eggs).

by irresponsible statements may be just as serious when using cosmetic products as when consuming foodstuffs.

73. I therefore propose that in Case C-221/00 the Court should:

(1) declare that, by interpreting and applying Paragraph 9(1) of the Lebensmittelgesetz (LMG) as meaning that health-related information on foodstuffs intended for general consumption is prohibited in a general and absolute manner, and by subjecting the affixing of such information to a prior authorisation procedure (Paragraph 9(3) of the LMG), the Republic of Austria has failed to fulfil its obligations under Articles 2(1)(b) and 15(1) and (2) of Directive 79/112;

(2) order the Republic of Austria to pay the costs;

(3) order the Kingdom of Denmark to bear its own costs.

E — *The proceedings for preliminary rulings (Case C-421/00, Case C-426/00 and Case C-16/01)*

— Case C-426/00

74. In Case C-426/00, the Commission has proposed that the Court should not answer the questions referred by the Unabhängiger Verwaltungssenat since they are manifestly inadmissible. The Commission submits that the order for reference does not include any grounds for the specific questions, any factual background on which the questions are based or any precise reasons which led the referring court to consider it necessary to make a reference for a preliminary ruling.

75. Those criticisms on the Commission's part are well founded, in my view. The referring court states in the order for reference that its questions are being submitted 'together with the documents in the case' ('unter Aktenvorlage').[48] In the grounds of the order, the Unabhängiger Verwaltungssenat merely reproduces the relevant provisions of national and Community law and observes that it is apparent from those provisions that Paragraph 9(1) of the LMG is stricter than Community law

48 — It is apparent from the order for reference that in the main proceedings Haug was held responsible for placing on the market the product 'Renatura Casterenum-Kapseln' which had been imported from Germany. It would not surprise me if the questions referred have some connection with the criminal proceedings against Mr Haug in Case C-16/01, but that cannot be stated with any certainty on the basis of the information made available.

as embodied in the labelling Directive. The Unabhängiger Verwaltungssenat also refers to the action brought by the Commission against Austria under Article 226 EC.

76. It is settled case-law that the information furnished in an order for reference does not serve only to enable the Court to give a helpful answer but also to enable the parties, the Member States and the Community institutions to submit observations in accordance with Article 20 of the Protocol on the Statute of the Court. In that regard, it must be borne in mind that only the order for reference — and not the rest of the file in the main proceedings — is notified to the interested parties. [49]

77. The referring court has failed to indicate why the facts in the main proceedings gave rise to the request for a preliminary ruling on the four questions submitted. The order for reference does not mention any facts on the basis of which Mr Haug was prosecuted. In my view, in those circumstances the Court cannot give a ruling. In the light of the legal framework which I have outlined, the Court lacks, in particular, any information as to the nature of the statements which formed the basis of the prosecution. I am therefore of the opinion that the Court must declare the reference from the Unabhängiger Verwaltungssenat Wien inadmissible.

— Case C-421/00

78. The reference from the Unabhängiger Verwaltungssenat für Kärnten bears great similarity to the Commission's application in Case C-221/00. The referring court requests an interpretation of Article 28 EC and Articles 2(1)(b) and 15(1) and (2) of Directive 79/112 in the light of the prohibition on health-related information appearing on the labelling of foodstuffs, subject to special authorisation, within the meaning of Paragraph 9(1) and (3) of the LMG. The questions are submitted in connection with national criminal proceedings against Ms Sterbenz who is held responsible for placing on the market foodstuffs bearing the prohibited claim 'a good name for healthy enjoyment'.

79. Ms Sterbenz argues in essence that Paragraph 9(1)(a) of the LMG contains a prohibition on referring to physiological or pharmacological effects of foodstuffs, or creating the impression of any such effect, and that it thus goes further than Articles 2(1) and 15(1) and (2) of Directive 79/112 allow. The claim 'a good name for healthy enjoyment' appearing on vegetable-based spreadable pâté is unlikely to mislead a consumer. Moreover, in her opinion, less

49 — See the judgment in Joined Cases 141/81 to 143/81 *Holdijk and Others* [1982] ECR 1299, paragraph 6, and the order of the Court in Case C-116/00 *Laguillaumie* [2000] ECR I-4979, paragraph 16.

restrictive instruments, such as regular monitoring of the market, could be used to verify whether statements appearing on foodstuffs are in accordance with those provisions.

80. The Commission does not see any conflict between the statement 'a good name for healthy enjoyment' appearing on the labelling of foodstuffs and Directive 79/112. The noun 'enjoyment' is medically neutral and so does not attribute to the foodstuff any properties of preventing, treating or curing a human disease, or even allude to such properties. Nor does the addition of the adjective 'healthy' attribute to the foodstuff any of the properties prohibited by the directive. In the Commission's view, it is hard to imagine the consumer being misled by the statement deemed illegal.

81. To begin with, I would point out that the Court has on several occasions held, in connection with secondary Community legislation designed to prevent any deception of consumers, that it is for the national court, under the division of powers laid down in Article 234 EC, to assess whether a statement may be misleading. Nevertheless, the Court may provide the national court with any relevant criteria for the interpretation of Community law.[50] I am of the opinion that that case-law also applies to the question whether a particular statement constitutes a danger to public health. In this case, the referring court has formulated its questions in the abstract, but the account of the facts in the main proceedings enables me to make the following observations.

82. I agree with the Commission that the statement 'a good name for healthy enjoyment' does not inherently contain any disease-related claims as referred to in Article 2(1)(b) of Directive 79/112. It belongs to the category of general health-related claims. Moreover, information for the reference consumer cannot be misleading merely because of its health-related nature. On the other hand, the view that the statement in question cannot, by definition, be misleading for the purposes of Article 2(1)(a) or Article 15(2) of Directive 79/112 seems to me to be too restricted. The word 'healthy' implies that the product possesses positive properties with regard to the promotion or maintenance of human well-being. In order to establish that the claim at issue is misleading, it is in any case necessary to examine the connection with the products in question. The order for reference merely states that they are the foodstuffs 'Tartex veget. Pastete Champig-

50 — See, for example, *Darbo*, cited in footnote 23, paragraph 20.

non' and 'Tartex veget. Pastete Kräuter'. Having regard to the Court's case-law, it must be examined, taking all relevant factors into account, whether an average consumer who is reasonably well informed and reasonably observant and circumspect would construe the statement in question, viewed in the context as a whole, as it is intended to be construed. [51] The Court is critical of excessively paternalistic interpretations: the existence of a group of consumers which may be misled by a claim is not in itself sufficient to justify a barrier to the free movement of goods. [52] There must be a real risk that the average consumer would be confused or misled and that his economic behaviour would be affected as a result. [53] The fact that certain consumers may not be aware of the meaning of the claims being made and may thereby be misled is not a sufficient justification for characterising the statements in question as misleading and for prohibiting them on that basis. [54]

83. The abbreviation 'veget.' in the statement suggests that it describes a pâté which has been made without meat. However, without needing know the exact composition of the products 'Tartex veget. Pastete Champignon' and 'Tartex veget. Pastete Kräuter', it is difficult on the face of it to see how the words 'healthy enjoyment' could create false expectations in the mind of the average consumer when purchasing those foodstuffs. The situation would only be different if it could not be stated with certainty in relation to the foodstuff in question that it was also a healthy product. To that end it could be examined whether, in nutritional terms, the products possessed recognised positive properties in relation to the promotion or maintenance of health. Moreover, even if that were the case, the statement could still be said to be misleading if similar products which met a comparable demand had a healthier composition.

84. The burden of proof can be placed on the trader responsible for the product, who must demonstrate sufficiently the accuracy of the factual claims. [55] He may take as his basis, *inter alia*, prevailing opinions in the international field of nutrition.

85. It is ultimately for the referring national court, taking into account the

51 — *Darbo*, cited in footnote 23, paragraph 20.

52 — *Darbo*, cited in footnote 23, paragraph 28.

53 — *Sektkellerei Kessler*, cited in footnote 39, paragraph 33.

54 — See, in this connection, *Darbo*, cited in footnote 23, paragraph 28. The view adopted in practice in Austrian case-law, namely that the average consumer may be misled if at first glance he gets the impression that consumption of the foodstuff in question has a favourable effect on health, is therefore untenable.

55 — See also point 69 of this Opinion.

relevant circumstances, to examine whether the statement concerned is actually misleading. I propose that the Court answer the questions referred by the Unabhängiger Verwaltungssenat für Kärnten as follows:

'Articles 2(1)(b) and 15(1) and (2) of Directive 79/112 preclude national legislation which prohibits, generally and absolutely, any health-related information from appearing on foodstuffs intended for general consumption and makes health-related information subject to a prior authorisation procedure.'

— Case C-16/01

86. In this case the Verwaltungsgerichtshof seeks in essence a similar interpretation of the Community provisions to that requested by the Unabhängiger Verwaltungssenat für Kärnten in Case C-421/00. The main proceedings concern the sale of pumpkin seed capsules under the name 'Renatura Kürbiskernkapseln mit Vitamin E Blase und Prostata', the accompanying leaflet for which contains the following health-related information: 'for protection of the cell membrane from free radicals'; 'important for the functioning of many enzymes'; 'important as a building block for bones and teeth'; 'regulation of the fluid balance (bladder functioning)'.

87. The Commission observes that those claims may give the average consumer the impression that the product has properties of preventing, treating or curing a disease, thereby falling, in its view, within the scope of the prohibition laid down in Article 2(1)(b) of Directive 79/112. In particular, that is the case because of the reference to specific human organs, the bladder and the prostate. Furthermore, it is not clear what the link is between those organs and the claims 'for protection of the cell membrane from free radicals'; 'important for the functioning of many enzymes' and 'important as a building block for bones and teeth'. Those statements may therefore also be misleading for the purchaser and for that reason not permitted under Directive 79/112. The same applies, according to the Commission, to the claims concerning linoleic acid, tocopherols, trace elements, minerals and potassium, which are also clearly made in connection with the organs 'bladder and prostate'.

88. In the Commission's view, those claims are nevertheless permitted if they are purely concerned with a physiological effect, meaning that they merely contain a reference to a healthy function and have no connection with human organs. In that

sense, the claims 'regulation of the fluid balance' or 'important as a building block for bones and teeth', for example, are permissible, according to the Commission.

89. The Commission also has difficulty with the phrase 'physiological or pharmacological effects' in the referring court's first question, because it is unclear. The decisive consideration is always the context in which claims are made. The Commission therefore disputes the assertion that information on matters such as 'preserving youthfulness, inhibiting signs of ageing, promoting slimming or maintaining health' is automatically connected with preventing, treating or curing a disease. An assessment of whether information is actually misleading can only be made in relation to an individual case.

90. In this case also, it is for the national court to assess whether the statements at issue are in fact misleading or constitute a danger to public health. Since the claims at issue are different but nevertheless interrelated, and the questions referred for a preliminary ruling are formulated in the abstract, the Court can only provide the national court with general criteria for interpretation. I shall confine myself to a few observations.

91. Since the national court has not submitted a question on the matter, I shall assume in the first place that the pumpkin seed capsules referred to in the main proceedings must be characterised as a foodstuff within the meaning of Directive 79/112. [56] It must also be assumed that a statement appearing on or accompanying pumpkin seed capsules falls, as labelling of foodstuffs, within the scope of Article 1 of Directive 79/112. The term 'labelling' in Article 1(3) of Directive 79/112 covers *inter alia* any words placed on notices accompanying the foodstuff, so that the information in the accompanying leaflet falls within the scope of the directive.

92. Secondly, I share the Commission's view that claims must be assessed on a case-by-case basis taking into account all relevant factors. A statement on the labelling may be truthful in itself and the content of the information may not be confusing to an average consumer, but suggestive positioning or even the form of the packaging may cause the statement to have a misleading effect.

56 — It is possible that pumpkin seed capsules may be covered by the Community definition of medicinal products, or that they may constitute a specific foodstuff falling within the scope of Community legislation on foodstuffs for particular nutritional uses or novel foods. Derogating rules on labelling apply to these latter categories of foodstuffs.

93. Thirdly, in this case the claims at issue can be regarded as functional, which means that the words indicate the purpose of the product or of an ingredient. Thus, for example, potassium is important in regulating the fluid balance and the title 'Renatura Kürbiskernkapseln mit Vitamin E Blase und Prostata', makes, as the Commission rightly states, a connection between vitamin E and the bladder and prostate functions. The statement that the oil pumpkin seeds are enriched with extra vitamin E also makes it a composition-related claim. In so far as the prostate and bladder are mentioned, that is an allusion to a specific disorder, namely prostate and bladder cancer, which in my view gives grounds for regarding those statements as prohibited disease-related statements as referred to in Article 2(1)(b) of Directive 79/112. Contrary to the Commission's argument put forward in its written observations both in Case C-221/00 and in the proceedings for preliminary rulings under consideration here, the scope of the prohibition on disease-related claims in Directive 79/112 may, in my opinion, extend beyond a mere connection with medicinal products within the meaning of the Community legislation governing the latter.

94. In so far as the national court finds that the statement does not give rise to any associations with the control or prevention of diseases, and in so far as it can accept that the labelling does not generate any misconceptions as to the characteristics of the product, it may consider whether the claims involved are prejudicial to public health. It is for the trader or manufacturer responsible to demonstrate, on the basis of international scientific information, that the product possesses the properties attributed to it, in particular that the pumpkin seed capsules help to protect the cell membrane against free radicals and to ensure the functioning of many enzymes, and that they are important as a building block for bones and teeth and for regulating the fluid balance.

95. In this case also, I propose that the questions referred for a preliminary ruling be answered as follows:

Articles 2(1)(b) and 15(1) and (2) of Directive 79/112 preclude a national provision which prohibits, generally and absolutely, any health-related information from appearing on foodstuffs intended for general consumption and makes health-related information subject to a prior authorisation procedure.

VI — Conclusion

96. In the light of the foregoing, I propose that the Court should:

in Case C-221/00:

(1) declare that, by interpreting and applying Paragraph 9(1) of the Lebensmittelgesetz (LMG) as meaning that health-related information is prohibited, in a general and absolute manner, from appearing on foodstuffs intended for general consumption, and by subjecting the affixing of health-related information to a prior authorisation procedure (Paragraph 9(3) of the LMG), the Republic of Austria has failed to fulfil its obligations under Articles 2(1)(b) and 15(1) and (2) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer;

(2) order the Republic of Austria to pay the costs;

(3) order the Kingdom of Denmark to bear its own costs.

in Case C-426/00:

declare the reference for a preliminary ruling submitted by the Unabhängiger Verwaltungssenat Wien to be inadmissible;

in Case C-421/00:

answer the questions referred by the Unabhängiger Verwaltungssenat für Kärnten

and

in Case C-16/01:

the questions referred by the Verwaltungsgerichtshof as follows:

Articles 2(1)(b) and 15(1) and (2) of Directive 79/112 of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer preclude national legislation which prohibits, generally and absolutely, any health-related information from appearing on foodstuffs intended for general consumption and makes health-related information subject to a prior authorisation procedure.