

Deutsche Vereinigung
für gewerblichen Rechtsschutz
und Urheberrecht e.V.

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Sitz Berlin
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Europäische Kommission
z.Hd. Mr. Patrick Deboiser
- DG Sanco -
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Unser Zeichen:
(Bei der Antwort bitte angeben)

Regulation of the European Parliament and of the Council on nutrition and health claims made on foods (Proposal for a Regulation COM(2003) 424 final) of 16 July 2003

- Second Legal Opinion -

Dear Mr. Deboiser,

The *Deutsche Vereinigung für gewerblichen Rechtsschutz und Urheberrecht GRUR* (German Association for the Protection of Intellectual Property Rights), being a scientific association not tied to the interests of a particular group, seeks to support legislative projects by contributing both scientific expertise as well as practical experience from the advisory and court practice. The *GRUR Fachausschuss für Arznei- und Lebensmittelrecht* (GRUR expert committee for medicinal products and food law) considers the draft of the European Parliament and of the Council for a Regulation on nutrition and health claims made on foods (COM(2003) 424 final – hereinafter referred to as Draft Regulation), as prepared by the Directorate-General SANCO, to be inappropriate, in particular for regulative and legislative reasons as well as under aspects of Community law and consumer protection policy.

In view of the fact that the first opinion delivered by the committee referred to a preliminary draft of the Regulation, please find below a revised and completed version of such opinion.

Outline summary

I. Incompatibility with superior Community law

- (1) The regulative instrument of a regulation is in breach of the principle of subsidiarity enshrined in Article 5 (2) of the EC Treaty and the principle of proportionality laid down in Article 5 (3) of the EC Treaty as well as in conflict with the Commission's obligation to primarily use the directive as regulative instrument.
- (2) There is a paradigm shift: from a subsequent state control of health claims – accompanied, in many Member States, by self-controlling measures being taken by the industry – to a mixed system of general prohibitions and a preventive authorisation procedure at Community level. This constitutes a serious interference with the right of free dissemination of opinions and information as well as with the right of unhindered access to information, both protected at the European level. The consumer's right to obtain information guaranteed under Article 153 of the EC Treaty would be violated and restricted with lasting effects.
- (3) A preventive authorisation procedure for health claims is disproportionate since, among other reasons, it is unsuitable for the promotion of consumers' interest in obtaining information and since sufficient protection has already been provided for by the prohibition to mislead consumers in relation to health claims pursuant to Article 2 (1) lit. a) and b) of Directive 2000/13/EC (ex Directive 79/112).
- (4) When the Commission calls for the establishment of nutrient profiles in accordance with Article 4 (1) of the Draft Regulation, it thereby makes a distinction between good and bad foodstuffs, i.e. it pursues a specific health policy without having the power to do so (Article 152 (4) of the EC Treaty).

II. Regulative objections – incoherence of Commission activities

- (1) The draft is inconsistent with the legal view previously taken by the Commission, for example with regard to comparable Austrian regulations in the proceedings C-221/00, C-421/00, C-426/00 and C-16/01, which was comprehensively adopted by the ECJ in its judgments of 23 January 2003. According to this legal view, formalised absolute advertising bans prohibiting specific advertising claims

irrespective of their truthfulness and irrespective of any concrete danger are to be judged in a very critical manner under proportionality aspects.

- (2) A stricter treatment of food compared to medicinal products with regard to the requirements concerning scientific evidence to be provided for advertising claims is not objectively justified.
- (3) The procedure for the registration of a health claim is technically and financially so expensive and time-consuming that only major companies can carry out this procedure in an economically justifiable manner for individual products. This practice thus constitutes a breach of the requirement of equal economic opportunities and is unfavourable for innovation.
- (4) The requirement to introduce nutrient profiles is not based upon sufficiently assured scientific data.
- (5) Both the distinction between good and bad foodstuffs under nutrient profile aspects and the far-reaching formalised advertising bans are inconsistent with the European general concept of a consumer being an economically responsible citizen, i.e. a well informed and information-seeking, circumspect and critical consumer. This consumer model has been the basis of the Commission's previous policy and has been cited by the ECJ in its consistent court rulings.

III. Legislative drafting deficiencies

- (1) The legislative tool of the regulation is, contrary to the system, applied with a view to bringing about substantial legal harmonisation by eliminating national laws, which have already been harmonised and shaped by the requirements set out in Community directives.
- (2) By integrating various provisions of directives in the Regulation, such provisions are given a Janus-headed character, thereby triggering persistent legal uncertainty.

- (3) The legislative drafting quality of the Draft is, in many respects, insufficient. For example, the relationship between “implied health claims” and specific health claims is not clear. Furthermore, it has not been clearly specified which scope of protection is granted by including a permitted advertising claim in the register (does it also cover claims with similar contents or explanations and comparable foreign-language claims?). The meaning of some generalising statutory requirements such as “psychological function or behaviour” and “normal function of the body” is much too vague and unspecific. The contents of the envisaged nutrient profiles have not yet been defined either.

IV. TBT Agreement

Ultimately, the Draft is to be rejected for being suited to establishing, contrary to Article 2 (2) of the Agreement on Technical Barriers to Trade (TBT Agreement), new barriers to trade in the movement of foodstuffs in relation to third-party countries.

A. General

The Directorate-General SANCO of the Commission of the European Communities has submitted a draft of the European Parliament and of the Council for a Regulation on nutrition and health claims made on foods. The *GRUR Fachausschuss für Arznei- und Lebensmittelrecht* already presented its comments on the previous working document (Sanco/1832/2002) in summer this year. The revision of the working document relating to the Draft Regulation in its final version (COM(2003) 424 final) requires a revision of these comments.

B. Aims of the Draft Regulation

The primary aim of the Draft Regulation is the adoption of Community rules on the use of nutrition and health claims made in relation to food products with the purpose of ensuring adequate and appropriate labelling with the prime consideration being the need to protect the consumer’s interest in obtaining information. This is intended to ensure a proper use of food products. The Regulation is also meant to harmonise any differences between national legislative provisions relating to claims and their conditions of use that may impede the free

movement of goods (Recitals 1 through 3).

By involving the European Food Safety Authority, a uniform approval procedure shall be introduced for health claims at Community level and a public register established for approved claims.

C. Contents of the Draft Regulation

The Draft Regulation is dedicated to nutrition claims and in particular to health claims made on foods. Pursuant to Article 2 (5) of the Draft Regulation, the term “health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food product or its constituents, and health.

Based upon Article 10 of the Draft Regulation, according to which the only admissible health claims shall, in future, be the claims approved by the Community in accordance with the Draft Regulation, Article 11 (1) (a) of the Draft Regulation further provides for a general prohibition of “implied” health claims. Potentially admissible health claims shall, according to Articles 14 et seq. of the Draft Regulation, be subject to a comprehensive and complex authorisation procedure at the end of which each individual claim applied for must be approved by a final decision, published in the Official Journal of the European Community and subsequently registered.

It is true that Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs specifically prohibits attributing to foodstuffs any properties of preventing, treating or curing a human disease or any reference to such properties. However, the Commission fails to recognise the significance of the submitted proposal for a Regulation when Recital 3 merely states that “this Regulation should complement the general principles laid down in Directive 2000/13/EC”. The intended Regulation in fact leads to a paradigm change because the present system of a subsequent state control of health claims on a case-by-case basis –accompanied, in many Member States, by self-controlling measures being taken by the industry – is abandoned by introducing a mixed system of general prohibitions and a preventive authorisation procedure at Community level.

D. Fundamental objections in respect of the freedom of opinion and information

The system of a general prohibition of health claims in conjunction with an authorisation procedure at Community level for subsequently permitted claims is - as such - already subject to considerable objections, irrespective of any further points of criticism in relation to individual provisions, both from a constitutional and from a Community perspective. The objections are not simply based upon the fact that the paradigm change resulting from the Regulation is in conflict with the principle of subsidiarity enshrined in Article 5 (2) of the EC Treaty as well as with the Commission's obligation to primarily use the directive as legal instrument rather than the regulation.¹ In particular, a system of a general prohibition of claims and an authorisation procedure would result in a massive interference with constitutional positions of both the advertising companies and the consumers who are the addressees of the advertising and the recipients of information. Manufacturers and distributors will be affected with regard to their freedom of opinion if they are prevented in the future from making health claims, to the same extent as they do at present, about the food products they offer. The consumers will simultaneously be restricted in their freedom of information because they will be deprived of sources of information in relation to the purchase of food, which have been available to them so far.

I. Scope of protection of the freedom of opinion and information

The freedom of opinion and information is protected at various levels by national constitutional law, by general legal principles of Community law as well as by the European Convention on Human Rights.

1. Community law

The free dissemination of opinions and information and the unhindered access to them are also protected by Community law. According to established ECJ rulings, the Community legislator is bound to observe the general legal principles of

¹ Protocol on the application of the principles of subsidiarity and proportionality, Section 6, sentence 3, OJ 1997 No. C 340/105 et seq.; Declaration No. 4 on Article 95 (ex Article 100 a) of the Treaty establishing the European Community (declarations annexed to the final act of the Single European Act).

Community law², including the common constitutional traditions of the Member States, on the one hand, and the European Convention on Human Rights, on the other hand. Even if the latter has no direct binding legal effect on the Community, the principles laid down therein must be complied with by the Community bodies in accordance with Article 6 (2) of the EU Treaty. Pursuant to Article 10 (1) of the European Convention on Human Rights, everyone has the right to the freedom of expression. This right shall include the freedom to hold opinions and to receive and impart information and ideas. It can even be gathered from the wording that the protection covers factual claims as well as mere opinions.³ The scope of protection granted under Article 10 (1) of the European Convention on Human Rights also covers commercial information in general. This is not only assumed by the Commission on Human Rights,⁴ but was also confirmed by the European Court of Human Rights (ECHR) in its “*markt intern*” decision of 1989.⁵ The protection of commercial information under Community law is also reflected by the recently proclaimed Charter of Fundamental Rights of the European Union. Although the Nice proclamation has no direct legal effect, the ECJ is not allowed to ignore the consensus laid down in the Charter in compliance with the order set out in Article 6 (2) of the EU Treaty to identify the constitutional traditions common to the Member States.⁶ Article 52 (3) of the Charter expressly provides that the freedom of expression and information guaranteed under Article 11 of the Charter shall have the same scope of protection as that laid down in Article 10 of the European Convention on Human Rights.

² ECJ, ECR 1964, 1251 et seq. – *Costa/ENEL*; ECR 1979, 3727 et seq. – *Lieselotte Hauer et al.*; ECR 1989, 2859 et seq. – *Hoechst AG/Commission* (ECJ decision Brenner blockade); *Engel*, ZUM 2000, 978 with further citations; *Kühling*, Die Kommunikationsfreiheit als Europäisches Gemeinschaftsgrundrecht, 1999; *Rengeling*, Grundrechtsschutz in der Europäischen Gemeinschaft, 1993.

³ *Frowein/Peukert*, EMRK-Kommentar, 2nd ed. 1996, Article 10 note 5.

⁴ E 7805/77; DR16, 68 (73).

⁵ ECHR, EJIL 1996, 302; see also ECHR, Ser. A No. 178, para. 47; No. 173, para. 55; No. 285 (A), paras. 37, 51; most recent judgment of 28 June 2001 (VGT Verein gegen Tierfabriken); also *Schorkopf*, in: Ehlers (Hrsg.), Europäische Grundrechte und Grundfreiheiten, 2003, Section 14 note 64; *Frowein/Peukert*, EMRK-Kommentar, 2nd ed. 1996, Article 10 note 9; *Viliger*, Handbuch der Europäischen Menschenrechtskonvention, 2nd ed. 1999, Section 26 note 614.

⁶ OJ C 364 of 18 December 2002; *Hilf*, Charta der Grundrechte der EU, special supplement to NJW 2000, p. 6; see also *Callies*, in: Ehlers (fn. 4), Section 19 note 28; *Walter*, in: Ehlers (fn. 4), Section 1 note 32; *Grabenwarter*, DVBl 2001, 1, 11 et seq.; *Kloepfer*, Informationsrecht, 2002, Section 2 note 12.

Pursuant to Article 153 (1) of the EC Treaty, the Community, for the purpose of ensuring a high level of consumer protection, shall contribute to promoting the consumers' right to information.⁷ The Regulation's intention is also to promote this right, but it completely fails as a result of the comprehensive prohibitions set out in Articles 10 and 11 (1) of the Draft Regulation, and thus the consumer's guaranteed right to receive correct and truthful information is finally denied. The well informed, reasonably observant and circumspect average consumer – the standard applied in established rulings of the European Court of Justice for the assessment of whether or not an advertisement may be misleading – is thereby regarded to be unable to correctly understand accurate claims and make an appropriate choice.

2. **Article 5 (1) of the German Basic Law (*Grundgesetz*)**

This finding under the aspects of Community law is basically identical with the constitutional analysis based upon the German Basic Law. Under the provisions of the Basic Law, the scope of protection of the freedom to express and disseminate opinions and to receive and impart information pursuant to Article 5 (1) of the German Basic Law does not rule out in advance the supply of factual product-related information. In spite of the terminological contrast between subjective expressions of opinion, on the one hand, and objective factual information, on the other hand, which is, at first sight, difficult to rebut, there is wide consensus today that both forms are protected by Article 5 (1) of the German Basic Law. The Federal Constitutional Court (*Bundesverfassungsgericht*) has approved the inclusion of factual claims because and if they are required for the formation of opinions.⁸

Even the fact that the relevant information may also be given with a view to promoting sales will not constitute a barrier to the protection granted under Article 5 (1) of the German Basic Law. It has been recognised, at the latest, since the Federal Constitutional Court's "*Benetton*" decisions that even advertising claims of commercial enterprises may fall within the scope of protection of the freedom of expression.⁹ At first glance, the Constitutional Court applied in these decisions the

⁷ See *Gorny*, EFLR 1998, 373 et seq.

⁸ BVerfGE 54, 208, 219; 61, 1, 8; 85, 1, 15; BVerfG, GRUR 1992, 866, 870 – *Hackethal*.

⁹ BVerfGE 102, 347 et seq. – *Benetton-Werbung I*; BVerfG, GRUR 2003, 442 et seq. – *Benetton-Werbung II*.

standard of the freedom of the press under Article 5 (1) sentence 2 of the German Basic Law because the proceedings at issue dealt with an anti-competitive act of a newspaper publisher by its printing of a Benetton advertisement. As the Federal Constitutional Court, however, incidentally also examined the freedom of expression of the commercially advertising enterprise, there can be no doubt that the scope of protection of the freedom of opinion also covers the advertising statements of companies.

Article 5 (1) sentence 1 of the German Basic Law further protects the right to inform oneself from generally accessible sources without any restriction. This personal fundamental right is considered to be a key requirement for a free and well-informed democratic public. The scope of protection covers the entire process of gathering information from the simple receipt of information up to the active procurement of information. The methods of gathering information are also protected under the Basic Law such as (national or foreign) newspaper subscription, listening to radio programmes or the reception of radio satellites, including the purchase and use of the required technical equipment. A source of information is to be considered as being generally accessible if it is technically suitable and designed to provide the general public, i.e. an indeterminate group of persons, with information, for example, the traditional mass media (press, radio, television and movie) as well as exhibitions, pamphlets, hand-outs, advertising pillars, poster boards and inscriptions. As a result, any governmental restriction of access to specific product information may also lead to a restriction of the consumer's interest in obtaining information as protected under the Basic Law and, therefore, requires a constitutionally sufficient justification.

II. Limits to the freedom of opinion and information

It is self-explanatory that the freedom of opinion and information is not guaranteed without any restrictions under European Community law or under German constitutional law. The consumer protection from "confusing and misleading" health claims referred to in the statement of reasons of the Draft Regulation¹⁰ thus constitutes, in principle, an objective of general interest within the meaning of Article 52 (1) of the

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See No. 28.

EU Charter. It should, however, be noted that the European legislator's freedom to limit the rights guaranteed by the EU Charter is not granted without restriction. Rather, Article 52 (1) of the EU Charter provides that all rights and freedoms shall, in their entirety, be subject to the guaranteed principle of essence and proportionality thereby adopting a wording that is also often used in the European Convention of Human Rights.¹¹

Furthermore, the principle of proportionality with binding effect upon Community institutions is also based upon the general principles of Community law. Irrespective of the various dogmatic inferences¹², the claim for normative application of the principle of proportionality cannot be disputed and is part of the established "*acquis communautaire*" of Community law. According to the principle of proportionality, the means applied under a Community provision should not be obviously unsuitable to, or go beyond the action required for, the attainment of the objective pursued, taking into consideration extensive discretionary powers to achieve those objectives.¹³ Thus, the provisions proposed in the Draft Regulation must, in particular, be reviewed under the aspects of whether they are proportionate, i.e. necessary, in order to actually meet the objectives of general interest recognised by the Union.

1. Contents of the principle of proportionality

In this context, particular attention should be paid to the rulings of the Court of Justice addressing the issue of the compatibility of national rules with European law, which prohibit specific advertising claims as abstract strict liability torts irrespective of their truthfulness and irrespective of any concrete danger. The Court of Justice has recently had the opportunity to assess the Community compliance of national provisions that show some parallels, in terms of their contents, to the proposals submitted in the Draft Regulation.

¹¹ See in more detail *Engel*, ZUM Sonderheft/2000, 975, 993.

¹² As to the various views – inference from the rule-of-law principle / the analysing comparison of laws / by deduction from the provisions of the Treaty – see in detail *Schwarze*, *Europäisches Verwaltungsrecht*, 1988, vol. 2, p. 692 et seq.

¹³ cf. most recently ECJ, ECR 2002-I, 6453, para. 59 – *Käserei Champignon Hofmeister*; EuZW 2003, 107, 109, para. 122 – *British American Tobacco*, each with further citations.

- a) The judgment of the Court of Justice in Case C-99/01 regarding *Linhart/Biffi* of 24 October 2002¹⁴ should be mentioned first. This decision dealt with the Community compliance of an Austrian provision that prohibited the marketing of cosmetic products by pointing to claims referring to the prevention, alleviation or cure of diseases or disease symptoms or to physiological or pharmacological effects, in particular effects relating to the preservation of a youthful appearance, effects that inhibit the symptoms of old age, slimming effects or health-maintaining effects or claims that give the impression of such effects. Health claims relating to cosmetic products can only be authorised upon application and with the permission granted by the competent minister if such an authorisation is compatible with the protection of consumers against deception.¹⁵ The appellant in the proceedings submitted to the Court of Justice had placed a soap on the market, which was stated to have been “dermatologically tested”. The Court of Justice had to decide within the scope of a preliminary ruling whether or not the Austrian provision that generally prohibits such a statement unless it is authorised by the competent minister on a case-by-case basis is consistent with Community law.

This was denied by the ECJ. In its statement of the reasons, the Court of Justice – by expressly referring to its *Clinique*,¹⁶ *Unilever*¹⁷ and *Estée Lauder*¹⁸ decisions – primarily pointed to the principle of proportionality. According to the Court, the assessment of the risks for consumers, on the one hand, and the requirements of the free movement of goods, on the other hand, should be based upon the presumed expectations of an average consumer who is reasonably well informed and reasonably observant and circumspect under the aspects of the applicable principle of proportionality, provided that a mistake as to the product’s characteristics cannot pose any risk to his/her health.¹⁹ The relevant statement “dermatologically tested” could, however, only give the idea that the product is “well tolerated” or at least “harmless”. The question of whether the statement was in fact

14 See under <http://curia.eu.int>.

15 Section 9 i.c.w. Section 26 of the Austrian Food Act LMG.

16 ECJ, ECR 1994-I, 330 et seq.

17 ECJ, ECR 1999-I, 431 et seq.

18 ECJ, ECR 2000-I, 117 et seq.

19 ECJ, loc.cit., para. 31.

accurate could be supervised by the national authorities. The Court held that if such a statement is not misleading, the Member States are not entitled to take measures whose effect is to restrict a marketing of the cosmetic product bearing such a statement. Therefore, the requirement of a prior authorisation by the competent minister was found to be incompatible with Community law. The Court of Justice made a similar decision in the previous case regarding “*Unilever*”²⁰ to the effect that it would be disproportionate to make health claims relating to a tooth cream (“protection against the development of periodontosis and prevention of the formation of tartar”) subject to an authorisation requirement, because a sufficient control would be ensured by requiring the advertising company, in the event of a dispute, to furnish evidence of the accuracy of the statement in compliance with Article 6 of Directive 84/450/EEC.

- b) In the *Linhart/Biffi* case, special regard should be given to the Opinion delivered by Advocate General Geelhoed on 7 March 2002²¹ pointing to the strict requirements to be met by such national provisions:

“The case law shows that the Court of Justice, when examining the question of whether a specific statement or advertisement is misleading within the meaning of Directive 76/768, takes a critical attitude towards national provisions prohibiting an actually correct statement. The principle of proportionality often constitutes a barrier to such provisions. An abstract risk of misleading consumers is not sufficient; measures taken to the effect that the placing on the market of a product is subject to several requirements will be admitted only in such cases where the consumer might really be misled with regard to a significant detail.”²²

- c) These requirements – defining the scope of the principle of proportionality – do not only apply to the cosmetics sector, but to all goods and services, including the advertising and labelling of foodstuffs. The ECJ – in agreement with the Opinion

20 ECJ, ECR 1999-I, 431 et seq.

21 See under <http://curia.eu.int>.

22 Advocate General *Geelhoed*, loc. cit, para. 35.

delivered by Advocate General Geelhoed on 4 July 2002 – also applied these principles to the food sector in Case C-221/00 and in Joined Cases C-421/00, C-426/00 and C-16/01²³ with its judgment of 23 January 2003. The Commission had initiated proceedings against Austria for a violation of the Treaty after having received several complaints that food products produced and marketed in other Member States could not be placed on the market in Austria because they contained health claims that had not been previously authorised by the competent minister. The complaints concerned statements such as “beneficial to a cholesterol-conscious diet” (on the label of salmon oil capsules), “contribution to a healthy intestinal flora and healthy cells” (on the label of bread) and “fibre and *satiating* material in the case of diet-related constipation” (on the label of linseed). Following the action filed by the Commission, some Austrian courts also submitted questions to the Court of Justice concerning the compatibility of the said national provision with Community law. The questions put forward were based upon advertising claims such as “a good name for healthy enjoyment” (on the label of a pie). The ECJ denied the proportionality of the Austrian provision because the indicated residual risks to the public health could be avoided by less restrictive measures, in particular the manufacturer’s obligation to furnish evidence, in cases of doubt, for the accuracy of the factual claims contained on the labelling.²⁴ The Austrian provision, however, was held to have the effect that food products containing health claims could not be freely marketed in Austria even when they are unlikely to mislead the consumer. The Court stated that no specific reasons had been given to support the argument that a system of subsequent control of previously marketed food products would not be sufficient and the provisions in question would thus have to be regarded as disproportionate.

As shown by the statements of Advocate General Geelhoed, this decision is not confined to a specific individual case. Rather, the guidelines defined by the ECJ for the interpretation of the principle of proportionality are of fundamental importance. In his Opinion delivered on 4 July 2002, Advocate General Geelhoed expressly emphasized that the impression of the average consumer was the decisive criterion in the protection of consumers against misleading advertising not only in the food

²³ See both decisions under <http://curia.eu.int>.

²⁴ ECJ, judgment of 23 January 2003, Case C-221/00, para. 47 et seq.; Cases C-421/00; C-421/00; C-426/00 and C-16/01, para. 37 et seq. [im deutschen Text steht “ECJ, loc. cit., para. 37 et seq.”] [2]

sector but also for cosmetic products, because the use of cosmetic products might cause, in the case of irresponsible statements, serious damage to public health in the same manner as food consumption. He also pointed out that there is

“a fundamental difference between statements relating to the prevention, treatment and cure of a disease and statements referring to the enhancement of human well-being”.²⁵

In the case of disease-related claims, the emphasis was said to be put on the treatment or curing of a specific disease or its prevention. In contrast thereto, health-related claims were found to be based upon a positive basic idea, namely the maintenance or improvement of health.²⁶ Even if the demarcation line between these advertising variants might, according to Advocate General Geelhoed, sometimes be difficult to draw because certain health claims might also give rise to the impression that a product has a curing effect, these two categories would nonetheless have to be basically distinguished. As the statements at issue were not related to a disease, but to a person's health, they were held to go beyond the scope of Article 2 (1) b) of Directive 79/112. They could also not be justified pursuant to Article 15 (2) of Directive 79/112 as they had turned out to be disproportionate. It was said to be true that, under Community law, the Member States were granted relatively extensive discretionary powers with regard to health issues in the absence of a specific Community rule. However, in such cases as well, the principle of proportionality requires that the measures adopted should not be more restrictive than is necessary to achieve the pursued objective. This requirement was said to have been ignored in the case of a comprehensive general prohibition of all health claims accompanied by a burdensome authorisation procedure because Article 2 (1) lit. a) and b) of Directive 79/112 already prohibited any incorrect or misleading statements referring to health effects as well as any and all disease-related claims. Accordingly, a health improvement claim could, for example, be critically reviewed with regard to the product characteristics and any other relevant factors and be prohibited, if required. National control might even be carried out by requiring the

²⁵ Advocate General *Geelhoed*, loc. cit., para. 53.

²⁶ Advocate General *Geelhoed*, loc.cit., para. 53 ff.

manufacturer or distributor of the food product concerned to furnish, in the case of a dispute, evidence of the accuracy of the alleged factual claims contained on the labelling. However, a general prohibition of health claims on food labelling was held to be disproportionate.

2. Conclusions

In its previous consistent practice, the Commission has very clearly expressed its view that provisions prohibiting health claims on cosmetic or food products subject to authorisation are disproportionate. This opinion has persistently been supported by Advocate General Geelhoed. Both the Commission and Advocate General Geelhoed can additionally base their position upon the established case law of the Court of Justice, according to which formalised absolute prohibitions of specific advertising claims, irrespective of their truthfulness and a concrete existing danger, are, in principle, to be critically assessed.²⁷ Such an “excessive level of prohibition” can only be regarded to be proportionate if it is really required to protect the consumer from concrete health risks. This assumption does, however, not apply to general health claims in relation to food products – in contrast to disease-related claims.

It is all the more astonishing that the Commission has now made proposals with the Draft Regulation, which, under regulatory aspects, point in the opposite direction. It is an incomprehensible deviation from its previous position and a violation of the standard of coherence applicable to any policy pursued. At the same time, a Community rule would be introduced which is practically diametrically opposed to the case law of the Court of Justice on the issue of the proportionality of comparable national provisions. A comprehensive prohibition of the dissemination of truthful statements is not consistent with the legitimate objectives pursued by Community food law.

E. Evaluation of individual provisions, in particular by applying the principle of proportionality

Against this background, a large number of provisions contained in the proposed Regulation turn out to be manifestly disproportionate. They are already unsuitable to achieve the aims pursued therewith.

The key objectives of the Draft Regulation can be found in Recital 1, which reads as follows:

²⁷

ECJ, ECR, 1999, I-431 – *Unilever*; ECJ, ECR, 2000, I-117 – *Estée Lauder*.

“There is an increasing number of foods labelled and advertised in the Community with nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market must be safe and adequately labelled.”

These objectives defined by the Draft itself are not met. Furthermore, there are less stringent and burdensome means available in order to achieve the specified targets. In detail:

I. Nutrient profiles

1. Pursuant to **Article 4 of the Draft Regulation**, the Commission shall, in accordance with a regulatory committee procedure described in Article 23 of the Draft Regulation, establish specific nutrient profiles, to which food or certain categories of foods must conform in order to be able to bear nutrition or health claims. In contrast, the envisaged rule means that all food products that do not comply with the nutrient profiles still to be defined may not be advertised with nutrition and health claims.

Article 4 of the Draft Regulation recognisably serves the purpose of managing the dietary habits of consumers within the European Union thereby implementing measures in the domain of nutrition and health policy.

2. However, the European legislator is not responsible for issues of public health protection. The Commission has based its proposal for a Regulation primarily upon Article 95 of the EC Treaty and thus refers to its power of harmonisation in relation to the internal market. Article 152 (4) of the EC Treaty, however, clearly states that measures for an approximation of the Member States' legal provisions shall be ruled out in the field of public health protection. If the Commission thus requires the setting of nutritional profiles without any comparable models existing for such provisions in the legislation of any Member State, it would thereby be entering new legislative territory without any need for harmonisation, i.e. without any power to take legislative action. A reference to Article 95 (1) of the EC Treaty or any other

rule relating to legislative powers for the internal market shall also be ruled out in accordance with ECJ rulings if it serves the purpose of evading another competence provision such as the exclusion provision under Article 152 (4) of the EC Treaty.²⁸

3. Apart from the Community's lack of competence for issues of health policy, it is to be criticized that, so far, there has been no recognised scientific basis for the formulation and function of nutrient profiles. The contents of the nutrient profiles to be established remain completely unclear. As this Regulation will be directly applicable to, and impose specific duties upon, all legal subjects in the Member States of the Communities, it will also have to meet the legal requirements concerning the sufficiently precise specification of a rule providing for criminal sanctions, i.e. the parties concerned, in particular the undertakings would have to be able to precisely identify the scope of the obligations imposed upon them by this rule.²⁹

As regards regulatory policy, it is disquieting that the Commission patronizes the economically responsible consumer: It anticipates the consumer's decision by making a distinction between the foods it considers to be good and bad.

4. The prohibition of a nutrition or health claim on beverages containing more than 1.2% by volume of alcohol (Article 4 (3) of the Draft Regulation) constitutes a serious breach of the system and allows a differentiation of the labelling of desirable and undesirable types of foods. Consumers may, however, also be passively interested in being informed of the calories of alcoholic beverages such as beer. Such indications may, for example, when being integrated in a diet scheme, inform the consumer of the significance of consuming such a product as regards potential overweight. The provision further prohibits any advertising of a herbal liqueur using traditional product characteristics such as "bitters". The Regulation thereby exceeds the objective of ensuring consumer protection by providing true and correct information and is an example of consumer patronization,

²⁸ cf. as to the prohibition of an abusive circumvention in more detail ECJ, ECR 2002 I – 11453, 11608 – *Imperial Tobacco*; Selmayr/Kamann/Ahlers, EWS 2003, 49, 57 with further citations.

²⁹ ECJ, ECR 1998 I – 5655 note 35.

obviously based upon the idea of an immature consumer who is not responsible for his/her own acts, a concept that is not compatible with the idea of the responsible consumer as decisively developed by the European Court of Justice (in agreement with the Commission).

5. The authorisation rule of Article 4 (4) of the Draft Regulation permitting the European Commission to prohibit claims on undesirable foods also gives rise to similar concerns. This provision is meant to be applicable irrespective of whether the labelling concerned is objectively correct and would thereby result in a prohibition of information instead of the supply of appropriate information.

II. **Comprehensive advertising prohibitions**

The detailed advertising prohibitions set out in Article 11 of the Draft Regulation prevent appropriate consumer information.

1. The general prohibition of **Article 11 (1) (a) of the Draft Regulation**, which has again been extended, compared with the first draft, with regard to claims that make reference to general, non-specific benefits of food for good health and well-being (e.g. contributes to the strengthening of the body's immune system) cannot be derived from the general prohibition of misleading statements. The consumer rather has a legitimate need for information regarding health-related issues, in particular in respect of a healthy nutrition. General health claims relating to food do not involve, at the outset, an inherent specific potential of misleading consumers. Their definition in contrast to other more specific health claims is problematic; the prohibition of disease-related claims made on foods under Article 2 of the Food Labelling Directive and Section 18 (1) no. 1 of the German Act on Foodstuffs and Goods in Daily Use (*Lebensmittel- und Bedarfsgegenstandegesetz*) does not generally prohibit health references of a general nature. General health claims such as

- “eating fruit is healthy”

- “eat more fruit and you make an important contribution to maintaining your health”³⁰

have, in particular in recent times, been confirmed to be justified and are not misunderstood by consumers as to their meaning. In future, however, such claims could not even be authorised as a result of their being insufficiently precise. The entire range of the so far permitted general health claims in the advertising of foodstuffs would accordingly become illegal with the entering into force of the present Draft Regulation even if the claims in question were factually correct and did not give rise to any potential risks to public health. The Draft does not give any comprehensible reasons why consumers should be protected from health-related advertising claims in excess of their protection from misleading statements. It is also beyond our understanding why food products should be subject to more stringent advertising restrictions than other products that are comparable with regard to their health reference. Ultimately, the proposal submitted by the DG SANCO is in contrast to the information norm consistently supported by the Commission itself and the resulting European model of an average consumer who is reasonably well informed and reasonably observant and circumspect, which has also been adopted by the ECJ.³¹ Thereby, objectively correct information should, in principle, not be withheld from the economically responsible consumer.

2. The scope of protection envisaged by **Article 11 (1) (b) of the Draft Regulation** (prohibition of claims making reference to psychological or behavioural functions) is unclear. It obviously addresses statements that attribute to the advertised foodstuffs positive or beneficial effects on the psyche (mood, mind, well-being) or the type of behaviour (performance, including learning ability, attentiveness, energy, vitality). Such advertising descriptions of features have been used for centuries in Europe in respect of established food products with stimulating effects such as coffee and tea. The consumer is familiar both with the features of such products and with the advertising descriptions of their effects. Such statements are neither new nor

³⁰ For further examples see *Gorny*, ZLR 2003, 253 et seq.; *Meisterernst*, ZLR 2002, 569 et seq.; *Sosnitza*, WRP 2003, 669 et seq.

³¹ See ECJ, ECR I 1994, 317 et seq. – *Clinique*; ECJ, ECR 1998, I-4657 – *Gut Springenheide*; ECJ, ECR 1999, I-513 – *Kessler Hochgewächs*; WRP 2000, 289 et seq. – *Lifting*.

misleading for the consumer. Such a far-reaching prohibition is not even included in the Community code for medicinal products for human use (Directive 2001/83 - ex EC Directive 92/28/EEC on the advertising of medicinal products for human use³²). A general prohibition of such statements beyond the existing prohibition of misleading statements is, therefore, manifestly disproportionate.

3. **Article 11 (1) (c) of the Draft Regulation** (prohibition of claims making reference to slimming, a reduction in the sense of hunger or an increase in the sense of satiety; exception: the cases permitted under Directive 96/8/EC) is superfluous and disproportionate in view of the general prohibition of misleading advertising. This rule would unjustly also generally prohibit truthful advertising statements that are permitted under German court practice in spite of Section 6 of the Nutritional Labelling Regulation (*Nährwertkennzeichnungsverordnung*) in accordance with the so-called “mosaic” or “contribution” theory if they give a correct description of the contribution made by the advertised food product within the scope of a purposeful diet scheme.³³

4. **Article 11 (1) (d) of the Draft Regulation** prohibits any reference to the advice of doctors and other health professionals as well as their professional associations and prohibits giving the impression that the health of a person could be affected by not consuming the (advertised) food. This provision as well is disproportionate due to its generalisation. It will make it impossible – without exception – to mention in public the scientific evidence justifying an advertising claim. This general prohibition is even meant to cover any advertising reference to expert opinions of recognised national and international professional associations whose findings are of particular interest to risk groups and sick persons requiring a particular diet.

The further prohibition set out in this Article of suggesting in advertising that a person’s health might be adversely affected if the (advertised) food product is not consumed is unclear as to its intended scope of application and counterproductive

³² OJ EC No. L 331/67, ex Directive 92/28/EEC of 31 March 1992, OJ EC No. L 113/13; cp. in this context and as to the, in our opinion, excessive German prohibition in Section 10 (2) HWG alt. 3: BGH, WRP 2000, 502 et seq. – *Johanniskraut-Präparat*; *Bülow/Ring*, Heilmittelwerbegesetz, 2nd ed., Section 10 note 2; *Gröning*, GRUR Heilmittelwerberecht, Art. 3 note 6 et seq.

³³ OLG Hamburg, LRE 18, 350 et seq. ; Kammergericht, Pharma Recht 1991, 151 et seq.

at least with regard to dietetic foodstuffs – except for cases of misleading claims which have already been regulated – because in this food category it is absolutely necessary to point to a diet including this product in order to show its dietetic character. The advertising of a preventive consumption of vitamins and minerals as foods would also be disproportionately limited by such a prohibition.

5. **Article 3 (d) of the Draft Regulation** contains a prohibition of improper, alarming or misleading terms, including pictorial, graphic or symbolic representations referring to changes in bodily functions. This prohibition is associated with a number of uncertainties with regard to its interpretation. Such a general prohibitive rule whose substance is difficult to identify and demarcate and which is obviously intended to prevent any advertising arousing fear even goes far beyond corresponding rules in the field of advertising of medicinal products.³⁴ The intended prohibition is, therefore, not only disproportionate; due to its broad wording, this provision is also in breach of the requirement of a sufficiently precise specification recognised under Community law.³⁵

III. Expensive and time-consuming procedure for the registration of health claims

If voluntary information for consumers should, beyond the mandatory declaration, be subject to an authorisation by means of an expensive, time-consuming and scientifically and methodically complicated procedure, the flow of information being of importance to both the food manufacturers and the consumers would be impaired, the opportunities of advertising innovative products curtailed and, thus, the incentive for the development and manufacture of such goods paralysed and finally the general competition restricted. This bureaucratic regulation would also have an indirect impact on economic growth in the EU. The envisaged procedure is also in breach of the principle of proportionality. In detail:

³⁴ Cf. as to the German prohibition of advertising by arousing fear outside the expert circles for medicinal products in Section 11 (1) no. 7 HWG and the absence of a relevant express provision in Directive 92/28/EEC *Doepner*, *Heilmittelwerbegesetz*, 2nd ed., Section 11 no. 7 note 15.

³⁵ See in this context ECJ, ZLR 2000, 744 et seq., 756 para. 66 – *Rombi*, with annotation by Schroeter (loc.cit., 761).

1. Scope

The entire scope of this preventive authorisation procedure can be derived from the broad definition of the term “claim” as laid down in Article 2 of the Draft Regulation. The definition covers any openly available statement and representation, including graphic elements and symbols and thus also any product names, or components thereof, that have been established for decades.

2. The authorisation procedure

The filing of the application is followed by a comprehensive licensing procedure. According to the intended periods granted for the submission of observations by the committees and boards involved, the procedure will take at least nine months, but is likely to take much longer in most cases. There are two procedures available for this purpose:

The procedure defined in Article 12 of the Draft Regulation deals with the collection and assessment of statements generally concerning the effects of a nutrient or other substance on growth, development and the normal functions of the body as accepted by scientific data. Following a one-year compilation by the Member States and a subsequent assessment by the European Food Safety Authority (EFSA), after not more than two years, the Commission shall enter such statements in a register (of approved claims) (Article 18 of the Draft Regulation).

Other health claims shall be subject to an individual and complex application, accompanied by the documents and evidence specified in Article 14 of the Draft Regulation, as well as to the positive decision of the EFSA under Articles 14 – 16 of the Draft Regulation. Such claims may be used only if these requirements are met (Article 10 (1)) and provided they contain specific information (Article 10 (2)). The application shall be evaluated by the EFSA within six months. This period, however, only constitutes a target period that may also be extended. In view of the anticipated large number of applications to be filed, it is likely that evaluation will not be possible within this period. The subsequent publication, collection of observations by the public, assessment and registration in the register is likely to take at least one year.

The application is to be accompanied by extensive documentation, in particular with regard to the studies that have been carried out and any other material that is available to demonstrate that the health claims comply with the criteria laid down in the Regulation (copies of scientific studies and a proposal for the wording – in all Community languages – of the health claim for which approval is sought including specific conditions for use).

3. Consequences for competition

The procedure is complicated and costly and will, therefore, probably only be viable for financially strong food groups. The fact that such undertakings may, pursuant to Article 19 of the Draft Regulation, obtain protection for the scientific documents filed by them will monopolise their market position upon receipt of an approval of the claim applied for. This will result in monopolisation. The procedure for the registration of a health claim as provided for by Articles 14 through 17 of the Draft Regulation is technically and financially so expensive and time-consuming that only major internationally active companies can carry out this procedure in an economically justifiable manner in relation to particular product categories. There is no evidence that these serious competition-related objections would be at all compensated by the envisaged increase in the consumer protection level, which is ultimately not achieved.

4. Disproportionality of the authorisation procedure when compared with the advertising rules for other product categories

Consumers need to be protected against incorrect and also against incomplete and unclear misleading statements in the field of health-related advertising. For this reason, advertising claims have to satisfy strict requirements as to their truthfulness, unambiguousness and clarity as well as the substantiation of the facts claimed.³⁶ The consistent case-by-case application of this principle of a strict interpretation of product-specific advertising prohibitions, notably the prohibitions of

³⁶ Cf. as to the German practice in the field of health claims, which is in both respects traditionally very strict and occasionally criticized by the Commission, BGHZ 47, 259 – *Gesunder Genuß*; BGH, GRUR 1971, 153, 155 – *Tampax*; GRUR 1975, 664 – *Idee-Kaffee III*; GRUR 1980, 797, 799 – *Topfit-Boonekamp*; GRUR 1991, 848, 849 – *Rheumalind II*; GRUR 1993, 756, 757 – *Mild-Abkommen*.

misleading claims in the field of medicinal products, medical devices, cosmetic and food products, makes authorisation procedures redundant. Any prior control (“advertising censorship”) or prior approval of advertising claims will constitute an unnecessary interference with the companies’ freedom of expression and the consumers’ right of access to information (see in more detail under D. above).

The European legislator has even refrained from initiating any authorisation procedures for the advertising of those categories of products that affect consumers’ and the public’s health interests to a much more significant extent (medicinal and medical products).

Thus, in the field of food advertising, the principle of proportionality and the prohibition of excessive measures should be given particular consideration – a requirement that has not been met by the Draft.

IV. Exaggerated requirements concerning scientific evidence

Ultimately, the requirements laid down with regard to the scientific substantiation are manifestly disproportionate. In detail:

1. The future standard of a substantiation of facts

Article 6 (1) of the Draft Regulation contains the following provision: “Nutrition and health claims shall be based on and substantiated by generally accepted scientific data.” Furthermore, pursuant to Article 6 (2), the enterprise placing the product on the market has the responsibility to “justify the use of the claim”. According to Article 6 (3), it must “produce the scientific work and the data establishing compliance with this Regulation”, with the latter obligation being subject, however, to a corresponding request by the competent authority of the Member State.³⁷

According to Recital 14 of the Draft Regulation, the scientific substantiation of health claims shall be reviewed by applying the highest possible standards before

37

Cp. also the requirements to be met by the application for authorisation under Article 14.

being authorised.³⁸ According to Article 11 of the Draft Regulation, corresponding studies are to be submitted in the authorisation procedure. If the application of the highest possible standard generally involves the requirement of controlled randomised double-blind trials with the highest possible number of participants,³⁹ this means that other scientific findings and practical experience will be irrelevant. This would result in the establishment of standards that are stricter than those applied by the law on advertising of medicinal and medical products, where the examination of a sufficient scientific substantiation of advertising claims is also based upon other scientific findings and practical experience and where the identification and verification of facts are subject to differentiated requirements depending on the product category concerned (different criteria for medicinal products of special therapeutic fields such as homeopathy, anthroposophic medicine and partially also phytotherapy as well as so-called traditional medicinal products).⁴⁰

2. Inappropriateness and disproportionality of the standard

Such generalising standard formulas used to establish a stricter standard for the substantiation of advertising claims made on foods compared with that applied to medicinal products do not take sufficient account of the generally deviating degree of correlation between the advertising claim and the substantiation of facts in the case of foods, on the one hand, and medicinal and medical products, on the other hand. Foodstuffs regularly show no, but in any event a significantly lower, risk potential than medicinal or medical products. Furthermore, it cannot be seen why food products should be subject to stricter requirements as to the substantiation of facts regarding functional claims than corresponding claims made about cosmetics. Such a practice would be in breach of the prohibition of excessive measures.

3. Lack of clarity

³⁸ “Health claims should only be authorised for use on the Community market after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessments of these claims, the European Food Safety Authority should carry out such assessments.”

³⁹ Cp. as to the relevant dispute with regard to Section 17 (1) no. 5 LMBG *Großklaus*, DLR 2001, 329 et seq., 330 right-hand col., on the one hand, and *Hagenmeyer*, DLR 2000, 431 et seq. 433 and *Meisterernst*, ZLR 2002, 569 et seq., 581, on the other hand.

⁴⁰ Cp. in more detail, as to the necessary differentiation in this context, *Doepner*, Heilmittelwerbeengesetz, 2nd ed., Section 3 notes 71 et seq. with further citations.

The more significant the interference of a rule with the addressees' rights of freedom, the more precisely specified the rule should be. This legal requirement has also been disregarded by the Draft.

In this context, it is first of all unclear whether or not the requirements to be met by the substantiation of facts are to be judged differently depending on the product category and type of advertising claim (deviating degree of correlation between advertising claim and substantiation of facts on a case-by-case basis?).⁴¹ Furthermore, it is questionable whether and to what extent the evidence required in respect of claims may also depend on the understanding of the average consumer who is reasonably well informed and reasonably observant and circumspect. In addition, a provision of the type intended by Article 6 of the Draft Regulation would require the development of a generally valid uniform EC standard. However, in the scientific field there is regularly no "generally accepted" knowledge, which has also been recognised by the EMEA and the national authorisation and monitoring authorities for the marketing and advertising of medicinal products. A consistent application of the requirement of a "generally accepted" scientific basis for such advertising claims would, therefore, make an acceptance of such claims largely impossible.

4. A more flexible standard required

Generalising standard formulas such as "generally accepted scientific data" (Article 6 (1) of the Draft Regulation) should be avoided. They should be replaced by a more flexible wording, which, on the one hand, would allow for the different expectations of the public to be addressed depending on the product category and type of advertising claim and, on the other hand, would not rule out the use of other scientific findings and practical experience.

German court rulings and – based thereupon – the German legislator have established such a flexible provision for the food and cosmetic advertising sector (Sections 17 (1) no. 5 a and 27 (1) no. 1 LMBG), allowing a graduated assessment of the requirements to be met by the substantiation of facts in relation to the

41

See *Hahn*, ZLR 2003, 543 et seq., 559 et seq.

relevant advertising claims at issue (“*wissenschaftlich hinreichend gesichert*” / “sufficiently evidenced by scientific data”).

F. Fundamental objections considering the TBT Agreement

Under Article 2 para. 2.2 of the Agreement on Technical Barriers to Trade (TBT Agreement), the members are required to ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. Rules on the allowed use of statements in the labelling or presentation are technical regulations according to Annex 1 no. 1 of the TBT Agreement. Technical regulations shall be applicable if and to the extent required in addition to the relevant international standards. International standards within this meaning shall, according to the definition in Annex 1 no. 2, also include the standards and guidelines set out in the Codex Alimentarius. The guidelines for the use of nutrition claims (CAC/GL 23-27) contain no prohibition of general statements referring to the effect of foods on the general well-being or to physiological effects; such prohibitions are not intended either (ALINORM 03/22 APPENDIX VII). A prohibition of such statements must, therefore, be regarded as a violation of the rules of the TBT Agreement.

G. Fundamental objections in respect of the legislative form of action (regulation)

The Draft has been issued in the form of a regulation, i.e. legislative provision that is directly applicable in all Member States for citizens as well as companies (Article 249 (2) EC). A reason why this matter should not, in line with the decades-old practice in Community food legislation, be regulated by a directive is not mentioned.

I. Priority of the directive

The legislative instrument of a regulation is already inconsistent, firstly with the principle of subsidiarity enshrined in Article 5 (2) of the EC Treaty and Declaration No. 8 annexed to the Single European Act, but also in view of the fact that the

characteristic way of a process-related approximation of the Members' legal systems will now be disrupted and distorted.⁴²

As a consequence of this regulatory technique, the Member States are prevented from legally adjusting, by means of an act of transformation, the regulatory contents of the intended regulation within their legal system in their respective national legislation.⁴³ The national food law has, however, in the course of decades been structured by Community requirements as issued by directives. A legal harmonisation by the instrument of the Community regulation, therefore, results in an elimination of certain laws, which, in turn, will lead to disruptions and distortions of the legal system". This will result in a substantial loss of planning and legal certainty for citizens and food producers. In this very complex and technical legal domain, the persons and parties involved have become used to inferring their legal obligations from national provisions. The present two-level regulatory system has also proven to be successful because the food provisions largely provide for administrative fines and often also for sanctions under criminal law, with the qualification and punishment of acts under the administrative offences law and criminal law being the undisputed responsibility of the national legislator.

⁴² Official Journal 1987, L 169/24; as to breaches of the system in the approximation of laws see in more detail *Biervert*, *Der Mißbrauch von Handlungsformen im Gemeinschaftsrecht*, 1999, p. 134 et seq. with further citations; in detail as to the Basic Food Regulation *Streinz*, *Was bleibt vom LMBG?*, ZLR 2000, 803 et seq.

⁴³ *Lenz*, EG-Vertrag, 2nd ed., 1999, Article 249 note 7.

II. Janus-headed provisions

Inappropriate – and very doubtful with regard to the planning and legal certainty required for citizens and food companies – is furthermore the legislative technique already chosen in the definition of food in Article 2 of the Basic Food Regulation⁴⁴, namely the implementation of provisions of directives in the regulation itself by means of reference. Thus, the relevant directives become part of the regulation and as such directly applicable law. Article 7 of the Draft Regulation, for example, provides that nutrition labelling shall be compulsory in accordance with the provisions laid down in Directive 90/496/EEC. Provisions set out in directives which, according to their function and thus often also according to their degree of specification, were not designed for direct application, but, according to the ideas of the European legislator, required the more specific transformation by the national legislator, thus become directly applicable law. A partial transfer of provisions of directives into regulations will thus give them in future an unclear Janus-headed character in respect of the application of law.

Under legislative aspects, the implementation of any additional labelling rules in the previously existing Food Labelling Directive or the Nutrition Labelling Directive⁴⁵ would be the more obvious approach. Such a legislative practice would also make numerous - exhaustively repetitive - provisions in the Draft Regulation superfluous.

III. Further deficiencies

There are further examples showing that the Draft does not comply with legal and legislative minimum requirements, in particular the common guidelines for the editorial quality of the Community provisions.⁴⁶ In detail:

⁴⁴ Regulation (EC) 178/2002; see with regard to the controversy as to the practical consequences BGH, ZLR 2002, 638 et seq. - *Muskelaufbaupräparate*; ZLR 2002, 660 et seq. - *Sportlernahrung*; *Doepner/Hüttebräuker*, ZLR 2001, 515 et seq.; *Gorny*, ZLR 2001, 501 et seq.; *Köhler*, GRUR 2002, 844 et seq.

⁴⁵ At least the provisions regarding nutrition claims could be included there in closer conformity with the system.

⁴⁶ OJ EC No. C 73, p. 1 et seq. of 17 March 1999.

1. The unclarity of the generalising provisions set out in Article 11 (1) of the Draft Regulation such as “psychological and behavioural functions” and “normal function of the body” has already been addressed.

The contents of the envisaged nutrient profiles also remain unclear.

Articles 7 and 8 of the Draft Regulation provide for nutrition information going beyond the present Nutrition Labelling Directive. It can, however, not be seen why a nutrition or health claim should result in the obligation to label the product with the complete nutritional information. This will, in practice, often lead to “zero information”.

The systematic solution of regulating nutrition information in an exhaustive positive list is inappropriate. Such positive lists have always been incomplete and prevent innovations in the food industry. The list submitted as an Annex is already now recognisably incomplete; it does not include, for example, the term “gluten-free”.

2. Furthermore, the effect of the registration of a permitted statement remains unclear, in particular whether or not all food manufacturers of identical or similar products can use this statement and precisely how it is to be registered for a specific product. Those applying the law also cannot know whether the approval is limited to the specific wording or also covers similar statements of identical contents as well as explanations relating to registered generic terms.

H. Conclusion and appeal

For the aforementioned reasons, the *GRUR Fachausschuss für Arznei- und Lebensmittelrecht* urgently appeals to the European legislator not to adopt this Draft on nutrition and health claims in relation to foods.

Dr. Kunz-Hallstein
President

Dr. Loschelder
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