

Deutsche Vereinigung
für gewerblichen Rechtsschutz
und Urheberrecht e.V.

Deutsche Vereinigung für gewerblichen Rechtsschutz und Urheberrecht
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Unser Zeichen:
(Bei der Antwort bitte angeben)

Opinion of the Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

Dear Mr. Davies,

Deutsche Vereinigung für gewerblichen Rechtsschutz und Urheberrecht e.V. (German Association for the Protection of Industrial Property and Copyright) is a scientific association of legal scientists and practitioners in the fields of protection of industrial property, copyright and competition law. According to its articles, it aims at promoting scientific development in the field of protection of industrial property and at providing assistance to legislative organs and to ministries and institutions competent in matters of intellectual property and fair competition.

1. Regulation (EC) No 178/2002, which lays 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 No L 31/1 of 1 February 2002), and which entered into force on 21 February 2002, introduced a definition of „food“ in Art. 2. For the purpose of this Regulation (Art. 2, Para. 1) „food“ shall mean:

"any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans."

2. According to Art. 2 Para. 3 (d) „food“ shall not include medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC. Among other directives relating to medicinal products, Directive 65/65/EEC has been integrated into Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ No L 311/67 of 28 November 2001) with its wording to the greatest possible extent unmodified.

3. According to Art.1 Para. 2 Sentence 2 of Directive 2001/83/EC medicinal products include:

"any substance or combination of substances which may be administered to human beings with a view ... to restoring, correcting or modifying physiological functions in human beings ..."

4. Food is administered to human beings also with a view to restoring, correcting or modifying physiological functions. The definition of „food supplements“ in Art. 2 of the Council Common Position of 31 December 2001 for adopting Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements (Interinstitutional Dossier 2000/0080 (COD)) can serve as an example in this connection. According to Directive 80/777/EEC of the Council on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters (OJ No L 299/26), the Member States may allow assertions like „stimulates digestion“ in the advertising of mineral water, indicating a definite influence on a physiological function.

5. Basically it is to be assumed that the macro and micro nutrients including minerals and trace elements and other components (secondary plant components) contained in foodstuffs restore, correct or modify human

physiological functions. The mere action of providing a thirsting person with water will result in an improvement of the electrolytic metabolism in the cells of the human body and thus in an improvement of physiological functions like concentration and efficiency.

6. As both foodstuffs and medicinal products hold the purpose of restoring, correcting and modifying human physiological functions, and the largely shapeless European definition of foodstuffs mentioned above does not provide criteria for delimitation, it is necessary to integrate such criteria into Directive 2001/83/EC, in order to provide a distinction between foodstuffs and medicinal products and further product categories, where appropriate, which is unambiguous for the EC citizen on the one hand and manageable for the state authorities and courts of the Member States on the other.

7. The systematically appropriate place for the integration of a qualified delimitation criterion should be Art. 1 No 2 b of the Review. It is proposed to amend Art. 1 No 2 b of Directive 2001/83/EC as follows:

" Any substance or combination of substances which may be administered to human beings with a view (...unmodified) to restoring, correcting or modifying physiological functions in human beings, as far as its medicinal-pharmacological effect outweighs other physiological effects."

8. Although the proposed term „medicinal-pharmacological qualities“ of a substance constitutes a criterion requiring interpretation, the characteristic feature „pharmacological“, however, has already been established as a delimitation criterion within the jurisdiction of the European Court of Justice and was of decisive importance in the policy-making decisions mentioned below (see: ECJ, Decision of 30 November 1983, Case 275/82 – van Bennekom, ECJ, Decision of 21 March 1991, Case C-369/88 – Delattre, ECJ, Decision of 16 April 1991, Case C-112/89 – Upjohn). This criterion is also used by both the Supreme Court and the superior courts within the German jurisdiction (see

BGH/Federal Supreme Court, ZLR 2000, 375 et seq.– L-Carnitin; KG/Berlin Court of Appeal, ZLR 2001, 576 et seq.). The integration of the adjective „medicinal“ defines in brief the main field of application of medicinal products (diseases and sufferings). Besides, the introduction of this demitiation criterion takes account of security needs: It helps to avoid that substances or preparations made substances with pharmacological efficacy on diseases can be placed on the EU market without any prior qualified market access control.

9. Pursuant to the proposal for a Directive, Art. 2 Para. 2 shall be revised in such a manner that a substance or a combination of substances fulfilling the definition of medicinal products, has to be subject to the provisions of the Directive, even if the substance or combination is also subject to other areas of application under Community law regulations.

10. In the proposal for a Directive, it is intended to give priority in the application of provisions of law relating to medicinal products to those products which are of an ambiguous nature regards their purpose or their composition and properties– even if their medicinal properties are only of secondary importance; this proposal would result in substantial distortions of the legal structures and would lead to a long-term shift in the boundaries between various branches of industry. It would for example amount to the fact that food supplements but also foodstuffs pursuant to Directive 89/398/EEC relating to foodstuffs for particular nutritional uses, which comply with their respective specific directives, would then be governed by the amended version of Directive 2001/83/EC. Similar alterations would occur regarding other borderline product categories of medicinal products, e.g. medical devices and cosmetics. This would constitute an unjustified infringement of the constitutionally protected freedom of trade for the food industry and the other industries mentioned above. The protection of consumers and of public health does not require such strict regulations as these interests have been taken account of within the framework of the respective regulations under Community law for the others product categories according to the nature of those products. The proposal for Art. 2 Para. 2 of the Directive should thus be deleted without replacement.

Should the European legislator intend to categorically hold to the revision according to the proposal for a Directive, it is proposed, pursuant to the aforementioned considerations, to integrate the delimitation criteria cited under No 7 at that position within the Directive.

11. In conclusion, it is requested that the determination and delimitation of basis definitions of Community law in the health sector, as regards the contents, more appropriately fulfil the legislative requirements of clearness, unambiguity and coherence (cf European Parliament, Council, Commission, Interinstitutional Agreement of 22 December 1998, Common Guideline for the Quality of Drafting of Community Legislation. Unfortunately it has not yet become visible that the European definitions of the bordering and partly overlapping product categories of the health sector, foodstuffs medicinal products, medical devices and cosmetics, will be classified and delimited according to a uniform more general legislative guiding idea. Ultimately it would be desirable to achieve more clearness and coherence particularly in the interest of the reliability in use as well as in planning and in legal matters.

Dr. Kunz-Hallstein
President

Dr. Loschelder
Secretary General