Area of focus: Product differentiation (last updated: 18.03.2015)

Position paper by FNMD e.V.

on *"Statement (No. 01/2014) by the Joint Expert Commission BVL/BfArM on the classification of certain medicinal mushroom products (here: Cordyceps sinensis, Coriolus versicolor and Ganoderma lucidum)"*

1 ABOUT FNMD E.V.

The Federation of Nutritional Mushroom Distributors e.V. (FNMD) was founded in Munich in summer 2015 by members from Germany, Austria and Switzerland and represents the joint interests of the distributors of nutritional mushroom products with regard to national and European institutions and legislative bodies. In particular, it is committed to bringing about a positive change to the legal framework conditions specifically for the use of more exotic mushrooms as dietary supplements and making their distribution throughout Europe legally compliant.

2 ON THE CONTENT OF THE STATEMENT BY THE JOINT EXPERT COMMISSION

The Joint Expert Commission BVL/BfArM (hereinafter "Joint Expert Commission"), which is intended to provide expert support to the German supervisory bodies in decisions concerning differentiation between medications and foodstuffs, has concerned itself in its first statement with the three medicinal mushroom types *Cordyceps sinensis (*hereinafter "Cordyceps"), *Coriolus versicolor (*hereinafter "Coriolus") and *Ganoderma lucidum* (hereinafter "Reishi"). The full text of the statement can be accessed **here**.

In this, the Joint Expert Commission supports the following arguments concerning preparations made from these three mushroom types, which are distributed as foodstuffs or dietary supplements:

Preparations made from these mushrooms exhibit a **medical purpose** and thus generate a **therapeutic consumer expectation** where **the mushrooms are identifiable as a significant component**. This applies to products that are brought onto the market **without additional presentation** (**without advertising, instructions for use**) as consumer expectations are significantly shaped by the many Internet articles that have a medicinal purpose. These products are thus to be considered as **drugs based on their presentation** in accordance with section 2 para. 1 No. 1 AMG due to their exclusive use and existing public perception as "natural remedies", even **without an explicit medicinal claim** and **while taking into account all further features** of the respective product on an individual basis.

3 ON THE CRITICISM OF THE STATEMENT BY THE EXPERT COMMISSION

The opinion of the Expert Commission regarding the classification of correctly labelled products without advertising on the packaging that are made from preparations of the three medicinal mushrooms Cordyceps, Coriolus and Reishi is **not legally justifiable**. It ignores the **settled case law by the ECJ, BGH, BVerwG and the relevant Higher Administrative Courts (Oberverwaltungsgericht) (e.g. OVG NRW, VGH Baden-Württemberg, OVG Lüneburg) on the classification of products as drugs based on their presentation**. In detail:

3.1 In accordance with settled case law, **a product only fulfils** the prerequisite as a drug based on presentation if it either (itself) is expressly described as such a product or otherwise intentionally creates the impression among consumers, even just logically, that it must have the respective properties **in view of its presentation**[1], e.g. because **similarity between the product** and a drug is sought for reasons of business policy.[2]

3.2 According to the case law of the ECJ, a product can be considered a drug based on presentation if it sufficiently resembles a drug as a result of its form and its presentation and **if, in particular, its packaging (!) and its package insert (!) include reference to research by pharmaceutical laboratories, to methods or substances developed by doctors, or to certain certificates of doctors to the benefit of properties of the product.**[3] The external form of a product (e.g. the capsule or tablet form typical of dietary supplements) is **not in itself a decisive indicator.**[4]

3.3 Furthermore, in accordance with settled case law in Germany, it always depends on the **overall impression**[5] that the averagely informed customer base gains

- From the **product presentation** (e.g. label, promotional claim),
- From the **overall appearance of the product** (including material composition) and
- Based on preconditioning of their consumer understanding (e.g. due to the **product environment**, the opinion of nutritional and pharmaceutical science)[6]

3.4 As the BGH regularly emphasises, a well-informed average consumer will generally not assume that a product offered as a dietary supplement is actually a drug if it has **no pharmacological effects** at the recommended dosage.[7] To have the "appearance" of a drug, [8]it is also not sufficient that a product is attributed with general health-related effects according to the generally accepted view. Instead, a product is only "presented" as a drug if it gives the impression on **the label**, **with a statement on the packaging** or **in another**

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[1] cf. ECJ, judgment of 30.11.1983, case 227/82 – van Bennekom; BVerwG, judgment of 26.05.2009, reference 3 C 5. 09, recital 21; ECJ, judgment of 15.11.2007 - C-319/05, recital 46 – garlic capsules
[2] cf. ECJ, judgment of 21.03.1991, case C-60/89, recital 24 - Monteil and Samanni
[3] ECJ, judgment of 21st March 1991, case C-369/88, recital 41 - Delattre
[4] cf. ECJ, judgment of 15.11.2007, case C-319/05, recital 53 – garlic capsules
[5]The Joint Expert Commission also does not ignore this in the statement Medicinal Mushrooms p. 10 with citations
[6] according to BGH, GRUR 2003, 631, 632 – L-Glutamine; OLG Cologne, LMuR 2008, 100, 101 – Donaprevent
[7] cf. BGH, judgments of 10th February 2000, reference: I ZR 97/98, ZLR 2000, 375 = LRE 38, 157 and BGH, judgment of 11th July 2002, reference: I ZR 273/99 – ZLR 2002, 660 = LRE 44, 253
[8] Rennert, NVwZ 2008, 1179

manner that it possesses properties that cure or prevent human illnesses.[9] The ECJ has otherwise already expressly ruled that the **mere reproduction of the photograph of a plant** (or, accordingly, also a mushroom) on the packaging of a product is not sufficient to give an averagely informed consumer the confidence that a drug normally generates.[10]

3.5 On the German (and European) market itself, products made from the three medicinal mushrooms Coriolus, Cordyceps and Reishi **have so far been exclusively distributed as dietary supplements or foodstuffs**. At no time were these products sold as a drug, nor may they be sold as such in the future for functional reasons in light of the lack of scientific evidence so far of what is referred to as a pharmacological effect (including in the view of the Joint Expert Commission). This circumstance alone has so far significantly influenced general public perception for decades. Corresponding medicinal mushroom products are **not known as drugs** by consumers. There are also no products made from Coriolus, Cordyceps or Reishi that are to be approved in accordance with section 109a AMG, let alone traditional plant-derived drugs registered in accordance with 39a AMG. On what basis the Joint Expert Commission thus wishes to derive the exclusive use or public perception as a "natural remedy" remains its secret. If the Joint Expert Commission advocates the claim that the BGH has concerned itself with health-related information for foodstuffs with regard to medicinal mushrooms but not how to distinguish them from drugs[11], then this once again highlights that drug properties have so far never been discussed or accepted for such products.

3.6 It should be noted that there are also many plants that can be sold either as a drug or a foodstuff based on dosage. However, according to the case law of the ECJ or BGH/BVerwG, this is not sufficient to justify the unquestionable classification of such plants or a product containing their preparations as a drug.[12] Certainly, it is not possible to derive from this a general public perception that justifies this very classification for a product that is generally considered **functionally unsuitable as a drug**.

3.7 In addition, the corresponding medicinal mushroom products are **not typical of drugs based on their material composition**, especially as they **do not differ significantly from the composition of other (edible) mushrooms** in their specific analytical composition.[13] The respective medicinal mushrooms are also generally **not used unprocessed**, but either ground as powders or processed into an (aqueous) extract. Both processing forms can be enjoyed and are **palatable**. To this extent, the **offered forms exclusively encountered on the market** for the corresponding medicinal mushroom products resemble those of herbs or tea plants.

3.8 Not every "raw material" is "enjoyable" in an unprocessed state. The Joint Expert Commission also overlooks this. For instance, no one would consume a raw cinnamon stick or a vanilla pod in this no one. Potatoes can even be poisonous when consumed in a raw state and it is not only minced meat that must be heated through well before consumption for hygiene

[9] cf. ECJ, judgment of 15.11.2007, case C-319/05, recital 45 and 64
[10] cf. ECJ, judgment of 15.11.2007, case C-319/05, recital 50 – garlic capsules
[11] cf. ECJ, judgment of 15.11.2007, case C-319/05, recital 49
[12] Cf. ECJ, judgment of 15.11.2007, case C-319/05, recital 50 – garlic capsules; BGH, judgment of 14.01.2010, reference: I ZR 138/07- cinnamon capsules; BGH, judgment of 01.07.2010 - I ZR 19/08; BVerwG, judgment of 26.5.2009 - 3 C 5/09 – red fermented rice
[13] Evidence of this at Döll, Vitalpilze für ein gesundes Leben, 2012, p. 25 f.; Zhou et al, Int J Med Mushrooms. 2015;17(1):43-9; Kalač, A review of chemical composition and nutritional value of wild-growing and cultivated mushrooms, J Sci Food Agric. 2013 Jan;93(2):209-18; Ulziijargal/Mau, Nutrient compositions of culinary-medicinal mushroom fruiting bodies and mycelia, Int J Med Mushrooms. 2011;13(4):343-9.

reasons. Not least because of this, the European definition of food in Art. 2 of Regulation No 178/2002 also recognises that "'food' (or 'foodstuff') means any substance or product, whether **processed**, partially processed **or** unprocessed, intended to be, or reasonably expected to be ingested by humans". Ergo, the decision is always to be based on the food offered for consumption. The OLG Munich previously also explained this as follows:[14]

> "In accordance with section 11 para. 2 No. 1 of the German Food and Feed Code (LFGB), it is prohibited to bring food, other than that subject to the ban of Art. 14 para. 1 in conjunction with para. 2 lit. b) of the Regulation (EC) No. 178/2002 of 28.1.2002 (OJ EC L 031, p. 1), that is unfit for human consumption onto the market. It is thus necessary that the **preparations brought onto the market** by the defendant (!) are unsuitable for consumption. **Whether the mushrooms that serve as the initial substances are themselves suitable for consumption is of no importance, contrary to the opinion of the district court.** As the properties on which the district court based the mushrooms' unsuitability for consumption with reference to expert evidence, i.e. the mushrooms' leathery or cork-like consistency, **do not apply to the preparations offered by the defendant**, they cannot justify their **unsuitability for marketing**."

3.9 However, where preparations from the three medicinal mushrooms are unlawfully advertised with reference to illness on the **websites of independent third parties**, to which the respective medicinal mushroom distributor neither makes reference nor over which he has an influence, this must **not be attributed** to the distributor. Accordingly, the information disseminated about a product by a third party of his own accord in complete legal and actual independence from the manufacturer or distributor **cannot be attributed** to the manufacturer or distributor of a product, as the term "presentation" always **inevitably refers solely to the product presentation specified by the manufacturer.**[15] In this regard, the ECJ has already stated expressly in the aforementioned judgment "Ter Voort":

> "In contrast, the dissemination of information about the product, in particular about its therapeutic or prophylactic properties, **by a third party acting on his own initiative and completely independently, de jure and de facto, of the manufacturer or the seller** does **not** constitute by itself a "presentation" within the meaning of the directive, since it does not disclose an intention on the part of the manufacturer or the seller to market the product as a medicinal product."

It also states:

> "In the event that the **publication is disseminated by a third partly independently of the sale of the product**, the national court's questions refer to Article 10 of the European Convention on Human Rights concerning freedom of expression. (…) **Freedom of expression**, as embodied in Article 10 of the European Convention on Human Rights, is among the general principles of law the observance of which is ensured by the Court (judgment in Elliniki Radiophonia Tileorassi AE, cited above, paragraph 44). But the **freedom of expression of a third party** who, in accordance with that which has been stated in paragraph 31 above, acts completely

[14] cf. judgment of 21.01.2010, reference: 29 U 3012/09

[15] cf. ECJ, case C-219/91, recital 31, LMRR 1992, 54 – Ter Voort; Zipfel/Rathke, Food Law, Regulation 178/2002, Art. 2, recital 67; VGH Mannheim, LMRR 2010, 6 ff.; OVG NRW, ZLR 2006, 339, 345 – "OPC"

> independently of the manufacturer or the seller is **not affected, directly or indirectly**, by the application of Directive 65/65. **The presentation made by such a third party of a product has no bearing on the definition of that product in accordance with the directive**."

3.10 Another interpretation would namely result in a medicinal mushroom product advertised in such a manner losing its **marketability** without the affected distributor being able to react directly to this.[16] It is self-evident that this cannot be lawful or constitutional (infringement against Art. 12, 14 German Basic Law). Furthermore, in such a case, it is even questioned whether the affected manufacturer or distributor of a product unlawfully advertised by a third party is himself actually obliged to strive to ensure that such information from third parties is prohibited or whether this would not already be disproportionate and unacceptable.[17]

3.11 However, the view represented by the Joint Expert Commission also ignores the fact that not every therapeutic advertisement of products also justifies classification as a drug based on presentation. Otherwise, for instance, the ban on the illness-related advertising of foods (now Art. 7 para. 3 food information law) would be redundant. Considering that the legislator already specifies a clear legislative instrument that should be applied **predominantly for reasons of proportionality**, such information certainly cannot make a product a drug based on presentation.[18] Instead, it would be necessary for the corresponding product to **otherwise significantly** present itself as a drug, particularly on the **display packaging itself**, which is not the case here. The OVG Lower Saxony has also already associated itself with this opinion and stated as follows:[19]

> "From the existence of these provisions, it can be deduced, in the view of the Senate, that at least not every single promotional statement in the wider context of the product that, as an individual criterion, "goes beyond" the line of distinction as a drug may immediately also justify a property as a drug based on presentation. If this were the case, the scope of application of the stated provisions on food law, particularly section 12 para. 1 No. 1 of the German Food and Feed Code (LFGB) based on directive specifications, would be significantly restricted (...)
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> The references that can be found on the Internet concerning the use of (...) as a remedy in traditional Chinese medicine (TCM) are thus not relevant to the decision. Even if one wishes to see this differently, the statements that can be found on the Internet regarding (...) do not result in an overall image of a drug based on presentation for the product (...). If one were to actually consider liability for the statements of third parties possible, in the view of the Senate, the drug property of the products in question **would have to be obvious**."

3.12 The OVG Lower Saxony had also already stated the following in a case regarding the differentiation of "mushroom powders":[20]

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[16] cf. here also BVerwG, judgment of 25.07.2007, reference: 3 C 22/06, ZLR 2008, p. 80, recital 26
[17] cf. VGH Mannheim, LMRR 2010, 6 ff.
[18] explicitly BGH, GRUR 2003, 631, 632 f. – L-Glutamine
[19] Judgment of 03.02.2011, reference: 13 LC 92/09 – Red Rice capsules do not qualify as a drug based on presentation

[20] cf. ruling of 08.07.2004, 11 ME 12/04

> “There are doubts whether the defendant in this connection can refer to the publications from the Internet submitted by her, **in which other providers of comparable mushroom products** advertise with reference to their healing effects when combatting cancer and other cancers. The consumers are addressed directly here, while the plaintiff exclusively supplies her information materials to the stated expert circles at their request and no longer wishes to use the brochures objected to by the defendant in their current form. At the same time, competing products on the market can certainly show distinctions in their presentation and design, **so that accountability for statements by third parties can by no means be assumed in this area.”**

The Senate otherwise indicates in this connection (here related to the separate, exclusive expert circles with regard to advertising by the company affected):

> “The defendant deduces the drug property of the questionable Myko San products above all from the content of the brochure "SP TM Holistische Therapie” published by the plaintiff. In this, not only are general health-related statements made concerning mycotherapy (treatment with mushrooms), but the healing effects of the individual Myko San products on certain illnesses, such as cancer, stroke, heart attack, are clearly highlighted. The appearance of a drug is created due to this highlighted naming of indications. The administrative court has already rightly indicated this. However, it should be qualified by the fact that, according to credible information from the plaintiff, these brochures are not intended for end users, but are exclusively provided to doctors, pharmacists, alternative practitioners and nutritionists on request. Apart from this, the plaintiff (cf. her letter dated 15.9.2003 to the defendant) has now herself accepted that “certain improvements must be made so as not to create a monocausal therapeutic effect” in her information brochures. As confirmed by a file note, the attorney of record for the plaintiff additionally offered to “massively reduce” the health-related claims in a telephone call to the defendant on 3.11.2003. **In view of this, for reasons of proportionality, the defendant would at least have been able to consider whether setting conditions for the promotion of the contested products would have sufficed as a less burdensome measure instead of a prohibition of sale.** (….)."

4 CONCLUSIONS

In accordance with settled case law, a product is not **a drug based on presentation per se** because it contains mushroom types such as Coriolus, Cordyceps or Reishi, which can regularly only be consumed following processing and which are above all offered for dietary supplementation purposes based on their nutritional profile, which is otherwise comparable to that of edible mushrooms. These may be unknown to the average consumer, as they have certainly not yet achieved the level of awareness of button mushrooms or chanterelle mushrooms. However, consequently, the consumer does not yet inevitably classify such mushrooms as drugs, especially if these have so far exclusively been presented and distributed as foodstuffs/dietary supplements and are not advertised as a drug by the manufacturer/distributor himself.