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Dietary Supplements from Medicinal Mushrooms: Diversity of Types and Variety of Regulations

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ABSTRACT

Many pharmaceutical substances with potent and unique health-enhancing properties were isolated recently from medicinal mushrooms and distributed worldwide. Many of them are not strictly pharmaceutical products (‘real’ medicines), but rather represent a novel class of dietary supplements (DSs) or “nutraceuticals.” They are also known as functional or designer foods, nutraceuticals, phytochemicals, mycochemicals, and biochemopreventatives. Mushroom-based DSs are products from either the mycelia or the fruiting bodies of mushrooms, and are consumed in the form of capsules, tablets, or extracts, and have potential therapeutic effects. We describe here the diversity of different DSs available today on a world market. Most of mushroom products of that sort are dried powders and extracts from naturally growing or commercially cultivated mushroom fruiting bodies, or dried or extracted biomass of mycelium grown in a solid state or in submerged culture. The clear advantages of using mushroom-based DSs in regard to safety (as opposed to herbal preparations) are: (1) The overwhelming majority of mushrooms used for production of DSs are cultivated commercially (and not gathered in the wild). This provides very good chances of proper identification, and for pure and unadulterated products. In many cases it also means genetic uniformity. (2) Mushrooms are easily propagated vegetatively, and thus keep to one clone. The mycelium can be stored for a long time, and the genetic and biochemical consistency may be checked after a considerable period of time. (3) The main advantage, in our opinion, is that many mushrooms that cannot produce fruiting bodies artificially are capable of growing in the form of mycelial biomass in submerged cultures. The problem is that DSs made from mushrooms are highly diverse, and there are currently no standard protocols for ensuring their product quality. There is a serious need for critical analysis, improved quality and legal control, which are essential both to increasing and maintaining consumer confidence, and to meeting the current and future standards set by the regulatory authorities. The usual criticism of DSs concerns standardization, that is, preparing herbs or mushrooms in a way that ensures the consistency and predictability of chemical composition and minimizes the deviations between different batches. This depends on numerous factors including cultivation conditions, composition of substrates, purity of ingredients, stability of active compounds, storage, etc. The regulations of DSs from herbs and mushrooms in a number of major industrial countries are analyzed. In 1991, the World Health Organization (WHO) published its “Guidelines for the assessment of herbal medicines.” Regulatory steps taken by most developed countries are usually in accordance with those guidelines of the WHO. The present regulations of the United States (carried out by the Federal Food and Drug Administration (FDA) treat DS as a separate entity. After passage of the Dietary Supplements Health and Education Act of 1994, the FDA has issued a number of regulations that do not require the manufacturers of DSs to prove their effects and safety in very lengthy and expensive procedures of drug approval. On January 6, 2000, the FDA issued its final regulations on structure/function (SF) claims for DS under the DSHEA of 1994. In these rules, a significant shift is made in relation to SF claims for over-the-counter drugs, including DS. In particular, the FDA has enlarged the range of SF claims by approving with the comments of the American Herbal Products Association of Nutraceuticals (AHPA) and thedietary supplements from medicinal mushrooms: diversity of types and variety of regulations / S.P. Wasser, E. Nevo, D. Sokolov [et al.] // International Journal of Medicinal Mushrooms. –2000. –Vol.2. –P. 1–19. To determine types of nerve cell receptors that were activated during extract actions and showed some inhibition as a basic response, antagonists ofvarious types of synaptic transmission were applied. The y-aminobutyric acid (GABA) receptor antagonist bicuculline blocked the extract actions partially or completely in two out of three cases.