

## **Dietary Supplements from Medicinal Mushrooms: How We Are Going to Ensure Their Quality and Safety**

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The concept of “functional foods” encompasses the foods that are eaten not only to satisfy functional dietary needs but also to elicit additional health effects. Most mushroom-derived preparations and substances find their use not as pharmaceuticals (“real” medicines) but as a novel class of dietary supplements (DSs) or “nutriceuticals” that fall very well into the concept of functional foods. Mushroom-based DSs are products from either the mycelia or the fruiting bodies of mushrooms; are consumed in the form of capsules, tablets, or extracts; and have potential therapeutic effects. Regular intake of mushroom DSs enhances the immune responses of the human body, thereby increasing resistance to disease, and in some cases causing regression of a disease state.

The diversity of different DSs available today in the world market is described. The various questions and problems of their safety are discussed both from scientific and regulatory points of view. First, we analyze the regulatory laws in relation to DS from herbs and mushrooms in major industrial countries. In essence, they follow the “Guidelines for the Assessment of Herbal Medicines” of the World Health Organization published in 1991. Mostly they treat DSs as a separate entity, distinct from foods and from drugs.

The present regulations of the United States follow the Dietary Supplements Health and Education Act of 1994. This does not require the manufacturers of DSs to prove their effects and safety in very long and expensive drug approval procedures. Recently they were amended in an important manner, when on January 6, 2000, the

FDA issued its final regulations on structure/function claims for DSs under the DSHEA of 1994. Many claims are permitted now for DS description and advertising, which are not disease claims, but are instead claims that deal with the structure or function of the body. This became possible with a change of disease definition. Previously, the definition of disease was formulated as “any deviation from, impairment of, or interruption of the normal structure or function . . .”, and now the FDA uses the definition “damage to an organ, structure, or system . . .” By this alteration of the definition, the FDA automatically reduces the range or number of the health claims for DSs that should be considered drugs.

A more arbitrary system of DS regulation has been developed in Germany. Commission E, a special organization for regulating natural products, actively collects information on them and evaluates their safety and efficacy. These evaluations are published in the form of brief monographs that either approve or disapprove the particular preparation for over-the-counter sale and use.

One of the major current problems is that DSs made from mushrooms are highly diverse, and there are currently no standard protocols for ensuring their product quality. We describe advantages of growing fungal material for DSs in the form of mycelial biomass in liquid culture. Such biotechnology provides many benefits, especially with regards to the question of safety and standardization. We provide examples of successful experiments in producing DSs from submerged mycelia.