Food Supplements: Under Higher Scrutiny Than Ever

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Food supplements — vitamins, minerals, botanicals, etc. compacted into a single pill, powder, or other concentrated form — are en vogue. After a long delay, manufacturers are now zooming in on the specific needs of female consumers. But the legal environment surrounding food supplements in the EU is a difficult one to navigate, and manufacturers and importers (i.e., food business operators or FBOs) must consider various aspects when entering the markets of EU Member States and Switzerland.

Food supplements form part of many consumers' way of life

The Covid-19 pandemic has raised or intensified the need of many consumers to pay attention to the extra support for the human body that food supplements promise. Around half of Germans buy food supplements regularly. It is similar for France and Austria. In Switzerland, one-third of the population consumes at least one dietary supplement. Women supplement far more often than men, which FBOs have realized. Thus, supplements tailored to women's needs are now entering the market at a more rapid pace.

FBOs that wish to avoid negative publicity must navigate a sea of applicable law

The media have made food supplements a seemingly constant topic of discussion. In Germany, the magazine *Der Spiegel* published a cover story in June 2023 on food supplements, criticizing the limited regulatory oversight over these "quasi-medicines." And both large news channels as well as consumer protection agencies regularly analyze specific food supplements and their health claims. Governments and competition and consumer protection agencies are more alert and active than ever in their quest to ensure safe products and fair advertising through unfair competition rules.

FBOs must navigate various laws. To be compliant with the regulatory requirements and to avoid being in the media spotlight, FBOs should in particular consider the following three main considerations when they first enter the EU or Swiss market.

Is the product correctly classified? In many EU jurisdictions, FBOs must notify the relevant competent authority prior to placing a food supplement on the market. However, authorities typically do not confirm or deny the classification as a food supplement. A marketing authorization or a conformity assessment, as for medicinal products, is not required. The food supplement is

therefore subject to self-regulation, which means that the FBO is responsible for ensuring that its food supplement is safe and that all relevant provisions of food legislation are met. In the past couple of years, there have been various cases where FBOs had incorrectly assumed that what could be a supplement elsewhere (e.g., in the U.S.) would also qualify as a supplement in the EU or Switzerland — to have, for instance, the highest federal administrative court in Germany (*Bundesverwaltungsgericht, Decision of 24 August 2022, reference 3 B 36.21*) rule that indeed the supplement in question had too high a concentration of a certain substance to be classified as a food supplement. Due to its pharmacological effect, the product was to be reclassified as a medicinal product, requiring withdrawal from the market and obtaining of a marketing authorization as a medicinal product. The Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Food Safety and Veterinary Office (FSVO) have developed criteria for the classification of products and published a respective guide, "Criteria for the delimitation between medicaments, food-stuffs and utility articles."

Is my food supplement safe? Food supplements are subject to general principles and requirements of food law laid down in Regulation (EC) No 178/2002 for the EU markets and the respective Swiss regulation for Switzerland (Verordnung des EDI vom 16. Dezember 2016 über Nahrungsergänzungsmittel (VNem), SR 817.022.14. This includes, in particular, that the food supplement must be "safe." For it to be safe, the food supplement must generally comply with all EU food law, and further all available (peer-reviewed) scientific evidence regarding its substances has to be considered. Certain substances may not be used in food supplements due to toxicological concerns. FBOs must, in particular, review Member State-specific risk assessments, such as those of the German Federal Institute for Risk Assessment, to avoid allegations that their supplements are not safe. Unsafe products must not be placed on the market or might have to be withdrawn or recalled. Importantly, placing a food supplement that is already on the market elsewhere on the market in the EU or Switzerland oftentimes requires reformulation of the product. In addition, specific rules exist, *inter alia*, with respect to maximum residue levels, hygiene standards in manufacturing processes, and food contact material.

Is my marketing material in line with Health Claims Regulation? In the EU, the so-called EU Register on Health Claims, available here, lists all authorized health claims and their conditions and restrictions of use. The entries in the EU Register reflect European Food Safety Authority (EFSA) assessments of available scientific evidence. FBOs cannot make claims that are not listed (or that are listed as unapproved). For example, claims such as "*copper contributes to the normal function of the immune system*" are authorized. However, for lack of scientific evidence the EFSA has not authorized the claim that caffeinated carbohydrate-containing energy drinks "*enhance mental performance*" or give "*an energy boost.*" Notably, the scientific review of

certain botanicals has been pending with EFSA for years, and FBOs can make these "on hold" health claims as long as certain requirements are met, including, in particular, that the "*beneficial nutritional or physiological effect (...) has been established by generally accepted scientific evidence*". In Switzerland, specific labeling regulations for food supplements (e.g., warnings) are specified. Health claims may be used if they are explicitly recognized or if they are approved by the FSVO.

In view of the initially mentioned increasing media attention and heightened consumer awareness, noncompliances are easily visible and can cause significant damage to a company's reputation and commercial strategy. FBOs are well advised, in particular, to review their portfolio to ensure all products marketed as food supplements indeed classify as such and to ensure the health claims they make are authorized and backed by scientific evidence.