

EU: Proposed safety measures for 'other substances' and botanicals

The European Commission (EC) has recently published a working paper on the draft implementing regulation establishing rules for the application of Article 8 of Regulation EC No 1925/2006 on the Addition of Nutrients to Foods. The EC is now seeking comments from stakeholders on how the proposals in the draft will work in practice.

The importance of the document for the supplement industry is that Article 8 of the Regulation provides a procedure to prohibit, restrict or place under Community scrutiny substances other than vitamins or minerals, or ingredients containing substances other than vitamins or minerals that are added to foods or used in their manufacture.

Key concerns for the supplement industry are:

- The proposed exclusion of fortified foods and supplements from consideration as part of the "normal" dietary intake that will be considered in the assessment of whether a substance greatly exceeds the normal intake and can thus should be subject to scrutiny. The proposed exclusion would allow any substance used in supplements but not in the normal diet to be subject to Community scrutiny - for instance, glucosamine.
- The definition of "greatly exceeding" average intake by reference to three times the average intake as demonstrated by data in at least one Member State. This proposal greatly oversimplifies the complexity of the European diet where there are many wide variations of intake of particular substances, making it well-nigh impossible to determine a true average intake.
- The requirement that submissions from companies to establish the safety of botanical substances under Community scrutiny be based on the European Food Safety Authority (EFSA) Guidance on Botanical Safety and its accompanying Compendium. The EFSA Guidance recommends the submission of data (toxicological and other) that is not currently available for the majority of botanicals and ignores the fact that many of the safety concerns can be addressed through relevant quality control and preparation measures which negate the need to undertake further studies.

Source: EBF, EHPM, ERNA