

Use of chondroitin sulphate in food supplements

BfR Opinion No. 031/2007, 15 June 2007

Chondroitin sulphate is a natural component of cartilage and other body tissue. This substance is not authorised in Germany as a medicinal product for oral administration. However, chondroitin sulphate is to be found in numerous products that are on sale as food supplements. The Federal Institute for Risk Assessment (BfR) was asked to undertake a health assessment of the use of isolated chondroitin sulphate in foods (food supplements) in amounts at which no pharmacological (medicinal/therapeutic) effect is to be expected.

Food supplements are foods. Unlike medicinal products they do not, in principle, require marketing authorisation. They must be safe and not harmful to health. Their ingredients should not have any pharmacological effects. The manufacturer is responsible for compliance with all statutory food provisions. It is the task of the official food control authorities of the federal *Laender* to decide on the classification of preparations containing chondroitin sulphate as medicinal products or foods. This also applies to the question whether chondroitin sulphate is a substance that can be equated with additives and, therefore, requires marketing authorisation.

As, up to now, no oral dose could be established by the national drug authority (Federal Institute for Drugs and Medical Devices - BfArM) upwards of which the therapeutic (pharmacological) efficacy of a substance can be assumed, BfR based its assessment of the use of isolated chondroitin sulphate in food supplements on intakes of between 800 and 1200 milligram per day. BfR expressly points out that no statement is made about possible pharmacological effects, and that this is not a recommendation to admix amounts of this kind as daily intakes to food supplements/foods. The official food control authorities in the federal *Laender* decide on the extent to which chondroitin sulphate products require marketing authorisation and whether and in what amounts the use of chondroitin sulphate is, in principle, possible in food supplements.

The health assessment of chondroitin sulphate in the above-mentioned amounts (800-1200 mg/day) comes with major uncertainties because of the sparse data situation. The available data do not indicate that in the case of healthy and non-pregnant adults serious health risks are to be expected. Because of the missing data and existing uncertainties, however, protective measures are recommended on precautionary grounds for pregnant and breast-feeding women, children, adolescents and individuals who are on anti-coagulant medication. These groups of individuals should be advised against consuming products of this kind by the corresponding wording on the label.

Products containing chondroitin sulphate produced from fish tissue should carry an indication on the label of the source of the chondroitin sulphate in order to protect people who are allergic to fish protein.

The full version of the BfR Opinion in German is available on http://www.bfr.bund.de/cm/208/verwendung_von_chondroitinsulfat_in_nahrungsergaenzungsmitteln.pdf