

Mr. Robert Andrews

Hygieia Health Company
Bldg 54, 5/F
No. 1089 N. Qinzhou Rd. (N)
Shanghai 200233
China

August 13, 2008

Dear Mr. Andrews,

I am contacting you in regard to the application by Hygieia Health Company Ltd. for a substantial equivalence opinion relating to fungal glucosamine sulphate KCL in accordance with *Article 3.4.* of the novel food Regulation (EC No. 258/97). The proposal is to use glucosamine sulphate KCL produced from *Aspergillus niger* as an ingredient in food supplements based on its substantial equivalence to food supplements already on the EU market containing a shellfish counterpart.

Based on the information provided, the Food Safety Authority of Ireland (FSAI) is of the opinion that glucosamine sulphate KCL produced by Hygieia Health Company from *Aspergillus niger* is substantially equivalent to that from shellfish in terms of its composition, nutritional value, metabolism, intended use and level of undesirable substances. This opinion is subject to the fungal ingredient being produced to the specifications outlined in the application, its use being limited to food supplements in line with Directive 2002/46/EC and adherence to the proposed labelling regime.

Before placing this ingredient on the market you should notify the European Commission, in line with *Article 5.* of the novel food Regulation. In order to avoid confusion it is recommended that you await a response from the Commission prior to placing the product on the market.

Commission contact details:

Mr Andreas Klepsch
European Commission
DG SANCO
Rue de la Loi 200
B-1049, Brussels
Belgium

Regards,

Dr. Pat O'Mahony
Chief Specialist, Biotechnology

SUBSTANTIAL EQUIVALENCE OPINION

Glucosamine Sulphate KCL

The FSAI received an application dated May 22nd 2008, from Hygieia Health Company Ltd. requesting an opinion on the substantial equivalence of a fungal glucosamine sulphate KCL to a shellfish counterpart that is already on the EU market. The FSAI has reviewed the information provided on the ingredient from both sources particularly with respect to composition, nutritional value, metabolism, intended use and level of undesirable substances.

Composition

Glucosamine is a naturally occurring amino sugar derived from glucose that forms an essential intermediate in the energy metabolism of multi-cellular organisms. Glucosamine has been derived from fish by-products (e.g. crustacean shell) since the mid-20th century, although reports of its potential therapeutic value have resulted in an increase in demand.

The structure of glucosamine sulphate KCL from both *Aspergillus niger* and shellfish was shown by the applicant to be almost identical through infrared absorption, ¹H NMR, ¹³C NMR and mass spectrum. The production process for the shellfish and fungal products are the same except for the starting material, resulting in a white crystalline powder of greater than 98% purity. The starting material for the fungal product is *Aspergillus niger* biomass, a by-product of citric acid production. The results of tests on three batches of glucosamine sulphate KCL from both sources reveal a very similar composition.

Nutritional Value and Metabolism

Glucosamine sulphate KCL is a single molecule and the applicant demonstrates (Table 1.) that the source of the raw material (shellfish or fungal) has little or no impact on the final nutritional value of the ingredient.

Intended Use

Glucosamine sulphate KCL from *Aspergillus niger* is to be used in food supplements only, similar to the existing shellfish counterpart. The applicant notes that there is no established formal RDI for glucosamine sulphate KCL and while recommendations vary, the most widely accepted intake level is up to 1,500mg per day.

Levels of Undesirable Substances

The source of raw material for the production of fungal glucosamine sulphate KCL is *Aspergillus niger* biomass, a by-product of the citric acid production process. *Aspergillus niger* is not known to be toxic or pathogenic for humans and the release specifications for glucosamine sulphate KCL from both the shellfish and fungal sources are similar. Certain strains of *Aspergillus niger* however, have been known to

produce Ochratoxin-A, but additional tests carried out by the applicant yielded satisfactory results. The tests for microbial contaminants yielded identical results for product derived from both sources.

Labelling

The applicant provided a copy of the proposed label which includes the words “Derived from *A. niger*” prominently displayed, among other details.