SUBSTANTIAL EQUIVALENCE OPINION

Nantong Vegan Glucosamine HCL

In February of 2015, the Food Safety Authority of Ireland (FSAI) received an application from the Healy Group in Ireland for an opinion on the substantial equivalence of glucosamine HCL (Trade name: Vegan Glucosamine HCL) derived from the fungus *Aspergillus niger*. The applicant claims their novel ingredient is substantially equivalent to a fungal glucosamine HCL authorised for the EU market through a substantial equivalence opinion from the UK addressed to Cargill Acidulants in August 2004.

Glucosamine is a naturally occurring amino sugar derived from glucose and 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 and reports of its potential therapeutic value have resulted in increased demand at a global level. In 2004, an Opinion from the UK authorities established that the Cargill fungal glucosamine HCL was substantially equivalent to that derived from shellfish as long as it was also used in food supplements and foods for particular nutritional uses (PARNUTS) in accordance with Directives 2002/46/EC and 89/398/EEC.

Nantong Vegan Glucosamine HCL is manufactured in China to good manufacturing practices standards and in accordance with HACCP principles. It has been marketed in the USA as a food supplement for a number of years and has a minimum shelf life of two years.

Composition

The production process for Vegan Glucosamine HCL is very similar to that for the Cargill product. Acid hydrolysis of *Aspergillus niger* biomass, a by-product of citric acid production followed by a concentration step results in a crude glucosamine HCL intermediate. This intermediate product is further concentrated and purified to yield a crystalline free flowing powder of >98% purity with a shelf life of at least two years. By simultaneous analysis with the Cargill product, the applicant demonstrates the similarity of both ingredients with respect to glucosamine HCL content, fat, carbohydrate and protein which is not detected at any significant level.

Nutritional Value and Metabolism

Glucosamine HCL is a single molecule and its nutritional value and metabolism does not vary with the source of the raw production material. The applicant provides a table of nutritional data that shows the levels of fat, protein, carbohydrate, calories etc. are almost identical for glucosamine HCL from both sources.

Intended Use

The applicant intends to use their Vegan Glucosamine HCL in food supplements and foods for particular nutritional uses (PARNUTS) at the same levels currently used in the EU, similar to the authorised Cargill counterpart.

Levels of Undesirable Substances

A. niger is not known to be toxic or pathogenic for humans. The source of raw material for the production of the novel ingredient is *A. niger* biomass, a by-product of the citric acid production process. The applicant provides analytical results for the presence of the heavy metals arsenic, cadmium lead and mercury, as well as aflatoxins and microorganisms including *E. coli*, *Salmonella*, yeasts and moulds.

Labelling

The applicant plans to label their product "non-Shellfish Glucosamine HCL" and/or "Vegan Glucosamine HCL". To be in line with the authorised comparator, product labels will also include information on the source displayed in a footnote: "from the fungus *Aspergillus niger*".

Conclusions

The FSAI is satisfied from the information provided by the applicant that the glucosamine HCL to be marketed by the Healy Group is substantially equivalent to that authorised in 2004 to Cargill in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances. The product will be labelled "non-Shellfish Glucosamine HCL" and/or "Vegan Glucosamine HCL" and will be used in PARNUTS and food supplements at dose levels similar to the Cargill comparator. Products containing the novel ingredient will indicate the source of the ingredient in a footnote: "from the fungus *Aspergillus niger*".