

SUBSTANTIAL EQUIVALENCE OPINION

Goldcell[®] Beta-Glucan

The Food Safety Authority of Ireland (FSAI) received an application in June of 2013 from Açucareira Quata S.A. of Brazil for an opinion on the substantial equivalence of its insoluble yeast beta-glucans (Goldcell[®] Beta-Glucan) to the same ingredient previously authorised to Biothera Inc. through Commission Implementing Decision 2011/762/EU. The EU-authorised insoluble beta-glucans from Biothera Inc. is extracted and purified from the cell walls of the yeast *Saccharomyces cerevisiae* (more commonly known as brewers/baker's yeast). The Goldcell[®] Beta-Glucan is also extracted and purified from *S. Cerevisiae* cell walls, with only minor differences in the production process that do not significantly alter the characteristics or quality of the final product compared to that from Biothera Inc. The Goldcell[®] Beta-Glucan will be designated as “yeast (*Saccharomyces cerevisiae*) beta-glucans” similar to the authorised equivalent from Biothera Inc. The applicant considers the ingredient to be novel and fall within the category of “foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae” as set out in *Article 1.2(d)* of the novel food Regulation EC No. 258/97.

Composition

The beta-glucans from both sources is derived from the cell walls of *S. cerevisiae* using very similar production and purification processes. A compositional comparison identifies only a few insignificant differences, some of which are possibly related to the different analytical techniques used. The applicant demonstrates that the composition of the Goldcell[®] Beta-Glucan is consistently within specifications for different production batches.

Nutritional Value and Metabolism

Because the Biothera and Goldcell[®] Beta-Glucans are compositionally similar, it is reasonable to assume that their nutritional value and metabolism will also be equivalent. Similar to the Biothera Inc. beta-glucan, the compositional specifications of the Goldcell[®] Beta-Glucan list carbohydrate, primarily in the form of beta-glucans

as the main constituent, with only minor amounts of protein, fat, and ash. The nutritional value of beta-glucans is low as they are generally indigestible, with some microbial fermentation possible in the colon.

Intended Uses

The applicant intends placing the Goldcell[®] Beta-Glucans on the EU market in foods for general purposes, food supplements and foods for particular nutritional (PARNUTS), with the exception of infant and follow-on formulae. The defined use and maximum levels set out in Annex II of Commission Implementing Decision 2011/762/EU that pertains to the authorised Biothera Inc. yeast beta glucans will also apply to the Goldcell[®] Beta-Glucan. This will be without prejudice to the provisions of Directive 2002/46/EC, Regulation (EC) No. 1925/2006 and Directive 2009/39/EC.

Level of Undesirable Substances

Yeast beta-glucans from both sources is isolated from the same microorganism using a largely similar process and therefore it can be assumed that there will not be any significant differences in the levels of undesirable substances. The applicant demonstrates a satisfactory microbiological profile along with heavy metal specifications covering lead, cadmium, arsenic and mercury, all of which are within regulatory standards.

Conclusions

The FSAI is satisfied from the information provided by the applicant that Goldcell[®] Beta-Glucan is substantially equivalent to insoluble yeast beta-glucans authorised to Biothera Inc. for the EU market through Commission Implementing Decision 2011/762/EU. The Goldcell[®] Beta-Glucan will be designated as “yeast (*Saccharomyces cerevisiae*) beta-glucans” and be used within the maximum levels in the foods specified in Annex II of Commission Implementing Decision 2011/762/EU.