

## SUBSTANTIAL EQUIVALENCE OPINION

### Biocentras Beta-Glucans

The Food Safety Authority of Ireland (FSAI) received an application in March of 2015 from JSC Biocentras of Lithuania for an opinion on the substantial equivalence of its insoluble and soluble yeast beta-glucans to the same ingredients previously authorised to Biothera Inc. through Commission Implementing Decision 2011/762/EU. The EU-authorised 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 Biocentras beta-glucans is also extracted and purified from *S. cerevisiae* cell walls, with one minor difference in the production process that does not significantly alter the characteristics or quality of the final product compared to the authorised comparator. The Biocentras beta-glucans will be designated as “yeast (*Saccharomyces cerevisiae*) beta-glucans” similar to the authorised Biothera product.

#### Composition

The novel beta-glucans, like the authorised comparator, is derived from the cell walls of *S. cerevisiae* using similar production and purification processes. Both processes first yield insoluble beta-glucans which is then processed further to yield soluble beta-glucans. The only difference in the production of the Biocentras beta-glucans is that the *S. Cerevisiae* cells are enzymatically lysed compared to autolysis initiated by heat for the Biothera product. Compositional analysis demonstrates strong similarities in terms of insoluble and soluble beta glucans content as well as levels of moisture, fat, protein and ash.

#### Nutritional Value and Metabolism

The nutritional value of beta-glucans is low as it is generally indigestible, with some microbial fermentation possible in the colon. Because the Biothera and Biocentras beta-glucans are compositionally very similar, it is reasonable to assume that their nutritional value and metabolism will also be equivalent. Similar to the Biothera beta-glucans, the compositional specifications of the Biocentras beta-glucans list

carbohydrate, primarily in the form of beta-glucans as the main constituent, with minor levels of protein, fat, and ash.

### **Intended Uses**

The applicant intends placing the novel beta-glucans on the EU market in foods for general purposes, food supplements and foods for particular nutritional uses (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 pertain to the authorised Biothera yeast beta glucans will also apply to the Biocentras beta-glucans, and 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 for the novel ingredient along with acceptable heavy metal specifications for lead, cadmium, arsenic and mercury.

### **Conclusions**

The FSAI is satisfied from the information provided by the applicant that JSC Biocentras beta-glucans, both insoluble (ING) and soluble (SBG), extracted from *S. cerevisiae* is substantially equivalent to insoluble and soluble yeast beta-glucans authorised to Biothera Inc. for the EU market through Commission Implementing Decision 2011/762/EU. The Biocentras beta-glucans will be designated as “yeast (*Saccharomyces cerevisiae*) beta-glucans” and will be used in accordance with the maximum levels and in the food categories specified in Annex II of Commission Implementing Decision 2011/762/EU.