Ms. Hilde Raa
Science Manager
NutraQ
PB 3 Manglerud
N-0612 Oslo,
Norway

May 10th, 2012

**Re: Substantial Equivalence opinion on insoluble yeast beta-glucans**

Dear Ms. Raa,

I am contacting you in regard to the application by NutraQ for an opinion under *Article 3.4.* of the novel food Regulation (EC No. 258/97) on the substantial equivalence of an insoluble yeast beta-glucans (NBGP) to a similar ingredient which was authorised for the EU market through Commission Implementing Decision 2011/762/EU.

Based on the information provided, the Food Safety Authority of Ireland (FSAI) is satisfied that the insoluble yeast beta-glucans produced by NutraQ is substantially equivalent to insoluble yeast beta-glucans authorised by Commission Decision 2011/762/EU with respect to its composition, nutritional value, metabolism, intended use and level of undesirable substances.

A summary of the information considered and the FSAI opinion is included.

If you are satisfied with this opinion you should notify the European Commission in accordance with *Article 5* of Regulation EC No. 258/97 prior to placing this product on the market.

*Commission contact details:*

Mr Andreas Klepsch
European Commission
DG SANCO, E6
Rue de la Loi 200
B-1049 Brussels, Belgium

Regards,

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Dr. Pat O'Mahony
*Chief Specialist, Food Technology*

**SUBSTANTIAL EQUIVALENCE OPINION**

# NutraQ Insoluble yeast beta-glucans

The Food Safety Authority of Ireland (FSAI) received an application on March 1st, 2012 from NutraQ for an opinion on the substantial equivalence of its insoluble yeast beta-glucans 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 yeast *Saccharomyces cerevisiae* (more commonly known as baker's yeast). The NutraQ product is also extracted and purified from *S. cerevisiae*, 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 NutraQ product 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. This substantial equivalence opinion makes no comment on the nutrition and health claims referred to in the application.

## Composition

The beta-glucans from both sources is derived from *S. cerevisiae* and any compositional differences would be as a result of the minor variations in the production and purification processes. The applicant notes that the use of citric acid to neutralise the cell wall slurry compared to the stronger sulphuric acid used in the preparation of the Biothera Inc. product means that there is less likelihood of beta-glucans degradation. In addition, sulphuric acid enhances the solubility of minerals and this is proposed by the applicant as a possible reason for the lower ash content evident in the Biothera Inc. product. The applicant also utilises a final ethanol extraction step which is not employed in the Biothera Inc. process, but this does not have a significant impact on the composition of the final product. The applicant compares the compositional specifications of yeast beta-glucans from both sources, with the difference in ash content being the only notable variant.

## Nutritional Value and Metabolism

Similar to the Biothera Inc. product, the compositional specifications of the NutraQ product 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. Because the products from both sources are compositionally similar, it is reasonable to assume that their nutritional value and metabolism will also be equivalent. The applicant has demonstrated that, under various conditions of humidity and temperature, NutraQ beta-glucans is stable over a five year period with respect to microbial contamination and the content of carbohydrate, lipids, protein and minerals (ash). This is similar to the stability profile of the Biothera Inc. product and the applicant concludes by recommending that the product is stored in a dry environment.

## Intended Uses

The applicant wishes to place the insoluble yeast 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 NutraQ product. 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 NutraQ insoluble yeast beta-glucans is substantially equivalent to insoluble yeast beta-glucans

authorised to Biothera Inc. for the EU market through Commission Implementing Decision 2011/762/EU. The NutraQ product 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.