Summary of the application: Iron-containing yeast (*Saccharomyces cerevisiae*) biomass

Applicant: Danstar Ferment AG, Postrasse 30. 6300, Zug (Switzerland)

The Novel Food (NF) application concerns a request for authorization to place on the market an iron-containing yeast.

Iron-containing yeast is an inactivated dried whole cell yeast obtained from culture of a strain of Saccharomyces cerevisiae yeast fermented on a carbon source and essential nutrients. An iron salt is added during batch preparation after which the yeast cream is pasteurized and spray dried. The resulting product is a non-viable iron-containing yeast with iron content of 10-13mg/g (1-1.3%). The elemental iron in the novel food ingredients is complexed to the structures of yeast.

Iron-containing yeast is intended for use in food supplements in the form of tablets, capsules, and other food supplement formats, as defined under Article 2 of Directive 2002/46/EC and it is intended for general population above 3 years of age. The proposed maximum level of use of iron-containing yeast in food supplements is set at 0.3g for children aged 3 to 9, 1g for children and adolescents aged 10 to 17 and 2g of iron-containing yeast for individuals above 18 years of age, this is equivalent to 3.5mg, 11.5mg and 23mg of supplemental iron per day, respectively.

The information provided on the identity, composition, specifications, and lack of batch-to-batch variability of iron-containing yeast demonstrates control of the production process, that the product is compliant with EU regulations and neither nutritionally disadvantageous substances nor toxic contaminants are present.

Iron-containing yeast is sufficiently characterized. Digestion of the yeast cells and subsequent lysis of the yeast proteins in the gastrointestinal tract releases all cellular constituents all of which are anticipated to be endogenous in the human body. All studies and literature evidence presented substantiate the safety of the ingredient under the proposed conditions of use.