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Safety evaluation of the food enzyme β -amylase obtained from barley (*Hordeum vulgare*)

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Abstract

The food enzyme considered in this opinion is a 4- α -D-glucan maltohydrolase (EC 3.2.1.2) obtained from grain of barley (*Hordeum vulgare*), by the companies Genencor International B.V. and Senson Oy. This β -amylase is intended to be used in several food-manufacturing processes: baking and brewing processes, distilled alcohol production, and starch processing for the production of glucose syrups. The compositional data provided for the food enzyme were considered sufficient. The manufacturing process did not raise safety concerns. Based on the maximum use levels recommended for the respective food processes, dietary exposure to the food enzyme–total organic solids (TOS) was estimated on the basis of individual data from the EFSA Comprehensive European Food Consumption Database. This exposure estimate is similar to or lower than the exposure to a fraction of barley comparable to the food enzyme–TOS, resulting from the consumption of barley-derived foods. As the food enzyme is derived from edible parts of barley, in line with the requirements of the guidance document on food enzyme assessment, the Panel accepted that there was no need for the provision of toxicological data for this food enzyme and the Panel concluded that this food enzyme does not give rise to safety concerns under the intended conditions of use. Considering the potential for allergenicity, the gluten content of the food enzyme was below the detection limit of the analytical method, which is well below the level of 20 mg/kg for 'gluten-free' products. The amino acid sequence of the β -amylase was compared to those of known allergens and no match was found. The food enzyme β -amylase from barley is an occupational respiratory allergen and may contain low levels of other allergenic barley proteins that may trigger adverse reactions upon oral challenges in individuals with an oral sensitisation to cereals. The Panel considers that dietary exposure to the food enzyme β -amylase from barley may result in incidental cases of food allergic reactions.

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Keywords: food enzyme, β -amylase, 4- α -D-glucan maltohydrolase, EC 3.2.1.2, *Hordeum vulgare*, barley

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