

SCIENTIFIC OPINION

Scientific Opinion related to a notification from Genecor International BV on barley beta-amylase from unmalted barley to be used in starch degradation to produce glucose syrups rich in maltose pursuant to Article 6, paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Information is provided by the applicant on barley beta-amylase used in degradation of starch from different sources to produce glucose syrups rich in maltose which are used for confectionery products. The information provided concerns manufacturing, characterisation and use of the products. Ten samples of barley beta-amylase have been shown not to contain gluten, with a detection limit of 3.1 mg gluten/kg. No laboratory data regarding the content of allergens in the final product were provided by the applicant. No historical or clinical data regarding non-allergenicity of barley beta-amylase in susceptible cereal-allergic individuals were provided by the applicant.

On the basis of the data presented, the Panel concludes that:

- Barley beta-amylase is a potentially allergenic protein and may, in addition, contain low levels of other barley proteins, peptides or fragments thereof. It is not known at which level of intake barley beta-amylase used for the production of glucose syrups rich in maltose from different sources of starch would cause allergic reactions in cereal-allergic individuals. The scientific data provided by the applicant are insufficient to predict the likelihood of adverse reactions in cereal-allergic individuals. The Panel considers that beta-amylase from barley may trigger adverse reactions in susceptible cereal allergic individuals.
- For coeliac disease, assessment of the evidence submitted indicates that barley beta-amylase is unlikely to cause an adverse reaction in individuals with coeliac disease, provided that the value of gluten considered by Codex Alimentarius for gluten-free foods (20 mg/kg) is not exceeded.

1 On request from the European Commission, Question No EFSA-Q-2009-00308, adopted on 15 October 2009.

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KEY WORDS

Barley, amylase, glucose syrup, maltose, coeliac disease, food allergy.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Article 6 paragraph 11 of Directive 2000/13/EC establishes the cases and conditions for amending Annex IIIa to that Directive, which includes a list of food ingredients or substances known as likely to trigger allergic reactions in sensitive individuals. It also sets up a procedure for exempting from labelling, under certain conditions, derivatives of these ingredients.

Pursuant to the procedure referred to above, a list of ingredients or substances derived from ingredients listed in Annex IIIa has been adopted by the Commission and is included in the Annex to Commission Directive 2007/68/EC of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. Applicants who are seeking the exclusion of a given product from Annex IIIa have to submit a request, completed with the results of relevant scientific studies.

Therefore, in the context of the permanent labelling exemption procedure, the European Food Safety Authority is asked to provide scientific opinions on the submissions in accordance with the present terms of reference.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) N° 178/2002, the European Commission requests the European Food Safety Authority to evaluate the scientific data submitted by Genecor International BV in the framework of the procedure laid down in Article 6, paragraph 11 of Directive 2000/13/EC. On the basis of that evaluation, EFSA is requested to issue an opinion on the information provided, and particularly to consider the likelihood of adverse reactions triggered in susceptible individuals by the consumption of the following ingredients/substances used under the conditions specified by the applicant: Barley beta-amylase enzyme from unmalted barley to be used in starch degradation to produce glucose syrups rich in maltose.

ASSESSMENT

1. Introduction

Since barley is relevant both as a source of epitopes known to elicit coeliac disease (EFSA, 2004) and as an allergen eliciting non-coeliac food allergy, it is appropriate to assess barley products, namely barley beta-amylase, for their potential to induce coeliac disease or food allergy.

The applicant states that barley beta-amylase is a highly purified product from barley and does not contain gluten. Also, the applicant states that barley beta-amylase is not likely to trigger adverse allergic reactions in susceptible individuals. Therefore, the applicant proposes to include barley beta-amylase in the list of exemptions for labelling in Directive 2000/13/EC as amended.

The following evidence is presented by the applicant in support of the statements and proposal given above.

2. Manufacturing process

The data provided show that in the preparation process of barley beta-amylase from barley grain good manufacturing practice is observed as well as ISO 9001:2000, ISO 14001:2004, and Hygiene Directive 93/43/EEC (replaced by Regulation (EC) No 852/2004⁴) including Codex Alimentarius HACCP principles. Beta-amylase is extracted by de-husking, steeping, ultra-filtration and stabilisation. The extraction involves treatment with SO₂ water (sodium sulfide, sodium metabisulfite). The applicant states that beta-amylase is extracted from the (water-) soluble section of unmalted barley grain, while gluten resides in the insoluble section. The applicant refers to laboratory-based tests (see section 4).

3. Characterisation of the product and its use

Barley beta-amylase is used in degradation of starch from different sources (wheat, barley, maize/corn) to produce glucose syrups rich in maltose. These syrups are used for confectionery products. The applicant states that starch hydrolysates in which barley beta-amylase has been used are not likely to trigger adverse reactions. Exposure studies or clinical studies were not considered necessary by the applicant and are not included in the application.

4. Evidence of non-allergenicity

4.1. History of non-allergenicity of the product

No data were provided by the applicant regarding a history of non-allergenicity of barley beta-amylase.

⁴ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. OJ L139, 30.4.2004, p.1.

4.2. Laboratory-based tests

4.2.1. Allergens

Except for gluten, no laboratory data regarding allergens present in the final product were provided by the applicant.

4.2.2. Gluten

Ten samples of barley beta-amylase at different stages of production (from crude barley extracts to ultrafiltration concentrates of barley extracts to different samples of barley beta-amylase) were selected by the applicant and subjected to further analyses (Imbiosis SL Laboratory, Cantoblanco Madrid, Spain) using the sandwich R5 ELISA method, which is the method endorsed by Codex Alimentarius (Codex standard 118 - 1979, revised 2008). In addition, the competitive R5 ELISA method has been used as well as Western blot immunochemical testing.

With a detection limit for gluten of 3.1 mg/kg, gluten was not detected in any of the ten samples tested, that is in crude barley extracts and also in the final product, barley beta-amylase, using an accepted method.

4.3. Clinical studies

No clinical data regarding non-allergenicity of barley beta-amylase have been submitted by the applicant. However, the Panel notes that barley beta-amylase is a protein and therefore a potential allergen. Further, the Panel notes that published data (not supplied by the applicant, Sandiford et al., 1994) demonstrate that a high proportion of sera from individuals with bakers' asthma contains specific IgE that binds to barley beta-amylase, a finding which supports the notion that barley beta-amylase may itself be an allergen that might trigger adverse reactions in cereal-allergic individuals (Tatham and Shewry, 2008). Finally, the Panel notes that laboratory investigations alone would not be sufficient to demonstrate the non-allergenicity of barley beta-amylase, and that appropriate clinical studies would have to be carried out.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- Barley beta-amylase is a potentially allergenic protein and may, in addition, contain low levels of other barley proteins, peptides or fragments thereof. It is not known at which level of intake barley beta-amylase used for the production of glucose syrups rich in maltose from different sources of starch would cause allergic reactions in cereal-allergic individuals. The scientific data provided by the applicant are insufficient to predict the likelihood of adverse reactions in cereal-allergic individuals. The Panel considers that beta-amylase from barley may trigger adverse reactions in susceptible cereal allergic individuals.
- For coeliac disease, assessment of the evidence submitted indicates that barley beta-amylase is unlikely to cause an adverse reaction in individuals with coeliac disease, provided that the value of gluten considered by Codex Alimentarius for gluten-free foods (20 mg/kg) is not exceeded.

DOCUMENTATION PROVIDED TO EFSA

Dossier submitted by Genecor International BV to the European Commission on Barley beta-amylase enzyme from unmalted barley to be used in starch degradation to produce glucose syrups rich in

maltose pursuant to Article 6 Paragraph 11 of Directive 2000/13/EC as amended by Directive 2003/89/EC. 26 January 2009.

REFERENCES

- Codex standard for foods for special dietary use for persons intolerant to gluten, 2008. CODEX STAN 118 - 1979, amended 1983; revised 2008.
- EFSA (European Food safety Authority), 2004. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission relating to the evaluation of allergenic foods for labelling purposes. The EFSA Journal 32, 1-197. http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html
- Sandiford CP, Tee RD, Newman Taylor AJ, 1994. The role of cereal and fungal amylases in cereal flour hypersensitivity. Clin. Exp. Allergy 24, 549-557.
- Tatham AS and Shewry PR, 2008. Allergens to wheat and related cereals. Clin. Exp. Allergy 38, 1712-1726.

GLOSSARY / ABBREVIATIONS

ELISA Enzyme-linked immunosorbent assay