

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

GLUCOSAMINE HCl (*Aspergillus niger*)

Issue

The Committee is asked to consider the information provided by Cargill Acidulants on glucosamine hydrochloride (HCl) derived from *Aspergillus niger*. The company requests the scientific opinion of the UK Competent Authority (CA) on this product, which it considers, should be treated as substantially equivalent to the existing glucosamine HCl derived from shellfish.

The Committee is asked whether it has any concerns regarding the marketing of this product and whether it considers that the product is substantially equivalent to an existing product.

Background

1. Given that the source is different, the applicant is asking for an opinion of the UK CA on the equivalence of glucosamine HCl derived from *Aspergillus niger*, under Article 5 of EC Regulation 258/97 (Dossier attached at Annex 1). All glucosamine HCl on the market in the EU is currently extracted from shellfish waste.
2. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has informed the Commission. In all cases to date, the Commission has required that the applicant first obtain an opinion on equivalence from a Member State. Cargill Acidulants is requesting such an opinion from the UK CA.
3. According to Article 3(4) of (EC) 258/97, the notification procedure applies to “foods or food ingredients ...which on the basis of the scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies ... are substantially equivalent to existing foods or food ingredients as regards their:
 - composition,
 - nutritional value,
 - metabolism,
 - intended use and
 - level of undesirable substances contained therein”.

Evaluation

4. Composition

- 4.1. After acid hydrolysis of the non-GM *A. niger* biomass at high temperature, glucosamine HCl is extracted using the same process used for the production of shellfish glucosamine HCl (Annex 1, p 9-10, figs 4 & 5 – confidential information). In both cases, the product is a crystalline product of high chemical purity.
- 4.2. Cargill Acidulants has noted that the molecular structures of glucosamine HCl obtained from *A. niger* and from shellfish are identical (Annex 1, p.6). In appendix 5 of Annex 1, the analytical certificates show that the composition of Cargill's fungal glucosamine complies with the monograph for glucosamine HCl in the National Formulary of the US Pharmacopoeia, supplemented by certain microbiological criteria (Annex 1, p11). Additionally, the infrared spectra (appendix 6 of Annex 1) illustrate the similarities between the fungal and shellfish derived glucosamine chemical profile.

5. Nutritional value

- 5.1. The bioactivity of the fungal glucosamine HCl is not thought to vary from the bioactivity of shellfish glucosamine HCl. Nutritional information of glucosamine HCl from *A. niger* is provided in table 1 of Annex 1, p.12.

6. Proposed Labelling

- 6.1. The applicant intends to label the product as “Non-Shellfish Glucosamine Hydrochloride” with a footnote referring to its source in the ingredient list (“from the fungus *Aspergillus niger*”).
- 6.2. Glucosamine HCl from *A. niger* products could also carry a certificate to indicate the product was Kosher.

7. Intended Use

- 7.1. Glucosamine HCl from *A. niger* will be used as a food supplement in the form that shellfish derived glucosamine already appears in the EU (Annex 1, table 2).
- 7.2. The applicant has highlighted that although the actual recommended daily intakes for glucosamine HCl vary, the most widely recommended intake is up to 1500 mg of glucosamine HCl per day (Annex 1, p.13). The fungal product would be used in the same way as its existing counterpart and at the same doses.

8. .Levels of undesirable substances contained therein

- 8.1. Cargill Acidulants has implemented a quality control system and uses good manufacturing practice for the production of its fungal glucosamine HCl (Annex 1, p10a). These include routine checks to ensure the absence of bacterial and fungal contamination (including bacterial and fungal spores).
- 8.2. Regarding the potential allergenicity of fungal glucosamine, the applicant has included an expert's opinion which states that this product should not be considered as potentially allergenic (Annex 1, appendix 1). The applicant has additionally provided data in appendix 4 of Annex 1 showing the absence of proteins with a size above 12 KDa in its products. Typical methods for quantifying low levels of proteins cannot be applied to the product due to the interference by the amino group of the glucosamine. The Secretariat has discussed potential allergenicity with the applicant who has stated that they would not make any claims on the allergenic potential of the product that exceed those of the existing product. However, the applicant would like to market their product in such a way that people wishing to avoid shellfish based products can do so, e.g.: to avoid both the issue of potential allergy to shellfish and for particular dietary requirements.
- 8.3. The fungal source, *A.niger*, is non-pathogenic and non-toxic for humans and is currently used for food production (citric acid). Although the species *A.niger* can produce ochratoxin A, the applicant has stated that this is not the case for the production strain (Annex 1, p. 7). This mycotoxin was not detected in a sample of fungal glucosamine, at the limit of detection (LOD) of the analytical method used (Annex 1, appendix 3). Similar results were obtained on the detection of aflatoxin in fungal glucosamine HCl (Annex 1, appendix 7).
- 8.4. No pesticide was found in glucosamine HCl from *A.niger*, at the LOD of the analytical methods used (Annex 1, appendix 7).

Committee action required

9. The Committee is asked if it has any objections or comments to raise or whether it is content to agree the equivalence of glucosamine HCl derived from *A. niger* to the existing glucosamine HCl derived from shellfish, in accordance with Article 3(4) of (EC) 158/97.
10. If not, the Committee is asked what additional information the applicant could supply in order to demonstrate equivalence.

Secretariat

March 2004

Annex attached: Annex 1 – application dossier from Cargill Acidulants
(pages 10 and 10a contain confidential information)