

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

OPINION ON AN APPLICATION UNDER THE NOVEL FOODS REGULATION FOR THE APPROVAL OF ISOMALTULOSE AS A FOOD INGREDIENT

Applicant: Cerestar (Cargill Cerestar BVBA)

Responsible Person: Yves Le-Bail Collet

Novel Food: Isomaltulose

EC Classification: 1.2

INTRODUCTION

1. An application has been submitted by Cerestar to the UK Competent Authority on 30th October 2003 for approval of isomaltulose for use in a range of food products. A copy of the Application dossier was placed on the FSA web-site at the same time.
2. The present application for authorisation of isomaltulose was prepared pursuant to Commission Recommendation (97/618/EC) of 29 July 1997 concerning the scientific aspects and presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients. Isomaltulose has been classified as a pure chemical or simple mixture from a non-GM source (class 1.2). The information presented in the dossier is structured accordingly and is considered below under the schemes outlined in this Commission Recommendation.

I. Specification of the novel food

Application Dossier, p 4-7

3. Certificates and methods for most analyses are to be found in the application dossier in appendix A. These analyses show isomaltulose to be a stable product under normal conditions and when subjected to heat treatments and of high purity containing low levels of arsenic and mercury. The certificates of analysis for the raw materials can be found in appendix B. Batch on batch variation was assessed by testing five non-consecutive batches for composition. The results of these analyses on the samples indicate a narrow range of variation in composition and contaminants. Isomaltulose is produced via enzymatic conversion of sucrose using the non-pathogenic bacteria *Protaminobacter rubrum*.

Discussion. *The Committee requested further analyses on heavy metals to be carried out on the final product. Members accepted the additional data offered reassurance of the heavy metal content of the novel food. Otherwise, Members were satisfied that the analyses carried out by the applicant on the raw materials, the final product and the bacteria, P. rubrum demonstrated the safety of the novel food. The applicants' response is tabulated below.*

| Summary of Metal Analysis Results | | | | | |
|-----------------------------------|-------------------|-----------|-----------|-----------|-----------|
| Specification Parameter | Manufacturing Lot | | | | |
| | (Batch 1) | (Batch 2) | (Batch 3) | (Batch 4) | (Batch 5) |
| Arsenic (ppb) | <100 | <100 | <100 | <100 | <100 |
| Cadmium (ppb) | <10 | <10 | <10 | <10 | <10 |
| Lead (ppb) | <20 | <20 | <20 | 21 | <20 |
| Mercury (ppb) | <5 | <5 | <5 | <5 | <5 |
| Nickel (ppb) | <50 | <50 | <50 | <50 | <50 |

II. Effect of the production process applied to the novel food

Application dossier, p 8-19

- The production process uses food-grade sucrose dissolved in water that is treated with a crude enzyme preparation consisting of *P. rubrum* cell mass killed using formaldehyde. After the enzymatic conversion the cells are removed by filtration. The product is then purified by demineralisation, crystallisation, washing, drying and cooling, producing a final isomaltulose product of at least 99% purity. Formaldehyde is not detectable in the final product.

Discussion. *The Committee was content that the production process is controlled and that the in-process monitoring steps were sufficient to ensure a safe and consistent product. The Committee was also reassured that the micro-organism P. rubrum is used in the commercial production of isomalt in the EU.*

III. History of the organism used as a source of the novel food

Application dossier, p 20

- No information is supplied under this heading, as isomaltulose is not sourced from an organism but from food grade sucrose.

IX. Anticipated intake/extent of use of the novel food

Application dossier, p 21-27

- The applicant intends to use their isomaltulose product as an ingredient in beverages and a variety of other products where it would partly replace other sugars as a source of energy. The availability of these products will not be restricted geographically and there are no plans to target these products at a particular consumer group.
- The applicant has stated that the highest intake figures from all proposed food categories when related to body weight were found amongst children with mean and 97.5th percentile intakes of 1.6 and 4.0g /kg body weight/day respectively. The lowest intake figures were found amongst the female adults group with a mean intake of 0.2g/kg body weight/day and a 97.5th percentile intake of 0.6g/kg body weight/day.

Discussion. *The Committee had concerns over the intended market and were concerned that the use of isomaltulose could result in an overall increase in energy intake due to the misinterpretation of any claims made for reduced sweetness or delayed energy release. This issue is addressed in the labelling section below.*

XI. Nutritional information on the novel food

Application dossier, p 28-29

8. Isomaltulose is hydrolysed to equal amounts of fructose and glucose and absorbed almost completely in the small intestine in a similar way to sucrose.
9. Isomaltulose is metabolised at a rate of one-fifth to one quarter that of sucrose, but the final calorific value is the same as sucrose because both disaccharides are cleaved to form glucose and fructose. Isomaltulose is also characterised by a reduced sweetness when compared to sucrose. These functional properties will not be used to target products containing isomaltulose at specific consumer groups but they will be used to alter the organoleptic and physical properties of the products in which it is used.

***Discussion.** The Committee had a concern over the study using 8 ileostomy patients outlined on page 48 of the dossier. Members were concerned over the possibility of a polymorphism in the population for isomaltulose metabolism that may cause problems. The applicant is of the opinion that there is no such polymorphism in the population as isomaltulose is metabolised by the same route as sucrose. The applicant has provided an expert confirming this view.*

The Committee were otherwise content with the nutritional properties of isomaltulose, but had concerns over the vagueness of the target market and possibility for misinterpretation by the public. These concerns are addressed in the response from the applicant that can be found in section IX.

XII. Microbiological information on the novel food

Application dossier, p 30

10. Microbiological information is presented under schemes XII and XIII in the application dossier.
11. The purity of the stock suspension of *P. rubrum* is verified at the time of its preparation and the absence of mycotoxins and contaminating micro-organisms is also routinely demonstrated. *P. rubrum* has also been demonstrated to be non-pathogenic and has a low order of toxicity (Application dossier, p. 32-34)
12. Specifications for most raw materials including micro-organism screens were reproduced in the application.

***Discussion.** The Committee was satisfied with the information supplied by the applicant and considered the production process, quality control measures and the nature of the final product to be sufficient to ensure no unintentional microbiological contamination of the product. They were also satisfied that the *P. rubrum* was suitable for food use and would cause no safety concerns.*

XIII. Toxicological information on the novel food

Application dossier, p 31-63

13. A number of toxicological studies have been provided to demonstrate the safety of isomaltulose including chronic and sub-chronic animal studies, developmental studies and various human studies. The toxicological tests described in the

dossier have primarily been carried out on isomaltulose products from the applicant and two other manufacturers.

Discussion. *The Committee was satisfied that the isomaltulose products produced by other manufacturers of isomaltulose were sufficiently similar to the product produced by the applicant for the toxicological studies to be relevant. The Committee was content that the toxicological data provided by the applicant were sufficient to demonstrate the safety of isomaltulose.*

Allergenicity

Application dossier, p 54

14. The applicant has addressed the possibility that protein from the *P. rubrum* may be released during the production process, or protein from other raw materials may pass into the final product. The presence of protein in the final product has been estimated to be 5.2ppm, based on a measured nitrogen concentration of 0.8ppm and a standard conversion factor of 6.25. The protein figure may be an overestimate, since the calculation assumes that all nitrogen is in the form of protein.

Discussion. *The Committee considered this level of protein to be sufficiently low to cause no problems with allergenicity, taking into account the quantities that might be consumed.*

Labelling

15. The applicant provided the following labelling suggestion:

"The designation 'isomaltulose' shall be displayed on the labelling of the product in the list of ingredients of foodstuffs containing it. In a prominently displayed footnote related to the designation isomaltulose by means of an asterisk (*), the words 'isomaltulose is like sugar, a source in equal parts of glucose and fructose, but has a slower rate of digestion and absorption' or 'Isomaltulose, like sugar, is a source of glucose and fructose which undergoes slower digestion and absorption' shall be displayed. The words of the footnote shall have a typeface of at least the same size as the list of ingredients itself."

Discussion. *The Committee was content that the labelling was sufficiently clear so that diabetics in particular would be aware that products containing isomaltulose were a source of glucose. In response to the Committee's earlier concern over the possibility of increasing calorific intake because of reduced sweetness and to clarify the exact role of isomaltulose as an ingredient the applicant has provided the following revised labelling suggestion:*

"Isomaltulose, like sugar, is a source of glucose and fructose, which undergoes slower digestion and absorption. A gram of isomaltulose provides as much total energy/calories as a gram of sugar, but over a prolonged period of time".

The Committee noted the inclusion of a statement about the energy content, but was concerned that the final part of the statement could lead to this information being misunderstood by consumers. The Committee concluded that any claims referring either to reduced sweetness of isomaltulose or to the rate of energy release should be accompanied by a statement of the energy equivalence of the novel ingredient

with other sugars, presented in a way that cannot be construed as misleading to consumers".

OVERALL DISCUSSION

16. The Applicant has provided a clear specification of the proposed novel food and indicated, on the basis of analysis from a number of non-consecutive batches that the specification is achievable. The production process differs very little from that used in the production of isomalt, an approved sweetener in the EU.
17. Given that isomaltulose is an isomer of sucrose and is broken down to glucose and fructose in the GI tract in a similar way to sucrose, no additional nutritional concerns were raised from the consumption of the novel food. The information supplied by the applicant offers sufficient reassurance that consumption of the novel food does not give rise to any toxicological concerns.
18. The applicant has demonstrated that the novel food is stable under normal conditions and also when subject to raised temperatures. The applicant has also demonstrated that the novel food is microbiologically safe.
19. The proposed labelling of the product is acceptable, nevertheless the applicant should be reminded of the need to comply with food labelling legislation and ensure that the labelling and presentation of the products does not mislead the consumer, particularly in relation to their energy content.
20. While the projected levels of isomaltulose intake do not give rise to any toxicological concern, the effect of substitution for sucrose on the overall pattern of extrinsic sugar consumption is unknown. The Committee noted concerns that the consumption of extrinsic sugars is already undesirably high and recommended that the applicant undertakes post-market monitoring to demonstrate the pattern of consumption of isomaltulose-containing products and to establish whether consumers correctly understand the energy content of such products compared with their existing counterparts

Conclusion

The Advisory Committee on Novel Foods and Processes is satisfied by the evidence provided by Cerestar that the range of uses for isomaltulose is acceptable, subject to the applicants' adherence to the specification and production parameters described in the application dossier. Isomaltulose containing foods should comply with existing legislation and should not make claims that are likely to mislead consumers. The applicant should establish a post-launch monitoring scheme to determine the patterns of consumption and to ascertain whether the use of isomaltulose leads to any misunderstanding of the energy content of foods in which it is used.

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