

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

TOUCHI (FERMENTED BLACK BEAN) EXTRACT

Issue

The Committee is invited to consider the response provided by CBC Co. Ltd to the comments raised at the July meeting and discuss whether it provides sufficient information for the Committee to conclude its evaluation of this novel food ingredient.

Background

1. At the July 2008 meeting, Members considered an application from CBC Co. Ltd for the authorisation of Touchi extract derived from the fermentation of black bean (*Glycine max*) by *Aspergillus oryzae* as a novel food ingredient (ACNFP/89/4).
2. A letter detailing the ACNFP's comments on this application was sent to the applicant on 29 July (see Annex 1) and these are summarised below:
 - I. **Tea/Soup formulation** – The Committee requested further detail on exactly how the tea/soup formulation will be marketed and whether the powdered product is intended for addition to other foods at the table.
 - II. **Similarity to black bean sauce** – The Committee noted that the safety assessment of touchi extract is largely based on its similarity to black bean sauce but requested further data to demonstrate this. In particular the Committee sought reassurance that the effect of processing steps did not alter the protein content.
 - III. **Production process** – The Committee requested further details on the fermentation conditions used in the manufacture and sought clarification as to whether the black bean fermented product is the same as the one used to create black bean sauce.
 - IV. **'Nutritional support'** –The Committee requested clarification on the meaning of this term, as it is not defined in EU legislation.
 - V. **Complaints procedure** – The Committee requested further information on the mechanisms that are in place to ensure that any complaints of adverse effects can be communicated to the manufacturer.
3. The applicant responded to these comments on 15 August (**see Annex 2**). The secretariat wishes to highlight the following points:

- I. **Tea/Soup formulation** - The applicant has provided examples of both tablet and tea/soup formulation products along with translated labels as Appendix 1. The applicant has advised that all powdered tea/soup formulations are specifically designed for consumption by mixing with hot water only and are not intended for addition to other foods. The applicant anticipates that consumers will enjoy the flavour of the tea/soup type products alone in a similar way to soy sauce flavoured products and that additional ingredients would not be required to enhance the sensory properties.
- II. **Similarity to black bean sauce** – The applicant states that it is the similarity to fermented black beans as consumed in Europe and typically used in recipes to form a sauce for meat, fish or vegetables that is the basis of the safety assessment of the NI and provides examples of recipes involving the use of fermented black beans to make a sauce in Appendix 2.

The applicant has provided the key stages involved in the preparation of both fermented black bean sauce and fermented black bean extract in Fig. 1. To obtain a dish containing the sauce, the fermented black beans are crushed or chopped to form a paste which is then combined with oil and other ingredients before heating at high temperatures in a wok (temperatures greater than 230°C for 5-25 minutes) as specified in recipes. Although production of the NI involves two heat treatments, the second treatment is the sterilisation step and is a controlled treatment performed over a short period of time (135°C, 15 seconds). The applicant notes that by comparison, the one heat treatment involved in preparing fermented black bean sauce involves higher temperature and less controlled conditions, therefore any general effects of heat treatment on the protein content will be consistent between the sauce and the extract as they are more likely to occur at this stage.

The applicant also provides the results of SDS-PAGE performed to demonstrate the effect of fermentation and hot water treatment on the protein content of the small soybean in Figure 2. The applicant is of the view that the fermentation process degrades the soyabean protein and that this can be seen in both the black bean used for sauces and the NI.

- III. **Production process** – The applicant has provided a more detailed overview of the production process. Solid state fermentation is carried out in an aerobic environment at 30°C over 7 days using the fungus *Aspergillus oryzae* (0.02% per gram of soybean). The fermentation is stopped by cooling to below 30°C before the mixture is washed with water in a continuous manner and dried in a dedicated drying room.

The applicant also confirms that the fermentation process used in the production of fermented black bean sauce and paste is identical to that used in the manufacture of the NI.

- IV. **'Nutritional support'** – The applicant explains that the term 'nutritional support' was used only to convey that the anticipated consumption of the NI is during a meal rather than on its own. The applicant again highlights their

view that the NI assists in slowing the breakdown of carbohydrates and is therefore most effective when consumed at meal times.

- V. **Complaints procedure** – The applicant explains that post-marketing surveys will be conducted to ensure any complaints of adverse effects can be communicated to both itself and to the manufacturer, Nippon Supplement Inc. The applicant anticipates this will provide a mechanism of identifying relevant aspects of the safety or quality of the NI when marketed in the EU and contribute to optimising the conditions for marketing and consuming the product.

The manufacturer currently sells the NI in Japan through its direct mail channel in the same supplement-style products proposed for the EU. The manufacturer conducted a post-marketing survey in 2005 which evaluated over 1500 consumer responses to factors including age variation, lifestyle, diet control and blood glucose levels during use. No adverse effects were reported at this time or have been reported to date.

Committee Action Required

4. The Committee is asked whether the applicant's response provides sufficient information and adequately addresses its concerns.
5. If so, the Secretariat proposes to draft an opinion incorporating the ACNFP's comments on CBC Co. Ltd's application which will be discussed at the next Committee meeting in November.
6. If not, the Committee is asked to indicate what additional information would be required.

**Secretariat
September 2008**

Annexes attached:

- ANNEX 1** Letter of 29/09/08 to the applicant with the Committee's comments
- ANNEX 2** Response from the applicant of 15/08/08 (Restricted)

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Letter to the applicant with the Committee's comments (29 July 2008)

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Response from the applicant (15 August 2008) (RESTRICTED)