COMMITTEE PAPER FOR DISCUSSION **ACNFP/130/3**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES
UV TREATED BAKERS YEAST EXTENSION OF USE - DOSSIER 214

ISSUE

1. The Danish Competent Authority (CA) has prepared an initial assessment report on an application for the extension of use of UV treated baker's yeast. The additional uses proposed are UV treated yeast to be sold in a pre-packed form of fresh or dry yeast directly to the consumer for home baking, and an inactivated yeast with lower vitamin D_2 content. The applicant is also seeking to use the novel food ingredient without the designated maximum use level in food supplements under the Novel Foods Regulation (EC) No 258/97.

2. The Committee is asked whether it agrees with the initial opinion and whether it would like to make any further comments on this application. The Committee's advice will form the basis for the UK's formal response to the Commission.

Background

3. On 7 July the European Commission forwarded the initial opinion of the Danish Veterinary and Food Administration Agency on an application made by Lallemand Bio-Ingredients Division under Article 4 of the Regulation for the extension of use of UV treated baker's yeast to be sold in a pre-packed form of fresh or dry yeast directly to the consumer, an inactivated yeast form of the novel food ingredient and to use the novel food ingredient with the designated maximum use level in food supplements.

4. The Commission has requested the views of Member States on the Danish CA's initial opinion. Member States have until 5 September to submit any comments and/or reasoned objections to the Danish assessment.

5. The application dossier is attached as **Annex A,** the Danish Initial Assessment Report is attached as **Annex B,** the ACNFP's initial opinion to the original application is at **Annex C** and EFSA's opinion on the original dossier is provided at **Annex D. Annex A, B and C** contain protected information.

6. The assessment of the original novel food ingredient application was undertaken by the ACNFP and later reviewed by EFSA following objections from other

Member States. Initially the applicant had sought authorisation for a wider range of ingredients but these were reduced to address concerns from other Member States. Where the ACNFP's previous assessment is particularly relevant to the assessment this has been highlighted below.

This application

7. The applicant intends to extend the authorised uses of UV treated baker's yeast to be marketed in a prepacked form or fresh or dry yeast directly to the consumer for home baking with a vitamin D_2 content varying between 45 and 200µg per 100g of yeast. The applicant is intending the packaging to include instructions for use in home-backed products as to reach a maximum final concentration of vitamin D of 5µg per 100g of final product (home baked products).

8. The applicant also intends to use the novel food ingredient in food supplements without the maximal use level of 5µg of vitamin D_2 per day. The rationale behind this request is that the novel food ingredient is treated in the same way as all other sources of vitamin D_2 which are included in Annex II of the EC Food Supplements Directive 2002/46/EC, which do not have specific maximum limits. The Danish CA considered that removing the maximum use level of the novel food ingredient would not be expected to increase the consumer's vitamin D intake as it would be substituted for other vitamin D sources.

9. The applicant also intends the UV treated baker's yeast to be used in another version of the novel food ingredient consisting of the inactivated yeast containing a lower content of vitamin D. This would add two additional steps to the production process which was evaluated by the ACNFP and by EFSA. The steps are described in the Danish opinion. The Danish CA considered that no difference in the potential formation of harmful compounds are expected from the additional processes.

10. In its initial opinion on the original application the ACNFP had accepted there were appropriate controls in place on the production of the novel food ingredient. It did not regard the methods employed by the applicant to be adequate to identify potential mutants but accepted the subsequent use of the vitamin D_2 yeast concentrate could not lead to a mutant becoming the dominant strain in the

final product. The process has remained unchanged in the extension of use with the exception of the new inactivated product.

11. In its initial opinion of the original application the ACNFP had noted the shortcomings in the approach used by the applicant to estimate intake, but agreed it did provide a reasonable estimate of the mean and high level consumption of vitamin D_2 yeast concentrate.

12. The Danish opinion argues that as the additional uses are consistent with the commercial use of UV treated yeast. It is noted that the nature of the EFSA assessment was to consider all users in these categories, and therefore they expect that the additional intake proposed is within the assessed levels. It is also noted that the removal of the maximum intake for food supplements is unlikely to increase consumer exposure as it will replace existing sources of vitamin D.

13. The initial opinion suggests the Danish CA had no concerns on allergenicity. In its initial opinion on the original application the ACNFP stated that the allergenic risk of the vitamin D_2 yeast concentrate was no greater than for other foods containing *S cervisiae* and although there is a risk of an individual with an inhalant allergy to *S cerevisiae* having a severe systemic reaction after consuming the yeast, this would apply equally to other (non-vitamin D enriched) *S. cerevisiae* preparations.

COMMITTEE ACTION REQUIRED

- Members are asked whether they agree with the initial opinion from the Danish CA, and whether they wish to make any comments on the application.
- The Committee's advice will form the basis for the UK's formal response to the opinion of the Danish CA.

Secretariat
July 2017

Annexes attached:

Annex A Application dossier for the approval of the extension of UV treated baker's yeast

Annex B Initial Opinion of the Danish Authority – Official Sensitive

Annex C UK Initial opinion on the original application - Official Sensitive

Annex D EFSA's opinion on the original application