

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

PHOSPHATED DISTARCH PHOSPHATE

Issue

The Committee is invited to consider the comments received during the second public consultation on their draft opinion for National Starch's Phosphated Distarch Phosphate and to agree on any amendments to the opinion in light of these comments.

Background

1. Members first considered National Starch's application for the authorisation of Phosphated Distarch Phosphate, a chemically modified starch, as a novel food ingredient (NI) in 2005 (ACNFP/73/2). After requesting and assessing additional information from the applicant on a number of occasions (ACNFP/74/1, 83/2, 84/3, 85/1), the Committee concluded their assessment of this application at the November 2007 meeting. The draft opinion was revised accordingly and was published for public comment.
2. A number of responses were received during this public consultation and one, raised by a dietician with responsibility for patients undergoing renal dialysis, highlighted that level of phosphorus in the NI may have an adverse effect in those individuals with serious renal disease who have to actively monitor and/or control their phosphorus consumption.
3. The Committee accepted this issue as a cause for concern (ACNFP86/1), noting that the food products for which the addition of the NI is proposed would not be viewed to be naturally high in phosphorus and would not, under normal circumstances be avoided by individuals with renal disease. In view of this the Committee advised that the product should be labelled to give a clear indication of the presence of phosphorus and proposed that the use of a name such as "resistant modified (maize) starch" would be appropriate in this regard. The Committee amended its opinion accordingly (attached at **Annex 1**) and an additional public consultation was carried out to ensure that interested parties were given the opportunity to comment on the revised opinion.
4. During the second public consultation only one response was received, from the applicant, and this is attached at **Annex 2**. The applicant's response addresses two unrelated labelling issues which are summarised below:

(a) Phosphorus levels (Annex 1, pages 12, 13 and 15)

5. The applicant is of the view that it is not necessary to advise renal patients of the presence of phosphorus by altering the name of the ingredient. The dietician's concern stated that '... the estimated added phosphate from the addition of [PDP] ...is as much as 288mg'. The applicant notes however that wheat flour, the ingredient that the NI would typically replace, contains broadly similar quantities of phosphorus. The NI contains up to 0.4% phosphorus, compared with 0.12%-0.32% in wheat flour¹. The applicant therefore contends that the resulting increase in phosphorus consumption is negligible and does not justify the Committee's recommendation to use a name such as "resistant phosphated (maize) starch" instead of "modified resistant (maize) starch".
6. In addition the applicant notes that the resistant nature of the NI is due to the phosphate cross links which would make it unlikely that all the phosphorus would be absorbed. In addition, the figure of 0.4% for the phosphorus content is the maximum allowed in the specification and actual content will be somewhat lower. The average phosphorus level measured in 5 batches of the NI was 0.31% (range 0.23% - 0.36%). The applicant estimates that portion of a food containing 15g of the NI would provide the same quantity of phosphorus as if it contained the same amount of wholemeal flour. If the NI replaces white flour, the difference in phosphorus content would be 30mg. For comparison, the recommended intake for renal patients is in the range 600-1400 mg phosphate/day, which is equivalent to approximately 200-450 mg of phosphorus.
7. (Note: The applicant's response refers to "low phosphate" foods specifically aimed at renal patients, which would be subject to EU legislation on parnuts and/or medical foods. The Food Standards Agency is not aware of any foods that are currently marketed in this way and the Secretariat understands that dietary advice for patients who need to regulate their phosphate intake is based on conventional foods that have a naturally high or low phosphate content.)
8. The applicant also highlights an error in paragraph 23 of the draft opinion, where the figure of 250 mg/day established by the Expert Group on Vitamins and Minerals should refer to intake expressed as phosphorus, not as phosphate.

(b) Advisory statement for young children (Annex 1 page 14)

9. The applicant has also reflected on the proposed warning for laxation in young children, which would be included on all products containing the NI irrespective of the level of incorporation. The applicant is of the view that this is unduly

¹ According to McCance and Widdowson, self-raising flour has the highest phosphorus content of 0.45% but this includes a contribution from added raising agents and is therefore not strictly comparable with the NI.

precautionary, and the NI cannot be compared with food ingredients or polyols² where there is clear evidence of intolerance above threshold levels.

10. The applicant highlights two studies where a type of resistant starch (amylase-resistant starch) was administered to infants (age: 6m–3yrs) with acute watery diarrhoea, and to adolescents and adults with cholera, noting that findings of these studies indicated that the consumption of resistant starch shortened the duration of diarrhoea. The Secretariat has attached these papers, together with the original human study that the applicant cites in support of their view that the NI does not cause intolerance in healthy adults, at **Annex 3**. The applicant has also questioned whether the gastrointestinal (GI) flora of children differs significantly from that of adults and cites two recent studies (attached at Annex 3) which indicate that there is little difference in the GI flora after 1-2 years of life.
11. The applicant is of the view that the evidence of a potential benefit of the consumption of resistant starch, coupled with the similarity between the GI flora of young children and adults, is sufficient for the Committee to consider an alternative approach to the labelling of the NI. The applicant has asked that the Committee consider that an advisory label should apply only when the food contains greater than 10% of the NI and that the wording be made more informative: *“This ingredient has dietary-fibre like properties which may cause laxative effects in young children”*.
12. The applicant states nevertheless that it would prefer to avoid an advisory label and, if the Committee's concerns in relation to young children are not satisfied, asks the Committee to advise what specific data could be provided to resolve this issue.

Committee Action Required

13. The Committee is asked for a preliminary view as to whether it wishes to amend its opinion in the light of this response to the public consultation, and to provide any further comments following the meeting by 1 August. When the text of the opinion is finalised it will be transmitted to the European Commission as the basis for the UK's initial assessment of this application dossier.
14. If the Committee has residual concerns in relation to consumption by small children, Members are asked to advise on the type of studies that could be undertaken to resolve this issue.

² Based on requirements for the novel ingredient D-Tagatose which requires the label “excessive consumption may produce laxative effects” on products that contain >15g per serving (1% in beverages). A broadly similar requirement applies to polyols, if added to food at >10%.

Annexes attached:

- Annex 1** Draft opinion, published for public comment on 9 July
- Annex 2** Comment received during the 10 day consultation
- Annex 3** Scientific publications provided by the applicant in support of in support of amending the precautionary label.

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

DRAFT INITIAL OPINION

(published for public comment on 9 July 2008)

**Secretariat
July 2008**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

**RESPONSE RECEIVED DURING THE PUBLIC CONSULTATION ON THE DRAFT
OPINION**

**Secretariat
July 2008**

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**SCIENTIFIC PUBLICATIONS PROVIDED BY THE APPLICANT IN SUPPORT OF
IN SUPPORT OF AMENDING THE PRECAUTIONARY LABEL**

- Ramakrishna et al, 2008 PLoS ONE. Feb, 13, 3(2)1587
- Ramakrishna et al, 2000 New England Journal of Medicine Feb 3,342(5)308-13
- Pieters et al (1971) TNO Report 3433 Unpublished Study
- Waligoriqa-Dupriet et al, (2007) International Journal of Food Microbiology, 113 (1) 108-113
- Scheiweller et al (2006) Journal of Pediatric Gastroenterology and Nutrition 43 (5) 584-591

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