

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

PHOSPHATED DISTARCH PHOSPHATE

ISSUE

The Committee is invited to consider whether the response provided by National Starch adequately addresses the comments raised at the July meeting, and to consider the text of a draft opinion on this novel food application.

Background

1. At the July 2007 meeting Members considered an application for the authorisation of Phosphated distarch phosphate as a novel food ingredient (NI). This application was accepted by the UK in 2005 and has been discussed by the Committee on a number of occasions (ACNFP/73/2, 74/1 & 83/2). At the July 2007 meeting, Members indicated that they were not completely satisfied with the scientific data and other responses provided by the applicant, and reiterated their concerns regarding the potential for the NI to give rise to gastro-intestinal intolerance in children. The Secretariat indicated that they would draft an initial opinion reflecting these concerns.
2. A letter detailing the ACNFP's outstanding concerns on this application was sent to the applicant on 26 July 2007 (see Annex 1) and these concerns are summarised below:
 - I. **Glycaemic response.** Members welcomed the glycaemic response study, but noted that there may also be a theoretical risk of hypoglycemia if insulin-dependent diabetics were to calculate their insulin dose on the basis of the glucose content of PDP.
 - II. **Intolerance:** Members were of the view that it is not possible to extrapolate from the available data on tolerance and fermentability to the situation in young children, whose gut flora is developing. The Committee cannot therefore be certain that the NI will be tolerated to the same extent by children as by adults and although the list of intended food applications has been refined, the NI is still being proposed for use in a wide range of different food types which, in the event that it did result in GI symptoms such as diarrhoea in young children, may be difficult for parents or clinicians to make a link. The applicant was requested to provide any evidence or scientific arguments as to whether the NI is likely to be tolerated to a greater or lesser extent by young children, compared with adults, and how the intake by this young age group could be controlled.
 - III. **Proposed name:** Members did not view the latest proposed names for the NI to be suitable given the previous advice regarding the use of the term fibre. Members also pointed out that food labelling regulations require that the legal

name of a food should be used in ingredient lists (where one has already agreed). Members indicated that this could be "phosphated distarch phosphate", which is the name that appears in the list of permitted food additives.

Applicant's response

3. The applicant responded to these comments on 20 August (Annex 2). The Secretariat wishes to highlight the following points:

- I. Glycaemic Response:** The applicant notes that (i) The glycaemic response is comparable to that of normal starch (flour). (ii) The NI would not be directly marketed to the consumer, and any claims (eg regarding glycaemic index) would be made on the basis of the products consumed.
- II. Intolerance** The applicant notes that (i) GI intolerance in children is of equal concern for all 'fibre' and 'fibre like' products and there are no data that give any indication that the NI would be disproportionately negative compared with other products. (ii) The available human data indicate that there is high tolerance in healthy adults following the consumption of 60g/day (as two 30g doses) of the NI. For a 30kg child, this equates to consumption of 15g per meal and as the maximum level of the NI is 15g per 100g of food it is unlikely that this will be exceeded for small children. The applicant has indicated that they would consider the use of an advisory label for any food that would be directly marketed at young children that provides more than 15g of PDP per serving.
- III. Labelling** The applicant argues that Phosphated Distarch Phosphate is not the legal name for the NI, and in accordance with the food labelling directive 2000/13/EC, the name prescribed by law appears to be 'modified starch'. The applicant recognises that any reference to the term 'fibre' is subject to national legislation. They propose the legal name be expanded to 'resistant (modified) (maize) starch' as being a name that offers additional clarification for the consumer. The Secretariat is seeking clarification on the legal requirements from the Agency's labelling experts.

Committee Action Required

4. The Committee is invited:
 - to consider whether the applicant's response provides sufficient information on the outstanding points and adequately addresses its concerns; and
 - to review the draft opinion attached at **Annex 3**.
5. The Secretariat will revise the draft opinion in the light of the discussion with a view to finalising it at, or before, the next meeting.

Secretariat
August 2007

Annexes attached:

- Annex 1 – Letter to the applicant with the Committee's comments
- Annex 2 – Response from the applicant
- Annex 3 – Draft Initial Opinion

ANNEX 1 to ACNFP/84/3

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

**Letter to the applicant with the Committee's comments
(26 July 2007)**

**Secretariat
September 2007**

PHOSPHATED DISTARCH PHOSPHATE – APPLICATION FOR AUTHORISATION AS A NOVEL FOOD INGREDIENT

I am writing to update you on the outcome of the ACNFP meeting on 18 July, when the Committee discussed the new information that provided with your letter of 18 June 2007 in response to their earlier concerns.

The ACNFP welcomed the glycaemic response study, which provides useful information about the risk of hyperglycemia if the ingredient is consumed by diabetics. The Committee noted that there may also be a theoretical risk of hypoglycemia if insulin-dependent diabetics were to calculate their insulin dose on the basis of the glucose content of PDP, and we would welcome your comments on this point.

The Committee also noted the results of the in vitro fermentation study. However, they consider that it is not possible to extrapolate from the available data on tolerance and fermentability to the situation in young children, whose gut flora is developing and does not have an adult composition until the age of about 11 or 12. The child's gut is a very different environment to that of adults, and it is known that children are more sensitive than adults to the laxative effects of other poorly absorbed ingredients e.g. polyols. The Committee cannot therefore be certain that PDP will be tolerated to the same extent by children as by adults.

Although you have refined the list of intended food applications, PDP is still being proposed for use in a wide range of different food types and, in the event that it did result in GI symptoms such as diarrhoea in young children, it is may be difficult for parents or clinicians to make a link between consumption of the ingredient and the onset of symptoms. We would therefore welcome any evidence or scientific arguments that you can offer as to whether PDP is likely to be tolerated to a greater or lesser extent by young children, compared with adults, and how the intake by this young age group could be controlled. Members observed that any evidence derived from the existing use of PDP as an authorised food additive would be of limited relevance, since the intake resulting from food additive use would be significantly lower than the likely intake as a novel food ingredient.

You also asked whether the alternative names that you proposed were suitable. We have already advised you about the UK position with regards to the term fibre. Members also pointed out that food labelling regulations require that the legal name of a food should be used in ingredient lists (where one has already agreed) and we have confirmed this with colleagues in the Agency's Food Labelling Branch. It therefore appears that you would have to use the name phosphated distarch phosphate if your application was successful. The labelling regulations require the legal name to be supplemented additional description, where this is necessary to inform consumers of the true nature of the food ingredient.

The Committee will meet again on 20 September, when it will consider the text of a draft opinion on this application. If you have any additional information to add to your dossier we would be grateful if you could provide this by **Friday 17 August** at the very latest.

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

**Response from the applicant
(20 August 2007)**

**Secretariat
August 2007**

RESPONSE - ACNFP Comments 18/7/2007: RS4-Fibre Novel Foods Submission

Comment 1:

The ACNFP welcomed the glycaemic response study, which provides useful information about the risk of hyperglycemia if the ingredient is consumed by diabetics. The Committee noted that there may also be a theoretical risk of hypoglycemia if insulin-dependent diabetics were to calculate their insulin dose on the basis of the glucose content of PDP, and we would welcome your comments on this point.

Response 1:

The glycaemic response of PDP is comparable to that of normal starch (flour) from a safety perspective.

It is important to note that PDP will not be marketed directly to the consumer and claims in relation to glycaemic index/response etc., just as they do at present for foods containing other slowly digestible carbohydrates, must be based on analysis of the final products that are consumed.

It is assumed that a diabetic would calculate the glycaemic (glucose) load via the carbohydrate content of the food listed on its nutrition panel. It is standard code of practice in food labelling to make allowance for the fibre content when calculating the g of carbohydrate. Under current UK FSA guidance, it is acceptable to analyse the fibre content of foods using the AOAC methodology for nutrition labelling purposes. Hence, it is the “available carbohydrate” (sum of free sugars and complex carbohydrates, but not fibre) that is listed on the nutrition panel (i.e. total grams of carbohydrate – grams of fibre = g of available carbohydrate). Thus only the available carbohydrate (digestible starch & glucose) from PDP will be labelled on the nutrition panel of the final food, therefore further avoiding the risk of hypoglycaemia. This is explained in more detail in Section XI.2 of the application dossier. Typically the food manufacturer will calculate the total carbohydrate content of the food per 100 g and then measure the total fibre content of the food per 100 g and subtract the fibre from the total to reach the “available carbohydrate”.

National Starch is familiar with the marketing responsibilities of resistant starch type products and provides advice for consumers, food manufacturers and health professionals on its supporting websites. For example please look at the National Starch international supporting website for resistant starch, www.resistantstarch.com. This web-site can be updated to provide more information on RS4 following novel foods approval. Currently there is a classification of the four types of RS referenced and, under the digestive health section within Health Focus, it states that “resistant starch promotes regularity with mild laxative effect “.

Comment 2:

The Committee also noted the results of the in vitro fermentation study. However, they consider that it is not possible to extrapolate from the available data on tolerance and fermentability to the situation in young children, whose gut flora is developing and does not have an adult composition until the age of about 11 or 12. The child's gut is a very different environment to that of adults, and it is known that children are more sensitive than adults to the laxative effects of other poorly absorbed ingredients e.g. polyols. The Committee cannot therefore be certain that PDP will be tolerated to the same extent by children as by adults.

Although you have refined the list of intended food applications, PDP is still being proposed for use in a wide range of different food types and, in the event that it did result in GI symptoms such as diarrhoea in young children, it is may be difficult for parents or clinicians to make a link between consumption of the ingredient and the onset of symptoms. We would therefore welcome any evidence or scientific arguments that you can offer as to whether PDP is likely to be tolerated to a greater or lesser extent by young children, compared with adults, and how the intake by this young age group could be controlled. Members observed that any evidence derived from the existing use of PDP as an authorised food additive would be of limited relevance, since the intake resulting from food additive use would be significantly lower than the likely intake as a novel food ingredient.

Response 2:

We understand the concerns of the Committee in relation to small children and recognise that is an issue for all fibre and “fibre-like” ingredients. We would also like to respectfully point out that there is no data from either animal or human studies that would indicate that GI symptoms would be disproportionately negative compared to other fibre and “fibre-like” ingredient sources. When reviewing the risk, arguably the issue of major concern for these types of effects, especially in children is the size of the individual serving, or the bolus dose. Results from the human clinical study (Pieters et al.1971) show that a dose of 60 g per day for adults, or approximately 1g/kg bw/day, delivered as 2 daily portions, was well tolerated. Taking into account that the maximum serving size for any of the food groups proposed is 15g per 100g, it is unlikely that this will be exceeded for small children. 15 g per day is also equivalent to the 97.5th percentile intakes for children. We also note that PDP is not proposed for use in any drinks. In review of the latest intake data we have provided, we would also like to note that the mean intake values for children are only a third to a half of the upper intake levels ranging between at 0.3-0.4 g/kg bw/day, making the above conclusions highly conservative.

A further review of individual food group intakes from Tables A1 and B1 of the most recent intakes report provided to the Committee further supports the fact that, even at maximum addition levels of 15 g per 100g of food daily consumption of any individual food group would not realistically exceed 15 g. Indeed in most cases it is less than half this level.

Table A-1 Estimated Daily Intake of RS4-fibre* from Individual Proposed Food-Uses by Children Aged 1½ to 4½ Years Within the U.K. (NDNS, 1992-1993)

Food-Use Category	% Users	Actual # of Total Users	All-Person Consumption				All-Users Consumption			
			Mean (g)	Percentile (g)			Mean (g)	Percentile (g)		
				90	95	97.5		90	95	97.5
<u>Cereals and Cereal Products</u>										
Batters and Breading	50.5	833	0.13	0.37	0.49	0.57	0.25	0.49	0.57	0.80
Biscuits (sweet)	82.9	1,366	1.97	4.44	5.52	6.43	2.23	4.54	5.57	6.30
Cakes and Muffins	32.7	539	0.59	2.09	3.21	4.21	1.80	3.73	4.66	5.89
Pizza Dough	14.1	233	0.26	0.81	1.92	3.01	1.80	4.03	5.27	6.01
Breakfast, nutritional, and energy bars	1.8	30	0.03	na	na	na	1.38	2.87	4.23	5.89
<u>Crisps and Savoury Snacks</u>										
Savoury biscuits, crackers and non-extruded snacks	64.6	1,064	1.04	2.85	3.61	4.50	1.58	3.30	4.06	5.04
<u>Pasta and Noodles</u>										
Canned Pasta	30.2	498	1.39	5.25	7.53	10.39	4.58	9.88	13.07	15.09
Pasta Contained in Ready Meals	1.3	21	0.02	na	na	na	1.91	3.21	3.86	6.09

Table B-1 Estimated Daily Intake on a Body Weight Basis of RS4-fibre* from Individual Proposed Food-Uses by Children Aged 1½ to 4½ Years Within the U.K. (NDNS, 1992-1993)

Food-Use Category	% Users	Actual # of Total Users	All-Person Consumption				All-Users Consumption			
			Mean (mg/kg bw)	Percentile (mg/kg bw)			Mean (mg/kg bw)	Percentile (mg/kg bw)		
				90	95	97.5		90	95	97.5
<u>Cereals and Cereal Products</u>										
Batters and Breading	50.5	833	8.7	25.9	33.5	40.3	17.3	33.1	40.3	50.8
Biscuits (sweet)	82.9	1,366	136.8	307.6	372.8	437.7	156.6	313.8	370.5	445.8
Cakes and Muffins	32.7	539	41.4	146.5	221.3	283.8	126.2	258.6	329.7	397.8
Pizza Dough	14.1	233	17.5	56.5	131.6	195.8	123.5	253.7	347.3	484.7
Breakfast, nutritional, and energy bars	1.8	30	1.8	na	na	na	101.1	243.2	323.1	479.1

Table B-1 Estimated Daily Intake on a Body Weight Basis of RS4-fibre* from Individual Proposed Food-Uses by Children Aged 1½ to 4½ Years Within the U.K. (NDNS, 1992-1993)										
Food-Use Category	% Users	Actual # of Total Users	All-Person Consumption				All-Users Consumption			
			Mean (mg/kg bw)	Percentile (mg/kg bw)			Mean (mg/kg bw)	Percentile (mg/kg bw)		
				90	95	97.5		90	95	97.5
<u>Crisps and Savoury Snacks</u>										
Savoury biscuits, crackers and non-extruded snacks	64.6	1,064	72.3	195.4	257.9	332.3	111.9	232.5	294.9	362.8
<u>Pasta and Noodles</u>										
Canned Pasta	30.2	498	99.0	351.7	546.6	791.3	327.6	746.3	879.0	1,094.2
Pasta Contained in Ready Meals	1.3	21	na	na	na	na	131.3	232.9	277.5	392.6

To reassure the Committee further, we would be prepared to consider additional labelling of any food product that would deliver in excess of 15g per serving, that is deliberately marketed to small children (for example with cartoon characters and other similar promotions) with the following:

“* may cause increased laxation in small children”

As an additional general note, we are aware that this food ingredient has been on the US market (estimated quantity of approx. 900 – 1800 tonnes/year) in tortillas, breads and sweet baked goods for the last 5 years. As far as we are aware there have been no warning letters issued by the FDA on this product and no recalls or published reports of unusual dietary events. We provided more detail on products on the market in the US in Annex H of the original application dossier (<http://www.food.gov.uk/multimedia/pdfs/annexh1.pdf>). More updated information is now available, please see the attached file. The product is used in a wide range of products including both traditional and non-traditional applications, including white pan breads and buns, whole grain foods, pasta, noodles, breakfast cereals, dairy products, confectioneries and meat products. Typical incorporation level is 10%.

Comment 3:

You also asked whether the alternative names that you proposed were suitable. We have already advised you about the UK position with regards to the term fibre. Members also pointed out that food labelling regulations require that the legal name of a food should be used in ingredient lists (where one has already agreed) and we have confirmed this with colleagues in the Agency's Food Labelling Branch. It therefore appears that you would have to use the name phosphated distarch phosphate if your application was successful. The labelling regulations require the legal name to be supplemented additional description, where this is necessary to inform consumers of the true nature of the food ingredient.

Response 3:

"Phosphated distarch phosphate" is not the "legal" name for this food ingredient. It is only one chemical name for it. Indeed it is not the name used in food additive labelling for the product. The Food Labelling Regulations 1996¹, as amended, state as follows:

Relevant sections with regard to the labelling of modified starches

Name prescribed by law

Reg 6.—(1) *If there is a name prescribed by law for a food, that is to say if a particular name is required to be used for the food, that name shall be used as the name of the food.*

(2) *The name used for food specified in Schedule 1 shall be the name required by that Schedule.*

(3) *A name that is required to be used for a food by paragraph (1) or (2) of this regulation may be qualified by other words which make it more precise.*

Indication of true nature of food

Reg 8. *If—*

(a) *there is no name prescribed by law for a food, and*

(b) *there is no customary name or the customary name is not used,*

the name used for the food shall be sufficiently precise to inform a purchaser of the true nature of the food and to enable the food to be distinguished from products with which it could be confused and, if necessary, shall include a description of its use.

SCHEDULE 4

Regulation 14(9)

CATEGORIES OF ADDITIVES WHICH MUST BE IDENTIFIED IN A LIST OF INGREDIENTS BY THEIR CATEGORY NAME

Modified starch²

The "name prescribed by law" used for this ingredient on food ingredients lists is, as stated above, "**modified starch**". The same provisions apply at EU level under Directive 2000/13/EC.

¹ 1996 No 1499 The Food Labelling Regulations 1996 – implement Council Directive 79/112/EEC (OJ No. L33 8.2.79) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (excluding the provisions relating to net quantity, and except in relation to certain additives), replaced by Council Directive 2000/13/EC (OJ No. L109 6.5.2000)

We would propose to modify this title to “**resistant (modified) (maize) starch**”, and maintain that this would provide an identification of the ingredient that is consistent with the “legal name” for this material that is “sufficiently precise” and is indeed far more understandable to the consumer than “phosphated distarch phosphate”, which has never appeared on food ingredient lists for the food additive application for the same material. The term would appear in the main part of the ingredients list and would not use the E1413 number that is used only with the food additive application. We acknowledge that the term “fibre” is a nutrition claim and subject at this time to individual Member State legislation and its enforcement. We also recognise the current UK position on this issue.

National Starch Food Innovation

20 August 2007

References

ANNEX 3 to ACNFP/84/x

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Draft Initial opinion

**Secretariat
August 2007**