

Mr Andreas Klepsch  
European Commission  
*By email*

2 September 2011

Reference: NFU 760

### **Initial Opinion: Phosphated Distarch Phosphate**

Dear Mr Klepsch,

On 13 November 2009, the UK Competent Authority accepted an application from MGP Ingredients for the use of Phosphate Distarch Phosphate as a novel food ingredient, in accordance with Article 4 of regulation (EC) 258/97. The Advisory Committee on Novel Foods and Processes (ACNFP) reviewed this application and their opinion is attached. I apologise for the delay in submitting this opinion as the ACNFP's evaluation was extended while we obtained additional information from the applicant.

In view of the ACNFP's opinion, the UK Competent Authority considers that Phosphate Distarch Phosphate at levels, not exceeding the maximum use levels described, meets the criteria for acceptance of a novel food defined in Article 3(1) of regulation 258/97, subject to the labelling requirements detailed in the attached ACNFP opinion.

I am copying this letter and the ACNFP's opinion to the applicant.

Yours sincerely,

*(By e-mail only)*

Dr Chris Jones  
For the UK Competent Authority

## ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

### OPINION ON AN APPLICATION UNDER THE NOVEL FOOD REGULATION FOR PHOSPHATED DISTARCH PHOSPHATE AS A FOOD INGREDIENT

**Applicant:** MGP Ingredients

**Responsible Person** Dr Ody Maningat

**EC Classification** 2.1

#### Background

1. An application has been submitted by MGP Ingredients for the authorisation of a phosphated distarch phosphate produced from wheat starch as a novel food ingredient in a range of low moisture food products.
2. Phosphated distarch phosphate is a chemically modified resistant starch derived from high amylose vegetable starch. Resistant starch (RS) is commonly defined as “the sum of starch and products of starch degradation not absorbed in the small intestine of healthy individuals”. RS is divided into four types and Phosphated distarch phosphate is classified as a type 4 resistant starch (RS4). This classification covers chemically modified starches, which are the most resistant forms of modified starch. The novel ingredient contains a minimum of 66% dietary fibre (as measured by the AOAC method) and not more than 0.4% residual phosphorus, which is covalently bound to the starch molecules.
3. Phosphated distarch phosphate is currently listed as an approved food additive (E1413)<sup>1</sup> for use *quantum satis*<sup>2</sup>. This approval applies only to its use for technological purposes and E1413 is currently used in products such as soups, sauces, gravies and fruit fillings as a freeze-thaw-stable thickener. The use of Phosphated distarch phosphate for nutritional purposes is a new development and is therefore subject to the Novel Food Regulation (EC) 258/97.
4. This application for authorisation 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. Phosphated distarch phosphate has been classified as a complex novel food ingredient from a non-GM source having a history of food use in the community (class 2.1).

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<sup>1</sup> European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (as amended)

<sup>2</sup> maximum level not specified, in accordance with good manufacturing practice at a level not higher than it is necessary to achieve the intended purpose

5. This is the second application for the authorisation of phosphated distarch phosphate that has been considered by the Committee<sup>3</sup>. In 2009 the Committee completed its assessment of a similar phosphated distarch phosphate product derived from maize starch<sup>4</sup>. This assessment highlighted concerns regarding potential gastro-intestinal (GI) intolerance in children and concluded that there should be an accompanying advisory statement on all products containing the product.
6. As there are significant similarities between these two applications, this opinion is broadly similar, and has the same conclusions as that issued in April 2009.

## I. Specification of the novel ingredient (NI)

Dossier p 11 – 19, Annex I-A, and I-B

7. The application is for two slightly different preparations of phosphated distarch phosphate which will be referred to as the novel ingredient (NI) with reference to the amount of RS-4 present (i.e. 66% or 76%) where it is necessary to distinguish between the two forms.
8. Although the specification for the NI given in Table I-2 of the dossier contained a number of inconsistencies, the specification detailed below has been amended to take account of these and is consistent with those seen for the previous application.
9. The applicant also carried out a routine analysis the raw material (wheat flour) for heavy metal, pesticide and mycotoxins and the analytical limits are detailed in Table 1-5 (p18) of the dossier and Annex 1-B. The applicant does not provide any analysis of individual batches of the NI, but has provided Technical Data Sheets which are supplied to customers (Annex 1-A) and these provide reassurance that the NI is produced within specification.

Company specifications for two phosphated distarch phosphate products made from wheat starch				
Analyte	Description		Method	Frequency
	Fibersym <sup>®</sup>	FiberRite <sup>®</sup>		
<b>Compositional (Dry basis)</b>				
Phosphated Distarch Phosphate	85%	75%	AOAC 991.43	Every Lot
Unmodified Wheat Starch	15%	25%		
<b>Physical</b>				

<sup>3</sup> Application from National Starch – see <http://www.food.gov.uk/multimedia/pdfs/phosphateddistarchphosphate.pdf>

<sup>4</sup> <http://www.food.gov.uk/multimedia/pdfs/pdpfinalopinionapril09.pdf>

<b>Company specifications for two phosphated distarch phosphate products made from wheat starch</b>				
<b>Analyte</b>	<b>Description</b>		<b>Method</b>	<b>Frequency</b>
	<b>Fibersym<sup>®</sup></b>	<b>FiberRite<sup>®</sup></b>		
Appearance	Fine Powder	Fine Powder	Visual	Every Lot
Colour	White to off white	White to off white	Visual	Every Lot
Odour	None	None	Sensory	Every Lot
<b>Chemical</b>				
Residual phosphorus	Not more than 0.4%	Not more than 0.4%	AOAC 995.1	Every lot
Arsenic	Not more than 1 mg kg <sup>-1</sup>	Not more than 1 mg kg <sup>-1</sup>	SW-8466010B R2.0	Annually
Lead	Not more than 2 mg kg <sup>-1</sup>	Not more than 2 mg kg <sup>-1</sup>	SW-8466010B R2.0	Annually
Mercury	Not more than 0.1 mg kg <sup>-1</sup>	Not more than 0.1 mg kg <sup>-1</sup>	SW-8467471A R1.0	Annually
PH (25% slurry)	4.5 – 6.5	4.5 – 6.5	PRL002 – pH meter	Every Lot
Ash	Not more than 3%	1	AACC 08-03	Every Lot
<b>Nutritional data (g per 100g)</b>				
Moisture	10.6	12.5	PRL019 Mettler moisture meter	Every Batch
Energy (Calories)	56.0	85 <sup>4</sup>		
Total Dietary Fibre (dry matter basis)	76.0 (minimum)	65.6 (minimum)	AOAC 991.43	Every Batch
Ash	0.99	1.17	AACC 08-03	Nutritional Sample
Protein	0.5%	0.5%	LECO Combustion	Nutritional Sample
Total fat	0.50	0.34	GC	Nutritional Sample

**Discussion:** *The Committee was satisfied with the additional information provided by the applicant on the specification of the NI and accepted that the compositional data show that it is reliably produced within the defined specification.*

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

Dossier p.19-22, Annex II-A

10. The starting material for the production of the NI is a starch slurry mixture derived from wheat starch (Figure II-1 of the dossier). Wheat starch is widely used in the food industry and the starch used in this instance is produced by the applicant. The starch is treated with sodium tripolyphosphate and sodium trimetaphosphate under alkaline conditions and with mild heating (47°C). The resulting slurry is then adjusted to pH 6, and is then dried to produce a final product with 76% fibre, or heat treated to produce a version containing 66% (See also Section XI below). The

production process yields products which are within the EU specification for production of phosphated distarch phosphate for additive purposes.

11. In response to a request from the Committee the applicant provided information regarding the stability of the products. The applicant investigated changes in moisture content and total dietary fibre and used infrared spectroscopy to identify changes in the physico-chemical structure of the carbohydrates. These studies found no substantive change in either form of the NI during a 2-5 year storage period.
12. The production of the NI is in accordance with Hazard Analysis Critical Control Point (HACCP) procedures (Dossier, Confidential Annex II-A).

*Discussion: The Committee noted that the production process of the NI is similar to that of the approved food additive phosphated distarch phosphate (E1413). Members accepted that there were appropriate controls in place on the production of the NI to ensure the safety of the final product. Although the applicant did not provide any data examining the stability of the NI in food matrices, Members were reassured by the analyses carried out by the applicant to demonstrate the stability of the NI over an extended time period.*

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

Dossier p.22-24

13. The applicant notes that the source material, wheat, is a widely available and extensively consumed commodity crop which has been subject to intensive breeding for many years. The applicant highlights that new varieties require a degree of scrutiny before they can be used commercially and notes that although there are few concerns about the safety of wheat *per se*, there are certain sets of the population for whom wheat is contra-indicated (see section XIII below).

*Discussion: The Committee noted that there is a substantial history of consumption of wheat, the source used to produce the NI.*

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

Dossier p.24-34

14. The applicant is proposing to market the NI as a source of dietary fibre and as a replacement for flour in a relatively diverse range of foods. The applicant has not specified whether the introduction of the foods containing the NI will be restricted geographically. The applicant originally proposed that the NI be incorporated into a wide range of products including bread products, breakfast cereals, pasta biscuits and cakes at levels of up to 15%. Based on these proposed use levels, the applicant used data from a number of UK National Diet and Nutrition Surveys (NDNS) to estimate the anticipated daily intake of NI and residual (bound) phosphorus for the

different population groups, in the EU. Although these data were viewed by the Committee to provide a reasonable estimate of consumption of the NI, as the applicant intended to incorporate the NI into a different range of foods to those proposed by the company responsible for the first application (see para 5 above), the Committee noted that an estimation of intake from these food groups was required to determine the potential level of consumption of phosphate distarch phosphate from all dietary sources.

15. As a result the applicant subsequently amended their proposed food categories to mirror those proposed in the earlier application, as shown in the following table.

<b>Amended proposed food uses and use levels for NI and the corresponding levels of added phosphorus</b>			
<b>Food Category</b>	<b>Proposed Food Uses</b>	<b>Maximum Use Level (%)</b>	<b>Added Phosphorus (1) (%)</b>
Cereals and Cereal Products (including bakery products)	Batters and breadings	15	0.06
	Biscuits (sweet)	15	0.06
	Cakes and Muffins	15	0.06
	Pizza Dough	15	0.06
	Breakfast / nutritional / energy bars	15	0.06
Crisps and Savoury Snacks	Savoury biscuits, crackers and non-extruded snacks	15	0.06
Pasta and noodles	Canned pasta	15	0.06
	Pasta contained in ready meals	15	0.06

(1) Assuming a maximum of 0.4% of residual phosphorus

16. An intake assessment was carried out for these food uses by the original applicant who estimated that the mean daily intake of the NI will vary between 4.9 g/person (0.07 g/kg bw) for adult women and 9.0 g/person (0.17 g/kg bw) for male teenagers and high level daily intake will vary between 14.2 g/person (0.22 g/kg bw) for adult women to 25.3 g/person (0.53 g/kg bw) for male teenagers. On a body weight basis, the highest estimated intake is in young children (mean 0.38 g/kg bw/day, high level 1.09 g/kg bw/day). In practice, it is unlikely that these “worst case” intakes will be reached as it would necessitate the incorporation of the NI at the maximum level in all staple “starchy” foods.

**Discussion:** *The Committee accepted that their previous view regarding estimated intake applied for the NI. The Committee previously noted that*

*exposure to the NI was within the range tolerated in clinical studies (1 g/kg bw/day), with the exception of high level intake in small children. While there is a degree of conservatism in the calculation of these intake estimates, the potential for high levels of intake by young children requires careful consideration (see section XI below).*

## **X. Information from previous human exposure to the novel food or its source**

Dossier p.34-37

17. The applicant notes that the NI is permitted as a food additive in the EU and although they are of the view that there are no available data quantifying consumption as a food additive in the UK, the previous applicant noted that the current consumption of the additive E1413 is less than 0.5g/day.

The applicant also cites UK Government data which states that average daily starch consumption is 156g per person, equating to 26.4% of a daily diet. *Discussion: The Committee accepted that there was evidence that the NI had been consumed as a food additive in the EU.*

## **XI. Nutritional information on the novel food**

Dossier p.37-50, Annexes XI-A,B, C and D

18. The applicant provided a detailed overview of the chemistry of starch and resistant starch. This aspect is covered in the previous application and is therefore not reproduced in this paper. Three studies which have been carried out by the applicant and were therefore not reported in the earlier application are detailed below.

- a) The applicant highlights an *in vitro* fermentation studied carried out on the NI (76%) comparing production of short chain fatty acids with a potato based resistant starch and the results of an earlier (1990) report which looked at a number of different starches. (Dossier, p45-46 and Annex XI-A). The applicant is of the view that, allowing for variation seen as a result of the two studies being carried out separately, the profiles are comparable, although there were some differences in the proportion of butyrate.
- b) The applicant reports a relatively old *in vivo* study where 12 healthy volunteers were fed 60g of a maize-based Phosphated distarch phosphate over 4 successive days with no adverse reactions. This study (Pieters *et al.*, 1971) was also reported in the previous application. To confirm these findings the applicant has carried out an additional human tolerance study using their NI (76%) (Dossier, p46-47 and Annex XI-B). In this study 10 young adults consumed 30-33g of a range of resistant starches including their NI (76%) every day over three 3 week periods. The applicant reports the study as showing no

adverse reactions other than a mild increase in flatulence which was associated with consumption of resistant starch. Although some subjects showed significant differences in the profile of faecal bacteria the possible consequences of this are not considered.

- c) The applicant has also carried out a study to assess the effect of the NI (76%) on the glycaemic and insulinaemic response of healthy individuals (Dossier p 47-48 and Annex XI-C, D) and monitored plasma insulin and glucose following consumption of muffins and cereal bars containing the NI. When incorporated into muffins, the NI had a greater effect on postprandial insulinaemia than it did on parallel measurements of glycaemia, while the reduction in glycaemia was greater when the NI was added to cereal bars. The applicant notes that similar matrix effects have been reported with other resistant starches.

19. Based on the results of these studies and others in cited from the scientific literature the applicant is of the view that the NI behaves no differently from naturally occurring resistant starch (RS1 & RS2) and resistant starch which is formed by cooking (RS3).

**Discussion:** *The Committee agreed that the points raised in their consideration of the earlier application applied directly to this NI. These were as follows:*

*A review article by Nugent, (2005)<sup>5</sup> investigated the health properties attributed to the consumption of resistant starch. This review summarises reports in the literature that indicate that the regular consumption of high levels (>30 g/day) of resistant starch may give rise to intolerance.*

*Although Members agreed that the human study carried out by the applicant together with an unpublished human study by Pieters et al., (1971) provided reassurance that the consumption of up to 60g of the NI per day would not give rise to GI significant intolerance in healthy adults, they questioned whether this conclusion could be extended to other population groups such as children, in whom gut microflora is still developing and does not have an adult composition until the age of about 11 or 12. Also, it is known that children are more sensitive than adults to the laxative effects of other poorly absorbed ingredients such as polyols.*

*Members noted that there are ongoing discussions at international level regarding the definition of 'fibre', independent of this application. The current UK advice, based on the view of the Scientific Advisory Committee on Nutrition is that the quantification of dietary fibre (for nutrition labelling purposes) should be carried out using AOAC methodology, a method that includes resistant starch in the definition of fibre. However, the UK currently*

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<sup>5</sup> Nugent, A.P. 2005. Health properties of resistant starch. Nutr Bull BNF 30:27-54.



*advises that, for the purpose of health claims, the term "fibre" means non starch polysaccharides and excludes chemically modified resistant starch.*

*In practical terms this means that food manufacturers in the UK could include the contribution of the NI in the declared fibre content for nutrition labelling purposes, but could not refer to 'fibre' in the context of dietary or health claims. Until health claims are harmonised at EU level, products marketed in other EU member states have to comply with the relevant national rules concerning nutrition and health claims.*

## **XII. Microbiological information on the novel food**

Dossier pp.15-17 & 50-51

20. The production of the NI does not involve the use of microorganisms and the manufacturing process is controlled through HACCP procedures
21. The applicant addresses issues of microbiological purity in the specification section (Appendix 1 p18), and also reports the results of a microbiological analysis of both forms of the NI (five independent batches), all of which were found to be within specification. The microbiological specification is as follows:

**Table I-2 Company specifications for two phosphated distarch phosphate products made from wheat starch**

Analyte	Description		Method	Frequency
	Fibersym <sup>®</sup> RW	FiberRite <sup>®</sup> RW		
<b>Microbiological</b>				
Aerobic plate count	10,000 cfu/g max	10,000 cfu/g max	FDA-BAM 8 <sup>th</sup> Ed Rev.A Ch. 3	Every Lot
Moulds & Yeasts	200 cfu/g max	200 cfu/g max	FDA-BAM 8 <sup>th</sup> Ed Rev.A Ch. 18	Every Lot
<i>Escherichia coli</i>	Negative	Negative	FDA-BAM 8 <sup>th</sup> Ed Rev.A Ch. 4	Every Lot
<i>Salmonella</i> spp.	Negative	Negative	AOAC 990.13	Every Lot

cfu = colony forming units

**Discussion:** *Members accepted that the production process did not give cause for microbiological concern, and that the compliance with the specification would require the NI to be demonstrably free from pathogenic micro-organisms.*

### **XIII. Toxicological information on the novel food**

Dossier p.51 - 73

22. The applicant notes that as the NI is an authorised additive it has undergone an extensive safety evaluation in the EU. The applicant reports a large number of studies which were similarly reported in the previous application (See para 5 above) and are not summarised here.

#### ***Discussion:***

*The Committee agreed that the points raised in their consideration of the earlier application applied directly to this NI. The Committee therefore accepted that the available toxicological data provided adequate reassurance that the NI was not toxic. The human study by Pieters et al., (1971) provided reassurance that the proposed uses of the NI would not give rise to GI intolerance in healthy adults but the Committee questioned whether these results were applicable to high level consumption in young children (See section XI above).*

#### **Allergenicity and labelling**

Dossier p.73-4

23. The applicant accepts that wheat is known to make a significant contribution to adverse reactions to food and acknowledges that the NI will have to be labelled in accordance with EU labelling requirements. The applicant states that the NI would not contribute any greater risk to wheat intolerant consumers than other commercially available wheat starch already used in the food industry.
24. The applicant acknowledged the concerns raised by the Committee regarding consumption by children highlighted in the previous application also apply to their products (see XI discussion, above) and in line with the Committee's conclusion regarding this issue (see footnote 4) proposes that they should include an advisory label to the effect that it may cause laxative effects in young children.

#### ***Discussion***

*The Committee accepted the applicant's view that, as an ingredient obtained from wheat, it is unlikely that the product presented any greater allergy risk to consumers than the source material and that it will be labelled in accordance with EU labelling requirements.*

*In line with the previous application the Committee noted that the use of a name such as "resistant modified (wheat) starch" would be appropriate for the NI and would be in line with EU food labelling regulations.*

*In its 2009 opinion (see paragraph 5,above) the Committee welcomed an applicant's intention to include an advisory label regarding possible GI intolerance noting that "this statement should clearly indicate that consumption of the NI may cause laxative effects in small children." Following a number of reasoned objections by other EU Member States, this application was referred to the European Food Safety Authority (EFSA) for additional assessment. EFSA recently issued a positive opinion on the safety of the product<sup>6</sup> which states that there was no evidence to justify the mandatory inclusion of such an advisory label.*

*This Committee has considered the EFSA opinion<sup>7</sup> and although Members do not accept this position they agreed to amend their suggested statement to "may cause altered bowel habits". In coming to this view the Committee noted that, as many of the food categories would be attractive to, and consumed by, children, it should be possible for an applicant to gain ethical approval to carry out a limited and non-invasive study to determine the level at which consumption of the NI by children gives rise to intolerance. However until these data were available it was prudent to require an advisory statement on all foods containing the NI.*

*In line with the previous application the Committee also remains of the view that the applicant should consider the provision of additional information to ensure that the consumer is fully informed as to the nature of the NI. This could be achieved via a reference to a website and a manufacturer's careline.*

## **Overall discussion**

*The Committee advised that issues of concern which were raised in the previous opinion (see para 5) were also applicable to this product. The Committee noted that the NI was an authorised food additive and, on this basis, accepted that it was unlikely to give rise to any toxicological concerns. However, Members expressed concern that use as an additive was at levels significantly lower than that proposed in this application. Although data were provided to demonstrate that the NI would not give rise to gastrointestinal intolerance in adults at the proposed levels of consumption, The Committee was concerned that a number of the proposed food categories would clearly be consumed to some extent by children, even if adults were the primary target for products containing the NI.*

*The Committee noted that, as a chemically modified starch, the NI was unlikely to be fermented by gut bacteria in the same manner as other classes of resistant starch. By comparison with other forms of resistant starch, it*

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<sup>6</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/1772.htm>

<sup>7</sup> ACNFP101/5

*seems likely that a higher proportion of RS4 (chemically modified) starch would reach the large intestine, as a result of its lower digestibility, and it is also possible that its influence on bacterial fermentation would extend further along the colon. This makes it difficult to predict the consequences of consumption in all groups of consumers with confidence. In view of this, and mindful that unexplained digestive disturbances in children are an increasingly common cause for concern among parents and physicians, the Committee concluded that all food containing the NI should carry an accompanying advisory statement for children.*

## **CONCLUSION**

The Advisory Committee on Novel Foods and Processes is satisfied by the evidence provided by the applicant, MGP ingredients that the range of uses for the novel ingredient (Phosphated Distarch Phosphate) is acceptable subject to the labelling requirement described above.

**August 2011**