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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to sodium phosphate and increase in endurance performance (ID 318, 2887) and increase in endurance capacity (ID 318, 2887) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to sodium phosphate and increase in endurance performance (ID 318, 2887) and increase in endurance capacity (ID 318, 2887) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to sodium phosphate and increase in endurance performance and increase in endurance capacity. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is sodium phosphate. The Panel considers that sodium phosphate is sufficiently characterised.

Increase in endurance performance

The claimed effects are "supports an increase in performance during maximal aerobic exercise lasting 10 minutes or longer" and "supports an increase in VO_2 max". The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to increase in endurance performance. The Panel considers that an increase in endurance performance is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the one human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of sodium phosphate on endurance performance.

¹ On request from the European Commission, Question No EFSA-Q-2008-1105, EFSA-Q-2008-3620, adopted on 08 April 2011.

Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: <a href="mailto:ndegard-

³ Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens.

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On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of sodium phosphate and increase in endurance performance.

Increase in endurance capacity

The claimed effects are "supports an increase in performance during maximal aerobic exercise lasting 10 minutes or longer" and "supports an increase in VO_2 max". The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to increase in endurance capacity. The Panel considers that an increase in endurance capacity is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of sodium phosphate and increase in endurance capacity.

KEY WORDS

Sodium phosphate, endurance capacity, endurance performance, health claims.



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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B



INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion, is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is sodium phosphate.

Sodium phosphate is the generic name denoting the salts of sodium and phosphoric acid, which for the purpose of this opinion include sodium dihydrogen phosphate (also known as monobasic sodium phosphate), disodium hydrogen phosphate (also known as dibasic sodium phosphate), and sodium phosphate (also known as tribasic sodium phosphate).

Sodium phosphates can be measured in foods by established methods.

The Panel considers that the food constituent, sodium phosphate, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Increase in endurance performance (ID 318, 2887)

The claimed effects are "supports an increase in performance during maximal aerobic exercise lasting 10 minutes or longer" and "supports an increase in VO₂ max". The Panel assumes that the target population is adults performing endurance exercise.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to increase in endurance performance. Endurance performance relates to the ability to complete certain tasks with higher intensity, faster, or with a higher power output when performing long-term exercise.

The Panel considers that an increase in endurance performance is a beneficial physiological effect.

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⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.



2.2. Increase in endurance capacity (ID 318, 2887)

The claimed effects are "supports an increase in performance during maximal aerobic exercise lasting 10 minutes or longer" and "supports an increase in VO_2 max". The Panel assumes that the target population is adults performing endurance exercise.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to increase in endurance capacity. Endurance capacity refers to the exercise time to self-reported fatigue when exercising at a constant workload or speed.

The Panel considers that an increase in endurance capacity is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The four references provided for the scientific substantiation of the claims reported on human intervention studies on the effects of (tribasic) sodium phosphate consumption in athletes performing endurance exercise (Cade et al., 1984; Kreider et al., 1990; Kreider et al., 1992; Stewart et al., 1990). While all four of these studies assessed the effects of the intervention on maximal oxygen uptake (VO₂ max), only three were considered pertinent for the respective claims considered in this opinion; these were the two which assessed changes in endurance performance (Kreider et al., 1990; Kreider et al., 1992), and the one which assessed changes in endurance capacity (Stewart et al., 1990).

3.1. Increase in endurance performance (ID 318, 2887)

In a randomised, cross-over, double-blind, placebo controlled, five-week intervention study (Kreider et al., 1990), seven male competitive distance runners (VO₂ max 73.9±6.3 mL/kg/min) received 1 g of tribasic sodium phosphate or 1 g placebo (unspecified) four times daily for six days each, with a two-week wash-out period in between. On days 3 and 6 of supplementation, either a maximal running stress test or a 5-mile performance run test on a treadmill (one on each day) were conducted, the order of which was randomised. Perception of work effort was monitored by Borg's 10 point rating of perceived exertion scale. Ventilatory anaerobic thresholds were determined subjectively by visual inspection of respiratory data. Other outcomes measured were biochemical variables (phosphate, lactate, haemoglobin, haematocrit, 2,3-diphosphoglycerate), heart rate, oxygen uptake, maximal ventilation, and respiratory quotient both during the maximal running stress test and during the 5-mile performance run test, as well as performance time during the 5-mile performance run test. No power calculations were performed and no adjustment for multiple comparisons was made. Performance time during the 5-mile run was assessed as a measure of endurance performance. No significant differences between the sodium phosphate and placebo groups were observed with respect to performance time during the 5-mile run. The Panel notes that this study does not show an effect of sodium phosphate consumption on endurance performance.

In a randomised, cross-over, double-blind, placebo-controlled intervention study (Kreider et al., 1992), six trained male cyclists and triathletes participated in assessing the effects of phosphate loading on maximal and endurance exercise performance. Subjects consumed either 1 g of tribasic sodium phosphate or placebo (glucose) four times daily for three days prior to performing either an incremental maximal cycling test or a simulated 40 km time trial on a computerised race simulator. They continued the supplementation protocol for an additional day and then performed the remaining maximal or performance exercise test. Subjects observed a 17-day wash-out period between testing sessions and repeated the experiment with the alternate supplement (tribasic sodium phosphate or placebo) in identical fashion. Outcomes measured were biochemical variables, echocardiographic and haemodynamic variables, and anaerobic thresholds during the maximal and during the 40 km performance time trial. No power calculations were performed and the primary outcome of the study is unclear. Final performance time during the 40-km race was assessed as a measure of endurance



performance. The Panel notes that it is unclear whether comparisons between groups were performed, and whether these were statistically significant. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that the one human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of sodium phosphate on endurance performance.

The Panel concludes that a cause and effect relationship has not been established between the consumption of sodium phosphate and increase in endurance performance.

3.2. Increase in endurance capacity (ID 318, 2887)

In a randomised, cross-over, double-blind, placebo-controlled intervention study (Stewart et al., 1990), eight well-trained male cyclists (VO₂ max 48.5±8.3 mL/kg/min) received 600 mg of sodium phosphate or 600 mg placebo (white flour) in capsules six times daily for three days prior to a cycling test, with a one-week wash-out period in between treatments. All subjects had a control cycling test first. Cycling tests consisted of a 5-min warm-up pedalling at a workload of 3 kp/min with a pedalling frequency of 60 rpm and a power output of 180 watts. After this warm-up, the workload increased by 60 watts every 2 min each time until the subjects could no longer maintain the pedalling frequency. Outcome variables were VO_2 max, biochemical variables (phosphate, 2,3-diphosphoglycerate), and endurance capacity (i.e. duration of performance on the bicycle ergometer). The Panel notes the small number of subjects recruited, that no power calculations were performed, that no adjustment for multiple comparisons was made, and that the primary outcome of the study is unclear. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of sodium phosphate and increase in endurance capacity.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

• The food constituent, sodium phosphate, which is the subject of the health claims, is sufficiently characterised.

Increase in endurance performance (ID 318, 2887)

- The claimed effects are "supports an increase in performance during maximal aerobic exercise lasting 10 minutes or longer" and "supports an increase in VO₂ max". The target population is assumed to be adults performing endurance exercise. In the context of the proposed wordings, it is assumed that the claimed effects refer to increase in endurance performance. An increase in endurance performance is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of sodium phosphate and increase in endurance performance.

Increase in endurance capacity (ID 318, 2887)

• The claimed effects are "supports an increase in performance during maximal aerobic exercise lasting 10 minutes or longer" and "supports an increase in VO₂ max". The target population is assumed to be adults performing endurance exercise. In the context of the



proposed wordings, it is assumed that the claimed effects refer to increase in endurance capacity. An increase in endurance capacity is a beneficial physiological effect.

• A cause and effect relationship has not been established between the consumption of sodium phosphate and increase in endurance capacity.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1105, EFSA-Q-2008-3620). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

REFERENCES

Cade R, Conte M, Zauner C, Mars D, Peterson J, Lunne D, Hommen N and Packer D, 1984. Effects of phosphate loading on 2,3-diphosphoglycerate and maximal oxygen uptake. Medicine and Science in Sports and Exercise, 16, 263-268.

Kreider RB, Miller GW, Williams MH, Somma CT and Nasser TA, 1990. Effects of phosphate loading on oxygen uptake, ventilatory anaerobic threshold, and run performance. Medicine and Science in Sports and Exercise, 22, 250-256.

Kreider RB, Miller GW, Schenck D, Cortes CW, Miriel V, Somma CT, Rowland P, Turner C and Hill D, 1992. Effects of phosphate loading on metabolic and myocardial responses to maximal and endurance exercise. International Journal of Sport Nutrition, 2, 20-47.

Stewart I, McNaughton L, Davies P and Tristram S, 1990. Phosphate loading and the effects on VO2max in trained cyclists. Research Quarterly for Exercise and Sport, 61, 80-84.



APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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⁶ OJ L12, 18/01/2007

⁷ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).



It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to



describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- ➤ Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- > The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- > the claimed effect of the food in the identified function is beneficial.
- ➤ a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity



consumed.

- ➤ where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- > the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- > the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

> on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.



APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.



APPENDIX C

Table 1. Main entry health claims related to sodium phosphate, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording	
318	Sodium phosphate	Supports an increase in performance during maximal aerobic exercise lasting 10 minutes or longer	Phosphate supplementation increases maximum oxygen uptake in endurance athletes Phosphate supplementation	
			aids aerobic performance in endurance athletes	
			Phosphate supplementation increases oxygen transport in endurance athletes	
	Conditions of use			
	- 3.6 grams per day for 3 d	ays prior to the exercise test		
ID	Food or Food constituent	Health Relationship	Proposed wording	
2887	Sodium phosphate	Supports an increase in VO2max	Phosphate supplementation increases maximum oxygen uptake in endurance athletes	
			Phosphate supplementation aids aerobic performance in endurance athletes	
			Phosphate supplementation increases oxygen transport in endurance athletes	
			Phosphate supplementation improves endurance performance in endurance athletes	
			Phosphate supplementation delays fatigue during intense exercise	
			Phosphate supplementation helps maintain endurance performance in endurance athletes	
			Phosphate supplementation delays time to exhaustion in endurance athletes	



GLOSSARY AND ABBREVIATIONS

rpm Rounds per minute

VO₂ max Maximal oxygen uptake