SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to phosphorus and function of cell membranes (ID 328), energy-yielding metabolism (ID 329, 373) and maintenance of bone and teeth (ID 324, 327) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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 phosphorus and the following claimed effects: normal function of cell membranes, normal energy-yielding metabolism, maintenance of normal bone and teeth. 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 phosphorus, which is a well recognised nutrient and is measurable in foods by established methods. The Panel considers that phosphorus is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of phosphorus and normal function of cell membranes, normal energy-yielding metabolism and maintenance of normal bone and teeth.

The evidence provided does not establish that inadequate intake of phosphorus leading to impaired function of the above health relationships occurs in the general EU population.

The Panel considers that, in order to bear the claims, a food should be at least a source of phosphorus as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

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**KEY WORDS**

Phosphorus, minerals, cell membrane, energy metabolism, bone, teeth, health claims.
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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to 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 phosphorus, which is a well recognised nutrient and is measurable in foods by established methods.


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

2. Relevance of the claimed effect to human health

2.1. Function of cell membranes (ID 328)

The claimed effect is “cell membrane's structure (in the form of phospholipids)”. The Panel assumes that the target population is the general population.

The Panel considers that normal function of cell membranes is beneficial to human health.

2.2. Energy-yielding metabolism (ID 329, 373)

The claimed effects are “energy production” and “energy metabolism”. The Panel assumes that the target population is the general population.

The Panel considers that normal energy-yielding metabolism is beneficial to human health.

2.3. Maintenance of bone and teeth (ID 324, 327)

The claimed effects are “structure of bones and teeth” and “bone and teeth structure”. The Panel assumes that the target population is the general population.

The Panel considers that maintenance of normal bone and teeth is beneficial to human health.

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3. **Scientific substantiation of the claimed effect**

Phosphates are involved in many metabolic and structural functions as well as the regulation of the acid-base balance. Phosphorus is part of many organic compounds such as nucleic acids, inositol triphosphate, creatine-phosphate, ATP, AMP or phospholipids. Phosphorus is an essential nutrient in energy metabolism as it intervenes in the production, storage and transfer of energy. Phosphorylation-dephosphorylation reactions are crucial to many aspects of metabolic control (Anderson et al., 2006).

3.1. **Function of cell membranes (ID 328)**

Phosphorus is a component of phospholipids, the major constituents of most biological membranes. Phosphorus-depleted rats show several abnormalities including reduction of myocardial inorganic phosphorus, phosphatidylcholine, phosphatidylethanolamine, total phospholipid phosphorus and impaired fatty acid oxidation; all suggesting defective phospholipid synthesis as a mechanism to explain cellular membrane injury (Knochel, 2006; IoM, 1997).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of phosphorus and the normal function of cell membranes. However, the evidence provided does not establish that inadequate intake of phosphorus leading to impaired function of cell membranes occurs in the general EU population.

3.2. **Energy-yielding metabolism (ID 329, 373)**

Energy production and storage in the body depend on adequate sources of phosphorus including adenosine triphosphate, creatine phosphate, and other phosphorylated compounds (Knochel, 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of phosphorus and normal energy-yielding metabolism. However, the evidence provided does not establish that inadequate intake of phosphorus leading to impaired energy metabolism occurs in the general EU population.

3.3. **Maintenance of bone and teeth (ID 324, 327)**

Phosphorus is a structural component of bone and teeth. Between 80 and 85% (600-900 g in adults) of total body phosphorus exists as phosphate in the calcium salt hydroxyapatite. Inorganic phosphorus (Pi) moves in and out of bone mineral by two processes: ionic exchange and active bone resorption. Adequate phosphorus intake throughout childhood and adolescence is needed to achieve maximum peak bone mass in young adulthood which is a determinant of bone mineral status in later life. Bone tissue typically has a slow rate of turnover (remodelling) in adults, but its dynamic ion exchange permits the maintenance of Pi concentration as well as that of the ionic calcium in blood serum and extracellular fluids (Anderson et al., 2006; IoM, 1997). Calcium, phosphate, and fluoride in saliva, plaque fluid, and the inter-crystal water are key components for maintaining intact hydroxyapatite crystals in teeth (ten Cate et al., 2008).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of phosphorus and maintenance of normal bone and teeth. However, the evidence provided does not establish that intake of phosphorus inadequate for the maintenance of normal bone and teeth occurs in the general EU population.
4. Panel’s comments on the proposed wordings

4.1. Function of cell membranes (ID 328)
The Panel considers that the following wording reflects the scientific evidence: “Phosphorus contributes to normal function of cell membranes”.

4.2. Energy-yielding metabolism (ID 329, 373)
The Panel considers that the following wording reflects the scientific evidence: “Phosphorus contributes to energy metabolism”.

4.3. Maintenance of bone and teeth (ID 324, 327)
The Panel considers that the following wording reflects the scientific evidence: “Phosphorus contributes to the maintenance of normal bone and teeth”.

5. Conditions and possible restrictions of use
The Panel considers that in order to bear the claims a food should be at least a source of phosphorus as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population. Tolerable Upper Intake Levels (UL) have not been established for phosphorus in children, adolescents and adults.

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

- The food constituent, phosphorus, which is the subject of the health claims is sufficiently characterised.

Function of cell membranes (ID 328)
- The claimed effect is “cell membrane's structure (in the form of phospholipids)”. The target population is assumed to be the general population. Normal function of cell membranes is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of phosphorus and normal function of cell membranes.
- The evidence provided does not establish that inadequate intake of phosphorus leading to impaired function of cell membranes occurs in the general EU population.
- The following wording reflects the scientific evidence: “Phosphorus contributes to normal function of cell membranes”.

Energy-yielding metabolism (ID 329, 373)
- The claimed effects are “energy production” and “energy metabolism”. The target population is assumed to be the general population. Normal energy-yielding metabolism is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of phosphorus and normal energy-yielding metabolism.
- The evidence provided does not establish that inadequate intake of phosphorus leading to impaired energy-yielding metabolism occurs in the general EU population.
The following wording reflects the scientific evidence: “Phosphorus contributes to energy metabolism”.

**Maintenance of bone and teeth (ID 324, 327)**

- The claimed effects are “structure of bones and teeth” and “bone and teeth structure”. The target population is assumed to be the general population. Maintenance of normal bone and teeth is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of phosphorus and maintenance of normal bone and teeth.
- The evidence provided does not establish that intake of phosphorus inadequate for the maintenance of normal bone and teeth occurs in the general EU population.
- The following wording reflects the scientific evidence: “Phosphorus contributes to the maintenance of normal bone and teeth.”

**Conditions and possible restrictions of use**

- In order to bear the claim a food should be at least a source of phosphorus as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

**DOCUMENTATION PROVIDED TO EFSA**

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1111, EFSA-Q-2008-1114, EFSA-Q-2008-1115, EFSA-Q-2008-1116, EFSA-Q-2008-1160). The scientific substantiation is based on the information provided by the Members 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:


**REFERENCES**


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 foods (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 FOOD

Foods are commonly involved in many different functions 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 phosphorus, including conditions of use from similar claims, as proposed in the Consolidated List.

<table>
<thead>
<tr>
<th>ID</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>324</td>
<td>Phosphorus</td>
<td>Structure of bones and teeth</td>
<td>Phosphorus supports the structure of bones and teeth</td>
</tr>
</tbody>
</table>

#### Conditions of use

- Daily amount to be consumed to produce claimed effect: 550 milligram(s)

Are there factors that could interfere with bioavailability: No

Length of time after consumption for claimed effect to become apparent: Habitual intake

The body can normally tolerate a wide range of phosphate intake. Supplemental intakes in excess of 750 mg/day may cause osmotic diarrhoea. Hyperphosphataemia usually has a pathological cause such as hypoparathyroidism or renal glomerular failure.

The product must contain at least 15% of the RDA

Agency guidance for supplements is that products containing >250 mg of phosphorus should carry the label advisory statement “[This amount of Phosphorus] may cause mild stomach upsets in sensitive individuals”

<table>
<thead>
<tr>
<th>ID</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>327</td>
<td>Phosphorus/Phosphates as Na-, K-, Ca-, Mg-salts</td>
<td>Bone and teeth structure</td>
<td>Phosphorus is necessary for the structure of bone and teeth</td>
</tr>
</tbody>
</table>

#### Conditions of use

- MINDESTENS 15% RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG

- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006

Agency guidance for supplements is that products containing >250mg phosphorus should carry the label statement ’[This amount of phosphorus] may cause mild stomach upsets in sensitive individuals.’

Agency guidance for supplements is that products containing >1500mg Calcium should carry the label statement ’[This amount of Calcium] may cause mild stomach upset in sensitive individuals.’

Agency guidance for supplements is that products containing >400mg Magnesium should carry the label statement ’[This amount of Magnesium] may cause mild stomach upset in sensitive individuals.’

Applicable to both children and adults

<table>
<thead>
<tr>
<th>ID</th>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>328</td>
<td>Phosphorus/Phosphates as Na-, K-, Ca-, Mg-salts</td>
<td>Cell membrane’s structure (in the form of phospholipids)</td>
<td>Phosphorus is necessary for the structure of cell membranes</td>
</tr>
</tbody>
</table>

#### Conditions of use

- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO
Phosphorus related health claims

REGULATION 1924/2006

Agency guidance for supplements is that Products containing >250mg phosphorus should carry the label statement '[This amount of phosphorus] may cause mild stomach upsets in sensitive individuals.'

Agency guidance for supplements is that products containing >1500mg Calcium should carry the label statement '[This amount of Calcium] may cause mild stomach upset in sensitive individuals.'

Applicable to both children and adults

Agency guidance for supplements is that products containing >400mg Magnesium should carry the label statement '[This amount of Magnesium] may cause mild stomach upset in sensitive individuals.'

- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance

  Number of nutrients/other substances that are essential to claimed effect: 1

  Names of nutrient/other substances and Quantity in Average daily serving: 160 mg phosphorus

  Weight of average daily food serving: 100 gram(s)

  Daily amount to be consumed to produce claimed effect: 100 gram(s)

  Number of food portions this equates to in everyday food portions: 1

  Length of time after consumption for claimed effect to become apparent: dependent on the individuals' nutritional status

  Other conditions for use: Product should be consumed in the context of a healthy diet and lifestyle

<table>
<thead>
<tr>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phosphorus/Phosphates as Na-, K-, Ca-, Mg- salts</td>
<td>Energy metabolism</td>
<td>Phosphorus is necessary for normal energy metabolism.</td>
</tr>
</tbody>
</table>

Conditions of use

- MINDESTENS 15 % RDA JE 100 G ODER 100 ML ODER JE PORTION GEMÄß 90/496/EWG

- MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006

  Agency guidance for supplements is that Products containing >250mg phosphorus should carry the label statement '[This amount of phosphorus] may cause mild stomach upsets in sensitive individuals.'

  Agency guidance for supplements is that products containing >1500mg Calcium should carry the label statement '[This amount of Calcium] may cause mild stomach upset in sensitive individuals.'

  Agency guidance for supplements is that products containing >400mg Magnesium should carry the label statement '[This amount of Magnesium] may cause mild stomach upset in sensitive individuals.'

  Applicable to both children and adults

- Daily amount to be consumed to produce claimed effect: 550 miligram(s)

  Are there factors that could interfere with bioavailability: No
Phosphorus related health claims

Length of time after consumption for claimed effect to become apparent: Habitual intake

The body can normally tolerate a wide range of phosphate intake. Supplemental intakes in excess of 750 mg/day may cause osmotic diarrhoea. Hyperphosphataemia usually has a pathological cause such as hypoparathyroidism or renal glomerular failure.

- Does claim rely on the presence/presence in a reduced quantity/absence of a nutrient or other substance: Presence of a nutrient or other substance

Number of nutrients/other substances that are essential to claimed effect: 8

Names of nutrient/other substances and Quantity in Average daily serving: 0.25mg Vitamin B1, 0.29mg Vitamin B2, 3.20mg Vitamin B3, 1.08mg Vitamin B5, 0.36mg Vitamin B6, 2.70mg Zinc, 144.00mg Phosphorus, .03mg Biotin

Daily amount to be consumed to produce claimed effect: 500g

Length of time after consumption for claimed effect to become apparent: Depends on the individual's nutritional status

<table>
<thead>
<tr>
<th>Food or Food constituent</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phosphorus</td>
<td>Energy production</td>
<td>Takes part in the energy production and in the metabolic processes at cellular level.</td>
</tr>
</tbody>
</table>

Conditions of use

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GLOSSARY / ABBREVIATIONS

AMP  Adenosine monophosphate
ATP  Adenosine-5’-triphosphate
Pi    Inorganic phosphorus
UL   Tolerable Upper Intake Levels