

Discussion Paper on
NUTRITION CLAIMS
AND
FUNCTIONAL CLAIMS

Prepared by Directorate General Health and Consumer Protection
(SANCO D4)
European Commission

http://europa.eu.int/comm/dgs/health_consumer/index_en.htm

This discussion paper attempts to present in a neutral and objective way the main issues that have emerged in discussions relating to the harmonisation of rules on nutrition claims and functional claims in order to extend understanding of the rationale behind the various approaches to these issues.

It does not represent the opinion of the Commission or its services.

This discussion paper presents the points that need to be considered and debated with a view to introducing a legislative proposal for harmonisation. It invites comments in particular on the following issues:

- definitions
- conditions under which claims may be made
- type of evaluation and authorisation system for claims

Parts of this discussion paper put forward criteria for making nutrition claims, since relevant work has already been carried out in national and international fora. These criteria are presented in order to have a starting point for the discussion.

On the basis of the comments received, the Commission services will prepare a proposal for a measure on this subject.

Health claims as such, and in particular “disease risk reduction claims”, are not dealt with in this paper. The Commission is aware that there are types of claims other than nutrition claims and functional claims used in labelling, presentation and advertising of foodstuffs. These are covered by legislation or other measures in some Member States. They are under discussion in other Member States and international fora, such as Codex Alimentarius and the Council of Europe. Given the complexity of the issue, these claims will be the subject of a separate consultation at a later stage.

The deadline for comments is:

FRIDAY 20 JULY 2001

Written comments should be sent to:

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INTRODUCTION:

1. As food production has become more and more complex, consumers are increasingly interested in the information appearing on food labels. They have also become more interested in their diet, its relationship to health, and, more generally, the composition of foodstuffs that they are selecting. For these reasons it is important that information about foodstuffs and their nutritional value appearing on the labelling and used for their presentation, marketing and advertising should be clear, accurate and meaningful.
2. The European Community has adopted detailed rules on labelling¹ and nutrition labelling². However, this is not the case with some specific claims. There is, of course, the basic provision that claims should not mislead the consumer to a material degree and proper enforcement would go a long way to prevent abuse in this area. However, Member States and stakeholders have pointed out that this general principal could be open to different interpretations and therefore was not satisfactory for dealing with some specific claims.
3. The food industry has responded to the increased interest of consumers in nutrition by providing nutrition labelling on many foods and by highlighting the nutritional value of products through claims in their labelling, presentation, marketing and advertising. Many would argue that this evolution could be considered as a positive one for providing relevant information to the consumer. However, for the food industry, it was also an opportunity to use claims as a marketing tool.
4. In view of the proliferation of the number and type of claims appearing on the labels of foodstuffs and in the absence of specific provisions at European level, some Member States have adopted legislation and other measures to regulate their use. This has resulted in different approaches and in numerous discrepancies both regarding the definition of the terms used and the conditions warranting the use of claims. These discrepancies could act as barriers to guaranteeing a high level of consumer and public health protection, and could constitute obstacles to the free movement of foodstuffs and the proper functioning of the internal market.
5. For these reasons, harmonisation of rules on claims at Community level is being advocated. For consumers, rules concerning classification and conditions for use of nutrition claims and functional claims have a very high priority. Industry also would favour uniform rules across the Community for a number of reasons. In its White Paper on Food Safety (Paragraph 101, Action n° 65), the Commission proposed consideration of whether to introduce specific provisions to govern “nutrition claims” and “functional claims”, in order to reach the twin objective of achieving both the free movement of foodstuffs between Member States and a high level of consumer protection.

GENERAL CONSIDERATIONS

6. Directive 2000/13/EC provides that the labelling, presentation and advertising of foodstuffs should not mislead the consumer as to the characteristics of the foodstuff, or by attributing to the product effects or properties it does not possess, or by suggesting that

¹ Directive 2000/13/EC of the European Parliament and of the Council relating to the labelling, presentation and advertising of foodstuffs, OJ L 109 p.29 of 6.5.2000.

² Council Directive 90/496/EEC on nutrition labelling of foodstuffs, OJ L 276 p. 40 of 6.10.1990.

the foodstuff possesses special characteristics when in fact all similar products possess such characteristics.

7. In this context, it may be necessary to ensure that claims made on specific foods do not state or imply that a varied and adequate diet cannot provide sufficient quantities of nutrients and that the presence or absence of a nutrient or other substance or ingredient is not emphasised as a special characteristic when in fact it is common to all similar products.
8. A very important aspect is the actual communication and presentation of claims in respect of food products. It is often argued that the information provided on foods is not always understood well by consumers. Therefore, ways in which information is communicated have to be considered very carefully. A claim that is not understood is completely useless while a claim that is misunderstood could even be misleading. The actual wording, logos and images used to state or imply a claim and product endorsements all play important roles in the way claims are perceived and understood by the final consumer. It has been suggested that all these aspects should be addressed in possible future legislation.
9. Some have argued in favour of allowing claims about a nutrient or substance only if the overall profile of the product is nutritionally “acceptable”. For example, a “low fat” claim should only be allowed if the product does not contain high quantities of sugar or salt, etc. However, defining what is a reasonable nutritional profile could be difficult. Some say that some products which could be defined as not acceptable from a nutritional point of view, could be acceptable in the context of a total diet, and discard the idea of classifying products as “good” or “bad”. Furthermore, many products could be borderline cases.
10. An important consideration is whether claims should only be allowed if the nutrient or other substance in question is contained in the final product in a form that is bio-available, and if it is present in a quantity to justify the claim during its shelf life.
11. It should also be considered whether these claims should refer to the food as it is sold or when consumed after preparation in accordance with the instructions for use appearing on the label (for example, concentrated or dehydrated foods which are to be diluted or reconstituted by the addition of water).

DEFINITION OF THE TERM “CLAIM”

12. One of the problems encountered when talking about claims is the lack of common understanding of the terminology used. It would therefore be very important to agree on a number of relevant definitions. As a starting point, it would be useful to find a common definition for the generic term “claim”.
13. The Codex Alimentarius defines “claim” in the General Guidelines on Claims (CAL/GL 1-1979 (Rev. 1-1991)) as
“Any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition, or any other quality”.

14. This definition has many of the elements of the EU definition on nutrition claims (see below) but is justifiably broader. It needs to be considered carefully as a starting point in the search for a Community definition.
15. There have been many attempts to define the different types of claims (nutrition claims, nutrient function claim, enhanced function claim, etc.). However, the difference between them may sometimes be not very significant. They often overlap, hence the difficulty in placing them in distinct categories. Furthermore, it is doubtful that all consumers will be able to distinguish clearly between different types of claims. Nevertheless, for reasons of clarity of the rules, it would seem necessary to provide such definitions in any future Community legal measure.

NUTRITION CLAIMS

16. **Council Directive 90/496/EEC on nutrition labelling includes a definition of “nutrition claim”**, and this definition could be used as a basis for discussion. The existing definition is as follows:

“Any representation and any advertising message which states, suggests or implies that a foodstuff has particular nutrition properties due to the energy (calorific value) it:

- provides,*
 - provides at a reduced or increased rate or*
 - does not provide,*
- and/or due to the nutrients it*
- contains,*
 - contains in reduced or increased proportions or*
 - does not contain.*

A reference to qualities or quantities of a nutrient does not constitute a nutrition claim in so far as it is required by legislation”.

17. This definition was adopted over 10 years ago and for the purpose of nutrition labelling. Although it is true that the majority of nutrition claims concern nutrients or substances that have a nutritional function, such as protein, carbohydrates, fat, components of macronutrients, vitamins and minerals, there is an increasing number of claims for other substances, such as fibre, antioxidants (lutein, lycopene) and lactic bacteria, which do not have a nutritional effect but rather a physiological effect. Some argue therefore that the definition of nutrition claims should take this fact into account.
18. In order to provide consumers and industry with clear benchmarks concerning the use of these claims, clear and simple rules should be set. At the international level Codex Alimentarius has developed such guidelines for the most commonly used nutrition claims (such as “low”, “rich”, “light”, etc.). Similar criteria also exist in some Member States. For the purpose of this paper and in order to provide a starting point that will facilitate discussion, a table including the different components of a foodstuff, the type of claim in relation to it, and the conditions to be met for making the claim has been compiled and included as an Annex. The compilation takes into account both existing legislation/guidelines in some Member States and the Codex Alimentarius guidelines.

Different types of nutrition claims:

19. Amongst the many types of nutrition claims, Codex Alimentarius has defined a “nutrient content claim” as “a nutrition claim that describes the level of a nutrient contained in a food”. For example, “source of calcium”; “high in fibre”, “low in fat”. These claims could be described as “absolute” nutrition claims. On the other hand, there are “comparative” nutrition claims, which Codex has defined as “a claim that compares the nutrient levels and/or energy value of two or more foods”. For example, “reduced”, “less than”, “increased”. A compilation of some of the most commonly found nutrition claims :
- | | |
|--------------------------------|---------------|
| High /rich/excellent source of | Without/free |
| Increased | Low/weak/poor |
| Source of/contains | Reduced/Light |
20. Other commonly found claims are “**Contains x% more**”, “**Contains x% less**” and “**Without added**”. It has to be noted that this last claim often refers to the absence of other substances than nutrients, for example, additives. Furthermore, claims as to the non-addition of a nutrient/ingredient/or other substance, remain forbidden if all products of the same category are requested to be produced without that addition by law.
21. For the use of the term “**light**”, Codex Guidelines propose to follow the same criteria as for the term “reduced” and to include an indication of the characteristics which make the food “light”. Indeed, this type of claim often refers to very different components of the food: it could refer to less fat, less sugar, or less caffeine, for example.
22. Special consideration should be given to the use of the term “**diet**”. Often it has similar connotations to the term “light”, but there is a high potential for confusion between the terms “diet” and “dietary”, the latter being reserved exclusively for foods for particular nutritional uses under Community legislation³.
23. Special consideration may also be needed for all **comparative claims**. Indeed, if a comparison is made, it has to be clear which products are being compared. For example, if a product bears the claim “reduced fat”, one would ask “reduced compared to what?” and therefore there would be the need for a **reference product** with which to compare. The question then is what is the reference product. It could be a same brand product, for example “Cream Cheese” and “Cream Cheese Light”, but sometimes a same brand product does not exist.
24. All **claims relating to dietary cholesterol** merit particular attention. Indeed, some have strongly argued that, since dietary cholesterol is not a major factor in coronary heart disease and since there is a danger of confusion with blood cholesterol levels, “low cholesterol” claims, “reduced cholesterol” claims, “X% less cholesterol” claims and “cholesterol-free” claims should not be made.
25. In many instances it has been pointed out that consumers do not understand the difference between **dietary and blood cholesterol**. Most people know that eggs are very high in dietary cholesterol so they assume that by avoiding eggs completely they are doing all that is needed to lower their blood cholesterol. But they continue to eat fatty foods very rich in saturated fats. This concept misleads consumers into thinking that as long as they avoid eggs or other foods containing dietary cholesterol, they can continue to have any other food including those high in saturated fat.

³ Council Directive 89/398/EEC relating to foodstuffs intended for particular nutritional uses, OJ L 186 P. 27 of 30.6.1989

26. As far as **“low sodium” and “very low sodium” claims** are concerned, a difference in approach exists between Community legislation and the Codex Guidelines for the use of nutrition claims. Indeed, under Community legislation these two types of claims are to be regulated under Directive 89/398/EEC on foods intended for particular nutritional uses (dietetic products). This means that products making such claims are considered to be dietetic foods. However under certain conditions that can be decided under procedures defined in the above Directive, it may be possible for foodstuffs for normal consumption, which are suitable for a particular nutritional use, to indicate such suitability. The Codex Guidelines do not reserve such a claim for dietetic foods. It should also be noted that many think that the terms “sodium” and “salt” are interchangeable and that, therefore, the conditions warranting the claims for sodium are also those for claims about salt content.

CRITERIA FOR MAKING NUTRITION CLAIMS

27. It is considered that if rules on claims are to be laid down, they should apply to all foods and not only to any specific groups, with the exception of foods for particular nutritional uses. This is in particular the case with functional claims. Some operators would promote the idea of limiting such claims to a distinct category of foods that they would like to call “functional foods”. However many would object to the idea. Every food has a function and there is no good justification for creating a specific category of “functional” foods.
28. Some maintain that since **“X% fat free” or “only X% fat” claims** can be misunderstood and potentially misleading, even if factually true, they should not be allowed. For example, a product claiming to be “80% fat free”, is a product with 20% fat content, quite a high fat content for most products, but the claim “80% fat free” can lead consumers to assume that the product is low in fat.
29. For the claims **“without added” or “no added”**, many have argued that they should apply when the product has not been manufactured with the addition of the nutrient that is the subject of the claim, while the nutrient is usually added to similar products. Furthermore, as mentioned above, these claims remain forbidden if all products of the same category are requested by law to be produced without the addition of the nutrient/ingredient/other substance in question.
30. Some of the criteria used to define the term **“low”** are reported in the Annex for some nutrients. However, there may be a need to distinguish those products that are **naturally low** in a given nutrient. In this case many have expressed the preference to communicate the claim in the form: “a low (*naming the nutrient*) food”; the same is valid for the term “high” or “rich”: “a high (*naming the nutrient*) food”.
31. Under Community legislation, **claims on vitamins and minerals** are allowed if these are present in significant amounts in the product. Directive 90/496/EEC on nutrition labelling contains an Annex listing the vitamins and minerals for which claims are allowed and their Recommended Daily Allowances (RDA) and states that, as a rule, 15% of that RDA should be taken into consideration in deciding what constitutes a significant amount. It should be noted that this list of vitamins and minerals and their respective RDAs dates back to 1990 and stems from the corresponding Codex Guidelines. The revision of this Directive has been announced in the White Paper on Food Safety. In the context of this revision of this Directive, it has been suggested that the figure of 15% should be revised

too. Indeed, some have argued that 15% is quite high and that, as a consequence, many foods that are generally considered as good dietary sources of some micronutrients would not qualify for a claim.

32. For **comparative nutrient claims**, it is considered desirable that a number of **general conditions** should apply. Such general conditions could include the following:
- The foods being compared should be different versions of the same food or similar foods.
 - A statement of the amount of difference in the energy value or nutrient content should be given.
 - The following information should appear in close proximity to the comparative claim:
 - The amount of difference, expressed as a percentage (fraction, or an absolute amount);
 - The identity of the food(s) to which the food is being compared.
33. For the term **“increased”** or the term **“reduced”** Codex Guidelines propose that these claims should only be made when there is a minimum 25% increase or reduction of the nutrient that is the subject of the claim by comparison with the equivalent standard product (for which no claim is made). As mentioned above, it is important to clarify what the standard product is.
34. The 25% minimum difference set by Codex, seems to pose no major problem for the energy content and for macronutrients. Member States have not expressed a particular concern as to this condition, even if some have adopted different criteria; for example, requiring a minimum increase or reduction of 33%, or, for reduced fat claims, a 50% difference. However, **specific conditions may be necessary for vitamins and minerals**.
35. As far as **micronutrients** are concerned, the **Codex Guidelines** provide for the following:
“For micronutrients a 10% difference in the NRV would be acceptable, between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as “low” or as a “source” in the Table to the Guidelines”. The point made in paragraph 32 is relevant.
36. The terms **“more”** or **“less”** could be used when making claims for foods with changes in their energy or nutrient content of less than 25%. Again, whether and how the final consumer perceives these differences should be considered.

Specific criteria for nutrition claims: SEE ANNEX

FUNCTIONAL CLAIMS

37. In its White Paper on Food Safety, the Commission described functional claims as “claims **relating to beneficial effects of a nutrient on certain normal bodily functions**”. This would cover the claims describing the physiological role of a nutrient or other substance in growth, development and normal functions of the body. Typical examples of functional claims would be stating the presence of a nutrient or other substance and its role on human physiology, for example: “High in protein. Protein helps build and repair body tissues”.

38. **Codex Alimentarius** Guidelines for the Use of Nutrition Claims define “nutrient function claim” as “a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body”. The following examples are given: “Calcium aids in the development of strong bones and teeth”; “Protein helps build and repair body tissues”; “Iron is a factor in red blood cell formation”; “Vitamin E protects the fat in body tissues from oxidation”; “Contains folic acid: folic acid contributes to the normal growth of the foetus.”
39. The above definition could be used as a basis for defining functional claims in possible future Community legislation. Some believe that rather than developing a new definition, it would be better to use the existing Codex one, in order to avoid confusion and limit potential trade disputes. The Commission services are not aware of other serious alternatives to the Codex definition.

CRITERIA FOR THE USE OF FUNCTIONAL CLAIMS

40. Following the definition of functional claims, consideration should be given to a number of **conditions to be fulfilled for the provision of such claims**.
41. The claim must be stated in the context of the total diet and should not encourage over-consumption of a given food product. Indeed, claims on specific products should not distort the fact that it is the total diet that is important and that there are no “good” and “bad” foods *per se*, but rather balanced and unbalanced diets. Claims should not encourage excessive consumption of one or other food to the detriment of a varied diet.
42. The food for which a claim is made must be at least a significant source of the nutrient in question in the case where increased consumption is recommended. The nutrient for which a claim is made must be present in the quantity and form to justify the claim during shelf life when stored under appropriate conditions. Likewise, the food for which a claim is made must be low in, reduced in or free of the nutrient in question where reduced consumption is recommended.
43. In the case of a foodstuff from which a particular substance has been eliminated in order to reduce the risk of a negative effect (for example, the allergenicity of a protein, “lactose-free” or “low lactose”), the degree of elimination must be controlled and it must be demonstrated that such elimination has not modified the normal nutritional value or other related properties of the food.
44. There must be one or more validated methods that allow control of the chemical identity and the quantity of the nutrient for which the claim is made.
45. The claim must be communicated in such a way as to assist consumer understanding of the basis of the claim (relationship between diet, specific nutrients, or substances, and physiological benefits) and to allow people to make informed and appropriate food choices.
46. The most important aspect in the acceptance of a functional claim is that it must be based on generally accepted **scientific evidence** that is kept under regular review. Key

questions, such as how often should a review of the scientific data take place and, most of all, by whom should it be carried out, should be given specific consideration.

47. The same questions have been raised in discussions on this subject that are taking place in Codex Alimentarius and in the Council of Europe. A number of conditions relating to the substantiation of claims have emerged from those discussions and are mentioned below as a basis for discussion in the context of this document:

- The claim must be substantiated by generally acceptable scientific data.
- The substantiation must be relevant to the product that is presented to the final consumer.
- The scientific substantiation must be reviewed as new knowledge becomes available.
- The scientific substantiation of the claim must:
 - Rely on the totality of evidence that includes human studies, where available;
 - Be plausible in terms of relationship between intervention and results (dose/ frequency/ effect); and
 - Meet scientific standards of statistical and biological significance.

48. Even if conditions as above were to be agreed some would express concern about their uniform application. They would therefore maintain that a **pre-marketing approval** is necessary to ensure that claims are appropriate and avoid disputes at national or intra-community level. It has been suggested that one possible approach would be to **compile a list of approved claims for each nutrient or substance** and possibly their specific wording. Some would suggest a procedure of co-operation between Member States and the Commission for compiling and updating this list. Others think that this should be done directly at Community level and with the involvement of the future European Food Authority.

49. Another possibility could be the introduction of a **notification procedure**, for food labels bearing a claim, **to the competent authorities of Member States**. This would facilitate monitoring and allow a prompt reaction, where necessary, from the competent authority when new products and/or labels are placed on the market. A variant of this option could be that the **label is notified at European level** and is valid for the Community as a whole. This, however, would require considerable resources at that level.

50. The so-called **“two-steps” Swedish system** for the assessment and approval of claims could also be a possible option for regulating functional claims. In this system the claim must be formulated in two parts: the first part of the claim consists of information about the diet-health relationship, and it is followed by information on the composition of the product. One of the main rules in this system is that claims based on the fact that a certain product has a specific effect should not be made. Claims of this kind are subject to an application to market the product as foodstuffs for particular nutritional uses, or for registration as a natural remedy, via the medicinal products’ agency.

ANNEX:

Claims and conditions warranting the claims for different nutrients (and other substances)

CLAIM	CONDITIONS
LOW ENERGY	Codex: less than 40 kcal/100g and less than 20kcal/100ml Conditions in use in some Member States: less than 50kcal /100 g and less than 20kcal/100ml
ENERGY -FREE / WITHOUT ENERGY	Codex: less than 4kcal/100ml
LOW FAT	Codex: no more than 3g/100g and 1.5g/100ml Conditions in use in some Member States: No more than 3g per 100g for solids or per 100ml for liquids.
FAT -FREE / WITHOUT FAT	Codex: no more than 0.15g per 100g or 100ml.
LOW SATURATES or SATURATED FATTY ACIDS	Codex: no more than 1.5g per 100g for solids, 0.75g/100ml for liquids Conditions in use in some Member States: Level of saturates in the fat at most 25% and polyunsaturates level at least 60%, and the product contains at least 5 g of fat in a reasonable daily consumption level; No more than 1.5g per 100g for solids or per 100ml for liquids and should not make up more than 10% of the total energy of the product.
SATURATES or SATURATED FATTY ACIDS - FREE / WITHOUT SATURATES or SATURATED FATTY ACIDS	Codex: no more than 0.1g per 100g or 100ml.
LOW SUGAR(S)	Codex: nothing Conditions in use in some Member States: Maximum 4g/100ml for soft drinks; No more than 5g per 100g or 100ml.
SUGAR(S)-FREE / WITHOUT SUGAR(S)	Codex: no more than 0.2g per 100g or 100ml. Conditions in use in some Member States: The product contains no sugars, similar products may contain sugars; The product does not contain any kind of sugar

CLAIM	CONDITIONS
LOW SODIUM or SALT	Codex: for low sodium: no more than 0.12g/100g; For very low sodium: 0.04g/100g EU: under Community legislation, low sodium and very low sodium foodstuffs are covered by the Directive on Foods for Particular Nutritional Uses Conditions in use in some Member States: For low sodium: no more than 0.04g sodium per 100g or 100ml.
SODIUM or SALT- FREE / WITHOUT SODIUM or SALT	Codex: no more than 0.005g/100g
SOURCE OF PROTEIN	Codex: at least 10% of the RNV per 100 g; 5% of the RNV per 100 ml, or 5% of the RNV/100 kcal OR 10% of the RNV per portion Conditions in use in some Member States: If the quantity of the food reasonably expected to be consumed in 1 day contributes at least 12 g of protein; At least 12% of the energy value of the food must be provided by protein
HIGH PROTEIN / RICH IN PROTEIN/ EXCELLENT SOURCE OF PROTEIN	Codex: twice the values for “source” Conditions in use in some Member States: If protein content is at least 20%; At least 20% of the energy value of the food must be provided by protein
SOURCE OF FIBRE	Codex: at least 3g /100g , or at least 1.5g /kcal or per portion Conditions in use in some Member States: At least 3g /100g , or at least 3g in the reasonable expected daily intake of the food; At least 2.5g/1000kJ
HIGH FIBRE / RICH IN FIBRE / EXCELLENT SOURCE OF FIBRE	Codex: at least 6g per 100g, or 3g/100kcal or per portion Conditions in use in some Member States: At least 6g /100g or 100ml, or at least 6g in the reasonable expected daily intake of the foods; At least 10g/100g
SOURCE OF VITAMINS and/or MINERALS	Codex: 15% of the RNV/100 g, 7.5% of the RNV/100 ml, or 5% of the RNV/100 kcal Conditions in use in some Member States: The quantity of the food that can reasonably be expected to be consumed in 1 day must contain at least 1/6 of the RDA of two or more of the vit. or min. specified, or of all vit. and min. if claim names them; 5 to 15% of the RDA per 100 kcal or 5 to 15% of the average daily allowance when no RDA exists for one or more of the vit. and min.

CLAIM	CONDITIONS
<i>HIGH IN VITAMINS and/or MINERALS/ RICH IN VITAMINS and/or MINERALS / EXCELLENT SOURCE OF VITAMINS and/or MINERALS</i>	Codex: twice the value of “Source of” Conditions in use in some Member States: 20% of the RDA in a daily consumption deemed reasonable; <u>For Rich/excellent:</u> If a product has been fortified and contains 15-40% of RDA / 100 kcal; The quantity of the food that can reasonably be expected to be consumed in 1 day must contain at least 50% of the RDA of two or more of the vit. or min. specified, or of all vit. and min. if claim names them; <u>For Naturally rich</u> More than15% of the RDA per 100 kcal or more than15% of the average daily allowance when no RDA exists for one or more of the vit. and min.