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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E – Safety of the Food Chain
Deputy Director General

SANCO

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Subject: Orientation Paper on setting maximum and minimum amounts for vitamins and minerals in foodstuffs.

Dear Colleague,

Directive 2002/46/EC on food supplements provides for the setting of maximum and minimum amounts of vitamins and minerals in these products via the Regulatory Committee procedure. Similar provisions are contained in Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

Directorate General Health and Consumer Protection issued in 2006 a Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs¹ to obtain the views of interested parties on how these issues might be addressed.

In order to pursue the discussions of the relevant measures, Directorate-General Health and Consumer Protection has now prepared an Orientation Paper on setting maximum and minimum amounts for vitamins and minerals in foodstuffs.

It is foreseen to discuss this document in a meeting of the "Expert group on food supplements and on the addition of vitamins and minerals and of certain other substances to foods" that will tentatively take place at the end of September.

Yours sincerely,

Paola Testori Coggi

To the 27 Permanent Representations to the EU (by e-mail)

Encl: Orientation paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

¹ http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf

http://ec.europa.eu/food/food/labellingnutrition/supplements/resp_discus_paper_amount_vitamins.htm



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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Safety of the food chain
E4 - Food law, nutrition and labelling

Orientation paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

Document prepared by Directorate-General Health and Consumer Protection
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Introduction

Food Supplements

1. Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet. They are marketed in dose form such as pills, tablets, capsules, liquids in measured doses etc.
2. Directive 2002/46/EC of the European Parliament and Council of 10 June 2002 on the approximation of the laws of Member States relating to food supplements¹ establishes harmonised rules for the labelling of food supplements and introduces specific rules on vitamins and minerals in these products. The aim is to harmonise the legislation and to ensure that these products are safe and appropriately labelled so that consumers can make informed choices.
3. Although food supplements can contain a wide range of ingredients, at a first stage the Directive lays down specific provisions only for vitamins and minerals (nutrients).
4. The Directive foresees the setting of maximum and minimum amounts for vitamins and minerals by the Regulatory Committee procedure as an implementing measure.

Addition of vitamins and minerals to foods

5. There is a wide range of nutrients and other ingredients that might be used in food, including (but not limited to) vitamins, minerals, amino acids, essential fatty acids, fibre, various plants and herbal extracts.
6. Regulation 1925/2006 of the European Parliament and of the Council of 20 December 2006 harmonises the provisions laid down in Member States which relate to the voluntary addition of vitamins and minerals and of certain other substances to foods² (informally often referred to as fortification). The aim is to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.
7. The Regulation provides for the setting of maximum amounts of vitamins and minerals in these products via the Regulatory Committee procedure. Minimum amounts are linked to the notion of significant amount, where this is defined according to the Annex to Directive 90/496/EEC on nutrition labelling³.

Maximum and minimum levels of vitamins and minerals

8. The criteria to be taken into account for the establishment of maximum amounts of vitamins and minerals present in foodstuffs (food supplements and normal foods) are already listed in the legal acts and are:

¹ OJ L 183, 12.07.2002, p. 51

² OJ L 404, 30.12.2006, p. 26

³ OJ L 276, 6.10.1990, p. 40

- (a) the upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;
 - (b) the intake of vitamins and minerals from other dietary sources;
9. Due account should also be taken of reference intakes of vitamins and minerals for the population.
 10. As regards normal foods, when maximum amounts are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following shall also be taken into account, as necessary:
 - (a) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population;
 - (b) the nutrient profile of the product established as provided for by Regulation (EC) 1924/2006 on nutrition and health claims⁴.
 11. Vitamins and minerals used in food supplements or added to foods should result in a minimum amounts being present.
 12. For food supplements the Directive foresees that minimum amounts per daily portion of consumption as recommended by the manufacturer have to be set.
 13. Minimum amounts for normal foods are linked to the significant amounts as defined according to the Annex to Directive 90/496/EEC on nutrition labelling.

The Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs

14. Directorate General Health and Consumer Protection published in June 2006 a Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs⁵, which identified the main issues to be considered in this exercise, in order to obtain the view of stakeholders on how these might be addressed.
15. The public consultation was formally closed on 30 September 2006, though some responses were received later. A total of 58 responses have been received and published on the Directorate General Health and Consumer Protection website⁶.
16. The paper was structured in separate sections each raising open questions on precise issues on which we were requesting advices.
17. The contributions varied from comments on all the questions raised to responses focused on one issue only. Some respondents made very detailed comments with arguments and evidence backing their position, while some others only formulated general remarks or just gave yes/no answers.
18. In the following section we analyse the issues raised and give an outline of the possible options identified following the responses received.
19. Taking into account the above consultations as well as other relevant considerations such as the principle of food law that food has to be safe, European Court of Justice

⁴ OJ L 12, 18.1.2007, p. 3

⁵ http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf

⁶ http://ec.europa.eu/food/food/labellingnutrition/supplements/resp_discus_paper_amount_vitamins.htm

jurisprudence and the principle of better regulation, the following orientations for setting maximum levels for vitamins and minerals in foods have been put forward by the Directorate General Health and Consumers protection as the basis for pursuing discussions and the preparation of the relevant measures.

Establishment of maximum amounts for vitamins and minerals in food supplements and other foodstuffs

Tolerable upper intake level (UL)⁷

20. As indicated in the introduction, one of the criteria to be taken into account for the establishment of the maximum amounts of vitamins and minerals in foods are the upper safe levels of vitamins and minerals established by scientific risk assessment.
21. The Commission requested the Scientific Committee on Food (SCF) and later the European Food Safety Authority (EFSA) to provide scientific opinions on tolerable upper intake levels on the 29 nutrients listed in Annex I of the Directive plus boron, vanadium, nickel, tin and silicon, as requested by the European Parliament in the frame of the discussions on the food supplements Directive⁸.
22. In those scientific opinions specific numerical tolerable upper intake levels have been established for 16 nutrients. For the others the lack of sufficient scientific data and in particular the lack of systematic oral intake dose-response studies, did not allow to derive numerical upper levels. However, for some nutrients extremely low or non-existent toxicity, even at very high doses of administration, is indicated from existing evidence available from observational studies.
23. Tolerable upper intake levels not established by SCF/EFSA for the nutrients mentioned above have been set by other scientific bodies, for example, the UK Expert group on Vitamins and Minerals (EVM)⁹ or the US Institute of Medicine (IOM)¹⁰.
24. The use as appropriate of such levels, selected on a case by case basis, to complete, as necessary, the ones established by SCF/EFSA would seem to be a reasonable and practical solution and would have good support among the major interested stakeholders.
25. An indicative table of the levels established by SCF/EFSA, EVM and IOM can be found in Annex 1.

Establishment of specific maximum amounts for all nutrients

26. For several nutrients it has been scientifically established, or indicated from observational studies, that there is extremely low or non-existent toxicity even at high doses of intakes. The question is, therefore, posed as to whether it would be necessary or appropriate, in the absence of any safety concerns, to establish maximum amounts for these nutrients.

⁷ Tolerable upper intake level (UL) - the maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans
The UL is not a recommended level of intake. It is an estimate of the highest level of intake which carries no appreciable risk of adverse health effects.

⁸ <http://www.efsa.europa.eu/en/publications/scientific.html>

⁹ <http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf>

¹⁰ National Academy of Sciences. Institute of Medicine. Food and Nutrition Board National Academy of Sciences. Institute of Medicine. Food and Nutrition Board.
http://fnic.nal.usda.gov/nal_display/index.php?info_center=4&tax_level=3&tax_subject=274&topic_id=1323&level3_id=5147

27. Many respondents to the consultation we launched in 2006 consider that in the case of nutrients which are not associated with any adverse effect, there would not be any scientific basis for taking risk management measures. Any decision to establish maximum amounts for these nutrients would be disproportionate and possibly challengeable in front of the Court. It should be noted here that technological and economic (cost) considerations would have a limiting effect on the amounts of vitamins and minerals used or added.
28. Others would prefer the establishment of maximum amounts for all the nutrients listed in the Annexes of the Community measures concerned for variable reasons. One, they argue, is that the lack of evidence of adverse effects should not be taken as evidence of absence. Therefore, they propose to establish maximum amounts for such nutrients on the basis of the precautionary principle. We however see this as a straightforward misinterpretation of that principle.
29. Some respondents suggest that for nutrients for which there is no indication of adverse effects even at high levels of consumption, labelling provisions and not compositional limits should be considered. For example, consumers should be informed by a label warning of a product containing one of these nutrients at a concentration higher than the highest level experimentally tested.
30. Finally, a small group of interested stakeholders would like to be able to go above the maximum amounts that may have been established if the adverse effects that would result are minor and reversible, provided that an appropriate labelling informs consumers of the potential to have these adverse effects. However, the idea of accepting the risk of adverse effects, even if minor and reversible, is strongly questioned by a number respondents who advocate a more conservative approach.
31. We consider that overall the position not to establish maximum amounts for nutrients for which there are no evident safety concerns would seem a proportionate approach, which would be also in line with the principles of better regulation. In order to avoid relevant stakeholder concerns about the functioning of the internal market, it should be clarified in the measure to be adopted that the issue of maximum limits is fully harmonised and thus national levels could not be set for those vitamins and minerals for which no limits have been set at EU level.
32. Finally, for the nutrients for which no maximum amounts will be established, a 'priority' review system should be envisaged in case new scientific data become available.
33. There seems to be an overall agreement on the nutrients for which setting maximum levels could be waived:
 - Vitamin B1 (thiamine)
 - Vitamin B2 (riboflavin)
 - Vitamin B12
 - Biotin
 - Panthenic acid
 - Chromium (III) (?)
 - Vitamin K (?)

Intake data

34. Another criterion to be taken into consideration for the establishment of maximum amounts for vitamins and minerals in foods is their potential intakes from the various dietary sources.
35. EFSA is in a very preliminary stage of thinking how to go about on this issue and would not be able to provide help for some years to come. In the absence of overall EU data national ones would need to be used.
36. During the consultation many Member States indicate their readiness to make available to the Commission data from national surveys. However a major problem, underlined by many respondents, is that these national surveys might not be compatible with each other as conducted with different methodologies; in addition, some of them are incomplete or not up to date.
37. Real pan-European intake data are not available for the moment. Some projects initiated during the 6th research framework program exist, but will be terminated only in several years time.
38. On the other side, it has been also underlined by some respondents that the analysis of the available national data has shown that the pattern of intake of nutrients in the different European diets is quite similar.
39. We consider that a pragmatic solution would be to use in general the most appropriate available data for this specific purpose. UK and Irish data are the more recent and complete available and refer to markets that can be considered as "mature" for both food supplements and fortified foods (important availability of both categories of products). Specific cases could be handled on a case-by-case basis using valid national data presented by Member States.
40. Some help could be provided on this issue from an initiative aiming to compile an overview of the existing EU intake data for those nutrients for which there could be risks of exceeding the upper safe level. The results of this study, coordinated by the International Life Science Institute (ILSI) should be made available at the beginning of 2008.

Recommended Daily Allowances/Reference Intakes (RDAs/PRIs)

41. The third element to be taken into account when establishing the maximum amounts of vitamins and minerals is the reference intake for the population. These are amounts that, if ingested, would ensure that no deficiencies occur for the majority of the population.
42. Some Member States would support the establishment of the maximum amounts based on or limited to multiple(s) of the RDA/PRIs. This has been challenged by the Commission and condemned by the Court of Justice. The Court indicated that a case by case approach is always necessary (more details are provided in paragraph 41 of the Discussion paper on the setting of maximum and minimum amounts of vitamins and minerals in foodstuffs¹¹)

¹¹ http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf

43. RDA/PRI, however, would serve as indicators to detect deficiencies for certain nutrients in the population and used to categorise nutrients on the basis of their risk of exceeding their upper intake levels.

Population groups

44. One final aspect to be considered in setting maximum amounts for vitamins and minerals is if and eventually how the degree of sensitivity of the different population groups that can be exposed to increased intake of vitamins and minerals should be taken into account.
45. It would be very difficult to determine different maximum amounts for the different population groups due to the lack of precise and reliable intake data. Moreover, the setting of different maximum amounts for different groups could be confusing for consumers and practically would be difficult to apply, given that many of the food supplements and fortified products (e.g. dairy products, cereals, juices and soft drinks, confectionary etc) are addressed to the whole of the population. It could also be argued that the upper intake levels already take into account the specificities of the different population groups.
46. It should also be noted that foods intended to satisfy particular nutritional requirements of specific groups of the population are specifically covered by the provisions on dietetic foods (Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses¹² and related Directives¹³)

Maximum amounts for food supplements and fortified foods

47. Taking into account the above criteria and considerations maximum amounts for vitamins and minerals in food supplements and other foods should be such as to ensure that total intakes from the overall food supply do not pose risks for public health, that is, they should be safety based.
48. In addition, appropriate management measures will be necessary to manage the total maximum amounts allowed in food supplements and in normal foodstuffs to which vitamins and minerals have been added (fortified foods).
49. This will imply decisions which will have to be based not only on scientific grounds but will have to take into account also current market practices. Further discussion with industrial stakeholders will be needed in order to identify these practices and at the same time protect consumers' health.
50. While for food supplements the maximum amounts of nutrients will be set per daily dose of consumption of the supplement (e.g. per one/two/three etc pills or drops or other measure indicated by the manufacturer), for fortified food, it should be set per weight or energy of the food consumed (e.g. per 100 kcal, per 100g/ml, per portion...).
51. In order to ensure that health driven practices are preserved and a minimum significant amount is present in foods (see below) without a risk of excess intakes, there would need to be limitations and restrictions to the addition of certain vitamins and minerals

¹² OJ No L 186, 30. 6. 1989, p. 27

¹³ http://ec.europa.eu/food/food/labellingnutrition/nutritional/index_en.htm

in normal foods (e.g. addition of iodine restricted only to salt or addition of vitamin A and D reserved in priority for specific products).

52. For the establishment of maximum amounts for food supplements, among the models mentioned in the discussion paper, one has received more support (an outline of this model is given in Annex 2). However, the results provided by this model should be closely examined in order to take into account also the addition of nutrients, especially those with a narrow margin of safety, to normal foods.
53. Furthermore, it is recognised that this model can provide with a general system for categorising nutrients accordingly to the risk of exceeding the ULs determined by EFSA or by other scientific institutions. Applying this model, nutrients for which there is a risk of exceeding the UL can be identified and a more cautious approach could be considered.

Establishment of minimum amounts for food supplements and other foodstuffs

54. Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods foresees that the minimum amounts for fortified foods are correlated to the significant amount as defined in the nutritional labelling Directive (i.e. 15% RDA). The Regulation provides also with the possibility to grant derogation (Regulatory Committee procedure) for the establishment of minimum amounts different from the significant amounts defined in the nutritional labelling Directive for specific foods or categories of foods.
55. We consider that the eventual revision of the RDAs should be undertaken in the frame of the revision of the nutritional labelling Directive, not in this exercise. However, the possibility for derogations should be considered on a case by case basis, in particular to take into account additions of vitamins and minerals for specific purposes (restoration, substitution...), the specificities of the addition of nutrients to particular foods (for example, iodine and fluoride to salt) or when there is a danger to exceed the tolerable upper intake even by addition of a significant amount to foods.
56. On the contrary, for food supplements, the minimum amounts are not related to the significant amounts as defined in the nutritional labelling Directive. Stakeholders have expressed very divergent views on the opportunity and the ways to establish minimum amounts of nutrients for food supplements. Some consider this exercise not necessary as they argue that even trace quantities of nutrients should be allowed to be added to supplements. Others indicate that the minimum amounts should be established at a level corresponding to the 7.5%, 15% or 30% of the RDA. Finally, a last group of stakeholders evaluates that also the minimum amounts should be established nutrient by nutrient, on a case by case basis, as for the maximum amounts.
57. Given the nature of food supplements, i.e. to supplement the normal diet, also the minimum amounts for food supplements could be established at the level of the significant amount as defined by the nutrition labelling Directive. Case by case derogation to this rule could be considered.

Annex I
UL established by SCF/EFSA, EVM and IOL

	SCF/EFSA (UL)	IOM (UL)	EVM (SUL or GL ¹⁴)
Biotin (µg)	-	-	900 (GL in addition to foods)
Folate (Folic acid) (µg)	1000	1000	1000 (GL in addition to foods)
Nicotinic acid (mg)	10	35 (niacin)	17 (GL for supplements only)
Nicotinamide (mg)	900	35 (niacin)	560 (GL)
Pantothenic acid (mg)	-	-	200 (GL in addition to food)
Vitamin B2 (mg)	-	-	40 (GL in addition to food)
Vitamin B1 (mg)	-	-	100 (GL in addition to food)
Vitamin B6 (mg)	25	100	10 (SUL in addition to food)
Vitamin B12 (µg)	-	-	2000 (GL in addition to food)
Vitamin C (mg)	-	2000	-
Vitamin A (retinol) (µg RE)	3000 (does not apply to postmenopausal women)	3000	1500 (GL)
β-carotene (mg)	-	25 (for smokers)	7 (SUL for supplements only)
Vitamin D (µg)	50	50	25 (GL in addition to food)
Vitamin E (mg)	300	1000	800 IU (SUL in addition to food)
Vitamin K (µg)	-	-	1000 (GL in addition to food)
Sodium (mg)	-	-	-
Chloride (mg)	-	-	-
Potassium (mg)	-	-	3700 (GL in addition to food)
Calcium (mg)	2500	2500	1500 (GL in addition to food)
Phosphorus (mg)	-	4000	250 (GL in addition to food)
Magnesium (mg)	250 (for supplements only)	350	400 (GL in addition to food)
Iron (mg)	-	45	17 (GL in addition to food)
Zinc (mg)	25	40	25 (SUL in addition to food)
Copper (mg)	5 (not applicable during pregnancy or lactation)	10	10 (SUL)
Iodine (µg)	600	1100	500 (GL in addition to food)
Selenium (µg)	300	400	450 (SUL)
Manganese (mg)	-	11	12.2 (GL)
Chromium (mg)	-	-	10 (GL)
Molybdenum (µg)	600	2000	-
Fluoride (mg)	7 (for children above 8 years and adults)	10	-
Boron (sodium borate and boric acid) (mg)	10	20	9.6 (SUL)
Nickel (µg)	-	1000	-
Tin (mg)	-	-	13 (GL)
Vanadium (mg)	-	1.8	-
Silicon (mg)	-	-	1500 (SUL supplemental silica equivalent to 700 mg of elemental silicon)

¹⁴SUL: Safe Upper Levels

GL: Guidance levels. GL are determined when the database is insufficient to establish an upper intake level or when, no adverse effect has been identified.

EVM has calculated also a GL for cobalt: 1.4 mg

ANNEX 2

VITAMIN and MINERAL SUPPLEMENTS: A RISK MANAGEMENT MODEL

Part 1: Quantitative and qualitative safety characterisation of the vitamins and minerals.

- a. When tolerable upper intake levels (UL)* are set by the Scientific Committee for Food (SCF) or European Food Safety Authority (EFSA), a **quantitative safety characterisation** is able to indicate the relative potential of higher intake groups to exceed the UL by the calculation of the Population Safety Index (PSI). Using the UL set by the SCF and EFSA, the following quantitative risk characterisation can be established (based on calculated PSI value above or below 1.5):

$PSI = \frac{UL - (MHI + IW)}{RLV}$ <p>PSI: Population Safety Index UL: Tolerable upper intake level as set by SCF or EFSA IW: Intake from water (only relevant for minerals) MHI: Mean Highest Intake: Highest intake from dietary sources (97.5th percentile) based on adult male intake data from available studies (Ire, N, NI, UK) RLV: Reference Values for Nutritional Labelling as set by SCF (Opinion of 5 March 2003, SCF/CS/NUT/GEN/18 Final)</p>	Low risk of exceeding the UL			
	Nicotinamide	52.8	Vitamin D	8.1
	Vitamin E	23.2	Molybdenum	7.4
	Vitamin C	22.0	Selenium	3.6
	Vitamin B6	21.9	Phosphorus	2.1
	Potential risk of exceeding the UL			
	Iron	1.5	Zinc	0.4
	Iodine	1.1	Vitamin A (preformed retinol)	-1.2
	Copper	0.8		
	Calcium	0.6		

- b. In those cases where an UL is not established, a **qualitative risk characterisation** is required on the basis of available risk assessment. Extensive reviews by the SCF and EFSA give indications of the nature of the adverse effects associated with each nutrient and potential risks in relation to existing patterns of intake. Qualitative assessment of the SCF opinions (and other authoritative reports) show no adverse effects in healthy individuals associated with high intakes of biotin, chromium, pantothenic acid, vitamin B2, vitamin B1, vitamin B12 and Vitamin K.

Part 2: Setting of maximum levels based on the risk characterisation described in part 1.

Three risk categories for setting maximum levels for food supplements (MSL) can be differentiated:

<p>A: No evidence of risk within ranges currently consumed; Does not represent a risk to human health Vitamin B1, Vitamin B2, Biotin, Vitamin B12, Pantothenic acid, Vitamin K, Chromium</p> <p align="center">→ No setting of MSL required</p>				
<p>B: Low risk of exceeding the UL Vitamin B6, Vitamin C, Vitamin D, Vitamin E, Nicotinamide, Molybdenum, Phosphorus, Selenium UL for supplementation set by SCF: Magnesium, Folic acid</p> <p align="center">→ MSL to take into account changing dietary patterns</p> <table border="1" style="width: 100%;"> <tr> <td align="center" colspan="2">Based on UK surveys (1986/7 - 2000/1): Intake from foods and fortified foods (in a liberal market place)</td> </tr> <tr> <td> <p>For vitamins</p> <p>Show increase of intake more than 20 % only for Vitamin B6 and C. A precautionary risk management factor of 50% to take into account potential changes in dietary pattern.</p> <p>$MSL = UL - (MHI \times 150\%)$</p> </td> <td> <p>For minerals</p> <p>For technical and taste reasons, mineral fortification is self-limiting. Therefore a factor of 10% could be set.</p> <p>$MSL = UL - [(MHI \times 110\%) + IW]$</p> </td> </tr> </table>	Based on UK surveys (1986/7 - 2000/1): Intake from foods and fortified foods (in a liberal market place)		<p>For vitamins</p> <p>Show increase of intake more than 20 % only for Vitamin B6 and C. A precautionary risk management factor of 50% to take into account potential changes in dietary pattern.</p> <p>$MSL = UL - (MHI \times 150\%)$</p>	<p>For minerals</p> <p>For technical and taste reasons, mineral fortification is self-limiting. Therefore a factor of 10% could be set.</p> <p>$MSL = UL - [(MHI \times 110\%) + IW]$</p>
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<p>C: Potential risk of exceeding the UL Vitamin A, Beta-carotene (smokers), Calcium, Copper, Fluoride, Iodine, Iron, Manganese, Zinc</p> <p align="center">→ MSL to take into account RLV, risk of deficiency and risk of excessive intake</p>				

*UL: Intake levels that can be consumed daily over a lifetime without being likely to pose a risk to health according to available evidence.

GENERAL SUMMARY

