



**Fuente:** European Federation Association of Health Products Manufacturers, EHPM, and European Responsible Nutrition Alliance, ERNA. Vitamins and mineral supplements: a risk Management model. November 2004.

A continuación resumimos las principales conclusiones del documento acerca de los Niveles Máximos de Vitaminas y Minerales en los Suplementos:

## 1. Risk characterisations of Vitamins and Minerals

... On the basis of the evaluations above, taking into consideration qualitative (where no UL is available) and quantitative risk characterisations using the PSI (population safety index), three categories of vitamins and minerals emerge.

Group A. No evidence of risk within ranges currently consumed; does not represent a risk to human health	Group B. Low risk of exceeding the UL	Group C. Potential risk at excessive intakes
Vitamin B1	Vitamin B6	Vitamin A
Vitamin B2	Vitamin C	Beta-carotene (smokers)
Biotin	Vitamin D	Calcium
Vitamin B12	Vitamin E	Copper
Pantothenic acid	Folic Acid	Fluoride**
Vitamin K	Nicotinamide	Iodine
*Chromium	Phosphorus	Iron
	Magnesium	Manganese
	Molybdenum	Zinc
	Selenium	

\* The classification is based on those sources currently approved in Annex II of Directive 2002/46/EC and 2001/15/EC.

\*\* Intake data for fluoride were not available in the UK NDNS study, so is provisionally placed in Group C. US FNB reported potential risk of fluorosis in children. The final categorisation would depend on relevant intake data.

Having established categories of vitamins and minerals according to risk, the risk manager must then develop risk management strategies that proportionately reflect the risk associated with each group.



## 2. Maximum Supplement Levels (MSL)

An approach should be developed by the risk manager that reflects the relative risk associated with each risk category of nutrients.

### **2.1. Group A - No evidence of risk within ranges currently consumed; does not represent a risk to human health.**

In this context, setting an MSL cannot on the basis of the science available be considered a necessary risk management measure. Moreover, quantitative restrictions on vitamin and mineral content which are not based on risk assessment would be in breach of EU and international trade law. The individual company should therefore be responsible for establishing appropriate levels for the content of vitamin B1, B2, B12, biotin, pantothenic acid, vitamin K and chromium.

### **2.2. Group B - Low risk of exceeding the UL**

Taking into account intake from dietary sources (including fortified foods) and water, and a risk management factor that allows for potential changes in intake, maximum supplement levels can be calculated as follows:

For vitamins:  $MSL = UL - (MHI \times 150\%)$

For minerals:  $MSL = UL - [(MHI \times 110\%) + IW]$

Using data from the United Kingdom, for example, the model would give MSLs for Group B nutrients as follows in Table 2. Data from other countries could lead to some modifications.

Group B nutrients	MSL(/day)
B6 (mg)	18-93*
C (mg)	1750
D (µg)	35
E (mg)	270-970*
Nicotinamide (mg)	820
Molybdenum (µg)	350
Phosphorus (mg)	1250
Selenium (µg)	200

\* In the case of vitamins B6 and E, the risk assessments undertaken by the EC SCF and US FNB have produced widely divergent ULs. Taking into account these discrepancies, the MSL Could ultimately vary between 18 and 93mg/day for B6 and 270 and 970mg/day for vitamin E.



### Magnesium

The UL established by the SCF for magnesium is 250mg/day is for supplementation only. For technical reasons, magnesium is unlikely to be used in significant quantities in foods. A further risk management measure beyond the limit established by the SCF is therefore unnecessary. The MSL for magnesium should therefore be 250mg/day.

### Folic Acid

The UL established by the SCF for folic acid of 1000µg /day is for supplementation only. Folic acid is found foremost in breakfast cereals at levels around 100-150µg per serving. Under current levels of fortification, an individual is unlikely to exceed 400µg/day. A MSL of up to 600µg/day would therefore currently be appropriate. An increase of the RDA from 200 to 400µg/day and the potential effects on population intake will need to be monitored.

## 2.3. Group C - Potential risk of exceeding the UL

Where there is a narrow range of safe intake and a potential risk that consumers may exceed the UL on a daily basis, it may not be possible for the risk manager to use the UL as a reference point for establishing a MSL. In addition, the risk manager will need to take into account not only the risk of excessive intake, but equally the risk of insufficient intake.

Risk managers have to address the overall balance of the diet, potential nutrient interactions, the contribution of specific foods and food supplements to the nutrient intakes, and clear labelling. In addition, they must take into account, on a case-by-case basis, both the risk of deficiency and excessive intakes.

Nutrient	Proposed MSL/day
Vitamin A (µg)	800-1000
Beta-carotene (mg)	4.8-7
Calcium (mg)	1000-1500
Copper (mg)	1-2
Fluoride (mg)	3.5
Iodine (µg)	150-200
Iron (mg)	14-20
Manganese (mg)	2
Zinc (mg)	10-15

### Texto completo:

<http://www.erna.org/UserFiles/Vitamin%20and%20Mineral%20Supplements.pdf>