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# Guidance for Food Businesses: The Safety of Vitamins and Minerals in Food Supplements

Establishing Maximum Safe Levels and Risk Assessment Approach for Products Marketed in Ireland

Based on the FSAI Scientific Committee Report

# Guidance for Food Businesses: The Safety of Vitamins and Minerals in Food Supplements

## Establishing Tolerable Upper Intake Levels and Risk Assessment Approach for Products Marketed in Ireland

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Food Safety Authority of Ireland

The Exchange, George's Dock

IFSC, Dublin 1

D01 P2V6

Tel: +353 1 817 1300

Email: info@fsai.ie

www.fsai.ie



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## Purpose

This document has been created specifically for food business operators (FBOs) such as retailers, distributors and manufacturers of food supplements. The purpose of this document is to provide guidance for FBOs in order to protect consumers from potentially harmful doses of vitamins and minerals delivered by food supplements and to make the rules clearer for both FBOs and food inspectors.

The document provides an overview of:

- General guidelines on maximum amounts of vitamins and minerals that can be added to food supplements
- Calculating maximum safe levels (MSL) of vitamins and minerals in food supplements
- Scientific assessment of vitamin and mineral composition of food supplements including a step by step guide to assessing the safety of the level
- The risk assessment (RA) approach

## Legislation[1]

European Union (EU) food law (Directive 2002/46/EC) sets out the legal requirements that must be complied with when a food supplement is placed on the EU market. It provides a list of vitamins and minerals and the forms which food supplements can contain. The list is updated regularly. It also states that maximum levels of vitamins and minerals shall be set for food supplements by the European Commission. However, harmonised levels have not been established yet. In the absence of legal EU levels, there is a need for the Food Safety Authority of Ireland (FSAI) to provide guidance on maximum levels of vitamins and minerals in food supplements in Ireland to protect consumers. It is important to point out that not all vitamins and minerals have adverse effects on health at high intakes.

This guidance is based on both relevant EU legislation (appendix 2) and on the advice provided to the FSAI by its independent Scientific Committee in its report 'The Safety of Vitamins and Minerals in Food Supplements – Establishing Tolerable Upper Intake Levels and a Risk Assessment Approach for Products Manufactured in Ireland' Revision 2, 2020.

1 Food legislation is subject to amendment and updates will be provided through the FSAI website https://www.fsai.ie/

## Supplement intake in Ireland

Widespread use of food supplements has been found in dietary surveys in Ireland. As many as 22% of men and 33% of women (18-64-year olds) reported the use of a food supplement in the National Adult Nutrition Survey 2011. Supplement use was highest (37%) in those aged 65 years and over. About one fifth of pre-school children and children aged 5-12 years were regular consumers of nutritional supplements (National Preschool Nutrition Survey 2012, National Children's Food Survey II 2019) and approximately one quarter of all teenagers took food supplements (National Teens Food Survey 2008).

## National food supplementation policy

There are two national food supplementation policies in Ireland

**Folic Acid**

- 400 µg daily folic acid supplement for women of child-bearing age who are sexually active.
- Due to the scientific evidence linking a mother's folate status with abnormalities which are likely to affect a baby's spine (such as neural tube defects) or the baby's brain (anencephaly), it is recommended that all women of child-bearing age consume a 400 µg folic acid food supplement daily in addition to the folate they receive from a varied diet.

**Vitamin D**

- Infants, from birth to 1 year of age, who are being breastfed should be given a daily supplement containing 5 micrograms (µg) of vitamin D. This should be provided by a supplement containing vitamin D exclusively.
- Infants, from birth to 1 year of age, fed infant formula should not be given a daily vitamin D supplement if they are having more than 300ml (about 10 fluid ounces) of infant formula a day. This is because infant formula is fortified with vitamin D and other nutrients.

# The maximum amounts of vitamins and minerals that can be added to food supplements

EU food law provides general guidelines which must be considered in relation to the maximum levels of vitamins and minerals that can be added to food supplements.

## Maximum levels

At present General EU Food Law governs the maximum amount of vitamins and minerals that can be used in the manufacture of food supplements in the EU.

A food supplement could be considered unsafe if the amount of a vitamin or mineral in food (Table 1) plus the amount in a food supplement (added together) leads to an excessive intake. By law, food supplements can only supplement the diet, they must not replace it. Safety becomes a consideration if very high intakes of some vitamins and minerals are consumed in food supplements alongside the diet.

**General food law states an FBO shall not place unsafe food on the market**

(Article 14 (1) of Regulation (EC)178/2002)

# Medicinal Products

Products containing vitamins and minerals that make medicinal claims or contain a medicinal ingredient are considered medicinal products unless reformulated / relabelled.

Medicinal products must be appropriately authorised by the Health Products Regulatory Authority (HPRA) or the European Commission via the centralised procedure for medicinal products before being placed on the market in Ireland. The levels of vitamins and minerals proposed for inclusion in medicinal products are reviewed as part of the HPRA marketing authorisation application process. For more information, visit the HPRA's website.

# Tolerable Upper Intake Level (UL)

**Tolerable upper intake level (UL) is the highest level of long-term daily intake of a nutrient (vitamin or mineral) from all sources (all dietary intake including fortified foods and food supplements) that is not likely to cause adverse health effects**

The tolerable upper intake level (UL) is a calculation with a starting point that is generally based on the highest level of intake of a nutrient where no adverse health effects were observed in individuals in scientific studies. This is known as the No Adverse Effect Level (NOAEL). If there are no studies demonstrating a NOAEL, then a lowest observed adverse effect level (LOAEL) may be used. A LOAEL is the lowest intake at which an adverse effect has been identified in scientific studies. An uncertainty factor (UF) is applied to the NOAEL (or LOAEL) to take account of uncertainty in data, incomplete knowledge or extrapolation from animal studies. Scientific bodies such as the European Food Safety Authority (EFSA) and the Institute of Medicine (IOM) have set ULs for various vitamins and minerals. However, not all nutrients have a UL value because there is not always sufficient scientific evidence to allow a value to be established.

There are 30 vitamins and minerals permitted to be sold as food supplements in Ireland, 21 of these have ULs which vary depending on age group and life stage. **The absence of a UL does not mean that any amount of that vitamin or mineral is safe.** For example, beta carotene does not have a UL, but there is a guidance level of 15mg/day for adults that is used to assess levels in food supplements. Further information is contained in the FSAI Scientific Committee report.

When using the UL value, it is important to consider the **level of intake above the UL** and the **length of time** someone may be taking a high dose vitamin or mineral food supplement. A UL is based on safe, long-term intake of a vitamin or mineral. UL values for vitamins and minerals are summarised in Table 2 and Table 3.

# Reviewing the safety of the vitamin and mineral content in food supplements

### Step 1. Define Tolerable Upper Intake Level (UL)

Scientific evidence of the effects of vitamins and minerals at varying doses on health are looked at when conducting a risk assessment. The FSAI Scientific Committee report looked at assessments of the highest level of long-term intake of vitamins and minerals (from all sources: food, fortified foods and food supplements)**. It assessed the level that was unlikely to cause a risk to health**. This is known as the tolerable upper intake level (UL). It was assessed for different age and life stages, because these factors can have a bearing on the effects of vitamins and minerals. This report is mostly based on ULs recommended by EFSA. The IOM ULs were used where EFSA scientific evidence was lacking, see appendix 1, Table 2 and Table 3.

### Step 2. Assess whether the amount of a vitamin or mineral in a food supplement is safe

To measure the safety of vitamin and mineral food supplements, FBOs should look at how much of these nutrients people with the highest intakes[2] are consuming through diet and how much they are consuming from foods supplements and compare the sum of both to the UL (see Figure 1.) For a step by step guide to assessing the level of a vitamin or mineral in a food supplement see Figure 4.

[2] The intakes of the highest consumers relates to the 95th percentile of the population, i.e. those reported to consume the highest amounts of a nutrient. This data is obtained from Irish national dietary surveys.

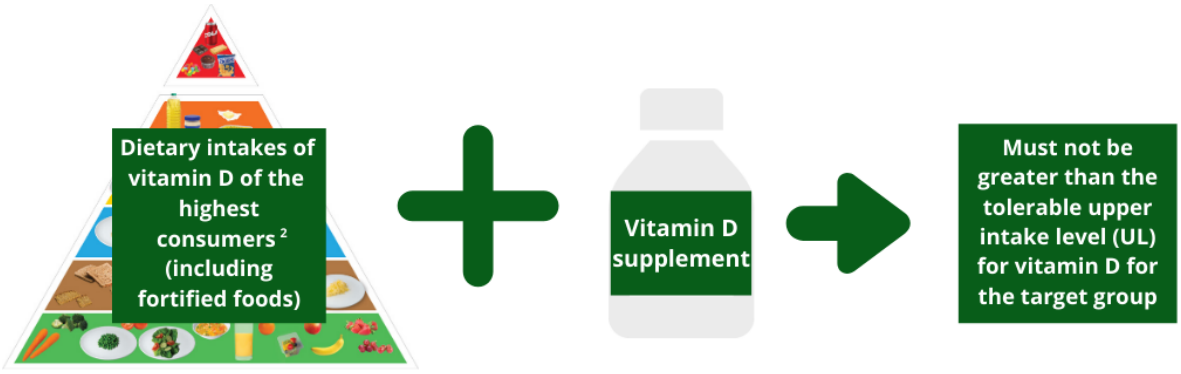



**Figure 1:** Vitamin and mineral intake from the diet plus the amount from a food supplement should not exceed the UL

Note: For some nutrients, different ULs exist for pregnant or breastfeeding women. Supplements targeting adults are also assumed to target pregnant and breastfeeding women unless the label states they are not intended for these groups. Food intake data for adults 18-64 years of age is used for pregnant and breastfeeding women.

## Accounting for Vitamins and Minerals from food and food supplements

The usual daily intake of vitamins and minerals from food (including fortified foods, but excluding food supplements) in people with the highest intakes[2] is the value used to represent dietary intake when making an assessment about the level of a vitamin or mineral in a food supplement (Table 1).

Vitamins and minerals in food supplements are easily absorbed by the body. If a food supplement with very high amounts of either a vitamin or mineral is taken alongside a varied and balanced diet, this may lead to high levels of vitamins and minerals in the body. Very high intakes can sometimes cause harmful effects. For example, high intakes of retinol in pregnancy can cause defects of the central nervous system, to the brain and the heart in infants born to these mothers.

[2] The intakes of the highest consumers relates to the 95th percentile of the population, i.e. those reported to consume the highest amounts of a nutrient. This data is obtained from Irish national dietary surveys.

# Calculating maximum safe level (MSL) of vitamins and minerals in food supplements

This document sets guideline values for safe maximum amounts of vitamins and minerals present in food supplements per daily dose as recommended by the manufacturer (maximum safe levels, MSL). They are applicable to food supplements placed on the Irish market and are set for adults and children separately. **The adult value is also suitable for teens with the exception of Vitamin A (retinol, RE µg)**. Vitamin and mineral supplementation in infants (0-1years) and young children (1–3 years) is subject to medical supervision or national public health guidelines.

Values are set for selected vitamins and minerals (7 in all) based on their potential public health importance and on recent experience of FSAI engagements with FBOs. See Table 4.

As specified in Directive 2002/46/EC, the criteria used to calculate MSL include:

(a) upper safe levels of vitamins and minerals (UL) taking into account the varying degrees of sensitivity of different consumer groups (e.g. children). A review of the literature has been completed to ensure that the ULs are still appropriate.

(b) intake of vitamins and minerals from other dietary sources in the highest consumers [2] (95th percentile of intake from foods, including fortified foods, with allowance for uncertainty in intake estimates, including possible future changes such as mandatory fortification of certain foods).

(c) taking account of reference intakes Table 5.

**General calculation: UL- 95th percentile of intake from foods + case by case review = MSL**

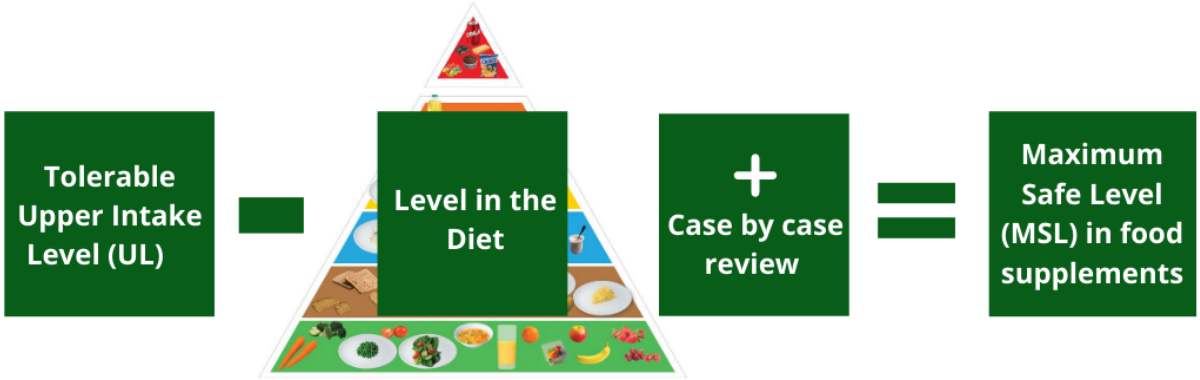



**Figure 2**: Diagram showing how the maximum safe level (MSL) of vitamins and minerals in food supplements is calculated

[2] The intakes of the highest consumers relates to the 95th percentile of the population, i.e. those reported to consume the highest amounts of a nutrient. This data is obtained from Irish national dietary surveys.

## Example: how the amount of a vitamin and/or mineral in food supplements sold in Ireland is assessed

- Maximum safe levels for a range of vitamins and minerals have been set Table 4.
- The amount of vitamins and minerals in the diets of different groups of people in Ireland has been measured over the last twenty years (Table 1).
- The amount of a vitamin or mineral in the diet is added to the amount of vitamins and minerals people are consuming from a food supplement.
- The total intake (from diet and food supplement) is compared to the UL for the group e.g. children, adults or pregnant women (Figure 3).
- The total intake (from diet and food supplement) is also compared to the reference intake (RI) for context (Figure 3). This allows us to compare the amount of a vitamin or mineral in a supplement to the level required for general health. The RIs have been set by European law and are based on an average sized adult doing an average amount of physical activity. RIs are a guideline to help consumers make healthy dietary choices (Table 5).

**Example**

Vitamin D supplement. The instructions for use on the supplement advise 1 capsule/day.

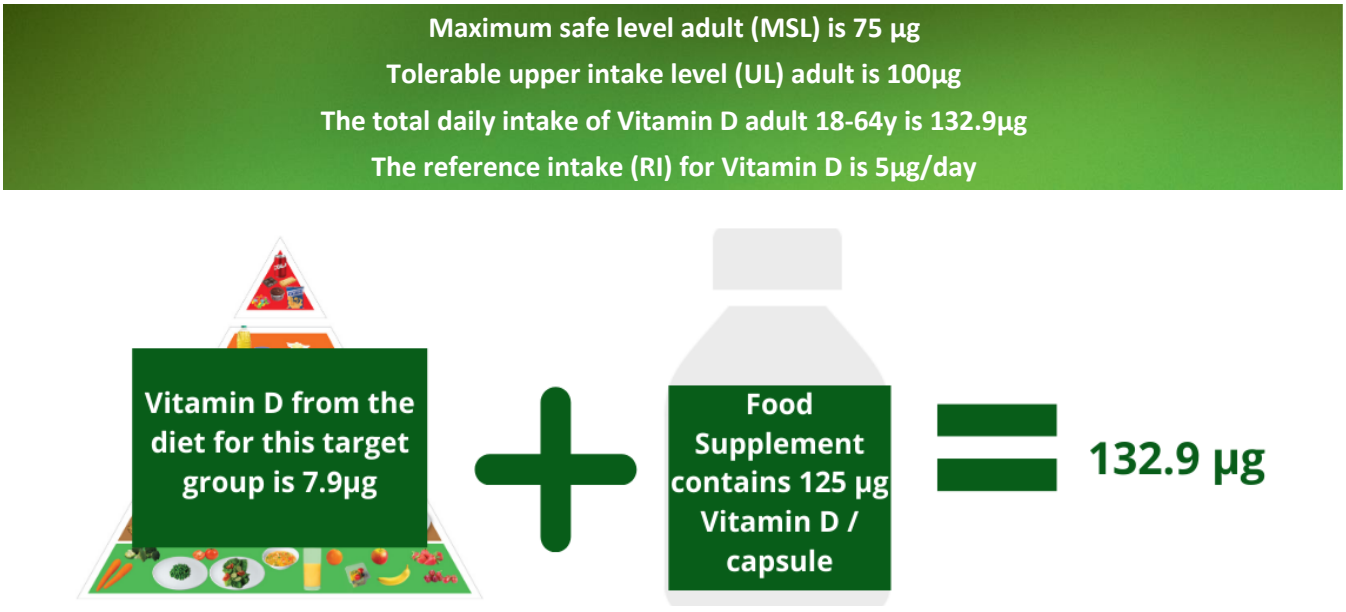
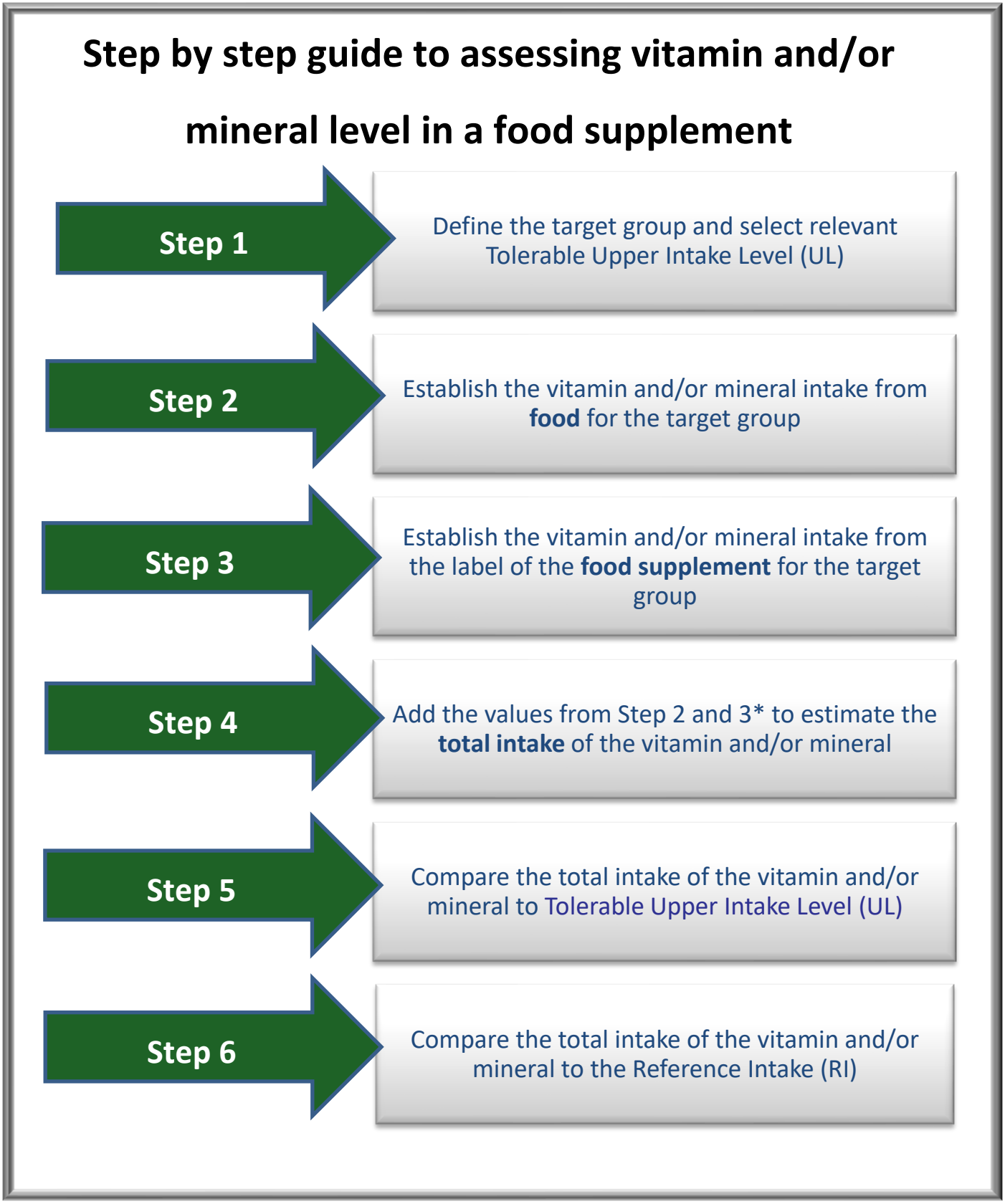



**Figure 3**: Diagram demonstrating how the level of a vitamin in a food supplement is assessed in line with the MSL, UL and the RI

Note: In the case of magnesium, dietary intake does not need to be included in the assessment. The form of magnesium found in food does not cause adverse effects in healthy people and the UL for magnesium is based on scientific evidence of supplement intake only.




* A measured value may be used on occasion if data becomes available from official sources

**Figure 4:** Guide to assessment of the level of vitamins and/or minerals in a food supplement

## Vitamin and mineral labelling on food supplements

Food law requires a label to contain information on the nutritional composition per daily portion as recommended by the manufacturer. The labelled value for each nutrient is the average value of that nutrient over the full shelf life of the food supplement. This labelled nutritional composition is mostly used for risk assessment. Therefore, the labelled value rather than a measured value is used for risk assessment in these circumstances. The exception is where a vitamin or mineral has an acute, short term effect e.g. retinol.
In this case, a measured value is used. In addition, a measured value is used if data becomes available from official sources.

In December 2012, the European Commission, Health and Consumers Directorate General published a guidance document on tolerances for nutrient values declared on a food label.

The guidance was introduced for the purposes of official controls so that Competent Authorities could judge when a product is not compliant with the labelling legislation. Tolerances for nutrition labelling are the acceptable difference between the nutrient values declared on the label and the actual values found in the food supplement when tested in a laboratory under official controls. The tolerances are as follows:

**Table 1:** Tolerances for Vitamins and Minerals in Food Supplements including Measurement Uncertainty

| **Tolerances for food supplements** (includes uncertainty of measurement) | |
|---|---|
| Vitamins | +50%* -20% (labelled amount) |
| Minerals | +45% - 20% (labelled amount) |

*For vitamin C in liquids, higher upper tolerance values could be accepted

The tolerance is guidance that allows a 'tolerable' difference between the labelled value and the analysed value. Tolerances are applied to the labelled value. It is important to note however that tolerances are not routinely taken into account when completing a risk assessment. They are examined if a risk assessment calculation results in an excessively high intake value for a particular vitamin or mineral food supplement.

It is common practice for FBOs to include a vitamin and mineral content at the higher end of the labelling tolerance to allow for longer shelf life and vitamin and mineral deterioration over time. However, the FBO must ensure the vitamin or mineral level is never outside the upper or lower tolerances that are applied to average labelled values. In addition, the MSL is the ultimate upper threshold that will trigger a risk assessment.

## Risk assessment of food supplements

The process of risk assessment takes into account:

- estimating exposure to a vitamin or mineral (through diet and supplement intake)
- the target group and when necessary, individual gender
- the maximum safe level of intake
- the tolerable upper intake level

Other issues such as:

- scientific evidence of groups or medical conditions that are vulnerable to the effects of the supplement
- the known and scientifically documented adverse health effects at varying levels of intake
- the frequency of intake is sometimes relevant and important
- the form of a vitamin or mineral can affect absorption, utilisation and the occurrence of side effects
- the labelling tolerances for vitamins and minerals in food supplements are looked at in certain circumstances
- the reference intake provides context

# Appendix 1: Tables of Reference

**Table 1:** Intake of vitamins and minerals in the diet of Irish consumers in the 95th percentile (excluding supplements) adopted for all people (combined gender)

| Vitamins | Preschool Children | 5-12y | 13-17y | 18-64y | >65y |
|---|---|---|---|---|---|
| **Retinol (µg)** | 620 | 426 | 715 | 768 | 1275 |
| **Carotene (µg)** | 5634 | 5478 | 7249 | 9623 | 10414 |
| **Vitamin D (µg)** | 9.1 | 7.0 | 5.9 | 7.9 | 9.4 |
| **Vitamin E (mg)** | - | 9.5 | 14.0 | 17.2 | 19.1 |
| **Vitamin C (mg)** | 161 | 116 | 181 | 191 | 175 |
| **Thiamine (mg)** | 1.6 | 2.0 | 3.0 | 2.9 | 2.7 |
| **Riboflavin (mg)** | 2.4 | 2.4 | 3.8 | 3.5 | 3.1 |
| **Pre-formed Niacin (mg)** | 18.3 | 24.8 | 37.1 | 44.6 | 37.7 |
| **Vitamin $B_6$ (mg)** | 2.2 | 2.0 | 4.1 | 4.9 | 4.7 |
| **Folic acid (µg )** | 153 | 160 | 220 | 229 | 263 |
| **Vitamin $B_{12}$ (µg)** | 7.2 | 7.2 | 9.4 | 11.3 | 10.7 |
| **Biotin (µg)** | 35.7 | 34.6 | 50.6 | 67 | 65 |
| **Pantothenate (mg)** | 6.6 | 7.7 | 10.6 | 10.6 | 9 |
| **Minerals** | | | | | |
| **Potassium (mg)** | 2475 | 2890 | 4234 | 4886 | 4381 |
| **Calcium (mg)** | 1296 | 1219 | 1654 | 1620 | 1518 |
| **Phosphorus (mg)** | 1268 | 1467 | 2030 | 2228 | 2169 |
| **Magnesium (mg)** | 227 | 276 | 385 | 467 | 430 |
| **Iron (mg)** | 12 | 12.7 | 19.6 | 5.9 | 5.1 |
| **Zinc (mg)** | 8.1 | 10.5 | 13.9 | 15.9 | 13.9 |
| **Copper (mg)** | 0.9 | 1.1 | 1.8 | 2.3 | 2 |
| **Iodine (µg)** | 316 | - | - | 316 | 292 |

**Sources:** Irish Universities Nutrition Alliance: The National Pre-School Nutrition Survey 2012 , National Children's Food Survey 2019 LINK, National Teens Food Survey 2008, and National Adult nutrition Survey 2011; LINK Based on food intake of consumers in the 95$^{th}$ percentile (top 5% of highest consumers.)

**Table 2.** Tolerable upper intake levels for vitamins & minerals recommended for Ireland derived from the European Food Safety Authority (EFSA)

| Life Stage Group | Vitamin A (µg RE/d)[a] | Vitamin D (µg/day) | Vitamin E (mg/d) | Niacin (mg/d) Nicotina \| Nicotinic mide \| Acid | Vitamin $B_6$ (mg/d) | Folic Acid (µg/d) | Calcium (mg/d) | Magnesium (mg/d)[b] | Zinc (mg/d) | Copper (mg/d) | Selenium (µg/d) | Iodine (µg/d) | Molybdenum[c] (mg/d) | Fluoride[c] (mg/d) | Boron[c] (mg/d) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Infants** | | | | | | | | | | | | | | | |
| **0-6 mo** | 600[d] | 25 | ND | ND | ND | ND | ND | See IOM | ND | ND | ND | ND | ND | ND | ND |
| **7-12 mo** | 600[d] | 25 | ND | ND | ND | ND | ND | See IOM | ND | ND | ND | ND | ND | ND | ND |
| **Children** | | | | | | | | | | | | | | | |
| **1-3 y** | 800 | 50 | 100 | 150 | 2 | 5 | 200 | See IOM | ND | 7 | 1 | 60 | 200 | 0.1 | 1.5 | 3 |
| **4-6 y** | 1100 | 50 | 120 | 220 | 3 | 7 | 300 | See IOM | 250 | 10 | 2 | 90 | 250 | 0.2 | 2.5 | 4 |
| **Teens** | | | | | | | | | | | | | | | |
| **7-10 y** | 1500 | 50 | 160 | 350 | 4 | 10 | 400 | See IOM | 250 | 13 | 3 | 130 | 300 | 0.25 | 2.5/5[g] | 5 |
| **11-14 y** | 2000 | 100 | 220 | 500 | 6 | 15 | 600 | See IOM | 250 | 18 | 4 | 200 | 450 | 0.4 | 5 | 7 |
| **15-17 y** | 2600 | 100 | 260 | 700 | 8 | 20 | 800 | 2500 | 250 | 22 | 4 | 250 | 500 | 0.5 | 8[f] | 9 |
| **Adults** | | | | | | | | | | | | | | | |
| **≥ 18 y** | 3000(1500[e]) | 100 | 300 | 900 | 10 | 25 | 1000 | 2500 | 250 | 25 | 5 | 300 | 600 | 0.7[f] | 8[f] | 11[f] |
| **Pregnancy** | 3000 | 100 | 300 | ND | ND | 25 | 1000 | 2500 | 250 | 25 | ND | 300 | 600 | 0.7[f] | 8[f] | 11[f] |
| **Lactation** | 3000 | 100 | 300 | ND | ND | 25 | 1000 | 2500 | 250 | 25 | ND | 300 | 600 | 0.7[f] | 8[f] | 11[F] |

**Tolerable Upper Intake Level (UL)** is the highest average daily nutrient intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. Unless otherwise specified, the UL represents total intake from food, water, and supplements. ULs could not be established for all vitamins. In the absence of a UL, extra caution may be warranted in consuming levels above the recommended intake, therefore sources of intake should only be from food to prevent high levels of intake.

**ND** = Not Determinable. This value is not determined due to the lack of data of adverse effects in this age group and concern regarding the lack of ability to handle excess amounts. Vitamins and minerals where no UL has been recommended for Ireland: Beta carotene, Vitamin K, Thiamin, Riboflavin, Vitamin $B_{12}$, Biotin, Pantothenic acid, Phosphorus, Potassium, Chromium, Silicon.

[a] As preformed vitamin A only.

[b] The EFSA UL for Magnesium represents intake from supplements, water or added to food and beverages. The UL does not include Mg normally present in food and beverages.

[c] Calculation of UL requires a body reference weight and the reference weight used by EFSA was 60kg which is low in an Irish context. Re-calculations were made using a reference body weight of 70kg

[d] The Institute of Medicine (IOM) for infants <1 year is recommended.

[e] Because the UL may not adequately address the possible risk of bone fracture in particularly vulnerable groups, it would be advisable for postmenopausal women, who are at greater risk of osteoporosis and fracture, to restrict their intake to 1500 µg RE/day.

[f] Re-calculated EFSA UL for adults using a reference body weight of 70kg.

[g] Children aged 4-8years/ adolescents aged 9-14 years.

**Sources:** EFSA (2006) Tolerable Upper Intake Levels for Vitamins and Minerals, Scientific Committee on Food, Scientific Panel on Dietetic Products, Nutrition and Allergies; EFSA (2012) Scientific Opinion on the Tolerable Upper Intake Level of vitamin D, Scientific Panel on Dietetic Products, Nutrition and Allergies.

**Table 3.** Tolerable upper intake levels for vitamins & minerals recommended for Ireland derived from the Institute of Medicine (IOM)

| Life Stage Group | Vitamin C (mg/d) | Sodium (g/d) | Chloride (g/d) | Iron (mg/d) | Manganese (mg/d) | Calcium (mg/d) |
|---|---|---|---|---|---|---|
| **Infants** | | | | | | |
| **0-6 mo** | ND | ND | ND | 40 | ND | 1000 |
| **7-12 mo** | ND | ND | ND | 40 | ND | 1500 |
| **Children** | | | | | | |
| **1-3 y** | 400 | 1.5 | 2.3 | 40 | 2 | 2500 |
| **4-8 y** | 650 | 1.9 | 2.9 | 40 | 3 | 2500 |
| **Teens** | | | | | | |
| **9-13 y** | 1,200 | 2.2 | 3.4 | 40 | 6 | 3000 |
| **14-18 y** | 1,800 | 2.3 | 3.6 | 45 | 9 | 3000 |
| **Adults** | | | | | | |
| **19-30 y** | 2,000 | 2.3 | 3.6 | 45 | 11 | See EFSA |
| **31-50 y** | 2,000 | 2.3 | 3.6 | 45 | 11 | See EFSA |
| **51-70 y** | 2,000 | 2.3 | 3.6 | 45 | 11 | See EFSA |
| **>70 y** | 2,000 | 2.3 | 3.6 | 45 | 11 | See EFSA |
| **Pregnancy** | | | | | | |
| **14-18 y** | 1,800 | 2.3 | 3.6 | 45 | 9 | 3000 |
| **19-50 y** | 2,000 | 2.3 | 3.6 | 45 | 11 | See EFSA |
| **Lactation** | | | | | | |
| **14-18 y** | 1,800 | 2.3 | 3.6 | 45 | 9 | 3000 |
| **19-50 y** | 2,000 | 2.3 | 3.6 | 45 | 11 | See EFSA |

**Tolerable Upper Intake Level (UL)** is the highest average daily nutrient intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. Unless otherwise specified, the UL represents total intake from food, water, and supplements. ULs could not be established for all vitamins. In the absence of a UL, extra caution may be warranted in consuming levels above the recommended intake, therefore sources of intake should only be from food to prevent high levels of intake.

Vitamins and minerals where no UL has been recommended for Ireland: Beta carotene, Vitamin K, Thiamin, Riboflavin, Vitamin $B_{12}$, Biotin, Pantothenic acid, Phosphorus, Potassium, Chromium, Silicon

**ND** = Not Determinable. This value is not determined due to the lack of data of adverse effects in this age group and concern regarding the lack of ability to handle excess amounts

**Sources:** IOM (2006) Dietary Reference Intakes: The Essential Guide to Nutrient Requirements; IOM (2011) Dietary Reference Intakes for Calcium and Vitamin D. Washington: National Academies Press

**Table 4.** Maximum Safe Levels

| Nutrient | Reference Intake (RI)[a] | Maximum Level permitted in Food Supplements (MSL) | | Notes |
|---|---|---|---|---|
| **Vitamin A (retinol, RE µg)**<br><br>Vitamin A supplements are not recommended during pregnancy[b] and not suitable for postmenopausal women[c] | 800 | Adults (>18 y)<br><br>Teens (11-17y)<br><br>Children (4-10y) | 1700<br><br>1300<br><br>650 | Based on EFSA UL adults of 3000 µg minus 95th percentile of dietary intake of 1275µg for >65y (as a precautionary measure to protect this age cohort on account of higher dietary intake) =1725µg and then rounded down to 1700µg.<br><br>In order to protect teenagers from high intakes of retinol the EFSA teenage (11-14years) UL of 2000µg minus 95th percentile of dietary intake 13-17 year olds of 715µg is used = 1285µg and then rounded to 1300µg<br><br>Based on EFSA UL for 4-6 year olds 1100µg minus 95th percentile of dietary intake 5-12y of 426µg = 675µg and then rounded to 650µg |
| **Beta Carotene (mg)** | NA | Adults (>18 y)<br><br>Children (4-10y) | 8<br><br>8 | Based on Guidance level[d] of 15mg minus the EFSA ANS Panel 2012[e] calculated from a range of European dietary studies of 3-7 mg/person/day = 8mg<br><br>Same value is considered appropriate for children |
| **Vitamin D (µg)** | 5 | Adults (>18 y)<br><br>Children (4-10y) | 75<br><br>35 | Based on EFSA adult UL 100µg minus 95th percentile of dietary intake 7.9µg = 92µg **and** taking into account the likelihood of increased future fortification = 75µg<br><br>Based on EFSA UL for 4-6 year olds 50µg minus 95th percentile of dietary intake 5-12y of 7µg = 43µg **and** taking into account the likelihood of increased future fortification = 35µg |
| **Vitamin B6 (mg)** | 1.4 | Adults (>18 y)<br><br>Children (4-10y) | 20<br><br>5mg | Based on EFSA adult UL 25mg minus 95th percentile of dietary intake 4.9mg = 20mg<br><br>The child intake is based on EFSA UL for 4-6 year olds 7mg minus 95th percentile of dietary intake 5-12y of 2mg = 5mg |

| | | | | |
|---|---|---|---|---|
| **Folic Acid (µg)** | 200 | Adults (>18 y) | 500 | Based on EFSA adult UL 1000µg minus FSAI 2016[f] estimated 95th percentile of dietary intake for vulnerable group assessed as adults greater than 50 years 477µg taking into account the likelihood of future mandatory fortification = 523 µg and then rounded to 500µg |
| | | Children (4-10y) | 200 | The child intake is a pragmatic level based on RDA for children 7-10 years old as no suitable UL for children. |
| **Magnesium[g] (mg)** | 375 | Adults (>18 y) | 250 | Based on EFSA UL for adults of 250mg. The form of magnesium found in food does not cause adverse effects and so no dietary intake is used in the calculation = 250mg |
| | | Children (4-10y) | 250 | Based on EFSA UL for 4-6 year olds of 250mg. The form of magnesium found in food does not cause adverse effects and so no dietary intake is used in the calculation = 250mg |
| **Vitamin C (mg)** | 80 | Adults (>18 y) | 1800 | Based on IOM UL for adults of 2000mg minus 95th percentile of dietary intake 191mg = 1809mg and then rounded to 1800mg |
| | | Children (4-10y) | 500 | Based on IOM UL for 4-8 year olds of 650mg minus 95th percentile of dietary intake 5-12year olds of 116mg = 534mg and then rounded to 500mg |

Note: The adult value is also suitable for teens with the exception of Vitamin A (retinol, RE µg).

**Maximum safe levels (MSLs)** for children 4-10y were calculated using EFSA UL (4-6y) or IOM UL (4-8y) when relevant and dietary intakes were 95th percentile for 5-12y using data from NCFS II 2019. The MSL for Teens 11-17y was calculated using EFSA UL (11-14y) or IOM UL (14-18y) when relevant and dietary intakes were 95th percentile for 13-17y using data from National Teens Survey 2008. The MSLs for Adults >18 y were calculated using EFSA UL (≥ 18y) or IOM UL (>19y) when relevant and dietary intakes were 95th percentile for 18-64y and >65y where there was a large divergence using data from National Adult Nutrition Survey 2011.

[a] The Reference Intake replaced Guideline Daily Amounts, which used to appear on food labels. These have been set by European law and are based on an average sized adult doing an average amount of physical activity. RIs are not targets for people to consume, but more a guideline or benchmark to help make healthy dietary choices and balance daily intakes.

[b] Healthy eating, food safety and food legislation. Food Safety Authority of Ireland 2019.

[c] Because the UL may not adequately address the possible risk of bone fracture in particularly vulnerable groups, it would be advisable for postmenopausal women, who are at greater risk of osteoporosis and fracture, to restrict their intake to 1500 µg RE/day. As dietary retinol intakes are in excess of this amount, postmenopausal women should not take retinol, RE supplements.

[d] European Food Safety Authority (EFSA) (2012) SCIENTIFIC OPINION. Statement on the safety of β-carotene use in heavy smokers. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2953

[e] European Food Safety Authority (2012) Scientific Opinion on the re-evaluation of mixed carotenes (E 160a (i)) and beta- carotene (E 160a (ii)) as a food additive. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2593

[f] FSAI (2016) Update report on folic acid and the prevention of birth defects in Ireland. Food Safety Authority of Ireland, Dublin. https://www.fsai.ie/news_centre/press_releases/folic_acid_report_04052016.html

[g] The EFSA UL for Magnesium is established for readily dissociable magnesium salts (e.g., chloride, sulphate, aspartate, lactate) and compounds like MgO in nutritional supplements.

**Table 5** Vitamin and mineral reference intake

| Vitamin / Mineral | Reference Intake (RI) |
|---|---|
| **Vitamin A** | 800µg |
| **Vitamin D** | 5µg |
| **Vitamin E** | 12mg |
| **Vitamin K** | 75µg |
| **Vitamin C** | 80mg |
| **Thiamin** | 1.1mg |
| **Riboflavin** | 1.4mg |
| **Niacin** | 16mg |
| **Vitamin B6** | 1.4mg |
| **Folic acid** | 200µg |
| **Vitamin B12** | 2.5µg |
| **Biotin** | 50µg |
| **Pantothenic acid** | 6mg |
| **Potassium** | 2000mg |
| **Chloride** | 800mg |
| **Calcium** | 800mg |
| **Phosphorus** | 700mg |
| **Magnesium** | 375mg |
| **Iron** | 14mg |

| | |
|---|---|
| **Zinc** | 10mg |
| **Copper** | 1mg |
| **Manganese** | 2mg |
| **Fluoride** | 3.5mg |
| **Selenium** | 55µg |
| **Chromium** | 40µg |
| **Molybdenum** | 50µg |
| **Iodine** | 150µg |

**Source:** Part A of Annex XIII of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

# Appendix 2: Legislation

## General Food Law:

- Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. This regulation establishes the basis for food law in Member States. It includes common definitions, general provisions and specific requirements. It establishes the requirement that all food must be safe.
- European Communities (General Food Law) Regulations 2007 is transposed into Irish legislation by **S.I. No. 747 of 2007** and European Communities (Food and Feed Hygiene) Regulations 2009 is transposed into Irish legislation by **S.I. No. 432 of 2009.**

**Food Supplements:**

- Directive 2002/46/Ec of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. This Directive establishes the requirements for the sale of food supplements in Ireland.
- European Communities (Food Supplements) Regulations 2007 is transposed into Irish legislation by S.I. No. 506 of 2007.

**Labelling:**

- Directive 2002/46/EC of The European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. This Directive outlines the general requirements for sale of food supplements and some of the labelling requirements for food supplements.
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (commonly known as FIC). This Regulation outlines the information FBO's are required to give to consumers regarding their products, and in the format it should be given.

- Guidance document for competent authorities for the control of compliance with EU legislation on: with regard to the setting of tolerances for nutrient values declared on a label. This document provides guidance on the acceptable levels of variation between nutrient content declared on a label versus what is actually contained in the product.

**Nutrition and Health Claims:**

- Regulation (EC) No 1924/2006 of the European Parliament and of The Council of 20 December 2006 on nutrition and health claims made on foods. This Regulation outlines what can and cannot legally be said in terms of nutrition and health claims made on all foods including food supplements.

# Appendix 3 Acronyms and Abbreviations

| Abbreviation | Explanation |
|---|---|
| **European Food Safety Authority (EFSA)** | A European agency funded by the European Union that operates independently of the European legislative, executive institutions and EU Member States. Most of EFSA's work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament and EU Member States. |
| **European Union (EU)** | The *European Union* is a unique economic and political union between 27 *EU* countries that together cover much of the continent. The EU has developed an internal single market through a standardised system of laws that apply in all member states in those matters, and only those matters, where members have agreed to act as one. EU policies aim to ensure the free movement of people, goods, services and capital within the internal market, enact legislation in justice and home affairs and maintain common policies on trade, agriculture, fisheries and regional development. |
| **Food Business Operator (FBO)** | Food Business Operator and Food Business are legally defined in Article 3 of General Food Law Regulation (EC)178/2002 as:<br>'Food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.<br>'Food business' is defined as meaning any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food. |
| **Food Safety Authority of Ireland (FSAI)** | A statutory, independent and science-based body with the purpose of protecting public health and consumer interests in the area of food safety and hygiene. |
| **Health Products Regulatory Authority (HPRA)** | The health products regulatory authority role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. They also monitor the safety of cosmetics. |
| **Health Service Executive (HSE)** | The Health Service Executive (HSE) (Irish: Feidhmeannacht na Seirbhíse Sláinte) is responsible for the provision of health and personal social services for everyone living in Ireland, with public funds. |

| | |
|---|---|
| **Grams (g)** | One thousand milligrams. An appropriate unit of measurement for certain vitamins and minerals. |
| **Institute of Medicine (IOM)** | A non-profit organisation that provides international advice on issues relating to health, medicine, health policy, and biomedical science. (Now known as the National Academy of Medicine) |
| **Lowest Observed Adverse Effect Level (LOAEL)** | The lowest intake of a nutrient at which adverse effects have been observed in the individuals studied. |
| **Milligram (mg)** | One thousandth of a gram. An appropriate unit of measurement for certain vitamins and minerals. |
| **Maximum Safe Level (MSL)** | MSLs are based on tolerable upper intake levels (UL) of different consumer groups for vitamins and minerals that pose a risk to health at high intakes. Not all vitamins and minerals pose a risk to health at high intakes.<br>MSLs are calculated by subtracting the amount of a nutrient in the diet of the highest consumers from the UL for that nutrient |
| **No Observed Adverse Effect Level** | The highest intake of a nutrient at which no adverse effects have been observed in the individuals studied (NOAEL) |
| **Reference Intake (RI)** | Replaced Guideline Daily Amounts, which used to appear on food labels. These have been set by European law and are based on an average sized adult doing an average amount of physical activity. RIs are not targets for people to consume, but more a guideline or benchmark to help make healthy dietary choices and balance daily intakes. |
| **Micrograms (µg)** | One millionth of a gram, or 0.001 milligrams. An appropriate unit of measurement for certain vitamins and minerals. |
| **Uncertainty Factor (UF)** | Used to compensate for a deficiency in knowledge concerning the accuracy of test results in estimating the health effects in a different species and/or in different exposure conditions. |
| **Tolerable Upper Intake level (UL)** | The highest level of long-term daily intake of a nutrient, from all sources, judged to be unlikely to pose a risk of adverse health effects to humans. |

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Food Safety
AUTHORITY OF IRELAND

**Food Safety Authority of Ireland**
The Exchange, George's Dock, IFSC,
Dublin 1, D01 P2V6

T +353 1 817 1300
E info@fsai.ie

Join us on LinkedIn
Follow us on Twitter @FSAIinfo
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**www.fsai.ie**