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DAS SCHWEIZER **LEBENSMITTEL**RECHT

The new Maximum Level Model in Switzerland

FSVO, May 2020

Contents

Framework Conditions

The Model:

- is intended to be aligned with the UL (Tolerable Upper Intake Level) (health protection)
- is geared towards a consistent, justifiable rule (no exemptions for various special cases)
- the levels are consistent with the spirit and purpose of the product groups, resp. Ordinances
- impacts industry as little as possible (reformulations, declarations).

The Reference Publication

J Consum Prot Food Saf (2018) 13:25–39 Journal of Consumer Protection and Food Safety
https://doi.org/10.1007/s00003-017-1140-y Journal für Verbraucherschutz und Lebensmittelsicherheit

RESEARCH ARTICLE

Höchstmengen für Vitamine und Mineralstoffe in Nahrungsergänzungsmitteln

Maximum levels for vitamins and minerals in food supplements

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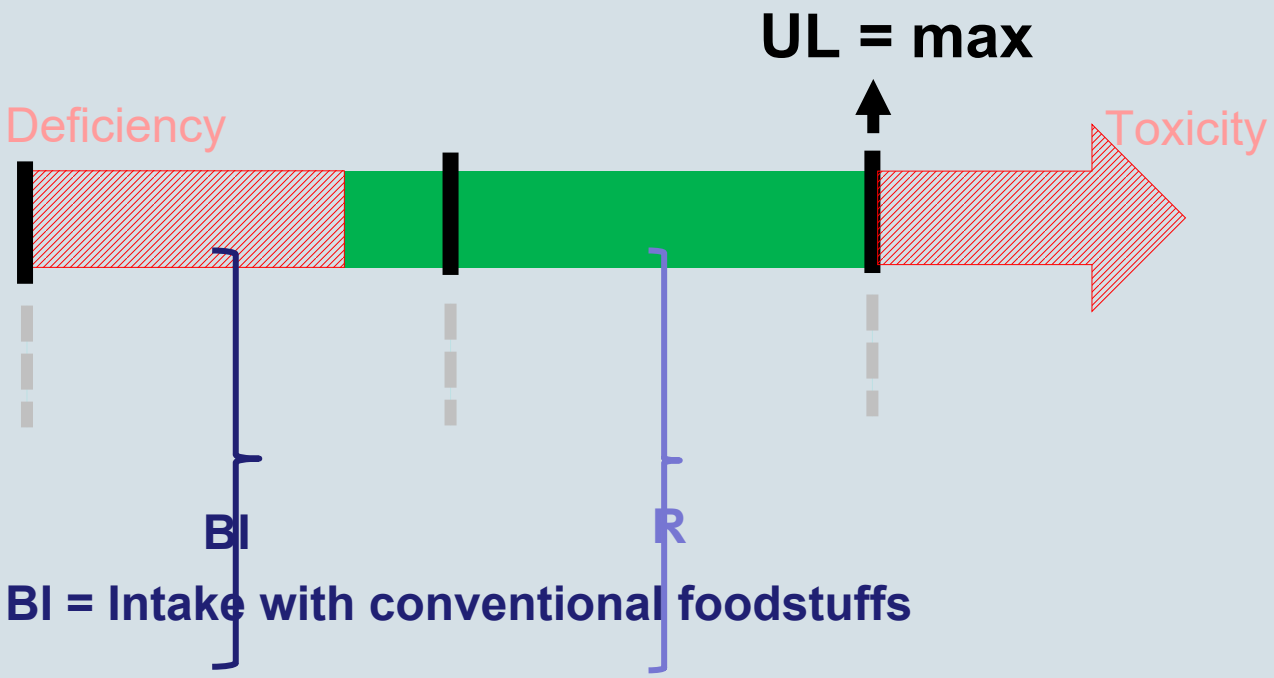
The Principle



BI = Intake with conventional foodstuffs

R = available for FS + F for sportswomen and sportsmen and for enrichment

The Groups

Distribution between fortification and FS

Classification of substances into four groups

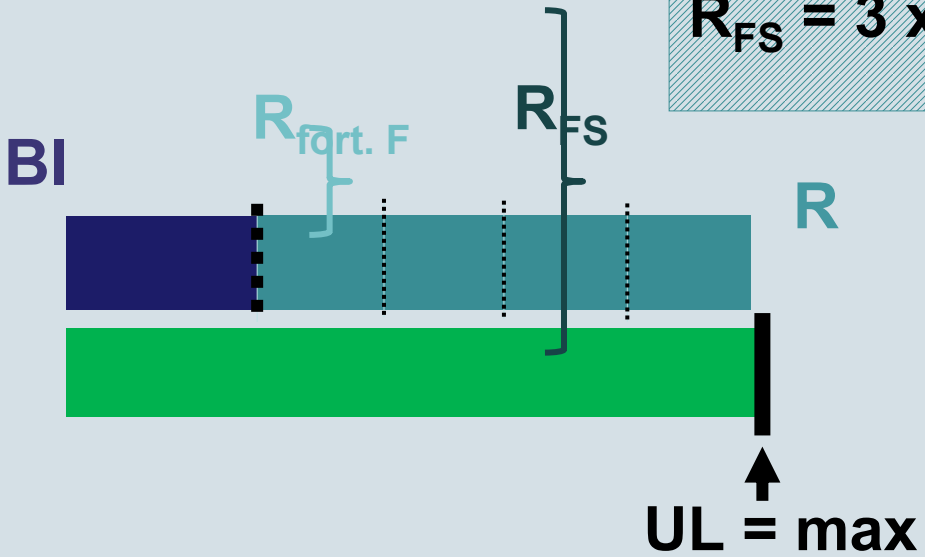
- **Group 1**: non-critical substances
- **Group 2**: substances with large difference in UL – BI
- **Group 3**: substances with small difference in UL – BI
- **Group 4**: substances with side effects or interactions above a certain dose
  - and thus require a warning label

The Assumptions

- **Group 1**: non-critical substances, no maximum levels
- **Groups 2 and 3**: substances with **high** and **low** difference *UL-P 90 distributed* **3:1** in FS and fortified foods
- **Group 4** with warning labels
- Max. **1 FS** and **1 fortified food** per day:
  No multiple exposure factor or “safety factor”
- Either FS or F for sportspersons

Allocation key for Groups 2 and 3

$R_{FS} = 3 \times R_{fortified\ F}$



Classification into Groups

Distribution between enrichment and FS

Group 1: non-critical substances, no maximum level

- Vitamin B_1
- Vitamin B_2
- Vitamin B_{12}
- Biotin
- Pantothenic acid
- Silicon

In the context of self-assessment, ensure compliance with health protection and protection against deception.

Classification into Groups

Distribution between enrichment and FS

Groups 2 and 3:

Distribution of available residual amount (UL-BI) **3:1**

- as FS is a concentrated form of nutrients → should contain more nutrient than a daily ration of a fortified food
- as thus-fortified F may still contain significant amount
- and not too much left for FS

  - In other respects high consumption data (P 95) must be taken into account
  - and/or multiple-/safety factors have to be introduced

Classification into Groups

Distribution between enrichment and FS

Group 4: Vitamin K and Magnesium

Vitamin K

- Insufficient data
- EFSA has not specified a UL
- Interactions with anticoagulants possible above 25µg/day
- With **fortified foods** keep the maximum level low, such that adverse reactions cannot occur
- For **FS**:
  - No adverse effects are known with the previous maximum level. → permitted maximum level is aligned with the existing maximum level
  - Warning label required above 25µg/day

Classification into Groups

Distribution between enrichment and FS

Group 4: Vitamin K and Magnesium

Magnesium

- UL EFSA 250mg/day due to mild reversible side effects (laxative effect in particular)
  - level, at which no participant in human studies was observed to have side effects
  - = NOAEL (No Observed Adverse Effect Level)
- The maximum level should be below this for fortified foods
- The present level is retained for **FS** (375mg/Tag)
  ~ LOAEL (Lowest Observed Adverse Effect Level)
  - Warning label required above 250 mg/day

Group 1 Levels

Substance	Unit	AVMO	DietSO
Vitamin B_1	[mg]	no maximum level	no maximum level
Vitamin B_2	[mg]	no maximum level	no maximum level
Vitamin B_{12}	[µg]	no maximum level	no maximum level
Pantothenic acid	[mg]	no maximum level	no maximum level
Biotin	[µg]	no maximum level	no maximum level
Silicon	[mg]	no maximum level	no maximum level

Group 2 Levels

Substance	Unit	AVMO	DietSO
β-Carotene	[mg]	2.7	8.2
Folic acid	[µg]	250	750/750*
Niacin	[mg]	200	600
Vitamin B_6	[mg]	5	15
Vitamin C	[mg]	250	750
Vitamin D	[µg]	23	70
Vitamin E	[mg]	68	205
Chromium	[µg]	62	188
Iron	[mg]	7	21/21*
Iodine	[µg]	200	200/200*
Potassium	[mg]	750	2250
Molybdenum	[µg]	100	300
Selenium	[µg]	55	165

Lower levels compared to Food Law 2017

*No longer any specific levels for pregnant or breastfeeding women

Group 3 Levels

Substance	Unit	AVMO	DietSO
Vitamin A	[µg]	**as β-Carotene[1]**	**as β-Carotene[1]**
Calcium	[mg]	**250 und 700[2]**	**750**
Copper	[mg]	**0.5**	**1.6**
Manganese	[mg]	**1**	**3**
Zinc	[mg]	**1.8**	**5.3**
Nicotinic acid and Inositol hexanicotinate	[mg]	**0**	**10**

[1]Retinol-equivalents, conversion factor: β-Carotene = 6 × Retinol-equivalent
[2]700mg for substitute dairy products

Lower levels compared to Food Law 2017

Group 4 Levels

Substance	Unit	AVMO	DietSO
Magnesium	[mg]	**250**	**375 with warning label above 250**
Vitamin K	[µg]	**24**	**225 with warning label above 25**

Lower levels compared to Food Law 2017

The Levels

…allow….

Group 1	nutrition/health claims possible	
Group 2	nutrition/health claims possible	
Group 3	nutrition claims **”contains…”** health claims possible	**Zinc** ⚠
Group 4	nutrition/health claims possible	