ANH BRIEFING PAPER

FOOD SUPPLEMENTS DIRECTIVE: MAXIMUM PERMITTED LEVELS (MPLs)

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ABOUT THE FOOD SUPPLEMENTS DIRECTIVE

- See separate ANH BRIEFING PAPER—FOOD SUPPLEMENTS DIRECTIVE: GENERAL for further information.

ANH KEY CONCERNS REGARDING METHODS FOR DETERMINING SAFE UPPER LEVELS

There are serious scientific weaknesses in the methods being considered by the European Commission for determination of Upper Levels (ULs) Maximum Permitted Levels (MPLs) (as per Article 5, Directive 2002/46/EC). These are described in detail in a peer reviewed review paper, authored by Dr Robert Verkerk (ANH) and Dr Steve Hickey (University of Staffordshire, UK): Verkerk, R.H.J., Hickey, S., A critique of prevailing approaches to nutrient risk analysis pertaining to food supplements with specific reference to the European Union. *Toxicology* (2010), doi:10.1016/j.tox.2009.12.017. Some salient problems for the risk assessment phase, which results in the determination of ULs, and the risk management phase, which yields the MPLs, are outlined below:

Key risk assessment challenges

- **The UL is equally applicable to all healthy life-stages and population groups.** However, susceptibility is clearly not equivalent across all life-stages and population groups, as recognised by the FAO/WHO expert group (2006).

- **Risk is determined on the basis of a single, most sensitive adverse effect.** These effects may be mild and transient, may occur only in the most susceptible populations and may not occur at all in the majority or following habitual intake. If this approach was used for risk analysis of conventional foods, wheat and dairy would be banned owing to gluten sensitivity and lactase deficiency respectively.

- **The UL or Guidance Level (GL) (Table 1) is based on the most hazardous member of a given nutrient group.** It effectively applies the precautionary principle disproportionately to safer members of the same nutrient group.

- **The UL is usually determined on the basis of consumption of the daily amount in a single dose either with or without conventional food. Where the nutrient has a short half-life in the bloodstream and is rapidly metabolised (e.g., vitamin C), such ULs do not apply to consumption of larger amounts in divided doses. imum dosage, 1000 mg every 3 h).**

- **The data on which ULs are based are limited in type, rarely relate to healthy populations and do not generally include evidence from clinical nutrition practice, medical records or government adverse event reports.**

- **There has been virtually no effort made by health authorities to validate ULs against clinical data. It can readily be shown that ULs (and especially MPLs) are often lower than those intake levels known to be optimal.**

Key risk management challenges

- **Where risk is managed by regulatory prohibition, benefits will be denied among population groups and for nutrients, or their specific molecular forms, where risks and benefits overlap** (see Verkerk, The paradox of overlapping micronutrient risks and benefits obligates risk/benefit analysis. Toxicology (2010), [in press].

- **Subtracting highest mean intakes from the diet from the ULs, as being contemplated by European authorities, results in levels that are so low that they may be less than those found in a single junk meal (Verkerk & Hickey, 2010; see above).**

"DELAY IS PREFERABLE TO ERROR" — Thomas Jefferson (3rd President of the USA, 1801-1809)

A petition questioning the validity of scientific methodologies being contemplated by the EC remains live in the European Parliament. The ANH believes that mandating MPLs into law across the EU is premature until these scientific problems have been resolved.