Legally binding maximum intake levels for nutrients, currently in development by the European Union (EU), are fundamentally flawed and could deprive consumers of major health benefits.[1,2]

The vital role of diet and nutrition in the prevention of disease, especially chronic disease, is gaining recognition. Increasing numbers of people throughout the industrialised world supplement their diet with vitamins and minerals to maintain or improve their health. To ensure public safety, the EU is assessing the risks associated with nutrients in order to generate upper levels (ULs) of daily intake ("the maximum level of habitual intake *from all sources* of a nutrient...judged to be unlikely to lead to adverse health effects"). The aim is to develop consistent regulation across EU member states, defining both lower and upper limits – or maximum permitted levels (MPLs) – of nutrients consumed in supplements and fortified foods.

There are serious problems with the process as it stands.[1,2] The methods of risk assessment being used to develop EU-wide laws have not been scientifically validated; and the chosen models are based on simple formulae that ignore complex interactions between nutrients, individuals and populations.[1]

The EU model proposes a single UL for each nutrient. This concept has several drawbacks, including:[1]

1. ULs vary in individuals at different stages of life, and in different populations
2. Adverse effects of relevance when calculating ULs occur differently across populations
3. Adverse effects may be unimportant relative to the benefits derived from the nutrient
4. It is assumed, incorrectly, that an identical risk of exceeding the UL applies to all nutrients
5. Where nutrients naturally occur in different forms, the UL is based on the most hazardous form.

Additionally, the methods used to produce MPLs pose several issues, such as:[1]

1. No consideration of different molecular forms of nutrients when calculating MPLs
2. Calculating risk based on the effect of the most hazardous form of a nutrient on the most sensitive populations

3. Ignoring, for convenience, differences in nutrient intake between EU member states
4. Calculating nutrient intake without considering that consumers of fortified foods and supplements are different groups.

This imperfect and highly cautious approach leads to various problems. In essence, these models assume a 'safe intake level', below which lies the risk of nutrient insufficiency and above which lies the risk of excess. In fact, numerous adverse effects and benefits can occur over a wide range of intake of any nutrient. An improved model is suggested that takes this into account, and which proposes a 'zone of overlap' between risks and benefits.[2]

Risk–benefit assessment was applied to four nutrients: folate (vitamin B9), niacin (vitamin B3), selenium and fluoride. A common finding was that doses in excess of the EU-defined ULs caused health benefits in most people, as well as risks to sensitive populations. This was the case for all of the nutrients studied except selenium, and is probably the norm.[2]

Rather than risk assessment, a more rational approach to regulation of nutrient dosage in the EU would apply risk–benefit analysis, possibly employing the 'zone of overlap' concept. Statutory restriction of nutrient dosages should be delayed until appropriate risk–benefit models can be developed, validated and adopted.[1,2]

[1] Verkerk RHJ, Hickey S. A critique of prevailing approaches to nutrient risk analysis pertaining to food supplements with specific reference to the European Union. *Toxicology* 2009;doi:10.1016/j.tox.2009.12.017.
[2] Verkerk RHJ. The paradox of overlapping micronutrient risks and benefits obligates risk/benefit analysis. *Toxicology* 2010;doi:10.1016/j.tox.2010.02.011.