

**Comment on the
FAO/WHO Nutrient Risk Assessment Report**

General comments

The Council for Responsible Nutrition (CRN) considers the report to be appropriate and to have numerous strengths. We hope and expect it to be recognized as an authoritative international statement on the methodology for the risk assessment of nutrients and related substance, and to gain recognition as such by organizations like the Codex Alimentarius.

We recognize and support the many merits of the report, but will focus our comments on the few areas of the report that may need special emphasis for full implementation, or that were not as strong or detailed as might have been useful..

Certain characteristics of the report should be noted by readers and emphasized by FAO/WHO in its use and distribution. In general, the FAO/WHO report:

- Provides an internationally recognized risk assessment methodology, but does not include a list of UL or product maximum content values. CRN recommends that FAO/WHO consider further work to develop such values and/or encourage and facilitate the efforts of others to do so. Certain Codex committees, notably the CCNFSDU, have working groups that could effectively perform such work in the context of their responsibilities.
- Involves methodology that goes well beyond the original UL method developed by the US IOM. Specifically, the FAO/WHO report addresses the intakes of nutrient and related substances from different sources (unfortified foods, fortified foods, and supplements), much in the manner of the UK EVM report; an important strength of the FAO/WHO report.
- Overtly recognizes and briefly describes an important procedure developed, promoted and recommended by CRN and IADSA – expressed as “highest observed intake” (HOI) in this report (Section 8.2.1) and similarly, as the “observed safe level” by CRN and IADSA publications in 2004. The HOI is a critically important concept; any list of ULs and product maximums derived from ULs should include HOI values when there is sufficient data to conclude safety but no data to establish an adverse effect at any known level of intake. Appropriate inclusion of the HOI can help prevent inappropriate and unnecessarily restrictive misinterpretation of the absence of a UL for a specific substance. The report would be strengthened by quantitative as well as qualitative examples to illustrate this concept.
- Will likely to be utilized or adopted by Codex committees, and thus become important in World Trade Organization dispute resolutions. National or regional authorities will recognize the authoritative status of the report.
- Demonstrates that risk assessment can be applied to nutrients and related substances, and should provide impetus for governments to develop regulatory maximums based on safety rather than dietary recommendations.
- Should allow the Risk Analysis Electronic Working Group of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to

recognize and utilize its recommendations; to help guide development of future reports so that they are compatible and supportive of the FAO/WHO report.

Overall the report is strong and authoritative, but two criticisms should be noted:

- Section 4.4 (page 52) gives excessive prominence to Benchmark Intake. Although this is a standard toxicological parameter that is frequently and effectively applied to animal data, none of the authoritative nutrient risk assessment documents have made any significant use of the concept. In the FAO/WHO report, it should not have been more than a footnote to a discussion of the No Observed Adverse Effect Level and the Highest Observed Intake.
- In Section 8.2.1, the Highest Observed Intake was appropriately characterized but the discussion was inadequate in relation to its importance. The example given, vitamin B12, was appropriate but the argument would have been much stronger if it had been quantified. Additional examples such as biotin, lutein and lycopene, with corresponding quantitative values, would have further enhanced the persuasiveness of the discussion.

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