## Foreword

In this age of concern for not getting enough essential nutrients, i.e., vitamins and minerals, one might ask what is the utility in providing guidance on the safe upper levels? Other than calories, which many members of Western societies are over-ingesting at toxic levels, morbidity and mortality data do not seem to indicate an epidemic of vitamin and mineral toxicities. In fact, for most people, even in well-fed societies, the greater concern is nutrient deficiency. However, the popularity and usefulness of the previous two editions of "Vitamin and Mineral Safety" handbook, authored by John N. Hathcock, Ph.D., for the Council for Responsible Nutrition (CRN) seem to corroborate the need for scientifically-based information on how much is too much. The CRN "upper levels for supplements (ULS)," as well as the key studies and dose levels that are used to derive these values, continue to be requested and cited by scientific organizations and regulators alike. Further, the assumptions, models and data being used by regulatory authorities, including the U.S. Institute of Medicine (IOM) Food and Nutrition Board (FNB) "tolerable upper intake level (UL)," the European Commission Scientific Committee on Food (EC SCF) UL and the U.K. Expert Group on Vitamins and Minerals (UK EVM) "guidance level (GL)," make the current edition of this handbook a continued trusted resource in the international arena.

The argument has been made that Western populations may be over-consuming vitamins and minerals, since much of our basic foodstuffs are fortified, often at levels that equal or approach the current "recommended dietary allowances (RDAs)" or "nutrient reference values (NRVs)." When one adds to that one or more of the plethora of designer or tailored products appealing to the sports-minded, the sensitive demographic, the consumer picking up the latest trend, or the impulse point-of-sale promotion, then the levels of vitamin and mineral consumption may reach levels equal to some of the higher tolerable levels of nutrients that are proposed for specific sub-populations. Addition of a multi-vitamin/mineral on top of this background ingestion does lend credence to the need to have some reliable, nutrient-appropriate, scientific risk assessments for safety.

When one talks of vitamin and mineral toxicity, it is important to note that from a safety perspective there exist "tolerable upper limits" (ULs) which, after a thorough review of the underlying safety information, attempt to put a numerical value on the maximum amount a person could consume without negative effects, based solely on good science. RDAs and NRVs attempt to delineate the amount of a specific nutrient a person should consume at a minimum to derive the expected benefit afforded by such a nutrient, i.e., just enough…but not too much. Because of the variability associated with the continuum of human consumers, i.e., intakes that are affected by gender, age, idiosyncratic sensitivities, physiological compromises, diets, and a multitude of other mitigating factors (nutritional as well as lifestyle), recommendations for normal intakes are complex and not a one-size-fits-all. This inability to provide the exact quantitative knowledge of what individuals should eat in order to maintain health makes this handbook's approach to providing guidance on the upper levels a plausible and useful reference. It is up to national, and in the case of Codex, multi-national, regulatory and standard-setting bodies to evaluate the safety data, and the efficacy data, and to set daily intake recommendations in line with the needs of their populations.

This current edition, the 3<sup>rd</sup>, has the same previously evaluated fourteen vitamins, four minerals, and ten trace elements, albeit re-examined with the addition of appropriate new references as needed. The Introduction describes the CRN Safety Methodology, the Nutrient-Appropriate Scientific Risk-Assessments, the IOM FNB Tolerable Upper Limit Method, the EC SCF UL Values and Proposal for Setting Maximal Amounts of Vitamins and Minerals in Supplements, the UK EVM Risk Assessments, and the overall CRN Approach to Supplement Safety—and these have remained intact from the 2<sup>nd</sup> edition, as has the comparison of scientifically-based risk assessment methodologies versus the RDA-based upper limit approach. In most cases, there is a wide range of safe intakes between the RDAs (or NRVs) and Upper Levels, giving consumers the ability to achieve levels within these ranges without concern for safety risks. This new edition, currently being updated chapter by chapter, provides updated research and calculations where appropriate, but continues to demonstrate that the question of over-nutrification is a very different analysis than one identifying levels of deficiency.