



Council for Responsible Nutrition

The Science Behind the Supplements

FOR IMMEDIATE RELEASE

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CRN RISK ASSESSMENTS FOR NON-ESSENTIAL NUTRIENTS PUBLISHED —Experts Fill in Gap to Promote Science-Based Regulation Internationally—

WASHINGTON, D.C., *July 7, 2006* — The Council for Responsible Nutrition (CRN) has authored risk assessments for coenzyme Q10 (CoQ10), carotenoids lutein and lycopene, and creatine monohydrate.

The risk assessments, published by the peer-reviewed journal *Regulatory Toxicology and Pharmacology*, were co-authored by CRN scientists John Hathcock, Ph.D., and Andrew Shao, Ph.D., to ensure regulators worldwide have a science-based guideline available to determine safe upper levels for these popular non-essential nutrients in dietary supplements.

“Coenzyme Q10, lutein, lycopene and creatine are becoming more popular and more prevalent in dietary supplements and a safe upper level has not as of yet been established by governing bodies for these nutrients,” explains Dr. Shao, co-author of the risk assessment papers and vice president of scientific and regulatory affairs for CRN.

Applying a safety evaluation method he developed and which has been recognized internationally as a scientifically valid way to evaluate nutrient safety, CRN’s Dr. Hathcock, vice president of scientific and international affairs, along with his co-author Dr. Shao, reviewed clinical trials for the non-essential nutrients CoQ10, lutein, lycopene, and creatine to determine the safe upper level for supplements (ULS) for each. The values noted in the risk assessments are identified as the ULS, since dietary intakes from food sources were not taken into consideration.

The ULS values were derived using basic elements of the U.S. Food and Nutrition Board’s (FNB) methods as well as the observed safe limit (OSL) method, developed by Dr. Hathcock and now used as the highest observed intake (HOI) by the Food and Agriculture Organization and World Health Organization.

For each nutrient Drs. Hathcock and Shao reviewed only randomized controlled trials (RCTs) conducted in humans, using uncontrolled trials and animal data as supportive information only. For CoQ10 the authors arrived at a ULS of 1,200 mg per day. For lutein the authors concluded that a ULS of 20 mg per day should be proposed for this carotenoid. For lycopene, the authors arrived at a ULS of 75 mg per day. Creatine was assigned a ULS of 5 grams per day.

Upper levels do not suggest that supplements taken above the level identified are unsafe, nor do they constitute a recommended intake. They simply identify a level at which there is “no known toxicity for these nutrients,” said Dr. Hathcock. “Risk assessments allow us to put forth science-based guidelines for safety levels. Since there are no observed adverse effects for these nutrients, governing bodies haven’t set upper limits, leaving the door open for regulatory mischief. We’ve seen that happen before, especially in Europe where countries have tried setting limits a hundred times lower than observed safe levels, using, implicitly or overtly, the precautionary principle instead of science as justification. These risk assessments are necessary to ensure that science, not rhetoric, leads the way when it comes to safety.”

The recently published risk assessments are currently available online through the International Society for Regulatory Toxicology and Pharmacology (IS RTP) and will be published in an upcoming issue of *Regulatory Toxicology and Pharmacology*, the official journal of IS RTP. Drs. Hathcock and Shao are also working on risk assessments for carnitine, and glucosamine and chondroitin sulfate, which have been accepted for upcoming publication in *Regulatory Toxicology and Pharmacology*.

Dr. Hathcock is also the author of the CRN publication, *Vitamin and Mineral Safety, 2nd Edition*, which provides an academic review of safety levels for 28 vitamins and minerals, with methodology, including CRN’s approach, on assessing safety along with a review of governmental and regulatory safety conclusions.

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Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement industry ingredient suppliers and manufacturers. CRN members adhere to a strong code of ethics, comply with dosage limits and manufacture dietary supplements to high quality standards under good manufacturing practices.