

## Opportunity to Respond to Questions

This form provides the opportunity to respond to the questions posed in the Background Paper: Joint FAO/WHO Development of a Scientific Collaboration to Create a Framework for Risk Assessment of Nutrients and Related Substances.

Responses may be typed in to the form directly or appended as an 'attachment' to each question (use 'Upload file'). Fields with asterisks are required. Responses and your name/organization will be available for public viewing.

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### *Name/Organization*

#### **Title**

Mr

#### **First name \***

Michael-Anthony

#### **Last name \***

:Seegers

#### **Name of Organization (Use 'None' if none) \***

Sovereign Protocol Group

#### **Affiliation Category (click on bar to select a sector) \***

Consumer

#### **Today's Date \***

10/12/2004

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## Question 1

The Background Paper discusses the possibility that hazard identification and hazard characterization have global relevance, while exposure assessment and risk characterization are relevant to populations. If such a conceptual framework for the four steps is appropriate, then scientific principles could be organized and considered along these same lines.

**Question 1a: Is the distinction between global relevance and population relevance for the four risk assessment steps a meaningful consideration for the purposes of developing an international nutrient risk assessment approach? (Please indicate why or why not)**

Perhaps. Your paragraph C on page 16 states that these data by their nature are relevant across wide and diverse populations. How is this statement derived? Your paper presents this statement as a fact rather than a possibility. Therefore if this statement is indeed sufficiently grounded as a fact then the distinction has the chance of becoming meaningful for the suggested approach.

However, that would depend on the underlying assumptions in place.

Your background paper is organized to set nutrient risk assessment within the existing approaches for non-nutrients and to highlight the special considerations needed to address nutrients and related substances. (As stated on page 4)

Has it been considered that perhaps a new paradigm is required here? What underlying assumptions of the non-nutrient model could be counter to the subject matter here?

And so your question regarding global relevance may be premature in that your assumptions are not yet properly identified with respect to a new and novel approach to a nutrient model, while your idea of population relevance will need to be further explored in light of the questions produced by developing such a model.

**Question 1b: If so, please provide specific suggestions about how best to further articulate and make good use of the differences in identifying the scientific principles for nutrient risk assessment.**

Given that the intention of the study proposed is the determination of ULs, I would give the following idea as relevant to the discussion of scientific principles.

1.) In the non-nutrient model a more direct approach is taken in that a single substance is being quantifiably assessed. In a nutrient model it may be more appropriate to utilize the naturally occurring forms of say vitamin E in conjunction with its synergistic component known as octacosanol as occurring in wheat germ. As we know that vitamin E is actually a group of substances which include  $\alpha$ ,  $\beta$ ,  $\gamma$ , and  $\delta$  tocopherol in the dextrorotary form as well as the four primary tocotrienols, and most studies use a synthetic levorotary form or a dl form of a single component ( $\alpha$  tocopherol) it becomes easy to understand why a UL may be determined inappropriately due to the metabolic inability of the test subject to process the substance in the absence of its naturally required synergistic components. This level may rightly be determined to be much higher in a synergistically considered environment. Also the fact that d-  $\alpha$  and dl-  $\alpha$  tocopherol are not in themselves vitamin e and that d-  $\alpha$  tocopherol is not even the most important component of the vitamin e complex but ranks fifth at best behind the four tocotrienols and  $\gamma$ -tocopherol.

Also as the importance of minerals has been reported quite succinctly in U.S. Senate Document No. 264 of the 74th Congress in 1936, it has been known for a long time that a vitamin is

considerably less effective in the absence of its synergistically required minerals. As demonstrated quite definitively by Dr Fritz-Albert Popp, whole new levels of vitality were discovered when a mineral solution was added to the nutrient base of the test subjects (*acetabularia mediterranea*) in question. In the consideration of a mineral such as calcium it would be useful to consider the electro-chemical properties of the proposed substance under test as we know that most calcium supplements are mere chalk and can not effectively be utilized by the body, whereas the Krebs cycle intermediates such as the esters have a much higher bioavailability.

Therefore the specific suggestion in the nutrient model would be to include as much as possible a utilization of known synergy mechanisms as given parameters for the test protocol.

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## **Question 2**

**Hazard identification and characterization involve a number of decision points that require scientific judgment in order to derive a UL. Please provide input as to how guidelines for these judgments can be developed for the following decision points:**

### **Question 2a: Criteria for the evaluation of the quality and utility of relevant scientific evidence.**

The first consideration that comes to mind is the underlying agenda of the researcher. Therefore I would ask the question who funded the research and what did they intend to prove by it?

Next I would bring the question of the individuals conducting the program and were they just pushing paper to get peer reviewed and published, was it part of a thesis and was there an honest protocol of disciplined research and enquiry taking place?

To suggest how guidelines for these judgments can be developed I would seek the answers to the following questions.

How exhaustively was the search for information carried out?

What assumptions were made in animal studies as to their relationship to human subjects?

What synergistic considerations were given credence? Or even considered?

What metabolic pathways were considered in the biochemical generation of potential toxins as byproducts?

Were natural or synthetic products used?

How do these outcomes relate to potential real world products under consideration?

What was the mode of administration of the substance under question in the quest for evidence?

Was the test evidence produced in vitro or in vivo or in theoretica?

### **Question 2b: Extrapolation to various age/gender groups.**

To suggest how guidelines for these judgments can be developed perhaps the question to explore is growth rates. What are the metabolic requirements of the growth rate of the various age and gender groups? This may be a very distinct consideration having little resemblance to the standard per kg bodyweight often used.

#### **Question 2c: Determination and use of uncertainty factors.**

Without going into the development of a mathematical model to assign a numerical value to the uncertainty factor I think that such a concept will remain seriously flawed in light of the vitamin A example used in your background paper when compared to the proposed nutrient model of my response to question 1b. I give this suggestion because again we have 'vitamin A' versus a carotenoid complex, and also knowing that many  $\beta$ -carotene studies use a synthetic product derived from acetylene gas, which is quite different from the naturally occurring substance.

#### **Question 2d: Other**

Given the time constraints of the deadline for submission of this response I must refrain from exploring such a wide open question at this time.

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### **Question 3**

**The conduct of exposure assessment and risk characterization also requires sound scientific principles that can be applied to the various decision points, including but not limited to compilation and collection of intake data and decision-making for summarizing the potential for harm.**

#### **Question 3a: Please provide input on general scientific principles relevant to the process of determining exposure for a nutrient or related substance.**

I think it necessary that an international standard of measurement be instituted across the field for each substance. For example it becomes cumbersome to convert between international units (IU) and retinol equivalents (RE) when discussing vitamin A and carotenoids. Also this pales in significance to what I have seen in the field of enzymes. Whether digestive or metabolic enzymes are discussed it is incredible how many different units of measurement are used and the convertibility of them is nearly impossible even to the many pharmacists that I have queried on the matter.

I think a unit of measure of metabolic activity would be a useful development such as the development of the mol as a measure in chemistry. This may require a whole new paradigm in nutrient research and may also shed tremendous light on the uncertainty question. For example we know that the mitochondrion is the powerhouse of the cell. Now when we boost the metabolic activity of the mitochondrion with notoginseng and provide l-carnitine to assist in the transport of fat molecules across the cell membrane, and then throw in a little chromium picolinate to regulate

the insulin release from the pancreas we can achieve a fat burning mechanism that totally redefines our preconceived notions of blood sugar metabolism and fasting glucose levels. In this model we have an increased requirement for all the B-complex vitamins in synergy with vitamin C etc and all their related mineral co-factors.

**Question 3b: Please provide input on general scientific principles for the characterization of the severity and the degree to which intakes exceed the UL or other aspects of risk characterization.**

In a non-nutrient model a toxicological study utilizing a basis of LD50 will necessarily kill a large number of the test subjects. This is obviously not possible in a nutrient model with human subjects. Therefore the license to determine upper levels is restricted to a new set of parameters which have perhaps as yet to be determined. Again a greater set of complexities arises which was not previously seen in the non nutrient model. At the other end of the graph we at least have the determinations of RDA based on known data with respect to disease prevention. If we design a nutrient model utilizing bio-photon emission for example we may be better able to establish a predictable range for optimum metabolic activity. Quoting Dr. Fritz Albert-Popp from the institute of Biophysics we have the following useful information....

It turns out that the entropy (or the thermodynamical probability  $W$ ) is the most essential quantity in macroscopic physics, since it is responsible for the dynamics of matter, e.g. the course of chemical reactions, degradation of structures, particle flow, and distribution of mechanical or electrical potentials (pressure, electrical or magnetic forces). Even the arrow of time is based on the 'second law of thermodynamics' which states that the entropy  $S$  (or  $W$ ) always takes its maximum under the boundary conditions of the system under study. Roughly speaking, this means that every system displays the tendency to arrive at the most probable state where the energy is distributed in the most uniform way.

Taking this into the metabolic arena we can develop a nutrient model of greater accuracy.

Another useful tool may be the tracing of energetic pathways utilizing Meridian Stress Assessment (MSA) testing which measures the energy at the meridian points, as discovered by Dr. Reinhold Voll, who found that certain acupuncture points showed abnormal readings when subjects were reacting allergically. With the biomeridian equipment available today it may be possible to determine dangerous levels without actually ingesting test substances.

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**Question 4**

**The Background Paper reflects a 'thought process' and is intended to inform a longer process for the development of a technical expert workshop. Clearly the process will benefit from additional input.**

**Question 4a: Please provide comments on other general factors or considerations that could be taken into account during the process of identifying principles for nutrient risk assessment.**

What has not been discussed in your paper is another concept which is perhaps even more relevant to concerned sectors of society than a UL and that is what I would call an OL or OPTIMUM LEVEL. In a nutrient model this type of research finds itself more specifically oriented

towards the athlete as well as the individual whose lifestyle choices are governed by a concern for optimum health and fitness. Research of this type has been done for many of the basic micronutrients and reported on by people like Dr. Richard Passwater as far back as 30 years ago.

Another consideration in a nutrient model would be therapeutic designs of a nutrient program. For example it has been demonstrated that schizophrenics respond extremely well to megadoses of B-complex vitamins as reported by Dr. Abram Hoffer and Dr. Humphrey Osmond. In response to this work of the 1950s and 60s we have such esteemed commentary as Dr. Linus Pauling coining the term "Orthomolecular Medicine" to describe the therapeutic protocol of optimum levels for specific metabolically unique subgroups of populations.

In the non-nutrient model a specific population under test will naturally have certain characteristics in common thus defining the group under consideration. In a nutrient model it may be reasonable to consider that certain populations exist which take these above mentioned factors and many others quite seriously, and have by conscious effort so enhanced the functioning of their digestive and metabolic systems that they can not even be measured in the same order of magnitude as the general population. For example with respect to the B-complex vitamins we have for a male aged 25 to 50 years a given RDA for riboflavin in the amount of 1.7 milligrams. This determination is merely a disease prevention level and bears no resemblance to the example I would give using myself as the test subject. After twenty five years of metabolic optimization I have the ability to utilize 300 mgs per day with no excretion of non-metabolized substance. Because I have a background in exercise physiology and biochemistry, and spent ten years in training for Olympic competition I have a totally different set of parameters not found in the general population. Due to the intensity and duration of exercise programs a proper nutrient assessment would necessarily be partly based upon caloric expenditure.

Therefore in situations as described here we have intakes severely exceeding general ULs that would be given for the general population. These can be characterized as optimum and therapeutic levels and would be determined by unique metabolic parameters not found in the majority of test subjects. I give these type of example knowing well that the motivations of the groups sponsoring such activity as the Codex Alimentarius Commission are backed financially by the pharmaceutical cartel not the least of which is Bayer, Hoechst and BASF who we know from the Nuremberg Tribunals are the renamed I.G. Farben gang, and that their agenda is so corrupt that they would suppress health information to sell more drugs. Therefore it is their intent to set ULs at such a low level that optimum health may never be achieved, and it is my intent to do everything possible to discover optimum levels such that drugs may never be required from birth to death.

**Question 4b: Please provide other comments on the content of the Background Paper.**

I find your final paragraph on page 7 disturbing.

Quoting,

"It will remain, of course, for risk managers in the Codex process as well as the risk assessors and managers at national levels or within other organizations to make use of the workshop outcomes in ways they

deem appropriate. Should resources allow, FAO/WHO may continue work to develop a set of upper levels

for vitamins and minerals."

After all the time and energy spent on this process so far, how can you possibly state in good conscience that the completion of this effort is not certain due to financial considerations? This process must continue if it takes another 20 years!!!