

## 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 \***

Gerd

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

Stueckler

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

None

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

Industry

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

09/12/2004

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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)**

**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.**

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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.**

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The criteria must concentrate on how to gather scientific evidence which can be trusted to be unbiased and not skewed. Without solving this daunting task this whole WHO and Codex Alimentarius project will fail and, what is even worse, would led to worldwide severe damage to the people up to genocide when continued without solving this problem. Therefore I recommend (see also "conclusion"):

- a) Exclusion of all research institutions and researchers which have skewed scientific evidence in the past, no matter how "famous" they are. (See example for Vitamin-B17).
- b) Predominantly using only scientific evidence from independent researchers and institutions who do not have or had close ties (personal or business) to big business oriented companies or institutions. This may be the most difficult part but is unavoidable due to the widespread conflicts of interest. (See "missing unbiased science").

c) Making public all financial ties of all scientists and institutions whose evidence on nutrients is used for evaluation by the WHO.

- >> The missing unbiased science and the missing quality of scientific evidence .....
- >> Conflicts of Interests (up to plain corruption) inside companies, universities .....
- >> Severe conflicts of interest in nutrient studies .....
- > A typical example of bad science are e.g. the Vitamin-A studies .....
- > Another example .... is the case of Vitamin-C and the amino acid Lysine .....
- > A further example of ... plain fraudulent science regarding nutrients is ..... Vitamin-B17....
- >> Conclusion .....

For details read my attachment "Letter to FAO-WHO Nutrient Risk Assessment" (uploaded PDF-file)

This is important !

Gerd Stueckler, Physicist

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

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

>> The definition of "NOAEL":

The introduction of the NOAEL "No-Observed-Adverse-Effect-Level" has no place in a scientifically approach because a level which can not be observed can not be used as a basis from which to deduce further results. This is bad science.

>> The definition of "Adverse-Effects" and "Adverse-Effect-Levels":

The meaning of these important definitions in the context of nutrition is not properly defined. Many adverse effects, e.g. diarrhea can not be defined as an adverse effect which must be included in the risk assessment, simply because most foods will lead to diarrhea when taking too much of them. People managed since millions of years to handle such adverse effects. To "protect" the people with upper levels for nutrients against such kind of adverse effects will above all cause severe harm instead.

In the context of nutrients Adverse-Effects and Adverse-Effect-Levels should be defined as effects or levels where health damage is observed which can not be reversed by simply reducing the intake of that nutrient.

>> The "Uncertainty Factor":

The introduction of an uncertainty factor of "up to 100 or more if the safe intake had to be based on an animal study because of the inadequacy of human data" has nothing to do with science in the context of nutrients. Because of wide spread none existence of human data this would inevitably lead to the "lower end of the acceptable range of intake" which was defined "as a level that maintains life and/or promotes health" and which strangely is meant to mean "optimal health" as well ! Where is the science gone ?

This brings me back to my first point: immediate suspension of this project until overwhelming amounts of peer reviewed data from independent nutrient research are existing.

>> The forgotten "Dynamics" of the body's demand of nutrients:

The FAO/WHO proposal completely misses the inclusion of the body's demand for nutrients according its momentary health status. When the human body is under constant stress caused by the modern life, by unavoidable chemicals or by a disease it needs much more nutrients, like vitamins, than usual. It is even possible to check the body's health status by taking high dose vitamin-C levels e.g. until one gets diarrhea. During a flu it is common that one can even take 100 (one hundred !) grams of vitamin-C without getting diarrhea. I personally could take 9 grams per day for many months (with surprising health benefits e.g. like complete loss of any sensitivity against our health threatening high ozone levels during summer).

This dynamic behavior of the human organism leads as well to the impossibility of defining upper levels for nutrients other than those which may be needed to protect against unrecoverable health threats.

>> The forgotten factor of health benefits compared to health problems of high dose nutrients:

The FAO/WHO proposal does not define such a factor. If the intake of high dose food supplements of Vitamin-C and the amino acid Lysine e.g. can be proven to result in 100 times less heart related deaths per year compared to additional deaths or severe unrecoverable problems in other areas it should be left up to the consumer to choose what to take (for this example it will turn out that this factor will be much much higher, because there are seemingly no adverse effects known which should be taken into consideration).

Please read my attachment "Letter to FAO-WHO Nutrient Risk Assessment" (uploaded PDF-file)  
Gerd Stueckler, Physicist

#### Question 2d: Other

Please read my whole document posted under Question 4a

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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.**

See Question 4a

**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.

See Question 4a

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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.**

Please read my attachment "Letter to FAO-WHO Nutrient Risk Assessment" (uploaded PDF-file)  
Gerd Stueckler, Physicist

(attachment)

#### To the FAO/WHO

##### **Regard: FAO/WHO Nutrient Risk Assessment and related Codex Alimentarius issues**

Dec. 9, 2004

Gerd Stueckler, Physicist

Thank you for giving me the opportunity to comment on the FAO/WHO Nutrient Risk Assessment project which is likely to become the most important part of the Codex Alimentarius program as its aim is to define upper limits for nutrients.

I am writing to you to make you aware of severe principal flaws I can see in your proposal for the "Development of a Scientific Collaboration to Create a Framework for Risk Assessment of Nutrients and Related Substances" (Oct. 2004) which in the end will lead into worldwide binding laws. Because of the severeness of these flaws I urge you to immediately suspend all projects which will lead to the regulation of upper levels of nutrients until the related problems are solved !

This is the first time in mankind's history that organizations like the FAO/WHO are trying to implement laws which will regulate and limit the access of the world's populations to nutrients and related substances. These laws would supersede all national laws of any country and would be enforced by the WTO. Any flaw within these laws would severely hamper any progress in the health and well being of the people worldwide. The resulting damage could easily become much more severe than the damage done to the people during all wars on this planet.

Any world wide regulations of nutrients would be of higher importance and impact to the well being of humans than any other trade regulations !

Because of this and because as I know as a German what terrible outcome wrong laws will have I feel obligated to comment on these important FAO/WHO proposals and on principal issues related to them.

As an independent physicist who runs his own business (since 37 years) and who never had to follow any one's interests, who's wife and friends are doctors of medicine and who was forced to learn a lot about nutrition and its effect on health I think I can provide some useful thoughts regarding the mentioned issues. Following are only some of the severe flaws of this FAO/WHO project I can see:

**1.) The flaw of the much too urgent time frame and the flaw of the non existence of educating the public** about all aspects of the far reaching implications of upper limits for nutrients. Nutrients inclusive supplements have above all very positive health effects - contrary to substances made from artificial molecules, as pesticides, pharmaceuticals etc.

In Sept. 2004 the FAO/WHO announced their intention to address the issue of identifying upper levels of nutrient intake which if exceeded may cause harm. In 2005 the Codex Alimentarius commission wants to have such upper levels implemented already which would finally become world wide binding law. This is way too soon ! No citizen in the world is informed yet about these projects. Virtually no German has ever heard of them, not even medical doctors. The worldwide media is absolutely silent about Codex Alimentarius issues. It will take many years to educate the world's population about the far reaching implications of restricting access to or imposing upper limits for nutrients.

Such restrictions would directly interfere with the freedom of nutritional choice of any individual of this planet ! People perfectly know since thousands of years what to eat and what not and even during the last decades during which people in western countries consumed lots of food supplements to complement their processed food there was no need to enforce maximum upper levels. The cases of alleged long term health damages caused by natural food supplements are - as seen from an unbiased scientifically view - non existent. The risks are not higher than the general risks of eating food and not comparable to the deadly risks of chemicals or pharmaceuticals or the risks of our organized western medical system (which in the USA e.g. is meanwhile recognized as the number one cause of deaths - this is not a joke !).

So there is no need at all for any urgent proceeding. This endeavor may take one generation or longer until all parties - consumers and foremost the worlds independent nutrient research scientists - might agree on a result.

**2.) Principal flaws in the FAO/WHO's "Risk Assessment Approach in the Nutrient Context":**

**2.a) The principle flaw in the proposed risk assessment procedures:**

The application of risk assessment procedures for hazardous chemicals and pharmaceuticals can never be applied to nutrients. The human organism is perfectly adapted since millions of years to all molecules which are part of used natural food nutrients - contrary to the artificial molecules of chemicals like pesticides and pharmaceuticals. This can be easily seen in the light of several hundred thousand deaths per year caused by correctly prescribed pharmaceuticals compared to virtually no deaths caused by nutrients from food or food supplements.

So the risk lies mostly in the lack of sufficient nutrients. All this leads to a completely different risk assessment procedure which must also take into consideration the many scientific discoveries of major health benefits of some nutrients (Vitamins, Minerals, etc.) when taking much higher doses of them as the average modern food provides.

**2.b) The definition of "NOAEL":**

The introduction of the NOAEL "No-Observed-Adverse-Effect-Level" has no place in a scientifically approach because a level which can not be observed can not be used as a basis from which to deduce further results. This is bad science.

**2.c) The definition of "Adverse-Effects" and "Adverse-Effect-Levels":**

The meaning of these important definitions in the context of nutrition is not properly defined.

Many adverse effects, e.g. diarrhea can not be defined as an adverse effect which must be included in the risk assessment, simply because most foods will lead to diarrhea when taking too much of them. People managed since millions of years to handle such adverse effects. To "protect" the people with upper levels for nutrients against such kind of adverse effects will above all cause severe harm instead.

In the context of nutrients Adverse-Effects and Adverse-Effect-Levels should be defined as effects or levels where health damage is observed which can not be reversed by simply reducing the intake of that nutrient.

**2.d) The "Uncertainty Factor":**

The introduction of an uncertainty factor of "up to 100 or more if the safe intake had to be based on an animal study because of the inadequacy of human data" has nothing to do with science in the context of nutrients. Because of wide spread none existence of human data this would

inevitably lead to the "lower end of the acceptable range of intake" which was defined "as a level that maintains life and/or promotes health" and which strangely is meant to mean "optimal health" as well ! Where is the science gone ?

This brings me back to my first point: immediate suspension of this project until overwhelming amounts of peer reviewed data from independent nutrient research are existing.

#### 2.e) The forgotten "Dynamics" of the body's demand of nutrients:

The FAO/WHO proposal completely misses the inclusion of the body's demand for nutrients according to its momentary health status. When the human body is under constant stress caused by the modern life, by unavoidable chemicals or by a disease it needs much more nutrients, like vitamins, than usual. It is even possible to check the body's health status by taking high dose vitamin-C levels e.g. until one gets diarrhea. During a flu it is common that one can even take 100 (one hundred !) grams of vitamin-C without getting diarrhea. I personally could take 9 grams per day for many months (with surprising health benefits e.g. like complete loss of any sensitivity against our health threatening high ozone levels during summer).

This dynamic behavior of the human organism leads as well to the impossibility of defining upper levels for nutrients other than those which may be needed to protect against unrecoverable health threats.

#### 2.f) The forgotten factor of health benefits compared to health problems of high dose nutrients:

The FAO/WHO proposal does not define such a factor. If the intake of high dose food supplements of Vitamin-C and the amino acid Lysine e.g. can be proven to result in 100 times less heart related deaths per year compared to additional deaths or severe unrecoverable problems in other areas it should be left up to the consumer to choose what to take (for this example it will turn out that this factor will be much much higher, because there are seemingly no adverse effects known which should be taken into consideration).

### 3.) The missing unbiased science and the missing quality of scientific evidence.

It is welcomed to see that the FAO/WHO proposal talks about the scientific challenges regarding the quality of scientific evidence. I consider this a key issue which must be addressed carefully. Unfortunately this quality is nowhere to be seen. Just now we are witnessing the complete breakdown of the quality of scientific evidence. It got so bad that it will take a very long time to fix these problems. Without principal reform it will not be possible at all. There will never be a solution to this problem e.g. unless all aspects and results of studies are kept in a publicly free accessible database which must include all financial dependencies of any of the involved scientists and managers and unless all publicly funded institutions accept only scientists which never had ties to pharmaceutical companies or other business oriented entities. Until then the Codex Alimentarius process must be stopped immediately when the WHO wants to prevent severe damage to the world's people. Because of limited space I can provide only a few key points and examples:

#### 3.a) Conflicts of Interests (up to plain corruption) inside companies, universities, research facilities and public organizations:

The outcome of studies more than often depends on the financial interests in a specific outcome instead of unbiased scientific evidence. The latest example is the Vioxx scandal which again exposed these conflicts of interests. This scandal alone costs an estimated 55.000 people their life and millions are now frightened to death about what may happen to them. Meanwhile many ways to get the wished "scientific evidence" or outcome (data) of a study are known, e.g.:

- > Several studies are run in parallel and the one with the most convenient outcome is presented,
- > Studies are outsourced and this process is repeated until one contractor comes up with a convenient result,
- > Studies on nutrients which seem to lead to an "unwanted" positive result are aborted (as happened with a Calcium study),
- > Research facilities provide positive results for their customers because they depend on their continuing support,
- > Scientists who provide inconvenient results are suppressed or get fired or withdrawn from the studies,
- > The regulative authorities often know the dangers since many years without taking action because key personal are the very same people who used to work for the pharmaceutical companies or still have interests in these companies.

The before mentioned cases are not just a few exceptions. The general situation got so

bad that just recently some leading scientific journals made public that they will (from 2005 on) not accept any studies for publication anymore unless all activities and results regarding such a study will be provided.

### 3.b) Severe conflicts of interest in nutrient studies:

As the majority of the research facilities depend more or less on the pharmaceutical industry or have close ties to this industry it is especially hard for them to produce unbiased scientifically results or unbiased interpretation of results on nutrient studies. The reason for this is because nutrients like vitamins, minerals etc. are the biggest financial competitors to pharmaceuticals. They are much cheaper, more effective, have close to zero adverse reactions and compete directly with the pharmaceuticals which bring in a hefty 5,000 to 500,000 % gain without demanding higher research costs compared to many other industries. Besides this only nutrients are proven to successfully tackle chronic diseases which, when applied on a grand scale, would put a big part of the medical systems out of business.

A typical example of bad science are e.g. the Vitamin-A studies as mentioned in this FAO/WHO proposal: Mostly artificial Vitamin-A is studied instead of the different natural Vitamin-A. The potential harm of this artificial substance to the liver was presented without mentioning that natural Vitamin-A in form of an emulsion like in the mother's milk can be taken to good effect even in huge quantities like 300.000 I.U. or 100 mg without any damage to the liver. The outcome of such biased research can already be felt in Europe: the European Food Supplement Directive banned the natural form of Vitamin-A with the result that it is not available any more.

Another example of bad and biased science is the case of Vitamin-C and the amino acid Lysine: This time the culprit lies in the stubborn refusal of the medical systems to study the effect of high dose (several grams per day spread over the day) supplementation with these nutrients. Only small studies with promising outcome are done despite the potential of eradicating one of the biggest health threats to mankind namely the coronary diseases. These discoveries are coming from the Nobel laureate Dr. Linus Pauling but are completely disregarded. Unless these and other important discoveries are either confirmed or disproved on a grand scale the WHO must stop all of their Codex procedures due to lack of unbiased scientific evidence.

A further example of not only bad but plain fraudulent science regarding nutrients is the case of Vitamin-B17: Already many years ago the most famous cancer researcher of that time in the USA Dr. Kanematsu Sugiura confirmed in a 5 year long study the extraordinary effect of this vitamin in treating and preventing cancer. But the president of the Sloan Kettering University told the world that B17 had no effect on cancer at all - which was the ultimate lie. Instead Vitamin B17 was said to be poisonous even though this is a lie as well, so the trading of B17 is forbidden in the USA since today. The B17 molecule and its effect on cancer cells and on healthy tissue are well understood. And it is known that all populations which eat high amounts of food rich in nitrilosides (B17) never get cancer. This would be the simple solution to easily prevent the worlds population against getting cancer and at a cost close to zero. Again the European Food Supplement Directive e.g. has banned this Vitamin B17 recently "to protect the public". This leaves any real independent scientist just plain speechless. If the WHO would listen to these European and American "scientifically derived" decisions then the WHO would become liable for this ongoing world wide genocide.

### **Conclusion:**

The existing regimentation for vitamins in minerals in some first world countries like the European Union shows already that biased, distorted or plain fraudulent scientific evidence was chosen to define law. The European Food Supplement Directive e.g. banned the most important vitamins like vitamin B17 or natural forms of vitamins and banned all of the 77 minerals but about 12 and allowed these minerals only in forms which the human body hardly can make use of. **As the WHO works close together with the European Union and other countries which suppress sound scientific evidence I can only demand that the WHO must stop these Codex proceedings until the problem with the missing quality of scientific evidence is solved.**

### **4. Conclusion:**

Until the before mentioned issues regarding quality of scientific evidence are not principally and extensively solved there is not the slightest excuse left for the WHO not to immediately cease this Codex process.

When the WHO continues anyway on this fast track I must conclude that the whole Codex

Alimentarius endeavor is not about protecting the world's public health but that it is only about protecting the profits of pharmaceutical companies and the profits of the health industry in general and that the WHO is willing to support the enforcement of a genocide on a world wide scale.

Last words:

The truth regarding nutrients never depends on the number of how many scientists have the same opinion. It is as in our nature in general: the planets are circulating the sun and they don't care if people insist for hundreds of years that the sun circles our planet earth. There is a universal rule that every time mankind has tried to improve our nature it was a complete failure. We are just witnessing this again as we try to improve on our food by processing it and applying pesticides and chemical fertilizers instead of improving our health just with all that natural nutrients we have learned through our experience and unbiased science to be of good advantage to our well being.

Sincerely

Gerd Stueckler

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