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Sent: Thursday, September 16, 2004 6:45 PM
To: Saldanha, Leila (NIH/OD)
Cc: Milner, John (NIH/NCI)
Subject: Comments on Proposed Definition of Bioactive Food Components

Dear Dr. Saldanha,

I am submitting the following comments in response to the notice in the Federal Register September 16, 2004 (Volume 69, Number 179) regarding this proposed definition of bioactive food components: "Bioactive food components are constituents in foods or dietary supplements, other than those needed to meet basic human nutritional needs, that are responsible for changes in health status." I will respond the suggested questions below:

(1) What categories/classes of compounds should be considered as bioactive food components?

Any compound that occurs naturally in foods commonly consumed in the United States in quantities sufficient or likely to cause a detectable biological effect in humans should be included in the definition. If there is not some threshold dietary intake required for this definition, then any trace amount of a substance could qualify and the whole concept of "being part of food" will become irrelevant as analytical methods get more and more sensitive.

(2) What categories/classes of compounds should not be considered as bioactive food components? How should the definition be modified to reflect exclusion of these compounds?

Man-made substances that do not otherwise occur in foods should be excluded. The definition could include the wording above "Any compound that occurs naturally in foods commonly consumed in the United States in quantities sufficient or likely to cause a detectable biological effect in humans."

(3) Should essential nutrients be included as bioactive food components?

YES! Essential nutrients are a subset of bioactive food components and should NOT be excluded, regardless of dose. Although there may be administrative reasons to draw a distinction between essential nutrients and other bioactive food components, there is no scientific basis for it. Today's bioactive food component may turn out to be tomorrow's essential nutrient, witness the case of selenium.

(4) Should synthetically derived components used in fortified foods and dietary supplements be considered under this definition?

Only if they are chemically identical or biologically equivalent to naturally occurring bioactive food components. If the substances are not chemically identical, then the FDA would consider them food additives. That should be sufficient reason to exclude them.

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"Leave your drugs in the chemist's pot if you can heal the patient with food"

- Hippocrates, the Father of Medicine

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