June 14, 2005

To: Dr. Edward Scarborough
U.S. CODEX Manager
U.S. CODEX Office
United States Department of Agriculture
South Building, Room 4861
1400 Independence Ave, SW
Washington, DC 20250

AMENDMENT to CITIZEN PETITION
to U.S. CODEX Office for
Adoption of Dietary Supplement Harmonization Policy
by the U.S. CODEX Delegation
in Harmony with DSHEA and 19 USC 3512

This AMENDMENT is submitted with regard to the Citizen Petition of June 1, 2005, urging the US Codex Office to adopt, as its policy, harmonization with international standards only in conformity with existing US Law, further now stating:

1. The CODEX Vitamin and Mineral Standard uses inappropriate science (Risk Assessment procedures [toxicology] rather than nutritional science [biochemistry] to mandate maximum permissible levels of nutrients so low that they are, by intention, without impact on any human being; a Fact Hearing must be held to determine the scientifically factual basis for the use of Risk Analysis in decisions pertaining to nutrition.

The US Codex Office has accepted the use of Risk Assessment procedures for nutrients although Risk Assessment is a methodology relevant to toxicology and both irrelevant and antithetical to nutritional science and biochemistry. Over the past many years, the United States has failed to oppose the use of Risk Assessment techniques in the CODEX Committee on Nutrition and Foods for Special Dietary Purposes and, since 1994, has failed to make its opposition to the use of Risk Analysis or any other attempt to limit access to nutrients clear in order to prevent the restrictive, and, because of US law, the illegal Vitamin and Mineral Standard from moving forward via consensus to Step 8 in preparation for ratification.

The Technical Report discussing the application of Risk Assessment to nutrients makes it clear that this procedure does not apply to nutrients because, unlike drugs, they have minimum intake limits which are required for life. Risk Assessment procedures were modified without scientific validation or clinical testing. Has the United States held a public fact finding hearing to determine if this jerry-rigged statistical system has any applicability to nutritional science? If not, why has the US supported the use of this technique in the nutritional determinations made by the CCNFSDU when so many lives are at stake in this issue? Why has the US adopted this scientifically factually indefensible

policy which should not be abandoned in favor of a policy which supports and promotes DSHEA as the international standard?

2. The US Codex Office and all other involved agencies are without legal authority to set, as was announced at the Public Hearing of June 9, 2005, as its Policy for the United States Government, and its Delegates to the 28th CAC meeting next month, a Policy which explicitly and specifically violates US law as set forth in the Natural Solutions Foundation's Citizen's Petition presented to the US Codex Office on June 1, 2005:

> Title 19, Section 3512, forbids the US from harmonizing with standards which violate US law;
>
> The Dietary Supplement Health Education Act (DSHEA), 1994 classifies supplements as foods which therefore may have no Safe Upper Limits, Maximum Permissible Upper Limits or other restrictions upon their use.

The adoption of the Risk Assessment Model and the anti-DSHEA harmonization Policy are *ultra vires* and premature; have occurred without sufficient Public Hearings and in direct contravention of the Public Policy of the United States as enacted by Congress.

Dated: June _____, 2005

Natural Solutions Foundation

Cc:
CODEX Office via facsimile and email
George W. Bush, President
Secretary HHS
Secretary of Commerce
Secretary of Agriculture
Secretary of Transportation
Commissioner of EPA
Commissioner of FDA

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Maj. Gen. Albert N. Stubblebine III (US Army, Ret.)
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