May 16, 2001


Dear Ambassador Lund

We are writing in reference to the agenda of the Internal Market Council of 31 May, specifically regarding the regulation of food supplements. The Transatlantic Consumer Dialogue (TACD) is a forum of US and EU consumer organisations that develops and agrees on joint consumer policy recommendations to the US government and European Union. The purpose of the TACD is to promote the consumer interest in EU and US policy making and its resolutions represent the views of consumer organisations on both sides of the Atlantic.

In its resolution on food supplements, the TACD calls upon the governments of the European Union and the United States to require that dietary supplement ingredients be subjected to a government safety and efficacy review which shall include the establishment of safe upper limits.

The TACD therefore agrees with the approach of the European Commission as it was stated in its amended proposal under:

Recital: (13) For vitamins and minerals excessive intakes may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer.

and

Recital (14) For that reason, when setting those maximum safe levels, account should be taken of the upper safe levels of the vitamins or minerals, as established by scientific risk assessment based on generally acceptable scientific data, of intakes of those nutrients from the normal diet and of the fact that for some nutrients upper safe levels may be close to the level that may be recommended for consumption. The latter
consideration is of particular importance where generally acceptable scientific data prove that excess intake of the vitamins and minerals concerned cause adverse effects.”

We therefore ask your support to maintain article 5(1)

1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set taking the following into account:
   (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally acceptable scientific data that take into account, as appropriate, the varying degrees of sensitivity of different groups of the population;
   (b) reference intakes of vitamins and minerals for the population, where these are close to the upper safe levels;
   (c) intakes of vitamins and minerals from other dietary sources

We hope you will find our position of use and contributing to your decision-making.

Yours Sincerely

Sue Davies, EU Chair of the Food Working Group