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Scientific Committee on Food **SCF/CS/ADD/NUT/54 Final**
18 March 2003

Statement of the Scientific Committee on Food

on the

D-α- tocopheryl acid succinate (TAS)

(expressed on 4 April 2003)

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Statement of the Scientific Committee on Food on

D-α- tocopheryl acid succinate (TAS)

The Scientific Committee on Food has evaluated a number of substances, including D-α-tocopheryl acid succinate (TAS), intended to be used in the manufacture of foods for particular nutritional purposes (PARNUTS) in May 1999 (SCF/CS/ADD/NUT/20 final, opinion expressed on 12/5/99). In the case of TAS, the Committee considered it temporarily acceptable, pending submission of additional information within one year of publication of the opinion to clarify the extent of hydrolysis of TAS in the gut and, consequently, whether any unhydrolysed TAS is available for absorption.

Further information, including published papers, was submitted by the petitioner within the deadline but it was not sufficient to clarify the extent of hydrolysis of TAS. At its 122nd Plenary meeting (on 6-7 September 2000), the Committee therefore requested further clarification on this issue from the petitioner. It agreed to extend its temporary acceptance of TAS for a further two years, in the light of the long history of use of TAS as a human medicine and studies in humans showing that tocopherol is bioavailable when TAS is ingested (though not the extent of bioavailability).

A further submission by the petitioner was received in 2001 informing the Committee that an *in vitro* hydrolysis study on TAS, using simulated gastric fluids, had been conducted but that the results were inconclusive, in accordance with some earlier published work. Following consideration of this and other published information about possible cellular effects of TAS at the biochemical level by the Additives Working Group of the Committee in 2002, the petitioner has offered to conduct an *in vivo* study to address both the bioavailability issue and the possible effects of TAS, should any be absorbed intact.

In view of this, the Committee recommends extension of the temporary acceptance of TAS for a further 2 years, with the provision that the results of the proposed study are submitted within one year from now to the European Commission/EFSA for evaluation.