

Dr Horst Messinger
Cognis Deutschland GmbH & Co. KG
Postfach 13 01 64
D-40551 Dusseldorf
Germany

14th July 2004

Reference: NFU 511

Dear Dr Messinger,

OPINION ON THE SUBSTANTIAL EQUIVALENCE OF PHYTOSTEROL ESTERS

The Food Standards Agency, the UK competent authority for all novel food issues has completed your request for an opinion on the substantial equivalence of your phytosterol ester ingredient. The basis of your request for an opinion is that you have been a major supplier of phytosterol esters to Unilever, who have used them in their Flora (Becel) *pro.Activ* yellow fat spread product since 2000, and in milk and yoghurt type products since March 2004.

We have reviewed the information you have supplied in support of this request and I am pleased to inform you that we accept that your phytosterol esters meet the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97.

This opinion is issued on the basis that your phytosterol ester ingredient is to be used in the following food products in accordance with the conditions specified in the named Commission Decisions:

- Milk type products and yoghurt type products, as described in Commission Decision 2004/335/EC.
- Yellow Fat Spreads, as described in Commission Decision 2000/500/EC.

We also advise that you inform all customers that food products containing plant sterols and sterol esters should be labelled in accordance with Regulation (EC) 608/2004.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission when you intend to market your phytosterol ester ingredients when they are first marketed.

You should send this to Mr Andreas Klepsch at the following address:

**European Commission
DG SANCO
Rue de la Loi 200
B-1049
Brussels
Belgium**

If you have any other queries, please do not hesitate to contact my colleague, Dr Chris Jones (Tel: 00 44 (0) 207 276 8572) or myself.

Yours sincerely,

Dr David Jefferies
Novel Foods Division