

Dairygold Food Products  
Clonmel Road  
Mitchelstown  
Co. Cork

11/August/2004

Dear Sir,

I am writing in response to your letter of July 1<sup>st</sup> 2004 requesting an FSAI opinion on substantial equivalence. Dairygold is proposing that its yellow fat spread with added plant sterol is substantially equivalent to a product(s) already on the EU market and thus wishes to place it on the EU market as provided for in Article 5 of the Novel Food Regulation EC 258/97.

The FSAI has reviewed the information provided by Dairygold and consulted with the Nutrition Sub-Committee of the FSAI Scientific Committee. The spread to which the proposed Dairygold product is being compared is on the EU market by virtue of Commission Decision 2004/333/EC which includes authorisation for the placing on the market of yellow fat spreads with added phytosterol. Dairygold's yellow fat spread is established on the market and the phytosterol to be added is of the same specification as that added to products already on the market.

Overall, the FSAI is satisfied that the proposed Dairygold yellow fat spread with added phytosterol is substantially equivalent to a similar product on the EU market with respect to composition, nutritional value, metabolism, intended use and level of undesirable substances (Article 3.4 of Regulation EC 258/97).

The FSAI opinion is based on the information provided by Dairygold and an assurance that the labelling provisions set out in Commission Regulation EC 608/2004 and listed in the letter of July 1<sup>st</sup> will be adhered to. The yellow fat spread will comprise that defined by Council Regulation EC 2991/94 and exclude cooking and frying fats and spreads based on butter or other animal fats. The total anticipated intake of 1.47g per day of the proposed spread is within the range that has been shown to provide a benefit to the consumer, but below the recommended maximum daily intake of 3 g per day above which no added benefit is observed.

If you are satisfied with this opinion, Dairygold may communicate to the European Commission its intention to place the product on the EU market. The following is the name and contact address for the individual responsible in the Commission.

Mr Andreas Klepsch  
European Commission  
DG SANCO D4  
Rue de la Loi 200  
B-1049 Brussels  
Belgium

In order to avoid any confusion and to ensure that your notification has been received, I recommend that you await a response from the European Commission prior to placing this product on the market. I would also recommend that you send this letter, the Dairygold letter requesting an FSAI opinion and all other information you have provided to the FSAI in support of the application to the Commission for their files.

If you have any further comments or questions please do not hesitate to contact me.

Regards,

Dr. Pat O'Mahony

Chief Specialist, Biotechnology