Dairygold Consumer Foods Division
Cahir Hill
Mitchelstown
Co. Cork

2 June 2005

Dear Sir,

I am writing in response to your letter of April 26th 2005, requesting an opinion on substantial equivalence from the Food Safety Authority of Ireland (FSAI). Dairygold Consumer Foods is proposing that its yoghurt-type drink with added plant sterols is substantially equivalent to a product 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 you and consulted with the Nutrition Sub-committee of the FSAI Scientific Committee. The yoghurt-type drink to which the proposed product is being compared is on the EU market by virtue of Commission Decision 2004/335/EC. The Cognis Vegapure plant sterol fatty acid esters which will be used are the same as those used in other approved yoghurt-type drinks.

The FSAI is satisfied that the proposed Dairygold yoghurt-type drink with added plant sterols 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 Consumer Foods and an assurance that the labelling provisions set out in Commission Regulation EC 608/2004 and listed in the letter of April 26th will be adhered to. One bottle (100 g) of the yoghurt-type drink will contain 1.6g of free plant sterols and will be the recommended daily intake. The required labelling will be carried on the packaging.

If you are satisfied with this opinion, Dairygold Consumer Foods may communicate to the European Commission its intention to place the proposed product on the market. I recommend that when notifying the European Commission you should send a copy of this letter along with all of the information you provided to the FSAI in support of this substantial equivalence application. 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 the product on the market.

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

Yours sincerely,

Dr. Pat O'Mahony

Chief Specialist, Biotechnology