

Kerry Ingredients  
Tralee Road  
Listowel,  
Co. Kerry

3 June 2005

Dear Sir,

I am writing in response to your correspondence of April 22nd 2005, requesting an opinion on substantial equivalence from the Food Safety Authority of Ireland (FSAI). Kerry Ingredients is proposing that its yellow-fat spread with added plant sterols is substantially equivalent to products 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 yellow-fat spreads to which the proposed product is being compared are on the EU market by virtue of Commission Decisions 2004/333/EC, 2004/334/EC and 2004/336/EC.

The FSAI has reviewed the information provided by you and consulted with the Nutrition Sub-committee of the FSAI Scientific Committee. The FSAI is satisfied that in principle the proposed yellow-fat spread with added plant sterols is substantially equivalent to similar products 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). However, a few issues need to be addressed before the FSAI opinion is final.

In your application you refer to and provide examples of certificates of analysis that are included however, a certificate for aflatoxins is not included in Appendix A. An example of a certificate of analysis for aflatoxins would be useful for completion.

The FSAI substantial equivalence opinion is based on the information provided by Kerry Ingredients and an assurance that the labelling provisions listed in the request of April 22<sup>nd</sup> and set out in Commission Regulation EC 608/2004 will be adhered to. There are three items in your proposed labelling provisions that need to be clarified or amended.

1. It should be clarified that it is the added plant sterols that are clinically proven to reduce blood cholesterol levels.
2. The statement advising that the product be “used as part of a balanced and varied diet” should also include the wording “including regular consumption of fruit and vegetables to help maintain carotenoid levels” as stated in Regulation 608/2004 (Article 2.6).
3. The proposed statement “Consumption of greater than 3g of the free plant sterol .....” should read “Consumption of greater than 3g/day of the free plant sterol .....”.

Once these amendments or clarifications have been agreed with the FSAI, Kerry Ingredients may communicate to the European Commission its intention to place the product on the market. It is recommended that when notifying the European Commission, a copy of this letter should be sent along with all of the information 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 the notification has been received, it is recommended that a response is received 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

cc: Nigel Baldwin