

Nature's Best Limited
Greenvale Park
Donore Road
Drogheda
Co. Louth

22/Dec/2004

Dear Sir,

I am writing in response to your letter of October 28th 2004, requesting an opinion on substantial equivalence from the Food Safety Authority of Ireland (FSAI). Nature's Best is proposing that its salad dressing 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 Nature's Best and consulted with the Nutrition Sub-Committee of the FSAI Scientific Committee. The salad dressing to which the proposed Nature's Best 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 salad dressing with added plant sterol. Nature's Best salad dressing is already established on the market and the plant sterol 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 Nature's Best salad dressing with added plant sterol 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 Nature's Best and an assurance that the labelling provisions set out in Commission Regulation EC 608/2004 and listed in the letter of October 28th will be adhered to. The salad dressing will be marketed as an ingredient in potato salad. One portion of potato salad (100g) will contain 33.5g of salad dressing which in turn will deliver a total of 1.48g of plant sterol and the required labelling will be carried on the potato salad packaging.

If you are satisfied with this opinion, Nature's Best may communicate to the European Commission its intention to place the product on the 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 also recommend that you send to the European Commission this letter, the Nature's Best letter requesting an FSAI opinion and all other information you have provided to the FSAI in support of the application.

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

Regards,

Dr. Pat O'Mahony

Chief Specialist, Biotechnology