

Dr. Albert Bär
Bioresco Ltd.
Bundestrassse 29
CH-4054 Basel
Switzerland

September 6, 2006

Dear Dr. Bär,

I received your formal application on August 29, 2006 for a substantial equivalence opinion from the Food Safety Authority of Ireland (FSAI) on a low fat cheese with added plant sterols. Since your first contact with me regarding this application on August 11th, I have examined the issues involved and consulted widely.

I am in general agreement with the sentiments of the UK Trading Standards officer who pointed out that the initial basis for placing the low fat cheese product with added plant sterol on the UK market may have been somewhat misguided. I believe it is possible that the low fat cheese (fat content $\leq 12\text{g}/100\text{g}$) might not be considered substantially equivalent to cheese type products simply based on the description of the latter in Commission Decisions 2004/333/EC and 2004/336/EC. I would agree that the proposed low fat cheese is very similar to the cheese type products already on the market on the basis of the low fat content ($\leq 12\text{g}/100\text{g}$), added plant sterols as well as general composition and nutritional value. However, the cheese type products listed in the Commission Decisions are specifically described as having the milk fat and/or protein replaced partly or wholly by vegetable fat and/or protein. This qualification could be interpreted as differentiating between the proposed low fat cheese and cheese type products as described in the relevant Commission Decisions.

Notwithstanding this, the qualification of cheese type products in the Commission Decisions is vague in that “partly replaced” can be taken to mean very low or even insignificant levels of replacement. The lack of a definitive lower limit of replacement leaves room for interpretation with two possible scenarios emerging; one where the cheese and cheese type product could not be considered substantially equivalent because the level of replacement of milk fat and/or protein is significant; the other scenario is where they could be considered substantially equivalent due to very little or insignificant replacement.

Article 3(4) of the novel food Regulation (EC No. 258/97) clearly stipulates that new foods falling outside the scope of this regulation must be substantially equivalent to existing foods as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein. Based on these criteria it is reasonable to conclude that the proposed low fat cheese with added plant sterol is substantially equivalent to a “cheese type product” with added plant sterol where a low level of milk fat and/or protein has been replaced.

In June 2006 a Member State Competent Authority delivered a positive substantial equivalence opinion on a type of plant sterol, even though the level of a major constituent was greater than that cited in the relevant Commission Decision. That opinion placed greater emphasis on the substantial equivalence criteria set out in article 3(4) of the novel food Regulation rather than the precise wording of a Commission Decision. Therefore, it is possible that substantial equivalence with regard to nutritional value, composition etc. may, in some cases, be at variance with the precise wording of a Commission Decision on novel food while in keeping within the spirit of the Decision.

In conclusion, the FSAI is of the opinion that Kingdom Cheese low fat cheese with added plant sterol is substantially equivalent with regard to composition, nutritional value etc. to “cheese type products” with added plant sterols (Commission Decisions 2004/333/EC and 2004/336/EC) in which a low level of milk fat and/or protein has been replaced. This opinion is based on the information provided by you with regard to the cheese and the particular plant sterol added. As you are aware, all such products must adhere to Regulation EC No. 608/2004 in regard to labelling and presentation. If you are satisfied with this conclusion, you may notify the Commission through the following contact prior to placing the proposed product on the market.

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

If you have any questions on this matter please feel free to contact me at your convenience.

Regards,

Dr. Pat O'Mahony

Chief Specialist, Biotechnology