

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

OPINION ON SUBSTANTIAL EQUIVALENCE OF PHYTOSTEROL ESTER CONSIDERED UNDER ARTICLE 3(4) OF THE NOVEL FOODS REGULATION 258/97

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Introduction

1. In 2004, Archer Daniels Midland (ADM) gained authorisation for use of its phytosterols as a novel ingredient in the following products: yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products.
2. Under Article 3(4) of the Novel Foods Regulation (EC) 258/97, the Chinese company Xi'an Healthful Biotechnology is requesting an opinion from the UK Competent Authority (CA) on the equivalence of their phytosterols with phytosterols sold by ADM, for use in the same range of products.
3. Regulation (EC) 258/97 makes provision for novel foods or ingredients that are substantially equivalent to an existing product to be placed on the market once the applicant has notified the Commission. In most cases, the Commission requires that the applicant first obtain an opinion on equivalence from a Member State. Xi'an Healthful Biotechnology is requesting such an opinion from the UK Competent Authority.
4. According to article 3(4) of (EC) 258/97, the notification procedure applies to "foods or food ingredients ... which on the basis of scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies ... are substantially equivalent to existing foods or food ingredients regarding their:
 - Composition,
 - Nutritional value,
 - Metabolism
 - Intended use and

- Level of undesirable substances contained therein.”¹

Evaluation

Composition

5. The Xi'an Healthful Biotechnology phytosterol ingredient is isolated from non GM by-products of the edible oil industry largely from soybean oil with some use of corn and tall oil. The applicant states that the production process is very similar to the one described in the SCF Opinion on the ADM novel food application. A comparison of three batches of the phytosterol ester to the specification in the implementing decision 2004/333 EC for the ADM phytosterol ingredient is reproduced from the dossier below.

Composition GC-FID or equivalent method as %	Requirements of 2004/333/EC for ADM	Xi'an Healthful Biotechnology Esterified phytosterol
β-sitosterol	<80%	44.13 - 45.82%
Sitostanol	<15%	0.00%
Campesterol	<40%	25.03 - 26.12%
Stigmasterol	<30%	25.21 - 26.31%
Brassicasterol	<3%	0.66 - 0.76%
Campestanol	<5%	1.36 - 1.42%
Other Sterol/Stanol	<3%	Not calculated

Discussion: The Committee sought further information on the composition of the novel food ingredient to evaluate the substantial equivalence of the product compared to the product from ADM. The applicant clarified that they were seeking authorisation for the phytosterol esters and that feedstocks used in the process are managed to ensure the specification for the product is met consistently.

Following questions on the production process of the novel ingredient the applicant clarified that they had changed their production process to remove the need for a catalyst and reduce the levels of undesirable substances. A further three batches of the final product produced using the new production method were analysed and compared against the ADM specification. It is this product that is now assessed for substantial equivalence.

Nutritional Value and Metabolism

6. The applicant suggests that the nutritional value or metabolism of Xi'an Healthful Biotechnology's phytosterol ingredient will be the same as that of the ADM product.

¹http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004D0333&model=guichett

Discussion: The Committee did not raise any concerns relating to this section of the dossier.

Intended Use

7. The applicant intends the ingredient to be used in yellow fat spreads, salad dressing (including mayonnaise), milk type products such as semi skimmed and skimmed milk products, fermented milk products, such as yoghurt, soya drinks, and cheese. These products are the same as those authorised for ADM phytosterols.

8. The applicant suggested that the anticipated intake of phytosterols is not likely to be increased as the ingredient is to be used in the same range of products already approved for ADM, as an alternative to phytosterols produced by other manufacturers

Discussion: The Committee noted that the applicant was seeking authorisation to use phytosterols in the same food categories as ADM. However, further clarification was sought that the company had considered the potential for an increase in intake from authorisation of an alternative source for the ingredient. The applicant explained that the Xi'an Healthful product would be an alternative to existing phytosterols. The Committee noted that in the original assessment the intake of phytosterols was calculated on the basis of phytosterols being present at the highest level of addition when the authorised food categories were consumed.

Levels of Undesirable Substances

9. Limited information on the levels of undesirable substances was given in ADMs application. However, Xi'an Healthful Biotechnology have provided data on the levels of a number of classes of potential contaminants including, polycyclic aromatic hydrocarbons (PAH's) herbicides and pesticides, heavy metals, organic solvents and biological contaminants such as aflatoxins and microbiological contamination. The applicant claimed that all contaminants measured are within acceptable levels and in compliance with EU regulations.

Discussion: The Committee raised comments in relation to the analysis of heavy metals. Further analysis was provided for three batches to ensure the full standard panel of heavy metals had been analysed. This addressed the questions of the Committee.

The Committee also queried the potential for pesticide residues to be present in some of the source materials for the novel food. Information was considered for three batches of the novel ingredient where no pesticide residues were present at the limit of detection. It was noted that the novel ingredient would be required to be compliant with specific EU legislation on pesticide residues and therefore the concern was considered to have been addressed.

Additional information

10. The applicant states that labelling of the products containing the phytosterols will be in accordance with Commission Regulation (EC) 608/2004 and Annex III of 1169/2011 EC concerning the labelling of foods with added phytosterols.

Discussion: The Committee did not raise any concerns relating to this section of the dossier.

Toxicology

11. The applicant has given a brief overview of relevant publications looking at the long-term safety of phytosterols. No adverse effects were reported in any of these studies. The applicant also shared information on internal toxicological studies undertaken on the Xi'an Healthful product.

Discussion: While noting that the application was a substantial equivalence and therefore not required to provide toxicological data, as this had been provided in the dossier this was evaluated by the ACNFP. As the information provided was largely from other suppliers' phytosterols the Committee considered their relevance to the phytosterol under consideration. This was addressed in part by the assessment of this novel ingredient's substantial equivalence to those on the market. The applicant also supplied further information on their internal toxicological studies which addressed the outstanding questions from the Committee.

CONCLUSION

The Committee is content that the applicant's approach to demonstrating the equivalence of their phytosterols with the existing phytosterol ingredient is consistent with the criteria set out in Article 3(4) of the Novel Food Regulation (EC) 258/97.

Therefore phytosterols marketed by Xian Healthful Biotechnology Ltd can be considered to be substantially equivalent to the existing phytosterol ingredient marketed by Archer Daniel Midland.

Xian Healthful Biotechnology Ltd should ensure that the labelling of products containing their phytosterols comply with Regulation number 1169/2011 EU concerning the labelling of foods with added phytosterols, and more specifically to point 5 of Annex III of this regulation.

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