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Opinion of the Scientific Committee on Food on an application from ADM for approval of plant sterol-enriched foods

(expressed on 4 April 2003)

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1. TERMS OF REFERENCE

With reference to the initial assessment carried out by the authorities of the Netherlands, taking into account the relevant comments/objections presented by Member States and pursuant to Article 11 of Regulation (EC) N° 258/97, the Committee is asked to assess the safety, from the point of view of consumer health, of phytosterols and phytosterol esters as requested by Archer Daniels Midland (ADM).

2. BACKGROUND

Within the framework of Regulation (EC) N° 258/97 on novel foods and novel food ingredients, the Commission has received a request by the company ADM for authorisation to place on the market vegetable oil-derived plant sterols and sterol esters as novel food ingredients. The applicant requests permission to use phytosterols as such or in esterified form in fat spreads, salad dressings, health bars, health drinks, yoghurt type products and processed meats in amounts that provide about 1-3 g plant sterols per day to lower the plasma levels of total cholesterol and LDL cholesterol. In addition, the applicant intends to provide the unesterified sterols to the food and pharmaceutical industry for use as starting materials for esterification to produce sterol esters, and for chemical hydrogenation to produce stanols.

The Competent Authority of the Netherlands has concluded that the novel food ingredient can be used in fat spreads up to a maximum level of 8% (w/w) phytosterol equivalents, which had already been accepted by the Committee in the case of a comparable application (SCF, 2000). The Competent Authority has objected, however, to the use in other products.

The major concerns and suggestions raised by the Member States including the Competent Authorities of the Netherlands focussed on:

- potential risks from cumulative and long-term consumption of plant sterols from different products and the necessity to establish a safe level of consumption,
- effects on the absorption of fat-soluble vitamins and carotenoids,
- the specification of the phytosterol mixture and its stability,
- possible consumption by non-target groups, particularly children and pregnant and lactating women,
- the need for appropriate labelling.

This opinion takes into account the original information submitted by the applicant, the initial assessment carried out by the Competent Authority of the Netherlands, the

comments/objections to the initial assessment report forwarded by the Member States and the previous opinions of the Committee concerning phytosterols.

The Committee has so far expressed two opinions on applications for approval of plant sterol-containing foods. The first one concerns the safety in use of phytosterol esters of fatty acids in yellow fat spreads (SCF, 2000). The second opinion has addressed the use of non-esterified phytosterols, containing some phytostanols, in bakery products, grain-based snack products, gum arabicum pills, frankfurters, sausages and cold cuts, and the use of a sterol-enriched fat ingredient to be used in yoghurt, fresh cheese, margarine and fruit-milk drinks. In this opinion, the Committee has also made a recommendation concerning a phytosterol/phytostanol profile of up to 80% β -sitosterol, 15% β -sitostanol, 40% campesterol, 5% campestanol, 30% stigmasterol, 3% brassicasterol and 3% other phytosterols which is considered acceptable in general (SCF, 2003).

In addition, the Committee has expressed a general view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources. The Committee concluded that a numerical upper level for the total daily intake of phytosterols could not be established on the basis of the available data. In consideration of the dosages found to be effective for cholesterol-lowering, without evidence of additional benefits at higher intakes and the possibility that high intakes might induce undesirable effects, it was considered prudent to avoid plant sterol intakes exceeding a range of 1-3 g/day (SCF, 2002).

3. EVALUATION

The application presented by the petitioner follows the SCF recommendations concerning the assessment of novel foods expressed on 29th September 1997 and published as Commission Recommendation 97/618/EC (European Commission, 1997).

3.1 Production process

ADM plant sterols are by-products of traditional vegetable oil refining. According to the applicant, the source is commonly a blend of crude edible oils, consisting largely of soy bean oil and lesser amounts of other edible oils, e.g. corn, rapeseed and palm oil in varying proportions. The seeds are procured from the world oil seed supply and some may be derived from genetically modified (GM) plant varieties.

The crude oil, which is obtained by pressing or solvent extraction, undergoes a series of refining processes to remove solvents, lecithins, free fatty acids, color bodies, off-odors and off-flavors. In one of these steps, the oil is subjected to steam distillation at reduced pressure (deodorisation) and the resulting distillate contains the sterol fraction. From this fraction, fatty acids, lecithins and other compounds are removed by fractional distillation, ethanolysis/transesterification, distillation and crystallisation from a heptane solution, and the sterols are further purified by recrystallisation using food grade materials and good manufacturing practices. According to the applicant, the extraction and purification steps are standard methods and similar to the procedures used traditionally by the food industry for the production of plant sterols.

Sterol esters are produced from the sterols using food grade vegetable oil-derived fatty acids or triglycerides and applying standard methods for esterification or transesterification commonly used in the fats and oils industry.

3.2 Compositional data

3.2.1 *Phytosterol profile*

According to the specification provided by the applicant, the plant sterol mixture contains at least 90% sterols, composed of 40-58% β -sitosterol, 20-30% campesterol, 14-22% stigmasterol, 0-6% brassicasterol and 0-5% β -sitostanol. The mixture contains tocopherols in amounts of up to 15 mg/g.

Five representative batches collected over a period of 2 years were analysed for the major sterol components β -sitosterol, campesterol and stigmasterol and were found to comply with the specification provided by the applicant. Minor sterols were not included in these analyses. According to the applicant, the contents of minor sterols can vary depending on the type and proportion of seed oil used and the growing conditions of the plants, e.g. 2.3-2.4% for β -sitostanol and 3.8-5% for brassicasterol. According to additional information, however, the contents of minor sterols can be up to 6% brassicasterol, 4% Δ^5 -avenasterol, 4% β -sitostanol, 2% campestanol and 5% other sterols. These contents of minor sterols are not covered by the specification provided by the applicant, which includes only β -sitostanol and brassicasterol, and do not comply with the recommendation given by the Committee with regard to an acceptable phytosterol profile (SCF, 2003).

3.2.2 *Potential impurities*

According to the applicant, the plant sterols contain a number of other minor oil constituents, including mono-, di- and triglycerides, wax esters and squalene. The levels of heavy metals were below 10 ppm. In addition, a certificate of analysis has been provided showing that residues of 20 organochlorine pesticides were not detectable.

PCR analyses performed on three sterol samples using primers specific for the detection of the CaMV 35S promoter and the nos terminator produced negative results. These elements are often used in the generation of genetically modified plants. Primers for the detection of these elements are therefore used in screening PCR systems for the analysis of foods derived from genetically modified organisms. Due to the processing methods used it is not expected that the final sterol preparation contains any genetic materials or proteins.

3.3 Anticipated intake

According to the applicant, the sterol contents will be 8.0 g/100 g in fat spreads, 7.1 g/100 g in salad dressings, 3.3 g/100 g in yoghurt type products and 2.0 g/100 g processed meat products. Health bars and health drinks will contain sterols in amounts of 1 g/50 g and 1 g/250 g portion size, respectively. Health bars are described as cereal bars with a high protein and/or energy content which may be fortified with vitamins and minerals and/or have a reduced fat content. Health drinks may include liquid and reconstituted meal replacements and dry powder products as well as sports drinks.

The applicant has estimated the intake of plant sterols from consumption of the foodstuffs on the basis of the proposed levels of added sterols and the production levels of the respective foodstuffs within eight EU Member States (Eurostat, 1999). The Committee noted that the use of production data is not adequate to estimate consumption especially in the case of foodstuffs which are not consumed by the whole population.

The data obtained by this calculation were compared to the specific information available for the Netherlands, which is based on consumption data of the respective food items (TNO, 1997; TNO, 1998). It is not clear, however, whether the figures indicated by the applicant reflect average or high intake levels.

Based on an estimated consumption of 27 (Eurostat data) or 22 (Dutch data) g fat spread and margarine/person/day, sterol intakes of 2.2 or 1.8 g/day, respectively, would result. According to the applicant, additional data from a dietary survey conducted by the Institute of European Studies (IES) on adolescents in five European countries (Belgium, Germany, Finland, Ireland and Italy) have revealed an average fat spread consumption of 13 g/person/day and a high consumption of 28 g/person/day (90th percentile), resulting in sterol intakes of 1 and 2.2 g/day, respectively. Based on a daily consumption of 14 (Eurostat data) or 2 (Dutch data) g salad dressing and mayonnaise, 30 or 39 g yoghurt type products and 50 or 26 g processed meat products, sterol intakes of 1.0 or 0.14 g/day, 1.0 or 1.3 g/day and 1 or 0.52 g/day, respectively, would result.

Considering that, for the time being, the levels of phytosterols in various foodstuffs is calculated to provide 1-2 g per day, the Committee considers that consumption of 4 different products will provide 4-8 g sterols/day. In addition, consumption of one portion of health bar or drink will provide 1 g/day for each product type.

3.4 Nutritional and toxicological information

The applicant refers to the scientific literature and previous evaluations of phytosterols. New nutritional and toxicological information has not been provided.

4. COMMENT

The vegetable oil-derived phytosterol mixtures which are the subject of the present application do not comply fully with the phytosterol/phytostanol profile of up to 80% β -sitosterol, 15% β -sitostanol, 40% campesterol, 5% campestanol, 30% stigmasterol, 3% brassicasterol and 3% other phytosterols, considered acceptable in general by the Committee (SCF, 2003). The amounts of the major sterols β -sitosterol, campesterol and stigmasterol as well as of β -sitostanol and campestanol are in accordance with the accepted profile. The phytosterol mixtures can contain, however, up to 6% brassicasterol, 4% Δ 5-avenasterol and 5% other sterols, resulting in a content higher than 3% for brassicasterol and 3% for total other phytosterols. As brassicasterol and other phytosterol esters of fatty acids were only minor constituents of the phytosterol esters tested in the relevant toxicological studies (SCF, 2003), the amounts must not exceed 3%.

The applicant has not made recommendations regarding the intake levels of phytosterol-containing foodstuffs but relies on the assumption that normal consumption of the products will provide the amounts necessary for plasma cholesterol reduction and will not lead to intakes above acceptable levels. However, the applicant's estimate of the phytosterol intake, which is based on production data of the respective foodstuffs in eight Member States (Eurostat data) and on consumption data from one Member State (Dutch data), does not reflect the real consumption behaviour of an individual. For example, in the case of yoghurt type products containing 3.3% sterols, a daily consumption of 30 or 39 g/person has been

assumed, providing 1.0 or 1.3 g sterols/day, respectively. As portion sizes for such products are usually 100 or 150 g, much higher sterol intakes of 3.3 or 5.0 g, respectively, can result if only one portion of a yoghurt type product is consumed per day. In the case that more than one product is consumed, the actual sterol intake can be even higher. For example, the sterol intake from 150 g yoghurt and 25 g fat spread would amount to about 7 g/day.

5. CONCLUSION

The Committee has previously determined that the use of phytosterols is safe provided that the sterol-containing foodstuffs are not consumed in amounts resulting in total phytosterol intakes exceeding 3 g/day (SCF, 2002; SCF, 2003). In principle, this can be applied also to the phytosterol and phytosterol ester mixtures, which are the subject of the present application.

However, the mixtures can only be accepted if the composition complies with the phytosterol/phytostanol profile accepted by the Committee (SCF, 2003). Therefore, the mixtures must not contain more than 3% brassicasterol and 3% total other sterols (in addition to β -sitosterol, campesterol, stigmasterol, β -sitostanol and campestanol).

The Committee reiterates the previous recommendation that appropriate risk management measures should be developed to minimise the likelihood of a daily intake exceeding 3 g phytosterols/phytosterols, in particular from the cumulative intakes of different types of products (SCF, 2002; SCF 2003). The Committee notes that the Commission is working with Member States to develop such risk management measures.

In addition, the Committee wishes to draw the attention to the point that in this application it is intended to add sterols to beverages for the first time. With regard to the sterol intake from such products it should be noted that portion sizes are difficult to control.

The Committee also reiterates the recommendations:

- that the small number of people with inborn error of phytosterol metabolism (phytosterolaemia) should be made aware of the presence of higher levels of phytosterols in the product,
- that patients on cholesterol-lowering medication should only consume the products under medical supervision, and
- that the potential β -carotene lowering effect should be communicated to the consumer, together with appropriate dietary advice regarding the regular consumption of fruits and vegetables.

The Committee notes again, that the consequences of a persistently decreased blood concentration of β -carotene on human health are largely unknown and that situations where vitamin A requirements are greater than normal as in pregnancy, lactation or infancy may be of concern (SCF, 2002; SCF, 2003).

5. REFERENCES

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