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Opinion of the Scientific Committee on Food

on

Soybean Hemicellulose

(opinion expressed on 4 April 2003)

Rue de la Loi 200, B- 1049 Bruxelles/Wetstraat 200, B-1049 Brussel- Belgium-Office: G-1 01/242
Telephone: direct line (+32-2) 29 84698, swithboard 299.11.11 Fax: (+32-2) 2994891
http://europa.eu.int/comm/food/fs/sc/scf

OPINION OF THE SCIENTIFIC COMMITTEE ON FOOD
ON SOYBEAN HEMICELLULOSE

Terms of reference
The Committee is asked to evaluate the safety of soybean hemicellulose to be used as a food additive, as emulsifier, thickener, stabiliser and anti-caking agent.

Background
In general terms, hemicelluloses are defined as cell wall polysaccharides extractable in dilute sodium hydroxide solutions. It includes all the cell wall polysaccharides except cellulose and pectin. On hydrolysis, hemicelluloses yield an abundance of pentose sugars along with d-glucuronic acid and some deoxy sugars (Macrea et al, 1993).

Soybean hemicellulose is extracted from soy fibre. Soy fibre is a mixture of cellulosic and non-cellulosic structural components of the internal cell wall of soybeans. Its major fractions are non-cellulosic. (Aspinall et al., 1967). The raw material ('Okara') from which the soluble hemicellulose is extracted, is a high-fibre containing by-product of the soy oil and soy protein production process.

Soy fibre can be added to many food systems and is available in various forms that are tailored to specific applications. In the US different soy-fibre sources are used in liquid diets, specifically hospital enteral nutrition formula, low-calorie breads and baked goods including muffins, cookies and crackers (Anonymous, 1987).

In the present application (Maeda, 2000a) approval is requested for the incorporation of soybean hemicellulose as emulsifier in flavour oil, vitamin oil and β-carotene, as thickener in baked goods and jelly confectionery, as stabiliser in frozen foods and yoghurt drinks, and as anti-caking agent in noodles and rice.

Chemical information
The product under consideration (Soyafibe-S) is a water-soluble soybean hemicellulose (CAS number 9.34-32-6) obtained after hot water extraction of natural soybean fibre. The structure of the fibre component is that of a polysaccharide which contains a rhamno-galacturonic acid chain with galactan and arabino-galactan side chains.

Some technological differences exist between the commercial varieties of Soyafibe-S. The physical characteristics, i.e. most importantly the viscosity, determine the choice of a given variety in a given application.

Compositional data and physical characteristics of the different Soyafibe-S varieties are shown in Table 1.

Table 1. Composition and physical characteristics of Soyafibe-S varieties

Variety	Crude Protein (%)	Crude Ash (%)	Viscosity (mPa.s)	% Soluble fibre
SOYAFIBE-S-DN	9.2	8.6	56	75.1
SOYAFIBE-S-DA100	6.2	8.4	62	75.7
SOYAFIBE-S-LN	10.4	6.6	24	65.5
SOYAFIBE-S-LN1	13.9	6.8	13	64.3
SOYAFIBE-S-LA200	7.5	6.5	16	66.6
SOYAFIBE-S-EN100	8.7	7.2	71	79.2
SOYAFIBE-S-FA100	5.8	6.0	140	74.3
SOYAFIBE-S-RA100	4.8	6.4	78	75.9

Sugar composition

The sugar composition of all varieties is fairly similar and represented by the same sugar types, i.e. galactose (Gal), arabinose (Ara), galacturonic acid (Gal A), rhamnose (Rha), fucose (Fuc), xylose (Xyl) and glucose (Glc) with some minor differences in their actual percentages. The individual sugar profile of each of the varieties is shown in Table 2. It appears that the fluctuation in the sugar levels between the different varieties is not significant.

Table 2. Sugar composition of the commercial SOYAFIBE-S varieties

Variety	Rha	Fuc	Ara	Xyl	Gal	Glc	GalA
DN	5.0	3.2	22.6	3.7	46.1	1.2	18.2
DA100	5.2	2.5	25.3	4.1	43.6	1.0	18.3
EN100	5.8	1.3	24.8	2.5	45.1	1.5	19.0
LA200	6.0	2.1	19.6	4.6	42.8	1.1	23.8
LN	6.5	2.3	18.1	5.0	44.7	1.4	22.0
LN1	5.9	2.0	18.7	5.1	44.0	1.8	22.5
FA100	4.8	1.9	25.3	2.3	46.1	1.2	18.4
RA100	5.0	2.0	27.2	3.0	42.2	1.5	19.1
RANGE	4.8-6.5	1.3-3.2	18.1-27.2	2.3-5.1	42.2-46.1	1.0-1.8	18.2-23.8

The sugar profile of natural soy fibre and that of the natural insoluble hemicellulose fraction as compared to the commercial Soyafibe-S hemicelluloses is shown in Table 3. Except for glucose, the sugar composition of the commercial hemicelluloses is very similar to that of the natural fibre.

Table 3. Sugar profiles of natural soy fibre and its insoluble residue as compared to the commercial SOYAFIBE-S

	Natural soy fibre (Okara)		SOYAFIBE-S		Natural soy fibre (Okara) Insoluble residue	
Nature of sugar	**Percentage sugar composition**	**Sugar/Galactose ratio**	**Percentage sugar composition**	**Sugar/Galactose ratio (mean)**	**Percentage sugar composition**	**Sugar/Galactose ratio**
Rhamnose	1.9	0.05	4.8-6.5	0.13	0.4	0.02
Fucose	3.3	0.09	1.3-3.2	0.05	3.3	0.12
Arabinose	19.3	0.53	18.1-27.2	0.51	13.7	0.51
Xylose	6.1	0.16	2.3-5.1	0.08	7.4	0.27
Mannose	1.0	0.03	0.0	0.0	1.6	0.06
Galactose	36.3	1.00	42.2-46.1	1.00	26.7	1.0
Glucose	18.6	0.51	1.0-1.8	0.03	45.8	1.71
Galacturonic acid	13.6	0.37	18.2-23.8	0.48	-	-

Dietary fibre
The total dietary fibre content of natural dried soybean is 17.1%, which is, equivalent to 9.2% water-soluble dietary fibre (Kikuchi et al., 1971). This water-soluble portion in natural soy fibre is bonded to the water insoluble fraction, rendering the natural soy fibre, as such, insoluble in water. The soluble fibre content of the different Soyafibe-S varieties is shown in Table 1.

Molecular mass distribution
The petitioner has provided analytical data showing the presence in the commercial product varieties of three main hemicellulose fractions at masses around 550,000, 25,000 and 5,000 Daltons. The molecular mass distribution profiles of the different Soyafibe-S varieties show great similarities and there is good correlation between the proportions of low, medium and high molecular mass fraction of the varieties and their physical characteristics.

Extraction conditions (i.e. pH, temperature and extraction time) have an important effect on the yield of the high-molecular weight fraction (Mw >500,000). Keeping these parameters under control ensures the required product characteristics in stable quality. The Committee is content with the provided data.

Product specification
The different varieties of the commercialised products are similar enough in their composition as to allow them to be treated as one single food additive, i.e. water-soluble soy fibre.

The characteristic composition is as follows: moisture: 4.5-6.5%; crude protein: 4.8-13.9%; ash: 6.0-8.6%; carbohydrate: 74.0-83.0%; dietary fibre (water soluble): 60.0-77.0%; others: 6.0-14.0%. The latter fractions are small fragments of dietary fibre, which cannot be detected as dietary fibre by a standard analytical method for fibres (Prosky et al., 1985).

Acidity: pH (1% solution) 5.5 ± 1.5; heavy metals (expressed as lead) not more than 10 ppm; arsenic not more than 2 ppm; viscosity (10% solution) not more than 200 mPa.s.

Standard plate counts: not more than 3000 cfu/g; yeast and moulds: not more than 100 cfu/g, *E. coli,* negative.

The chemical and microbiological methods of analysis are fully described by the petitioner.

Using PCR technology, no genetically modified DNA is detected, using genetically modified 'Round Up Ready' soybean taken as reference material. The petitioner has stated that the manufacturer of soybean hemicellulose (a Japanese company) will only use traditional, non-GMO, soya for the manufacture of soybean hemicellulose intended for sale in the EU. It is further stated that appropriate measures and controls are taken from the farm producing soya to the importing port where each cargo is inspected by a third party to ensure that only traditional (non-GMO) soya is supplied to the manufacturing sites.

Isoflavones

Isoflavones are separated and removed with the solid residue at the extraction process, followed by a purification step with activated charcoal. The level of residual isoflavones is checked on a routine basis (method described in the application). Data show that soybean hemicellulose does not contain isoflavones above the detection limit of 10 ppm.

Technological information

The raw material used for the production of soybean hemicellulose is "Okara", a by-product of the soy oil and soy protein production process. The production process is fully described and the Committee is content with the information provided.

Reaction and fate in food

As a result of the extraction conditions used it is unlikely that degradation of Soyafibe-S hemicellulose would occur, due to thermal treatment, under the usual production conditions for the food categories considered in this application.

Data were provided demonstrating that the presence of water-soluble hemicellulose in the diet does not affect the bioavailability of other nutrients. It has been shown that the effect of 3% Soyafibe-S in the diet on the absorption of the main nutrients is less than that of 5% cellulose in a standard diet.

Concerning the effect of the substance on the absorption of minerals like calcium, data show that its effect is much less than that of pectin. Therefore no adverse effect is to be expected on mineral absorption (Slavin, 1991).

Exposure information

Soy from natural sources

The most common and widely consumed soy based foodstuffs are soybeans, soymilk, tofu, miso, tempeh and soy sauce. The petitioner provided estimates of the intake of soy fibre from these sources in Japan and in Europe, for comparison with intakes from use of soybean hemicellulose as an additive.

In Japan the per capita daily consumption of natural soluble soy fibre is estimated to be 0.6 g/day (Maeda, 2000a). In Europe, considering that only a very small percentage of the population is consuming soy products, the use of per capita intake data is not relevant. Nevertheless, it may reasonably be assumed that the average consumption in Japan is of the same order as that of the high consumers in Europe.

Soybean hemicellulose

The intended uses and use levels of the Soyafibe-S varieties are given in Table 4. The intake of Soyafibe-S can be calculated from data on the estimated food consumption in Europe for the products listed. Based on a worst-case assumption that all products contain Soyafibe-S at the maximum inclusion level, the calculated total intake in Europe would amount to 0.5 g/person/day. On the same assumption, based on the individual intake data for the same food categories in the UK, a total estimated intake of 1.5 g/person/day can be calculated.

Table 4. Intended uses, use levels and estimated intakes of Soyafibe-S

Application	**Function**	**Amount in the final product (g/kg)**	**Estimated consumption of relevant food in Europe[1] (g/person/day)**	**Estimated consumption of relevant food in UK[2] (g/person/day)**	**Estimated intake of Soyafibe-S at maximum inclusion level in Europe (g/person/day)**	**Estimated intake of Soyafibe-S at maximum inclusion level in UK (g/person/day)**
Yoghurt drinks	Stabiliser	1 – 5	0.68	0.78[3]	0.003	0.004
Dressing	Emulsifier	1 - 30	2.5	2.1	0.08	0.06
Baked goods	Thickener	1 – 10	18.56	55	0.2	0.6
Noodles	Anti-caking	1 – 10	5.17	35	0.05	0.4
Rice	agent					
Frozen foods	Anti-caking	0.5 – 10	12.8	43	0.1	0.4
Jelly	agent					
confectionery	Stabiliser	1 – 10	2.45	-	0.03	-
	Thickener	1 – 10	3.48	7.14	0.04	0.07
					Total: 0.5	**Total: 1.5**

Toxicological data

Acute oral toxicity

An acute oral toxicity test was performed with soluble soy fibre, based on a 14-day observation period on 5 male and 5 female rats using dose levels of 2000 mg/kg b.w. The LD_{50} of soybean hemicellulose exceeded 2000 mg/kg b.w. (Maeda, 2000b).

[1] Data from Eurostat Data Shop Brussels and French marketing data on yoghurt drinks (CIDIL), Leatherhead Food RA 1998, GDO Week, 6 April 1998, Convenience Store, March 3-16.
[2] Data taken from 'The Dietary and Nutritional Survey of British Adults (DNS)' (1990)
[3] Value derived from the DNS value for yoghurt consumption (43.3 g/ person/ day) assuming the ratio of yoghurt drinks to production (1.8%) as given by CIDIL.

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Gene mutation in bacteria
Soluble soy fibre was examined for mutagenic activity in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 and *Escherichia coli* strain WP2 uvrA, at five different dose levels ranging from 62 to 5000 µg per plate, with and without metabolic activation. The results did not indicate mutagenicity (Maeda, 2000c).

Subchronic oral toxicity
To 120 Sprague-Dawley CD® rats (20/sex/group) soluble soybean fibre (SSF) was given *ad libitum* in the diet for 90 days at concentrations of 0, 20,000, 30,000, or 40,000 ppm (Unpublished report submitted by petitioner, 2001). There were no test article-related mortalities during the study. The main clinical finding was unformed stool, which was noted in all groups treated with the test article. This was considered a normal physiological response to the amount of fibre in the diets, similar to that observed with other water-soluble fibres, and not a specific adverse effect of the test article.

There were statistically significant decreases in mean body weights and in body weight gains for males and females in all groups treated with SSF, compared to the controls. The decreases ranged from 1% to 5% and were not dose-related. The decreases occurred mainly during the first half of the study and appeared to reflect decreased food consumption during that time. Subsequent increases in mean body weight and body weight gain appeared to be correlated with increased food consumption.

Statistically significant changes in haematology parameters were noted at termination. These included increases in erythrocyte count and decreases in reticulocyte count for the males at all doses and increases in percent hematocrit for females at all doses and increases in haemoglobin concentration and erythrocyte count for the high-dose females. These changes were slight and not considered biologically significant. With regard to clinical chemistry parameters, there were statistically significant decreases in serum cholesterol values of 25% and 17% for the mid- (30,000 ppm) and high-dose (40,000 ppm) males, respectively, but this was not considered an adverse finding.

There were statistically significant decreases in absolute and relative spleen weights for all groups treated with SSF. No related microscopic findings were found and the decreases were not considered biologically significant.

Based on the findings in this study, the no observed adverse effect level (NOAEL) for soluble soybean fibre when administered to rats via the diet for 3 months was 40,000 ppm equivalent to 2.43 g/kg body weight/day for males and 2.91 g/kg/body weight for females (Maeda, 2000d).

Allergenicity
The allergenicity potential of soy polysaccharides was assessed in guinea pigs, sensitised with soy proteins, and challenged with soy polysaccharides via oral and intravenous routes (Unpublished report by petitioner, 1996). The animals in which the challenge exposure was performed by oral administration of soy polysaccharides showed neither active systemic anaphylactic (ASA) nor passive cutaneous anaphylactic (PCA) reactions. Those animals where the challenge exposure was performed by intravenous administration of soy polysaccharides, gave no ASA reaction but very weak positive PCA reaction (antibody titer increased 5-fold). In animals where the challenge exposure was via intravenously administered soy proteins the ASA reaction was negative but the PCA reactions gave an antibody titer increase of 5-125 fold in four out of five animals. These results demonstrate that soy derivatives do not have an important allergenicity potential, when compared to PCA antibody titer increases in the order of 600-3000 for ovalbumin, a widely used positive control (Maeda, 2000e). Based on this animal study, the allergenicity potential of orally

administered soy polysaccharides may be concluded to be very low, compared with that of soy proteins. However, given the presence of residual proteins in soybean hemicellulose and the absence of clinical data in humans, this decreased allergenicity does not guarantee the absence of risk in persons allergic to soybeans.

Comparison with other dietary fibres

A comprehensive review by FASEB (1987) evaluated data on a wide range of dietary fibres, a number of which have many chemical and physical properties that are similar to soybean hemicellulose. This review concluded that dietary fibres are safe for human consumption at levels far higher than the likely dietary intake of soybean hemicellulose in the intended applications. Other reviews have considered physiological and nutritional issues related to the consumption of soybean fibre as part of the diet (Slavin, 1991; Lo, 1990; Erdman and Fordyce, 1989; Witherly, 1990). Based on these reviews there appears to be a consensus that soy based dietary fibre may be safely used at levels up to 25-35 grams per day, which is considerably above the range of intake estimates of up to 0.05 g/person/day for soybean hemicellulose from the intended applications.

Conclusion

The Committee is of the opinion that the use of soybean hemicellulose in the foods requested and at the inclusion levels requested, is acceptable. The Committee recommends that the level of heavy metals in the commercial Soyfibre-S products should comply with the maximum limits for these elements in the specifications of other bulk additives. In view of the possible allergenic potential, consumers should be informed that the product is derived from soybean.

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