

Mr Andreas Klepsch
European Commission
By email

2 September 2011

Reference: NFU 779

Initial Opinion: A Taxifolin Rich Extract From Dahurian Larch

Dear Mr Klepsch,

On 23 August 2010, the UK Competent Authority accepted an application from Ametis JSG for the use of a Taxifolin Rich Extract from Dahurian Larch as a novel food ingredient, in accordance with Article 4 of regulation (EC) 258/97. The Advisory Committee on Novel Foods and Processes (ACNFP) reviewed this application and their opinion is attached. I apologise for the delay in submitting this opinion as the ACNFP's evaluation was extended while we obtained additional information from the applicant.

In view of the ACNFP's opinion, the UK Competent Authority considers Taxifolin Rich Extract from Dahurian Larch at levels not exceeding the maximum use levels described, meets the criteria for acceptance of a novel food defined in Article 3(1) of regulation 258/97.

I am copying this letter and the ACNFP's opinion to the applicant.

Yours sincerely,

(By e-mail only)

Dr Chris Jones
For the UK Competent Authority

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

OPINION ON A TAXIFOLIN-RICH EXTRACT FROM DAHURIAN LARCH

Applicant	Ametis JSG
Responsible Person	Inga Yegorova
EC Classification	2.2

Background

1. An application was submitted by Ametis JSG for authorisation of a taxifolin-rich extract as a novel ingredient in the EU, for use as an ingredient in a number of different food products.
2. Taxifolin, or (2R,3R) trans-dihydroquercetin, is a flavonoid extracted from the wood of Dahurian larch (*Larix gmelinii*), a species of larch native to eastern Siberia, adjacent regions of Mongolia and northeastern China. The product, which is obtained by hydro-alcoholic extraction of larch wood, has been marketed in Russia and the US for 15-20 years as a food supplement (e.g. a dietary antioxidant), and it is also authorised for as a food additive (preservative) in a wide range of foods in the Russian Federation.
3. The application is for authorisation of a taxifolin-rich extract which is referred to as “taxifolin” in this opinion. It has been prepared pursuant to Commission Recommendation (97/618/EC) of 29 July 1997 concerning the scientific aspects and presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients.
4. The applicant has classified taxifolin as a pure chemical or simple mixture from non-GM sources where the source of the novel food has a history of food use in the EU (class 1.2). As it is questionable whether the source material has a history of use in the EU it would appear that Class 2 (a complex novel food from non-GM sources) may be more appropriate. However, as the information requirements for a submission for either class are the same, the risk assessment is unaffected.

I. Specification of the novel food

Dossier, p 7-15

5. The final product is composed of a minimum of 90% taxifolin (dry weight) together with a number of other identified and unidentified flavonoids (see para 7). The product specification is detailed below.

Parameter	Specification
Outward appearance	white or straw-colored powder
Moisture	10% max
Taxifolin (m/m)	90% min (dry weight)
Lead (ppm)	0.5 max
Arsenic (ppm)	0.02 max
Cadmium (ppm)	0.5 max
Mercury (ppm)	0.1 max
Dichlorodiphenyldichloroethane (DDT) & metabolites ¹ (ppm)	0.05 max
Ethanol (ppm)	5000 max
Solvent residues, Class I	not detected (ND)
Solvent residues, Class II	not detected (ND)

¹ testing is a requirement of the Russian Federation

6. Batch on batch variation was assessed by analyses of 5 non-sequential batches. The results of these analyses showed that all batches analysed met the required specification criteria as set out and there was little variation between batches.
7. Although taxifolin is the dominant flavonoid both in *L. gmelinii* and the novel ingredient the applicant has also sought to identify other flavonoids that are present in the final product. The results from the same 5 batches are detailed in Table II.3.3-1 of the dossier and the mean values are given in the table below. Allowing for the internal standard used in the analysis, (0.8% caffeine) there are approximately 2.8% unidentified compounds which could include trace quantities of ethanol and saponins (<0.5%). In response to a request from the Committee regarding the nature of the unidentified components present in the extract, the applicant carried out a literature review which showed that plant based foods contain a wide range of flavonoids, which are not normally associated with any effects of toxicological significance. The applicant also noted that there is a number of foods which contain the identified flavonoids at significantly greater levels than those found in the novel ingredient.

Flavonoid Composition	
Taxifolin	92.36%
Aromadendrin (Dihydrokaempferol)	2.99%
Eriodictyol	0.198%
Quercetin	0.436%

Naringenin	0.26%
Kaempferol	0.06%
Pinocembrin	0.088%
Total	96.4%

***Discussion** Noting that the source material was a plant source, the Committee was satisfied that the novel ingredient can be produced reproducibly by the applicant. The Committee accepted that there is a wide range of flavonoids present in plant based foods and that those present in the novel ingredient (identified or otherwise) were unlikely to give cause for concern. Given the reproducible nature of the product the Committee accepted the applicant's suggestion to increase the minimum level of taxifolin present to 90% dry weight (from 88%) in line with the specification used in the Russian Federation. The Committee agreed that, as the raw material was not subject to any herbicide or pesticide treatment there was no requirement to test for pesticide residues other than those listed as these were a mandatory requirement of the Russian Federation.*

II. Effect of the production process applied to the novel food

Dossier, p 16-30

8. The specifications of the raw materials used in the production process are detailed in Table II.1.1-1 and Appendix C of the dossier. The source material, tree stumps of *L. gmelinii*, is first tested for heavy metals, a limited range of pesticides as well as microbiological load and radionuclides. Taxifolin is present in the source material at levels not less than 3.3% and the ethanol (96%) used in the extraction process complies with Directive 2009/32/EC concerning extraction solvents. The water used complies with the EU directive concerning potable water (Directive 98/83/EC).
9. The source material is dried to moisture levels of around 25%, debarked and ground to sawdust before hydro-alcoholic (75-85%) extraction of soluble substances at a temperature of 45-50°C. The extracting agent is distilled off and the sawdust returned for an additional alcohol extraction. After cooling to 20-25°C to remove resinous compounds the resulting aqueous phase is evaporated and crystallised and, after drying, contains a minimum of 90% taxifolin on a dry weight basis. Details of the quality control procedure employed by the applicant are detailed in the dossier (pp22-24 and Appendix D).
10. The applicant has assessed the stability of the novel ingredient using accelerated testing conditions, which indicate that the product is stable for at least 5 years when stored under 'normal' conditions. These are defined

to be at temperatures above 4°C, 40-60% humidity, good ventilation and away from direct sunlight. The applicant does not comment on the stability of the product when added as an ingredient to other foodstuffs, nor is an indication of the proposed shelf life given.

Discussion The Committee accepted that appropriate quality control procedures were in place for individual batches of the novel ingredient. Members noted that the applicant did not specify an upper storage temperature, and while testing under accelerated testing conditions indicated that the novel ingredient was stable for up to 5 years, the stability of the product in food matrices had not been tested. The Committee also noted that the environmental impact of producing the novel ingredient was minimal as the tree stumps were a by-product of the logging industry and trees were not felled solely for the purpose of its production.

III. History of the organism used as a source of the novel food

Dossier, p 30-34

11. A limited number of species from the genus *Larix* have food uses. Larch arabinogalactan from *Larix occidentalis* has gelling characteristics and is marketed as a food supplement, as a source of fibre and as a prebiotic. Other species in the genus (*Larix rossiea* and *Larix lacricinia*) are used in a range of herbal remedies. There do not appear to be any other recorded food uses for *Larix gmelinii* and the applicant reports that there are no reported safety concerns attributed to its consumption.

Discussion The Committee noted that there was limited use of *Larix* spp for food production purposes and that the uses described were for products that bear little resemblance to taxifolin (see comment on para 4 above)

IX. Anticipated intake/extent of use of the novel food

Dossier, p 34-46

12. The applicant intends that the novel ingredient will be incorporated into a relatively wide range of products and the level of addition is adjusted in accordance with the amount of fat present in the food.

13. Due to their similarity, not all the proposed products are shown in the summary table below but they are listed in full in the dossier (Table IX.1.1.-1).

Food Category	Typical use	Use-Levels (g/l or g/kg)
Beverages	Concentrated soft drinks – not low calorie, as consumed	0.02

	Carbonated soft drinks – low calorie	0.01
Cereals and cereal & grain products	Biscuits	0.07
	Cereal Bars	0.07
	Energy and Diet Meal Bars	2.144
Meat	Ground meat	1.389
	Ground chicken	2.616
	Poultry sausage	1.390
	Coated and/or fried white fish (0.5 g/1 kg lipid mass - ca.10%)	0.161
Milk products	Dry milk, 15% fat	0.161*
	Dry soy milk concentrate	0.2*
	Curd desserts	0.13*
	Yogurt	0.050*
Sugar, Preserves, Confectionery	Chocolate confectionery	0.030*
Fats and oils	Butter	0.030*
PARNUTS*	Sport supplements	100mg
Food Supplement	Tablet or capsule	100mg (adult) 25mg (child)

* Foods for particular nutritional purposes

14. The applicant used published food consumption data from the UK National Diet and Nutrition Survey (NDNS) to provide a basic estimation of taxifolin consumption for the proposed range of products. The applicant did not explain in detail how the intake estimates for each of the food categories were calculated but provided 'worst case' and 'realistic' consumption based on the assumptions that either 100% or 10% of the products in an individual's diet will contain taxifolin. In order to estimate high level consumption the applicant has, based on literature surveys, assumed that intake at the 97.5th percentile is twice the mean figure.
15. Experts in food chemical intake from the Food Standards Agency advised that the assumptions noted above are not the usual approach, and that a better estimation of intake at the 97.5th percentile is three times the mean figure. However they also advised that the approach used by the applicant involved summing the high level exposure for each food category to give an overall figure for high level consumption. In practice would not be

possible for the same individuals to be a high level consumer for every food category and this approach would inevitably lead to an overestimation of the likely level of consumption at the 97.5th percentile. As the calculated value was well below the proposed ADI for taxifolin (see Section XIII), it was not considered necessary to make a more refined intake estimation in this instance.

16. The summary table below summarised estimated intake levels for each population group detailed in the published NDNS surveys. The summary does not distinguish between male and females but, for adults, the all user data does not seem to differ markedly between the sexes. Very little additional data are provided for other age groups.

Age years (body wt)	ADI*	All User data			
		Mean daily intake:		97.5 th tile daily intake:	
		mg	mg/kg body wt	mg	mg/kg body wt
1.5-4.5 (15 kg)	225 mg	33	2.2	65	4.3
4-10 (30 kg)	450 mg	43	1.4	86	2.9
10-18 (55 kg)	825 mg	65	1.2	130	2.4
Adult (70 kg)	1050 mg	65	0.9	130	1.9

*See section XIII

Estimates do not include use in supplements and PARNUTs

17. These estimates do not include use either as a supplement or in foods for particular nutritional uses (PARNUTs) but the consumption of both at the maximum recommended level would be well within the adult ADI.

Discussion The Committee noted the shortcomings in the approach used by the applicant to estimate intake, but agreed that it has led to a significant overestimation of likely consumption levels. As these intake estimates are well within the acceptable range, no further refinement is necessary in order to demonstrate safety.

X. Information from previous human exposure or its source

Dossier, p 47-55

18. Taxifolin is marketed as a dietary antioxidant in a wide range of foods and the applicant is the world's major supplier of taxifolin, producing around 70% of the taxifolin sold in the Russian Federation. Ametis' taxifolin is available in a range of products (mainly food supplements, but also soft drinks, and fruit bars) marketed by a number of different companies. These companies are predominantly in Russia, but also the US and Switzerland. Approximately 250 products containing taxifolin have been registered in Russia (142 supplement products, 40 food products with the remainder being cosmetics) and the applicant alone has sold over 18 tons of taxifolin for use in food supplements.
19. The Russian Federation has approved the use of taxifolin both in food supplements (100mg/day) and as a food additive (preservative). However, the applicant has confirmed that the proposed uses described in the current dossier are solely for nutritional purposes (Dossier 1 Table IX1.1, and p35).
20. The companies who produce taxifolin in the Russian Federation maintain databases to record product return information. Ametis note that they are unaware of any recorded side-effects reported to the companies, nor is there any instance of product returns reported either to the producer or distributor.
21. Taxifolin is also present in the supplement Pycnogenol, a flavonoid preparation extracted from the bark of French Maritime Pine (*Pinus pinaster*). This supplement has been on the EU market for over 20 years and contains a number of water soluble flavonoids including very small quantities of taxifolin (around 1.4mg per recommended daily dose). Although there are clear differences between taxifolin and the Pycnogenol product, the safety of the latter product was reviewed by the ACNFP in 1997 under the voluntary novel food review system which operated in the UK at that time. The ACNFP's concerns about poorly reported toxicological studies were referred to the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) for review. The COT also raised concerns about the quality of the data as many of the studies were either old or incomplete and also queried possible adverse effects seen in a 6 month canine study. As Pycnogenol had been on the market for many years in other EU countries it was subsequently found to fall outside the scope of the novel food regulation.
22. Small quantities of taxifolin are also seen in a number of commonly consumed fruit and vegetables, such as olive oil, red onions a range of citrus fruits and grapes

Discussion The Committee accepted that there was evidence of consumption of taxifolin as a constituent of existing foods. Although ACNFP and COT previously raised questions about another flavonoid product, Pycnogenol, these are not relevant to the current evaluation as the two products have very different compositions.

XI. Nutritional information on the novel food

Dossier, p 56-66

23. The applicant describes a number of perceived nutritional benefits that are attributed to the consumption of taxifolin. These include antioxidant effects, anti-inflammatory, anti-allergic properties and cardiovascular protection (Tables XI.2.1, XI.2.2). The applicant notes that the studies cited in support of nutritional effects, in which 20-100mg/kg body weight of taxifolin was consumed, also demonstrate that it is safe and does not give rise to adverse effects (see also section XIII below).

Discussion The Committee noted that the nutritional information supplied by the applicant largely relate to health claims. Such claims cannot be considered under the novel foods regulation but must comply with EU legislation on nutrition and health claims.

XII. Microbiological information on the novel food

Dossier, p 67-69

24. The final product is tested to confirm the absence of a number of pathogenic microorganisms in accordance with the European Pharmacopeia. The microbiological specification for the product is detailed in Table XII.1-1, Appendix B and summarised below. Analysis of 5 batches demonstrated compliance with this specification.

Specification Parameter	Specification
Total Plate Count, TPC	NMT 10 ⁴ CFU/g
Enterobacteria *	≤ 100/g
Yeast and Mold	NMT 100 CFU/g
<i>Escherichia coli</i>	Negative/1 g
<i>Salmonella spp.</i>	Negative/10 g
<i>Staphylococcus aureus</i>	Negative/1 g
<i>Pseudomonas spp.</i>	Negative/1 g

*Enterobacteria are only tested if the TPC exceeds 100 CFU/g.

Discussion: Members accepted that the production process did not give cause for microbiological concern, and that compliance with the specification would ensure that the novel ingredient is free from pathogenic

microorganisms. Given the nature of the raw material the Committee asked whether the applicant tested for the presence of mycotoxins. The applicant indicated that they did not routinely test for mycotoxins but the quality control (QC) systems that they employ in the selection of the raw material, coupled with routine testing for yeasts and moulds in the resulting sawdust, are adequate to ensure their absence. The applicant also carried out an analysis of one batch of the novel ingredient which showed that aflaxoxins were absent at the limit of detection. Members accepted that the QC systems appeared to be adequate but, in line with advice from Food Standards Agency officials who are responsible for the regulation of mycotoxins, noted that there is a wide range of mycotoxins that have adverse effects on human health and suggested that additional testing should be carried out during production.

XIII. Toxicological information on the novel food

Dossier, p 70-111

25. The dossier describes a number of relevant safety studies and, in response to questions raised by the Committee, the applicant confirmed that the sub-chronic and reproductive toxicity studies carried out by Dorovskikh and Celuyko, (2008) used their taxifolin product. Other studies had used taxifolin preparations from other manufacturers, using the same or very similar methods of extraction. The applicant also provided the specification of the taxifolin extract used by Shkarenkov *et al* (1998), who carried out a number of the toxicological studies cited in the dossier. This extract contained comparable amounts of taxifolin and other identified flavonoids to the applicant's product. Although other minor flavonoid components have not been identified, the applicant considered that these would not have any toxicological consequence due to their presence in a relatively large number of foods.
26. The applicant also noted that all taxifolin sold in the Russian Federation contained at least 90% taxifolin with the remaining 8-10% comprising other flavonoids such as dihydrokaempferol and naringenin.
27. **Acute Studies (taxifolin from larch).** Taxifolin toxicity was assessed following single administration (intraperitoneal or intragastric) to 60 rats and 80 mice. These studies brought about transient symptoms (shortness of breath, languor, cyanosis of skin augments of auricles and limbs) in a few animals indicating that the LD₅₀ was in excess of 560-580 mg/kg.
28. **Acute studies (taxifolin from other sources).** Intraperitoneal administration of taxifolin to albino rats indicated an LD₅₀ of 1200mg/kg.
29. **Subchronic studies (taxifolin from larch).** In a study carried out in 2008 (Dorovskikh and Celuyko), the applicant's product was administered orally (10g/kg body weight) to 20 rats for 7 days and no changes in the general condition of the animals were reported. In stage two of the same

study 15g/kg body weight taxifolin was administered and no mortality was observed. Histological examination did not record any changes in the vital organs.

30. **Chronic studies (taxifolin from larch)** A 6 month study carried out in 1998 (Shkarenkov *et al*) using a comparable test material did not show any changes in the systemic condition of the rats (dose 150 and 1500mg/kg body weight/day). Slight changes in the leukocyte and thrombocyte levels were viewed to be within normal levels of variation. Biochemical examination of blood and of the functional state of the liver, kidneys and cardiovascular system showed no evidence of toxicity. A 6 month study also carried out in 1998 by the same authors but using dogs (dose 190/mg/kg body weight/day) also showed no visible effects on the behaviour of the animals whilst electrocardiograms, investigations into central nervous system activity and extensive biochemical analysis of blood, marrow, and excretory systems did not indicate any adverse effects of taxifolin.
31. **Chronic studies (taxifolin from other sources)** Two 6 month studies in albino rats (carried out in 1957) showed no adverse effects in any of the treatment animals.
32. **Developmental studies (taxifolin from larch)** In a 2008 study (Dorovskikh and Celuyko,2008) the administration of 0.5g/kg body weight of the applicant's product to rats over a 90 day period during gestation and in the postnatal period did not result in any visible changes in the behaviour of the animals and no toxicosis or pathological reactions were seen. No changes were seen in newborns in the developmental and growth stages and histological examination did not report any changes in the heart, liver, spleen, kidneys, stomach, small and large intestine, cortex and spinal cord. Shkarenkov *et al* (1998) administered taxifolin (75 and 1500mg/kg body weight by i.p. injection) to 75 rats in each of the first 19 days of pregnancy. The same report also investigated the effect of taxifolin on the reproductive function of both male and female rats. Although some minor changes were seen in the haemopathological indices of newborn rats these were judged to be within normal ranges and the authors concluded that taxifolin had no effect on the reproductive function of the rats.
33. **Developmental studies (taxifolin from other sources)** a transcriptional activation assay carried out in cell culture found no effect on the oestrogen receptor. Although a very low measure of oestrogenicity was observed in morphological and biochemical assays there was no significant effect on the induction of lactoferrin. Another study with rat uterine cytosol showed that taxifolin does not bind to the uterine cytosolic oestrogen receptor.

34. **Mutagenicity and genotoxicity (taxifolin from larch).** Studies evaluating chromosomal aberrations of mice bone marrow cells showed that the administration of 1500mg/kg of taxifolin had no effect indicating a lack of mutagenic properties. *In vivo* genotoxic effects were studied using chromosomal aberration and DNA-comet assay methods. No DNA damage in the blood, liver or rectal cells of mice were seen
35. **Mutagenicity and cytotoxicity (taxifolin from other sources).** The mutagenicity of taxifolin (and other flavonoids) was assessed using an Ames test and was found to be non-mutagenic. A number of other mutagenicity studies are also detailed in the dossier and do not give any indication that taxifolin would be mutagenic. Cytotoxicity studies using human lung embryonic fibroblasts and umbilical vein endothelial cells, and also rat hepatocyte and HeLa tumor cells showed weak toxicity at high concentrations of taxifolin.
36. **Acceptable Daily intake** The applicant has sought to determine an Acceptable Daily intake based on the toxicological studies reported above. Noting that it is difficult to determine a no observable adverse effect level (NOAEL) because large doses of taxifolin (e.g. >1500mg/kg bodyweight in the 6 month oral toxicity study in rats) do not give rise to any adverse reactions. However based on the highest dose used in this study and applying a standard safety factor of 100, the applicant suggests that the ADI should be 15/mg/kg body weight.
37. **Absorption.** The results of absorption studies carried out on taxifolin (from larch wood) are detailed in Table XIII.2-1(p88 of the dossier). A 2009 study (Pozharitskaya *et al*, 2009) indicates that the bioavailability of taxifolin (36%) is higher in rabbits when consumed in lipid solution than in tablet form. In a separate study, trace amounts of taxifolin were detected after oral administration and, when compared with intravenous administration, a bioavailability figure of 0.17% was calculated. Intravenous injection to rats at levels up to 30mg/kg showed non-linear pharmacokinetic behaviour, and oral administration resulted in taxifolin being seen in the plasma only at trace levels. The pharmacokinetics of a single dose of taxifolin in 8 male rats show a rapid absorption from the GI tract, reaching a maximum concentration in the blood plasma after 30 min, and undetectable levels after 8h. The study authors (Seredin *et al*, 2007) viewed taxifolin to be a short lived product and the bioavailability was calculated to be around 23%.
38. **Distribution.** The same 2007 study also reviewed distribution indicating that taxifolin was detectable in the blood plasma, liver heart, spleen, brain skeletal muscles, lungs and kidneys for up to 24 hours after administration. Higher quantities were found in the kidneys whilst the low quantities seen in vascularised organs are indicative of low permeability.

39. **Metabolism.** A 1983 study (Voskoboinikova *et al*) reported the conversion of taxifolin to 3' or 4'-O-methyltaxifolin in rats. A study from the 1950's using two human volunteers consuming 2g of taxifolin reported its conversion to a number of hydroxyphenylacetic acids. Seredin *et al.* (2007) reported a number of taxifolin metabolites in the urine of rats, predominantly derivatives of diastereomers of taxifolin.
40. **Excretion.** HPLC analysis of rat urine by Seredin *et al*, (2007) found a number of peaks which corresponded to the metabolites reported above. The authors report that around 8% of the original dose (50mg) was seen in urine during the first 24h after administration, but none was seen in the urine or faeces in the following 24h indicating complete absorption into the blood system. In a separate study (Voskoboinikova *et al.*, 1993) the excretion of taxifolin over a 24h period did not exceed 6% of the dose administered, with a near linear increase with dose. The authors suggest that the contribution of the kidneys is of little significance as the majority of elimination takes place via a metabolic pathway.
41. **Human Studies.** No adverse effects have been reported in a large number of studies in which taxifolin (from larch) was administered to patients with a relatively wide range medical conditions, including atherosclerosis, arterial hypertension, ischemic heart disease, discirculatory encephalopathy, diabetes, Lyme disease, patients awaiting operations on ovaries and chronic pulmonary obstructive diseases (pp95-101 and table XIII.2.7-1 in the dossier). The applicant notes that at total of 507 patients were treated with taxifolin (40-120mg/day) for 2 weeks to 3 months and no side effects were reported.

Discussion In regard to the test material used in the safety studies, the Committee accepted a sufficient number of studies had been carried out using the novel ingredient, or a comparable counterpart, providing sufficient reassurance that it did not present a risk to consumers at the levels proposed by the applicant. The Committee noted the studies had been carried out to the standards of Good Laboratory Practice implemented by the Russian Federation.

Allergenicity

Dossier, p 72

42. Although the absence of protein in taxifolin has not been confirmed experimentally, the applicant notes that the production process would be unlikely to result in any measurable protein in the final product. Although there are no reports of allergy to taxifolin, the applicant acknowledged that, as allergy to birch pollen occurs, it is conceivable that there could be allergy to larch pollen, although the production process would appear to rule out any possibility of non-denatured pollen in the final product. Potential allergenicity was investigated in a range of tests involving guinea

pigs, which indicated that taxifolin did not give cause for concern in terms of hypersensitivity and anaphylaxis.

Discussion The Committee accepted that there was little likelihood that taxifolin would pose an allergenic risk to consumers

Overall Discussion

The Committee considered that the toxicological studies on Ametis' taxifolin product, and on comparable products, provided sufficient reassurance that the novel ingredient was safe for the proposed uses. With regard to potential intake, the Committee questioned the simplistic approach used by the applicant, but accepted the view of FSA officials that this approach provided an overestimate of the likely level of intake and concluded that these estimates provided a significant margin of safety for all population groups. The Committee also advised that the applicant should carry out regular testing to ensure that the final product is free from mycotoxin contamination. Although the precise frequency of this testing could be determined by the applicant, they should also ensure that this takes into account the range of yeast and moulds which could be introduced at each stage of production, either via the raw materials or during storage.

CONCLUSION

The Advisory Committee on Novel Foods and Processes is satisfied by the evidence provided by the applicant, Ametis, that the range of uses for the novel ingredient (Taxifolin Rich Extract from Dahurian Larch) is acceptable subject to the applicant's adherence to the proposed specification and the implementation of quality control measures described above and in their application dossier.

August 2011