



Advisory Committee on Novel Foods and Processes

Annual Report 2006

The Advisory Committee on Novel Foods and Processes (ACNFP)
is an independent body of experts whose remit is:

'to advise the central authorities responsible, in England, Scotland, Wales and Northern Ireland respectively on any matters relating to novel foods and novel food processes, including food irradiation, having regard where appropriate to the views of relevant expert bodies.'

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Foreword

This is the eighteenth annual report of the Advisory Committee on Novel Foods and Processes (ACNFP) and the fourth under my chairmanship.

The primary role of the ACNFP remains the safety assessment of novel foods and processes in line with the EU procedures set out in Regulation (EC) No 258/97. However as is reflected by the contents of this report the Committee continues to have a role in advising the Food Standards Agency on matters related to genetically modified (GM) foods.

In order to fulfil its role the ACNFP has an impressive membership with highly qualified expertise in a wide range of scientific disciplines as well as two consumer representatives and an ethicist. I would like to take this opportunity to thank my fellow Committee members for their expert advice, hard work and support throughout the year. At this time it is also appropriate for me to acknowledge the contributions of Professor James Dunwell, Dr John Fowler and Dr Clive Meredith, whose terms of appointment came to an end in September 2006,

This report illustrates the extent and variety of the applications that have been considered by the Committee and the hard work of the secretariat whose assistance and support is invaluable to the effective operation of the Committee.

Professor Mike Gasson

July 2007

Introduction

This is the eighteenth annual report of the work of the Advisory Committee on Novel Foods and Processes (ACNFP). The remit of the ACNFP can be found in **Appendix I**.

In 2006 the ACNFP considered a number of applications made under the novel food regulation, details of which are in Sections 1, 2 and 3 of this report. These have been split into 3 sections; full applications submitted to the UK Competent Authority; substantial equivalence applications submitted to the UK Competent Authority and applications submitted to other Member States. Those topics discussed during 2006 that were continuations of previous work are indicated as such. Section 4 provides information on notifications submitted to the European Commission.

Other issues that the Committee has dealt with during 2006 are described in section 5 of the report. A cumulative index of topics considered in the ACNFP's annual reports from 1989 to 2006 can be found in Section 9. Hard copies of previous reports can be obtained from the Committee Secretariat (see section 6). Alternatively all ACNFP reports, as well as other information on the Committee, can be found on its web pages at www.acnfp.gov.uk

1 Full applications submitted to the UK Competent Authority

1.1 Clinoptilolite

This application for the use of the mineral clinoptilolite as a novel food ingredient was described in the Annual Report for 2004 and 2005. The Committee's negative opinion on this application was sent to the European Commission in January 2006 (see Appendix II to the 2005 Annual Report). No member state raised objections to the UK's assessment and therefore this novel ingredient has not been authorised.

1.2 Chia Seed

This application for the use of chia seed (*Salvia hispanica*) as a novel food ingredient is described in the Annual Reports for 2003 and 2004. The Committee had issued a positive opinion on this application in April 2004. However, when the European Commission circulated this opinion to other Member States for comment, some of them raised reasoned objections on the basis of insufficient toxicological information, allergenicity, and the presence of anti-nutrients.

The European Food Safety Authority (EFSA) was therefore asked by the Commission to review the application and to address the concerns raised by Member States. In November 2005, EFSA issued an unfavourable opinion on the safety of whole chia seed and ground whole chia as novel ingredients.

The Committee had already considered the issue of allergenicity at length during its assessment and had concluded that appropriate labelling would control any risks associated with cross-reactivity. Members were asked whether they agreed with EFSA that there was a need for additional toxicity information and whether additional studies were required to investigate the potential presence of toxins and anti-nutrients.

Members noted that EFSA had considered additional data which had not been available when the Committee carried out its initial assessment, including three published studies into the effects of diets containing up to 30% chia seed on the performance of laying hens. They accepted EFSA's overall conclusion, that further data were needed to conclude the risk assessment, although they questioned whether all of the studies requested by EFSA would be necessary, given that exposure to chia seed would be limited by its use in one type of food.

1.3 Phosphated Distarch Phosphate

This application for the use of a modified starch, phosphated distarch phosphate, as a novel food ingredient was described in the Annual Report for 2005. The Committee was informed that the applicant was preparing responses to the questions that had been raised and discussions would continue in 2007.

1.4 Ice Structuring Protein from GM yeast

The Committee considered an application from Unilever for the use of a preparation containing ice structuring protein as a novel food ingredient. This preparation is obtained by fermentation using a genetically modified yeast and the active constituent of the preparation is a protein that is identical to an antifreeze protein found in ocean pout, a deepwater fish found in the North Eastern Atlantic Ocean. The preparation is intended for use as an ingredient in ice cream and other edible ices to increase their nutrition profiles, organoleptic properties and stability.

The Committee raised a number of questions and concerns about the variability between batches of the ISP preparation, including the extent and pattern of glycosylation, about the potential allergenicity of the preparation, and about the molecular characterisation of the genetically modified yeast. The Committee also requested clarification the composition of the ISP preparation that was used in the safety tests and on the need for studies to assess long-term inflammation in both young and older animals.

After considering the responses provided by the applicant and by external experts, the Committee sought additional information on the extent of purification of the active protein and the possibility of reactions in people with yeast allergy.

The Secretariat agreed to obtain further information from the applicant on these outstanding issues, for discussion at a future meeting.

1.5 Echium Oil

The Committee considered an application from Croda Chemicals Ltd., for the approval of refined echium oil as a novel food ingredient. The applicant proposed to use the ingredient in milk, yoghurt based drinks, breakfast cereals, nutrition bars and food supplements, as a source of omega-3 polyunsaturated fatty acids.

The Committee noted that a previous novel food application had been made in 2000 by John K King & Sons Ltd., for the use of echium oil as a dietary supplement and in other products such as nutritional bars. The Committee had raised a number of concerns and questions and the application had subsequently been withdrawn. This earlier application is described in the Annual Reports for 2000 and 2002.

The Committee requested further information on the proteins present in the ingredient, in order to clarify the methods used for measuring the protein content and to determine the potential for allergic reactions. The Committee noted that the applicant had provided a HACCP certificate that referred to production of animal feed and sought confirmation that the controls were appropriate for the manufacture of food ingredients. The Committee requested further information on the potential interaction between this type of ingredient and anti-coagulants such as warfarin, and also suggested that the proposed labelling was not sufficiently informative to the average consumer.

The Secretariat agreed to obtain further information on these points. The Committee's consideration of this application would continue in 2007.

1.6 Glucosamine hydrochloride from *Aspergillus niger*

The Committee considered an application from Cargill for authorisation of glucosamine hydrochloride from *Aspergillus niger* as a novel food ingredient under the Novel Foods Regulation (EC) 258/97. The applicant proposed to use the product in beverages and fermented milk-based products.

The Committee was concerned about the suitability of the ingredient for people with diabetes, as only limited data were provided on this point. It was also concerned that the ingredient was to be used in many products that would be attractive to children. Members noted that the applicant did not propose a safe upper limit for glucosamine intake, and that it was not possible to derive such a figure or to derive a margin of safety without fuller details of the studies mentioned in the dossier. Members also invited the applicant to explain more fully why an older study, which had reported adverse effects, should be discounted. The Committee would consider the applicant's response to these questions in 2007.

2 Substantial equivalence applications submitted to the UK Competent Authority

2.1 Noni Juice by Leap of Faith Farms

The Committee considered a request from Leap of Faith Farms for an opinion on the equivalence of their noni juice product compared with noni juice produced by Tahitian Noni International (formerly Morinda Inc), which was approved as a novel food in the EU in 2003. This noni juice was intended to be marketed in four forms: (i) pure fresh juice; (ii) fresh juice with an admixture of 3-15% other fruit juices for taste; (iii) fresh juice concentrated and frozen (for transport and subsequent reconstituting), (iv) dried fresh juice (for transport and subsequent reconstituting).

The Committee requested more details on the composition and shelf-life of the juice, on the botanical origin of the noni fruit, and on how long the analysed product was kept dried before it was reconstituted. The Committee considered the applicant's responses and, although more could have been done to establish more fully the botanical identity of the noni fruit used, they indicated that this uncertainty did not give rise to any safety concerns. The Committee suggested that the acceptable shelf life of the dried material should be 12 months. The Committee finalised its opinion in July 2006, indicating that substantial equivalence had been established for the noni juice to be marketed by Leap of Faith Farms (**Appendix II**).

The applicant must formally notify the European Commission before they first market the product in the EU.

2.2 Phytosterols produced by DDO processing

This application from DDO processing LLC for an opinion on equivalence for their phytosterols was described in the 2005 Annual Report.

During 2006 the Committee considered the applicant's responses to comments raised during the public consultation on the application, which concerned the analytical method used to determine the composition of the product, the higher beta-sitosterol level compared with the existing product, and the lack of data on solvent residues and the levels of other impurities.

In relation to the comment on the lack of data on the level of impurities, the Secretariat informed Members that the Scientific Committee on Food (SCF) had previously identified concerns over potential impurities in tall oil phytosterols. The SCF concluded that these concerns were best addressed by ensuring a purity level of above 99%, which was the case for both DDO's ingredient and the Forbes Medi-Tech ingredient to which equivalence is being claimed.

The Committee noted that the residues of heptane were very low (<0.1 mg/kg) and that residue levels of 5000 mg/kg were accepted for use in the manufacture of pharmaceuticals. The Committee therefore concluded that the residues were unlikely to present a safety concern. However, there remained an uncertainty over the legal status of heptane when used as an extraction solvent in the manufacture of the phytosterol product.

The additional compositional data that had been provided by the applicant showed that the maximum beta-sitosterol level (81%) was lower than reported in the original application (87%) and the Committee accepted the applicant's explanation that the lower figure was the correct one as it was obtained using more accurate methods. The Committee finalised its opinion in May 2006, indicating that substantial equivalence had been established between the products manufactured by DDO and by Forbes Medi-Tech (**Appendix III**).

The applicant formally notified the European Commission in July 2006 of their intention to begin marketing their phytosterol product, thus completing the authorisation procedure for this novel ingredient.

2.3 Astaxanthin

The ACNFP was asked to consider an application made by Cyanotech Corporation for an opinion on the substantial equivalence of their astaxanthin-rich extract compared with the existing whole-algal product marketed by Astacarotene.

Astaxanthin is a xanthophyll (oxygenated) carotenoid, which is found in *Haematococcus pluvialis*. This microalga is part of the diet of fish or crustaceans (e.g. salmon, shrimps) and is responsible for the pink coloration of their flesh, through the ingestion of astaxanthin. The applicant intends to market its extract as an ingredient to be used in hard and soft gelatine capsules and tablets to manufacturers of human dietary supplements.

The Committee noted that the applicant had not addressed possible differences between the proportions of esterified and non-esterified astaxanthin in the two products and requested compositional data showing the levels of free and esterified astaxanthin in both products. Members also requested details of the quality assurance procedures that

are in place to prevent contamination of the algal culture, including the potential impact of seasonal variations on levels of toxins, and information to demonstrate the absence of toxins during the production process.

The Committee was content that additional information regarding the proportions of free and esterified astaxanthin in the two products answered its concern. The Committee was also satisfied with measures proposed by the applicant to avoid contamination of the algal cultures and noted that batches of the product had been recently tested and found to contain no detectable levels of bacterial toxins. The Committee considered that such testing should be carried out periodically to confirm the effectiveness of the production controls.

The Committee would proceed to draw up a formal opinion at a subsequent meeting in 2007.

3 Applications submitted to other Member States

3.1 Zeaxanthin

This application for the authorisation of zeaxanthin as a novel ingredient and the Committee's consideration of an initial opinion from The Dutch Competent Authority were described in the 2005 Report.

The Committee had raised a number of concerns and the applicant provided reasoned arguments in response.

The Committee agreed that the applicant had satisfactorily demonstrated the stability of zeaxanthin in a range of food matrices and was satisfied that the acceptable daily intake established for zeaxanthin and lutein took account of 'at risk' groups.

However the applicant had not provided new data to explain the "polarising structures" observed in the eyes of monkeys given zeaxanthin. The Committee therefore sought specialist advice on the implications of this finding and was satisfied that they are not related to treatment.

The Committee remained concerned that the applicant had not provided information on the intended food uses and levels of incorporation and that without this information it was not possible to draw conclusions about the safety of the ingredient.

The Committee's comments on this application were forwarded to the European Commission in July 2006 (**Appendix IV**). The Commission subsequently forwarded the application to EFSA for further assessment.

3.2 Noni leaf

The Committee considered an initial opinion from the Belgian Competent Authority on an application for authorisation of noni leaf as a novel food ingredient. The applicant proposed to market noni leaf products in several forms, including dried roasted leaves, dried roasted leaves reduced to powder, a freeze dried aqueous infusion, and a pasteurised juice. The applicant also proposed to incorporate the novel ingredient into a wide range of foods, including cereals, meat and fish products, potato-based products, fruit juice, soft drinks, sauces and condiments.

The Committee noted that its earlier discussions on noni juice products had revealed that there is considerable variation within the noni species and indicated that the applicant should be more specific in defining the

plants used, as well providing an indication of the maturity of the leaves. Members were also of the view that the applicant should provide data on the variability of the phytochemical content of the noni leaf material as this may be significantly affected by various environmental and genetic factors.

The Committee also noted that the estimated intake seemed low given that the noni leaf products would be used in a wide range of food categories, including soft drinks, which are likely to be attractive to children. The Committee suggested that the safety of noni leaf products consumed by children required special consideration.

The Committee considered that the dose of noni leaf ethanol extract used in the sub-chronic 90-day oral toxicity study in mice was low in relation to the anticipated intake of the novel food ingredients. The Committee further noted that the intake of noni leaves resulting from their traditional use has not been quantified, but seems to be mainly from their use as a culinary herb. The existing toxicological data were therefore not sufficient to demonstrate the safety of the proposed uses of noni leaf products.

The Committee's comments on this application were forwarded to the European Commission in May 2006 (**Appendix V**) and the Commission subsequently forwarded the application to EFSA for further assessment.

3.3 Phytosterol food ingredient Cardiabeat

The Committee considered an initial opinion from the Dutch Competent Authority on an application submitted by Enzymotec Ltd., for the authorisation of a phytosterol food ingredient for use as a novel food ingredient.

The Committee confirmed it agreed with the Dutch assessment and was content for authorisation to be granted.

The Agency, as the UK Competent Authority, replied to the European Commission in July 2006 reflecting the Committee's conclusion (**Appendix VI**). The final decision on this novel food authorisation is expected to be taken in 2007.

3.4 Allanblackia seed oil

The Committee was asked to consider an initial opinion from the German Competent Authority on an application for the authorisation of allanblackia seed oil for use as a novel food ingredient. This novel ingredient is intended to be added in fat spreads at a level of up to 20%, as a substitute for palm oil or palm kernel oil.

The Committee noted the inclusion of a sustainable agriculture programme in the application but expressed concern that *Allanblackia stuhlmanii*, one of the sources of the novel food ingredient, is included

in the Conservation of Nature and Natural Resources (IUCN) red list of threatened species. The Committee noted that the applicant did not identify the species used to obtain the oil samples used in the toxicological tests. It was also unclear whether the samples subjected to chemical analysis were representative of the full diversity of *Allanblackia* species found in the different areas of Africa where the oil might be harvested.

Members noted that the applicant had not offered an explanation for the decrease in the white blood cells in the rats fed *allanblackia* seed oil compared with the control group during the toxicity study. The Committee recommended that this product be labelled as *allanblackia* seed oil.

The Committee's comments formed the basis for the UK response on this application, which was sent to the European Commission in July 2006. (Appendix VII). The Commission subsequently forwarded the application to EFSA for further assessment.

3.5 EFSA Opinions on maize-germ oil and rapeseed oil high in unsaponifiable matter

The Committee was invited to consider two positive opinions from EFSA on vegetable oil products high in unsaponifiable matter, and to consider whether the issues raised when the Committee first reviewed these products in 2002 had been addressed. These issues related to the product specification, limiting daily intake and labelling.

The applicant had provided further detailed information on the product specification and the Committee confirmed that this satisfied their earlier concerns.

Nevertheless, Members remained concerned about the lack of information on how the intended intake levels could be achieved in practice and the absence of any data on intakes for different age groups. The Committee further noted that the EFSA opinion did not include any consideration of the labelling of the products containing the oils.

The Committee therefore agreed with EFSA's overall conclusion that there were no specific safety concerns, but maintained its earlier concerns over limiting daily intake and labelling. Although not directly relevant to the assessment of the proposed level of intake of these two novel ingredients, the Committee continued to question the approach taken in the initial assessment, where the intake limit had been established as a multiple of the recommended daily intake for vitamin E and not on the basis of a scientific risk assessment.

These two novel ingredients were each authorised for use in the EU in October 2006, for use in food supplements with a maximum recommended daily dosage of 1.5 grams.

3.6 Alpha-cyclodextrin

This application and initial opinion from the Belgian Competent Authority on an application for the authorisation of alpha-cyclodextrin for use as a novel food ingredient was described in the 2005 report.

The applicant provided a response to the concerns that had been raised by the Committee in 2005. The applicant had not provided any new data but had provided reasoned arguments addressing each of the points.

The Committee was of the view that the applicant had provided an adequate response on the effect of consumption of this ingredient in the diabetic population.

The Committee accepted that there is currently no Europe-wide food consumption database that can be used to estimate the daily intake of alpha-cyclodextrin, but wished to confirm that the intake estimates provided by the applicant were consistent with UK National Dietary and Nutrition Survey (NDNS) database. The Secretariat later confirmed that the NDNS data provided similar values to the applicant's consumption estimates.

The Committee accepted that the overall digestibility of alpha-cyclodextrin is expected to be equivalent to that of similar existing ingredients but highlighted that it is important also to consider the rate of metabolism as it has an impact on gas production within the gut. The Committee considered that the product should not be marketed as an alternative to other natural dietary fibres as it could be nutritionally disadvantageous.

The Committee's further comments on this application were forwarded to the European Commission in 2006 (**Appendix VIII**). The Commission subsequently forwarded the application to EFSA for further assessment.

4 Notifications submitted to the European Commission

Under the novel food regulation authorisation applies to the applicant company only. However, where a novel food is “substantially equivalent” to a food already on the market, Regulation (EC) No 258/97 includes a provision for applicant companies to submit a notification to the European Commission after obtaining an opinion on equivalence from an EU Member State. According to Article 3(4) of Regulation (EC) No 258/97, that simplified procedure applies to foods or food ingredients that “are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein”.

4.1 Noni juice

During 2006, the European Commission distributed a total of 6 notifications from companies for the marketing of noni juice considered to meet the criteria for substantial equivalence with another product that is already on the EU market. The table at **Appendix IX** provides details regarding these notifications.

4.2 Phytosterols

As all phytosterol fortified products fall within the scope of the novel foods regulation, authorisations have been given to a number of companies for the use of plant sterols in a range of foods, including yellow fat spreads, milk type products, yoghurt type products, cheese type products, spicy sauces, soya drinks and salad dressings.

During 2006 the Commission distributed a total of 15 notifications from companies for the marketing of phytosterol fortified products considered to meet the criteria for substantial equivalence as these notifications raise no new issues, they have been brought to the Committee’s attention but not discussed. All the companies who have notified their products in the EU under this simplified procedure are listed in the table at **Appendix X**.

5 Other issues considered by the ACNFP

5.1 Nordic Council report on novel plant foods

The Committee commented on certain proposals related to the risk assessment and risk management of novel plant foods, made by a Working Group established under the Nordic Council. The report from the Nordic group (reference 1) focused on the situation where food plants with a traditional history of food use outside the EU are proposed for introduction to the EU.

The Committee discussed the two-stage evaluation process proposed in the report but indicated that it would need to see more closely worked examples before any conclusions could be drawn on its feasibility. Members also noted that the report did not describe any interface with scientific experts (e.g. EFSA) in the first stage of the process and that a non-scientific administrator might not be best placed to determine the type of risk assessment required for a novel food, especially when considering issues such as potential allergenicity. The Committee stated that extreme care would need to be taken to ensure that the introduction of any new procedures did not reduce the current high level of consumer protection provided by the existing evaluation framework.

The Committee noted the Nordic group's recommendation that 90-day feeding studies should be a routine part of the evaluation scheme and asked to see the background papers mentioned in the review before commenting on this issue.

The Committee agreed to revisit other issues raised by the report at a future meeting.

5.2 Codex guideline on foods derived from GM animals

The Committee considered a working draft of a guideline that was under development by the Codex Alimentarius Task Force on Foods Derived from Modern Biotechnology, in order to help the UK prepare for discussions on this topic at forthcoming Task Force meetings.

Members suggested that unintended changes in hormone levels and the potential for gene transfer should to be included in the list of issues relevant to the assessment of foods obtained from GM animals. The Committee also suggested that the possible role of new technologies such as proteomics and genomics in the evaluation should be considered.

The Committee later examined a more detailed draft of the guideline and advised that it would be valuable to have DNA sequence information from GM animals, in line with the approach currently taken for GM plants. Members emphasised the need to look for unpredictable effects, as metabolic connections in animals are not fully understood.

The guideline was further developed at a meeting of the Codex Task Force in November 2006 and is expected to be finalised in 2007 or 2008.

5.3 Review of novel processing techniques

The Committee discussed two recent reviews of novel processing techniques commissioned by the Agency in 2004/05, in order to identify any topics that required further consideration. In particular, the Committee focussed on thirteen processing techniques that were under development and were potentially "novel" (as defined in regulation (EC) 258/97). The Committee considered whether a new framework needed to be developed for the evaluation of foods or food ingredients produced using these processes, and whether their use would give rise to any safety concerns that required additional assessment by other advisory committees or experts in other fields.

The Committee observed that the report did not recognise the general obligations placed on the food industry to control the quality and safety of its products. Members also noted that some of the processes had been in use for some time and were likely to fall outside the scope of the novel foods regulation.

The Committee noted that the use of enzymes and ultraviolet (UV) light in food processing required consideration of microbiological safety issues that fall within the remit of the Advisory Committee on the Microbiological Safety of Food (ACMSF). Nevertheless, the Committee highlighted the absence of an industry standard governing use of UV in food processing and indicated that this type of radiation could result in the chemical degradation of organic molecules such as vitamins. Given the reported interest in this technology, the Committee suggested that the impact of the use of UV on nutrient levels should be considered further. Members had no specific safety concerns over the use of infrared (IR) radiation in food processing, where the key issue was effective management of the process.

The Committee suggested that many ingredients produced using the chemical processes described in the reviews were likely to be covered by additives legislation. Other novel substances used as ingredients in food would be subject to evaluation and authorisation under the novel foods legislation.

Members suggested that any future consideration of the food applications of nanotechnology, such as nanoemulsions and nanofiltration, would require additional input from a biophysicist.

Finally, the Committee was also asked if it wished to identify any other emerging issues that would require consideration in the next twelve months. The Committee drew attention to its previous discussions regarding the possibility of setting up a working group to examine issues related to the wider allergenicity assessment of GM and other novel foods (see the Annual Report for 2005).

5.4 Update on G03 research programme

The Committee was updated on the commissioning of two research projects and three research requirements within the new G03 research programme. Members had previously put forward suggestions for these topics.

Commissioned projects included:

- 1) a two-year study at the University of Wales, Aberystwyth which addresses the need to have baseline metabolomic data for crops to use as a reference in assessing new crop varieties and also how the quality of raw data used for assessment purposes may affect the safety assessment. The project will use previous data from the Agency's G01 and G02 research programmes and include the further development of an internet accessible metabolomics database.
- 2) a three-year study at Royal Holloway, University of London which investigates the use of Multidimensional Protein Identification Technology as a quantitative procedure to compare protein profiles in GM and non-GM plants.

Three research requirements were issued in December 2005 as follows:

- 1) methods for the analysis of junction sequences in GM crop plants.
- 2) the development of new or improved methods for the identification of allergenic epitopes in novel (including GM) foods.
- 3) detection methods for GM foods that can be used as simple screening methods for enforcement work.

5.5 Nanotechnology

The Committee was updated on various activities in relation to nanotechnology, and commented on the possible outline of a public information document on nanotechnology in relation to food.

The Committee noted the joint COT/COC/COM statement on nanomaterial toxicology (reference 2) and the Institute of Food Science and Technology (IFST) statement on nanotechnology (reference 3), and agreed that it was essential to maintain an integrated Government

approach to issues related to nanotechnology. The Committee stressed the need to engage the public by inviting comments on areas of concern in relation to the application of nanotechnology to food.

The Committee supported the idea of a public information document but suggested that the proposed outline was too technical and that it was vital to provide clear definitions for all the terminology. Members also suggested that, if the document was published on the Agency's website, links could be provided to existing material on nanotechnology such as the Royal Society report or the IFST statement.

The Secretariat indicated that the Agency would consider the Committee's comments when publishing any public information on nanotechnology.

5.6 Allergenicity Testing of GM foods

The Committee considered a report published by Friends of the Earth on allergy risks associated with GM foods (reference 4).

The Committee acknowledged that the science of allergenicity of foods (including GM foods) is still developing and that the current EU guidelines for the safety assessment of GM foods have evolved from earlier Scientific Committee on Food guidelines and a consultation undertaken by WHO/FAO in 2001. The Committee also noted that the current guidelines take account of scientific developments and practical experience during the intervening period and that it was incorrect to suggest that evolution of the guidelines have resulted in a less rigorous approach to the allergenicity assessment of GM foods.

The Committee noted that the original hypothesis that allergenic proteins were likely to be resistant to digestion was not always supported by evidence gained from later studies and, as a result, less weight is placed on pepsin digestion tests. The use of screening tests using human serum is only recommended in cases where there is evidence to suggest a cross-reaction with existing allergens. It would not be feasible to design a routine screening test for all known human allergies, given that many of these allergies are quite rare and that the human serum samples needed for such tests are limited in their availability.

The Committee further noted that the possibility of using animal models to predict the allergenicity of new proteins is being investigated and that animal tests could be incorporated into the safety assessment process in future, but only if the models can be validated as useful predictors of human sensitisation reactions.

The Committee noted the comments in the report regarding the altered protein structures obtained in different expression systems, as demonstrated in the recent Australian work on transgenic peas, and referred to the previous discussion on this issue at the meeting in November 2005.

The Committee noted that the Friends of the Earth report suggested that scientific uncertainties in GM risk assessments required the strict application of the precautionary principle, and that GM products should not be marketed. Members were of the view that this was ultimately a risk management decision, but noted that logically such an approach would also prevent the marketing of many foods introduced to the UK market without any formal safety assessment, including traditional foods from other countries and new (non-GM) crop varieties.

The Food Standards Agency subsequently replied to Friends of the Earth outlining the Committee's comments on the report **Appendix XI**.

5.7 Governance of Science / Best Practice Agreement

The Committee was informed of the approach being developed within the Agency to the governance of science and commented on two aspects of this work as follows:

(a) Development of a Science Check List

The Committee discussed the draft of a check list being developed for use by the Board of the Food Standards Agency and welcomed the consideration being given to social science, which not only gave insights into consumer behaviour but also addressed other aspects of decision-making such as the handling of uncertainty. Additionally, the Committee suggested that consideration should be given to obtaining data sets for specific population groups, for example on the basis of region, age or ethnicity.

The Committee highlighted the importance of peer review in the validation of scientific advice although in specific circumstances it might be appropriate also to seek out unpublished data. Members commented that it was difficult to make blanket statements about the value of different types of studies and an important role of the expert committees is to exercise judgement on the strength of the available evidence on a case by case basis (reference 5).

The science check list was subsequently amended and adopted by the Board of the Food Standards Agency.

(b) Best Practice Agreement for Scientific Advisory Committees

At the end of 2005, the Chairs of the scientific committees that advise the Agency had undertaken to develop a best practice guide that would describe the processes by which the committees develop the opinions and reports that are presented to the Agency Board.

The draft agreement was presented to the ACNFP and each of the other Committees for discussion, prior to its final consideration at a meeting of Committee Chairs in November 2006. In future, the Committee's Annual Reports will include an assessment of the Committee's work against the criteria set out in the final version of the Agreement **Appendix XII**.

5.8 Research on sub-cellular effects on GM soya

The Committee considered a series of papers published by Italian researchers which examined the differences between the cells from mice given either genetically modified (GM) or non-GM soya. Members were asked to identify any conclusions that could be drawn regarding the safety of the GM herbicide-resistant soya.

Members noted that the papers did not state the origin of the GM and non-GM soya used in these studies. There were no details of whether the soya had been grown commercially or under controlled conditions and whether or not the GM and non-GM soya were grown, handled and processed under similar conditions. It was also not clear whether the soya used in the control and GM experiments had a similar genetic background.

Although the authors had suggested that differences in residual levels of glyphosate might be responsible for the observed differences, the Committee was unable to determine whether the GM and/or the non-GM soya crops had been treated with the herbicide glyphosate.

The Committee also noted the absence of data on the nutritional equivalence of the two diets and as well as confirmation on whether or not the same experimental animals were used in each study.

The Committee will reconsider these studies once clarification is obtained from the authors.

5.9 Consumer research on the consumption of cholesterol lowering products

The Committee commented on and provided peer review for a research report on the consumption patterns of plant sterol containing foods designed to lower cholesterol levels (reference 6). The Committee had previously highlighted the need for post market monitoring in order to understand who consumes such products and to check whether consumption is within the recommended limits, so that the effectiveness of advice given on the label can be monitored.

The project indicated that only a minority of consumers of these products were diagnosed with high cholesterol and that consumers were confused with products designed to benefit the digestive system. Consumption guidelines on minimum and maximum amounts for nutritionally inappropriate groups did not seem to have been successfully communicated to the majority of consumers. Despite this there was very little over-consumption and indications of under-consumption. Consumption amongst children under 5 years of age was low.

The Committee accepted the findings of the report and raised concerns regarding the low level of consumer understanding of such products, noting the results were in line with the Food Standards Agency's 2005 Consumer Attitudes Survey (reference 7), which indicated that 24% of consumers rarely or never read food labels. The Committee recommended that the situation continue to be monitored as further products were introduced to the market.

5.10 Effect of GM soya on newborn rats

As recorded in the Annual Report for 2005, the Committee issued a statement in December 2005 about a study conducted by the Russian scientist Dr Irina Ermakova into the effect of GM soya on newborn rats.

In 2006 the Committee considered two emails from the organisation GM Free Cymru, which invited the Committee to withdraw or substantially revise its statement. These emails were based on the premise that the Committee had considered Dr Ermakova's study to be invalid because the results were contradicted by a paper published in 2004 by Brake and Evenson (reference 8). In fact this was not the case and the statement reflected the view that it was not possible to draw any conclusions from the Ermakova study because there was insufficient information about the experimental conditions. It was clearly indicated that ACNFP would consider any further information that can be obtained.

The ACNFP Chairman's reply to GM-Free Cymru is attached at **Appendix XIII**.

5.11 Unauthorised presence of GM rice LLRICE601 in long grain rice

The Secretariat provided an update on the situation following the identification in August 2006 of unauthorised GM materials in long grain rice from the US. The Committee noted the actions that had been taken and considered how it might be possible to carry out an urgent assessment of a GM food in the event that future unauthorised GM material is discovered in the food supply.

The Committee noted that it was unlikely that the available data on an unauthorised GM material would be sufficient to allow a complete risk assessment according to the usual guidelines. In the case of LLRICE601, there had been detailed information on the genetic modification and it was possible to draw some parallels with other herbicide-tolerant GM crops.

The Committee suggested that, where the unauthorised material was from a GM event that had been rejected during a breeding programme, it was important to know the basis for the decision not to place it on the market. In the case of GM events that had been used in field trials in the EU, the dossier required for consent under the deliberate release directive (2001/18/EC) would provide a body of relevant data.

The Committee was of the view that the standard risk assessment approach should apply to adventitious presence of unauthorised GM material, and risk assessors should describe the gaps and uncertainties in the available data, alongside any indications of risk. Risk managers would then decide on the appropriate action. The Committee considered that it was not appropriate to establish a reduced set of guidelines for the urgent risk assessment of unauthorised GM material.

6 Contact points

For further information about the general work of the Committee or about specific scientific points concerning individual submissions (which have been made or are being made) contact in the first instance:

ACNFP Secretariat
Room 515B
Aviation House
125 Kingsway
London
WC2B 6NH

Tel: 020 7276 8595
Fax: 020 7276 8564

The ACNFP website can be found at:
www.acnfp.gov.uk

Information can also be requested via e-mail at:
acnfp@foodstandards.gsi.gov.uk

7 References

1. Nordic Council report: Risk assessment and risk management of novel plant foods: Concepts and principles (2005)
Available at: www.norden.org.
2. COT/COC/COM Joint Statement on Nanomaterial Toxicology (2005)
Available at: <http://www.food.gov.uk/science/ouradvisors/toxicity/>
3. Institute of Food Science and Technology (IFST) – Information Statement on Nanotechnology (2006)
Available at: www.ifst.org.
4. Friends of the Earth briefing paper “Could GM foods cause allergies? – a critique of current allergenicity testing in the light of new research on transgenic peas” (2006)
www.foe.co.uk.
5. FSA Science Check List 2006
Available at:
<http://www.food.gov.uk/multimedia/pdfs/board/fsa071005a.pdf>
6. Consumer Research on the Consumption of Phytosterols. Report prepared for the Central Office of Information and the Food Standards Agency by TNS™ (2006)
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<http://www.food.gov.uk/science/research/researchinfo/foodcomponentsresearch>
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<http://www.food.gov.uk/science/surveys/foodsafety-nutrition-diet/cas2005>
8. Brake DG, Evenson DP. (2004) A generational study of glyphosate-tolerant soybeans on mouse fetal, postnatal, pubertal and adult testicular development. *Food and Chemical Toxicology* 42:29-36.

APPENDIX I

ACNFP – remit, membership and list of Members' interests, code of conduct and interactions with other committees.

Remit

The Advisory Committee on Novel Foods and Processes is an independent body of experts whose remit is:

"to advise the central authorities responsible, in England, Scotland, Wales and Northern Ireland respectively on any matters relating to novel foods and novel food processes including food irradiation, having regard where appropriate to the views of relevant expert bodies"

Officials of the Food Standards Agency provide the Secretariat. As well as formal meetings, the Committee organises workshops on specific topics related to its remit.

The interactions between the ACNFP and other independent advisory committees are outlined in Figure 1 (page ?).

Membership and Members' interests

The membership of the Committee provides a wide range of expertise in fields of relevance in the assessment of novel foods and processes. A list of the membership during 2005, together with the names of the FSA assessors can be found overleaf.

In common with other independent advisory committees the ACNFP is publishing a list of its members' commercial interests. These have been divided into different categories relating to the type of interest:

- Personal:
- a) direct employment or consultancy;
 - b) occasional commissions;
 - c) share holdings.
- Non-personal:
- a) fellowships;
 - b) support which does not benefit the member directly e.g. studentships.

Details of the interests held by members during 2006 can be found on page 25.

A copy of the code of conduct for ACNFP members can be found on page 28.

Membership of the Committee during 2006

Chairman

Professor Mike Gasson BSc, PhD

Head of the Food Safety Science Division at the Institute of Food Research, Norwich.

Members

Jill Brand MPhil, FICSc (Consumer Representative)
Home economist.

Professor Ruth Chadwick BA, BPhil, DPhil (Ethicist)
Director of the ESRC Centre for Economic and Social Aspects of Genomics, Lancaster University.

Dr Hilary Close BSc, PhD, PG Dip (Consumer Representative)
Member of the Science and Technology Committee of the National Council of Women of Great Britain.

Neville Craddock MA, CSci, FIFST
(Food Processing and Quality Assurance Expert)
Independent Consultant.

Professor James Dunwell BA, MA, PhD (Plant Biotechnologist)
Professor of Plant Biotechnology, School of Biological Sciences, University of Reading.

Professor Gary Foster BSc, PhD (Molecular Biologist)
Professor in Molecular Plant Pathology, School of Biological Sciences, University of Bristol.

Dr John Fowler BVM&S, PhD, FATS, CBiol, FIBiol, FRCPath, FRCVS
(Toxicologist)
Independent consultant and registered toxicologist with experience in pharmacology and pathology.

Professor Stephen Holgate BSc, MBBS, MD, DSc, FRCP, FRCPath, FIBiol, FMed Sci (Allergenicity expert)
Medical Research Council Clinical Professor of Immunopharmacology at the University of Southampton.

Dr Peter Lund BA, MA, DPhil (Molecular Biologist)
Senior Lecturer, School of Biosciences, University of Birmingham.

Professor Alan Malcolm MA, DPhil, FIFST, FIBiol, CBiol, FRSC
(Nutritionist)
Chief Executive Institute of Biology.

Dr Clive Meredith BA, MA, MSc, PhD (Toxicologist/Immunologist)
Head of Immunology at BIBRA International Ltd.

Professor Ian Rowland BSc, PhD (Nutritionist/Toxicologist)
Professor of Human Nutrition at the University of Ulster and Head of
the Northern Ireland Centre for Food and Health.

Professor Peter Shewry BSc PhD DSc (Plant Biochemist)
Associate Director of Rothamsted Research

Dr Anthony Williams BSc, MB, BS, DPhil, FRCP, FRCPC (Paediatrician)
Consultant Neonatal Paediatrician and Senior Lecturer at St George's
Hospital Medical School, London.

FSA Assessors

Dr C Baynton	Food Standards Agency
Mr P Morgan	Food Standards Agency (Wales)
Ms E MacDonald	Food Standards Agency (Scotland)
Mr G McCurdy	Food Standards Agency (Northern Ireland)

ACNFP Members Interests during 2006

Member	Personal Interests		Interest	Non-personal Interests	
	Company	Company		Company	Interest
Professor M Gasson (Chairman)	Novacta Biosystems Ltd.		Shareholder.	Various.	IFR Food Safety Science Division industry-funded research projects.
Miss J Brand	None.		None.	None.	None.
Professor R Chadwick	Glaxo SmithKline.		Occasional consultant.	Food Ethics Council.	Member.
				ESRC, Wellcome Trust.	Research Funding
				Eursafe.	Member of Executive Committee.
				Food & Agriculture Organisation Panel of Ethical Experts	Member
				MRC.	Steering Committee on DNA Banking.
Dr H Close	None.		None.	None.	None.
Mr N Craddock	Various.		Consultant on short-term projects.	None.	None.
Professor J Dunwell	None.		None.	BBSRC / EU.	Research Funding.
				Biohybrids	Studentship
Professor G Foster	BBSRC RAE Institute Assessment Exercise Science Panel.		Member.	BBSRC/DEFRA/DfID/Gatsby.	
	BSPP/Blackwells Molecular Plant Pathology.		Editor-in-Chief.	Horticultural Research International.	
	Adjudication Panel for Science & Technology R&D funding in Ireland.		Panel Member.	Central Science Laboratories.	Research Funding
	Biotech/Molecular/Biomedical Enterprise Ireland.			British Society of Plant Pathology. Molecular Biotechnology.	
				Glaxo Smith Kline	

ACNFP Members Interests during 2006 (continued)

Member	Personal Interests		Non-personal Interests		Interest
	Company	Interest	Company	Interest	
Dr J Fowler	None.	None.	None.	None.	None.
Professor S Holgate	Merck Research Laboratories. Novartis. Laboratorias Almirall. Pfizer. Alitana Pharm. Centecor Ferring Wyeth Angen Synairgen (Spin out company University of Southampton). Cambridge Antibody Technology. Kyowa Hakko. York Laboratories	Consultant.	Novartis. MSD. Wyeth. Avantec	Research Funding.	
Dr P Lund	Synaigen. Southampton Asset Management None	Shareholder/Director Director None	Various charities and trusts. BBSRC. Leverhulme Trust. Darwin Trust. Food Ethics Council.	Trustee. Departmental Research. Director. None.	
Professor A Malcolm	None.	None.	None.	None.	
Dr C Meredith	None.	None.	Various.	Departmental Commissioned Research.	
Professor I Rowland	Alpro foundation. Glanbia. Clasado. Scientific Advisory Board of European Natural Soy foods Association (ENSA) Halifax. Woolwich.	Consultant Geest.. Cerestar (Belgium) Yakult UK. Member Shareholder	Vitacress.	Funded Research.	

ACNFP Members Interests during 2006 (continued)

Member	Personal Interests		Interest	Non-personal Interests		Interest
	Company	Company		Company	Company	
Professor P Shewry	Journal of Cereal Science.		Reviews editor.	Defra LINK programmes.		Funded Research.
	Various. Various. Institute of Biology. Biochemical Society. Society for Experimental Biology. Phytochemical Society. American Association of Cereal Chemists.		Occasional laboratory. review panel member Editorial. Fellow. Member.	NIAB.		Trustee and Board Member.
Dr A Williams	None.		None.	Rank Prize Funds. Children Nationwide.		Sponsorship of college course.
				National Childbirth Trust. La Lèche League. Baby Milk Action. UK Association for Milk Banking. Breastfeeding Network. UNICEF (UK). Baby Friendly Initiative. Child Advocacy International. Nutricia. Interagency Group on Breastfeeding Monitoring. Women & Children First (charity organisation).		Provision of un-paid advice. Trustee.

A CODE OF CONDUCT FOR MEMBERS OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES (ACNFP)

Public service values

The Members of the ACNFP must at all times:

- observe the highest standards of impartiality, integrity and objectivity in relation to the advice they provide and the management of this Committee;
- be accountable, through the Board of the Food Standards Agency and Health Ministers, to Parliament and the public for its activities and for the standard of advice it provides.

The Board of the FSA and Health Ministers are answerable to Parliament for the policies and performance of this Committee, including the policy framework within which it operates.

Standards in Public Life

All Committee Members must:

- follow the Seven Principles of Public Life set out by the Committee on Standards in Public Life (page 31);
- comply with this Code, and ensure they understand their duties, rights and responsibilities, and that they are familiar with the function and role of this Committee and any relevant statements of Government policy. If necessary members should consider undertaking relevant training to assist them in carrying out their role;
- not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations; and
- not hold any paid or high profile unpaid posts in a political party, and not engage in specific political activities on matters directly affecting the work of this Committee. When engaging in other political activities, Committee members should be conscious of their public role and exercise proper discretion. These restrictions do not apply to MPs (in those cases where MPs are eligible to be appointed), to local councillors, or to Peers in relation to their conduct in the House of Lords.

Role of committee members

Members have collective responsibility for the operation of this Committee. They must:

- engage fully in collective consideration of the issues, taking account of the full range of relevant factors, including any guidance issued by the Food Standards Agency or Health Ministers;
- in accordance with Government policy on openness, ensure that they adhere to the Code of Practice on Access to Government Information (including prompt responses to public requests for information); agree an Annual Report; and, where practicable and appropriate, provide suitable opportunities to open up the work of the Committee to public scrutiny;
- not divulge any information which is provided to the Committee in confidence;
- ensure that an appropriate response is provided to complaints and other correspondence, if necessary with reference to the sponsor department; and
- ensure that the Committee does not exceed its powers or functions.

Individual members should inform the Chairman (or the Secretariat on his or her behalf) if they are invited to speak in public in their capacity as a committee member.

Communications between the Committee and the Board of the Food Standards Agency will generally be through the Chairman except where the Committee has agreed that an individual member should act on its behalf. Nevertheless, any member has the right of access to the Board of the FSA on any matter that he or she believes raises important issues relating to his or her duties as a Committee member. In such cases the agreement of the rest of the Committee should normally be sought.

Individual members can be removed from office by the Board of the FSA, if they fail to perform the duties required of them in line with the standards expected in public office.

The role of the Chairman

The Chairman has particular responsibility for providing effective leadership on the issues above. In addition, the Chairman is responsible for:

- ensuring that the Committee meets at appropriate intervals, and that the minutes of meetings and any reports to the Board of the FSA accurately record the decisions taken and, where appropriate, the views of individual members;

- representing the views of the Committee to the general public; and
- ensuring that new members are briefed on appointment (and their training needs considered), and providing an assessment of their performance, on request, when members are considered for re-appointment to the Committee or for appointment to the board of some other public body.

Handling conflicts of interests

The purpose of these provisions is to avoid any danger of Committee members being influenced, or appearing to be influenced, by their private interests in the exercise of their public duties. All Members should declare any personal or business interest that may, or may be perceived (by a reasonable member of the public) to, influence their judgement. A guide to the types of interest that should be declared can be found below.

(i) Declaration of interests to the Secretariat

Members of the Committee should inform the Secretariat in writing of their current personal and non-personal interests, when they are appointed, including the principal position(s) held. Only the name of the organisation and the nature of the interest are required; the amount of any salary etc. need not be disclosed. Members are asked to inform the Secretariat at any time of any change of their personal interests and will be invited to complete a declaration form once a year. It is sufficient if changes in non-personal interests are reported in the annual declaration form following the change. (Non-personal interests involving less than £1,000 from a particular company in the previous year need not be declared to the Secretariat).

The register of interests should be kept up-to-date and be open to the public.

(ii) Declaration of interest and participation at meetings

Members of the Committee are required to declare any direct interests relating to salaried employment or consultancies, or those of close family members, in matters under discussion at each meeting. Having fully explained the nature of their interest the Chairman will, having consulted the other members present, decide whether and to what extent the member should participate in the discussion and determination of the issue. If it is decided that the member should leave the meeting, the Chairman may first allow them to make a statement on the item under discussion.

Personal liability of Committee members

A Committee member may be personally liable if he or she makes a fraudulent or negligent statement which results in a loss to a third party; or may commit a breach of confidence under common law or a criminal

offence under insider dealing legislation, if he or she misuses information gained through their position. However, the Government has indicated that individual members who have acted honestly, reasonably, in good faith and without negligence will not have to meet out of their own personal resources any personal civil liability which is incurred in execution or purported execution of their Committee functions save where the person has acted recklessly. To this effect a formal statement of indemnity has been drawn up.

THE SEVEN PRINCIPLES OF PUBLIC LIFE

Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interests.

Leadership

Holders of public office should promote and support these principles by leadership and example.

Different types of interest

The following is intended as a guide to the kinds of interests that should be declared. Where Members are uncertain as to whether an interest should be declared they should seek guidance from the Secretariat or, where it may concern a particular product which is to be considered at a meeting, from the Chairman at that meeting. **If Members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.** However, neither the Members nor the Secretariat are under any obligation to search out links of which they might reasonably not be aware. For example, either through not being aware of all the interests of family members, or of not being aware of links between one company and another.

Personal Interests

A personal interest involves the Member personally. The main examples are:

- **Consultancies and/or direct employment:** any consultancy, directorship, position in or work for the industry or other relevant bodies which attracts regular or occasional payments in cash or kind;
- **Fee-Paid Work:** any commissioned work for which the member is paid in cash or kind;
- **Shareholdings:** any shareholding or other beneficial interest in shares of industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management;
- **Membership or Affiliation** to clubs or organisations with interests relevant to the work of the Committee.

Non-Personal Interests

A non-personal interest involves payment which benefits a department for which a member is responsible, but is not received by the member personally. The main examples are:

- **Fellowships:** the holding of a fellowship endowed by industry or other relevant body;
- **Support by Industry or other relevant bodies:** any payment, other support or sponsorship which does not convey any pecuniary or material benefit to a member personally, but which does benefit their position or department e.g.:
 - (ii) a grant for the running of a unit or department for which a member is responsible;

- (ii) a grant or fellowship or other payment to sponsor a post or a member of staff or a post graduate research programme in the unit for which a member is responsible (this does not include financial assistance for undergraduate students);
- (iii) the commissioning of research or other work by, or advice from, staff who work in a unit for which a member is responsible.

Members are under no obligation to seek out knowledge of work done for, or on behalf of, industry or other relevant bodies by departments for which they are responsible, if they would not normally expect to be informed. Where members are responsible for organisations which receive funds from a very large number of companies involved in that industry, the Secretariat can agree with them a summary of non-personal interests rather than draw up a long list of companies.

Trusteeships: any investment in industry held by a charity for which a member is a trustee. Where a member is a trustee of a charity with investments in industry, the Secretariat can agree with the member a general declaration to cover this interest rather than draw up a detailed portfolio.

Definitions

For the purposes of the ACNFP 'industry' means:

- Companies, partnerships or individuals who are involved with the production, manufacture, packaging, sale, advertising, or supply of food or food processes, subject to the Food Safety Act 1990;
- Trade associations representing companies involved with such products;
- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a food product which is being considered by the Committee.

'Other relevant bodies' refers to organisations with a specific interest in food issues, such as charitable organisations or lobby groups.

In this Code 'the Secretariat' means the Secretariat of the ACNFP.

APPENDIX II

Peter D Martin
Perspekt Consulting
PO Box 2797
Faringdon
Oxfordshire
SN7 7WX

28 September 2006

Reference: NFU 569

Dear Mr Martin,

Request for an opinion on the substantial equivalence of noni juice produced by Leap of Faith Farms.

The Advisory Committee on Novel Foods and Processes (ACNFP) has now completed your request for an opinion on the equivalence of noni juice produced by Leap of Faith Farms used as a fruit juice ingredient in pasteurised fruit juice drinks, compared with the existing noni juice ingredient from Tahiti. The Committee's opinion is enclosed.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, which is the UK Competent Authority for all novel food issues, is content that noni juice products produced by Leap of Faith Farms meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97. This conclusion applies to the fresh pasteurised juice (to be sold as such or combined with other fruit juices) and to reconstituted products prepared from the frozen concentrate or the dried juice. Each product should be appropriately labelled to inform consumers of the nature of the processing and labelled in accordance with European Community Law and any relevant national provisions.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission when you first intend to market your noni juice products. You should send this notification to Mr Andreas Klepsch at the following address:

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

Yours sincerely,

Michelle Young
Novel Foods, Additives and Food Supplement Division

Opinion on substantial equivalence of noni juice produced by Leap of Faith Farms considered under article 5 of the Novel Foods Regulation

Applicant Leap of Faith Farms
26677 Foxtan Court
Perrysburg
OHIO 43551
USA

Responsible Person Mr Peter Martin
Perspekt Consulting
PO Box 2797
Faringdon
Oxfordshire
SN7 7WX

Introduction

1. A request was submitted by Perspekt Consulting, on behalf of Leap of Faith Farms, to the UK Competent Authority on 5 January 2006 for an opinion on equivalence of noni juice products produced in Panama to the approved noni juice produced by Tahitian Noni International (formerly Morinda Inc), which was approved for sale in the EU in 2003 by Commission Decision 2003/426/EC.
2. Noni juice is produced from the fruit of the plant *Morinda citrifolia* L. that is commonly grown in the Pacific region where the juice is traditionally consumed.
3. 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 as regards their:
 - Composition
 - Nutritional value
 - Metabolism
 - Intended use
 - Level of undesirable substances contained therein.”

Evaluation

(a) Composition and (d) Intended use

4. The approved ingredient marketed by Tahitian Noni International is produced using noni fruit grown in French Polynesia, whereas the noni fruit used by the applicant is grown and harvested in Panama. The noni plant is indigenous to both regions and the applicant has stated that they use the same species, *Morinda citrifolia* L. which is a botanically stable species. The applicant notes that botanical experts such as Dr Will McClatchey (University of Hawaii) have extensively reviewed and characterised the noni plant. Dr McClatchey provided the expert botanist opinion for a previous applicant who obtained a positive opinion on equivalence from the UK in June 2003 for noni juice from Hawaii. Although there is morphological diversity within the species, the applicant has provided evidence that the plants used for production of juice in Panama are very similar to those in French Polynesia.
5. The noni fruit is hand picked in order to ensure that no leaves or twigs enter the production process and washed in potable water. The skin and seeds are mechanically separated from the flesh. The flesh of the fruit is then pureed and the juice separated from the pulp and pasteurised. The juice will be produced in four forms and the applicant has provided a flow chart detailing the production processes in the application dossier:

(i) and (ii) Pure and mixed noni juice

Noni juice or noni juice mixed with other fruit juices. Both the pure and mixed noni juice are then subject to 'flash' pasteurisation before being packaged and bottled.

(iii) Concentrated and frozen juice

Noni juice is concentrated by thermal evaporation and frozen. The applicant states that the temperature involved in this process would also destroy pathogens. The concentrated juice would be reconstituted with water and pasteurised before bottling.

(iv) Dried juice

The juice is dried for ease of transport. The drying method, removes water by reducing water to a point where neither pathogens nor spoilage organisms can multiply. The dried juice will be reconstituted with water and pasteurised before bottling and sale.

The applicant has stated that the recommended shelf life of the dried noni product is 2 years when stored in dry, cool conditions and away from direct sunlight, as indicated on the packaging. However, in practice the dried noni ingredient is normally reconstituted between 60 and 90 days.

6. Fruit juices and nectars which are sold in the UK must comply with the provisions of the Fruit Juices and Nectars Regulation 2003. This Regulation clearly defines the terms ‘fruit juice’ and ‘dehydrated or powdered fruit juice’ and requires that such products be described using these terms.
7. Compositional analyses have been provided on the fresh juice and the dried juice, reconstituted with water. The dried product was stored for more than 12 months prior to reconstitution and analysis. These have been compared with a commercially available Tahitian noni juice. As with previous applications, a pure noni juice from Tahiti was used in the compositional analysis as a surrogate for the product marketed by Tahitian Noni International, as the latter is a noni juice-based drink containing additional ingredients that would invalidate the comparison.
8. The Scientific Committee on Food (SCF) opinion of 4 December 2002 refers to a daily intake of 30 ml for TNI's noni juice containing 89% noni juice and 11% fruit juice concentrate. The applicant intends to market all four of their products as an ingredient in pasteurised fruit drinks with a recommended daily intake of 30ml, which is in accordance with both the SCF opinion and all other opinions issued for noni juice products.
9. **Discussion:** *The Committee was content that the fresh and reconstituted products have an equivalent composition to the Tahitian juice. The Committee noted that the applicant will not market the dried juice directly to the consumer and noted that the products must be clearly labelled to indicate that the juice has been dried and reconstituted so that it is accurately described and does not mislead the consumer.*

Members noted that there is considerable diversity in noni trees and noni fruit in the Pacific region¹, and the information provided by the applicant did not fully establish the genetic identity of the plants found in Panama compared with those in French Polynesia. However, the applicant has demonstrated that the plants are similar and Committee agreed that any small variations would not invalidate a case for substantial equivalence.

The Committee also noted that the dried noni ingredient (iv) is similar to a dried noni product that is currently being assessed by the German Competent Authority for use as a dietary supplement. However, the latter product is produced from the whole noni fruit (including peel and seeds) and is consumed in a different form. The Committee's conclusions about the dried and reconstituted juice cannot therefore be extended to the material that is under evaluation in Germany is intended for use in food supplements.

¹ “Diversity of Uses and Growth Forms in the *Morinda citrifolia* Complex” W. McClatchey. Proceedings of the 2002 Hawai'i Noni Conference, available at www.botany.hawaii.edu

Regarding the stability and the shelf-life of the dried noni juice, Members noted that the tested material was drawn from stock of approximately 12 months. Members noted that the manufacturer should not recommend shelf life without the stability data to support it and therefore the maximum recommended shelf life should be 12 months.

The Committee confirmed that the applicant's noni juice is to be consumed at the same levels as the approved product, and in line with the SCF recommendation that intake should not exceed 30 ml/day (see paragraph 8 above).

(b) (c) Nutritional value and metabolism

10. The applicant considers the nutritional value and metabolism of their noni ingredient to be substantially equivalent to the noni juice produced by Tahitian Noni International. This conclusion is based on the fact that they are both produced from fruits of the same species using a similar process that is at least as hygienic as the approved noni ingredient, and supporting analytical data indicates that they are compositionally comparable.
11. **Discussion:** *The Committee was content that the evidence provided by the applicant demonstrates that the nutrient content was substantially equivalent to the existing product.*

(e) Levels of undesirable substances

12. The products are manufactured according to GMP standards and the applicant has a HACCP system in place in order to minimise the risk of contamination throughout all stages of the production. The procedures involved are monitored and inspected at least once a month by the local health ministry.
13. Microbiological analysis has been conducted on two samples each of the applicant's noni juice and dried powder and the certificate of analyses. The results of this analysis demonstrated a total viable count of 20 and 40 cfu/g for the powder and juice respectively, along with the absence of coliforms, E. coli, Listeria, S.aureus, yeast, and moulds.
14. The potential presence of anthraquinones in noni juice has previously been raised as a potential concern due to their presence in other parts of the noni plant, namely the leaves and twigs. The applicant highlights the fact that their noni fruit is hand picked and an additional inspection stage is employed after harvesting to ensure that no leaf or twig material is processed.
15. The applicant has also analysed for anthraquinones, namely rubiadin and lucidin, using HPLC on samples of the juice and dried powder. These analyses indicate that neither of these anthraquinones is present in either product at the limit of detection.

16. **Discussion:** *The Committee was content that the applicant had provided sufficient information that their product was substantially equivalent in terms of undesirable substances and that the quality control procedures would minimise the risk of extraneous part of the plant being used.*

Conclusion

17. The Committee is content that Leap of Faith Farms has demonstrated the equivalence of their noni juice products with the existing noni juice ingredient according to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC) 258/97. This conclusion applies to the fresh pasteurised juice (to be sold as such or combined with other fruit juices) and to reconstituted products prepared from the frozen concentrate or the dried juice. Each product should be appropriately labelled to inform consumers of the nature of the processing.
18. Therefore, noni juice produced by Leap of Faith Farms can be considered to be substantially equivalent to the existing noni juice produced by Tahitian Noni International.

September 2006

APPENDIX III

Dr James Barnett
DDO Processing LLC
3117 Southside Avenue
Cincinnati OH 45204
USA

6 June 2006

Reference: NFU 592

Dear Dr Barnett,

Opinion on the substantial equivalence of phytosterols

The Advisory Committee on Novel Foods and Processes (ACNFP) has now completed your request for an opinion on the equivalence of your phytosterols (Nutraphyl™) with the phytosterols marketed by Forbes Medi-Tech. The Committee's opinion is enclosed.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, which is the UK Competent Authority for all novel food issues, is content that your phytosterol ingredient meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97.

This opinion is issued on the basis that your phytosterol ingredient is to be used in yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and spicy sauces in accordance with the conditions specified in Commission Decisions 2004/333/EC, 2004/334/EC and 2004/336/EC and 2004/845/EC.

We also advise that you inform all customers that food products containing plant sterols should be labelled in accordance with Regulation (EC) 608/2004.

Please note that, in accordance with Article 5 of (EC) 258/97, you should notify the European Commission when you first intend to market your phytosterol ingredient. You should also list the intended uses of your ingredient and indicate that the final products will be presented as detailed in Article 2 of the above mentioned Commission Decisions. You should send this notification to Mr Andreas Klepsch at the following address:

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

Yours sincerely,

Annie-Laure Robin
Novel Foods, Additives and Food Supplement Division

Opinion on substantial equivalence of phytosterols considered under article 5 of the Novel Foods Regulation

Applicant DDO Processing
 17 Southside Ave.
 Cincinnati, OH 45204
 United States

Responsible Person Dr James Barnett

Introduction

1. A request was submitted by the American company DDO Processing to the UK Competent Authority, in November 2005, for an opinion on the equivalence of its phytosterols (Nutraphyl™) to be used in yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and spicy sauces with the phytosterols marketed by Forbes Medi-Tech.
2. Forbes Medi-Tech initially gained authorisation for use of its phytosterols in milk based beverages through Commission Decision 2004/845/EC, in March 2004. A subsequent authorisation, based on an opinion on substantial equivalence from the Finnish Competent Authority in April 2005, extended the range of Forbes Medi-Tech products to include yellow fat spreads, salad dressings, fermented milk type products, soya drinks, cheese type products, yoghurt type products, spicy sauces and milk based fruit drinks with added phytosterols/phytostanols. DDO Processing is therefore seeking a view on equivalence for the use of their phytosterol ingredient in the food categories included in Forbes Medi-Tech original authorisation and the two subsequent notifications granted by the Finnish Competent Authority.
3. According to Article 3(4) of (EC) 258/97, the notification procedure applies to “foods or food ingredients ...which on the basis of the 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 as regards their:
 - composition,
 - nutritional value,
 - metabolism,
 - intended use and
 - level of undesirable substances contained therein.”

Evaluation

(a) Composition

4. DDO Processing is proposing to produce its phytosterols and phytosterol esters from crude tall oil, using a patented production process. The applicant does not specify the exact source of its crude tall oil but indicates that it is generally derived from by-product of paper pulp production from tree sources such as pine trees. This process involves the hydrolysis and saponification of the crude tall oil pitch (distilled tall oil), followed by the removal of the soaps. The crude sterols are then re-dissolved, crystallised and purified through filtration and washing with heptane. After removal of the solvent, the sterol crystals are finally prilled (granulated) for packaging. To obtain phytosterol esters, DDO Processing will trans-esterify its phytosterols using fatty acids derived from oilseed. The final product contains >99% sterols and stanols.
5. The applicant indicates that their production process is similar to those used by Forbes Medi-Tech and others to produce existing phytosterol ingredients from tall oil, although it leads to a slightly higher beta-sitosterol content. The applicant initially provided certificates of analysis for six batches of its tall oil derived phytosterol. The results of these analyses showed that the composition of the final tall oil product complies with the specification laid down in Commission Decision 2004/845/EC, apart for beta-sitosterol.
6. The data initially submitted by the applicant indicated levels of beta-sitosterol up to 87% compared to 80% for Forbes Medi-Tech phytosterols. The applicant carried out analysis of four additional batches of his phytosterol product with a more accurate and representative method based on gas chromatography–flame ionisation detection. The maximum beta-sitosterol level obtained was 81%, which the applicant considers to be a more accurate measurement. The proposed specification for DDO Processing ingredient is indicated below:

Composition (%)	Commission Decision 2004/845 (Forbes Medi-Tech)	Proposed Tall oil plant sterols(*)
Beta-sitosterol	<80%	<81%
Beta-sitostanol	<35%	<35%
Campesterol	<40%	<40%
Campestanol	<15%	<15%
Stigmasterol	<30%	<30%
Brassicasterol	<3%	<3%
Other phytosterol	<3%	<3%

(*) purity of > 99%

Discussion: *The first phytosterols authorised in the EU in 2000 had a maximum beta-sitosterol content of 65%. A higher limit of 80% was accepted by the Scientific Committee on Food in 2003¹, on the grounds that beta-sitosterol esters and beta-sitosterol had been the main constituents in the sterol mixtures originally tested for sub-chronic toxicity, genotoxicity, reproductive toxicity and oestrogenic activity studies, without showing effects causing concern. In addition, the SCF had reviewed additional animal studies on sterol mixtures with a high content of beta-sitosterol derived from tall oil.*

The Committee was satisfied that the slightly higher upper limit of 81% for beta-sitosterol, compared to 80% for Forbes Medi-Tech phytosterols, did not have significant consequences for the safety or biological properties of the product, whose composition could be regarded as “substantially equivalent” to the authorised product marketed by Forbes Medi-Tech. This is consistent with the approach taken in the UK for other applications for opinions made under Article 3(4) of the novel foods regulation, for which minor variations in composition are accepted².

(b),(c) Nutritional value and metabolism

7. There is no information to suggest that the nutritional value or metabolism of DDO Processing phytosterols will be any different to those used by Forbes Medi-Tech. The phytosterols content of both products is at least 99%.
8. The applicant mentions 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, as an alternative to existing ingredients from other manufacturers.

Discussion: *The Committee did not comment on the above information provided by DDO Processing.*

(d) Intended use

9. DDO Processing intends that its phytosterols will be used in yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks, spicy sauces. These products are the same as those authorised to be placed on the market when containing Forbes Medi-Tech phytosterols.

Discussion: *The Committee was content that DDO Processing phytosterols are to be consumed at the same levels than phytosterols sold by Forbes Medi-Tech in the same range of products mentioned above.*

¹ SCF Opinion on Applications for Approval of a Variety of Plant Sterol-Enriched Foods (March 2003), see http://europa.eu.int/comm/food/fs/sc/scf/out174_en.pdf

² ACNFP guidelines for the presentation of data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart (March 2005), see <http://www.food.gov.uk/multimedia/pdfs/seguidelines.pdf>

(e) Levels of undesirable substances

10. The applicant has not carried out analyses to check for the presence of protein allergens but they point out that it is unlikely that allergens would be found in the final product after the heating and distillation operations. Residues of solvents used in the manufacturing process (methanol and heptane) were initially reported to be below 10 mg/kg. The applicant has also provided additional information indicating that his ingredient has a heptane residue level below 0.1 mg/kg.
11. The applicant has provided no information on the levels of a range of other undesirable components which were previously reported to be at low levels or undetectable in plant sterols manufactured by Forbes Medi-Tech³.
12. The applicant also highlights that the purity of its tall oil phytosterols is above 99% and therefore complies with the purity criteria set in Commission Decision 2004/845/EC for tall oil derived phytosterols.
13. The safety and the quality of the ingredient will be controlled through HACCP schemes which are used on conventional foods. The applicant also indicates that products containing DDO Processing plant sterols will be controlled for their quality and safety using Good Manufacturing Practice (GMP).

Discussion: *The Committee noted that DDO ingredient complies with recommendations from the Scientific Committee for Food and EFSA that plant sterols derived from tall oil should contain more than 99% sterols/stanols, and should comply with solvent limits set out in directive 88/344/EEC⁴ (which defines a limit of 50 mg/kg for methanol and does not include a limit for heptane). It was not clear to the Committee whether the use of solvents in the manufacture of phytosterols was within the scope of Directive 88/344/EEC. The Committee also noted that the residues of heptane reported by the applicant were very low (<0.1 mg/kg) and that residue levels of 5000 mg/kg were accepted for use in the manufacture of pharmaceuticals, although this does not necessarily mean that heptane should be permitted in food production. The Committee concluded that the heptane residues in DDO's ingredient were unlikely to present a safety concern.*

Additional information

14. Labelling DDO Processing will advise its customers that all products containing its phytosterols must be labelled in accordance with the requirements set in Commission Regulation (EC) No. 608/2004⁵.

³ EFSA opinion on novel food application from Forbes Medi-Tech for approval of plant sterol-containing milk-based beverages (November 2003), see http://www.efsa.eu.int/science/nda/nda_opinions/216_en.html

⁴ Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

⁵ Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters.

15. Safety assessment The applicant refers to the equivalence of phytosterols and phytosterol esters in relation to their low order of toxicity (except in individuals with sitosterolemia), metabolic handling and cholesterol lowering activity, which had been assessed by the SCF.

Discussion: *The Committee did not comment on this additional information provided by DDO Processing.*

Conclusion

16. The Committee concludes that DDO Processing has demonstrated the equivalence of their phytosterols (Nutraphyl™) to be used in yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and spicy sauces with the existing Forbes Medi Tech phytosterol ingredient, according to the criteria set out in Article 3(4) of the Novel Food Regulation (EC) 258/97.
17. Therefore, the phytosterols produced by DDO Processing can be considered to be substantially equivalent to the existing phytosterol ingredient marketed by Forbes Medi Tech used in the same range of products.
18. DDO Processing has indicated they will ensure that its customers are aware that the labelling of products containing their phytosterols must comply with Commission Regulation (EC) 608/2004 concerning the labelling of foods with added phytosterols, and that the conditions set out in Article 2 of this regulation must be respected.
19. The Committee notes that phytosterol ingredients must comply with all relevant legislation, which may include the extraction solvents directive 88/344/EEC.

June 2006

APPENDIX IV

Mr A Klepsch
European Commission
DG-SANCO
Rue De La Loi 200
Brussels
Belgium B-1049

26 July 2006

Reference: NFU 518

Dear Mr Klepsch,

Application under (EC) 258 / 97 for the novel food ingredient zeaxanthin (Bioresco, on behalf of DSM Nutritional Products)

As the UK Competent Authority (CA), the Food Standards Agency has sought advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on the applicant's response to the concerns raised by the Committee on the above at the September 2005 meeting. This was discussed at the meeting on 22 March 2006.

Previously the Committee agreed with the Dutch initial opinion that it was not possible to complete the safety assessment of zeaxanthin without a list of proposed food uses and raised a number of concerns. In considering the applicant's response, the Committee noted that the applicant had not provided any new data on their ingredient but had provided reasoned arguments in response to the points raised by the UK and other Member States. In their discussion, the Committee, however, only focused on the responses to the UK concerns. I have detailed the Committee's comments on the applicant's response below.

(i) Stability of zeaxanthin in foodstuffs

The Committee was of the view that the applicant had satisfactorily demonstrated the stability of zeaxanthin in a range of food matrices.

(ii) Absence of safety data on high level of consumers such as elderly people

The Committee was satisfied that the acceptable daily intake proposed by the applicant considered 'at risk' groups.

(iii) Need to evaluate the implication of the formation of "polarising structures" in the eyes of tested monkeys given the high doses of zeaxanthin in relation to high level consumers

The Committee noted that the applicant had not provided any new data to explain the "polarising structures" observed in the eyes of

tested monkeys. However, the Committee's toxicological expert was of the view that, as these were only seen in "control" animals, this would indicate that they are not related to treatment.

(iv) Information on intended food uses and levels of incorporation

The Committee remained concerned that the applicant had not provided information on the intended food uses and levels of incorporation. The Committee therefore reiterated that the safety assessment of zeaxanthin could not be completed without this information.

In conclusion, the UK Competent Authority cannot support the marketing of this novel food ingredient until a list of proposed food uses has been provided.

Yours sincerely,

Dr Sandy Lawrie
Novel Foods, Additives and Supplements Division

Cc: Albert Bär, Bioresco

APPENDIX V

Mr Andreas Klepsch
European Commission
DG-SANCO
Rue De La Loi 200
Brussels
Belgium B-1049

26 May 2006

Reference: NFU 508

Dear Andreas,

Application under Regulation (EC) 258/97 for products derived from Noni Leaf (Morinda Inc)

As the UK Competent Authority (CA), the Food Standards Agency has sought advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial assessment report prepared by the Belgian CA for the above product. This was discussed at the Committee's meeting on 17 May 2006.

The Committee agreed with the Belgian assessment body that the four proposed noni leaf products should not be authorised to be placed on the EU market as novel food ingredients and made the following additional comments:

1. Earlier discussions on noni juice products have revealed that there is considerable variation within the species *Morinda citrifolia*. The applicant should therefore be more specific in defining the plants which are used, as well as the maturity of the leaves.
2. The applicant should also provide data on the variability of the phytochemical content of the noni leaf material as this may be significantly affected by various environmental and genetic factors.
3. Knowing that the noni leaf products will be used in a wide range of food categories, the estimated intake values provided by the applicant seem low.
4. The list of proposed uses includes soft drinks, which are likely to be attractive to children. The safety of noni leaf products consumed by children requires special consideration.
5. The daily dosage of 20 mg of noni leaf ethanol extract used in the sub-chronic 90-day oral toxicity study in mice (p. 38 of dossier and Appendix 5) seems very low and not very relevant to the anticipated intake of the novel food ingredients.

6. Intake of noni leaves resulting from their traditional use has not been quantified, but seems to be mainly from their use as a culinary herb. In view of the potentially high intake resulting from the very broad range of uses proposed by the applicant, the existing toxicological data are not sufficient to demonstrate the safety of these noni leaf products.

The UK Competent Authority therefore cannot support the authorisation of the four noni leaf products until these issues, and the concerns expressed by the Belgian assessment body, have been addressed.

I apologise for the slight delay in forwarding these comments to you.

Yours sincerely

[Sent by email]

Dr Sandy Lawrie
Novel Foods, Additives and Supplements Division

APPENDIX VI

Mr Andreas Klepsch
European Commission
DG-SANCO
Rue De La Loi 200
Brussels
Belgium B-1049

21 July 2006

Reference: NFU 619

Dear Andreas,

Application under Regulation (EC) 258/97 to market a phytosterol food ingredient (Cardiabeat™) as a novel food ingredient

As the UK Competent Authority (CA), the Food Standards Agency has sought advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial assessment report prepared by the Dutch CA for the above product. This was discussed at the Committee's meeting on 20 July 2006.

The Committee raised no objections and agreed with the Dutch assessment body that the phytosterol food ingredient (Cardiabeat™) should be granted authorisation to be placed on the EU market as novel food ingredient.

Yours sincerely

[Sent by email]

Dr Sandy Lawrie
Novel Foods, Additives and Supplements Division

APPENDIX VII

Mr Andreas Klepsch
European Commission
DG-SANCO
Rue De La Loi 200
Brussels
Belgium B-1049

26 July 2006

Reference: NFU 542

Dear Andreas,

Application under Regulation (EC) 258/97 for Allanblackia seed oil as a novel food ingredient

As the UK Competent Authority (CA), the Food Standards Agency has sought advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial assessment report prepared by the German CA for the above product. This was discussed at the Committee's meeting on 20 July 2006.

The Committee was unable to agree with the positive opinion of the German CA and concluded that additional information is required before the assessment of the safety of this product can be concluded. Members highlighted the following issues as requiring additional clarification:

1. The Committee noted that the applicant has a sustainable agriculture programme (p.24 of the application) but highlighted that *Allanblackia stuhlmanii*, one of the two sources of the novel food ingredient, is included in the International Union for the Conservation of Nature and Natural Resources (IUCN) red list of threatened species (See <http://www.iucnredlist.org/search/details.php/34745/summ>).
2. It is not clear whether the samples analysed represent the full diversity of the Allanblackia species found in the different areas of the tropical rain forests of Africa.
3. The Committee questioned the significance of the decrease in total white blood cells and lymphocytes observed in male rats fed Allanblackia oil compared to the control group and shea oleine group, in the 13-week oral toxicity study.
4. The Committee agreed with the German CA that “*only the species used as test material in the toxicological studies should be authorised for extraction*” (p. 8 of opinion) but the species has not been specified by the applicant and this needs to be addressed.
5. The Committee recommended that this novel ingredient should be labelled as Allanblackia seed oil.

In view of the ACNFP's assessment, the UK Competent Authority cannot support the marketing of this novel food ingredient until the issues listed above have been satisfactorily addressed.

Yours sincerely,

[Sent by email]

Dr Sandy Lawrie
Novel Foods, Additives and Supplements Division

APPENDIX VIII

Mr A Klepsch
European Commission
DG-SANCO
Rue De La Loi 200
Brussels
Belgium B-1049

26 July 2006

Reference: NFU 545

Dear Mr Klepsch,

Application under (EC) 258/97 for the novel food ingredient alpha-cyclodextrin (Bioresco, on behalf of Wacker Chemie GmbH)

As the UK Competent Authority (CA), the Food Standards Agency has sought advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on the applicant's response to the concerns raised by the Committee on the above, at the November 2005 meeting. This was discussed at the meeting on 20 July 2006.

Previously, the ACNFP was unable to agree with the Belgian CA and therefore could not support the marketing of this novel food ingredient until a number of issues had been satisfactorily addressed.

The Committee noted that the applicant had not provided any new data on their ingredient but had provided reasoned arguments in response to the points raised by the UK and other Member States for consideration. In their discussion, the Committee, however, only focused on the responses to the UK concerns. I have detailed the Committee's comments on the applicant's response below.

a) Effect of the novel food ingredient (NI) consumption on diabetics

The Committee was of the view that the applicant had provided an adequate response on the effect of the NI consumption in the diabetic population.

b) Inconsistency between the values of consumption estimates obtained from the US food consumption database and GEMS/Food "large portion" database

Members agreed with the applicant that there is currently no European food consumption database to estimate the daily intake of the NI. But, the Committee needed to check whether the UK National Dietary and Nutrition Survey database provided similar values to the applicant's consumption estimates. Once this information has been obtained, the Committee final view on this issue will be passed to the Commission.

c) Absence of data on the gastrointestinal tolerance of the NI by young children

The Committee accepted that the digestibility of the NI is expected to be equivalent to that of similar existing ingredients. However, the Committee highlighted that the rate of metabolism of the NI is also an important point to consider as it has an impact on gas production. Members therefore suggested that the applicant could carry out an in vitro study looking at the rate of fermentation of the NI compared to that of other similar type of ingredients such as inulin or polysaccharides.

d) Designation of the NI as a source of fibre

The Committee did not consider the applicant's response to satisfactorily address their concerns.

The Committee was of the view that the product should not be marketed as an alternative to other natural dietary fibres as it could be nutritionally disadvantageous.

e) Nutritional labelling with respect to energy value.

The Committee was satisfied with the applicant's response that the nutritional labelling of the NI should be in line with Directives 2001/13/EC and 90/496/EC.

In view of the ACNFP's assessment, the UK Competent Authority cannot support the marketing of this novel food ingredient until some of the above issues have been satisfactorily addressed.

Yours sincerely,

[Sent by email]

Dr Sandy Lawrie
Novel Foods, Additives and Supplements Division

Cc: Dr Albert Bär, Bioresco

APPENDIX IX

Noni Juice Notifications submitted to The European Commission during 2006

Date of notification	Notifier	Product	Opinion prepared by
17 May and 27 September 2005	Dynamic Health Laboratories Inc. and NCT Nord Trading GmbH	Noni juice	Germany
11 January 2006	Hanoju Europe Ltd	Noni juice	Netherlands
18 January 2006	Joy Products S.A.	Noni juice	Italy
13 March 2006	Pacifique Sud	Noni juice	France
22 May 2006	Oy Foodfiles Ltd	Noni juice	Finland
23 February 2006	Noni Vida and Tropic Noni D. por A.	Noni juice	France

APPENDIX X

Phytosterol Notifications submitted to The European Commission during 2006

Date of notification	Notifier	Product	Opinion prepared by
12 January 2006	Westland Kaasspecialiteiten B.V.	Cheese type products with added phytosterols	Directly to the Commission (The phytosterols are provided by ADM)
30 January 2006	Vitae-Caps S.A.	Yellow fat spreads as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; Milk type products; and Yoghurt type products with added phytosterols	Spain
14 February 2006	Glanbia consumer foods	Yoghurt type products with added phytosterols	Ireland
13 March 2006	Tucano Vertrieb GmbH & Co. KG	Soya drink with added phytosterols	Directly to the Commission (The phytosterols are provided by Cognis)
21 March	Dragsbæk	Yellow fat spreads with added phytosterols	Directly to the Commission (The phytosterols are provided by Forbes MediTech)

Phytosterol Notifications submitted to The European Commission during 2006 (continued)

Date of notification	Notifier	Product	Opinion prepared by
13 March 2006	Kingdom Cheese Company	Cheese type products with added phytosterols	Directly to the Commission (The phytosterols are provided by Forbes MediTech)
13 March 2006	Quality management	Yellow fat spreads as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; milk type and fermented milk type products; yoghurt type products; cheese type products and soya drinks with added phytosterols	Directly to the Commission (The phytosterols are provided by PrimaPharm)
3 May 2006	Direttore di Stabilemento	Yellow fat spreads as defined by Council Regulation (EC) No. 2991/94, excluding cooking and frying fats and spreads based on butter or other animal fat; milk type and fermented milk type products; yoghurt type products; cheese type products and soya drinks with added phytosterols	Directly to the Commission (The phytosterols are provided by PrimaPharm)
8 May 2006	Cognis Deutschland GmbH & Co KG	Rye bread with added phytosterols or phytosterol esters	Finland

Phytosterol Notifications submitted to The European Commission during 2006 (continued)

Date of notification	Notifier	Product	Opinion prepared by
Inpharma SA	Milk type products, - fermented milk type products, yoghurt type products and cheese type products with added phytosterols	Italy	
7 June	Walter Rau Lebensmittelwerke GmbH	Yellow fat spreads with added phytostero, esters	Directly to the Commission (The phytosterol esters are provided by Cognis)
12 June 2006	Forbes Medi-Tech Inc.	Rye bread with added phytosterols	Finland
5 July 2006	Kampffmeyer Food Innovation GmbH	Rye bread with added phytosterols and/or phytosterol esters	Directly to the Commission (The phytosterols and phytosterol esters are provided by Cognis and Cargill)
13 July 2006	Karwendel-Werke Huber GmbH & Co. KG	Cheese type products with added phytosteols	Directly to the Commission (The phytosterols and phytosterol esters are provided by Cognis)
26 July 2006	Granarolo	Fermented milk type products with added phytosterols	Directly to the Commission (The phytosterol esters are provided by Cognis)

APPENDIX XI

25/04/2006 15:02

To: Liz Wright

Subject: New research exposes flaws in GMO allergenicity testing

Dear Ms Wright

Thank you for your email of 16 February regarding allergenicity testing for GMOs. On 7 March I emailed to indicate that the Food Standards Agency was looking into the issues raised in your email and that it would obtain advice from the relevant expert advisory committee, the Advisory Committee on Novel Foods and Processes, when it met on Wednesday 22 March. The Committee's advice is summarised below.

The Committee acknowledged that the science of allergenicity of all foods is still developing and that the current guidelines for the safety assessment of GM foods have evolved from the previous Scientific Committee on Food guidelines and the 2001 WHO/FAO consultation documents. Members also noted that the current guidelines take account of scientific developments and practical experience during the intervening period and that it was incorrect to suggest that evolution of the guidelines has resulted in a less rigorous approach to the allergenicity assessment of GM foods.

The Committee indicated that the hypothesis that allergenic proteins were likely to be resistant to digestion was not always supported by evidence gained from later studies. As a result less weight is placed on pepsin digestion tests. Members also noted that the use of screening tests using human serum is only recommended in cases where there is evidence to suggest a cross-reaction with existing allergens. It would not be feasible to design a routine screening test for all known human allergies, given that many of these allergies are quite rare and that the human serum samples needed for such tests are limited in their availability.

The Committee further noted that the possibility of using animal models to predict the allergenicity of new proteins is being investigated and that animal tests could be incorporated into the safety assessment process in future, but only if the models can be validated as useful predictors of human sensitisation reactions.

The Committee noted the comments regarding the altered protein structures obtained in different expression systems, as demonstrated in the recent Australian work on transgenic peas, and referred to its previous discussion on this issue in November 2005. The minutes of the

meeting where this discussion took place can be found on the ACNFP website (<http://www.acnfp.gov.uk/>).

The Committee noted that the report attached to your email suggested that scientific uncertainties in GM risk assessments should require the strict application of the precautionary principle, and that GM products should no longer be marketed. Members were of the view that this was ultimately a risk management decision, but noted that logically such an approach would also prevent the marketing of many foods introduced to the UK market without any formal safety assessment, including traditional foods from other countries and new (non-GM) crop varieties.

Yours sincerely

Colin Ross

Food Standards Agency

APPENDIX XII

GOOD PRACTICE GUIDELINES FOR THE INDEPENDENT SCIENTIFIC ADVISORY COMMITTEES

Preamble

*Guidelines 2000: Scientific Advice and Policy Making*¹ set out the basic principles which government departments should follow in assembling and using scientific advice, thus:

- think ahead, identifying the issues where scientific advice is needed at an early stage;
- get a wide range of advice from the best sources, particularly where there is scientific uncertainty; and
- publish the scientific advice they receive and all the relevant papers.

*The Code of Practice for Scientific Advisory Committees*² (currently being updated) provided more detailed guidance specifically focused on the operation of scientific advisory committees (SACs). The Agency subsequently commissioned a *Report on the Review of Scientific Committees*³ to ensure that the operation of its various advisory committees was consistent with the remit and values of the Agency, as well as the Code of Practice.

The Food Standards Agency's Board has adopted a **Science Checklist** (Board paper: FSA 06/02/07) to make explicit the points to be considered in the preparation of papers dealing with science-based issues which are either assembled by the Executive or which draw on advice from the Scientific Advisory Committees.

The Board welcomed a proposal from the Chairs of the independent SACs to draw up **Good Practice Guidelines** based on, and complementing, the **Science Checklist**.

¹ Guidelines on Scientific Analysis in Policy Making, OST, October 2005. *Guidelines 2000: Scientific advice and policy-making*, OST July 2000

² Code of Practice for Scientific Advisory Committees, OST December 2001

³ Report on the Review of Scientific Committees, FSA, March 2002

THE GOOD PRACTICE GUIDELINES

These Guidelines have been developed by 9 advisory committees:

Advisory Committee on Animal Feedingstuffs ⁴

Advisory Committee on Microbiological Safety of Foods

Advisory Committee on Novel Foods and Processes

Advisory Committee on Research

Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment ⁵

Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment ⁶

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment ⁷

Scientific Advisory Committee on Nutrition ⁸

Spongiform Encephalopathy Advisory Committee ⁹

These committees share important characteristics. They:

- are independent;
- work in an open and transparent way; and
- are concerned with risk assessment not risk management.

The Guidelines relate primarily to the risk assessment process since this is the committees' purpose. However, the Agency may wish on occasion to ask the independent scientific advisory committees whether a particular risk management option is consistent with their risk assessment.

Twenty eight principles of good practice have been developed. However, the different committees have different duties and discharge those duties in different ways. Therefore, not all of the principles set out below will be applicable to all of the committees, all of the time.

This list of principles will be reconsidered by each committee annually as part of the preparation of its Annual report, and will be attached as an Annex to it.

⁴ Joint FSA/Defra Secretariat, FSA lead

⁵ Joint FSA/HPA Secretariat, HPA lead

⁶ Joint FSA/HPA Secretariat, HPA lead

⁷ Joint FSA/HPA, FSA lead

⁸ Joint FSA/DH Secretariat

⁹ Joint Defra/FSA/DH Secretariat

Principles

Defining the issue

1. The FSA will ensure that the issue to be addressed is clearly defined and takes account of stakeholder expectations. The committee Chair will refer back to the Agency if discussion suggests that a re-definition is necessary.

Seeking input

2. The Secretariat will ensure that stakeholders are consulted at appropriate points in the committee's considerations and, wherever possible, SAC discussions should be held in public.
3. The scope of literature searches made on behalf of the committee will be clearly set out.
4. Steps will be taken to ensure that all available and relevant scientific evidence is rigorously considered by the committee, including consulting external/additional scientific experts who may know of relevant unpublished or pre-publication data.
5. Data from stakeholders will be considered and weighted according to quality by the committee.
6. Consideration by the secretariat and the Chair will be given to whether expertise in other disciplines will be needed.
7. Consideration will be given by the Secretariat or by the committee to whether other scientific advisory committees need to be consulted.

Validation

8. Study design, methods of measurement and the way that analysis of data has been carried out will be assessed by the committee.
9. If qualitative data have been used, they will be assessed by the committee in accordance with the principles of good practice, e.g. set out in guidance from the Government's Chief Social Researcher¹⁰.
10. Formal statistical analyses will be included wherever possible. To support this, each committee will have access to advice on quantitative analysis and modelling as needed.

¹⁰ There is a guidance issued under the auspices of the Government's Social Research Unit and the Chief Social Researcher's Office (Quality in Qualitative Evaluation: A Framework for assessing research evidence. August 2003. www.strategy.gov.uk/downloads/su/qual/downloads/qqe-rep.pdf and The Magenta Book. www.gsr.gov.uk/professional_guidance/magenta_book/guidance.asp).

11. When considering what evidence needs to be collected for assessment, the following points will be considered:
 - the potential for the need for different data for different parts of the UK or the relevance to the UK situation for any data originating outside the UK; and
 - whether stakeholders can provide unpublished data.
12. The list of references will make it clear which references have either not been subject to peer review or where evaluation by the committee itself has conducted the peer review.

Uncertainty

13. When reporting outcomes, committees will make explicit the level and type of uncertainty (both limitations on the quality of the available data and lack of knowledge) associated with their advice.
14. Any assumptions made by the committee will be clearly spelled out, and, in reviews, previous assumptions will be challenged.
15. Data gaps will be identified and their impact on uncertainty assessed by the committee.
16. An indication will be given by the committee about whether the database is changing or static.

Drawing conclusions

17. The committee will be broad-minded, acknowledging where conflicting views exist and considering whether alternative hypotheses fit the same evidence.
18. Where both risks and benefits have been considered, the committee will address each with the same rigour.
20. Committee decisions will include an explanation of where differences of opinion have arisen during discussions, specifically where there are unresolved issues and why conclusions have been reached.
21. The committee's interpretation of results, recommended actions or advice will be consistent with the quantitative and/or qualitative evidence and the degree of uncertainty associated with it.
22. Committees will make recommendations about general issues that may have relevance for other committees.

Communicating committees' conclusions

23. Conclusions will be expressed by the committee in clear, simple terms and use the minimum caveats consistent with accuracy.
24. It will be made clear by the committee where assessments have been based on the work of other bodies and where the committee has started afresh, and there will be a clear statement of how the current conclusions compare with previous assessments.
25. The conclusions will be supported by a statement about their robustness and the extent to which judgement has had to be used.
26. As standard practice, the committee secretariat will publish a full set of references (including the data used as the basis for risk assessment and other committee opinions) at as early a stage as possible to support openness and transparency of decision-making. Where this is not possible, reasons will be clearly set out, explained and a commitment made to future publication wherever possible.
27. The amount of material withheld by the committee or FSA as being confidential will be kept to a minimum. Where it is not possible to release material, the reasons will be clearly set out, explained and a commitment made to future publication wherever possible.
28. Where proposals or papers being considered by the Board rest on scientific evidence, the Chair of the relevant scientific advisory committee (or a nominated expert member) will be invited to the table at Open Board meetings to provide this assurance and to answer Members' questions on the science. To maintain appropriate separation of risk assessment and risk management processes, the role of the Chairs will be limited to providing an independent view on how their committee's advice has been reflected in the relevant policy proposals. The Chairs may also, where appropriate, be invited to provide factual briefing to Board members about particular issues within their committees' remits, in advance of discussion at open Board meetings.

December 2006

APPENDIX XIII

Dr Brian John

GM Free Cymru

[by email]

3 February 2006

Dear Dr John

THE RELEVANCE OF THE ERMAKOVA FEEDING STUDY FOR GM FOOD SAFETY

Thank you for your emails of 21 and 23 January concerning the ACNFP's December 2005 statement on the study conducted by Dr Irina Ermakova. These were discussed by the Committee when it met last week. You asked the ACNFP to take action on three points and the Committee's responses are set out below:

(a) to withdraw or substantially revise your statement, with a recognition that the study published by Brake and Evenson is not "well controlled"

The points that you have raised in relation to this work are based on the premise that we considered the Ermakova study to be invalid because the results were contradicted by the Brake and Evenson publication. This is not the case and the statement does not include this opinion. Our view is that it is not possible to draw any conclusions from the Ermakova study because there is insufficient information about the experimental conditions. We have not declared this work invalid, as we have clearly indicated that we will consider any further information that can be obtained.

The final paragraph of the statement notes that there is a published study in a different rodent species fed GM soya. We consider that it is appropriate to refer to this work because, in addition to reporting the results of specific investigations into testicular development, the Brake and Evenson paper includes information on the same basic reproductive parameters reported by Dr Ermakova (i.e. litter sizes, survival of the offspring and growth rates). GM soya was fed to mice over four generations and no adverse effects were found. We consider this to be relevant information but it did not influence our comments on Dr Ermakova's report. For this reason it is mentioned only at the end of the statement.

We described the study as "well-controlled" because it included both negative and positive controls. The GM soya and control diets were designed to ensure that the basic nutritional needs of the animals were met and the two diets were virtually identical in their macronutrient and

micronutrient composition, thus minimizing any confounding effects of differences in nutrient intake. Treatment with hydroxyurea comprised a positive control with regard to effects on testicular development. We did not accept the conclusions reported by these authors solely because of the peer review process, and we only referred to this study after a detailed reading of the published paper.

(b) to issue an unequivocal statement to the effect that the Brake and Evenson study cannot be used to support the thesis that GM soya is safe for inclusion in either animal feed or human foods.

We see no reason to issue such a statement. We have not stated that the Brake and Evenson study “*supports the thesis that GM soya is safe for inclusion in... human foods*”, simply that the findings reported are inconsistent with Dr Ermakova’s. Animal feed is not within our remit.

(c) to advise FSA to commission immediate and urgent research into the health effects of GM soya in view of the major concerns that are now emerging in the literature

We are unaware of “major concerns” in the scientific literature. We have stated that it is not possible to draw conclusions from the information provided about Dr Ermakova’s study. Indeed the methodological detail provided is insufficient to support replication of the study. We do not think it would be appropriate to recommend urgent research until more details become available and it is possible to critically evaluate the conclusions which she has made.

Yours sincerely

Professor Mike Gasson
Chairman, ACNFP

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