ACNFP

Advisory Committee on Novel Foods and Processes

Annual Report 2003

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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Advisory Committee on Novel Foods and Processes

Annual Report 2003

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Foreword

This is the fifteenth annual report of the ACNFP and the first under my Chairmanship, which I was delighted to take up during 2003.

I would like to express a considerable debt of gratitude to my predecessor, Professor Janet Bainbridge, for the substantial amount of work carried out during her six years as Chairman. Under her guidance the Committee has made a considerable contribution to the safety assessment of novel foods throughout Europe, and worked towards promoting public knowledge and understanding through its commitment to transparency. I look forward to continuing this work throughout my term of office.

At this time it is also appropriate for me to acknowledge the contributions of Dr John Heritage, whose appointment to the Committee also came to an end during 2003, and to Professors Peter Aggett and Mac Johnston who previously provided cross-membership links with the Committee on Toxicity (COT) and the Advisory Committee on the Microbiological Safety of Food (ACMSF).

In her foreword to last year's Annual Report my predecessor made reference to some upcoming changes in the regulatory process within which the ACNFP operates. During 2003 significant progress has been made and new rules on genetically modified organisms (GMOs) were adopted by the European Union.

The new GM Food and Feed Regulation came into effect on 18 April 2004 and provides a harmonised procedure for the scientific assessment and authorisation of GMOs and GM food and feed. The assessment procedure will be more centralised than before and the European Food Safety Authority (EFSA) will have responsibility for safety assessments. This replaces the existing approval procedures for GM foods under the Novel Foods Regulation, but the ACNFP will still have an important role in advising UK regulators and in providing initial assessments requested by EFSA. The proposed review of the Novel Foods Regulation, also noted by Professor Bainbridge, has been delayed to allow for the development of these regulations and is now expected to take place during 2004-2005.

The primary role of the ACNFP will continue to be the safety assessment of novel foods and processes, based on the close scrutiny of scientific data. The Committee will proceed in the provision of robust and rigorous advice by calling upon an impressive membership with expertise in a wide range of scientific disciplines including genetic modification, nutrition, microbiology, food technology, toxicology, and allergenicity. The ACNFP is also fortunate to have two consumer members and an ethicist, who provide additional perspectives into the issues on which we are called to advise.

The Committee has once again assessed a number of applications and issues ranging from deerhorn powder and Tahitian noni juice, to postmarket monitoring and gene transfer. As the amount of work involved in these considerations continues to increase, the effective and efficient running of the ACNFP is only possible due to the high quality of support provided by the Secretariat, for which I would like to record the Committee's continued gratitude.

Professor Mike Gasson
February 2004

Introduction

This is the fifteenth Annual Report of the work of the Advisory Committee on Novel Foods and Processes (ACNFP).

The major part of the Committee's work is the assessment of dossiers for authorisation of new products under the EU procedures for novel foods, which are set out in Regulation (EC) No 258/97.

The ACNFP considered a number of novel food applications in 2003, details of which are in Sections 1, 2 and 3 of this report. The summary reports of applications have been split into 3 sections; full applications submitted to the UK Competent Authority; applications submitted to other Member States; and notifications received by the UK Competent Authority. Those topics discussed during 2003 that were continuations of previous work are indicated as such.

Other issues that the Committee has dealt with during 2003 are described in section 4 of the report. A cumulative index of topics considered in previous Annual Reports can be found in Section 11. Hard copies of previous reports can be obtained from the Committee Secretariat (see section 7), and all ACNFP reports, as well as other information on the Committee can be found on its webpages on the Food Standards Agency (FSA) website.[1]

[1] www.food.gov.uk/science/ouradvisors/novelfood

1 Full applications submitted to the UK Competent Authority

1.1 Chia (*Salvia hispanica* L)

The ACNFP received an application from the UK company R Craig & Sons [M] Ltd seeking authorisation of whole chia (*Salvia hispanica* L) seed and ground whole chia as a novel food ingredient.

Chia is a summer annual herbaceous plant belonging to the mint family (Labiatae). The authorisation sought by the Applicant is for incorporation of whole and ground chia seed into certain types of bread.

The seed of the chia plant has a long history of consumption in South America but has not been consumed to a significant degree in Europe. Whole chia seeds and ground whole chia belong to Class 2.2 of the Novel Food Regulation (EC) No. 258/97 ("complex novel food from a non-GM source", "the source of the novel food has no history of use in the community").

The ACNFP considered this application at its July meeting. There were no concerns raised over nutritional effects from consumption of this novel food. Chia seed has an oil content of approximately 32%, of which 60% is alpha-linolenic acid, a significant contributor to the intake of n-3 polyunsaturated fatty acids, and can be elongated and desaturated *in vivo* to its long-chain derivatives eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). However, the extent and regulation of this conversion in humans is unclear.

The Committee discussed the potential risk from microbiological contamination during storage and transportation of chia and requested further information to provide assurance that appropriate controls are in place to protect chia seeds from pests or from chemical, physical and microbiological contaminants during handling, storage and transport.

The main concerns raised by the ACNFP were regarding the potential allergenicity of chia seeds. The Committee considered that the approach to allergenicity screening was correct but that the target of this screening (sera from individuals with peanut and tree nut allergies) was incorrect, given that chia seeds would be expected to have closer similarities to other seeds, and the reported finding in the application dossier of cross-reactivity to sesame seed. The Committee therefore agreed that before a positive opinion could be given for authorisation of chia as a novel food ingredient, further information would be needed to address this question. The Applicant was requested to provide data to determine the

potential for cross-reactivity between chia seeds and other seeds (e.g. sesame seed and mustard seed) and to conduct further skin prick tests as in the original study, but followed by formal food challenge studies on a reasonable number of sesame and/or mustard seed allergic individuals.

The Secretariat wrote to the Applicant with the Committee's comments and requested further information to address these points.

1.2 Isomaltulose

The ACNFP were asked to consider an application from Belgian company Cargill Cerestar BVBA for the use of isomaltulose in a range of foodstuffs.

Isomaltulose is a reducing disaccharide composed of a glucose and fructose molecule joined by a 1,6-glycosidic link. The Applicant produces isomaltulose through the enzymatic rearrangement of sucrose using sucrose glucosylmutase from the organism *Protaminobacter rubrum*. Relative to sucrose, isomaltulose has a sweetening potential of 42%.

The Committee considered this application at their November meeting and requested clarification of various points from the Applicant.

Members were content that the toxicological data present in the application were sufficient to reassure them of the safety of isomaltulose but they requested additional information on the heavy metal content of the final product.

The Committee was concerned over the proposed labelling and the scope for misleading the consumer. Members were of the opinion that consumers might associate "reduced sweetness" with "reduced calorie" and subsequently calorific intake would increase. The Applicant was asked to clarify their intended use and revise their labelling suggestion to remove the risk of misinterpretation.

Members raised the issue of a possible polymorphism in isomaltulose metabolism. The Applicant was asked to demonstrate that this would not cause a problem when the product is marketed.

The Applicant's responses will be considered at the February 2004 meeting of the ACNFP with a view to finalising the initial assessment of this application.

1.3 Lycopene from *Blakeslea trispora*

The ACNFP was asked to consider an application from the Spanish company Vitatene for authorisation of lycopene derived from the fungus *Blakeslea trispora* for use as a novel food ingredient in a range of foodstuffs.

Solvent extracted lycopene from tomatoes is approved for use as an additive (E127) and is used as an ingredient in dietary supplements. Strains of *B.trispora*, a fungus found on a number of tropical plants, are able to synthesise large quantities of carotenoids. Following the publication of a positive opinion from the SCF in 2001, beta-carotene from *B.trispora* was approved for food additive use. Although lycopene *per se* has a history of consumption, and is produced using the same biosynthetic pathway as ß-carotene, the organism has not hitherto been used for production of lycopene sold in the EU and the product requires authorisation under Regulation (EC) No. 258/97 before it can be marketed.

The application was considered at the November meeting and Members requested clarification of a number of points concerning the scope of the toxicity tests, the level of extraction solvents and the potential presence of anaerobic bacteria in the final product. The Applicant's responses will be considered at the February 2004 meeting of the ACNFP with a view to finalising the initial assessment of this application.

1.4 Unilever: An application to extend the range of uses of phytosterols in food products – update

This application was described in the 2002 Annual Report. A decision on the authorisation of this application, and a range of similar applications submitted through other Member States, was postponed pending the implementation of an appropriate risk management strategy for this group of ingredients. A labelling regulation which will address concerns regarding the management of the risk of consumption of phytosterols, phytostanols and esters thereof from multiple dietary sources was agreed at the Standing Committee on the Food Chain and Animal Health in December 2003. A draft approval for the Unilever application was also agreed at the same meeting, although at the time of going to press a decision had not been published by the Commission.

1.5 DHA Gold™ – update

This application was described in the 2001 and 2002 Annual Reports. Following a positive vote at the Standing Committee on Food Chain and Animal Health in April 2003, the Commission Decision (2003/427/EC) authorising DHA gold was published in the Official Journal on 12 June 2003.[2]

[2] http://europa.eu.int/eur-lex/en/index.html

2 Applications submitted to other Member States

2.1 Betaine (Finland)

The ACNFP considered the Finnish Competent Authority's favourable opinion on the application from Finnfeed Finland Ltd to place betaine on the market as a novel food ingredient.

The Committee was unable to agree with the Finnish positive opinion on this application and raised a number of safety concerns relating to the proposed uses of this product in the fortification of foods.

Based on the available evidence, the Committee could not support the conclusion that foods with added betaine are expected to be nutritionally advantageous. Members raised a number of concerns specifically relating to effects on methylation. For instance, betaine is a methyl donor (a substrate for the enzyme homocysteine methyltransferase) and could have the potential to mask symptoms of vitamin B12 deficiency, similar to effects arising from folic acid fortification in individuals with vitamin B12 deficiency. Added to this, Members noted that disturbances in the kinetics of methylation in healthy males had been reported at doses as small as 3g betaine per day. This level would be exceeded if consumers followed the manufacturer's recommended level of intake for the fortified foods.

The Committee also raised concerns regarding the potential toxicity of betaine. No studies had been undertaken to investigate a number of changes observed in the sub-chronic rat toxicity study. The Committee considered that statements on reversibility of observed toxicological effects may not be relevant if betaine is to be taken continuously to achieve a persistent reduction in homocysteine levels. Furthermore, a separate animal study reported haematological effects with a NOAEL equivalent to 9-15g of betaine per day for adult consumers. The estimated levels of intake from fortified foods leave no margin of safety for this observed effect.

Information on the proposed uses was limited and the range of foods to be used for betaine fortification was poorly defined. Furthermore the level of consumption of betaine from the proposed novel food uses could be towards the upper limit of the medicinal dose administered in the United States to individuals with an inborn error of metabolism known as homocysteinuria. Betaine is regulated in the US as a medicine for treatment of this disorder. The Committee concluded that healthy adults with normal levels of homocysteine could thus be consuming betaine at levels above those used in clinical practice.

The ACNFP agreed with the Finnish Competent Authority that the product should not be marketed to children, pregnant women and breastfeeding mothers since the consequences of consumption of the novel food product in such individuals have not been investigated. The Committee expressed concern that young people might be attracted to some of the target foods for betaine incorporation, such as confectionery and soft drinks. Since betaine will be marketed as a functional food ingredient, there is a general concern that such ingredients should not be added to foods that have little nutritional value, such as confectionery products and soft drinks.

The Secretariat forwarded the Committee's concerns and its objection to the marketing of this product to the Commission (Appendix II).

2.2 Deerhorn powder (France)

The ACNFP was asked to consider an initial opinion from the French Competent Authority (CA) regarding powdered velvet antler from red deer. The French CA had issued an unfavourable opinion for this application.

The product is obtained by removing antlers from Canadian Red Deer of four years of age and above. The antlers are dried, the velvet is removed and the antler is ground into a powder. The product is to be sold in a capsule form to be taken daily as a food supplement. There is reported to be a history of consumption of this product in Korea, Japan and China.

Members agreed with the French CA that this product should not be granted approval due to lack of toxicology and allergenicity data. The Committee also considered the risk of Transmissible Spongiform Encephalopathy to be a significant safety concern that needed to be addressed in the evaluation.

Members were concerned that the heat treatment used to pasteurise the antlers would not inactivate bacterial spores such as *Clostridium botulinum*, and that details of the encapsulation procedure and transport and storage arrangements were not included in the application. Additionally the Applicant did not supply justification for the "adaptogenic" claims made in the dossier.

The UK's opinion of this product was forwarded to the Commission in October 2003 (Appendix III).

2.3 Diacylglycerol oil (Enova^{TM} oil) (Netherlands)

The ACNFP considered the favorable initial opinion of the Dutch Competent Authority on an application from Archer Daniels Midland Company (ADM) to market Diacylglycerol Oil (Enova^{TM} Oil) as a novel food ingredient in Europe.

The Committee considered this application by post in February 2003 and at their March meeting. While broadly agreeing with the Dutch initial opinion on this product, Members highlighted various issues where clarification and/or further information was required to support claims made in the dossier. The European Commission was informed of the Committee's views by letter on 20 March 2004 (Appendix IV).

The company produced an additional dossier to address the concerns of the Committee, together with those raised by other Member States. The Applicant also provided further data on the resin component of the immobilised enzyme preparation used in the manufacture of the oil.

At its November meeting the Committee concluded that their earlier concerns had been resolved but they were still concerned about the potential allergenicity of the enzyme and sought reassurance on the levels of protein in the treated oil. The Applicant provided additional data to answer this question and a letter confirming that the Committee had no outstanding questions was sent to the Commission in early January 2004 (Appendix V).

2.4 Maize line MON863 and MON863 x MON810 hybrids (Germany)

The Committee was asked to consider the initial opinion of the German Competent Authority on an application from Monsanto for authorisation under the Novel Food Regulation (EC) No. 258/97, to import grain and grain derived food ingredients from insect-resistant maize line MON863 and maize hybrid line MON863 x MON 810.

Although the Committee agreed with the German initial opinion that there were no safety concerns with MON863 maize, it did not agree that an additional assessment was necessary with regard to the presence of the antibiotic resistance marker *npt*II, as the use of this marker had been considered in detail on a number of previous occasions.

Monsanto's application also sought authorisation of products from hybrids between MON863 and another GM maize line (MON 810). Products from MON810 were cleared for food use in 1997. The Committee considered carefully the data supplied on hybrids between MON863 and MON810 and noted that there was no precedent for assessing hybrids between GM lines under the novel food regulation. The Committee advised that it was not sufficient to rely on data on the two parent lines and that more data were required on the hybrids, noting that the available compositional data indicated some reduction in mineral levels that could be indicative of other changes.

On the basis that there was insufficient information for a complete evaluation of the hybrid line, the UK lodged a formal objection to the application and the Committee's opinion was forwarded to the Commission in August 2003 (Appendix VI).

2.5 Maize line NK603 (Netherlands)

The Committee was asked to consider the initial opinion of the Dutch Competent Authority (CA) on an application by Monsanto for authorisation under the Novel Food Regulation (EC) No. 258/97 of maize products from the herbicide-tolerant maize line NK603. This maize line has been modified by the inclusion of a gene that confers resistance to the herbicide glyphosate (Roundup^{TM}).

The initial assessment report from the Dutch CA stated that it was of the opinion that the consumption of NK603 maize, and food and food ingredients produced from it, is as safe as the consumption of maize, and maize products that have not been genetically modified. In order to meet the deadline for comments the Committee considered the application dossier and the initial opinion by a postal procedure during February 2003. Members were satisfied with the Dutch initial opinion and raised no concerns over the authorisation of this maize line.

The Committee's opinion on this application was forwarded to the Commission in March 2003 (Appendix VII).

2.6 Unsaponifiable matter of palm oil (France)

The ACNFP was asked for its views on an application made to the French Competent Authority (CA) for approval of palm oil high in unsaponifiable matter. The application was considered to be a novel process and therefore falls under Article 1(f) of the Novel Foods Regulation (EC) No. 258/97. The French CA carried out an initial assessment and produced an unfavourable initial opinion for its use as an ingredient which would provide a source of vitamin E and provitamin A in various food products, functional foods, or food supplements.

The Committee generally agreed with the initial opinion of the French CA but raised some additional points. Members noted that the available toxicity studies were inadequate for risk assessment purposes, although such studies would not normally be required for a product derived from an edible oil by the sort of processes described in this application. The Committee also commented on the failure to address consumption levels and were concerned about an increased intake of vitamin E as 1g of the novel food would provide 80% of the recommended daily allowance (RDA). Members additionally noted that potential allergenicity had not been considered. Due to the nature of the processing it was unlikely that any protein would be present, however no analyses had been carried out to confirm this.

The UK CA objected to the marketing of this product. The Committee's opinion on this application was forwarded to the Commission in October 2003 (Appendix VIII).

In light of similar responses from the Competent Authorities in other Member States the application was withdrawn.

2.7 Tahitian noni juice – update

This application was described in the 2001 Annual report. The Commission's draft decision authorising the placing on the market of 'noni juice' (juice of the fruit of *Morinda citrifolia* L) as a novel food ingredient was considered at the May 2004 meeting of the Standing Committee on the Food Chain and Animal Health. Member States agreed to approve this application subject to minor amendments and the Commission Decision (2003/426/EC) was published in the Official Journal on 5 June 2003.[3]

[3] http://europa.eu.int/eur-lex/en/index.html

3 Notifications

3.1 Noni juice from Hawaii

At its meeting in July the ACNFP considered a submission received from the US company Neways seeking an opinion on the substantial equivalence of noni juice (juice of the fruit of *Morinda citrifolia* L) grown in Hawaii. The Applicant was of the view that with the exception of country of origin, the product should be treated as substantially equivalent to the noni juice ingredient that has been assessed under Regulation (EC) No. 258/97 and was approved on the 5 June 2003 (see Section 2.7 above).

The Committee agreed that they could not give an opinion on equivalence due to the lack of compositional data supplied by the Applicant. Members requested further details on the composition of noni fruits from the two geographical regions. The Applicant's response to the request for further data will be considered by the Committee in 2004.

3.2 Microalga *Odontella aurita*

The ACNFP considered the notification sent to the Commission by the French company Innovalg on the 13 August 2002 regarding the marketing of microalga *Odontella aurita* under article 5 of the Novel Foods Regulation (EC) No. 258/97. The Committee raised a number of issues with regard to this notification, which was made on the basis of an opinion from the French authorities that the product was substantially equivalent to certain species of macroalgae (seaweeds).

Members questioned the validity of a comparison with species that were fundamentally different to microalgae. There were few toxicity data and Members requested further details especially on studies investigating possible effects on the gastrointestinal tract. Concerns were also raised with regards to the amount of iodine present in the product.

The Committee also expressed concerns over the allergenic potential of this product. No studies had been provided to examine potential allergenicity from oral consumption. The data provided on allergenicity were therefore not sufficient to satisfy the ACNFP that the product is non-allergenic.

The Applicant stated that on approval of this product an arsenic purification plant will be constructed. The ACNFP was of the opinion that this should be a condition of approval and that the HACCP procedure should be completed and reviewed before the product is marketed. Members also sought clarification with regard to the exact extent of use of the product and the anticipated level of consumption.

The UK Competent Authority's letter regarding this notification was sent on 17 April 2003 (Appendix IX).

4 Other issues considered by the ACNFP

4.1 Assessment of microorganisms

Members were invited to comment on a Commission paper regarding the assessment of microorganisms and its applicability to the assessment of novel foods that are, or are produced by, microorganisms. Members were informed that their views would be incorporated into the Food Standards Agency's formal response to the Commission paper.

Members agreed that it was a useful document and stressed the importance of basing evaluations on carefully defined taxonomic units. The molecular methods used for identification must be of a very high standard. Members felt that more clarity was needed with regard to who was taking the responsibility for the running of the assessment scheme.

Members' comments were passed to the Agency's Microbiological Safety Division.

4.2 Consumer concerns

At the ACNFP open meeting in November 2002, comments from the floor had highlighted that consumers have a broad range of concerns over novel foods that go beyond the potential health risks which are the focus of the risk assessment within the framework of the authorisation process.

At its May meeting the Committee discussed the ways different consumer concerns are currently addressed in the novel food assessment procedure. The Committee considered this issue by reference to the widely accepted list of 7 consumer principles: access; choice; safety; information; equity; redress; and representation. These principles are supported by the right to be heard, both collectively and individually.

In its discussion, the ACNFP considered its remit "to advise ... on any matters relating to novel foods and novel food processes". Although constituted primarily as a scientific committee to give technical advice, it has a broad-ranging membership that includes two consumer representatives and an ethicist in its membership. The Committee concluded that 2 of the 7 consumer principles – Access and Choice – are not explicitly addressed within the regulatory framework for authorisation of novel foods. The issue of 'who is consuming what' is increasingly important and Access, while frequently understood as an equity issue, also has safety implications, as certain foods or food ingredients may not be safe in some doses or for some categories of consumers, such as children. The Committee agreed that Access and Choice should be addressed in future papers dealing with novel food authorisations.

On the question of ethical concerns, Members concluded that the key point was to identify and flag up the issues, rather than to attempt to offer definitive advice. In conclusion, the Committee agreed that it would highlight any issues of consumer concern for wider consideration if it felt it was not qualified to provide advice.

4.3 Gene transfer

The Committee discussed the question of gene transfer between GM plants and bacteria that inhabit the gastrointestinal tract on various occasions, in the context of antibiotic resistance marker genes that are present in some GM food crops. The likelihood of transfer was considered to be small but finite and it was concluded that the resulting risk from consumption of GM foods was remote. To investigate the issue further a number of research projects were commissioned to quantify the risk of gene transfer. The Committee considered the outcome of projects commissioned by the Food Standards Agency at its meeting in July 2002 but did not specifically discuss whether the research commissioned had fully answered the uncertainties identified in the earlier discussions.

The Committee was therefore asked to consider whether the work commissioned by the Food Standards Agency (or other published work on gene transfer) had answered its original questions on the presence of antibiotic resistance markers and potential for gene transfer. The Committee was also asked to consider whether further work is required in this area and to identify any remaining issues that need to be addressed.

At the Committee's March meeting, Members suggested that a review of all the recent work carried out on gene transfer would be helpful. They recognised the difficulty of such a review and noted that this exercise was already being carried out as part of the Science Review[4] as part of the Government's GM Public Debate. Members thought that there was insufficient information to allow quantitative estimates of gene transfer and also commented on the relative lack of information on gene transfer in environments other than the gut flora. The Secretariat will ensure that these comments are taken into account when the Food Standards Agency is commissioning future research in this area.

4.4 GM Debate – Science Review

In 2002, the Government announced three linked activities looking at the future use of genetically modified organisms in the UK. One of these was a review of the science underpinning the GM assessment and approval process in the UK. The other two were a study into the costs and benefits associated with growing or not growing GM crops, and a public debate.

[4] The GM Science Review reports are available at http://www.gmsciencedebate.org.uk

The Science Review was conducted by an independent Panel, chaired by the Government's Chief Scientific Advisor. The ACNFP contributed to the review via the Food Standards Agency, by reviewing and commenting on a draft of the food safety section of the Panel's first report. Due to time constraints this review was undertaken during May by post. The Committee's comments were relayed to the Science Review Panel who were able to use them to refine various aspects of their report, which was published in July 2003. The Agency's contribution, dated 3 June 2003 and incorporating the view of Members of the ACNFP and the Advisory Committee on Animal Feedingstuffs, is published on the Science Review web site.[5]

4.5 Increasing the openness of the ACNFP

In March 2003 the Committee considered how to implement the recommendation in the FSA's March 2002 Report on the Review of Scientific Committees that 'all Committees should move to a position where they conduct as much of their business as possible in open sessions.'

Members agreed that holding meetings in public would be challenging, but were not opposed to the idea. The ACNFP differs from most other committees that advise the Agency since much of its work involves assessment of dossiers that contain commercially sensitive information. Members therefore considered draft guidelines for the handling of items that involve restricted information in open session.

Members agreed that such discussions involving confidential data should be held in two parts, with a closed session either before or after the open meeting. The minutes of such meetings would clearly reflect this separation.

Revised draft guidelines were considered at the May meeting, when Members had a further discussion on the format of open meetings. Subsequent advice from Agency lawyers was that open meetings may not be compatible with the European legislation governing applications for novel foods. Since EU applications form the major part of the Committee's work, the Secretariat is resolving this question with the European Commission before the ACNFP holds any of its normal committee meetings in public.

[5] http://www.gmsciencedebate.org.uk

4.6 Post market monitoring feasibility study

At its November meeting, the Committee considered the outcome of a study commissioned by the Food Standards Agency that had examined the feasibility of conducting nutritional surveillance using commercially available sources of food purchase data. Members discussed what further steps might be taken towards developing an effective monitoring system for different types of novel foods. This topic had also been discussed at the Committee's open meeting on the previous day.

The Committee considered post market monitoring to be a potentially useful tool but noted that there were a number of difficulties associated with the collection of meaningful information for such a study. There was a wide divergence in both lifestyle and diet among the UK population and it might be expected that there would be variations in the manifestation of unexpected adverse effects. These presented significant obstacles to the detection of subtle effects related to novel foods and ingredients that would typically form a small percentage of the diet.

The Committee recommended that the likely sensitivity of any proposed monitoring should be assessed before any further studies were commissioned, bearing in mind that any unexpected long-term effects might be small and cumulative. Members considered that alternatives to population-based monitoring may be more effective, such as studies designed to test specific hypotheses or a formal system for collecting reports of adverse reactions to novel foods.

The Committee will continue its discussions in 2004.

5 Other activities

5.1 ACNFP factsheets

The ACNFP Secretariat issues a corporate brochure to interested parties. This brochure outlines the work of the Committee, and is in the form of a folder containing fact sheets.

During 2003, Members were asked to approve a new fact sheet covering the links between the ACNFP and other advisory committees.

Copies of this fact sheet and an updated version of the fact sheet on ACNFP Members are available from the Secretariat. *See page 16 for further details.*

5.2 ACNFP open meeting

The ACNFP held its third open meeting on 19 November 2003 in London.

The aim of the meeting was to give the general public the opportunity to meet with the Committee and to discuss some of the issues that fall within the remit of the ACNFP.

The meeting was chaired by Professor Mike Gasson and was divided into four sections:

- A short introduction on the role of the ACNFP and how it links to other advisory committees on food safety and to the European Union.
- A discussion on the post market monitoring of novel (including) GM foods.
- Small group discussions on consumer concerns related to the assessment of novel (including) GM foods.
- An open discussion with tabled audience questions.

A Secretary's note of this meeting is available on the ACNFP pages of the FSA website.[6]

The Committee welcomed this opportunity to meet a range of stakeholders, and found the meeting to be very valuable.

[6] http://www.food.gov.uk/science/ouradvisors/novelfood/acnfpmeets/

6 Developments elsewhere

6.1 Commission proposals on the traceability, authorisation and labelling of GM foods

Two new EU Regulations on GM food and feed and the traceability and labelling of genetically modified organisms (GMOs) were adopted at the EU Agriculture Council in July 2003 and published in the Official Journal of the EU on 18 October 2003. These regulations will become effective in all Member States in April 2004.

The Food and Feed Regulation (1829/2003) will replace the existing approval procedures for GM foods, as contained in the Novel Foods Regulation (EC) No. 258/97 and introduce for the first time rules for the labelling of GM animal feed and a harmonised procedure for the scientific assessment and authorisation of GMOs and GM food and feed. The Regulation will require labelling of all GM food and feed products derived from GMOs, regardless of the presence or absence of GM material in the final food or feed product.

The Traceability and Labelling of GMOs Regulation (1830/2003) will create a regime for tracing and identifying GMOs and food and feed products derived from GMOs at all stages of their placing on the market. The Regulation will require business operators when using or handling GM products to transmit and retain information at each stage of the placing on the market. Information concerning the presence of GMOs in products must be transmitted throughout the commercial chain and must be retained for five years.

Further details on these Regulations can be found on the FSA website.[7]

6.2 Review of the Novel Food Regulation (EC) No. 258/97

The Novel Food Regulation came into force in May 1997 and Article 14 requires the Commission to undertake a review of its operation after 5 years. In practice this review has been delayed while new legislation on GM foods has been developed. The European Commission published a consultation paper in July 2002 and organised a stakeholder meeting in January 2003 to discuss potential changes to the legislation.

There was no further progress during 2003 and discussions on revisions to the regulation are expected to begin in 2004.

[7] http://www.food.gov.uk/gmfoods/

7 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:

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The Food Standards Agency website can be found at:
http://www.food.gov.uk

Information on the ACNFP can be found at:
http://www.food.gov.uk/science/ouradvisors/novelfood

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

8 References

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9 Glossary

Allergenicity: The potential or ability of an allergen (usually a protein) to elicit an allergic response.

Allergenicity Screening: Process for identifying allergenicity.

Allergenic: Having the properties of an allergen (usually a protein).

Beta-carotene: An antioxidant that protects the cell against oxidative damage, which may lead to cancer. Beta-carotene can be converted into Vitamin A if needed.

Biosynthetic pathway: A process/sequence of building chemical compounds in the physiologic processes of living organisms.

Cross reactivity: If someone reacts to one food (e.g. peanut) it is possible that they will react to another with a similar chemical structure (e.g. lupin).

Disaccharide: A carbohydrate composed of two sugar molecules.

GM: Genetically Modified

HACCP: Hazard Analysis Critical Control Point.

Homocystinuria: Recessive condition in which the enzyme (cystathione synthetase) that converts homocysteine and serine into cystathione, a precursor of cysteine, is missing.

Hybrid: Progeny of a cross between parents of a different genotype.

***In vivo*:** Within the body.

Methylation: Addition of a methyl group.

Methyltransferase: The enzyme responsible for the transfer of methyl groups to a substrate.

NOAEL: No observable adverse effect level.

Phytosterol esters: Compounds found in vegetable oil, seeds, nuts and coniferous trees that interfere with the absorption of cholesterol in the intestine due to their similar structure.

Polycyclic Aromatic Hydrocarbons (PAH): A major group of unsaturated cyclic hydrocarbons containing two or more rings.

Polymorphism: Variation in a gene or its expression.

Polyunsaturated: Of or relating to long chain carbon compounds, especially fatty acids having two or more double bonds between carbon atoms. Food containing polyunsaturated fatty acids may help reduce blood cholesterol.

SCF: EC Scientific Committee on Food.

Transmissible Spongiform Encephalopathy (TSE): Progressive disease where the substance of the brain becomes vacuolated, giving it a spongy appearance when viewed under the microscope.

Unsaponifiable: A fat which cannot be hydrolysed by an alkali to form a soap and an alcohol.

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 35).

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 2003, 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 2003 can be found on page 24.

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

MEMBERSHIP OF THE COMMITTEE DURING 2003

Chairman

Professor Janet Bainbridge OBE, BSc, PhD, Grad.Cert.Ed (Tech), FRSA, SOFHT (*until 31 August 2003*)
Chief Executive of EPICC subsidiary of the University of Teeside, Middlesborough.

Professor Mike Gasson BSc, PhD (*from 1 September 2003*)
Head of the Food Safety Science Division at the Institute of Food Research, Norwich.

Deputy Chairman

Professor Phil Dale BSc, PhD, CBiol FIBiol (Molecular Biologist/plant geneticist)
Leader of the Genetic Modification and Biosafety Research Group at the John Innes Centre.

Members

Professor Peter Aggett OBE, MSc, MB, ChB, FRCPCH, FRCP(L)(E)(G) DCH (*until 31 March 2003*)
Head of the Lancashire Postgraduate School of Medicine and Health.

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, FIFST (Food Processing and Quality Assurance Expert)
Non-Executive Director of Law Laboratories Ltd.

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

Professor Gary Foster BSc, PhD (Molecular Biologist) (*from 20 November 2003*)
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.

Dr John Heritage BA, DPhil , CBiol, FIBiol (Microbiologist) (*until 31 August 2003*)
Senior Lecturer in Microbiology at the University of Leeds.

Professor Mac Johnston BVM&S, DVet Med, Hon FRCVS, Dip ECVPH (*until 31 August 2003*)
Professor of Veterinary Public Health, Royal Veterinary College.

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

Professor Alan Malcolm MA, DPhil, FIFST, FIBiol, Cbiol (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 Diet and Health.

Professor John Warner MB ChB, MD, FRCP, FRCPCH, FMed,Sci (Allergenicity Expert)
Professor of Child Health, University of Southampton.

Dr Anthony Williams BSc, MB, BS, DPhil, FRCP, FRCPCH (Nutritionist)
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 2003

	Personal Interests		**Non-personal Interests**	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor J Bainbridge (Chairman) (*until 31 August 2003*)	None	None	Various	Departmental commissioned research and student placements
Professor M Gasson (Chairman) (*from 1 September 2003*)	Novacta Biosystems Ltd	Shareholder	Various	IFR Food Safety Science Division industry-funded research projects
Professor P Dale (Deputy Chair)	John Innes Centre EU/United Nations Environment Program/United Nations Industrial Development Organisation/ DEFRA/OECD Agriculture and Environment Biotechnology Commission	Salary Occasional Advisor Member	University of East Anglia University of Sheffield Various Societies, Institutes, Associations and Steering Groups Institute of Biology BBSRC/DEFRA/EU Rockerfeller Maize Biotechnology Research Programme	Honorary Professor Member Fellow Research Funding Member of Advisory Committee
Professor P Aggett (*until 31 March 2003*)	None	None	Astra-Zeneca Smith & Nephew Nestec ILSI Abbott Welcome Trust Yakult Wyeth SMA Int Copper Association	Departmental commissioned research and education in medicine and health including safety and metabolism
Miss J Brand	None	None	None	None

ACNFP Members Interests during 2003 *(continued)*

	Personal Interests		Non-personal Interests	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor R Chadwick	Glaxo Smithkline	Occasional consultant	Food Ethics Council ESRC Eursafe Wellcome Trust MRC	Member Research Funding Member of Executive Committee Research Funding Member of Advisory Council on Scientific Advances in Genetics
Dr H Close	None	None	None	None
Mr N Craddock	Law Laboratories Ltd Various	Fees Consultant on short-term projects	None	None
Professor J Dunwell	Syngenta	Minimal Shareholder	BBSRC/EU Biohybrids	Research Funding Studentship
Professor G Foster (*from 20 November 2003*)	BBSRC RAE Institute Assessment Exercise Science Panel BSPP/Blackwells Molecular Plant Pathology Adjucation Panel for Science & Technology R&D funding in Ireland Biotech/Molecular/Biomedical Enterprise Ireland	Member Editor-in-Chief Panel Member Panel Member	BBSRC/DEFRA/DfID/Gatsby Horticultural Research International Central Science Laboratories British Society of Plant Pathology Molecular Biotechnology	Research Funding Research Funding (PhD student support) Research Funding (PhD student support) Member Editorial Board
Dr J Fowler	Syngenta	Minimal shareholder	None	None
Dr J Heritage (*until 31 August 2003*)	Ray A. Kroc Foundation Medical Research Council	Visiting professor at east Virginia Medical School Advisory Board Member	None	None

ACNFP Members Interests during 2003 *(continued)*

	Personal Interests		**Non-personal Interests**	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor M Johnston (*until 31 August 2003*)	Tesco	Consultant	Various	Departmental research on animal and public health issues
Dr P Lund	Celltech	Minimal shareholder	BBSRC Food Ethics Council	Departmental Research Member
Professor A Malcolm	Associated British Foods Unilever	Shareholder Shareholder	None	None
Dr C Meredith	None	None	Various	Departmental Commissioned Research
Professor I Rowland	Colloides Naturels International Cerestar	Consultant Consultant	Robert Craig and Sons Vitacress Geest Valio (Finland) Alpro (Belgium) VK Muehlen (Germany) Biohit (Finland) Danone (France) Orafti (Belgium) Kelloggs UK Unilever UK Alpro Cultech UK	Funded Research Partners in EC funded Projects PhD Studentships PhD studentship

ACNFP Members Interests during 2003 *(continued)*

	Personal Interests		Non-personal Interests	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor J O Warner	None	None	UBC Pharma	Research
			Merck	Research
			ILSI Europe	Editorial
Dr A Williams	None	None	Rank Prize Funds	Sponsorship of college course
			Children Nationwide	Sponsorship of college course
			National Childbirth Trust La Léche 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	Provision of un-paid advice
			Women & Children First (charity organisation)	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 32);

- 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 on page 32 of this report.

(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,[8] 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.

[8] Close family members include personal partners, parents, children, brothers, sisters and the personal partners of any of these.

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.:

  (i) 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;

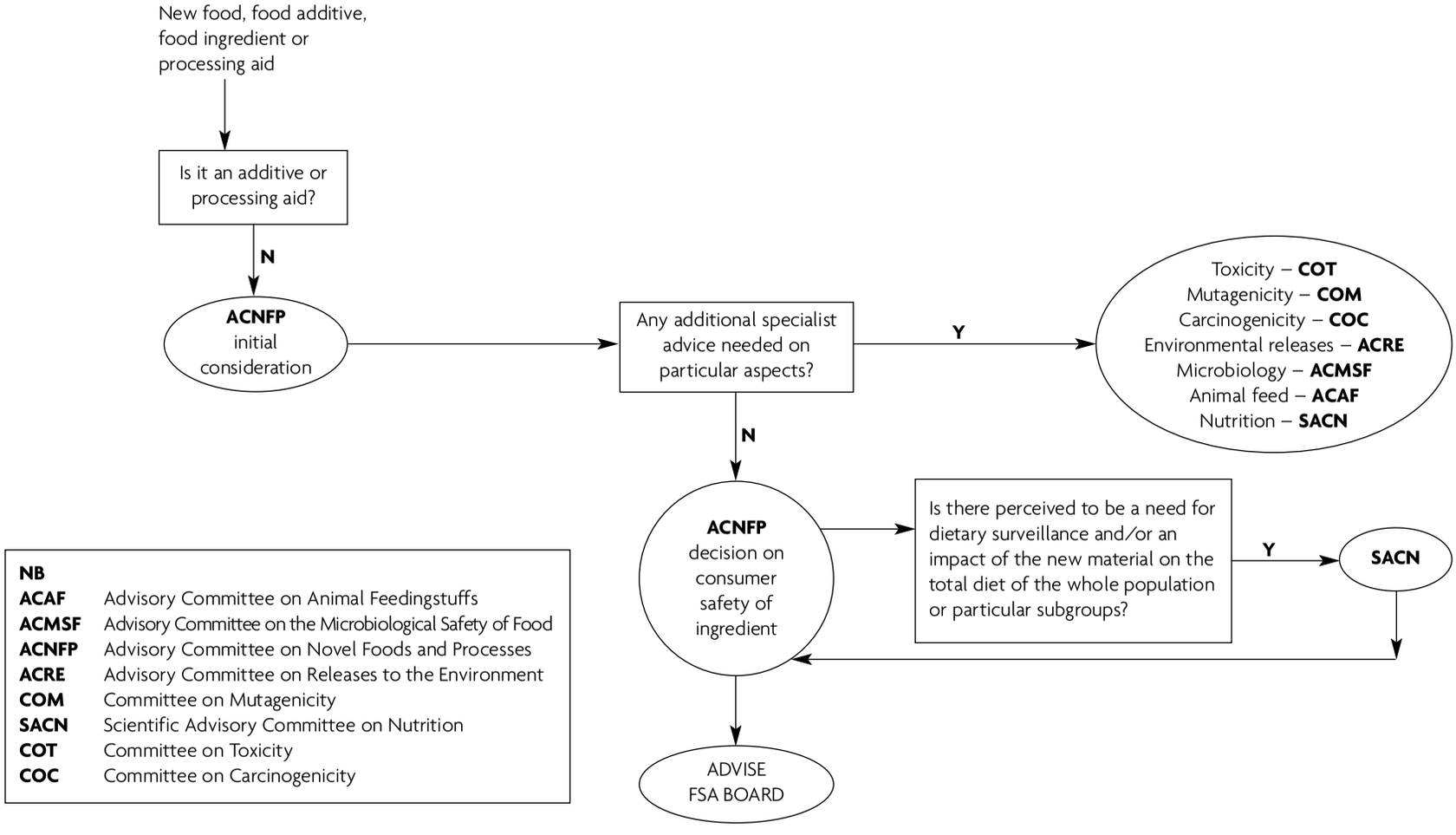
- Trade associations representing companies involved with such products;

- 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.

Figure 1: Relationship of ACNFP with other expert committees involved in the assessment of food safety



APPENDIX II

Mr Andreas Klepsch
DG SANCO Unit D/4
European Commission
Rue de la Loi 200
Brussels
Belgium B-1049

20 October 2003 Reference: NFU 448

Dear Mr Klepsch

Application under Regulation (EC) No 258/97 to market betaine (Finnfeeds Finland Ltd)

As the UK Competent Authority, the Food Standards Agency has sought comments from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial assessment report on this product, prepared by the Finnish CA under the novel foods regulation (EC) No 258/97.

The Committee was unable to agree with the positive initial opinion of the Finnish Competent Authority for the marketing of betaine, and highlighted a number of concerns, as set out in the attached paper.

We cannot support the marketing of this product until these considerations have been satisfactorily addressed.

Yours sincerely

Dr Sandy Lawrie
Novel Foods Division

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

BETAINE

1. Nutritional effects

Based on the available evidence, the Committee does not support the conclusion that foods with added betaine are not expected to be nutritionally disadvantageous. Specifically, the following effects on methylation have not been addressed:

Betaine is a methyl donor, a substrate for the enzyme homocysteine methyltransferase, which is peripherally distributed (probably mainly in the liver and kidney in humans). This enzyme is not present in the brain where the methionine synthetase (B12 dependent) pathway principally governs methylation of homocysteine. Betaine therefore has the potential to correct peripheral methylation, but not central methylation, in vitamin B12 deficient people and therefore to mask the symptoms of deficiency. This effect cannot be ruled out in the absence of clinical studies in individuals with an abnormal vitamin B12 status. Similar problems are known to arise from folic acid fortification in individuals with vitamin B12 deficiency, which includes about 2-5% of the UK population aged 65 years and over.

Storch *et al*[1] describes disturbances in the kinetics of methylation at doses as small as 3g betaine per day when administered to healthy males. This further highlights the concern with betaine consumption from fortified foods.

Paragraph 35 of the initial assessment report highlights certain population groups which may be at risk of nutritional deficiency if they consume betaine-enriched foods, due to an increased requirement for dietary methionine. This risk is identified on the basis of limited data and studies on individuals consuming a low protein (low methionine) diet would be necessary in order to know whether this is a real concern. However, having identified this potential risk the report does not go on to propose any risk management steps. Consumers who have a diet that contains adequate quantities of protein and energy are unlikely to be at risk, but in the absence of a more complete risk assessment it may be prudent to avoid consumption by those eating a reduced diet.

2. Toxicology

The summaries of the toxicity studies were poorly and incompletely reported. In the sub-chronic rat toxicity study, there were a large number of changes with increased size of mesenteric lymph nodes in male rats, altered haematological indices and changes in liver function tests. It

[1] Am J Clin Nut 1991; 54:386-94

seems that no attempt has been made to investigate the nature of the observed changes, for example by special staining of the affected tissues. The implications for potential liver and kidney effects in humans is of considerable concern, taking into account the observations in animals and the large doses that may result from intake of betaine-incorporated foods.

Statements that the changes observed in the animal studies are "generally" or "mainly" reversible are not reassuring. Reversibility may not be relevant if betaine is being taken continuously to achieve a persistent reduction in homocysteine levels.

One of the animal studies reported in the dossier (page 58) reported haematological effects with a NOAEL equivalent to 9-15 g of betaine per day for adult consumers. The estimated levels of intake from fortified foods leave no margin of safety for this observed effect.

Betaine exerts osmotic effects and clinical experience indicates that patients taking betaine may complain of diarrhoea. The Applicant has not addressed the possibility of a similar effect resulting from consumption of fortified foods.

Consideration should be given to the dietary effects of methyl donors, such as betaine, on epigenetic gene regulation.[2]

3. Proposed uses and labelling

The range of foods intended to be used for betaine fortification is very broad and not well defined. The Applicant states that food manufacturers' recommendations will likely restrict the use of betaine-enriched foods although there could be many betaine-enriched products in the same food group on the market. Information should be presented on how foodstuffs will be labelled and consideration should be given to whether portion sizes should be recommended for different foods.

Consumption of fortified confectionery could increase the daily intake of refined sugars by 30g. This is dismissed on the grounds that it represents only 120kcal/day and is therefore of minimal nutritional importance in the overall diet. However, this is a significant increase given the recommended dietary target for refined sugars, which is equivalent to 60g/day.

The Committee agreed with the Finnish Competent Authority that the product should not be marketed to children, pregnant women and breastfeeding mothers since the consequences of consumption of the novel food product have not been investigated. (A similar caveat applies to the clinical use of betaine, at least in the US). The Committee also expressed concern that young people might be attracted to some of the target foods for betaine incorporation, such as confectionery and soft

[2] For example, see Waterland and Jirtle. Mol Cell Biol 2003; 23:5293-5300

drinks. Since betaine will be marketed as a functional food ingredient, there is a general concern that such ingredients should not be added to foods that have little nutritional value, such as confectionery products and soft drinks.

4. Other observations

The ACNFP also made the following observations on the application:

The product is presented as a potential beneficial nutrient to reduce the risks of cardiovascular disease. Although epidemiological evidence would suggest that high levels of serum homocysteine is linked to the development of cardiovascular disease, there is no evidence at present to support the theory that a reduction in these levels would reduce the risk of cardiovascular disease. The Applicant should also be aware that claims of disease prevention are not allowed for foods.

Betaine is a regulated medicine administered to individuals with an inborn error of metabolism, known as homocysteinuria (6-20g/day). However, the relevant UK authorities have advised that fortified foods are unlikely to be classed as medicinal. From the proposed novel food uses in this application, the intake of betaine could be towards the upper limit of the therapeutic range. In fact, when betaine intake is calculated on the basis of average consumption of the foodstuffs concerned, the Finnish Competent Authority estimates the daily intake of betaine to be 13-20g, with high level intake estimated at 39g. Thus, healthy adults with normal levels of homocysteine could be consuming betaine at levels above those used in clinical practice.

There are interspecies differences between the enzyme distribution in rats, and in pigs and humans. The enzyme is present only in liver in rats.[3] Also if the methylation ratio is abnormal this appears to disturb methylation in the brain of pigs and man, but not in the rat.[4] In general, findings in animal studies with betaine must be treated with caution when applied to humans.

October 2003

[3] McKeever *et al*. Clin Sci 1991; 81: 551
[4] Clin Sci 1995; 88: 73-9

APPENDIX III

Mr Andreas Klepsch
DG SANCO Unit D/4
European Commission
Rue de la Loi 200
Brussels
Belgium B-1049

20 October 2003 Reference: NFU 447

Dear Mr Klepsch

Application under Regulation (EC) No 258/97 to market powdered deer horn (Velnor Inc.)

As the UK Competent Authority, the Food Standards Agency has sought comments from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial assessment report on this product, prepared by the French CA under the novel foods regulation (EC) No 258/97.

The Committee agreed with the initial opinion of the French Competent Authority that the toxicological data provided by the Applicant were insufficient to assure them that the product was safe, and the lack of allergenicity studies was of concern.

The Committee also raised the following additional issues:

The Committee considered the risk from Transmissible Spongiform Encephalopathy to be a significant safety concern that needs to be addressed in the evaluation. Chronic Wasting Disease is found amongst both farmed and wild deer in North America and the implications for human health were highlighted in the Scientific Steering Committee's opinion of 6-7 March 2003.

The heat treatment used to pasteurise the antlers would not be sufficient to inactivate bacterial spores such as Clostridium.

The Applicant did not supply any information regarding the encapsulation process or the transport and storage arrangements.

The Applicant did not provide any data to justify the "adaptogenic" claims that are made for the product. If the product has biological activity, the safety assessment ought to take account of the mechanisms involved.

We therefore agree with the French CA that this product should be given a negative opinion, and do not support the marketing of this product.

Yours sincerely

Dr Sandy Lawrie
Novel Foods Division

APPENDIX IV

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

20 March 2003 Reference: NFU 403

Dear Mr Klepsch

Application under Regulation (EC) No 258/97 – Diacylglycerol Oil (ENOVA^{TM} Oil)

The UK Competent Authority has sought comments from the Advisory Committee on Novel Foods and Processes on the initial assessment report from the Netherlands Competent Authority under the 60-day rule of the Novel Food Regulation (EC) No. 258/97 and we consider that consent should only be granted if the following conditions are met:

Analytical evidence should be presented to confirm that the end product does not contain any intact enzymes or other proteins.

The use of validated standard techniques in the analysis of the oil's composition should be confirmed.

Information on the stability of the oil should be provided to confirm that its shelf life and quality criteria comply with those for edible fats and oils.

The Applicant should confirm that levels of heavy metals comply with existing standards for oils. EC legislation sets a limit of 0.1 mg/kg for lead in fats and oils, while the Codex Standard for named vegetable oils sets a maximum permissible concentration of 0.1mg/kg for both lead and arsenic.

We also have a concern relating to the assessment of the immobilised enzyme used in the manufacture of the modified oil. We note that this is described by the Applicant as being authorised for use as a processing aid in the UK, but this is not the case since this enzyme preparation has not been cleared under the voluntary arrangements for assessment of food enzymes that operate in the UK. In the early 1990s the UK Committee on Toxicity evaluated an immobilised lipase which may be the same product as in the current application or closely related to it. However, this evaluation was not finalised due to incomplete data.

The Dutch initial opinion refers to a supplementary package of toxicological data on the immobilised enzyme preparation (ADM205, appendix F) which has been judged to meet the SCF guidelines and to be adequate. These data were not available for us to review but are described as identical to the information reviewed by the Australian authorities. However, the lipase covered by the Australian review is not immobilised. We therefore need more information to confirm that issues relating to the immobilisation system, such as the nature and quality of the support material and the potential extraction of impurities into the treated oil, have been adequately considered by the Dutch authorities.

Yours sincerely

Dr Sandy Lawrie
Novel Foods Division

APPENDIX V

Mr Andreas Klepsch
DG SANCO – Unit D2
European Commission
200 Rue de la Loi
Brussels
Belgium B-1049

14 January 2004 Reference: NFU 403

Dear Mr Klepsch

Application under Regulation (EC) 258/97 – Diacylglycerol Oil (ENOVA^{TM} Oil): Additional Information from the Applicant in Response to UK Comments

Further to my letter of 10 October, I can confirm that we have received additional information from the Applicant addressing the points raised at the end of that letter.

These new data were discussed on 20 November 2003 by our expert advisory committee, the Advisory Committee on Novel Foods and Processes, which concluded that all these points had been satisfactorily addressed. Committee members however asked one final question about the presence of potentially allergenic proteins in the product, noting that the absence of protein had been demonstrated using a relatively insensitive analytical method.

The Applicant has now conducted additional analyses showing that protein is only detectable at levels around 0.2 mg/kg (200ppb). The Committee has no concerns over the presence of protein at such low levels.

Conclusion

In view of the data provided by the Applicant at the July 2003 Competent Authority meeting, and the additional information that were subsequently provided directly to the UK, we have no outstanding objections to this application.

Yours sincerely

Dr Sandy Lawrie
Novel Foods Division

cc L Mejia, M Empie (ADM); B van der Heide (Netherlands CA)

APPENDIX VI

Mr Andreas Klepsch
DG SANCO – Unit D2
European Commission
200 Rue de la Loi
Brussels
Belgium B-1049

4 August 2003 Reference: NFU 443

Dear Mr Klepsch

Initial Opinion from the German Competent Authority on the application under Regulation (EC) No 258/97 – insect resistant maize MON863 and MON863 X MON810

The Food Standards Agency is the UK Competent Authority for assessment of novel foods according to Regulation 258/97. The Agency has sought comments from the Advisory Committee on Novel foods and Processes (ACNFP) on the Initial Opinion from Germany under the 60-day rule (Article 6(4) of Regulation (EC) No 258/97).

In the light of the ACNFP's comments, the UK Competent Authority would like to present its reasoned objection to the Initial Opinion on this application to place on the market grains and grain derived food ingredients from maize line MON863 and hybrids between this line and another GM maize line, MON810.

The ACNFP considers that there is insufficient information on MON863 X MON810 insect resistant maize hybrids for the purposes of safety assessment. This is the first novel food application for hybrids between two GM lines and the Committee has noted that there are no guidelines for the data which should be submitted in this situation before a safety assessment can be made. The Applicant has presented only limited data relating to the hybrids and argues that an adequate assessment can be made by reference to data on the individual parent lines. However, this approach does not allow all the properties of the hybrids to be assessed. In particular the potential for interactions between the two sets of inserted genes needs to be considered.

The ACNFP also notes that the available data do not adequately address potential allergenicity of products derived from the hybrids and there is insufficient data to demonstrate compositional equivalence. Data on the composition of the hybrids indicate that there are significant, unexpected differences in some constituents (for example, in the levels of copper) and this reinforces the need for further assessment.

Yours sincerely

Submitted by e-mail

Dr Sandy Lawrie
Novel Foods Division

APPENDIX VII

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

3 March 2003 Reference: NFU 428

Dear Mr Klepsch

Initial opinion from the Dutch CA on the application under EC Regulation 258/97 – Roundup Ready Maize NK603

The UK Competent Authority (UK CA) sought comments from the Advisory Committee on Novel foods and Processes (ACNFP) on the initial opinion from Holland under the 60-day rule of the Novel Food Regulation (EC) 258/97 and is content for consent to be granted.

Yours sincerely

Dr Sandy Lawrie
Novel Foods Division

APPENDIX VIII

Mr Andreas Klepsch
DG SANCO Unit D/4
European Commission
Rue de la Loi 200
Brussels
Belgium B-1049

20 October 2003 Reference: NFU 441

Dear Mr Klepsch

Application under Regulation (EC) No 258/97 to market palm oil high in unsaponifiable matter (Laboratoires Expanscience)

As the UK Competent Authority, the Food Standards Agency has sought comments from the Advisory Committee on Novel Foods and Processes (ACNFP) on the initial assessment report on this product, prepared by the French CA under the novel foods regulation (EC) No 258/97.

The Committee shared the concern expressed by the French Competent Authority that the process of molecular distillation would lead to an increase in the level of polycyclic aromatic hydrocarbons (PAHs) and agreed that this was undesirable. The Committee also agreed that the levels of consumption of the novel ingredient would not be controlled.

In addition, while it appears unlikely that there would be protein present in the final product due to the nature of the process, the ACNFP commented that the Applicant's statements about the absence of protein should be supported by results of appropriate analyses.

We therefore agree that this product should be given a negative opinion, and do not support the marketing of this product.

Yours sincerely

Dr Sandy Lawrie
Novel Foods Division

APPENDIX IX

Andreas Klepsch
DG SANCO
European Commission
by e-mail

17 April 2003 Reference: NFU 430

Dear Mr Klepsch

Odontella aurita

As the UK Competent Authority, the Food Standards Agency has sought expert advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on the notification submitted to the Commission by the French company Innovalg on the 13 August 2002 under Article 5 of the Novel Foods Regulation (EC) 258/97, regarding the marketing of the microalga *Odontella aurita*. The UK is not convinced that this product can be regarded as substantially equivalent to existing foods and wishes to highlight a number of specific concerns regarding the safety assessment of this product.

(i) Substantial equivalence

The UK is of the opinion that this notification does not meet all of the criteria set out in Article 3(4) of (EC) 258/97. The microalga *O. aurita* is taxonomically distinct from macroalga species (seaweeds) proposed as equivalents by the Applicant. Also the UK questions whether a novel food can claim to be substantially equivalent to more than one different product. (We raised similar concerns over the recent Article 5 notification for Argan Oil). The UK is therefore of the opinion that this application should not have been submitted as an Article 5 notification and a full novel food safety assessment is required.

(ii) Undesirable substances

Toxicity data are generally lacking and the ACNFP was of the opinion that further information is needed in order to perform an adequate risk assessment. The Committee noted that, unlike the macroalgae with which it is compared, *Odontella aurita* has a silica containing cell wall and crystalline surfaces such as these are known to provoke irritation and inflammation of the gut. Specific data would be required to address this point. The Committee was also concerned with the potential intake of iodine from this product.

(iii) Allergenicity

The Committee expressed concerns regarding the allergenic potential of this product since no studies have been provided which examine potential allergenicity following oral consumption. While dermal and

subdermal investigations were carried out, we do not consider that these are sufficient to demonstrate that the novel food is unlikely to elicit an allergenic response when consumed. The skin irritation studies carried out stimulate a type 4 allergic reaction, whereas consumption of the product could elicit a type 1 IgE allergic response. The cosmetic allergenicity studies also appear to be very superficial in nature with only macroscopic examinations carried out while more comprehensive immunogenic tests were not performed. The dossier appears contradictory in places, stating variously that the product has significant immunostimulatory effects and a high protein content, but it is considered unlikely to provoke an allergic reaction. The finding that the product enhances the expression of the adhesion molecule ICAM-1 requires further investigation, since this may increase the risk of sensitisation.

(iv) Quality Assurance

The ACNFP noted that the Applicant intends to construct a purification plant to reduce arsenic levels once approval is granted and suggests that this should be an explicit condition of approval. Similarly, the HACCP procedure currently being implemented by the Applicant should be completed and reviewed before the product is marketed.

(v) Estimated consumption

The Committee was of the opinion that the consumption data should be further clarified with regard to the product's exact extent of use, and anticipated level of consumption. Although the Applicant explains that the product's unpleasant taste would limit its consumption, one of the uses indicated is as a food supplement (possibly in capsules where the taste is not noticed). Further details on how the anticipated intake was calculated is requested.

Given that the Finland Competent Authority has also raised concerns over the application of the Article 5 procedure to this product, we would welcome the opportunity to discuss this issue at the next meeting of the Novel Food Working Group.

Yours sincerely

Dr Sandy Lawrie
Novel Foods Division

cc Competent Authorities

Cumulative index

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