The Advisory Committee on Novel Foods and Processes (ACNFP)
2009 Report

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NOVEL FOOD APPLICATIONS SUBMITTED TO THE UK

(a) Full applications

In 2009 the ACNFP considered four new applications under Article 4 of regulation (EC) 258/97 (Table 1, below). Details of the issues that were raised by the Committee can be found in the Minutes of the relevant meetings (Annex 2). The Committee did not conclude its assessment of any of these applications during this calendar year.

Table 1: Novel food applications made via the UK that were considered by the Committee during 2009

Novel food (Applicant)	***Meeting discussed***	***Initial opinion***	***Comment***
Isomaltooligosaccharides (Bionutra Inc)	Feb	-	Positive initial opinion was issued in 2012
Bee Venom for addition to honey (Nelson Honey)	Sept, Nov	-	Negative initial opinion was issued in 2010
Magnolia Bark Extract (William Wrigley Jr. Co.)	Sept, Nov	-	Positive initial was issued in 2010
Phosphated Distarch Phosphate (MGP Ingredients)	Nov	-	Positive initial was issued in 2011

(b) Opinions on substantial equivalence

In 2009 the ACNFP considered one request for an opinion on equivalence in accordance with Article 3(4) of regulation (EC) 258/97. This is detailed in Table 2, below. Details of the issues that were raised by the Committee can be found in the Minutes of the relevant meeting (Annex 2). The ACNFP did not conclude its assessment of this request during this calendar year.

Table 2: Applications for an opinion on substantial equivalence that were considered by the Committee during 2009

Novel food (Applicant)	***Meeting discussed***	***ACNFP Opinion***	***Comment***
Astaxanthin (Parry Nutraceuticals)	Feb	-	Awaiting data from the applicant

NOVEL FOOD APPLICATIONS SUBMITTED TO OTHER MEMBER STATES

In 2009 the ACNFP considered eight initial opinions from other EU Member States. These are detailed in Table 3, below. The ACNFP's advice formed the basis of the UK's comments or objections to the marketing of these novel foods. Details of the issues that were raised by the Committee can be found in the Minutes of the relevant meeting and in the responses sent to the European Commission.

Table 3: Novel foods considered by the Committee during 2009 following an initial assessment in another Member State

Novel food (Member State)	*Meeting discussed*	*UK response*	*Comment*
Liquorice Root Extract (Belgium)	April (postal)	Annex 3 (a)	Objections (blood coagulation, oestrogen like effects)
Astaxanthin (Finland)	Feb (postal)	Annex 3 (b)	Objections (long term exposure)
Cis-9 Cetyl Myristoleate Rich Complex (Italy)	April	Annex 3 (c)	Objections (insufficient toxicological data, cholesterol intake)
Chitin-Glucan (Belgium)	April	Annex 3 (d)	Objection (allergy)
Arracacha Root (Spain)	Sept	Annex 3 (e)	Objections (allergy)
Sucromalt (Netherlands)	Nov	Annex 3 (f)	Minor comments only
Rev 7 chewing gum base (Netherlands)	Sept (postal)	Annex 3 (g)	Objection (fate during transit)
Sardine Peptide Product (Finland)	April	Annex 3 (h)	Objections (insufficient toxicological data, medicinal)

NOVEL FOOD APPLICATIONS CONSIDERED IN PREVIOUS YEARS

During 2009 the ACNFP also considered one response from an applicant company, and two opinions from the European Food Safety Authority (EFSA) following reasoned objections to the marketing of novel foods (Article 6(4) of regulation (EC) 258/97). These are detailed in Table 4, below. Details of the issues that were raised by the Committee can be found in the Minutes of the relevant meeting

Table 4: Novel foods considered by the Committee during 2009 following an initial assessment in another Member State

Applicant response or EFSA opinion	*Meeting discussed*	*Comment*
Zeaxanthin (EFSA)	Nov	Accepted
Sardine Peptide Product (Response)	Sept	Objection sustained (need for a 90-day toxicity study before the safety of this product could be determined expressed concern about the potential for sardine peptide product to interfere with medication (such as ACE inhibitors) likely to be taken by hypertensive individuals)
Glucosamine from *A. niger* (EFSA)	Nov	Concerns expressed regarding an advisory label for diabetics. Members noted that as undiagnosed diabetics, likely to be prevalent amongst the target demographic, would not be aware that they should be monitoring their consumption of sugar.

OTHER ISSUES

In 2009 the ACNFP also considered a number of other issues which related to novel foods, GM plants and the functioning of the Committee. These are detailed in Table 5, below.

Table 5 Other Issues	***Meeting discussed***	***Comment***
Scientific Publications concerning safety of GM food	Feb	Papers regarded to be broad observational studies which were not regarded to be definitive.
FSA Scientific Advisory Committee guidance	Feb, April	Self assessment guidelines regarded to be appropriate
The role of ethics in the work of the ACNFP	Sept	Committee work in context of frameworks for applying ethical principles and assessing consumer concerns was considered
Report on long term effects of GM crops	Sept	Literature review was useful and well constructed, but survey was poorly structured and had a disappointingly low response rate. Committee noted that the report concluded that no adverse long term effects of GM crops on human or animal health have been established.
EFSA Opinion GM plants : Antibiotic resistance genes	Sept	The Committee noted there are still groups of bacteria which have not developed antibiotic resistance despite the widespread prevalence of the ARM genes in the environment and gut flora. And the existence of a new route for the potential transmission of ARM genes may conceivably lead to the development of antibiotic resistance in these groups Letter to EFSA Annex 3 (i)
ACNFP Guidance on substantial equivalence	April	Minor revisions to existing guidance.

ANNEX 1 – Information about the Committee

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.

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 2012`, 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 2009 and a copy of the code of conduct for ACNFP members can be found on the following pages.

Membership of the Committee during 2009

Acting Chairman

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

Members

Dr Paul Brantom BSc, PhD, MIBiol (Toxicologist)
Independent consultant and registered European toxicologist.

Professor Michael Bushell BSc, PhD (Microbiologist)
Professor of Microbiology and Head of Microbial Sciences at the University of Surrey.

Professor Andrew Chesson BSc, MSc, PhD, CChem, FRSC (Nutritionist)
Independent Scientific Adviser and Honorary Professor at the University of Aberdeen.

Jayam Dalal (Consumer affairs)
Freelance marketing consultant and Independent Public Appointments Assessor accredited by the Office of the Commissioner for Public Appointments.

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

Professor Harry Flint BSc, PhD (Microbiologist)
Head of the Gut Microbiology and Immunology Division at the Rowett Research Institute.

Dr Paul Haggarty BSc, PhD (Nutritionist)
Head of Nutrition & Epigenetics and Senior Lecturer, Rowett Institute of Nutrition and Health, University of Aberdeen and Honorary Clinical Scientist in Grampian NHS Trust.

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.

Professor John Mathers BSc, Dip. Nutr, PhD (Nutritionist)

Professor of Human Nutrition and Director of the Human Nutrition Research Centre at Newcastle University

Dr Clare Mills BSc, PhD (Plant science and allergy expert)
Head of the Structuring Food for Health Programme at the Institute of Food Research in Norwich.

Gillian Pope (Consumer affairs)
Company Secretary for NRC (Europe) Ltd.

Professor Christopher Ritson BA, MAgrSc (Expert in Ethics)
Professor of Agricultural Marketing and former Dean of the Faculty of Agriculture and Biological Sciences at Newcastle University.

Kevin Swoffer BSc, FIFST (Food chain expert)
Independent food safety consultant

Professor John Warner MB, ChB, MD, FRCP, FRCPCH, FMed Sci (Allergenicity Expert)
Professor of Child Health at the University of Southampton;
now Head of the Department of Paediatrics at Imperial College.

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 2009

Personal Interests			Non-personal Interests	
Member	Company	Interest	Company	Interest
Professor Peter Shewry	Journal of Cereal Science	Reviews editor	EU	Funded Research
			Fra	Funded Research
	Various	Occassional laboratory review panel member	FSA	Funded Research
			NIAB	Trustee and Board Member
	Variouis	Editors and other Royalties	Rank Prize Funds	Trustee
	Syngenta	Consultant	Alpro Foundation	Member of Advisory Committee UK
Dr Paul Brantom	Elanco Animal Health.	Consultant.	[none]	
	Veterinary Products Committee (VPC).	Committee Member		
	Veterinary Residues Committee (VRC).			
	Advisory Committee on Animal Feedingstuffs (ACAF).			
	EFSA Panel on Additives & Products or Substances used in Animal Feed (FEEDAP).			
Professor Michael Bushell	Abbott Laboratories Chicago	Consultant	none	

Personal Interests			Non-personal Interests	
Member	Company	Interest	Company	Interest
Professor Andrew Chesson	None	None	European Food Safety Authority	Chair of FEEDAP panel and member of Scientific Committee
Jayam Dalal	Agricultural Wages Committee.	Vice Chair.		
Professor Harry Flint	Shell.	Shareholder.	Provexis Alizyme.	Research funding.
	Syral.	Member of Scientific Advisory Board		
Professor Gary 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. Biotech/Molecular/ Biomedical Enterprise Ireland.	Panel Member.	Central Science Laboratories. British Society of Plant Pathology. Molecular Biotechnology. Glaxo Smith Kline	Research Funding.

Personal Interests			Non-personal Interests	
Member	Company	Interest	Company	Interest
Dr Paul Haggarty	Smith Nephew	Shareholder	Pharmaton	Unpaid advisor on pregnancy study protocol.
	Diageo	Shareholder		
	Cafe Direct	Shareholder	Editorial consultant on the American College of Physicians' Information and Education Resource	Consultation fee contributed to research funds.
			Nutrition and Health Conference and German Society for Reproductive medicine	Lecture fees contributed to research funds.
Professor Stephen Holgate	Merck Research Laboratories. Novartis. Laboratorias Almirall. Pfizer. Altana Pharm. Centecor. Ferring. Wyeth. Amgen. Synairgen (Spin out company University of Southampton). Cambridge Antibody Technology. Kyowa Hakko. York Laboratories.	Consultant.	Novartis. MSD. Wyeth. Avantec.	Research Funding.

Personal Interests			Non-personal Interests	
Member	Company	Interest	Company	Interest
	Synairgen.	Shareholder/ Director.	Various charities and trusts.	Trustee.
	Southampton Asset Management.	Director.	Advisory Committee on Hazardous Substances	Chair
Professor John Mathers	none		EU	Research Funding
			FSA	Research Funding
			BBSRC	Research Funding
			Welcome Trust	Research Funding
			MRC	Research Funding
			Governing Council of the British Nutrition Foundation	Member
			Lifelong Health and well being Rsearch Advisory Panel	Member
			DRINC Advisory Panel	Member

Personal Interests			Non-personal Interests	
Member	Company	Interest	Company	Interest
Dr Clare Mills			FSA.	External reviewer of Food Allergy and Intolerance Research Programme.
			BBSRC	Member of DRINC steering group Core member Committee C
			IFRExtra.	Analysis of Proteins in Oils. Starch work.
			Various.	Member of IFR Food and Health Network (Allergy cluster).
			Various.	EuroPrevall (EU funded) Industry partner .
			EU	Funded Research
			BBSRC	Funded Research
			FSA	Funded Research

Personal Interests			Non-personal Interests	
Member	Company	Interest	Company	Interest
Mrs Gillian Pope	None		None	
Professor Chris Ritson	Home Grown Cereals Authority	Deputy Chairman (June 2000- March 2008)	Food Ethics Council Cereals Industry Forum EU	Director/Trustee Chairman Research Funding
Mr Kevin Swoffer	None		none	
Professor John Warner	UCB Pharma Ltd. Merck. Danone Novartis Allergy Therapeutics	Chairman of Scientific Advisory Board. Member of Scientific Advisory Board. Member of Scientific Advisory Board Research Funding Scientific Advisory Board Scientific Advisory Board	Danone UCB Pharma. Food & Drink Federation. Anaphylaxis Campaign.	Funded Research 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 (see below);
- 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 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.

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 33 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, 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.

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.:
- a grant for the running of a unit or department for which a member is responsible;
- 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);
- 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

FSA 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.

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]

[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
[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

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 seven 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.

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] Joint FSA/DH Secretariat
[9] Joint Defra/FSA/DH Secretariat

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 Researcher[10].
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.
11. When considering what evidence needs to be collected for assessment, the following points will be considered:
12. 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
13. whether stakeholders can provide unpublished data.
14. 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

15. 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.
16. Any assumptions made by the committee will be clearly spelled out, and, in reviews, previous assumptions will be challenged.
17. Data gaps will be identified and their impact on uncertainty assessed by the committee.
18. An indication will be given by the committee about whether the database is changing or static.

Drawing conclusions

19. The committee will be broad-minded, acknowledging where conflicting views exist and considering whether alternative hypotheses fit the same evidence.
20. Where both risks and benefits have been considered, the committee will address each with the same rigour.
21. 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.
22. 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.
23. Committees will make recommendations about general issues that may have relevance for other committees.

Communicating committees' conclusions

[10] There is of 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/qge-rep.pdf and The Magenta Book. www.gsr.gov.uk/professional_guidance/magenta_book/guidance.asp).

- Conclusions will be expressed by the committee in clear, simple terms and use the minimum caveats consistent with accuracy.
- 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.
- The conclusions will be supported by a statement about their robustness and the extent to which judgement has had to be used.
- 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.
- 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.
- 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.

Financial Statement

ACNFP is an independent SAC, but does not have resources of its own. The operation of the Committee is funded by the FSA. In the period of this report, costs for this support (covering Members expenses and fees and administrative cost for the meetings) were £22,209 (comprising £17,449 members fees and expenses – actual cost and £4,760 estimated cost of photocopying, hospitality and hotel accommodation)

MINUTES OF ACNFP MEETINGS DURING 2009

Minutes of the 92nd meeting (February 09)

3. Matters Arising

The Secretariat provided the following update on items arising either following the previous meeting or in the previous meeting:

Item 3 Extranet

The development of the Agency's extranet is currently on hold. The Secretariat will discuss with the FSA's IT security officer whether ACNFP papers can be provided to members on compact discs.

Item 4 Phosphated Distarch Phosphate

The opinion has not yet been finalised but it will be circulated to Members for their final clearance in the next few days.

Item 5 Touchi (Black Bean) extract

The applicant provided the missing information, as requested by the Committee, and the draft opinion was issued for public comment. As there were no responses the opinion was forwarded to the Commission as the basis of the UK's initial assessment of this ingredient.

Item 6: Draft EFSA Opinion on Nanotechnology

The FSA submitted comments based on the discussions by both ACNFP and COT. The final version of the EFSA opinion is expected to be issued in the next 2-3 weeks.

Item 7: CLA-rich oil

The Commission is forwarding this application for EFSA for advice on the objections and other questions raised by the UK and other Member States.

Item 9: Reproduction studies in mice with GM maize

The Committee's observations on this report were circulated to the Commission, EFSA and other Member States. The Austrian authors have provided some initial comments on the points raised by the Committee. They have also responded to some of the points raised by EFSA's GMO Panel, who considered this report at their meeting in December. The Austrian authorities are considering

whether further details of the work can be circulated to EFSA and other Member States (on a confidential basis) prior to publication in the scientific press.

4. Review of Open Event on Novel Foods

The Committee considered that the previous day's Open Event was a good one and that the right topics had been selected for discussion.

The discussion group on intake levels queried whether the ACNFP should consider higher levels of consumption than the 97.5th percentile currently used when evaluating the safety of products. However, consumption at the top end of the distribution is unlikely to be maintained over a sustained period and therefore it was not considered necessary to evaluate for this volume of consumption.

The discussion group on intake levels also highlighted the weak data on food consumption in the European Union (EU) as a whole and the need for an EU-wide database. The Committee agreed that there was a lack of data across the EU and that there was a need for contemporary data to bring it up to date. It considered the UK's NDNS programme, which the FSA sponsors was amongst the best and in future will take the form of a rolling survey. EFSA recognises the need for better data across the EU and is working on a pan-European database. It will take several years before it is available.

A discussion group on labelling suggested that a list of novel foods which have been authorized together with their labeling requirements be published. The Secretariat agreed to include the list in an information paper to be presented to the Committee at its next meeting.

The ethical remit of the ACNFP was questioned during the open discussion. The Committee's ethicist agreed to draft a discussion paper for the committee. This will include the ethics of testing on children to determine both the benefits and risks of certain foods consumed by children.

The Committee requested that the secretariat collate feedback obtained from delagates. It also asked that the next open event should include a report on the actions taken from the previous event.

5. Isomalto-oligosaccharides ACNFP/91/1

The Committee was asked to consider this application from Bioneutra Inc. to the UK Competent Authority for the approval of Isomalto-oligosaccharides (IMO) as a novel food ingredient.

One public comment was received during the 21 day consultation period and this provided data showing that two other IMO preparations (not Bioneutra's) were fully absorbed and altered

serum insulin levels. The Committee considered this comment and the associated data as part of their assessment of the novel ingredient.

The Committee requested that given the variability in the composition of IMO preparations from different sources, data from tolerance studies and absorption studies using Bioneutra's own IMO preparation would be required.

The Committee considered that the applicant should consider the effects of their IMO preparation on blood glucose/insulin levels and should provide relevant data, particularly if the novel ingredient is absorbed to a significant degree.

The Committee was concerned that, if there is significant absorption, the novel ingredient may have the potential to mislead diabetics who might consume the product because they have perceived it to be a prebiotic dietary fibre rather than a mixture of carbohydrates that may be largely or fully absorbed. It also noted that the applicant's proposed product label would need to be amended in line with EU legislation to state that the product is "derived from a source of wheat".

The Secretariat agreed to obtain further information from the applicant on these points.

6. Astaxanthin (Parry Nutraceuticals) ACNFP/92/2

The Committee was asked to consider whether an application made by Parry Nutraceuticals for an opinion on whether their astaxanthin-rich oleoresin extracted from *H. pluvialis* is substantially equivalent to an existing product from Cyanotech.

The Committee considered it was impossible to make an assessment using the data presented by the applicant from batches produced in different years, given that the manufacturing process has changed during that period.

The Committee also sought clarification on the criteria for substantial equivalence and the secretariat agreed to circulate the existing guidance for discussion at a future meeting.. It also agreed to obtain further information from the applicant to improve the quality of the data.

7. Astaxanthin (Bioreal AB) ACNFP/92/3

The Committee considered the Finnish Competent Authority's (CA) initial opinion on this application for authorisation of astaxanthin-rich extract as a novel food ingredient.

The Committee was concerned that evidence from rat studies indicated that astaxanthin accumulates in the eye to the same extent as canthaxanthin and concluded that further studies on food safety aspects of astaxanthin should be concluded. The Committee considered that long term exposure and the potential for accumulation of astaxanthin in tissues need to be examined further.

The Committee was not satisfied with the applicant's proposal to label products with a statement that they are only intended for healthy adults and not for consumption by children or pregnant women. The Committee noted that adults may still regard themselves as healthy whilst still taking medication to manage their conditions and a number of women may not know they are pregnant until after the critical stages of development that take place in early pregnancy. The consumption of astaxanthin by at-risk groups therefore needs to be considered further.

The Committee considered that astaxanthin residues in food, resulting from its use in animal feed, were considered acceptable on the basis that it is a normal constituent of wild fish. However, its use as a food ingredient would lead to increased levels of intake and the data indicated a toxicological concern. The Committee noted that the available data were not sufficient to establish an acceptable daily intake..

The Secretariat agreed to transmit the Committee's comments to the European Commission as part of the UK's formal response to the Finnish opinion.

8. New Publications Relevant to the Safety of GM Foods: ACNFP/92/4

The Committee considered 3 published papers comparing the effects of GM and non GM crops. The papers were on the following:

1. A long term (24 month) proteomic and ultrastructural study on the effects of GM soya on liver ageing in rats;

2. A three generation study on the effects of GM Bt corn on various biochemical and histopathological parameters in rats;

3. A study of the gut and peripheral immune response to GM maize MON810 in mice.

The Committee considered the papers were not definitive. The studies were broad observational studies and therefore appeared to have no clear goals. There was a lack of comparability between the GM and non GM feed given to the rats which would add to the difficulty in interpreting the

results. The Committee considered the results in all three papers were inconclusive and could not draw any conclusions about their significance caused by the transgenes.

The Committee noted also that papers 1 and 2 had no protection against false positives. Also, the results were interpreted solely in terms of differences introduced by genetic modification, with no allowance for other factors such as mycotoxins, some of which were above the legally allowed level for food. The third study was better designed but the Committee was concerned that differences may have been misinterpreted as changes.

9. 2008 Annual report/Review of SACS Guidance ACNFP/92/5

The Committee was asked to comment by post on a first draft of its 2008 Annual Report and to consider a self assessment questionnaire. Comments received will form the basis of a discussion at the next Committee meeting.

10. Items for Information

10.1 EU update ACNFP/92/6

10.2 Update on other Scientific Advisory Committees ACNFP92/8

11 Any other business

The Committee noted that the FSA used to have special events for consumer representatives on FSA advisory committees. The consumer representatives on the committee considered these were a useful means of sharing information about activities on all of the committees, which were of interest to consumer representatives and asked if the FSA had any plans to continue these events.

The Committee raised the issue of ethnic and religious population subgroups which may have particular dietary habits. Members noted that research into cultural aspects of diets may be of particular interest to the Economic and Social Research Council.

(b) Minutes of 93rd meeting (April 2009)

2. Minutes of the 92nd meeting DRAFT/ACNFP/92/Min

Subject to minor amendments members agreed that the minutes were a true record of the 92nd meeting of the ACNFP held on Thursday 19 February 2009

3. Matters Arising

The Secretariat provided the following update on items arising either following the previous meeting or in the previous meeting:

Postal Consultation: Licorice Root Extract (Glavonoid) ACNFP/P93/1

The European Commission timetable did not allow this application to be taken to the 93rd meeting. The Committee was therefore consulted by post and its written comments were compiled into a short report that was sent to the Commission. The Committee was concerned over the potential for effects on blood coagulation, particularly in sensitive individuals including patients undergoing anti-coagulant therapy, and for oestrogen-like effects. Other concerns were raised about the potential to exceed the recommended intake levels and the consumption of products by children.

On the basis of this advice, the Agency had written to the European Commission objecting to the authorisation of this novel ingredient.

Item 3:

Extranet The Food Standards Agency's IT section was testing an encryption system for CDs, which should be available to be trialed at the Committee's July meeting.

Phosphated Distarch Phosphate The Committee's opinion was finalised by post and submitted to the European Commission on 27 April.

Draft EFSA Opinion on Nanotechnology The EFSA statement on nanotechnology was published on 5 March and would be presented in a paper to the next meeting

Item 7:

Astaxanthin (Bioreal AB) The UK opinion, based on the Committee's advice, was forwarded to the Commission on 25 March.

Item 11:

Meetings of consumer representatives serving on scientific committees No further information was available for the Committee.

4. Cis-9 Cetyl Myristoleate Rich Complex ACNFP93/1

The Committee considered the Italian Competent Authority's (CA) initial opinion on this application for authorisation of a cis-9 cetyl myristoleate rich complex as a novel food ingredient.

The Committee agreed with the Italian CA that the toxicological data were poor and queried whether the novel ingredient was being marketed as a medicine or food. The Committee was concerned that one form of the product contained significant quantities of myristic acid esters which could contribute to an increase in cholesterol. This was of particular concern as the product would be targeted at individuals with arthritic conditions who may also be elderly and overweight and should not consume products which could increase cholesterol levels.

The Committee also highlighted the atherogenic effect of myristic acid and the applicant's reference to interactions with steroids and immunosuppressant drugs, which may be being taken by the target population.

The Secretariat agreed to write to the Commission reflecting the Committees discussion.

5. Sardine Peptide Product. ACNFP/93/2

The Committee considered the Finnish Competent Authority's (CA) initial opinion on this application for authorisation of a sardine peptide product (SPP) as a novel food ingredient.

The Committee's main concern related to the animal studies presented in the dossier. The Committee's view was that a 28 day feeding study was not sufficient to provide reassurance on the safety of sardine peptide product, particularly as it showed some marginal effects which should have been followed up in further investigations, such as a 90-day study. This concern formed the basis as to why the Committee was unable to agree with the positive opinion of the Finnish CA.

The Committee agreed with the Finnish CA that the novel ingredient was unlikely to cause an allergic reaction except to those who already have an allergy to fish. The Committee stated that the previous history of consumption of sardine meat was of limited relevance to the risk assessment of SPP given that SPP is a highly processed product.

The Committee noted that there may be potential for SPP to interfere with medication (such as ACE inhibitors) likely to be taken by hypertensive individuals. Additionally, the Committee was concerned that hypertensive individuals may consume foods containing SPP in favour of prescribed medication to control their blood pressure.

The Committee stated that as sardine peptide product is on the Japanese market, it would have been useful if the applicant had provided information about reports of adverse reactions and post-market monitoring.

The Committee discussed written comments submitted in advance of the meeting by absent memberswhich were tabled at the meeting. The comments highlighted the possibility of immunological reactions in fish-allergic individuals and drew attention to a published study on cat peptides which indicated that peptides, such as those in SPP, might have the potential to generate a Th2 T cell response leading to IgE responses if the intact protein is then ingested. It was the view of members at the meeting that this was applicable only for larger peptides than those present in SPP.

The Committee questioned the applicant's proposed intake estimate of 0.6g SPP per portion for all products and considered that consumption of some products such as confectionery could lead to higher intake levels. The Committee also questioned the estimated daily intake values proposed by the applicant and expressed concern that some of the products categories would be particularly attractive to children.

The Committee questioned the conclusion of the Finnish CA that SPP is unlikely to alter the absorption of captopril or other ACE inhibitors, noting that high doses of valine-tyrosine may inhibit absorption of ACE inhibitors.

The Secretariat agreed to write to the Commission reflecting the Committee's discussion

6. Chitin-Glucan ACNFP/93/3

The Committee considered the Belgian Competent Authority's (CA) initial opinion on this application for authorisation of chitin-glucan, extracted from the fungus *Aspergillus niger,* as a novel food ingredient.

The Committee noted that there were numerous literature reports of *A. niger* allergy following spore inhalation. The Committee therefore considered that there was a significant risk of oral allergy as the novel ingredient contained significant quantities of protein. In this regard the Committee considered that it was misleading to call the product hypoallergenic did not accept the applicant's view that it was not possible to characterise the proteins present. The Committee also noted that the source fungus is not generally consumed in the diet and in view of this the applicant should carry out a thorough investigation of the allergenic potential of the novel ingredient including an appropriate analysis of the protein component.

The Secretariat agreed to write to the Commission reflecting the Committee's discussion.

7. 2008 Annual Report/Review of SACs Guidelines ACNFP/93/4

The Committee considered the revised draft of its 2008 annual report, which has been amended following the Committee's comments in February, and discussed its self assessment against the Food Standards Agency's Good Practice Guidelines for scientific advisory committees.

The Committee was content with the draft 2008 Annual Report and the self assessment of the guidelines subject to minor amendments. The Committee agreed that the self-assessment was a useful reflection of the Committees processes.

The Secretariat agreed to incorporate the amendments into the draft Annual Report and self assessment and to publish the Annual Report.

8. Guidance on Substantial Equivalence ACNFP/93/5

Following the Committee's recent discussions on the criteria for acceptance of requests for opinions on substantial equivalence, the Secretariat proposed revisions to the guidelines that the Committee had drawn up in March 2005 The Committee considered the Secretariats proposals and agreed them subject to minor amendments.

The Secretariat agreed to incorporate the amendments into the guidelines and publish the revised document.

9. Items for Information

9.1 Open Event ACNFP/93/6

The Committee noted the feedback and agreed that specific comments on small discussion groups would be considered when planning the next open event.

9.2 EU Update ACNFP/93/7

9.3 Novel Food Notifications ACNFP/93/8

9.4 Update on Scientific Advisory Committees ACNFP/93/9

9.5 Labelling Requirements for Novel Foods. ACNFP/93/10

The Committee noted the other information papers listed above, without comment.

10 Any other business

The Committee was invited to attend a workshop to be held on 24 June by the Food Standard Agency's General Advisory Committee on Science. Some members had already volunteered to attend the workshop. Other members were encouraged to inform the Secretariat if they wished to attend.

(c) Minutes of 94th meeting (September 2009)

2. Minutes of the 93rd meeting DRAFT/ACNFP/93/Min

Members agreed that the minutes were a true record of the 93rd meeting of the ACNFP held on 29 April 2009.

3. Matters Arising

The Secretariat provided the following update on items arising either following the previous meeting or in the previous meeting:

Postal Consultation: REV – 7 chewing gum base ACNFP/P94/1

Due to cancellation of the July meeting and the European Commission (EC) deadline this application was considered by post and Members' comments and objections were compiled into a short report that was sent to the Commission in accordance with the timings set out in the novel food regulation (EC) 258/97. \Members raised a number of questions regarding the possible fate of REV-7 in the gut and the Committee was informed that the applicant plans to conduct studies to address these.

Provision of ACNFP documents on compact disk

The Secretariat reported that the Agency did not yet have all the software needed for encryption of discs but it was expecting to receive the remaining software shortly. The ACNFP will then be able to trial the use of encrypted CD-ROMs to provide Members with archive information, as an alternative to paper storage.

4. Bee Venom for addition to honey ACNFP/94/1+Addendum

The Committee was asked to consider this application that had been submitted to the UK competent authority for the approval of bee venom for addition to honey as a novel food ingredient.

The Committee discussed written comments submitted by members in advance of the meeting. The Committee noted that bee venom has the potential to cause allergic reactions including anaphylaxis in already sensitised individuals and could sensitise other individuals, particularly very young children. Allergic effects (anaphylaxis) were clearly reported in the dossier for one individual. It acknowledged that honey naturally contains a small amount of bee venom, but suggested the commercial addition of large amounts of bee venom to honey may have a sensitising effect in susceptible individuals. The Committee noted the dose of 400 micrograms used in the product is within the range associated with a significant allergic response.

The Committee reviewed additional information submitted by the applicant in response to the Committee's initial written comments, which suggested that sublingual (or oral/mucosal) immunotherapy (SLIT) is a viable method of administering bee venom to desensitise people with a history of reactions to bee stings. The Committee viewed the use of SLIT to treat bee sting allergy as speculative, and it was uncertain whether the product would actually have a desensitising effect. In addition, regularity of dosing is an essential part of the immunotherapy regimen and this could not be predicted. In this regard, the Committee considered the data submitted was not relevant to oral consumption.

The Committee agreed that the product is clearly contraindicated for individuals with bee sting allergy, and this indicated the need for a warning label, if the product were to be authorised.

The Committee discussed written comments submitted by members which questioned the analysis of data from the human clinical trial presented in the dossier. This trial revealed minimal activity in inflammatory arthritis, in only on end point and with borderline statistical significance. The Committee was not convinced by the applicant's response, which only reiterated information regarding the efficacy study.

The Committee stated the product should not be used as a like for like replacement for traditional honey products as specific recommendations for dose and frequency of consumption were stated by the manufacturer.

The Committee disagreed with the claim that consumption of Manuka honey could reduce dental caries as it was not substantiated by the available evidence.

A representative from the Medicines and Healthcare products Regulatory Agency (MHRA) attended the meeting to explain the rationale regarding the classification of products under the medicines legislation and advised that bee venom added to honey would not be considered a medicinal product.

The question of animal bee welfare was raised during the public consultation, but the applicant had clearly stated the manufacturing process did not harm bees.

The Committee noted concerns from the pubic consultation which related to the product being marketed as a food that provides a health benefit. It was noted, the applicant would not be able to make any medicinal claims and any health-related claims would need to be considered under the Nutrition and Health Claims Regulation.

The Committee did not reach an overall conclusion on the acceptability of this product and the Secretariat agreed to draft an opinion summarising the discussion to date, for the next meeting.

5. D-Ribose ACNFP/94/2+Addendum

The Committee considered this application for the authorisation of D-ribose as a novel food ingredient in April, June and September 2008. It was asked to consider further information provided by the applicant in response to earlier comments.

The Committee agreed that a further reproductive toxicity study was still required. The Committee stated the existing reproductive study did not include dosing of D-ribose prior to conception and a further study was needed that included dosing during the stages of conception and early development . The concern was related to the timing of the dosing during this critical period, and recognition that changes in blood glucose levels in diabetic women are known to be associated with increased risk of birth defects including skeletal changes, particularly if diabetes is poorly controlled, in the earliest stages of pregnancy.

The Secretariat agreed to request further information from the applicant.

6. Magnolia Bark Extract ACNFP/94/6

The Committee was asked to consider this application from William Wrigley Jr. Company, to the UK competent authority for the approval of supercritical carbondioxide extract of magnolia bark for addition to chewing gums, as a novel food ingredient.

The Committee noted that the compositional analysis of some batches of the extract did not total 100 per cent and requested the applicant account for the missing data. The Committee also requested evidence for the statement concerning the absence of protein in the product.

The Committee noted that magnolia bark extract (MBE) contains small amounts of plant alkaloid, and therefore it requested details of the quality control procedures set in place by the applicant, as specifications limit alkaloids to a maximum of 100 ppm.

The Committee discussed the 90-day toxicity study and noted one of the effects was increased levels of bilirubin, specifically in male rats, and that magnikiol is excreted in the bile and broken down in the liver to magnolol. The Committee questioned whether the metabolism of magnolol could interfere with the break down of other substances in the liver, such as drugs.

The Committee noted that magnolia bark has traditionally been used in herbal remedies and not for the purposes of breath freshening as intended by the applicant. The Committee was interested to find out now this product is currently being marketed in the United States (US).

Although not part of the novel food application, the Committee was interested to know what measures are in place to ensure the magnolia bark is harvested from a sustainable source.

The Committee asked for further information about the 3 mg per stick criterion that had been suggested by the MHRA for differentiating between classification as a medicine and a food.

The Committee was concerned the product may have an effect on gut microflora, as magnolol is excreted in the bile and delivered into the small bowel. In addition, the adverse effects reported in the US included gastrointestinal intolerance.

The Committee questioned how the applicant calculated the stability figures given there is no assay for MBE and asked how the figures related to shelf-life of the product.

The Secretariat agreed to request further information from the applicant.

7. Sardine Peptide Product ACNFP/94/7

The Committee considered this application for the authorisation of sardine peptide product as a novel food ingredient in April 2009. It was asked to consider further information provided by the applicant in response to earlier concerns. The Committee reiterated the need for a 90-day toxicity study before the safety of this product could be determined, given the findings of the 28-day study that was reported in the dossier.

The Committee also reiterated its concern about the potential for sardine peptide product to interfere with medication (such as ACE inhibitors) likely to be taken by hypertensive individuals. The Committee stated the evidence presented by the applicant was speculative and suggested additional studies need to be done as the effects on drug metabolism were unpredictable.

The Secretariat agreed to transmit the Committee's concerns as necessary at the next meeting of national authorities in Brussels.

8. Arracacha Root ACNFP/94/8

The Committee considered the Spanish Competent Authority's (CA) initial opinion on this application for authorisation of arracacha root (*Arracacia xanthorrhiza*) as a novel food ingredient.

The Committee noted this product belongs to the *Umbelliferae* family and is botanically related to celery, celeriac and carrot. The Committee expressed concern that some individuals with birch

pollen allergy have subsequently developed an allergy to celeriac. The Committee noted that sensitivity to celeriac is not observed in countries where birch pollen is not present in the environment,, but given that there were reports celeriac can cause severe allergic reactions in sensitised individuals, this issue needs to be examined further. The Committee noted that cooking does not eliminate the allergens found in celeriac and suggested this may also be the case for arracacha root.

The Committee therefore recommended that a study should be carried out to identify the potential risks for sensitised individuals consuming Arracacha root in order to determine the need for risk management and the form that this might take, for example raising awareness among the allergy community and clinicians.

The Committee also noted that the product was available in the US, and queried whether this could provide additional evidence for the history of consumption and safe use of arracacha root in other ethnic groups.

The Secretariat agreed to write to the Commission reporting on the Committee's concerns.

9. The role of ethics in the work of the ACNFP ACNFP/94/3 revised

The Committee discussed the application of ethics in the Committee's work, in the context of established frameworks for applying ethical principles and assessing consumer interests in relation to food.

The Committee noted this was a very useful and well constructed paper which warranted publication, and suggested the paper should be discussed at the next open event.

The Committee noted there are aspects of the ethical matrix involved in all of the different issues it discusses regarding novel food applications, such as food safety and quality of life.

The Committee discussed the importance of informed choice, and highlighted the need to ensure food is appropriately labelled in order the consumer can make sensible choices. The Committee acknowledged consumers have the right to chose products that are based on scientific evidence of benefit. However, it is important consumer choice is not restricted in terms of denying access to products on the grounds that they may not provide any additional benefit over other foods already available. Restrictions could also arise if new ingredients were labelled on a precautionary basis with warning labels that were, in reality, unnecessary,

It was noted some issues raised in the paper were outside the Committee's remit. Nevertheless, the Committee does identify issues such as sustainable production, maintenance of biodiversity and conservation, and where possible these concerns are explored before a novel food is approved. The Committee is prepared to comment and draw attention to these issues, although not part of the novel food application procedure, to ensure they are dealt with in an effective manner.

The Committee noted that the cost benefit analysis for approval of a novel food ingredient is different for the applicant, regulator and the consumer. The Committee noted that there is an ethical question about asking applicants to undertake further research into product safety, which may involve tests using human and/or animal subjects, in cases where the efficacy of a product has not been proven. The Committee also noted that clinical studies for medicines can be designed so that the research is terminated when the results reach statistical significance, although ti was not clear whther the same considerations could be applied to novel foods and food ingredients..

10. Report on the long term effects of genetically modified crops ACNFP/94/4

The Committee considered a report prepared by a consortium of researchers for the European Commission on the long term effects of genetically modified (GM) crops.

The Committee noted that the literature review was useful and well constructed, but the online survey was poorly structured and had a disappointingly low response rate (on average 14% per question).

The Committee noted that a synthesis of scientific opinion may not be the most reliable way of obtaining 'correct' answers to scientific unknowns. Even though the report was quite explicit when reporting 'opinion' the members were concerned that the media and others may interpret these opinions as scientific 'fact'.

The Committee noted that sample selection bias and respondent bias, particularly in the on-line questionnaire, posed problems for the use of such survey-based techniques to assess scientific opinion. One possible way of improving the quality of opinion would be to convert the responses into a Delphi survey, where a second round questionnaire allows each respondent to re-consider their response to each question together in light of the mean survey response. This has the effect of revealing genuine divergence of opinion and encourages consensus when this is possible.

The Committee acknowledged that, as the report focussed on authorised events, there was little discussion on the impact of stacked events which are currently undergoing authorisation by the European Food Safety Authority (EFSA), and are not yet marketed in the EU. Nevertheless, the report concluded that no adverse long term effects of GM crops on human or animal health have been established.

11. EFSA Opinion on antibiotic resistance marker (ARM) genes in GM plants ACNFP/94/5

The Committee noted that, as a resulting of consultation with the European Medicines Evaluation Authority (EMEA), some antibiotics were now recognised to be more clinically important than previously.

The Committee noted there are still groups of bacteria which have not developed antibiotic resistance despite the widespread prevalence of the ARM genes in the environment and gut flora. The existence of a new route for the potential transmission of ARM genes may conceivably lead to the development of antibiotic resistance in these groups. The Committee noted that when bacterial sequences are present in the tDNA that is inserted into plants a homology is created between the plants and bacteria in the gut microflora.

The Secretariat agreed to ask the EFSA Secretariat about the issues raised by the Committee, and whether they had been considered in the elaboration of the EFSA opinion.

12. Items for Information

12.1 EU Update ACNFP/94/9

12.2 Update on Scientific Advisory Committees ACNFP/94/10

12.3 Update on GM food and feed applications ACNFP/94/11

The Committee noted the information papers listed above. Members who attended the General Advisory Committee on Science (GAGS) workshop on 24 June reported that it was a very productive workshop with a fruitful exchange of views, and were interested to know what impact the ideas and issues identified in the workshop will have in the future.

The Secretariat agreed to consult GACS and request feedback.

13. Any other business

Some members expressed an interest in attending the Advisory Group on Consumer Engagement.

Members were reminded about the importance of providing written comments, particularly on the issues that are within their specific area of expertise, if they are unable to attend committee meetings.

(d) Minutes of 95th meeting (November 2009)

1. Apologies and announcements

Five members had sent apologies for non-attendance. Apologies were also received from observers from FSA offices in Scotland, Wales and Northern Ireland (Mrs. Elspeth MacDonald, Mr. Phil Morgan and Mr. Gerry McCurdy).

Clair Baynton has moved to Nutrition Division and her role as assessor was taken over by Alison Gleadle. Dr Gleadle sent her apologies for this meeting.

A new Chairman, Professor Peter Gregory, and a new expert in molecular biology, Professor Peter Meyer have been appointed. Their terms will start on 1 December 2009.

The Chairman reminded Members of the need to announce any commercial interests in the business of the Committee, prior to the discussions on each item.

2. Minutes of the 94th meeting DRAFT/ACNFP/94/Min

Members agreed to provide written comments on the draft minutes following the meeting.

3. Matters Arising

The Secretariat provided the following update on items arising from the previous meeting:

Provision of ACNFP documents on compact disk

The Secretariat reported that there was no further information on the provision of secure compact disks, as this was still under development by the Agency's IT department.

4. Bee Venom for addition to honey ACNFP/95/1

The Committee was asked to consider the text of a draft opinion for the authorisation of bee venom for addition to honey. The application had previously been discussed by the Committee in September.

The Committee considered that the novel ingredient should not lead to an increase in the daily intake of sugar and people consuming this novel ingredient should make compensatory changes to the rest of their diet. The novel ingredient should therefore be seen as a replacement for sugar in the overall diet.

The Committee recommended that the novel ingredient was labelled so that consumers are made aware of the possibility of life threatening allergic reactions if the product is consumed by those who are allergic to bee stings. This risk was highlighted by a case of anaphylactic shock following the consumption of the ingredient in New Zealand. The Committee had no data on the incidence of bee sting allergy in the population of New Zealand to compare with the incidence of allergic reactions in the UK or the EU. The Committee considered that the labelling should be strong and clear, providing a warning of a serious reaction for people with bee sting allergies so they can avoid the novel food ingredient.

The Committee did not reach an overall conclusion on the acceptability of this product, in advance of hearing further advice from members of the Committee who are experts in allergenicity, particularly in relation to the possibility that oral doses of bee allergens might sensitise consumers to venom in bee stings. The Secretariat agreed to amend the draft opinion by incorporating the points raised in the meeting by the Committee.

5. Magnolia Bark Extract ACNFP/95/2

The Committee initially considered this application for the authorisation of supercritical carbon dioxide extract of magnolia bark as a novel food ingredient in September 2009. The applicant had now provided further information in response to earlier comments.

The Committee was not satisfied that the new data on the absence of protein in the novel ingredient was reliable, and suggested the use of a more precise assay such as mass spectrometry. The Committee was also concerned that the applicant did not provide sufficient data to explain the raised levels of bilirubin seen in female rats in a 90 day feeding study. The applicant presented data from a recent publication but the Committee asked to see the original study report containing data on individual animals before drawing any conclusions from these findings.

The Committee noted the claims made legally in the USA on anti-microbial effects of the extract would not be legal in Europe as it is not permitted to make medical claims about food in the EU.

The Secretariat agreed to request further information from the applicant and to draft an opinion for the next meeting.

6. Phosphated Distarch Phosphate ACNFP/95/3

The Committee was asked to consider this application from MGP Ingredients to the UK competent authority for the approval of phosphated distarch phosphate (PDP) as a novel food ingredient.

The Committee was concerned about the potential for high levels of intake as the applicant was planning to add the novel food ingredient to a large range of products. As with the previous application for a similar ingredient, the Committee considered that it could be misleading to call the novel ingredient "fibre" and was concerned that it may compete with other different sources of natural starches. As a consequence consumers would reduce their intakes of other sources of dietary fibre.

The Committee noted that it was necessary to consider the total intake of PDP, by including the intake of this novel ingredient together with other products on the market. The highest predicted intakes should not exceed the intakes that have been tested in human studies. As with the previous application, the Committee was concerned that it was difficult to predict the possible GI intolerance in children.

The Secretariat agreed to draft an opinion for the next meeting and to request further information from the applicant on the estimated total intake of PDP.

7. Sucromalt ACNFP/95/4

The Committee considered the Dutch Competent Authority's (CA) initial opinion on this application for authorisation of Sucromalt as a novel food ingredient.

The Committee sought a clear statement from the applicant on the particular benefits of this novel food to consumers and why they wanted to put it in food. It was concerned that as this novel ingredient was a type of sugar it could lead to diabetics unwittingly increasing their intake of sugar. The Committee advised that products containing sucromalt should be labelled as "equivalent to sucrose" [*or not suitable for diabetics].* The Committee noted there were problems with nutrition labelling when products contained different types of sugar as they are not listed individually. Current labelling requirements lead to only monosaccharides being declared and in the case of this novel ingredient this could affect the "traffic light" labelling, for example moving it from amber to green.

The Committee endorsed the views of the Dutch CA on the toxicology situation and were therefore content with the safety of the novel ingredient.

The Secretariat agreed to seek further information from the applicant and to write to the Commission reporting on the Committee's conclusions.

8. Zeaxanthin ACNFP/95/5

The Committee considered a new proposal for the use level of Zeaxanthin as a novel food ingredient, following an opinion from the European Food Safety Authority (EFSA).

The Committee agreed with EFSA's observation that, on the basis of the available data, it was not possible to assess whether additional zeaxanthin at the proposed level of use would increase the risk of lung cancer in heavy smokers, as reported for beta-carotene.

The Committee was not persuaded by the arguments put forward by the applicant but considered that the proposal to limit intake to 2mg per day was acceptable and reduced the safety concerns. It considered that a further assessment would be required if Zeaxanthin was used in such a way that intake levels were increased.

The Secretariat noted that the Agency would draw on the Committee's advice during any future discussions on the authorisation of zeaxanthin.

9. Glucosamine from Aspergillus niger ACNFP/95/6

The Committee considered an opinion by EFSA on this application for authorisation of Glucosamine from *Aspergillus niger* as a novel food ingredient.

The Committee noted glucose metabolism is affected by glucosamine. It also noted that the risk due to consumption of glucosamine is negligible compared with the overriding risk to undiagnosed diabetics of unregulated sugar consumption. It considered the number of diabetics who had not been diagnosed was increasing in the population. It was concerned that EFSA had suggested labelling as the way to alleviate the risk to this group as undiagnosed diabetics would not be aware that they should be monitoring their consumption of sugars. The Committee considered the possible risk of consuming glucosamine could push possible diabetics to become diabetic.

The Secretariat agreed to report the Committee's concerns to EFSA.

10. Items for Information

10.1 EU Update ACNFP/95/7

10.2 Update on Scientific Advisory Committees ACNFP/95/8

The Committee noted the information papers listed above.

11. Any other business

The Chair of the Food Standards Agency, Lord Rooker, introduced himself to the Committee and highlighted the importance of independent scientific advice to the Agency.

Jayam Dalal noted the FSA's consultative group on faith groups have signed up to a cross government faith group. She informed the Committee that the Agency would arrange a meeting with faith groups. She noted that the FSA had arranged a meeting with industry to discuss faith groups' concerns, which included labelling issues.

ANNEX 3. COMMITTEE ADVICE ISSUED DURING 2009

(a) Liquorice Root Extract

COMMENTS FROM MEMBERS (Sent to European Commission as the UK response 15 April 2009)

a) Composition

We appear to know little about many of the individual components, or their degradation products. Some 24% of the product is said to consist of "polyphenols" but qualitative data are provided only for the iso flavone glabridin and two related compounds, together with data to demonstrate the minimal occurrence of glycyrrhizinic acid. This information accounts for only 4% of the product leaving a residual approximately 20% phenolics by weight.

HPLC data established the qualitative similarity of the extract and the original root and provides some information on possible identities of some components. However, there is no information on possible selective isolation and concentration relative to existing licorice products (the root and the aqueous root extracts) that are used as the basis for arguments for a history of apparent safe use. This paucity of information emphasises the need for good toxicological studies with the NI.

b) Intake by children

It appears to be quite easy for consumers to exceed the recommended maximum; and the opportunity to consume both the functional foods and the food supplements. The Committee did not share the confidence of the Belgian Competent Authority that appropriate labelling would prevent this happening.

There are no data on likely intakes in teenagers and younger children, although many of the food category that might contain the ingredient are potentially attractive to young age groups.

c) Haematological effects

Data from the 90-day study reveals a rather severe anti-coagulant effect, which was responsible for the death of 9/24 animals at the highest dose of 1600 mg kg-1 bw day-1. Significant effects were also seen at the next dose of 800 mg kg-1 bw day-1. There are related effects even down to the lowest dose of 400 mg kg-1 bw day-1 and these cannot be ignored, simply because the differences do not reach statistical significance or because they are present in only one sex. The Committee would be reluctant to derive a NOAEL from these data thus cannot support the Belgian conclusions in this respect.

The clinical data do not provide any detailed results of haematological investigations, which would be essential given the findings in the 90-day study. While it is reassuring that there were no significant differences seen in haematology and coagulation in the clinical trials that were conducted, it is necessary to look for small trends and indication of marginal effects in those data. There is no reassurance, from the analysis presented, that this type of specific analysis has been done.

At a daily intake of 300 mg a 60kg consumer would receive a dose of 5 mg kg-1 bw day-1giving a margin of safety significantly less than 100 (relative to the lowest dose of the 90-day study – as noted above the Committee has reservations about defining this as a NOAEL). For those consumers who happen to be on anti-coagulant therapy or who may be vulnerable to such effects the margin is not great enough. The toxicological data lead the Committee to question the suitability of such a product for a range of sub-groups in the population.

In the Committee's view, it is necessary to carry out full and specific investigation of the potential for this product to cause or affect anti-coagulant and haematological end-points in all potential consumers. The mechanism of anti-coagulant effects may be additive to other factors in the normal life of consumers (e.g. aspirin intake). The absence of such interaction needs to be demonstrated.

There also appears to be a published report of clinical studies made with this ingredient, which does not appear to accord with the repeat dose study reported in the dossier (See Aoki et al. 2007. Clinical safety of Licorice Flavonoid Oil (LFO) and pharmacokinetics of glabridin in healthy humans. Journal of the American College of Nutrition, 26(3), 209-218). In this account, doses of 300, 600 and 1200 mg/d NI were used in a four week repeat dose study with healthy males/females. This reports the absence of “clinically noteworthy” changes in haematological and related biochemical parameters. However changes did occur and these need to be seen in the context of the discussion above, about small trends being possibly indicative of long term concerns and possibly exacerbated in those in at risk sub-groups.

d) Estrogen receptors

Components of the extract have structural similarities with estrogens and there is therefore a potential for interaction with estrogen receptors and concerns around cancer and breast cancer in particular. If there is any potential for effects on the estrogen receptor this could be of particular concern in infants and young children. A related question arises over the effect of the extract on the efficacy of drugs such as Tamoxifen (an antagonist of the estrogen receptor in breast tissue), used in the treatment of breast cancer. Breast cancer in particular should be actively considered in the safety evaluation of any compound intended for widespread use that interacts with the estrogen receptor, notwithstanding the reported IC50 values.

(b) Astaxanthin

Mr Andreas Klepsch

European Commission

By email

25 March 2009 Reference: NFU 733

Dear Mr Klepsch

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 Finnish CA for the above product. This was discussed at the Committee's meeting on 19th February 2009. The UK is unable to agree with the positive opinion of the Finnish CA and concludes that additional information is required before the assessment of the safety of this product can be concluded.

Long-term exposure to astaxanthin

The Finnish CA accepted the applicant's view that levels of canthaxanthin in its product was too low to be a cause for concern in relation to the well-known adverse effects of canthaxanthin accumulation in the eye. The UK however notes a 2007 publication which indicates that in rats, astaxanthin accumulates in the eye to the same extent as canthaxathin and concludes that further studies on food safety aspects of astaxanthin should be conducted.

The UK therefore considers that long term exposure and the potential for accumulation of astaxanthin in tissues need to be examined further

Consumption by at-risk groups

The Finnish evaluation highlights a potential interaction between astaxanthin and medicinal products and an absence of data on the effects of astaxanthin ingestion on children and pregnant women. The Finnish CA considers that these risks and uncertainties can be adequately addressed by the applicant's proposal to label products with a statement that they are only intended for healthy adults and not for consumption by children or pregnant women. However we are not satisfied that this labelling will have the desired effect given the large numbers of people who are users of medicinal products (many of whom would regard themselves as "healthy" if their condition is well-controlled) and the number of women who may not know they are pregnant until after the critical stages of development that take place in early pregnancy.

Astaxanthin is a normal part of the diet as a component of wild fish and the EFSA FEEDAP Panel has accepted its use in fish feed, essentially on the ground that the resulting intake will match that from wild fish. However the intake resulting from the use of astaxanthin as a food ingredient will supplement its intake from fish and will be at a significantly higher level.

Yours sincerely,

(By email only)

Shuhana Begum

Novel Foods, Additives and Supplements Division

(c) Cis-9 Cetyl Myristoleate Rich Complex

Mr Andreas Klepsch

European Commission

By email

11 May 2009

Dear Mr Klepsch

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 Italian CA for the above product. This was discussed at the Committee's meeting on 29 April.

The Committee agreed with the Italian CA that the applicant has not provided sufficient toxicological information on the product. In addition the Committee noted that one form of the product contains large proportion of esters of myristic acid, a substance that could contribute to an increase in cholesterol. This was of particular concern as the ingredient would be targeted at individuals with a range of arthritic conditions including osteoarthritis, which is prevalent in elderly, often overweight, individuals who should not consume products which may lead to an increase in cholesterol levels. The Committee also highlighted the atherogenic effect of myristic acid and the applicant's reference to interactions with steroids and immunosuppressants, drugs that are likely to be taken by the target population. They therefore viewed the proposed use of the novel ingredient as a potential cause for concern.

In conclusion, the UK is in agreement with the Italian CA that this product should not be given a positive initial opinion. However, we question whether EFSA will be able to complete the safety assessment due to the paucity of data provided by the applicant. We therefore suggest that, in advance of the Commission submitting a request for an additional assessment by EFSA, the applicant should be contacted to determine whether they will be able to provide additional data, particularly in regard to toxicity studies.

(By email only)

Dr Chris Jones

For the UK Competent Authority

(d) Chitin Glucan

Mr Andreas Klepsch

European Commission

By email

9 May 2009

Dear Mr Klepsch

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 29 April.

The UK agrees with the Belgian CA's unfavourable initial opinion on this ingredient and has some additional points of concern.

The main concern expressed by the ACNFP related to potential allergenicity of the ingredient. The ACNFP advised that the possibility that chitin-glucan may be allergenic cannot be ruled out, particularly as the product can contain up to 6% protein and the protein components have not been characterised. The Committee also questioned the applicant's suggestion that the product should be labelled as "hypoallergenic". The ACNFP provided details of published reports of immune reactions to *Aspergillus niger* and also raised the question of the possibility of cross-reactivity in relation to IgE sensitisation to *Aspergillus fumigatus*, a major respiratory and skin allergen.

The Committee agreed with the Belgian authorities that the applicant had provided insufficient information relating to compositional data (particularly in relation to protein and lipid components).

The ACNFP were uncertain about the intestinal fate of chitin-glucan.. The applicant provided only a vague description on the anticipated uses of the product referring to "intestinal comfort" (when consumed in the short term) and use as a "fibre nutritional supplement" (with prolonged intake). The ACNFP was unable to understand the basis for these apparent benefits in the light of the apparent lack of any effects in a rat study (section II.4.1.4 of the application states that there is evidence of no effect on gut transit time or faecal output) and the vague nature of the information provided about whether, and to what extent, chitin-glucan is fermented in the large bowel.

The Committee noted that prior use of chitin-glucan as a fining-type product for musts and wines in France does not provide good evidence of its safety. In the case of wines, it was doubted whether residues will be present in the final product and it is likely that human exposures via this route will have been relatively low.

To conclude, the UK is unable to support the authorisation of chitin-glucan for the above reasons and would agree with the Belgian CA's unfavourable initial opinion.

(By email only)

Yours sincerely,

Dr Manisha Upadhyay

Novel Foods, Additives and Supplements Division

(e) Arracacha Root

Mr Andreas Klepsch

European Commission

By email

9 October 2009

Dear Mr Klepsch

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 Spanish CA for the above product. This was discussed at the Committee's meeting on 24 September.

Due solely to concerns about potential allergic reaction amongst individuals who are allergic to celery and celeriac, the UK is unable to agree with the positive opinion of the Spanish CA. However, we accept that arracacha root is a traditional product, consumed widely in South America with no evidence that it is harmful, and it is therefore acceptable for consideration under (EC) 258/97 without all the conventional safety studies than are usually required for novel foods. In view of this, if the applicant company is able to address the ACNFP's concerns regarding potential allergenicity, then we would be able to support the authorisation of arracacha root.

Potential cross reactivity amongst individuals who are allergic to celery / celeriac.

The ACNFP notes that arracacha (*Arracacia xanthirrhiza*) is taxonomically related to celery / celeriac, (*Apium sp*), being of the same botanical family (*Apiaceae*). There is significant evidence of cross reactivity and adverse reactions to celeriac amongst birch pollen allergic individuals both in the UK and in Central Europe where celeriac is more widely consumed. These adverse reactions can often be serious and cooking celeriac does not reduce its allergenic potential. In view of this the UK seeks information regarding the likelihood that individuals with an existing allergy to birch pollen will react in a similar manner to arracacha root and, if necessary, a proposed risk management strategy. Information regarding allergenic potential could be in the form of protein homology analyses and, if necessary, *in vitro* serum testing and *in vivo* studies involving allergic individuals. We understand that birch pollen allergy may be less prevalent in South America than in Europe, which may explain why this issue has not been considered by the applicant.

Yours sincerely,

(By email only)

Dr Chris Jones

Novel Foods, Additives and Supplements Division

(f) Sucromalt

Mr Andreas Klepsch

European Commission

By email

22 December 2009

Dear Mr Klepsch

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 26 November.

The UK agrees with the positive opinion of the Dutch CA; however it has comments regarding the labelling of the product. The Committee commented that products containing sucromalt should be labelled in order to make it clear to consumers that sucromalt is a sugar, this is particularly important for diabetics.

Yours sincerely,

(By email only)

Shuhana Begum

Novel Foods, Additives and Supplements Division

(g) Rev 7 Chewing Gum Base

Mr Andreas Klepsch

European Commission

By email

29 June 2009

Dear Mr Klepsch

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.

We consulted ACNFP members by post and their comments are provided in the attached document. Due to time constraints this document has not been endorsed by the whole Committee. However, it contains sufficient detail to explain that the UK has reasoned objections to the authorisation of this novel ingredient. Our concerns relate to a significant underestimation of the consumption of chewing gum (and as a consequence the novel ingredient) and a lack of human studies which are required to determine its fate during transit through the human gastrointestinal (GI) tract. We

are also concerned about the proposal that the new ingredient should not be identified on food labels.

We also note the argument that REV-7 is intrinsically of low concern because it is a large polymer and EFSA has endorsed an earlier view from the Scientific Committee on Food that polymers derived from food contact materials (FCM) with a molecular weight in excess of 1000 daltons are of little toxicological relevance (1) .1 However, it is important to differentiate between low level migration of polymers into food from FCM and their intentional addition to food at high levels, which will result in regular intake at much higher levels

In view of these comments, the UK would not be able to support the authorisation of

REV-7 until these issues have been addressed.

Yours sincerely,

(By email only)

Dr Chris Jones

(1)http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/CEF_note_for_guidance_FCM_evaluation_2008.08.07.pdf?ssbinary=true

Chewing Gum Base (REV-7)

Comments from ACNFP Members

Intake Estimation.

The applicant's assessment of consumption of chewing gum used poor quality or old data, and significantly underestimated likely average and high level consumption. UK dietary survey data and figures in two recently published EFSA reports give more appropriate estimates(2) . These figures indicate that consumption of chewing gum is 3-4 times higher than the 4.8g/day figure which was proposed by the applicant. Given that children can consume chewing gum, consumption by children who, by kilogram body weight, would be likely to be amongst the highest consumers and may also be more likely to swallow chewing gum to be of particular concern. Consumption in adults is likely to be particularly high in specific sub-groups, including individuals who regularly consume chewing gum when dieting.

Safety Studies.

Although it is accepted that chewing gum is not intended to be swallowed, Members agreed with the Dutch opinion that the assessment of safety cannot assume this to be always the case. Even when the higher consumption values for chewing gum are used, the available data provide sufficient margin of safety for low molecular weight materials and other potential contaminants that are associated with REV-7. However, it is questionable whether the 28 day sub-chronic toxicity study provides sufficient safety margins when considering the safety of the polymer at the higher levels of consumption. Also, such a study cannot replicate the effect of transit through the human gastrointestinal tract and, although the applicant had carried out two *in vitro* studies to model the conditions in the human upper GI tract, these studies were limited in scope and did not investigate the effect of digestive enzymes and bacterial degradation that may occur elsewhere in the GI tract and under different pH conditions. The absence of such data is a particular cause for concern because REV-7 is a novel polymer that has not been consumed elsewhere in the world and has been developed specifically so that the gum exhibits different adhesion properties to existing products. It is necessary to consider the effect of the differing environmental stresses that it will encounter during passage through the entire human GI tract. It is possible that some of these may alter the visco-elastic nature of the polymer leading to an increased risk of intestinal obstruction, particularly in children. There also needs to be reassurance that the consumption of REV-7 does not affect the digestion or absorption of any nutrients or other bioactive components of food.

Labelling

Although current food labelling legislation does not require that individual components of chewing gum base are identified, Members were of the view that 4 REV-7 is a novel food ingredient

component with no understanding of the effect of prolonged use, it should be clearly identified in the list of ingredients.

(2) http://www.acnfp.gov.uk/meetings/acnfpmeet09/acnfp02jul09/acnfpagendajul09

(h) Sardine Peptide Product

Mr Andreas Klepsch

European Commission

By email

8 May 2009

Dear Mr Klepsch

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 Finnish CA for the above product. This was discussed at the Committee's meeting on 29 April.

The Committee's main concern related to data from animal studies presented in the dossier. The ACNFP's view is that a 28 day feeding study is not sufficient to provide reassurance on the safety of sardine peptide product, particularly as it showed some marginal effects which should have been followed up in further investigations, such as a 90-day study. Without this further study, the UK is unable to agree with the positive opinion of the Finnish CA.

The ACNFP also raised some other questions relating to the application. The potential of sardine peptide product to interfere with medication (such as ACE inhibitors) likely to be taken by hypertensive individuals was considered. Additionally, the ACNFP was concerned that hypertensive individuals may consume foods containing sardine peptide product in favour of prescribed medication to control their blood pressure.

The ACNFP stated that as sardine peptide product is on the Japanese market, it would have been useful if the applicant had provided data relating to post-market monitoring.

To conclude, on the basis that data from 90 day animal studies have not been provided to provide reassurance of the safety of sardine peptide product, the UK is unable to support the Finnish CA's positive initial opinion.

Finally, as a result of the blood pressure-related health claims made by the applicant and the fact that the ACE-inhibitory activity of sardine peptide product matches the mode of action of blood pressure lowering drugs, we have sought advice from the UK Medicines and Healthcare Regulatory Agency (MHRA). The MHRA's initial view is that products containing this sardine peptide product would probably be considered medicinal in the UK.

(By email only)

Dr Manisha Upadhyay

Novel Foods, Additives and Supplements Division

(i) GM: Antibiotic resistance genes. Response to EFSA

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Open Meeting – London 2003	2003	14
Open Meeting – Cambridge 2002	2002	17
Open Meeting – Birmingham 2001	2001	14
Passion fruit seed oil	1991	7
	1990	4
Pine Bark Extract	1997	9
Phospholipids from Egg Yolk	1999	9
	1998	9
Phosphated distarch phosphate	2008	1
	2007	9
	2006	9
	2005	2
	2009	2
Phytosterols	2008	6, 15
	2007	13, 15
	2006	18
	2005	5, 6, 11
	2004	4, 8

	2003	3
	2002	1, 5, 6, 9
	2001	3
	2000	8
	1999	8
Phytosterol food ingredient Cardiabeat	2006	15
Phytosterols produced by DDO processing	2006	11
Policosanol	2008	11
Pollen from GM plants in honey	1992	11
	1991	13
	1990	9
Polyporus squamosus mycelial protein	1993	8
Polysaccharide fat replacers	1997	9
Post market monitoring of novel foods	2003	13
- ACNFP sub group	1999	18
	1998	14
GM potato research at Rowett Institute	1999	14

		1998	12
Potatoes genetically modified for insect resistance		1997	12
PrimaDex		2000	6
		1999	11
Psyllium seed husk		2008	8
Public Hearing on T25 Maize		2002	11
Quinoa		1995	16
		1992	15
		1991	13
		1990	8
Radicchio rosso		2001	7
		2000	9
		1999	10
Reducol		2001	43
Research and Development	- Workshop	2000	19
	- Reports	2001	15
		2000	12

Rethinking Risk	2000	14
Review of risk procedures	2000	14
Rev 7 chewing gum base	2009	3
Riboflavin from GM *Bacillus subtilis*	1996	7
Risk assessment: role of Advisory Committees	1998	11
Royal Society statement on GM plants for food use	1998	12
Salatrims	1999	5
Sardine peptide product	2009	3
Saskatoon berries	2004	9
Scientific Committee on Food		
- Opinion on GA21 Maize	2002	8
- Guidance document on the risk assessment of GM plant derived food and feed	2002	12
Seminar on allergenicity	1999	16
Seminar on novel techniques	1999	16

Single cell protein	1997	10
	1996	12
Soya beans – herbicide tolerant	2001	11
	2000	13
	1994	5
Starlink /Tortilla flour contamination	2001	74
Statistically valid data to support safety clearance of crops products	1998	10
Stevia rebaudiana Bertoni	1999	10
	1998	8
Structure and immunogenicity of bean alpha-amylase inhibitor expressed in peas	2005	16
Substantial Equivalence	1999	1
	1998	1
Substantial Equivalence Guidance	2009	4
Sucromalt	2009	3
Sugar beet fibre	1992	17

Synthetic Lycopene		2007	16
Taste trials	- guidelines	2002	18
		2001	12
		2000	11
		1992	9
		1991	10
	- beers from GM yeasts	1990	2
		1989	5
	- GM tomatoes	1990	5
Processed products from GM tomatoes		1999	6
		1997	7
		1995	9
		1994	3
GM tomatoes to be eaten fresh		1995	8
Touchi (black bean) extract		2008	4
Toxicological assessment of novel foods		1998	11
Transformation –induced mutations in transgenic plants		2007	20

Transgenic animals	1994	9
	1992	7
	1991	7
	1990	7
	1989	8
- ethics group	1993	9
Transparency of the ACNFP	1999	18
	1998	14
	1997	14
Trehalose	2001	2
	2000	4
	1991	8
	1990	4
Unsaponifiable matter of palm oil	2003	7
US Food and Drugs Administration paper on antibiotic resistance markers	1998	12
Virgin prune oil	2001	10
WHO workshop	1994	12

Zeaxanthin	2006	14
	2005	10
	2009	3