The Advisory Committee on Novel Foods and Processes (ACNFP)

2016 Report

Contents

Foreword

I am delighted to present the 2016 Annual Report of the Advisory Committee on Novel Foods and Processes (ACNFP).

The safety assessment of novel foods and processes rests with the ACNFP, which carry these out in line with the EU procedures set out in Regulation (EC) No 258/97. The content of this report also reflects the role the Committee continues to have in advising the Food Standards Agency on matters related to genetically modified (GM) foods.

In order to fulfil its role, the ACNFP has an impressive membership with highly qualified expertise in a wide range of scientific disciplines as well as two consumer representatives and an ethicist. The Committee welcomed 4 new Members in September. I would like to take this opportunity to thank my fellow Committee members for their expert advice, continued hard work and support throughout the year.

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

Professor Peter Gregory
April 2017

INTRODUCTION

The primary role of the ACNFP is the safety assessment of any novel food or process submitted for approval or notification under the Novel Foods Regulations (EC) No. 258/97.

Under the Novel Foods Regulations (EC) No. 258/97 a novel food is defined as a food that does not have a significant history of consumption within the European Union before 15 May 1997. Such foods are subject to a pre-market safety assessment before a decision is made on EU wide authorisations.

A company planning to market a novel food submits an application to a single EU Member State. Once the application has been accepted the Member State produces an initial opinion. This opinion is then circulated to Member States who are given a further 60 days to comment or make a reasoned objection. If there are no objections the novel food will be authorised. If there are objections a decision on the authorisation will be taken by a vote among Member States at the Standing Committee on the Food Chain and Animal Health. Prior to a vote taking place the European Food Safety Authority may be asked its opinion on any outstanding safety questions.

The Novel Food Regulation also provides a simplified route for manufacturers to bring certain novel foods and food ingredients to the market by making a notification in accordance with article 5 of the regulations. The product must be shown to be substantially equivalent to an existing food or food ingredient as regards its composition, nutritional value, metabolism, intended use and level of undesirable substances. Each notification requires a suitable opinion from a single EU Member State.

The following tables provide details of:

- novel food applications submitted to the Food Standards Agency as the UK Competent Authority,
- applications from other EU Member States,
- notifications under the simplified procedure, and
- other issues discussed by the Committee during the year.

1. NOVEL FOOD APPLICATIONS SUBMITTED TO THE UK

a) Full applications

In 2016 the ACNFP carried over its assessment of three applications from previous years. These are detailed in Table 1, below. Three new applications were accepted under Article 4 of regulation (EC) 258/97 in 2016.

Details of the issues that were raised by the Committee can be found in the minutes of the relevant meetings on the ACNFP website. Minutes can be found under sections **ACNFP Meetings → ACNFP meetings in 2016**

Formal written opinions on UK applications considered by the Committee can be found on the ACNFP website under the relevant application. Opinions can be found under sections **Novel Food Assessments → Full Application to the UK**

Authorisation decisions and opinions on full applications can be found under the section **Authorisations** on the European Commission website.

Table 1: Novel food applications made via the UK considered by the Committee during 2016

Novel food (Applicant)	***Meeting discussed***	***ACNFP Opinion***	***Comment***
Calanus finmarchicus	Feb/April/June	Completed	
Ketone Ester	Feb/April		Evaluation is still ongoing
Oligonol® Amino Up Chemical Company Ltd	April		Evaluation is still ongoing
M Aurum	April/June		Evaluation is still ongoing
Tongkat Ali	Sept		Evaluation is still ongoing
DHA Rich Algal Oil from Schizochtrium species 18 extension of use	Nov		Evaluation is still ongoing

(b) Opinions on substantial equivalence

In 2016 the ACNFP considered three requests for an opinion on equivalence in accordance with Article 3(4) of regulation (EC) 258/97. These are detailed in Table 2, below. Details of the issues that were raised by the Committee can be found in the minutes of the relevant meetings on the ACNFP website. Minutes can be found under sections **ACNFP Meetings → ACNFP meetings in 2016.** Formal written opinions on UK applications considered by the Committee can be found on the ACNFP website under the relevant application. Opinions can be found under sections **Novel Food Assessments → Simplified Procedure**

Authorisations of Notification (substantial equivalence) applications can be found under the section **Authorisations** on the European Commission website.

Table 2: Applications for an opinion on substantial equivalence considered by the Committee during 2016

Novel food (Applicant)	***Meeting discussed***	***ACNFP Opinion***	***Comment***
Chia Seed (Crescendo Organics)	Feb	Completed	The Committee agreed equivalence had been demonstrated between these chia seeds and an existing product.
Chia Seeds (Terrafertil)	Feb/April	Completed	The Committee agreed equivalence had been demonstrated between these chia seeds and an existing product.
Chia Seeds (Selva Organics)	Sept	ongoing	Evaluation is still ongoing

2. NOVEL FOOD APPLICATIONS SUBMITTED TO OTHER MEMBER STATES

In 2016 the ACNFP considered seven 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 meetings on the ACNFP website. Minutes can be found under sections **ACNFP Meetings → ACNFP meetings in 2016.**

Table 3: Novel foods considered by the Committee during 2016 following an initial assessment in another Member State

Novel food (Member State)	*Meeting discussed*	*Status*	*UK response Comment*
N-Aceyl-D-Neuramic Acid (NANA, Sialic Acid)	April	Evaluation is still ongoing	The Committee agreed with the favourable initial opinion from the Member States Competent Authority and raised comments.
DeltaGold®70,DeltaGold® 50, and DeltaGold®35	June	Evaluation is still ongoing	The Committee agreed to the favourable initial opinion from the Member States Competent Authority and raised comments.
Ecklonia Cave Phlorotannins (Sea Polynol)	Feb	Evaluation is still ongoing	The Committee agreed with the favourable initial opinion from the Member States Competent Authority and raised comments.
2'-Fucosyllactose	June	Evaluation is still ongoing	The Committee agreed to the favourable initial opinion from the Member States Competent Authority and raised comments.
Xylo-oligosaccharide	September	Evaluation is still ongoing	The Committee agreed to the favourable initial opinion from the Member States Competent Authority and raised comments.
Pyrroloquinoline Quinone Disodium Salt (PQQ)	September	Evaluation is still ongoing	The Committee agreed to the favourable initial opinion from the Member States Competent Authority and raised comments.
MemreePlus – Extension of use	September	Evaluation is still ongoing	The Committee agreed with the favourable initial opinion from the Member States Competent Authority and raised comments.

*Applications considered by the committee members by consultation

3. NOVEL FOOD APPLICATIONS CONSIDERED IN PREVIOUS YEARS

During 2016 the ACNFP also considered the response from one applicant company following consideration of an initial assessment in another Member State later forwarded to the European Food Safety Authority (EFSA). The ACNFP's advice formed the basis of the UK's comments to the marketing of this novel food. 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 meetings on the ACNFP website . Minutes can be found under sections **ACNFP Meetings → ACNFP meetings in 2016**

Table 4: Novel foods considered by the Committee during 2016 following an initial assessment in another Member State

EFSA opinion	*Meeting discussed*	*Comment*
Monomethylsilanetriol (MMST)	June	The Committee agreed with EFSA's assessment. It noted that a use level above 90ml would not be supported by the risk assessment. It agreed with EFSA that silicon was not an essential nutrient. It was unclear on the proportion of the novel ingredient which becomes othosilicate. Evidence used for bioavailability was for a much larger molecule than the siloxane molecule of the novel ingredient.

4. OTHER ISSUES

In 2016 the ACNFP consulted on EFSA's Draft Guidelines on Data Requirements for Applications under the Revised Novel food Regulation, EFSA's Draft Guidelines on Data Requirements for Notifications on Traditional Foods and EFSA's Public Consultation on the Draft Guidance Document on Allergenicity Assessment of GM Plants. Details are provided in Table 5, below.

Table 5: Other Issues

Issue	*Meeting discussed*	*Comment*
EFSA Guidelines on Data Requirements for Applications under the Revised Novel Food Regulation.	April	The Committee considered this EFSA guidance. The discussion focussed on the need for a flexible approach given the many types of food and food ingredients that are assessed under the framework and on allergenicity, toxicology, intake levels and compositional data issues.
EFSA Guidelines on Data requirements for Notifications on Traditional Foods.	April	The Committee considered this EFSA guidance. The main focus of the discussion was on the need for a proportionate response to take into account the length of time the food had been consumed by humans, compostional data and data from experience of use, particularly on recording experience and oral tradition.
Public Consultation on the draft Guidance Document on Allergenciity Assessment of GM Plants.	September	The Committee considered the paper was of good quality and the protocol and process could be usefully applied more widely to novel foods and any proteinaceous food.

ANNEX 1 – Information about the Committee

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

REMIT

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

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

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

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 2015, 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 2016 and a copy of the code of conduct for ACNFP members can be found on the following pages.

Membership of the Committee during 2015

Chairman

Professor Peter Gregory BSc, PhD
Professor of Global Food Security at the University of Reading.

Members

Dr Anton Alldrick BSc. Hons, PhD (from September 2016)
Special Projects Manager at Campden BRI.

Dr Camilla Alexander-White BSc (Hons) DPhil CChem MRSC ERT (Toxicologist)
Senior Manager/Consultant Toxicologist at ENVIRON International Corporation until March 2016.
Programme Manager in Chemical Regulation, Royal Society of Chemistry (from April 2016)

Professor Michael Bushell BSc, PhD (Microbiologist)
Emeritus Professor of Microbiology in the Microbial Sciences Department at the University of Surrey.

Professor Susan Duthie BSc, MSc, PhD (Nutritionist)
Associate Head of the School of Pharmacy and Life Sciences, The Robert Gordon University, Aberdeen

Simon Flanagan BSc, FIFST (Quality Assurance/Food Processing) (until June 2016)
Senior Consultant in Food Safety and Allergens for Reading Scientific Services Ltd.

Dr Hamid Ghoddusi BSc, MSc, PhD
Head of the Microbiology Research Unit at the London Metropolitan University.

Nichola Lund LLB (Consumer Affairs Representative)
Trading Standards Officer with the North East London Metrology Partnership.

Dr Rohini Manuel MB BCh BAO, MSc, MD, FRCPath (Microbiologist and Mycologist)
Consultant Medical Microbiologist at the Public Health Laboratory London, Barts Health NHS Trust.

Professor John Mathers BSc, Dip. Nutr, PhD (Nutritionist)
Professor of Human Nutrition and Director of the Human Nutrition Research Centre at Newcastle University

Mrs Rebecca MacKenzie BSc, MSc
Allergy specialist dietician in the Adult Allergy Team at the Royal Brompton Hospital.

Professor Harry McArdle BSc, PhD, FRSB (Nutritionist)
Professor Emeritus of Biomedical Sciences, Rowett Research institute, University of Aberdeen
Honorary Professor of Biomedical Sciences, University of Nottingham

Professor Clare Mills BSc, PhD (Plant Science and Allergy Expert)
Professor of Molecular Allergology, at the School of Translational Medicine, University of Manchester.

Ms Claire Nicholson BA and MBA (Consumer Affairs Representative)
Independent Consumer Advisor to the FSA and other food industry organisations.

Professor Christopher Ritson BA, MAgrSc (Ethicist)
Emeritus Professor of Agricultural Marketing, Newcastle University.

Dr Lesley Sands MA(Oxon), PhD
An independent consultant in biomedical science and investigative toxicology

FSA Observers

Ms Alice Teague	Food Standards Agency (Wales)
Ms Georgina Finch	Food Standards Agency (Scotland)
Ms Esther Chartres	Food Standards Agency ((Northern Ireland)

ACNFP Members' Interests during 2016

	Personal Interests		Non-personal Interests	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor Peter Gregory	East Malling Research	Director	BBRSC	Funding
	Royal Horticultural Society	Trustee		
	Peter Gregory Consulting Ltd	Director		
	Rank Prize Nutrition Committee	Member		
Dr Anton Alldrick	Campden BRI	Employee		
Dr Camilla Alexander-White	Royal Chemistry Society (May 2016 onwards)	Employee		
	Ramball Environ UK Ltd (Until March 2016)	Employee		
	LHASA Ltd	Director		
	MKTox- sole trader	Consultant in Toxicology		
	Great Ormond Street Hospital, NHS Foundation Trust Board	Governor		
Emeritus Professor Michael Bushell	Abbott Laboratories, Chicago	Consultant	None	

	Personal Interests		Non-personal Interests	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor Susan Duthie	None		UK Environmental Mutagen Society Molecular Epidemiology Group (UKMEG) Rank Prize Funds Tenovus UK Scottish Government (RESAS)	Secretary Funded PhD Studentship Funded PhD Studentship Research Funding
Mr Simon Flanagan	Reading Scientific Services Ltd Subsidiary of Kraft Foods Inc	Employee	UK Food and Drink Federation Food and Drink Europe ILSI Europe	Member of Allergen Steering Group Member of Allergen Working Group Member of Food Allergy Taskforce
Dr Hamid Ghoddusi				
Mrs Nicola Lund	Chartered Trading Standards Institute of (CTSI)	Member	None	
Dr Rohini Manuel	None		PHE Pipeline Fund Health Foundation Gilead Fellowship RCPath Astellas	Research funding Research funding Research funding Public Engagement grant funding Clinical trial

	Personal Interests		Non-personal Interests	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor John Mathers	None		EU	Research funding
			BBRSC	Research funding
			MRC	Research funding
			Governing Council of the British Nutrition Foundation	Member
			BBRSC Basic Bioscience underpinning Health	Member
			Rank Prize Nutrition Committee	Member
			ESRC Understanding Society Governing Board	Member
			BBRSC DRINC Advisory Panel	Member
Professor Harry McArdle	None		Scientific Advisory Committee on Nutrition (SACN)	Member
			Nutrition Society	Honorary Treasurer
			International Copper Assocation	Funds to support visiting scientists

	Personal Interests		Non-personal Interests	
Member	**Company**	**Interest**	**Company**	**Interest**
Mrs Rebecca McKenzie	Royal Brompton and Harefield NHS Foundation Trust	Employee		
Professor Clare Mills	React Biotech Ltd	Spin-out Company Director	FSA BBSRC TSB	i) Occasional external reviewer. ii) PI on FSA funded project T07062 iii) CoI on FSA funded TRACE i) Member of DRINC steering group ii) Grant Holder iii) CASE students sponsored by Campden BRI, Genon and Waters Corp Collaborative project with Waters Corp, LGC and Romer Labs on allergen analysis
			EU funded research	CHANCE and IFAAM projects
			EFSA (2012-2013)	Tender for systematic review for the GMO panel

	Personal Interests		Non-personal Interests	
Member	**Company**	**Interest**	**Company**	**Interest**
Professor Clare Mills (Cont)			University of Nebraska Food Allergy Research and Resource Programme, USA Industry funded research Novartis DBV Solazyme Pepsico	Joint PhD student Allergen expert advice
Ms Claire Nicholson	Red Tractor Farm Assurance Current and future meat controls stakeholder group (FSA)	Independent Director for Consumer Interests Consumer representative	Smedvigcapital	Partner's shareholding and employment. May invest in food businesses.
Professor Christopher Ritson	Food Ethics Council	Trustee Director	None	
Dr Lesley Stanley	Edinburgh Napier University (zero hours lecturing contract) FMP Corporation	Employment Fee-paid work		

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

Public service values

The Members of the ACNFP must at all times:

- observe the highest standards of impartiality, integrity and objectivity in relation to the advice they provide and the management of this Committee;

- be accountable, through the Board of the Food Standards Agency and Health Ministers, to Parliament and the public for its activities and for the standard of advice it provides.

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

Standards in Public Life

All Committee Members must:

- follow the Seven Principles of Public Life set out by the Committee on Standards in Public Life (page 19);

- 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 21-22 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 (Revised and updated July 2012)

GOOD PRACTICE GUIDELINES FOR THE INDEPENDENT SCIENTIFIC ADVISORY COMMITTEES

INTRODUCTION

The Government Chief Scientific Adviser's *Guidelines on the Use of Scientific and Engineering Advice in Policy Making*[1] set out the basic principles which government departments should follow in assembling and using scientific advice. The key elements are to:

- **identify early** the issues which need scientific and engineering advice and where **public engagement** is appropriate
- draw on a **wide range of expert advice** sources, particularly where there is uncertainty;
- adopt an open and transparent approach to the scientific advisory process and publish the evidence and analysis as soon as possible;
- **explain publicly the reasons for policy decisions**, particularly when the decision appears to be inconsistent with scientific advice; and
- **work collectively** to ensure a joined-up approach throughout government to integrating scientific and engineering evidence and advice into policy making.

The *Code of Practice for Scientific Advisory Committees*[2] and the *Principles of Scientific Advice to Government*[3] provide more detailed guidance on the operation of scientific advisory committees (SACS) and their relationship with their sponsor Departments.

The Food Standards Agency's Board adopted a **Science Checklist** in 2006 (updated in 2012) that makes explicit the points to be considered in the preparation of papers and proposals dealing with science-based issues, including those which draw on advice from the Scientific Advisory Committees (SACS).

These **Good Practice Guidelines** were drawn up in 2006 by the Chairs of the independent SACs that advise the FSA based on, and complementing, the Science Checklist. They were updated in 2012 in consultation with the General Advisory Committee on Science (GACS).

[1] http://www.bis.gov.uk/assets/bispartners/goscience/docs/g/10-669-gcsa-guidelines-scientific-engineering-advice-policy-making-pdf

[2] http://www.bis.gov.uk/assets/BISPartners /GoScience/Docs/C11-1382-code-of-practice-scientific-advisory-committees.pdf

[3] http://www.bis.gov.uk/go-science/principles-of-scientific-advice-to-government

The Guidelines apply to the SACs that advise the FSA and for which the FSA is sole or lead sponsor Department:

Advisory Committee on Animal Feeding stuffs
Advisory Committee on Microbiological Safety of Foods
Advisory Committee on Novel Foods and Processes
Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment[4]
Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment[5]
Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment[6]
General Advisory Committee on Science
Social Science Research Committee

For the SACs with a shared sponsorship the Guidelines apply formally to their advice to the FSA; they may opt to follow them also in advising other sponsor Departments.

These committees share important characteristics. They:

- are independent;
- work in an open and transparent way; and
- are concerned with risk assessment and/or science governance, not with decisions about risk management.

The Guidelines relate primarily to the risk assessment process since this is the main purpose of most of the SACs. However, the SACs may, where appropriate, comment on risks associated with different risk management options, highlight any wider issues raised by their assessment that they feel should be considered (distinguishing clearly between issues on which the SAC has an expert capability and remit, and any other issues), or any evidence gaps and/or needs for research or analysis.

In addition, GACS and SSRC may advise the FSA on aspects of the governance of risk management, or on research that relates to risk management.

Twenty nine 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.

The SACs have agreed to review their application of the principles annually and report this in their Annual Reports. Compliance with the Guidelines will also be covered in the annual self assessments by Members and annual feedback meetings between each SAC Chair and the FSA Chief Scientist.

[4] Joint FSA/HPA Secretariat, HPA lead
[5] Joint FSA/HPA Secretariat, HPA lead
[6] Joint FSA/HPA, FSA lead

ACNFP self-assessment against the Good Practice Guidelines

Issue	Compliance?	Notes/Comments
Defining the problem and the approach		
1. The FSA will ensure that issues it asks an SAC to address are clearly defined and take account of stakeholder expectations in discussion with the SAC Secretariat and where necessary the SAC Chair. The SAC Chair will refer back to the FSA if discussion suggests that further iteration and discussion of the task is necessary. Where an SAC proposes to initiate a piece of work the SAC Chair and Secretariat will discuss this with FSA to ensure the definition and rationale for the work and its expected use by the FSA are clear.	Yes	ACNFP does this on a routine basis
Seeking input		The main part of the ACNFP's work is the evaluation of dossiers submitted under EU procedures for authorisation of novel foods. For applications made directly to the UK, each dossier is published for public comment and the Committee carries out a second consultation on its draft opinion before it is finalised. That level of consultation cannot be achieved for applications made via other member states, as the Committee must comply with EU rules on access to documents. For the same reason, the Committee cannot discuss the documents in public. The ACNFP does however hold an annual open event, which allows Members to discuss relevant topics with members of the public.
2. The Secretariat will ensure that stakeholders are consulted at appropriate points in the SAC's considerations. It will consider with the FSA whether and how stakeholder views need to be taken into account in helping to identify the issue and frame the question for the committee.	Yes	
3. Wherever possible, SAC discussions should be held in public.	yes	
4. The scope of literature searches made on behalf of the SAC will be clearly set out.	N/A	

5. 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.	Yes	The Committee (via the Secretariat) requests relevant information from applicants and gives an appropriate time to respond. The Committee, with the assistance of the Secretariat, also seeks further information and advice when required, from other Committees or individual experts.
6. Data from stakeholders will be considered and weighted according to quality by the SAC.	Yes	
7. Consideration by the Secretariat and the Chair (and where appropriate the whole SAC) will be given to whether expertise in other disciplines will be needed.	Yes	
8. Consideration will be given by the Secretariat or by the SAC, in discussion with the FSA, as to whether other SACs need to be consulted.	Yes	
Validation		
9. Study design, methods of measurement and the way that analysis of data has been carried out will be assessed by the SAC.	Yes	The Secretariat and Committee critically review the methods and statistical treatments used in dossiers and published and seeks further information from authors and other bodies as required.
10. Data will be assessed by the committee in accordance with the relevant principles of good practice, e.g. qualitative social science data will be assessed with reference to guidance from the Government's Chief Social Researcher[7].	Yes Where relevant	For complex statistical questions, the Secretariat is able to consult with specialists within the FSA.

[7] Quality in Qualitative Evaluation: A Framework for assessing research evidence http://www.civilservice.gov.uk/w-content/uploads/2011/09/a_quality_framework_tcm6-7314.pdf; The Magenta book http://www.hm-treasury.gov.uk/d/magenta_book_combined.pdf

11. Formal statistical analyses will be included wherever appropriate. To support this, each SAC will have access to advice on quantitative analysis and modelling as needed.	Yes	The Committee has commented about the value of using detailed information on the dietary habits of UK consumers, so that risk assessments of novel foods can take account of potential intake by UK consumers, including relevant at-risk groups.
12. When considering what evidence needs to be collected for assessment, the following points will be considered: • the potential for the need for different data for different parts of the UK or the relevance to the UK situation for any data originating outside the UK; and • whether stakeholders can provide unpublished data.	Yes Yes	Evaluations of novel foods are mainly based on evidence provided by the applicant, including unpublished studies and commercially-sensitive information about manufacturing processes. For applications made via the UK, the dossier (less any confidential sections) is published via the Committee's website.
13. The list of references will make it clear which references have been subject to external peer review, and which have been peer reviewed through evaluation by the Committee, and if relevant, any that have not been peer reviewed.	Yes	Novel food application dossiers include a list of references which make it clear whether or not they have been peer reviewed.
Uncertainty		
14. When reporting outcomes, SACs 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.	Yes	ACNFP complies with items 14 to 17 – outcomes are critically evaluated and uncertainties are identified.
15. Any assumptions made by the SAC will be clearly spelled out, and, in reviews, previous assumptions will be challenged.	Yes	

16. Data gaps will be identified and their impact on uncertainty assessed by the SAC.	Yes	
17. An indication will be given by the SAC about whether the evidence base is changing or static, and if appropriate, how developments in the evidence base might affect key assumptions and conclusions.	Yes	
Drawing conclusions		
18. The SAC will be broad-minded, acknowledging where conflicting views exist and considering whether alternative interpretations fit the same evidence.	Yes	ACNFP complies with this – uncertainties and interpretations are identified clearly in the Committee's opinions.
19. Where both risks and benefits have been considered, the committee will address each with the same rigour, as far as possible; it will make clear the degree of rigour and uncertainty, and any important constraints, in reporting its conclusions.	N/A	The Committee's assessment focuses on safety and labelling and it does not address any nutrition or health benefits that may be claimed for the novel ingredient or for foods that contain it. Nutrition or health claims may only be made if they are specifically authorised under EU Regulation (EC) No 1924/2006
20. SAC 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. If it is not possible to reach a consensus, a minority report may be appended to the main report, setting out the differences in interpretation and conclusions, and the reasons for these, and the names of those supporting the minority report.	Yes	The final opinions are adopted by consensus, identifying the key issues and generally explaining the reasoning behind the Committee's conclusions.
21. The SAC's interpretation of results, recommended actions or advice will be consistent with the quantitative and/or qualitative evidence and the degree of	Yes	

uncertainty associated with it.		
22. SACs will make recommendations about general issues that may have relevance for other committees.	Yes	
Communicating SACs' conclusions		
23. Conclusions will be expressed by the SAC in clear, simple terms and use the minimum caveats consistent with accuracy.	Yes	
24. It will be made clear by the SAC where assessments have been based on the work of other bodies and where the SAC has started afresh, and there will be a clear statement of how the current conclusions compare with previous assessments.	Yes	
25. The conclusions will be supported by a statement about their robustness and the extent to which judgement has had to be used.	Yes	
26. As standard practice, the SAC secretariat will publish a full set of references (including the data used as the basis for risk assessment and other SAC 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.	Yes	
27. The amount of material withheld by the SAC 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.	Yes	
28. Where proposals or papers being	N/A	

considered by the FSA Board rest on scientific evidence produced by a SAC, the Chair of the SAC (or a nominated expert member) will be invited to the table at the Open Board meetings at which the paper is discussed. To maintain appropriate separation of risk assessment and risk management processes, the role of the Chairs will be limited to providing an independent view and assurance on how their committee's advice has been reflected in the relevant policy proposals, and to answer Board Members' questions on the science. 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.		
29. The SAC will seek (and FSA will provide) timely feedback on actions taken (or not taken) in response to the SAC's advice, and the rationale for these.	Yes	

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 £23,644