

# Annual Report 2021

## Foreword

Dear Reader,

I am delighted to present the 2021 Annual Report of the Advisory Committee on Novel Foods and Processes. This report summarises the work of the Committee from January to December 2021 and details the context and values which have guided the Committee's work.

This year the Committee have begun assessments on a number of novel foods, our first full application assessments since 2018, as part of our repatriated role in advising the FSA and Governments of the nations of the UK on the risks of novel foods. The Committee and FSA secretariat has risen to the new challenges seeking to undertake proportionate risk assessments that support the values and remit of the FSA and its changed role post EU Exit.

We are starting to see new trends emerging in the dossiers received, associated with the increased demand for products for plant-based diets. This adds momentum to a long-standing area of interest for the Committee around alternative proteins and safety considerations particularly around allergy. We will be following developments in these exciting and rapidly moving sectors with interest.

A significant and challenging area of work has been on novel food products containing cannabidiol (CBD) and ensuring a rigorous assessment of the technical dossiers that have been validated. Preparatory work in 2020 enabled the Committee to consider the existing evidence and the risks of different sources and uses of CBD, as applicant dossiers moved through the early stages of the system to validation. In 2021, the ACNFP reviewed the first dossiers on CBD and we expect CBD products to be a key and ongoing area for the FSA in 2022 and 2023.

We have also been preparing for an increased role in assessing Genetically Modified Organisms (GMOs) and Precision Bred Organisms (PBOs) produced using

a range of techniques for use in food and feed. The Committee provided initial thoughts on the potential risks from food and feed produced by gene editing and other techniques as part of Defra's work in this area. In March 2021, the ACNFP submitted a [response to the Defra consultation](#) on the regulation of new genetic technologies. To further build our capacity in these areas we recruited new expert members on gene editing technologies and gained expanded expert input from a range of relevant disciplines, including the ethical and lay representative view. In 2021, it was envisaged that a dedicated ACNFP sub-committee would be needed in 2022 to work specifically on Products of Genetic Technologies (PGT). We look forward to providing further scientific advice and insight on this important issue as policy and legislation in this area develops.

Novel foods and products of modern biotechnology are growing and high-profile areas of food policy in the UK. In 2021, the membership of the Committee has continued to evolve to ensure we have expertise to cover the wide range of issues on which the ACNFP is asked to provide advice. This allows us to continue to strengthen our multidisciplinary approach for the provision of sound scientific advice and prepare for future challenges and needs. I would like to welcome all our new members who add to our impressive membership of highly qualified experts.

The report for our work this year shows the breadth of products under review within the ACNFP remit. It also shows the response of the Committee to ensure the public can have confidence in the assessments made by the Committee in the face of the next generation of food innovations.

Dr Camilla Alexander-White

October 2022

## **1. Introduction**

The ACNFP has a long history of providing advice to the FSA on novel foods and processes. Under Regulation (EU) 2015/2283 as retained in UK law post EU Exit, a novel food is defined as a food that does not have a significant history of consumption within the United Kingdom before 15 May 1997. As a regulated product, the food is subject to an assessment process to ensure that it is safe, does not mislead the consumer and would not put consumers at a nutritional disadvantage. The Committee's advice to the FSA contributes to the development of the Agency's strategic objectives and ways of working to ensure that food is safe and what it says it is.

Over recent years the work of the FSA has evolved to reflect the legal context in which it operates. Prior to the 2018 revision of the EU Novel Food Regulation, the ACNFP looked at all novel foods submitted to the UK for evaluation and reviewed the opinions of other authorities in the EU, undertaking these assessments. Since January 2018, the ACNFP became responsible only for reviewing novel food dossiers of the 'traditional food' ([footnote 1](#)) type. This was undertaken alongside the Committee's role in advising on the products of genetic technologies.

The decision for the UK to leave the European Union brought subsequent changes to the Committee's roles and responsibilities. Since 1 January 2021, at the end of the EU-exit transition period, the remit of the ACNFP was to provide national advice to the FSA on the scientific evaluation, once again, of all novel foods and GM products of genetic technologies used as food and feed. The FSA and the Secretary of State became responsible for implementing national regulation in full relating to novel foods and processes. In 2021, the work of the ACNFP as the science advisory committee (SAC) for novel foods and processes, including for the products of genetic technologies, increased significantly.

In undertaking its work, the ACNFP continues to be bound by the principles in its code of practice. At the heart of its approach to assessing the applications received is:

- **Openness and transparency** – While the information reviewed by the Committee has commercial sensitivity, the Committee with the support of the Secretariat, endeavours to be open about the work and the nature of the assessment being undertaken to ensure consumers can have confidence in the independence of the view generated and applicants have the tools to do the right thing.
- **Proportionality** – Seeking to strike a balance where each application is subject to a thorough assessment proportionate to the food safety risks it might pose. Achieving this is a continuous improvement process embedded into the ways of working of the Committee. While all uncertainty and risk cannot be removed for food and feed seeking authorization, the Committee seek to be clear on the sources of risk and uncertainty in order to inform the decisions of Risk Managers in the risk analysis process.
- **Supporting businesses to do the right thing** – providing clear advice and guidance to the applicants so that they can provide the information needed for assessment and ensure the safety of their products
- **Innovation**- Seeking to evolve the Committee's ways of working and practices to ensure the core objectives are achieved using the best available

science and up to date thinking in the members areas of expertise and on the approach to assessment.

In this context in 2021, the primary role of the ACNFP has been to provide scientific advice to FSA and FSS on novel foods applications considered under the regulatory process and for which scientific and technical advice is requested.

New novel food applications - The ACNFP began the review process for six novel foods dossiers. These are the first full assessments by the Committee following EU Exit. The assessments continue to be based on the requirements in the retained legislation. Full details for the UK processes for applicants can be found on the [ACNFP Food Assessment](#) pages.

Assessments by the Committee are tailored to the nature of the products and the risks they pose as proposed to be consumed. The role of the Committee is to review the assessment developed by the applicants to ensure any key food safety risks with the product or its production are identified. This supports any risks being managed and informs risk management decisions by Ministers in the nations of the UK on authorisation or the conditions of their use. In the initial review further information is sought if necessary to better understand data gaps identified. The assessment will continue into 2022 for these products as information is provided.

Traditional Foods from Third Countries - The Committee completed one review of a notification for a traditional food from third countries. This is a separate assessment process under the novel food regulation allowing rapid consideration of the information provided by applicants in order to inform decisions by risk managers on whether a further review is needed. The emphasis for the assessment is to understand the learning on how the product can be used safely from the experience of its use in third countries.

Cannabidiol - The final major area of work on novel foods was the reviewing of submissions for cannabidiol (CBD) containing products. This is a clearly defined area of [FSA policy](#). Since CBD was confirmed as a novel food in January 2019 there have not yet been any authorised CBD products on the UK market. In February 2020, the FSA set a deadline of 31st March 2021 by which businesses already selling CBD must have submitted a dossier to the FSA for assessment. In 2021 the Committee has considered and provided advice on the handling of cannabidiol (CBD) applications post EU-Exit by the FSA and began to review dossiers that satisfied the process validation criteria, in terms of their scientific quality and completeness. This will provide a framework for reviewing the volume

of applications that are being considered under the service as part of the wider CBD policy.

Products of modern biotechnology - In 2021, the Committee has also regained responsibilities in relation to the safety assessment of GM food and feed. With developments in genome edited (GE) foods and precision breeding technologies the Committee's remit and expertise has been updated to reflect the need for review and application of new technologies. In light of the ACNFP remit, the Committee responded to Defra's consultation in this area, which can be found on the [ACNFP website](#). The advice from the ACNFP is to recognise that there will be a spectrum of outcomes from modern biotechnology that could be considered within the scope of the DEFRA policy. As such it is recommended that an appropriate case-by-case risk assessment be performed.

We have held a workshop in 2021 to consider some of the potential safety issues relating to GM/GE food and precision breeding technologies in particular, so that we are well prepared to advise on these matters in the coming months and years, based on the best scientific developments. This led to the agreement of creating an ACNFP subcommittee that would focus on all matters relating to GM/GE food and feed and provide a scientific basis to policy making on this going forward. This sub-committee will feed back into the ACNFP, such that a thorough multidisciplinary review can be performed as the work evolves in 2022 and 2023.

Further detail on the work of the Committee in 2021 is detailed below.

## **2. Novel Food Applications**

In 2021, the ACNFP began assessment of six new novel food applications that were accepted under Article 10 of Regulation (EU) 2015/2283 as retained in UK law. The applications that could be considered in open session is detailed in Table 1, below. The dossiers for CBD were considered by reserved business to reflect the commercial sensitivities and are detailed in section 4.

Details of the issues that were raised by the Committee can be found in the minutes of the relevant meetings on the [ACNFP website](#).

### **Table 1: Novel Food applications considered by the Committee during 2021**

| Application         | Reference Number | Meeting                       | Committee's Response   |
|---------------------|------------------|-------------------------------|--|
| Mung Bean Protein   | RP32             | April, September and November | <ul style="list-style-type: none"> <li>• This new novel food was considered by the Committee for the first time at the April.</li> <li>• The application had data gaps on specification, production, proposed use and intake, nutrition, toxicology and allergenicity. Further information was sought on these aspects from the applicant.</li> <li>• The dossier continues to be under review.</li> </ul> |
| Barley Rice Protein | RP19             | April and September           | <ul style="list-style-type: none"> <li>• Another new protein application was considered by the Committee for the first time in April.</li> <li>• Information gaps were identified on the production process, nutrition and allergenicity. Further information was sought on these aspects from the applicant.</li> <li>• The dossier continues to be under review.</li> </ul>                              |

|                       |       |                   |  |
|-----------------------|-------|-------------------|--|
| Calcidiol             | RP 35 | June and November | <ul style="list-style-type: none"> <li>• This application was reviewed for the first time in June.</li> <li>• Data gaps were identified on identity, production process, proposed use and intake and toxicology and were sought from the applicant</li> <li>• The dossier continues to be under review.</li> </ul>   |
| Cetylated Fatty Acids | RP200 | November          | <ul style="list-style-type: none"> <li>• This application proposed as a food supplement was reviewed by the Committee for the first time in November.</li> <li>• Following the review, members requested clarification on the manufacturing process and ADME with a request for further information sent to the applicant.</li> <li>• The dossier continues to be under review.</li> </ul> |

### 3. Traditional Food Applications

In 2021, one traditional food from third countries notification was validated under Regulation (EU) 2015/2283 and passed on to the ACNFP Committee for review. This notification was for Go Wolffia. The notification was assessed by the Committee and their advice passed to risk managers at the FSA and FSS to inform the UK position on this dossier. The notification is detailed in Table 1

Minutes and details of the issues that were raised by the Committee can be found in the relevant meetings on the [ACNFP website](#).

#### **Table 2: Traditional Food notifications considered by the Committee during 2021**

## Application

### Meeting Outcome

### Committee's Response

|            |      |  |  |
|------------|------|--|--|
| Go Wolffia | June | Advice Provided to Food Policy - Currently not Authorised in the UK due to reasoned safety objections. | <ul style="list-style-type: none"><li>• The Committee identified several areas of where further information would be needed to complete an assessment and therefore could not reach a conclusion based on the evidence provided.</li><li>• Their advice was passed to risk managers to decide on whether to raise reason safety objection and trigger the second stage of the traditional food from third country process.</li></ul> |
|------------|------|--|--|

## 4. Other Issues

### a) Ways of Working

In 2021 the ACNFP was consulted on several topics relating to the scientific work of the FSA and how this is managed. Topics included: FSA's approach to the evaluation of Cannabidiol (CBD), further develop documents and processes to support the FSA's future work, as well as governance processes such as the annual report and the revised terms of reference.

Minutes and details of the issues that were raised by the Committee can be found in the minutes of the relevant meetings on the [ACNFP website](#).

### Table 3: Other Issues



| <b>Topic</b>  | <b>Meeting</b> | <b>Committee's Response</b>  |
|---|----------------|--|
| DEFRA consultation on the Regulation of Genetic Technologies                | March          | The Committee commented on the genetic technologies' consultation response drafted by the GM working group.  |
| Annual report 2020  | April          | The Committee reviewed and agreed the annual report for the ACNFP's work in 2020.  |
| Code of Practice and Terms of Reference                                     | June           | The Committee discussed updates to the ACNFP's Code of practice and the Terms of Reference.  |
| Update on Regulated Products & Risk Analysis Processes                      | September      | The Committee was provided an update on work conducted in other areas of the FSA.  |
| Proposal for an ACNFP subgroup to consider issues in GMO & GE food and feed | November       | The Committee was asked to consider a proposal to establish an ACNFP subgroup to consider GM dossiers and develop guidelines for the assessment of Genome Edited products. |

## **b) Reserved Business Items**

A number of items were considered under reserved business in 2021 (Table 4). The discussions for these items are primarily in relation to new ways of working or handling sensitive issues or dossiers on CBD where there are particular commercial sensitivities. While considered as reserved business during the assessment phase, it is expected that final outputs will be placed in the public domain in due course.

### **Table 4: Items considered under reserved business**

## **Application**

## **Meeting**

## **Committee's Response**

CBD applications exercise and initial CBD dossier - RP07

January, April, June

The Committee were invited to review a CBD dossier, the first to be considered by the FSA post EU-exit.

Consideration at further meetings provided appropriate review and feedback to the applicant to further assessment.

GM Application

April

The Committee discussed a process question regarding an existing GM application in relation to new technical development.

Genome Editing Workshop

September

The Committee discussed developments around this area of work.

Approach to assessment of CBD

November

A paper seeking the Committee's views on the management of the assessment of the large volume of CBD dossiers was considered so as to ensure a robust review.

Consideration of data requirements for assessment of the toxicological risk of CBD

November

The Committee's advice was sought on the data needs for these applications to inform the suitability checks of future dossiers.

## **5. Annex 1 - Information about the Committee**

## **ACNFP - remit, membership and Members' interests.**

### **Remit**

The Advisory Committee on Novel Foods and Processes is an independent body of experts. This means they are not employed by the government. Their 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 periodically organises workshops on specific topics related to its remit.

### **Membership of the Committee during 2021**

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 2021, together with the names of the FSA assessors can be found below.

#### **Chair**

**Dr Camilla Alexander-White** BSc (Hons) DPhil CChem FRSC ERT (Toxicologist)  
*(Term began: July 2020)*

Senior Policy Advisor in Chemical Regulation, Royal Society of Chemistry

Director MKTox & Co Ltd – independent chemical safety assessor.

#### **Members**

**Dr Anton Alldrick** BSc. Hons, PhD (Safety Management)

Special Projects Manager at Campden BRI.

**Mrs Alison Austin** (Consumer Needs Representative)

Independent consultant Environmental, Social and Governance Strategy Development.

Non-Executive Director of the Consumer Council for Water.

**Dr Mark Berry** BA, PhD (Nutritionist)

Independent Consultant

Founder & Director at Food and Life Sciences Consulting Ltd

**Professor Susan Duthie** BSc, MSc, PhD (Nutrition Scientist)

Professor of Molecular Nutrition and Associate Head of School, Pharmacy & Life Sciences, The Robert Gordon University, Aberdeen

**Professor Paul Fraser** (Molecular Biologist)

School of Biological Sciences at Royal Holloway University

**Professor Susan Fairweather-Tait** BSc, MSc, PhD, DSc Hon FNS (Nutritionist)

Professor of Human Nutrition, Norwich Medical School, University of East Anglia

**Dr Hamid Ghoddusi** BSc, MSc, PhD (Food Scientist & Microbiologist)

Head of the Microbiology Research Unit at the London Metropolitan University.

**Professor Wendy Harwood** (Crop Genetics)

Head of Crop Transformation Group at John Innes Centre, Norwich

**Professor Huw Jones** (Translational Genomics)

Chair in Translational Genomics for plant breeding, Aberystwyth University.

**Ms Nichola Lund** LLB (Consumer Affairs Representative)

Food Safety Officer with the London Borough of Enfield.

**Dr Rohini Manuel** MB BCH BAO, MSc, MD, FRCPath (Microbiologist and Mycologist)

Consultant Medical Microbiologist at the Public Health Laboratory London, National Infection Service, Public Health England.

**Mrs Rebecca McKenzie** BSc, MSc (Allergy Dietician)

Senior Specialist Dietician in Allergy, University College London Hospitals NHS Foundation Trust, London.

**Professor Harry McArdle** BSc, PhD (Nutritionist)

Emeritus Professor of Biomedical Sciences at the Rowett Institute of Nutrition and Health, University of Aberdeen. Honorary Professor of Biological Sciences, Nottingham University.

**Dr Elizabeth Lund** PhD (Nutritionist and Ethicist)

Independent consultant in Research Ethics and Nutritional Study Design.

Vice-Chair of West London Gene Therapy Advisory Committee and Research Ethics Committee

**Dr David J Mela** PhD (Nutritionist)

Registered Nutritionist (Nutrition Science, Public Health), and Fellow of the Association for Nutrition.

**Professor Clare Mills** BSc, PhD (Plant Science and Allergy Expert)

Professor of Molecular Allergology, at the Manchester Institute of Biotechnology, and Division of Infection, Immunity and Respiratory Medicine, School of Biological Sciences, University of Manchester.

**Dr Lesley Stanley MA (Oxon)** PhD ERT FBTS (Toxicologist)

An independent consultant in biomedical science and investigative toxicology.

**Professor Hans Verhagen** PhD (Toxicologist and Nutritionist)

Independent consultant in Food Safety and Nutrition, Board-Certified Toxicologist and Nutritionist.

Visiting Professor at the University of Ulster and The Technical University of Denmark

**Dr Maureen Wakefield, FERA Science Ltd.** (Entomologist)

Head of Science at Fera Science Ltd.

**FSA Assessor**

**Dr Paul Tossell** – Team leader Regulated Products 1 Branch

**Observers from the Devolved Administrations**

Mr Adam McDowell – Food Standards Agency (Wales)

Ms Alexia Sully Karlis - Food Standards Agency (Wales)

Ms Siobhan Watts – Food Standards Scotland

Ms Georgina Finch – Food Standards Scotland

Ms Krystle Boss – Food Standards Scotland

Ms Karen Pearson - Food Standards Scotland

Ms Marianne James - Food Standards Scotland

Mr Will Munro - Food Standards Scotland

Ms Kerry Gribbin – Food Standards Agency (Northern Ireland)

Richard Annett – Food Standards Agency (Northern Ireland)

## **ACNFP Members' Interests during 2021**

In common with other independent advisory committees the ACNFP is publishing a list of its members' commercial interests. These are managed in line with Agency guidelines on handling of conflicts of interest revised in 2019. 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 2021 can be found on the ACNFP website.

## **Code of Conduct**

## **A code of conduct for members of the Advisory Committee on Novel Foods and Processes (ACNFP)**

### **Public service values**

All members must:

- Follow the guidance on the [Seven Principles of Public Life](#), these being selflessness, integrity, objectivity, accountability, openness, honesty and leadership.
- 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.
- 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 councillors, or to Peers in relation to their conduct in the House of Lords.

### **The role of the ACNFP Chair**

The Chair is responsible for:

- Providing effective leadership on the issues within the Committees terms of reference.

- Ensuring that the Committee meets at appropriate intervals and that the minutes of meetings and any reports to the Board of the Food Standards Agency accurately record the decisions taken and, where appropriate, the views of individual members.
- Representing the views of the Committee to the general public.
- Ensuring that new members are briefed 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.
- Ensure that every member of the Committee is heard and that no view is ignored or overlooked.
- Ensure unorthodox and contrary scientific views are given a fair hearing.
- Ensure that any significant diversity of opinion among the members of the Committee is accurately reflected in the report and in any other communications with the FSA.
- Advise on matters relating to FSA science as required by the FSA on an ad hoc basis or in emergencies.
- Engage with the wider networks of relevant experts including with the Chairs of SACs relevant to the FSA's work.

## **Role of Committee Members**

- Members are appointed as individuals to fulfil their role respective to the ACNFP.
- Members are not a representative of their profession, employer or interest group and have a duty to act in the public interest.
- If a member declares an organisation's view rather than a personal view, they should make it clear at the time

## **Members have collective responsibility for the operation of this Committee.**

They must:

- Engage fully in collective consideration of the issues, taking
- 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 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.
- Ensure that the Committee does not exceed its powers or functions.
- Members are free to question and comment on the information provided or the views expressed by any of the other members.
- Individual members should inform the Chair (or the Secretariat on his or her behalf) if they are invited to speak in public in their capacity as a committee member.
- A member's role on the Committee should not be limited by the expertise or viewpoint she or he was asked to bring to it. Any statement/report belongs to the whole Committee. Members should regard themselves free to question and comment on the information provided or the views expressed by any of the other members, even though the views or information provided do not relate to their own area of expertise.
- If members believe the committee's method of working is not rigorous or thorough enough, they have the right to ask that any remaining concerns they have be put on the record
- Communications between the Committee and the Board of the Food Standards Agency will generally be through the Chair; 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 Food Standards Agency 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 Food Standards Agency, if they fail to perform the duties required of them in line with the standards expected in public office.

## **Communications with the FSA Board, Chief Scientific Adviser and Executive**

- The Advisory Committee on Novel Foods and Processes works in collaboration with several other Committees where the topics under consideration would benefit from expert advice from other Committees. These include, but are not limited to:
- The FSA's Science Council.

- The Committee on Toxicity of Food, Consumer Products and the Environment (COT).
- The Committee on Carcinogenicity of Food, Consumer Products and the Environment (COC).
- The Committee on Mutagenicity of Food, Consumer Products and the Environment (COM).
- Communications between the ACNFP and the Board of the Food Standards Agency will generally be through the Chair except where the ACNFP has agreed that an individual member should act on its behalf. Nevertheless, any Member has the right of access to the Board of the Food Standards Agency on any matter that he or she believes raises important issues relating to his or her duties as an ACNFP Member. In such cases the agreement of the rest of the ACNFP should normally be sought.
- Similarly, communications between the ACNFP and the FSA Executive will generally be through the ACNFP Secretariat although the ACNFP Chair has the right of access to the FSA Chief Scientific Adviser and Deputy CSA at all times.
- Any member also has the right of access to the FSA Chief Scientific Adviser on any matter which he or she believes raises important issues relating to his or her duties as a member. In such cases the agreement of the ACNFP Chair should normally be sought.

## **Declaration of Interests and management of conflicts**

- As an independent, open and transparent advisory body the ACNFP's members must provide clear declarations of interests. The full guidance on declaration of interests for SACs should be consulted by all members, however a summary is provided below.
- Not all interests are necessarily ones that will cause conflict with a member's work with the ACNFP. Interests that may be seen to have relevance to their role (either personal, non-personal or those of family/friends) or the specific topics under discussion at a ACNFP meeting should be declared so the Secretariat can make an assessment of whether it could be considered a potential conflict of interests and what action may be needed in response.
- 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.
- The Secretariat maintains a register of interests for each member that is updated and published online regularly. The register of interests should contain current or previous interests (including things like employment, consultancies, memberships, investments or other personal interests) that may, in general, be seen to directly affect the perceived independence of the member or benefit from information gained whilst acting as a ACNFP member (that is not already public).
- The register of interests should be kept up-to-date and be open to the public.
- At the start of the meeting the Chair should ask members to declare any interests potentially relevant to the items under discussion relating to themselves or their close family members.
- Based on this information, the Chair will consult with Secretariat, FSA staff and potentially other SAC members, and decide on an approach to managing the interest.
- In the case of interests declared by the Chair, the same process will apply as to when there is an absence of the chair; the relevant FSA staff are responsible for deciding whether an interest is a conflict and if so, how it should be managed. FSA staff may also request input from other ACNFP members on appropriate action.
- The interests declared, and the chosen action should be recorded in the minutes of the meeting with the rationale for this decision.

## **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.

## **Openness and publication of documents - general principles**

- The Committee operates to the standards of openness and transparency. It will work in accordance with guidelines by the FSA and relevant guidance and rules established across Government. These include:

1. [The cross-Government Code of Practice for Scientific Advisory Committees \(CoPSAC\)](#), which includes the
2. Principles of Scientific Advice to Government
3. The FSA's Good Practice Guidelines for SACs
4. The provisions under the [Freedom of Information Act 2000 \(the Act\)](#).
5. Committee meeting agendas, papers, minutes and reports are published. While meetings are not open to the public as standard, open events are held regularly to provide public input into the work of the Committee
6. The Committee publishes an annual report.

## **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 organizations 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 organizations 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 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 and the Principles of Scientific Advice to Government 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) (since replaced by the Science Council (SC)).

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

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

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

Science Council

Advisory Committee for Social Science

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, the SC 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 the principles set out below will be applicable to all 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.

## **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 a 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 to the FSA if discussion suggests that further iteration and discussion of the task is necessary. Where a 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

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.

A role of the ACNFP in 2021 was to assess notifications for traditional foods from third countries. due to commercial sensitivities the Committee cannot discuss the documents in public. However, traditional food summaries of novel food notifications are produced by the Secretariat and cleared by the Committee which then go through a 10-day public consultation process.

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. Yes

The ACNFP periodically holds an open event, which allows Members to discuss relevant topics with members of the public as occurred in February 2018.

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, with the assistance of the Secretariat also seeks further information and advice from other Committees or individual experts where required.

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

The Secretariat and Committee critically review the methods and statistical treatments used in dossiers and ensure that this is considered in evaluating the contribution the data provides to the assessment.

## 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

For complex statistical questions the Secretariat can consult with specialists within the FSA.

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. Yes - Where relevant

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

Evaluations of novel foods are mainly based on evidence provided by the applicant, including unpublished studies and commercially sensitive information about manufacturing processes. As this information is requirements in the respective legislation there are limitations on the information that can be placed in the public domain.

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

Novel food application dossiers include a list of references which make it clear whether they have been peer reviewed

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

## 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

The Committee's assessment focuses on safety, 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.

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

ACNFP complies with this – uncertainties and interpretations are identified clearly in the Committees opinions.

## Drawing conclusions

18. The SAC will be broad-minded, acknowledging where conflicting views exist and considering whether alternative interpretations fit the same evidence. Yes

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

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 uncertainty associated with it. Yes

22. SACs will make recommendations about general issues that may have relevance for other committees. Yes

### **Communicating SAC's 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 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 issues within their committees' remits, in advance of discussion at open Board meetings.

N/A

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 £67,422.80.