Report

Annual Report 2022

Foreword

Dear Reader,

I am delighted to present the 2022 Annual Report of the Advisory Committee on Novel Foods and Processes (ACNFP). This report summarises the work of the ACNFP from January to December 2022 as part of the FSA regulated products process. This year has seen the ACNFP continuing to review the safety of a range of novel food and GM products at the forefront of food innovation.

It has also been an unprecedented year, as we began to consider the options for the UK's technical assessment of precision bred organisms (PBOs) as defined in the new Genetic Technology (Precision Breeding) Bill going through parliament in 2022-2023. The ACNFP along with its dedicated subcommittee on Products of Genetic Technologies (PGT) have published an initial statement on the issue in November 2022. This outlines the thinking behind the work of the ACNFP in developing an approach to review applications for PBOs. This will continue to be a key area for the ACNFP in 2023, as the Bill is expected to become the Genetic Technology (Precision Breeding) Act.

A significant and challenging area of work has been on the safety of novel food ingredients containing cannabidiol (CBD). Preparatory work in 2021 and 2022 enabled the ACNFP to consider the existing safety 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 2022, following the FSA call for evidence in 2021, new safety data on CBD in food became available for review. To support evaluation of the new toxicological information, a joint ACNFP and Committee on Toxicity (COT) subgroup on CBD and hemp derived products was formed. Their work to review new CBD evidence took place throughout 2022 and will continue into 2023 and beyond. The work begins with a review on data for >98% pure CBD .

The strength of the ACNFP continues to be the multi-disciplinary membership and the range of expertise being brought to the applications and issues under

consideration. I would like to thank the members and the FSA secretariat for their continued diligence, professionalism and flexibility in dealing with the large volume of work in 2022 and a wide range of applications. We look forward to a significant programme of work in 2023, continuing with the assessment of CBD and cannabinoids, GM foods, PBOs and other novel foods to support the FSA in its role of assessing the safety and integrity of UK food innovation.

Dr Camilla Alexander-White

September 2023

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. 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 2022, 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, endeavors 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 2022, the primary role of the ACNFP has been to provide scientific advice to FSA and FSS on novel foods and Genetically Modified Organisms applications considered under the regulated products process and for which scientific and technical advice is requested.

New novel food applications - The ACNFP carried out the review process for eleven novel foods dossiers, some of which commenced assessments in 2021 progressing to the first drafts for Committee advice in 2022. 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 2023 for these products as information is provided. Whilst the committee's remit is firmly in providing advice on the technical risk assessments, the risk context is also considered, and advisory comments can and are made to risk managers that are pertinent to the use of the technical advice in the novel food product and how it is anticipated to be used by consumers.

Traditional Foods from Third Countries - The Committee completed two reviews of notifications 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 - A major area of work on novel foods was the reviewing of submissions for cannabidiol (CBD) containing ingredients and the formation of a joint ACNFP/COT subgroup which aims to focus on assessing the significant volume of available toxicology data for these novel foods. This is a clearly defined area of FSA policy.

In 2021 and 2022, 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. In addition to this, the ACNFP along with the Committee on Toxicity (COT) agreed the formulation of a joint subgroup on CBD, cannabinoids and hemp derived products. 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 and allow the subgroup to tackle the toxicological datasets that have been provided.

Following its formation in 2022 the subgroup has held 3 meetings. Beginning their consideration of the additional datasets based on the composition of the ingredients subject to the toxicological testing. The first phase of work has focused on >98% pure form CBD. This work on CBD, cannabinoids and hemp will continue into 2023 as a major strand of work for the subgroup and then the ACNFP in the regulatory review of applications.

The final major area of work is to develop an assessment framework for Precision Bred organisms (PBOs). A first ACNFP statement was published in November 2022, drawing upon the work of the new ACNFP Subcommittee on Products of

Genetic Technologies (PGT). The statement concludes that many products of precision breeding will be similar in risk profile to their traditionally bred counterparts, where the level of risk has to date been accepted under the processes of industry due diligence and General Food Law. Some products produced through traditional breeding can also have risks regarding, for example, modification of antinutritional factors or alteration of the allergenic potential. A two-tier approach to the review of PBOs was supported by the ACNFP but further work was needed to develop the approach for technical safety assessment and the data needed to support the review. This will be a key workstream for the Subcommittee and ACNFP in 2023.

Further detail on the work of the Committee in 2022 is detailed below.

2. Novel Food Applications

In 2022, the ACNFP carried out assessment of eleven 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 2022

Application	Reference Number	Meeting	Committee's Response

Mung Bean Protein	RP32	March and June 2022	• This new novel food was considered by the Committee for the first time at the April 2021. • The application continued to have data gaps and further information was sought from the applicant. • The dossier continues to be under review.
Barley Rice Protein	RP19	February, June, September and November 2022	• This new protein application was considered for the first time in April 2021. • The application continued to have data gaps. Further information was sought on these aspects from the applicant. • The dossier continues to be under review.
Calcidiol	RP 35	June 2022	• This application was reviewed for the first time in June 2021. • Data gaps were identified and further information on these aspects was sought from the applicant. • The dossier continues to be under review.

Cetylated Fatty Acids	RP200	June, September and November 2022	• This application proposed as a food supplement was reviewed by the Committee for the first time in November 2021. • Following the review, members requested clarification on the manufacturing process and ADME with a request for further information sent to the applicant. • The dossier continues to be under review.
Lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2' FL) mixture (LNFP-I/2'-FL)	RP 549	June	• This new novel food, a source of human identical milk oligosaccharides, was considered by the Committee for the first time in June 2022. The application had data gaps with further information sought from the applicant. • The dossier continues to be under review with a draft Committee Advice output to be considered in early 2023.

3-Fucosyllactose	RP 1202	June 2022	• This new novel food, also a source of human identical milk oligosaccharides, was considered by the Committee for the first time in June 2022. The application had data gaps with further information sought from the applicant. • The dossier continues to be under review, with a draft Committee Advice output to be considered by the Committee in early 2023.
Magnesium L-Threonate	RP 956	September and November 2022	• This new novel food proposed to be used as a food supplement was considered for the first time in September 2022. • Data gaps were identified, and further information requested from the applicant. • The dossier continues to be under review.

3. Traditional Food Applications

In 2022, two ‘traditional foods from third countries’ notifications were validated under Regulation (EU) 2015/2283 and passed on to the ACNFP Committee for review. These notifications were for Bambara groundnut and *Tetradenia riparia*. The notifications were assessed by the ACNFP 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 2.

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 2022

Application	Meeting	Outcome	Committee's Response
Bambara Groundnut RP 1086	March 2022	Advice Provided to Food Policy – Currently not Authorised in the UK due to reasoned safety objections raised by the Food Safety Authority.	• The Committee identified several areas where further information would be needed to complete an assessment and therefore could not reach a conclusion based on the evidence provided. • Their advice was passed to risk managers to decide on whether to raise reasoned safety objections and trigger the second stage of the 'traditional food from third country' process.
Tetradenia riparia RP 1500	June 2022	Advice Provided to Food Policy – Currently not Authorised in the UK due to reasoned safety objections raised by the Food Safety Authority.	• The Committee identified several areas where further information would be needed to complete an assessment and therefore could not reach a conclusion based on the evidence provided. • 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.

4. The ACNFP subcommittee’s work

a) Products of Genetic Technologies (PGT) Subcommittee

Dr Andy Greenfield was appointed Chair of the PGT Subcommittee by ACNFP at their June 2022 meeting; the Subcommittee had four virtual and one face to face meeting in 2022. Work was required with urgency to support the development of the Genetic Technology (Precision Breeding) Bill. It was noted that at the first meeting held on 22 July 2022, links were established with Defra and ACRE (Advisory Committee on Release in the Environment) for whom a representative was invited to attend future meetings. In the following meetings, the Subcommittee completed their expertise by co-opting a Member of ACRE to provide ACRE’s perspective on discussed products, and a Veterinary nutritionist to support discussions on feeds.

FSA Policy has requested ACNFP to provide scientific advice to inform the development of the assessment approach, including outline principles and a possible two-tiered approach, to the safety assessment of Precision Bred Organisms (PBOs); this Subcommittee held a series of independent workshops, reconvening on a regular basis with the main ACNFP for the reviewing of their conclusions (Table 3):

- The Subcommittee discussed the risks which could arise from hazards they identified in possible examples of PBOs based on published scientific literature (case studies). Their conclusion in relation to a tiered approach to the assessment of the safety of PBOs was presented in a workshop with ACNFP (September 2022), and an ACNFP Statement was published on the ACNFP Website in November 2022 supporting, in principle, a two-tiered approach to a food and feed safety assessment for PBOs.
- The Subcommittee identified possible triggers to further reviewing and assessing PBOs, based on possible risks arising in PBOs as identified from new case studies; following a workshop with the main ACNFP (November 2022), the Subcommittee supported the assessment Tiers in a draft statement.

Table 3. Reserved Business Workshops on Precision breeding framework held in 2022

Meeting	Topic	Reference

July	Introduction to the work on PBOs	PGT/1/04
August	Potential risks arising in PBOs for food and feed (case studies) Scientific criteria and structure for both Tier 1 and 2	PGT/2/01
September	**Report to and Discussion with ACNFP**	**ACNFP /154/06**
October	Potential risks arising in PBOs for food and feed (case studies)	PGT/3/01
	Options for developing the framework for review of PBOs	PGT/3/02
	Scientific criteria for the tiered approach to the review of PBOs	PGT/3/03
November (16th)	**Report to and Discussion with ACNFP**	**ACNFP /155/02**
November (21st)	Review of ACNFP key conclusions	PGT/4/01
	Models for a tiered approach to the risk assessment of PBOs	PGT/4/02
December	Triggers to Tier 2 assessment of PBOs	PGT/5/01
	Models for a tiered approach to the risk assessment of PBOs	PGT/5/02

The Subcommittee also reviewed three applications for renewal of GMO authorisation (Table 4); no data gaps were identified in light of the Subcommittee’s expertise and draft opinions for the authorisation of these

applications were agreed by the Subcommittee to be escalated for review by the full ACNFP Committee.

Table 4. Genetically Modified Organisms (GMO) applications considered by the Subcommittee during 2022 (Reserved Business)

Application	Reference Number	Meeting	Subcommittee's Response
Genetically modified A5547-127 soybean for food and feed uses (renewal)	RP188	July and October 2022	• This renewal was considered for the first time in July 2022 • No data gaps were identified • A draft Opinion was prepared and agreed to be presented to ACNFP
Genetically modified 40-3-2 soybean for foods and food ingredients, animal feed, and products other than food (renewal)	RP212	July and October 2022	• This renewal was considered for the first time in July • No data gaps were identified • A draft Opinion was prepared and agreed, to be presented to ACNFP

Genetically modified MIR162 maize for food and feed uses RP652 (renewal)	July and October 2022	• This renewal was considered for the first time in July • No data gaps were identified • A draft Opinion was prepared and agreed, to be presented to ACNFP

b) Joint ACNFP and COT subgroup on CBD, cannabinoids and hemp derived products

The joint subgroup was established in July 2022 to ensure a robust and harmonised review of the new toxicological data supplied to support novel food applications for CBD ingredients. The group's remit includes consideration of:

- Review of the submitted toxicology studies to determine whether they are of an appropriate quality, including use of an appropriate test substance to support the novel food application;
- Review of the toxicology data to understand whether there is sufficient data to set safe upper intake levels for CBD-containing ingredients;
- Consideration of the evidence for the safety of other cannabinoids as a contaminant in foods.

The group held 3 meetings in 2022, beginning the review of data with >98% pure CBD ingredients (Table 5). Outputs from the group will be subject to review and agreement by both the COT and ACNFP before publication of joint statements.

Table 5. Initial reviews of pure form CBD (>98% purity) application data considered by the Subcommittee during 2022 (Reserved Business)

Meeting	Topic	Reference
27 July 2022	Introduction to the toxicological information submitted on ingredients with >98% pure CBD under the novel foods regulation.	CBD01/22

28 September 2022	Initial review of the toxicological information submitted on ingredients with >98% pure CBD under the novel foods regulation.	CBD02/22
30 November 2022	Initial review of toxicological data submitted for CBD by a consortium of applicants	CBD03/22

5. Other Issues

a) Ways of Working

In 2022 the ACNFP was consulted on several topics relating to the scientific work of the FSA and how this is managed (Table 6). Topics included: FSA's approach to the evaluation of Cannabidiol (CBD), further develop documents and processes to support the FSA's future work on regulated products, as well as governance processes such as the annual report and proposal for a subgroup to consider issues of CBD products.

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 6: Other Issues

Topic	Meeting	Committee's Response
Proposal for a subgroup of the ACNFP and COT to consider cross cutting issues of CBD products	March 2022	Following discussions on the need for a different approach to considering the cross cutting issues within the CBD dossiers, the Committee were requested for their agreement for the formation of a subgroup, their input on terms of reference as well as expression of interest in joining the subgroup.
Annual report 2021	June and November 2022	The Committee reviewed the annual report draft in June with a final agreement made in November for the ACNFP's work in 2021.

Approach to opinions for novel foods under assessment in the UK	June 2022	As the Committee would be reviewing its first assessments since the UK's departure from the EU, a paper was reviewed to support discussions aiding consideration of the style, approach, level of detail and consistency required for the committee's advice documents across novel food applications.
Introduction to the work on Net Zero Carbon and Food Safety by the Science Council	June 2022	The UK has a legal commitment to reach net zero carbon (NZC) emissions by 2050. The Science Council's member observer presented to the Committee the Council's work on Food Safety and Net Zero Carbon highlighting a number of areas that would be relevant in their future assessments including use of insects and alternative protein as a source of novel foods.

b) Reserved Business Items

A number of items were considered under reserved business in 2022 (Table 7). 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, final outputs will be placed in the public domain in due course.

Table 7: Items considered under reserved business

Application	Meeting	Committee's Response
Cannabidiol (CBD) dossier – RP70	Feb 2022	The Committee were invited to consider whether the available data provided a satisfactory basis for evaluating the safety for this application; synthetic CBD produced via chemical reaction as an ingredient for a range of foods.

Cannabidiol (CBD) dossier – RP85	Feb 2022	The Committee considered whether the available data provided a satisfactory basis for evaluating the safety for this application; synthetic CBD produced via solvent extraction from *Cannabis sativa* (Hemp) biomass as an ingredient for a range of foods.
Cannabidiol (CBD) dossier – RP07	March 2022	The Committee were invited to review a CBD dossier on further information provided to evaluate toxicology, ADME and production process so as to assess if this information was adequate for a safety evaluation and if further information was required.
Cannabidiol (CBD) dossier – RP793	March 2022	The Committee were invited to consider whether the available data was satisfactory basis for evaluating the safety for this application; synthetic CBD produced via solvent extraction from *Cannabis sativa* (Hemp) biomass as an ingredient for a range of foods.
GE work timeline for ACNFP subcommittee	March 2022	The Committee's advice was sought to develop criteria to inform a new regulatory framework for the authorisation and marketing of genome edited food and feed.

Workshop on PBOs	September and November 2022	• The purpose of the workshop in September was for the ACNFP to review the high-level criteria that could technically underpin a tiered approach to the assessment for PBOs as proposed by the FSA. The ACNFP prepared a final statement to support the strategic decision to develop a two-tier approach. • In November, a workshop was held for the ACNFP to review the work of the Subcommittee on the potential food and feed risks identified from case studies to help further develop models for operating a two-tier assessment approach.
Approach to assessment of solvent use for CBD applications	November 2022	Due to applicants reporting the use of solvents such as such as hexane, heptane and pentane in the production process of the novel ingredient, the Committee’s input was sought on what data would be required to demonstrate sufficient safety of any residues in the final product.

6. 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 2022

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 2022, 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)***

Lead Policy Advisor in Chemical Policy, Royal Society of Chemistry.

Director MKTox & Co Ltd – independent chemical safety assessor.

Also the Co-Chair of the CBD Subgroup.

Members

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

Currently a director of A & M Alldrick Ltd, providing consultancy services to the agri-food sector.

Mrs Alison Austin (Consumer Needs Representative)

Independent consultant Environmental, Social and Governance Strategy Development. Non-Executive Director of the Consumer Council for Water.

Also a member of the CBD Subgroup.

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)

Head of Plant Molecular Sciences, Royal Holloway University of London.

Also Member of PGT Subcommittee.

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.

Also Member of PGT Subcommittee.

Professor Huw Jones (Translational Genomics)

Chair in Translational Genomics for plant breeding, Aberystwyth University.

Also Member of PGT Subcommittee.

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.

Also Member of PGT Subcommittee.

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 and School of Biosciences, University of Surrey, Guildford.

Also Member PGT Subcommittee.

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

An independent consultant in biomedical science and investigative toxicology.

Also a member of the CBD Subgroup.

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.

Also Member of PGT Subcommittee.

Dr Maureen Wakefield, FERA Science Ltd. (Entomologist)

Principal Scientist at Fera Science Ltd.

Dr Ray Kemp (Consumer Representative)

Member of the Department of Business, Energy and Industrial Strategy’s Committee on Radioactive Waste Management (CoRWM), providing independent scrutiny and advice to the UK governments on the long-term management of higher activity radioactive wastes.

Also Member of PGT Subcommittee.

Dr Andy Greenfield (Genetics; Animals)

Member of the Regulatory Horizons Council (RHC), the Human Tissue Authority (HTA) and an honorary research fellow at the Nuffield Department of Women's & Reproductive Health, University of Oxford.

Also Chair of PGT Subcommittee.

Professor Bruce Whitelaw (Genetics; Animals)

He holds the Chair of Animal Biotechnology at the University of Edinburgh and is the Director of The Roslin Institute. He currently focusses on genome editing technology and animal stem cells, aiming to advance novel applications for the agricultural and biomedical communities.

Also Member of PGT Subcommittee.

Professor Dimitris Charalampopoulos (Fermentation Specialist)

Professor of Food Biotechnology at the University of Reading. Co-Director of the BBSRC Biomass Biorefinery Network (BBNet) and Senior Editor of the journal Food Chemistry.

Co-opted Members of the PGT Subcommittee

Professor Pete Lund (*ex officio* member, ACRE representative)

Professor Alastair Macrae (veterinary surgeon)

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)

Mr Andrew Dodd - Food Standards Agency (Wales)

Mr Xose Álvarez - 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

Mr Stephen Hendry - Food Standards Scotland

Ms Svetlozara Chobanova - Food Standards Scotland

Ms Tamara Satmarean - Food Standards Scotland

Joshua Evans – Food Standards Scotland

Lori Hanlon – Food Standards Scotland

Lucy Smythe - Food Standards Scotland

Dr Karen Pearson - Food Standards Scotland

Richard Annett – Food Standards Agency (Northern Ireland)

Ms Sharon Gilmore - Food Standards Agency (Northern Ireland)

Ms Nuala Meehan - Food Standards Agency (Northern Ireland)

Colleen Mulrine - Food Standards Agency (Northern Ireland)

Mr Ciaran Weir - Food Standards Agency (Northern Ireland)

ACNFP Members' Interest during 2022

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 2022 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.
- 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 were **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.	Yes	A role of the ACNFP in 2022 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. This has been reflected in the joint sub group on CBD and hemp derived ingredients.
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 £92,545.00.