

Annual Report 2023

Dear Reader,

I am delighted to present the 2023 Annual Report of the Advisory Committee on Novel Foods and Processes (ACNFP). This report summarises the work of the ACNFP from January to December 2023 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, and in world-leading areas.

2023 has seen significant progress towards the use of precision bred organisms (PBOs) in food and feed, following the Royal Assent of the Genetic Technology (Precision Breeding) Act on 23 March 2023. Discussions at the FSA board, commensurate with the world-leading approach being taken on PBOs, were informed by the publication of the ACNFP PBO statement in September 2023, supporting a tiered approach to safety evaluation. A significant amount of work of a challenging nature was completed by the ACNFP, and especially its Products of Genetic Technologies (PGT) expert sub-committee, to advise on the types of data that would be important for safety evaluation. The preparation of FSA technical guidance will continue to be a key area for the ACNFP to develop and provide advice on in 2024.

Another world-leading area of novel foods is the FSA's ongoing programme on the safety of cannabidiol (CBD) containing foods. The review of the technical data has been a significant and challenging area of work for the ACNFP, which merited the establishment of a specific joint ACNFP and Committee on Toxicity (COT) subgroup on CBD and hemp derived products. Preparatory and technical work began in 2022. In 2023, reviewing the data for pure >98% CBD as a novel food ingredient, allowed for the publication of a provisional Acceptable Daily Intake (ADI) of 10 mg/day in consumer advice in October 2023. This work led to a world first in establishing such advice. The publication of the provisional ADI for pure CBD will now provide a basis for the evaluation of applicants' dossiers on CBD-containing products in 2024. We look forward to the sub-group continuing with the work on ingredients containing a range of cannabinoids and hemp extracts in the months ahead.

This year has seen the publication of the first ACNFP Committee Advice Documents (CADs) for novel food applications to the UK. This is a significant milestone for UK novel foods post EU-exit and marks a meaningful step forward to ensure that consumers can access innovative products and be confident in their safety.

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 sincerely thank the members and the FSA secretariat for their continued diligence, professionalism and flexibility in dealing with the ever-increasing volume of work in 2023, of a high technical level, to high quality under time pressure. We look forward to a significant programme of work in 2024, supporting the FSA in its role of assessing the safety and integrity of UK food innovation.

Dr Camilla Alexander-White, Chair of the ACNFP.

June 2024

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 2023, the work of the ACNFP as the science advisory committee (SAC) for novel foods and processes, including for the products of genetic technologies, continued to increase.

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 characterisation of risk and uncertainty 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 2023, 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 eighteen novel foods dossiers, some of which commenced assessments in 2021 progressing to the first drafts for Committee advice in 2022 and the first publications of these in 2023. 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.

Alison Austin

“As a lay representative for consumers, I welcome the publication of the first ACNFP committee advice documents in 2023, and that the advice of the committee is not just informing the authorisation of novel foods but provides transparency by being available for all to see. Consumer safety is at the centre of all the work carried out by the committee, ensuring public confidence about consumption of the innovative products assessed and approved by the committee. I have also worked with my academic colleagues on the committee to ensure that the committee advice documents use accessible language and keep acronyms to a minimum. A glossary is now a standard feature so that when complex scientific language is required it remains approachable to anybody interested in following up in more detail.

A major concern for the committee has been allergenicity, specifically applicants request to use novel and innovative ingredients in 'unexpected' categories of foods. This has led to extensive consideration of the proposed uses for novel foods under assessment and the potential implications for allergic consumers. Due to the complex, interwoven nature of these assessments the discussions of the committee can stray beyond risk assessment into risk management, which we recognise is outside our remit. However, though the formal committee advice documents remain strictly risk assessment opinions, our views on managing risks are documented and passed on by the secretariat to risk managers to ensure they are considered in the final authorisation decision. “

Assessments by the Committee are tailored to the nature of the products and the risks posed by their proposed uses when 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 2024 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.

Rebecca McKenzie RD MSc

“Every novel food application assessed by the ACNFP includes a safety assessment of allergenicity.

Consideration of our allergic population is at the forefront of all assessments. Not just for those whose allergies fall under the umbrella of the 14 allergens required to be labelled, but also for those whose allergies fall outside this legislation. As the world looks to alternative protein sources to sustainably feed an ever-growing population, two categories of allergens have stood out.

1. Legume allergy is of concern as more applications are received for alternative protein sources from plants. Legislation currently only considers sensitization to peanuts, soy and lupin, but other legume allergies are on the rise and presenting in clinics (e.g. to peas, chickpeas, beans, lentils, fenugreek).

2. Another alternative protein source comes from edible insects. As there is cross-sensitization between house dust mites, insects, and shellfish, it is especially important to consider which food sources these products are approved for. For example, some applicants have proposed their products be included in food items where insects/shellfish would not be expected (e.g. breads and pastries). This would pose a risk to consumers with shellfish allergy and hence was flagged to risk managers.

Assessment of de novo allergens is difficult. It is hard to predict whether a new food on the market will cause sensitization or cross-react with known allergens. To address this, a workshop on de novo sensitisation was discussed and was held in February 2024.”

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 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 continuation of the work of the joint ACNFP/Committee on Toxicity (COT) subgroup. The

workstream aims to efficiently review and assess the significant volume of available toxicology data for these novel foods. This is a clearly defined area of [FSA policy](#).

In 2023, drawing upon the work of the Subgroup, the ACNFP along with the Committee on Toxicity (COT) agreed a joint statement on CBD of $\geq 98\%$ purity, establishing a provisional acceptable daily intake (ADI) of 0.015mg/kg bw/day or 10mg/day for a healthy adult of 70kg. This has provided a basis for updated consumer advice on the safety of CBD published in October 2023.

It has also provided a framework for the assessment of novel food applications with $>98\%$ pure CBD as an ingredient. Working through the many CBD product applications will form a significant part of the work of the Committee in 2024 as the non-toxicological aspects of the dossiers are reviewed. The Subgroup consideration moved to the next group of applications and identification of a proportionate assessment approach for CBD ingredients with a range of cannabinoids present. This is a technically challenging area of work given many of these ingredients do not appear to have been fully characterised by standard analytical methods.

Precision Bred Organisms (PBOs) - The final major area of work is to finalise a safety assessment framework for Precision Bred organisms (PBOs). The first ACNFP statement was published in November 2022, drawing upon the work of the new ACNFP Subcommittee on Products of Genetic Technologies (PGT). Building on this the ACNFP produced a draft statement supporting a two-tier approach for the review of PBOs, which was published on the ACNFP website in September 2023 and informed the FSA board discussion in September 2023 on the new regulatory framework for precision bred organisms used for food and animal feed

Further detail on the work of the Committee in 2023 can be found below.

2. Novel Food Applications

In 2023, the ACNFP carried out assessment of eighteen 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 the main sessions are detailed in Table 1, below. The dossiers for CBD and PGT 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 2023

Application	Reference Number	Meeting	Committee's Response
Lacto-N-fucopentaose I and 2'-fucosyllactose (LNFP-I & 2'-FL)	RP549	February and April	• This novel food was first reviewed by the committee in June 2022. • The Committee sought further information from the applicant to address data gaps. • Following these updates the assessment was finalised for publication. In August 2023 it was published and moved to risk management.
3'-Fucosyllactose (3'-FL)	RP1202	February	• This novel food was first reviewed by the Committee in June 2022. • The Committee sought further information from the applicant to address data gaps. • Following these updates the assessment was finalised for publication. In August 2023 it was published and moved to risk management.

Application	Reference Number	Meeting	Committee's Response
Calcidiol	RP35	February and April	• This novel food was first reviewed by the Committee in June 2021 • Further discussion was had on the data provided. Following these updates the assessment was finalised for publication. In April 2024 it was published and moved to risk management.
Isomalto-oligosaccharides (IMO)	RP1033	February, June and November	• This novel food extension of use was introduced to the Committee in February 2023 • The Committee sought further information from the applicant to address data gaps. • Following these updates the assessment was finalised for publication. In March 2024 it was published and moved to risk management.
Corn Protein	RP1238	February, April and September	• This novel food was introduced to the Committee in February 2023. • The Committee sought further information from the applicant to address ongoing data gaps. The dossier continues to be under review.

Application	Reference Number	Meeting	Committee's Response
Krill Protein Hydrolysate	RP1290	February	• This novel food was introduced to the Committee in February 2023. • The Committee sought further information from the applicant to address data gaps and agreed to review the toxicological and ADME evidence in more detail • The dossier continues to be under review.
<i>Schizochytrium</i> sp. Oil	RP1411	February and September	• This novel food was introduced to the Committee in February 2023. • The Committee sought further information from the applicant to address data gaps. • Following these updates the assessment was finalised for publication. In April 2024 it was published and moved to risk management.

Application	Reference Number	Meeting	Committee's Response
<i>Mycobacterium aurum</i>	RP1046	February	• This novel food was introduced to the Committee in February 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review.
Cellobiose	RP1109	February and September	• This novel food was introduced to the Committee in February 2023. • The committee sought further information from the applicant to address data gaps. • The dossier completed its Committee review and is being finalised for publication.

Application	Reference Number	Meeting	Committee's Response
Magnesium-L-threonate	RP956	April, September and November	• This novel food was first reviewed by the Committee in September 2022. • The Committee sought further information from the applicant to address data gaps. • Following these updates the assessment was finalised for publication. In March 2024 it was published and moved to risk management.
Olive fruit dry extract standardized in hydroxytyrosol	RP1074	April, September and November	• This novel food was introduced to the Committee in April 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review.
Dried Miracle Berry	RP1351	April and November	• This novel food was introduced to the Committee in April 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review

Application	Reference Number	Meeting	Committee's Response
Pasteurised <i>Akkermansia muciniphila</i>	RP1468	April and June	• This novel food was introduced to the Committee in April 2023 • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review
Vitamin D2 Mushroom Powder	RP1550	September	• This novel food was introduced to the Committee in September 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review.
2'-Fucosyllactose (2'-FL)	RP1476	September	• This novel food was introduced to the Committee in September 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review.

Application	Reference Number	Meeting	Committee's Response
3'-Sialyllactose (3'-SL)	RP1477	September	• This novel food was introduced to the Committee in September 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review.
6'-Sialyllactose (6'-SL)	RP1478	September	• This novel food was introduced to the Committee in September 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier continues to be under review.
<i>Clostridium butyricum</i>	RP1396	September	• This novel food was introduced to the Committee in September 2023. • The Committee sought further information from the applicant to address data gaps. • The dossier has been withdrawn by the applicant.

3. Traditional Food Applications

In 2023, 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 *Madhuca longifolia*. 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 2023

Application Meeting Outcome			Committee’s Response
<i>Madhuca longifolia</i>	RP1804	Advice Provided to Food Policy – Currently not Authorised in the UK as the application did not progress.	• The committee highlighted data gaps and found the proposed uses were not consistent with how it was used traditionally that would need to be addressed before a conclusion could be made. • Their advice was passed on to risk managers and the application did not progress in the service.

4. The ACNFP subcommittees' work

a) Products of Genetic Technologies (PGT) Subcommittee

The Subcommittee had five virtual and one face to face meeting in 2023.

Work by the subcommittee continued to be required, with a degree of urgency, to support FSA Policy through advice on the scientific evidence that could be applied in a tiered approach to the safety assessment of Precision Bred Organisms (PBOs). This was to inform the development of the [Genetic Technology \(Precision Breeding\) Act 2023](#) and its associated secondary legislations.

The conclusions of the Subcommittee in relation to possible triggers for further review and assessment of Precision Bred Organisms (PBOs), were presented at a workshop with ACNFP (January 2023). These were based on possible risks arising in PBOs as identified from case studies and suitable comparisons with products of traditional breeding. As a result of the ACNFP workshop, the [second Precision Breeding ACNFP Statement](#) on the criteria to be used to assign organisms to either of two tiers was published on the ACNFP website in January 2023. This timely publication supported the last stage of the Genetic Technology Bill going through Parliament before it became an Act in March 2023.

The Subcommittee held a series of independent workshops to identify the data requirements for Tier assignment and safety assessment of PBOs. These explored the application of the principles of assessment identified by the Subcommittee in previous statements and discussions. It discussed the developing approach on a regular basis with the main ACNFP for review of its conclusions (Table 3):

- The Subcommittee used possible examples of PBOs, all based on published scientific literature (listed in [tables of initial case studies](#)), to pilot the triage for Tier assignment according to the criteria published in the second PB ACNFP Statement.
- The PGT’s conclusions in relation to data requirements for Tier assignment of PBOs were presented in a workshop with the main ACNFP (June 2023), and further reviewed in a Subcommittee meeting before being summarised in a draft statement presented in a workshop to the main ACNFP (July 2023). As a result, the [third Precision Breeding ACNFP Statement](#) on the criteria to be used to assign organisms to two tiers was published on the ACNFP website in September 2023. This timely publication supported the discussion of the FSA Board (September 2023) on the new regulatory framework for precision bred organisms used for food and animal feed, and the follow-up consultation (November 2023).

Subcommittee Members were invited to opt in to support the drafting of the FSA technical guidance for applications for the authorisation of PBOs for food and feed marketing, to be developed between November 2023 and July 2024.

Table 3. Workshops on Precision breeding framework held in 2023
(Reserved Business)

Meeting Topic	Reference
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January	Report to and Discussion with ACNFP.	ACNFP /156/01
February	Piloting of Tier assignment using case studies.	PGT/6/03
March	Piloting of Tier assignment using case studies.	PGT/7/01
May	Identification of the key data requirements for Tier assignment and safety assessment of PBOs according to the principles of assessment identified by the Committee.	PGT/8/01
June	Report to and Discussion with ACNFP.	ACNFP /160/04
July (18 th)	Review of the data requirements for Tier assignment and safety assessment of PBO.	PGT/09/01
July (25 th)	Report to and Discussion with ACNFP.	ACNFP /161/01

The Subcommittee also reviewed one application for renewal of GMO authorisation and seven applications for new GMO authorisation (Table 4); two applications required additional information before the Subcommittee could conclude on safety assessments. Draft Committee Advice Documents (CADs) for the authorisation of these applications were agreed by the Subcommittee prior to escalation to the full ACNFP Committee for review and agreement.

Assessments by Defra (Department for Environment, Food and Rural Affairs) and its Scientific Advisory Committee ACRE (Advisory Committee on Releases to the Environment) of applications for GMO authorisation also contribute to the final safety assessment produced by FSA; to improve the consistency of the reviewing process of GMO applications. Links with Defra and ACRE were strengthened by the implementation of regular updates from ACRE/Defra in PGT meetings.

Table 4. Genetically Modified Organisms (GMO) applications considered by the Subcommittee during 2023 (Reserved Business)

Application	Reference Number	Meeting	Subcommittee's Response
Genetically modified cotton GHB811 for food and feed use (New Authorisation)	RP1232	February 2023	• This application for new authorisation was considered for the first time in February. • No data gaps were identified. • A draft Committee Advice Document was prepared and agreed, to be presented to ACNFP. • The assessment was finalised. In April 2024 it was published and moved to risk management.
Genetically modified cotton GHB614 for food and feed uses (Renewal)	RP608	February 2023	• This application for renewal was considered for the first time in February. • No data gaps were identified. • A draft Committee Advice Document was prepared and agreed, to be presented to ACNFP. • The assessment was finalised. In April 2024 it was published and moved to risk management.

Application	Reference Number	Meeting	Subcommittee's Response
Genetically modified soybean GMB151 for food and feed uses (New Authorisation)	RP1123	October 2023	• This application for new authorisation was considered for the first time in October. • No data gaps were identified. • A draft Committee Advice Document was prepared and agreed, to be presented to ACNFP. • The assessment was finalised. In April 2024 it was published and moved to risk management.
Genetically modified oilseed rape DP-Ø73496-4 for food and feed uses (New Authorisation)	RP1372	October 2023	• This application for new authorisation was considered for the first time in October. • No data gaps were identified. • A draft Committee Advice Document was prepared and agreed, to be presented to ACNFP. • The assessment was finalised. In April 2024 it was published and moved to risk management.

Application	Reference Number	Meeting	Subcommittee's Response
Genetically modified maize DP4114 x MON810 x MIR604 x NK603 for food and feed uses (New Authorisation)	RP1506	October 2023	• This application for new authorisation was considered for the first time in October. • No data gaps were identified. • A draft Committee Advice Document was prepared and agreed, to be presented to ACNFP. • The assessment was finalised. In April 2024 it was published and moved to risk management.
Genetically modified canola MS11 and MS11 x RF3 for food and feed uses (New Authorisation)	RP307	December 2023	• This application for two new authorisations, for two genetically modified oilseed rape products, MS11 <i>Brassica napus</i>, and MS11 x RF3 <i>B. napus</i>, was considered for the first time in December. • A draft Committee Advice Document was reviewed. • Additional information was requested by the Subcommittee. The Committee Advice Document to be amended to include any further information

Application	Reference Number	Meeting	Subcommittee's Response
Genetically modified maize NK603 x T25 x DAS-40278-9 for food and feed uses (New Authorisation)	RP1791	December 2023	• This application for new authorisation was considered for the first time in December. • No data gaps were identified. • A draft Committee Advice Document was prepared and agreed, to be presented to ACNFP 164.
Genetically modified oilseed rape MON 94100 for food and feed uses (New Authorisation)	RP1869	December 2023	• This application for new authorisation was considered for the first time in December. • A draft Committee Advice Document was reviewed. • Additional information was requested by the Subcommittee. The Committee Advice • This application has been withdrawn.

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

The subgroup held 6 virtual meetings in 2023 performing and finalising the review of all available safety data for >98% pure CBD and beginning the review of new data as relevant to a wider range of cannabinoids present in some ingredients (Table 5). Outputs and statements from the subgroup were subject to review and agreement by both the COT and ACNFP before publication. The conclusions of the Subgroup in relation to the safety of >98% pure CBD as an ingredient in novel foods, was presented in a meeting with ACNFP (March 2023). The advice from the subgroup and ACNFP enabled the FSA to derive a provisional ADI of 0.15 mg/kg bw/day or 10 mg/day for a healthy 70kg adult. Following this, a [Joint position paper from ACNFP & COT on establishing a provisional ADI for pure form CBD in](#)

[foods](#) was published on the ACNFP Website in May 2023.

The derivation of an ADI for pure form CBD supports the individual review by the ACNFP of CBD-containing novel foods applications as submitted in the regulated novel foods process. Each novel food application will be reviewed in the context of the application of a generic ADI, but also in consideration of the specific production process (either organic synthesis of CBD or from plant extraction) and the expected product use scenarios. There are significant data gaps for other cannabinoids in hemp derived extracts, challenges in the consistent analysis of cannabinoids in food matrices, and the possibility for contamination of foodstuffs by the hallucinogen THC. These areas will be reviewed by the ACNFP in 2024, in the continuing work programme on CBD and hemp derived novel food ingredients.

Work by the subcommittee continued to be required, with a degree of urgency, to support FSA Policy through advice on the scientific evidence that could be applied in updating the consumer guidance available to applicants and the public for the safety assessment and consumption of cannabinoids in products with a range of purities.

Table 5. Finalised reviews of pure form CBD (>98% purity) application data and group B CBD applications considered by the Subcommittee during 2023 (Reserved Business)

Meeting	Topic	Reference
January	Initial review of toxicological data submitted for CBD by a consortium of applicants.	CBD04/23
February	Conclusion to the review of toxicological data submitted for CBD by a consortium of applicants.	CBD05/23
March	Drafting and finalising the position paper statement on the updated consumer advice for $\geq 98\%$ pure form CBD ingredients.	CBD05/23

Meeting	Topic	Reference
May	Introduction to the toxicological information submitted on ingredients using CBD and mixture of cannabinoids (derived from either plant-based extraction or synthetic chemistry sources) under the novel food's regulation.	CBD06/23
July	Continuation of the toxicological review of information submitted on CBD ingredients with a range of cannabinoids present under the novel food's regulation.	CBD07/23
November	Continuation of the toxicological review of information submitted on CBD ingredients with a range of cannabinoids present under the novel food's regulation.	CBD08/23

5. Other Issues

a) Ways of Working

In 2023 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), documents to further develop the regulated products processes, as well as governance processes such as the annual report.

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
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Update to ACNFP terms of reference	February	The Committee reviewed minor amendments to the ACNFP Terms of Reference proposed by the Secretariat to remain consistent with the evolving responsibility of the Committee on Precision Bred Organisms. The Committee agreed the proposed changes, pending minor amendments and final agreement agreed by the Chair.
PGT Subgroup Update	April 2023	The Committee was updated on the work of the PGT Subcommittee and agreed to the strategy and objectives set for the next two months on the development of the Precision Breeding framework for authorisation and in particular on data requirements to support the process.
Annual report 2022	September 2023	The Committee reviewed the annual report draft and made changes to agree on the final report of the ACNFP's work in 2022 .

b) Reserved Business Items

A number of items were considered under reserved business in 2023 (Table 7). The discussions for these items are primarily in relation to new ways of working, handling sensitive issues such as precision breeding assessment guidance 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	Reference Number	Meeting	Committee's Response
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Genetically Modified Soybean A5547-127	RP188	February	• The Committee were invited to consider the data presented for the first time in the CAD informed by the discussions of this application in the PGT subcommittee. • This was agreed subject to amendments and moved to the publication process.
Genetically Modified Soybean 40-3-2	RP212	February	• The Committee were invited to consider the data presented for the first time in the CAD informed by the discussions of this application in the PGT subcommittee. • This was agreed subject to amendments and moved to the publication process.
Genetically Modified Maize MIR162	RP652	February	• The Committee were invited to consider the data presented for the first time in the CAD informed by the discussions of this application in the PGT subcommittee. • This was agreed subject to amendments and moved to the publication process.
Genetically Modified Cotton GHB614	RP608	February	• The Committee were invited to consider the data presented for the first time in the CAD informed by the discussions of this application in the PGT subcommittee. • This was agreed subject to amendments and moved to the publication process.

Genetically Modified Cotton GHB811 -	RP1232	June	• The Committee were invited to consider the data presented for the first time in the CAD informed by the discussions of this application in the PGT subcommittee. • This was agreed subject to amendments and moved to the publication process.
Precision breeding assessment criteria guidance	N/A	April, June and July	• The Committee were invited to feedback on the approaches proposed by the PGT subcommittee, considering the data requirements for assessment of PBO safety for food and feed. • The Committee supported the data requirements proposed for tier 1 and 2 applications. • The Committee requested amendments to the statement and the document finalised.
CBD purity position paper	N/A	March	• The Committee were updated on the ongoing work and progress of the ACNFP/COT subgroup. • The Committee were invited to review a position paper from the ACNFP/COT subgroup on CBD describing the provisional 10mg/day ADI for purified CBD. • Following comments the document was agreed and published in October 2023.

Update on the work of the CBD Subgroup	ACNFP /162/14	September	Members received an update from the Subgroup. It was noted the progress on the review of toxicological data. The outstanding cross cutting issues for CBD were explored and how they could be managed for the assessment of CBD applications being considered in the service was identified.
Cannabidiol (CBD) app	RP07	September and November	- The Committee reviewed the CAD for this application. - The assessment was finalised for publication. In April 2024 it was published and moved to risk management.

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 2023

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 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.

Dr Catharina Edwards (Nutrition Scientist)

Group leader at Quadram Institute Biosciences, within the Food, Microbiome and Health programme

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 George Bassel (Plant Scientist)

Professor of Plant Science at The University of Warwick

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 D Jones (Translational Genomics)

Chair in Translational Genomics for plant breeding, Aberystwyth University.

Also Member of PGT Subcommittee

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 adjunct professor at 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)

Dr Kemp is an independent consultant and social scientist specialising in risk perception and communication. He is currently a member of various advisory committees including the UK Department of Health and Social Care's Committee On the Medical Aspects of Radiation in the Environment (COMARE).

Also Member of PGT Subcommittee

Dr Andy Greenfield (Genetics; Animals; Bioethics)

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.

Associate members

Dr Kimon-Andreas Karatzas Microbiology Specialist)

Associate Professor of Food Microbiology at the University of Reading.

Dr Christine Bosch (Nutrition Scientist)

Associate Professor of Nutrition at the University of Leeds.

Dr Antonio Peña-Fernández (Toxicologist)

Associate Professor of Toxicology at the University of Alcalá (Madrid, Spain), and has an honorary position at the De Montfort University.

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 Andrew Dodd - Policy, FSA Wales

Mr Lloyd Evans - Policy, FSA Wales

Mr Xose Benitu Alvarez - Policy, FSA Wales

Ms Hannah Reid - Policy, FSA Wales

Mr Jeremy Mills - Policy, FSA Wales

Mr Peter Madden - Policy, FSA Wales

Ms Colleen Mulrine - Policy, FSA NI

Mr Ciaran Weir - Policy, FSA NI

Mr Daniel Lynch - Policy, FSA NI

Ms Siobhan Watt - Food Standards Scotland

Ms Krystle Boss - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Ms Georgina Finch - Food Standards Scotland

Dr Karen Pearson - Food Standards Scotland

Ms Tamara Satmarean - Food Standards Scotland

Mr Joshua Evans - Food Standards Scotland

Dr Svetlozara Chobanova - Food Standards Scotland

Ms Aileen Livingstone - Food Standards Scotland

Mr Evangelos Katsoulis - Food Standards Scotland

ACNFP Members' Interests during 2023

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 2023 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.
- 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 Chair 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.

Yes

A role of the ACNFP in 2023 was to assess novel food and GM applications which due to commercial sensitivities the Committee cannot discuss the documents in public. However, we invite internal FSA and FSS stakeholders to view the meetings. Applicants and external stakeholders can view minutes and papers that outline the nature of the discussions. For traditional foods from third countries 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

The Committee have indicated a wish to hold a public meeting, and this is being explored as part of their wider work programme for 2024.

4. The scope of literature searches made on behalf of the SAC will be clearly set out.

Yes

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

Assessing the quality and relevance of data is a core function of the Committee's work.

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

Members are regularly asked whether further expertise is needed to support the discussion of particular topics.

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

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. We consult experts in analytical methodology where this is needed, and the expertise does not reside in the Committee membership.

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. As such it is unlikely that there is sufficient data to apply quantitative methodologies. These are considered and applied where appropriate.

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 and GM dossiers are prepared in line with EFSA guidance inherited at the time of the UK's departure from the EU. This sets out clear data requirements and involves published and unpublished data. Consideration is given to whether there are specific areas for review of interest to different parts of the UK.

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

The outputs of the review of dossiers includes references so that the sources of data used in the assessment are communicated. The text will comment on whether the data was a peer reviewed publication or unpublished data.

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 and communicated.

15. Any assumptions made by the SAC will be clearly spelled out, and, in reviews, previous assumptions will be challenged. Yes

16. Data gaps will be identified and their impact on uncertainty assessed by the SAC. Yes

17. An indication will be given by the SAC about whether the evidence base is changing or static, and if appropriate, how developments in the evidence base might affect key assumptions and conclusions. Yes

Drawing conclusions

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

19. Where both risks and benefits have been considered, the committee will address each with the same rigour, as far as possible; it will make clear the degree of rigour and uncertainty, and any important constraints, in reporting its conclusions.

N/A

The Committee's assessment focuses on safety and performs risk assessments which under the assimilated regulation 178/2002 EC does not allow for consideration of benefits.

Within the scope of the ACNFP's work is providing technical advice on nutritional disadvantage. Assessment of this area is reported in line with lines 14-17 of this statement.

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. Where there are a range of views these are outlined.

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

The Committee uses a plain English approach to its outputs. Regular review of the clarity of the outputs is made to ensure these are of an appropriate quality and suitable for the audience.

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

The committee assesses dossiers for GM and novel foods. The legislative framework in which these assessments are done states what information can remain confidential and is outside the Committee's control.

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.

Regular policy updates on how Committee advice has been used is received at each meeting.

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 £130,370.00.