# ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

# MINUTES OF THE ONE HUNDRED AND FORTY SECOND MEETING HELD ON 23rd June 2020

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*Members are required to declare any personal interest in matters under discussion. Where Members have a particularly close association with any item, the Chairman will limit their involvement in the discussion. In cases where an item is to be discussed in their absence, a Member may make a statement before leaving.*

**MINUTES OF THE ONE HUNDRED AND FORTY SECOND MEETING OF THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES, HELD ON 23rd June 2020, ONLINE USING MICRSOFT TEAMS**

## ATTENDANCE

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| **Committee** | Professor Peter Gregory | **Chairman** |
| | Dr Anton Alldrick | **Member** |
| | Dr Camilla Alexander-White | **Member** |
| | Dr David Mela | **Member** |
| | Dr Hamid Ghoddusi | **Member** |
| | Dr Lesley Stanley | **Member** |
| | Dr Mark Berry | **Member** |
| | Dr Maureen Wakefield | **Member** |
| | Dr Rohini Manuel | **Member** |
| | Mrs Rebecca McKenzie | **Member** |
| | Ms Clare Nicholson | **Member** |
| | Ms Nichola Lund | **Member** |
| | Professor Clare Mills | **Member** |
| | Professor Harry McArdle | **Member** |
| | Professor Huw Jones | **Member** |
| | Professor John Mathers | **Member** |
| | Professor Michael Bushell | **Member** |
| | Professor Paul Fraser | **Member** |
| | Professor Susan Duthie | **Member** |
| | Professor Susan-Fairweather-Tait | **Member** |
| | Professor Wendy Harwood | **Member** |
| **Apologies** | Professor Chris Ritson | **Member** |
| **Assessor** | Mr Paul Tossell | **Allergy and Intolerance Team Leader** |
| **Observers (FSA)** | Mr Adam McDowell | **Policy Advisor FSA Wales** |
| | Ms Karen O'Conner | **Senior Novel Foods Policy Advisory** |
| | Dr Sabrina Roberts | **Senior GM Policy Advisor** |
| | Mr Hoa Chang | **GM Policy Advisor** |
| | Dr Chun-Han Chun | **Head of Science Strategy Assurance** |
| | Mr. Andrew Dodd | **Novel Foods Policy Officer** |
| | Ms Kerry Gribbin | **Senior Policy Advisor** |
| | Mrs Amie Adkin | **Head of Risk Assessment** |

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| **Secretariat** | Mrs Frances Hill | **Technical Secretary** |
| | Mrs Erin Oliver | **Senior Secretariat** |
| | Mr Richard Uchotski | **Secretariat** |
| | Dr Elspeth Ransom | **Secretariat** |
| | Mr Francisco Matilla-Garcia | **Secretariat** |
| | Ms Aisling Jao | **Secretariat Administrative Hub** |
| | Ms Beth Rendle | **Secretariat Administrative Hub** |

## 1. Apologies and announcements

The Committee welcomed Susan Fairweather-Tait as a new committee member for the ACNFP. Susan worked in the food industry for a short while and then moved to the Institute of Food Research, Norwich. Her research interests focus on mineral metabolism in humans, micronutrient requirements and dietary reference values, nutrient bioavailability, health claims and diet and aging.

The Committee welcomed the new chair Camilla Alexander-White, who will be taking over chairing duties of the ACNFP Committee commencing from the 24th June 2020.

The Committee were informed that Peter Gregory would be leaving the Committee. Peter served as the chair of the ACNFP Committee for over 10 years and has reached the maximum term time allowed. The secretariat and the Food Standards Agency thank him graciously for his contributions, competent chairing and excellent communication during his term and attaining his position on the science council.

The Committee were also informed that John Mathers, Chris Ritson, Mike Bushell and Claire Nicholson would be leaving the Committee. John, Chris and Mike have served as members of the ACNFP Committee for over 10 years and they have all reached the maximum term time allowed. Claire has accepted a position on the Food Standards Agency's Science Council and can no longer sit on the ACNFP Committee. The secretariat and the Food Standards Agency thanked them graciously for their contributions and efforts over the years.

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

## 2. Meeting Minutes for 141st Meeting ACNFP/141/MINS

The Committee agreed that the minutes were a true record of the 141st meeting of the ACNFP held on 29th April 2020, subject to minor amendments.

I. The Committee reviewed approaches for the risk assessment of GM Safety information under reserved business. The views of the Committee have been captured and taken on board by the FSA.

II. The Committee reviewed the annual report. The minor amendments have been made. The paper will be uploaded to the website.

III. The Committee submitted their yearly changes on the declaration of conflicts of interests. These have been captured and the form has been updated.

IV. The Committee members completed their feedback and appraisal forms. Members submitted the appraisal forms, which have been collected by the secretariat to review the yearly performance of the Committee.

V. The Committee members have tried to access the file point on teams. Issues were raised to the secretariat and have been escalated to the IT team.

As previously highlighted to the Committee, handling of genetically modified (GM) food/feed applications will be subject to the nature of the future relationship with the EU. However, it is anticipated that the UK and therefore the Committee would have a role in assessing applications for authorisation of GM food and feed to be marketed in the UK.

In light of future UK GM food and feed authorisations, this item is to seek the Committee's input on scientific technical guidance for UK applicants. This meeting provides an opportunity to discuss and explore the European Food Safety Authority (EFSA) guidance documents clarifying to EU applicants the scientific data requirements they must meet when submitting their scientific dossier for assessment.

The Committee examined the EFSA guidance documents presented within Annexes F to L of Committee paper ACNFP-142-01, considering Annexes A-E and Annex M. Members assessed the relevance of these documents to a UK system and informed the Secretariat of their suitability and areas for future discussion. In general, the Committee expressed that the EFSA guidance documents were comprehensive and appropriate for a UK system. However, Members acknowledged that specific areas could be updated in light of new scientific developments and new safety information.

**Annex F: Guidance on the agronomic and phenotypic characterisation of genetically modified plants**

Committee members commented that the agronomic and phenotypic characterisation guidance included a high level of detail, covering all relevant areas. It was noted that selection of test sites for UK assessments must be appropriate, considering extreme environmental conditions experienced within yearly time periods and complex traits. Member's recognised that the guidance is flexible, allowing for a case by case assessment considering genotype and environment interactions, which will be required in certain situations.

It was highlighted that the guidance was very appropriate for cultivation applications, focussing on annual seed crops, however it will need updating in the future to consider trees, perennials and root crops. Members commented that the level of agronomic and phenotypic data required was the same for cultivation or importation of seed. They proposed that this could be reassessed in the future to consider the requirement of

providing specific endpoints, dependent on whether the application was for cultivation or import.

Multiple members expressed concerns that any changes to the guidance documents should be carefully considered, as the documents have been developed over many years to build upon each other. Therefore, alterations may have knock-on effects on other areas of the risk assessment. Field trials are integral to providing information for the whole risk assessment, as samples collected following this guidance will be used for other risk assessment areas e.g. allergenicity assessment. It was also noted that they considered that the level of detail in guidance was appropriate, especially when considering intended and unintended consequences.

Members also highlighted that any changes to the guidance would have potential costs to industry, especially in the case that the guidance begins to deviate from that of the EU. Therefore, changes need to be carefully assessed to evaluate these costs and industry should be consulted with.

A question was asked on whether there were any known issues with the science within the guidance or if the UK had raised any scientific objections in the past. Members commented that in their opinion there was no issue with the quality of the science, which was very comprehensive. However, it was noted the guidance may not cover all scenarios which could be seen within the UK and that the guidance may need tweaking to keep up with scientific advancements. A further query was raised on whether there was guidance on the containment of test sites to prevent contamination. Other Members responded that detail on containment was present in separate environmental guidance documents.

**Annex G: Explanatory note on the determination of newly expressed protein levels in the context of genetically modified plant applications for EU market authorisation**

Members stated that the guidance was very inclusive, that the technologies mentioned were still appropriate and that quantification and sensitivity aspects were well detailed. It was noted that advances in proteomics have been made and that the guidance could be updated to reflect this, with more analytical aspects included, however inclusion of new analyses within the guidance may be criticised by industry. The Committee discussed that Annex D allowed them to see the guidance in action and it was good

to see that post translational modifications were considered. Members commented that in many cases proteins are produced in bacteria rather than in plants therefore post-translational modifications are not the same. They suggested that this guidance could be expanded to include consideration of the impacts of additional types of post-translational modifications such as O-linked glycosylation. Further to this the guidance on antibody technology could also be updated.

**Annex H: Safety and nutritional assessment of GM plants and derived food and feed – The role of animal feeding trials**

Members commented that the technical report was very well thought out but questioned the relevance of using the EU FRAME intake databases to model intake for a UK assessment. They noted that it may be more appropriate to use UK intake databases. The Committee commented that the underlying principles of the toxicology guidance are good, however that scientific knowledge and views in this area have developed substantially over the last 10 years since the guidance was published.

Questions were raised by the Committee on whether rat feeding trials provided the most pertinent data for examining the toxicological risk in humans. They highlighted the 90-day feeding study may not in every case be the best way of assessing safety to a GM food, and there is a risk of applicants doing unnecessary animal testing. It was commented that there must be a suitable alternative in place to consider changing this requirement; currently in vitro and in silico models are not suitable replacements. Members also noted that the EFSA toxicological guidance for GMO's often refers to REACH, which focussed on occupational chemical safety, rather than food safety legislation.

The Committee discussed that the guidance does not capture the full values of the use of post market monitoring. Whilst this is no substitute for a thorough risk assessment, Members highlighted that in cases where products have a history of consumption in other countries, post-market monitoring and information from other regulatory bodies may provide information which could support the risk assessment and further establish safety.

**Annex I: Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms.**

Members commented that it was not clear whether examination of horizontal gene transfer was within the FSA or DEFRA remit. They remarked that HGT was unlikely and has not been observed in the field, however assessment of the risk using the bioinformatic approaches presented in the guidance were appropriate and easy for applicants to do. Members agreed that the guidance provided a good foundation and could be updated to include new bioinformatics tools and approaches.

**Annex J: Human dietary exposure assessment to newly expressed proteins in GM Foods.**

The Committee praised the dietary exposure guidance for being extremely comprehensive and detailed for applicants, noting that it follows methods of population monitoring and examination of at-risk groups which they have favoured in the novel food's regime. Members stated that the guidance could be strengthened in the areas of expected intake and nutritional consequences.

The increasing development of GMOs expressing non-coding RNAs in which there is no new protein present, and the use of using RNA levels to calculate exposure, was discussed by the Committee. Members highlighted that using non-coding RNAs as an endpoint for calculating exposure should be included within the guidance. Furthermore, Members commented that the guidance utilises a deterministic approach and asked whether we could use probabilistic modelling to refine models.

**Annex K and L: Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed/guidance on allergenicity assessment of genetically modified plants**

The Committee expressed that the allergenicity guidance has been well developed and commended the addition of exploration of non-IgE mediated allergies in 2017. They reiterated that as had been discussed before, Members were in favour of applying this approach to allergy risk assessment of novel foods. Members stated that they still agreed with their previous comments on Annex L presented in Annex M but emphasised that the guidance should be reviewed in light of new data on in vitro digestibility models, which will be published by EFSA in the next year.

The use of in silico analysis of open reading frames was discussed, with Members expressing that that in some cases this can lead to the detection of unreliable or unreal hits, therefore ORF analysis should be balanced with the other information provided

by applicants. Members stated that the allergenicity guidance should not be a decision tree and has been developed to intentionally ensure that the safety data around allergenicity is assessed taking into account the wider context.

*Action: To further review other areas of the GM Guidance for re-examination and amendment to enable use within the UK framework*

**3. Code of Practice** **ACNFP/142/02**

The code of practice sets the standard for how the Committee operates. Members reviewed the updated version of the code of practice, as it contained new additions, removals and other changes. The Committee provided comments on whether these changes were apt and suggest improvements.

The Committee discussed the concept of transparency within the document, which enables the public to see how decisions are made which affect their lives. They explained that the code of practices does not specifically state how the committee should be making its operations transparent. To be more transparent it was suggested to hold one open meeting per year. Yet, this year it has been difficult to complete an open meeting due to EU exist commitments, times and workload. However, the Committee would like to have an opening meeting a year and would like one as soon as possible

Further considering transparency, the Committee suggested that they could improve the consultation process. Members suggested that the consultation could be made clearer on the website, so it is easier for the public to engage with it. They also suggested that the consultation time period could be longer and be more comparable to the 6-8 weeks seen for an EFSA consultation, to allow for more time for organisations and the public to respond to the call.

The Committee discussed the notion selecting a replacement for the Chair in the instance of absence. The members discussed whether the Committee should select a deputy chair on a permanent basis or whether the Committee should nominate a member of the Committee to chair on a per-meeting basis. After discussions, the Committee concluded that it is better to nominate a member on a per meeting basis. The Committee discussed the procedure for when Committee members speak in public. Members noted that speaking in public is a difficult area to navigate, especially

as the members are involved in many activities that may require it. The members suggested that the code of practice is improved regarding its procedure for public speaking to ensure that when a member speaks there is no conflict of interest with the Committee.

The Committee discussed setting a procedure for publishing dissenting views, as the new procedure added to the code of practice was not ideal. They suggested a new format where a minority report is produced and published at the same time as the Committee advice, and that the member with dissenting view would have to create the minority report. It would have to clearly state that it was the personal view of the member and that their view did not represent the view of the Committee.

The Committee discussed the concept of communication and collaboration when working with other committees. They stated that although they may be required to work with another Committee, that it was not clear how this would work. For instance, who decides the outcome, when do they involve other committees - is it on a regular basis on an ad hoc call?  The Committee suggested that the mechanism for working with other Committees is made clearer, such that Committee's know how to request information and work when needed.

*ACTION: These comments have been collected and will be used to make changes to the code of practice which will be circulated to the Committee at a later date.*

## 5. Gene Editing Statement ACNFP/142/03

This item provided the Committee with the opportunity to discuss and explore the Food Standards Agency (FSA's) position statement on the safety of genome editing technologies. These summarise the current safety approaches of the FSA towards genetically modified food/feed, provides a brief summary of the known uncertainties and details future risk assessment work in this area. The Committee provided feedback on the gene editing safety statement. The Comments were collected by the Secretariat and feedback to the FSA to improve the purpose of the document.

*Action: Comments on changes to the statement have been provided and the document shared with relevant parts of the FSA.*

## 6. The EU Novel Food Guidance Paper ACNFP/142/04

The Committee reviewed the novel food and traditional foods legislation, implementing acts and technical guidance in preparation for the Committee's future role in the safety assessment of novel foods and traditional foods from third countries in the UK. The members reviewed the guidance to check its applicability for the future use in the safety assessment of novel foods.

The Committee reviewed the structure and were content with it, but the members questioned how the ACFNP and FSA will deal with an expectantly high workload of novel food applications? In response, the Novel Food secretariat answered by stating that the FSA various options are being explored including prioritisation of risk assessments and staff movements.

The Committee requested a description of the structure of the FSA food policy team to gain a clearer understanding of their role in the process of the assessment of Novel Foods. The Novel Food Policy Secretariat explained they sit in the policy directorate and that they receive and process the applications before they go for risk assessment. However, they explained that that most of their function covers the risk management aspects of regulated products applications.

Regarding confidentiality the Committee asked what process would be undertaken to ensure applicant confidentiality. The Novel Food Policy team responding by stating that they are still developing the FSA processes, but that they FSA will be following the same legislation as the EU as the legislation will be brought into UK law at the end

of the transition period. This means that the same confidentiality processes outlined in the EU law will be adopted into the UK law.

The Committee questioned how the FSA will validate and check applications to ensure that only applications of a high enough standard are appraised for review. The Novel Food Secretariat outlined their 3-stage validation process when receiving applications. The members emphasized that applications must address all safety aspects of the application and Members mooted the idea of sharing good and bad practice in dossier preparation with applicants to encourage them to submit good quality dossiers.

The Committee asked whether the applicant will have the chance to see where the application is in the process and whether there is enough transparency about how the process works?

- The novel food policy team responded by stating that the new FSA website will incorporate an area where applications can be viewed, along with their progress through the risk analysis process and key documentation such as the publicly available summary.

The committee questioned which data sets the applicants should use in the exposure assessment. They discussed whether an applicant should use the EU consumption databases (FAME), or the UK databases (NDNS)?

- The Committee concluded that ideally an applicant should be using a database that is most appropriate for the target population in which their product is going to be consumed. So, for most of the UK an applicant should use the NDNS database.

- When considering dietary exposure or consumption, the Committee suggested that moving forwards, perhaps they could give examples of what we expect applicants to provide.

- The Committee noted that regarding dietary consumption, they often rely on using very scant information on where the target market is.

The committee discussed the prospect of producing an overarching document that analyses the guidelines (GM, Novel Food and Traditional Food) to see where the commonalties and difference lie.

- For instance, in the traditional food application, applicants are not required to provide toxicology studies, but they are meant to address the same questions as the toxicological studies through using a history of consumption.

The Committee made comments around the challenge that history of use has caused members in the past. They stated that many applicants document some history of use. However, this can often be anecdotal or historical and it often does not demonstrate a full history of safe use. The Committee concluded that what they really need is evidence of absence of bad effects rather than just saying there is no bad effect.

The committee considered the concept of allergenic risk assessment in the guidance. They noted that EFSA guidance for GM allergic risk assessment is based on a useful stepwise approach. Yet, the allergic risk to a traditional food is not as well considered in that guidance. This may be a concern as traditional foods may pose an allergenic risk to naïve populations, as allergies differ in different parts of the world.

The Committee considered that HACCP should be taken more seriously in the applications process and suggested that the guidance is revised in the future to incorporate HACCP. This is because HACCP will demonstrate to the Committee what the applicant believes the identified risks in the process are and will give a good indication of what the applicant is doing to make the food safe. It would also enable the ACNFP to see how the applicant is managing their risks and would contribute greatly to completing a risk assessment.

The Committee addressed the concept of a product being 'nutritionally disadvantageous'. They noted that this statement is complicated, because context of the product needs consideration. Members need to understand not just the nutrition of the product, but also how the product would be used, whether it would replace something in the diet, displace something, or if it is an addition. Even knowing the circumstance, it is still hard to predict the potential nutritional consequences. There are wider implications that need to be considered. What if the product changes the pattern or distribution of nutrients in other foods? Who is eating the food? What about specific/vulnerable groups who may consume the product?

The Committee also considered the concept of limiting acceptance of applications for products that have no nutritional value at all, although it was acknowledged that this

would require a significant change to the legislation and would limit innovation in the food sector.

The committee questioned whether the definition of a Novel Food needed updating. The definition that is “as a food that had not been consumed to a significant degree by humans in the EU before 15 May 1997” The committee felt that this may have lost context and could be updated to better define what a novel food is, i.e. define it on its characteristics rather than the date at which the legislation commenced. However, this require a change in the law so is not possible for the FSA or committee to make this change.

*Action: Comments have been taken on board and will be considered in any updates to the novel foods’ guidance.*

## 7. Items for Information

### 7.1 Novel Food Policy Update — Written

The Committee was provided with a written update on the issues under consideration in the EU on novel foods.

### 7.2 GM Policy Update — Written

The Committee was provided with a written update on the issues under consideration in the EU of GM issues.

## 8. Date of next meeting:

The next meeting is scheduled for 10th September 2020. The meeting will be online due to concerns surrounding Covid-19