September 2021 Board Meeting - Questions

Please note not all questions below were read out at the start of the meeting. All questions get a written response published on our website either within the Minutes or separately.

Questions read out and answered during the meeting

Question 1

I would like to submit the below question to the FSA Board for consideration at their September meeting:

"To ask the FSA Board why, in former FSA Chair Dr Ruth Hussey's letter to Defra Secretary Rt Hon George Eustice MP, dated 16 March 2021, the FSA suggests that the absence of data relating to the safety of gene edited products means that 'it is not currently possible to give a comprehensive safety statement on these technologies in food and feed', when the European Food Safety Authority, in a scientific opinion delivered in November 2020, confirmed that simple genome edited plants (ie the subject of the recent Defra consultation) pose no greater risks than equivalent conventionally bred plants, a scientific opinion which has been reiterated by other high-level scientific publications and advice including from the European Academies' Science Advisory Council (EASAC) and the European Commission's High Level Group of Scientific Advisors (SAM)?"

Samantha Brooke

Chief Executive

The British Society of Plant Breeders Ltd

Response to Question 1:

See Minutes for FSA 21/09/06

Question 2

Can you please consider making it mandatory in England (as I believe it is in Wales) to display the hygiene rating at every eating establishment. This would give the public an immediate knowledge of the eating place.
We have just returned from holiday and always check before we eat and its amazing how many low scoring eateries do not display their rating.
Also it would be a massive insentive to those who have a low score to upgrade their standards.
Thanks
Mr and Mrs D Poyner

Response to Question 2:

See Minutes for Chair's Report

Question 3

Dr Tina Barsby OBE, NIAB chief executive

"To ask the FSA Board why, in Paper FSA 21-09-06 on Genome Editing, the description of 'other existing regulated product regimes' does not include reference to the regulatory framework for the approval and consent to market new conventionally bred plant varieties. This is a proven system of robust, outcomes-focused regulation which operates effectively alongside existing UK food safety, environmental protection and novel foods legislation with an impeccable track record of safety. Over time, this system has been adapted to take account of new policy or market requirements, and can readily embrace plant varieties produced with new precision breeding techniques."

Response to Question 3:

See Minutes for FSA 21/09/06

Questions not read out and answered by correspondence

Question 4

I would like the following address at the next meeting.

Do the FSA still recognise in the context of BREXIT the following as evidence for the non-novel states of foods (ingredients) in the UK:

1. Member state lists of ingredients written into law (into a decree, regulation or similar)
2. Member state lists of ingredients in guidance documents
3. Notified and register products submitted under article Article 10 of 2002/46 where such notification includes an assessment of the products ingredients rather than simple technical submission of draft label that may or may not be assessed by a competent authority (example FSAI (no assessment guaranteed) vs. Belgium (Assessment conducted and a fee paid for it))

Regards

Dr Mark J. Tallon, LL.M MA Ph.D C.Sci RNutr FRSB FIFST FRSM
Managing Director
On Behalf of:
Legal Foods Ltd

Response to Question 4:

Thank you for your questions.

Novel foods which were authorised in the EU before the end of the transition period continue to be permitted under retained EU law. Moving forward we will continue to make decisions on whether an ingredient is novel or not by considering whether it has a significant history of consumption and subsequently Ministers will make decisions based on the recommendations of national authorities. The examples you have provided on the views of other countries' authorities may form part of such consideration.

Question 5

Good afternoon,

Can I please ask the board the question outlined under point 5, regarding edible insects. The question refers to a complex issue, hence I felt it was necessary to provide some background and context to the question.

Thank you for your comprehensive set of comments and questions on edible insects. They have been addressed individually by the responses after each question to help your understanding.

1. Background

EU regulation – "REGULATION(EU) 2015/2283 Article 35(2)" – protects a business already selling lawfully, as long as an application has been submitted by the date specified in the "COMMISSION IMPLEMENTING REGULATION (EU) 2017/2469 Article 8(5)" – 1st January 2019 (but in any case by 2nd January 2020). The cut-off date for application was therefore 1st January 2019, and the protection continues until such time as a decision has been taken on the application.

This Regulation has been retained in UK law.

Retained EU law made no provision for a transition from the EU to the GB novel foods authorisation regime. There is no legal basis for allowing unauthorised novel foods to remain on the GB market simply because they were covered by Article 35(2) under EU law and were therefore able to remain on the EU market pending conclusion of the EU authorisation process. If edible insects were not authorised in the EU before the end of Transition Period then, in the GB market, they are regarded as unauthorised novel foods and would require an application to be submitted and then be authorised in order to be in compliance with the legislation.

2. Trading before the end of Brexit Transition

Under the above Regulation, UK companies were legally trading Yellow Mealworms (*Tenebrio molitor*) and House Crickets (*Acheta domesticus*), thanks to the applications – without data protection provisions – submitted by The Belgian Insect Industry Federation (BIIF) to the EFSA in September 2018, i.e. before the deadline required by the EU.

This has been covered above under the reply to point 1

3. Declarations by the FSA

Without having consulted with businesses, the FSA on 31st December 2020 published on its website that after Brexit

. the UK would follow the EU Novel Food classification of edible insects.

. an application would have to be submitted in the UK.

. the authorisation process was "likely to be at least a year".

On 23rd August 2021 it further issued guidance [URN : PLGEN21022], declaring of the Regulation that “These transitional measures ended on 2 January 2020”.

With the UK leaving the EU it has been clearly and regularly stated that the FSA, along with Food Standards Scotland, would be responsible for the process of managing regulated products applications and making recommendations to Ministers. The development and preparation of the process has been discussed in various forums, covered on our website and presented at on line webinars leading up to the guidance being released at the end of the Transition Period to be ready to take over the system on 1st January 2021. As we have retained the EU law the timings of the process remain the same set out in legislation of up to nine months for risk assessment (longer if information is incomplete) followed by up to seven months for the risk management aspects.

Edible insects are considered novel food under retained Novel Foods Regulations EC 2015/2283. This covers any food that was not used for human consumption to a significant degree within the EU or the United Kingdom before 15 May 1997, irrespective of the dates of accession of Member States. Without this history of consumption, they remain novel and must be authorised before foods can be placed on the market. Applications must be submitted to the regulated products application service. Authorisation follows the processes and requirements set out in the implementing regulations, guidance on this can be found on the FSA web page.

4. Errors in the FSA’s declarations

4.1

How could the FSA announce (on 23rd August 2021) that the protections under “REGULATION(EU) 2015/2283 Article 35(2)” had ended 19 months before announcing this ?!

This is illogical.

4.2

The Regulation in any case contradicts this, as explained above – it states that protection continues until a **decision** has been taken on the application.

Please see response to Q1 for these two questions.

4.3

As the FSA states that the authorisation process is “likely to be at least a year”, in order to continue selling legally without interruption, a business would have had to submit an application **in the UK** around 1 year before the 2nd January 2020, i.e. by around 2nd January 2019. That is, almost 2 years before this was announced by the FSA !

This is illogical.

Furthermore, the UK was still in the EU at this point.

Edible insect businesses were able to submit applications to the EU under the Novel Food Regulations. If they had been authorised before the end of the Transition Period then this would have been reflected automatically in UK law. If this did not happen they

will need authorising through the GB system for the GB market. As yet we have not had any supported applications for edible insects to the regulated products system.

5. My question

When will these errors be rectified ?

Because of them, businesses have been made illegal, are freezing investments, or are shutting down.

The Novel Food Regulations were retained from EU law. The valid conditions set out in the regulations remained. These included the definitions of what novel foods are and what is required to have these novel foods authorised. There are no errors to correct. The opportunity for the edible insect industry to apply for authorisation for the GB market was available from the 1st January 2021 and the FSA has offered help in doing so and has discussed with parts of industry well before the system transferred from the EU to the UK.

Regards

Tiziana Di Costanzo (Director - Horizon Insects Ltd)

Question 6

Do the FSA have a timetable to notify CBD applicants of the outcome of the novel foods applications ?

Mike Turner
Director UK Beverage Services Ltd

Response to Question 6:

The Novel Food Regulations set out the timetable for the application process. Many applications are being assessed to see if they have sufficient content to pass the initial validation stage. Four applications have been validated so far and many are pending the provision of further information. If an application is deemed valid then the applicant is informed of this and an opinion needs to be formed on the safety of the product within nine months. During this nine months we undertake a risk assessment, including being reviewed by the independent Advisory Committee on Novel Food Processes (ACNFP). If further information or clarity is required, the nine month clock can be suspended pending restart upon supply of the missing information. If the information is not forthcoming or inadequate the application can be stopped. Assuming the outcome is a positive opinion from the risk assessment then there is up to a further seven months to form recommendations for a decision by ministers and if agreed to set out the authorisation in legislation.

Question 7

I would like to ask the following questions for the up coming meeting on the 15th of September.

1. Has the FSA recently been contacting companies to tell them that their Novel Foods applications would be best served if the were tied into a blanket application such as EIHA's or the ACI's?

   No. We have consistently said that applications can be either in consortium form (to potentially help smaller businesses) or from a single business, whether as a primary producer of the isolate/extract or a secondary product. We have said that we require complete applications, addressing the requirements to be supplied for the application as stated in the implementing legislation.

2. If the FSA have stated this to companies, what legal standing was used to determine that the FSA could look less favourably on singular applications than that of blanket applications?

   As above. It is not for the FSA to promote one organisation over another and we have made it clear that we are content for applications from individual companies or from consortia - the critical issue is that the application contains all the information set out in the legislation to make it a valid application. Our aim is to move the non-compliant industry into authorisation where possible.

3. Can the FSA confirm whether or not a company would have to provide an Article 4 Submission to launch a Cold Press hemp oil product in the UK, even if the true source of the oil has FSA approval for being novel exempt?

   The onus is on a food business to consider whether a food they intend to place on the market is novel or not and is in compliance with food law. Article 4 provides a method of seeking clarification where there is sufficient doubt. Hemp oil produced by cold compression is stated in the EU Catalogue as not being novel. If a food business has a product they believe to be hemp oil by cold compression they do not need to undertake an Article 4. However, if required to do so the business would need to be able to prove to enforcement authorities that the product matches the description set out in the EU catalogue stating that hemp oil is not novel. If it is unable to the product would need to be removed from the market.

4. A trade association recently released a statement suggesting that the Home Office (HO) has confirmed that MoDR 2001 Sect 2 (1mg rule) does not apply to hemp products, has the HO contacted the FSA to reinforce this at all?

   The Home Office has issued guidance on CBD products. We are not aware of any updates to the guidance to alter its approach.

5. Can the FSA explain why the Novel Foods validated products list hasn't been updated since the 19th of May, and can the FSA confirm whether or not it leaves the 3 listed companies in an unfair market position compared to those companies who have submitted yet have not seen the actual list updated weekly as it was suggested.

   The four companies on the public list have applications that have been validated to date. No other applications have been validated since April as they have either been deemed invalid, are awaiting provision of further information or continue being reviewed to assess their validity status. The majority of applications lack the necessary scientific evidence and data so this process is taking longer than hoped for. Other products will be added to the public list as applications are validated. Until the list is complete, local authorities can check the status of applications with the FSA to help them with enforcement considerations.

Cefyn Jones

Hemp Industry Specialist

Question 8

Hi,

I wish to ask the board of the FSA about alternative approaches to obesity, diet and types of food.

I recognise that obesity is a big challenge, not only for suffers, but the NHS and also, through implication - the food industry for providing foods that are high in fats, salt and sugar.

I also agree that the food industry has a large part to play in offering healthy alternatives to the fatty, salty and sugary foods that are often on the market.

I believe that the department of health and the FSA have a responsibility to re-instil previously known and now lost facts.

1) What a healthy and balanced diet is
- 'eat your greens'
- 'you can have too much of a good thing'
- 'eat rich foods in moderation'
2) How to cook and how to shop.
- The FSA, beyond encouraging the 5 a day should display and advertise what a balanced diet may look like. Apps are fine for people who are inclined to download them and use them. The FSA through guidance and repetitive publicity should remind all consumers of what a healthy diet is, just as QSRs remind us how cheap their signature meal is.
3) Anecdotal evidence has shown that at more than one birthday party, children's chocolate cakes are now so bitter than many children are opting for alternatives such as chocolate bars or ice cream.
4) The HFSS are damaging our food heritage. A heritage that the UK and the world have come to love.
5) Where is personal responsibility in all this?
6) The HFSS regulations still do not discourage or prevent members of the public from overindulgence nor eating a poor diet.

My question.

Please can the members of the FSA review, with the department of health, alternative or synergistic strategies that can enable us to maintain our food heritage whilst working with government, the department of education and the food industry in providing a strong message that indulgence can be OK in strict moderation and that a healthy balanced is, with a healthy lifestyle, the best way of managing weight and obtaining a balanced variety of nutrients.

Thank you and best regards

Julian Durrant

Response to Question 8:

Thank you for your question to board regarding advice on nutrition and healthy eating. The Food Standards Agency only has responsibility for this issue in Northern Ireland (NI). In England, it is the responsibility of the Department of Health and Social Care and in Scotland it is dealt with by Food Standards Scotland. In Wales, it is the Welsh Government who take responsibility for this. Details of what is happening regarding advice on healthy eating in England, Wales and Scotland can be provided by those departments.

The FSA in Northern Ireland (NI) responsible for the delivery of nutrition and dietary health policy. The aim is to improve nutrition and health outcomes by making healthier food products available and increasing consumers' understanding of nutrition, allowing the healthy choice to be the easy choice. The team leads and develops dietary health policy through working collaboratively with other government departments, district councils, academia, community groups, the food industry and organisations that influence and support them.

FSA NI has worked with local food manufacturers, retailers and the out-of-home sector (restaurants and others) on the 4-5-year 'Eating Well Choosing Better' (EWCB) programme. We support small and medium sized enterprises with reformulation and reducing portion sizes to make healthy choices easier. We align our action and delivery plan with relevant UK agencies to reduce children's sugar and calorie consumption.

An example of this is the work done in partnership with district councils to survey and sample cheesecakes sold in NI restaurants and hotels (samples taken between July – September 2019) which were analysed to determine nutritional content and typical portion size.

The findings were published in 2020 and will inform targeted interventions with food businesses and pudding manufacturers to increase availability of healthier products in local food businesses.

Within the out-of-home sector, the Calorie Wise scheme continues to be delivered in partnership with the 11 district councils. The scheme encourages food businesses to voluntarily calorie label food and drink items on their menus, with help from the FSA's free online calorie calculator, MenuCal. COVID-19 meant promotion of the scheme was limited in 2020, however, we provided virtual refresher training to district council Calorie Wise Champions.

In developing our dietary healthy policy, we ensure that our work is based on robust evidence. We previously worked with Kantar Fast Moving Consumer Goods to monitor take home food and drink purchasing in NI from 2014-2018. This data has been collated into a report examining key trends and identifying food and drink categories that are of concern to dietary health and has been shared widely with stakeholders.

We are continuing to improve consumers understanding of healthy eating by using the Eatwell Guide 17 widely available online and in hard copy.

We worked closely with the Public Health Agency and Department for Communities in NI to review the nutritional adequacy of the emergency food boxes and provide menu plans suggesting how to make use of the food provided.

Further information about the work of the FSA in NI can be accessed here. Further information with regards to the FSA and the work we do can also be found on our website.

Question 9

Dear sir/madam

I am writing on behalf of the Woven Network, which is the UK's platform for insects as food. The industry is currently in crisis following communications with the FSA regarding the legality of insects and the sudden loss of transitional measures previously granted to us prior to Brexit.
Please see the attached document, explaining the situation and our proposal for GB specific Transitional measures.

We look forward to discussing with you.

Nick Rosseau

Managing Director, WOVEN Network CIC

Response to Question 9:

The Novel Food Regulations are retained EU law. The valid conditions set out in the regulations remained. These included the definitions of what novel foods are and what is required to have these novel foods authorised. We have made it clear the process for applications to be submitted and have guidance on what is expected within the application, to allow the FSA to asses the scientific evidence, that the food does not pose a safety risk to human health. The opportunity for the edible insect industry to apply for authorisation for the GB market was available from the 1st January 2021 and continues, as have the offers of help in doing so. We discussed this process with parts of industry well before the system transferred from the EU to the UK. Until edible insects are authorised they remain unauthorised in GB as most edible insects do in the EU.

Retained EU law made no provision for a transition from the EU to the GB novel foods authorisation regime. There is no legal basis for allowing unauthorised novel foods to remain on the GB market simply because they were covered by Article 35(2) under EU law and were therefore able to remain on the EU market pending conclusion of the EU authorisation process. If edible insects were not authorised in the EU before the end of Transition Period then in the GB market they are regarded as unauthorised novel foods and must submit an application to be authorised to be in compliance to regulations.

Edible insect businesses were able to submit applications to the EU under the Novel Food Regulations. If they had been authorised before the end of the Transition Period then this would have been reflected automatically in UK law.

Any UK operator intending to export insects to the EU will need to ensure the product they are exporting is authorised as a novel food in the EU and ensure they are in compliance with the requirements of the competent authority in the relevant EU country.

Question 10

The Genome Editing Update Paper refers several times to conventional breeding. Does the Agency regard chemical and/or radiation-induced mutation to be within the scope of "conventional" breeding and has any research been conducted to explore how far consumers share this understanding?

Liz O'Neill - Director
GM Freeze - for a food system that is responsible, fair and sustainable

Response to Question 10:

From the Genome Editing Update paper, it was referred to that for conventional breeding in plant seeds, x-rays or chemicals can be used to increase both the range and number of random mutations in the DNA. The paper notes that conventional breeding in animals includes selective breeding and artificial insemination. Chemical and radiation induced mutation in animals is not noted for use within conventional breeding.

However, Annex I B from Directive 2001/18/EC states that techniques/methods of genetic modification yielding organisms are to be excluded from the directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed. This list highlights mutagenesis and suggests it does not fall within the scope of genetic modification.

Although not the focus of the research, the paper Consumer Perceptions of Genome Edited food notes comments around conventional breeding. Overall consumer knowledge and awareness of genome editing is particularly low; consumers struggled to identify an example of conventional breeding and assumed it to be genetic modification. The paper highlighted the blurred lines between editing and modifying which made it difficult for the consumers to identify the different techniques.