September 2022 Board Meeting - Questions

Question 1

Question submitted by Iain Mortimer, Group Technical Manager, Manufacturing, Apetito

While the UK Internal Market Act 2020 may permit goods produced in England to be sold throughout the mainland, it is recognised that trade with NI will be impacted. Has consideration been given to a similar impact for trade with Wales and Scotland due to those nations requiring clear GMO labelling (in line with EU regulation which this Bill amends). Such a labelling requirement could prevent adoption of produce using precision breeding and/or create another price tier and/or disadvantage such foods sold in England compared to equivalent foods that are only sold in England and therefore do not require labeling as containing GMO.

Our response:

The England only bill means authorised Precision Bred Organisms (PBOs) can be produced in and imported into England. Under the market access principles (of mutual recognition and non-discrimination) of the UK Internal Market (UKIM) Act (2020), where requirements are different in England, Wales and Scotland, products authorised under different regimes can be lawfully placed on the market throughout GB. This is a fundamental principle of the UKIM Act and is not specific to Precision Bred (PB) products, or to food and feed. The FSA is not in a position to comment on the market implications of this. Under the terms of the NI protocol, products sold in NI have to meet EU requirements so products authorised as PBOs will not be able to be sold in NI.

The Scottish Government indicated in a letter (10 June) their desire to ensure that steps are taken to prevent precision-bred products that do not meet Scottish standards from entering the Scottish market.

A Welsh Government spokesperson had emphasised that it is "essential there is full and open discussion between the four UK Governments" and confirmed that they will "continue to adopt a cautious approach".

Question 2

Question submitted by Liz O'Neill, Director, GM Freeze

Deliberation by the House of Commons Bill Committee revealed significant confusion over whether or not the definition of a "precision bred organism" in the bill text excludes the presence of exogenous genetic material. When consulting with citizens (through the consumer research study reported as Annex B and other means), does the FSA inform people that the insertion of exogenous genetic material is the first step in all gene editing

processes; that some gene editing techniques intentionally incorporate such material into the target organism's genome; and that, even when there is no intention of permanent incorporation, there are recorded incidents of unintentional integration of exogenous material?

Our response:

Exogenous DNA is DNA that originates from outside the organism in question. Exogenous DNA originating from e.g., bacterial or viral sources is naturally present in the genomes of many organisms and is not considered as GM because it is a result of natural processes (for instance, natural transformation or viral integration). An example of this is a cultivated sweet potato that naturally contains sections of DNA from a bacterium that is often used in gene editing and genetic modification. Additionally, traditional breeding practises often incorporate exogenous genes to introduce desired traits into an organism; for instance, by combining genetic material from two sexually incompatible species via a third ('bridge') species that is sexually compatible with both.
Exogenous genetic material is often (but not always) introduced into organisms to facilitate gene editing techniques, for example, sequences that guide the gene editing machinery to the precise target location within an organism's genome and the *cas9* gene for use in CRISPR/Cas9 techniques. It should be noted that steps are taken to ensure that no transgenes remain in the final edited organism. Some gene editing processes do not result in the incorporation of any exogenous DNA, because they are instead aimed at removing (rather than adding or modifying) DNA sequences.

The Bill therefore, allows for exogenous DNA to be present in precision bred organisms as long as the result would be achievable through natural processes or traditional breeding. This is reflected in clause 1(2)(c)(ii), which allows features which could have resulted from natural transformation, and clause 1(6), which provides for features of a genome to be disregarded for these purposes if they do not result in a functional protein.

We are conducting two phases of consumer research on precision breeding, building on our previous research in 2021. Phase one, collecting quantitative data, was completed in August 2022. Key findings are included in our published September Board Paper. Phase two focuses on gathering qualitative data via a citizens' forum approach in England, Wales and Northern Ireland. This work will soon be in the field with a view to being completed before the end of the year.

Question 3

Question submitted by Joe Ryan

The precision breeding bill sets out a list of scientific interventions that will be classed as "traditional processes". When the Food Standards Agency asks members of the public for their views on how these things should be regulated, do you explain that "traditional

breeding" isn't limited to sexual reproduction? If not, why not, as I think this would have a big influence on how people respond.

Our response:

For the purposes of identifying which changes could be achieved through traditional processes in the context of this Bill, traditional processes are those listed in clause 1(7).

Traditional breeding refers to any method that is not defined as a genetic modification technique. For example, traditional breeding methods include a wide range of sexual and *in vitro* fertilisation techniques, selection approaches and random mutagenesis techniques.

Precision Bred Organisms (PBOs), by definition, must have been able to occur through traditional breeding or natural processes, with the resulting plant or animal equivalent to and indistinguishable from one which could have been traditionally bred.

In our 2021 research with consumers, it was explained that conventional breeding included both selective breeding and *artificial insemination*. Further consumer research is planned this autumn including highlighting the role of mutagenesis techniques in traditional breeding and again this will be explained.

We are carrying out two phases of consumer research, with previous research published in 2021. Key findings from Phase one, (completed in August 2022) are included in our published September Board Paper. Phase two focuses on gathering qualitative data via a citizens' forum approach. This work will soon be in the field with a view to being completed before the end of the year. We publish all our research on precision breeding online to ensure we are open and transparent to consumers and industry.

Our research on consumer perceptions of genome edited food can be viewed here.

Question 4

Question submitted by Pat Walters

As one of many consumers who wish to avoid GMOs - including gene edited products - I would like to know if the FSA is going to commit to developing and supporting mandatory labelling for so called "Precision Bred Organisms"? I also wish to point out that the claim made by your scientist at the last Board meeting that these cannot be detected is inaccurate. Even my lay persons viewing of the literature has shown that.

Our response:

The scope of PB, as defined in The Bill, covers genomic changes achieved through modern biotechnology that could have resulted from traditional processes or natural transformation. Therefore, by definition, PBOs could theoretically be indistinguishable from other varieties bred through traditional methods. This poses challenges for the detection of PBOs in food and feed.

There is not currently a test that is able to determine if a product on the market has a trait that has been achieved using PB techniques rather than traditional breeding. The FSA is currently commissioning research into this area to better understand the possibilities, feasibility and limitations in this area. The outcomes of this review will feed into policy development.

The FSA will, where necessary, consider safety labelling of PBOs under their remit within the Food and Feed Safety and Hygiene (FFSH) Common Framework; for instance, if our risk analysis process identifies were to identify an allergy risk associated with a specific PBO. Non-safety labelling of PBOs in England would fall under Defra's remit, and therefore it is not within the FSA's power to mandate non-safety labelling of PBOs (in England) as part of this policy.

There are, however, potential impacts related to the market access principles contained in the UK Internal Market Act that could have implications for consumers in Wales and Northern Ireland, where the FSA do have a remit for non-safety labelling (under the Food Compositional Standards and Labelling Framework).

The FSA are engaging with Defra on these implications to ensure that relevant impacts of decisions being made by Defra are adequately assessed.

The FSA will also create a public register which will provide an accurate record of all PBOs that have been authorised for use in food and feed in England. The FSA will ensure it is transparent by publishing information on applications of authorised PBOs, as well as risk assessment findings on our website and details of authorised PBOs on the public register.

Question 5

Question submitted by Leonie Nimmo

Public consultations have shown time and again that UK citizens want food produced with all forms of genetic manipulation to be clearly identified. Indeed, the FSA's own research has found that most consumers want transparent labelling in this field, and that "maintaining consumer trust if vital". Why then is the FSA even considering options that do not involve clear on-pack labelling? Has the FSA considered the discriminatory impact against consumers that are not "tech savvy" enough to use QR codes, or do not have the time to scan all items that go into their supermarket trolley?

Why is the FSA considering the use of QR codes as a way of informing consumers about ingredients that have been artificially genetically manipulated, when the District Court of Northern California just ruled that the US Department of Agriculture broke the law by allowing GMOs to be labelled just with a QR codes, after its own study found that they aren't an adequate way to communicate with shoppers?

Our response:

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Question 6

Question submitted by Christopher Stopes, EcoS Consultancy

From my reading of FSA documents and its website, the FSA is giving the impression that "Precision Bred Organisms" are not genetically modified organisms (GMOs). In fact, in scientific and legal terms they are GMOs. The Genetic Technology (Precision Breeding Bill is built on the fact that they are GMOs (Part 1, 1(3)).

This Bill seeks to create a new category of GMOs which will receive a different regulatory approach, it does not change the fact that they are GMOs. The FSA is therefore giving a highly misleading impression to stakeholders and the public.

Will the Board take immediate action to cease doing this and remedial steps to correct the impression that it has created, including correcting all material and presentations (including the paper currently before the Board)?

Our response:

The FSA is responsible for Part 3 of the Bill which includes provisions for the FSA to create a new regulatory framework for food and feed derived from precision breeding organisms (PBOs), establish and update a public register for PBOs authorised for food and feed use and create an inspection and enforcement regime.

The Precision Breeding Bill is a government Bill which amends the definition of Genetically Modified Organisms (GMOs) to exclude certain organisms (plants, including algae) created by genetic technologies in ways which could have occurred naturally or been produced by traditional breeding.

Precision breeding describes a range of technologies, such as gene editing, that enables DNA to be edited much more efficiently and precisely than current breeding techniques, which can take decades to produce the same changes.

Precision breeding technologies can make targeted genetic changes to produce beneficial traits that can also occur through traditional breeding and natural processes. This is a key difference between precision breeding and 'classical' genetic modification, in which a range of techniques are used to insert genes or large sections of DNA from an unrelated species into another species to introduce a certain trait.

We have published research on the science behind precision breeding with key findings of consumer research on precision breeding published in the September Board Paper. This details our current plans and progress on developing a future regulatory framework for precision bred food and feed products. We will continue to provide regular updates on the progress of the Bill to ensure consumers are fully informed.

Question 7

Question submitted by Jacqueline Pearce-Dickens

In the past the FSA had a policy of publishing all advice and information it gave to the government. Assuming it still has this policy (and if not, why not?), will it publish promptly all the advice and information it has given to Defra and any other government agency or advisory body relating to The Genetic Technology (Precision Breeding) Bill.

Our response:

Yes, the FSA continues to work alongside Defra to ensure that officials across the four nations are engaged in regular discussions on policy development. We are also working

closely with FSS to ensure the obligations we are party to under the two FSA Common Frameworks that intersect with the Bill are delivered.

The FSA is committed to publishing the evidence upon which its advice is based. Transparency is one of the five key principles established by the FSA board underpinning policy on precision bred organisms, and this will continue to be evident in any proposals put to Ministers on the future regulation of precision bred food and feed.

The FSA is committed to being open and transparent. We provide the public with clear information that helps them understand risk. We publish our evidence in line with our commitment to transparency. This means it is freely available to others making policy and decisions, to inform guidance to businesses and so the public can trust our decisions.

Question 8

Question submitted by Mike Wilson, Managing Director, Cascade Associates

It was most encouraging to read the proposals to modernise food hygiene inspections within the Achieving Business Compliance paper. In particular to see proposals for the use of Remote technologies where these might be appropriate, where these can contribute towards better efficiency and reduced carbon footprint.

However, the 2021 ICF study was only a cursory survey based on a tiny sample size. It did not examine, in depth, the practical implications of using three quite different remote assessment techniques ie Telephone, Email and Video/Photographic.

Would the board agree that a more extensive evidence-gathering exercise around each of the remote methods needs to be undertaken, together with a comprehensive evaluation, before approving any proposals to deploy such technologies in the field on a regular basis?

Our response:

An evaluation on the use of remote assessments by local authorities during the COVID-19 pandemic was undertaken by ICF at the request of the FSA. This evaluation included reviewing the technology used for remote assessments and provides minimum technology requirements. A further exercise is being undertaken this financial year, also by ICF, to evaluate the use of remote assessment for requested FHRS re-ratings, which local authorities in England were also enabled to use during the COVID-19 pandemic and subsequent recovery period.

Local authorities in England and Northern Ireland that have been piloting the new food standards delivery model have also been able to use ‘targeted remote inspections’. This pilot took place over a 12 month period and an evaluation has been undertaken by ICF, which included evaluating the use of remote inspections.

The evaluation on the use of remote assessments undertaken to date provides sufficient evidence to demonstrate that they can be used effectively by local authorities, using a variety of methods, for activities such as, reviewing documentation and evidencing that

previously identified structural issues have been rectified. Therefore, it is not considered, at this stage, that there is a need to commission further evidence gathering on the use of remote assessments to support the development of its appropriate use within the modernised model.

We will be considering the findings from the evaluations on the use of remote assessment and other relevant guidance to develop proposals on its appropriate use within the modernised food hygiene delivery model. At this stage, recognising that every food business and local authority are unique, we anticipate providing principles on the use of remote assessment, which would include considerations as to the technology used, to ensure that they are used consistently and can effectively protect public health while verifying compliance. The proposals for a modernised food hygiene delivery model will be subject to consultation and subsequent evaluation. Training and guidance will also be provided to local authorities to enable consistent implementation of the modernised model.

Question 9

Please find below, questions for FSA board meeting.

Question submitted by Katie Doherty, CEO, The International Meat Trade Association

Lab capacity in the UK has been something we have highlighted as an area needing review for quite some time so we welcome the review of the UK Official Laboratory system. How will industry needs be included in the review – e.g. efficient sample turnarounds, choice of labs for different tests and transparency about the progress of processing of samples?

Our response:

The FSA's review of the official laboratories system has focused on the resilience of our Public Analyst Official Laboratories and their statutory capabilities (e.g., testing that is most needed from an enforcement and imports perspective). By identifying gaps within the UK's national capability and investing in those, we will bolster the capacity and capability of the overall lab system, resulting in additional expertise and testing infrastructure. This will in turn benefit industry, as improvements in government testing creates new capabilities and extra capacity that laboratories can also use for commercial testing.

The FSA has invested in supporting UK testing in numerous ways, including via the PATH-SAFE programme, National Reference Laboratories, surveillance sampling and Food Safety Research Network. All of these activities support the national capability.

Finally, we are keen to engage industry to ascertain where further capabilities gaps exist and to identify the key challenges faced by industry in relation to sampling and testing.

Question 10

Question submitted by Paul Carey

Would the FSA's Board please reiterate to the FSA's Executive the request from the meeting of 15th June that information about allergens in food offered by FBOs has to be in writing, supported by a conversation (if the consumer requires it)? Would they further confirm that the most logical place for such information to be provided is on the menu, be that on paper or on an electronic device?

Our response:

In June the FSA Board requested the Food Hypersensitivity Team to undertake further research on the provision of information in the non-prepacked sector including legislative options. The results of this work will be presented to the Board at a future meeting.

Question 11

Question submitted by Brett Smith, Brett Green World Holidays

We are writing in support of the proposal that the FSA will support changes to the law which requires FBOs to provide information on the 14 major allergens in their dishes in writing.

The law currently requires information to be provided, accurately, but "*by any means*", and therefore for allergy suffers
changing the Food Information Regulations of 2014 to say "*in writing on the face of the menu*" would make dining out a profoundly safer and more relaxing experience.

One additional point to mention for your discussion on Monday 26th Sep:

We have noticed in some restaurants now where menus are often largely or only available via an APP or online menu. The way it often works is you click on the allergens you are concerned about and the online menu then reduces to show what is possible to order.

However, for people with multiple allergies this sometimes means an enormous number of options are taken off the online ordering system.

For example, my daughter is allergic to nuts, dairy & sesame.

In a chain restaurant we go to – we have ordered off the traditional paper menu in the past and double checked with the allergen folder. One dish she has enjoyed is a Vegan Burger which is dairy & nut free – but traditionally was served in a sesame seeded bun.

We have previously been able to ask the FBO to check with the kitchen if its ok to swap the bun to a dairy free / seedless replacement; which they have duly been able to do.

However last time we were in the restaurant we were guided to the QR code on the table and asked to order from the online menu.

Of course, because we noted Sesame on the allergens list the 'Vegan' burger choice disappeared and it became extremely difficult communicating with the FBO about what we were trying to order.

In the end in this situation, we had to leave the restaurant as it was just becoming increasingly problematic & a totally unenjoyable experience.

Note: many of the FBO's are young and doing transient jobs. Some are trained well and communicate well; others you are left feeling with a worrying level of uncertainty [i.e. has my order been communicated correctly]. This is clearly not the best system to protect allergy sufferers or indeed businesses.

Having accurate allergen information on the face of menus will undoubtedly help allergy sufferers make their choices.

There are so many people with varied allergies and allergy combinations; it is much better for the information to be clearly presented at point of sale on paper and all electronic menus so they can understand clearly what is being offered.

Our response:

In June the FSA Board requested the Food Hypersensitivity Team to undertake further research on the provision of information in the non-prepacked sector including legislative options. The results of this work will be presented to the Board at a future meeting.