FSA Board Meeting - March 2024

FSA Board Meeting - March 2024: Video and Minutes

The agenda and papers for the FSA Board Meeting on Wednesday 20 March 2024.

Video of FSA Board Meeting March 2024

Minutes of FSA Board meeting - March 2024

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FSA Board Meeting - March 2024: Agenda and Papers

Agenda and papers for the FSA Board meeting on 20 March 2024. Crowne Plaza, Wellington Street, Leeds, LS1 4DL

The agenda for this meeting includes:

- Governance Review
- Regulated Products
- Precision Breeding
- Foodborne Disease
- Strategic Risk Management
- Report from the Chair of the Welsh Food Advisory Committee

9:00 - Chair's Introduction

Professor Susan Jebb presents the minutes and actions from the previous FSA Board meeting in December 2023 and presents the Chair's report.

FSA 24-03-01 - Minutes of the FSA Board Meeting on 13 December 2023

FSA 24-03-02 - Actions Arising - March 2024

09:20 - FSA Executive Governance Review: Next Steps (FSA 24-03-03)

Katie Pettifer and Sam Faulkner introduce a paper proposing a Board Operating Framework as the central guide to the FSA's governance structures.

FSA 24-03-03 - FSA Executive Governance Review: Next Steps

09:40 - Regulated Products (FSA 24-03-04)

Rebecca Sudworth, Peter Quigley, and Chris Rundle introduce this paper.

FSA 24-03-04 - Regulated Products

10:20 - Precision Breeding – Response to Public Consultation and Next Steps (FSA 24-03-05)

Rebecca Sudworth and James Cooper introduce a paper setting out the background and conclusions of the FSA's consultation on proposals for a new framework in England for the regulation of Precision Bred Organisms, plans for secondary legislation, and next steps.

FSA 24-03-05 - Precision Breeding – Response to Public Consultation and Next Steps

10:50 - Foodborne Disease Policy Overview (FSA 24-03-06)

Rebecca Sudworth and Anthony Wilson introduce a paper giving an overview of foodborne disease in the UK and how the FSA and others throughout the food chain are mitigating the associated risks.

FSA 24-03-06 - Foodborne Disease Policy Overview

11:20 - Break

Please note after the break the meeting will be chaired by FSA Deputy Chair, Timothy Riley, as FSA Chair, Professor Susan Jebb, has submitted apologies.

11:50 - Chief Executive's Report to the Board (FSA 24-03-07)

Emily Miles presents the Chief Executive's report to the FSA Board. This paper will be added on 18 March 2024.

FSA 24-03-07 - Chief Executive's Report to the Board

12:20 - Strategic Risk Management (FSA 23-03-08)

Ruth Nolan introduces a paper reflecting the FSA's approach to risk management, including identifying which responsibilities lie at Board, Audit and Risk Assurance Committee (ARAC) or Executive level, and providing an overview of the strategic risks being managed.

FSA 23-03-08 - Strategic Risk Management

12:40 - Report from the Chair of the Welsh Food Advisory Committee (FSA 24-03-09)

Rhian Hayward presents an update on the activity of the Welsh Food Advisory Committee from the period March 2023 to February 2024.

FSA 24-03-09 - Report from the Chair of the Welsh Food Advisory Committee

12:55 - Report from the Chair of the Business Committee (INFO 24-03-01)

The Chair of the Business Committee, Timothy Riley, presents a report from the Business Committee meeting that took place on 11 March 2024. This paper will be added on 18 March 2024.

INFO 24-03-01 - Report from the Chair of the Business Committee

13:10 - Report from the Chair of the Audit and Risk Assurance Committee (INFO 24-03-02)

The Chair of the Audit and Risk Assurance Committee (ARAC), Anthony Harbinson, presents a report from the ARAC meeting that took place on 5 March 2024. This paper will be added on 18 March 2024.

INFO 24-03-02 - Report from the Chair of the Audit and Risk Assurance Committee

13:20 - Reports from the Chairs of the Food Advisory Committees (Oral Reports)

The Chairs of the Northern Ireland Food Advisory Committee (NIFAC), Anthony Harbinson, and the Wales Food Advisory Committee (WFAC), Rhian Hayward, deliver oral updates from the recent meetings of the two Committees.

13:30 - Any Other Business

13:35 - Question and Answer Session

13:45 - End of meeting

Questions to the Board

We are keen to ensure, as far as is practical, that questions are addressed in the discussion at the Board meeting. Notwithstanding discussions on the day, all questions will receive a written reply within 20 working days of the meeting.

Please note questions are not listed below in the order in which they were received.

They are grouped according to the Board paper with which they are concerned and in the order of the papers as they appear on the Board agenda.

Questions on the Foodborne Disease Policy Overview paper (FSA 24/03/06)

Questions 1-8 are from Steve Nash, Campaigner on E.coli O157

The following questions are also asked due to the intention of the Food Standards Act 1999 that was the legislation that introduce the FSA which states:

“The main objective of the Agency in carrying out its functions is to protect public health from risks which may arise in connection with the consumption of food (including risks caused by the way in which it is produced or supplied) and otherwise to protect the interests of consumers in relation to food”

Question 1

Recent media reports indicate that people in England are facing food poisoning ‘Russian roulette’ as illnesses soared due to hospital admissions for Salmonella, between April 2022 and March 2023, according to NHS data. Campylobacter and E.coli hospital admissions have also reached record highs in the past two years. Surely now it is time to reflect and consider contributing factors such as any failings in horizon scanning, food policy and enforcement etc may have also contributed to this rise?

Answer 1

UKHSA and FSA work together to identify and understand the causes of any unusual patterns in occurrence of illness arising from gastrointestinal symptoms, which includes monitoring of unusual patterns in hospital admissions. The article referenced only looked at hospitalisation data from identified pathogens and therefore only gives a partial picture. Not all cases go to hospital and most (approximately 60%) foodborne disease cannot yet be attributed to the pathogens that caused it.

However, science is getting progressively better at testing and attribution. The data in this specific media report reflects the increase in the numbers of hospital cases that we can attribute to an identified pathogen (like Salmonella and Campylobacter), and these are increasing.

Overall, though, hospitalisations have been going down over the last ten years, and we have also seen a decrease in the number of cases where we can’t identify the cause. Taken together this strongly suggests that the apparent increase reflects a rise in identification of specific pathogens and not a rise in cases of food borne disease. Looking at all the lab report data including GP data, overall levels of FBD look relatively stable. The Third Infectious Intestinal Diseases (IID3) project funded by the FSA is currently gathering data that will allow levels of foodborne disease in the UK to be estimated and attributed more accurately.

Question 2

Do having thresholds for foodborne illnesses such as Campylobacter, Salmonella, E. coli O157 and Listeria monocytogenes indicate that whatever the number of confirmed cases for any given foodborne illnesses, that these are acceptable to the Agency and its Board?

Answer 2

The FSA has a statutory role to reduce the burden of foodborne disease. Under our general powers, the FSA monitors rates of foodborne disease, develops policy and provides advice to Ministers on its mitigation, and issues advice and guidance to local authorities, food businesses and consumers to support the reduction of foodborne disease. The FSA is one of several

stakeholders in the food system who contribute to mitigating the risks of FBD, which also includes wide stakeholder groups such as farmers, manufacturers, retailers, and consumers.

Pathogenic microorganisms are ubiquitous in the environment and present an inherent risk to food. While the total elimination of pathogenic microorganisms is not realistic, the FSA is committed to taking actions which fall within our remit, are proportionate, and are effective to reduce the burden of foodborne illness. There are significant controls in place to minimise the levels of illness in the population and we are working to do more. If the trend starts to move in the wrong direction that can be an indication of something new, an issue in the system or as a result of enhanced surveillance and improved detection capability. Threshold levels which are both realistic and ambitious are necessary to identify where these changes are outside of normal statistical variation and to guide FSA actions and resource allocation. They are a warning system not a target.

Question 3

Have the FSA including the Board, considered that having thresholds may be seen as a lack of ambition in trying to reduce the number of foodborne illness cases, rather than setting targeted reductions for all foodborne diseases, which even if they do fail, could appear to be a more proactive, positive and open approach?

Answer 3

While the FSA has established threshold levels for the four key pathogens associated with foodborne illness, our activities aim to continually reduce incidence of foodborne illness. We work with our partners and stakeholders along the whole food chain to identify and mitigate foodborne disease risks. The thresholds are part of our monitoring system not a statement of ambition. As such they are reviewed when that baseline might change for example as a result of successful pathogen reduction campaigns or changes in sampling or identification capability. They are set to account for the expected statistical variation to ensure they give us accurate warning if disease trends change. This varies between pathogen and therefore the thresholds are also different.

We are always seeking to lower rates of foodborne disease and the FSA carries out a significant amount of proactive work which aims to prevent incidents of foodborne disease. This includes providing regular updates to local authorities on various food safety issues; developing consumer advice to raise awareness on potential food risks and how consumers can reduce these risks (e.g. advice on enoki mushrooms, infant formula preparation machines, etc.); and continually raising awareness about food safety in social media campaigns.

Question 4

Given that detection methods have improved, do the FSA and Board agree that this will lead to more reported and confirmed cases. This could lead to a more accurate number of cases being reported and more sources of cases and outbreaks being identified by the UK Health Security Agency (UKHSA). This may then enable the Agency to target those food businesses who are not compliant, as well as other Government departments responsible for those cases that are in the environment?

Answer 4

We agree that with improved detection methods such as PCR and whole genome sequencing, linked cases, outbreaks, and associated food sources of contamination can be identified earlier and effective control measures established sooner to prevent further cases of illness.

The FSA works closely with our partners at UKHSA, as well as Public Health Wales, Public Health Agency Northern Ireland, and Public Health Scotland and Food Standards Scotland, to share data to support effective and timely management of outbreaks and take proactive actions in the event of signal detection to prevent outbreaks.

Question 5

Refers to [9] at the bottom of the board paper. Are the FSA and board saying that they are going to include the total number of Shiga toxin-producing Escherichia coli (STEC) non O157 and O157 cases together as one total figure for the number of cases. Also allowing an estimate of 50% coming from a food source until a more accurate percentage can be identified via scientific results and its data from the improved detection methods? If so, is this being done in conjunction with the UKHSA?

“[9] Many types of E. coli bacteria carry one or more shigatoxin-producing genes (making them shigatoxin-producing E. coli, or STEC). The commonest type is called O157, but we are increasingly finding disease caused by other types, partly as a result of new more accurate testing. This means that we may have an incomplete estimate if we only look at O157. In IID2 we estimated that half of STEC cases (O157 and non-O157) come from food”.

Answer 5

The FSA will be working with UKHSA to agree an approach on detection and reporting. This will be discussed with the Board at a future meeting.

Question 6

The board paper mentions about being proportionate, which basically means being equivalent. “Individuals and carers are the group bearing the largest cost of FBD in the UK at £8.9bn in 2018”. This was published in 2020 in “The Burden of Foodborne Disease in the UK”. However, these sufferers of food borne illness are not entitled to freely know what food businesses were involved in their cases or outbreaks in the food supply chain, where traceability is a requirement and where government reports etc conceal this information. Is that proportionate to the sufferers or carers?

Answer 6

During outbreak investigations there is an extensive multi-agency effort to identify the outbreak source, the root cause that led to safety risks and to ensure effective corrective actions plans are developed and effectively implemented to reduce the risk of re-occurrence. Outbreaks are confirmed by either microbiological and/or food chain evidence, and in some cases, it is not possible to identify the the cause of the outbreak.

The nature of food chain investigations makes it a labour-intensive task, with increasingly complex supply chains. Naming an organisation or business could have serious repercussions, especially where there are uncertainties over the point of failure that led to safety risks. For example, for chilled foods, it is possible that storage anywhere in the cold chain, including in the home is the cause of food becoming unsafe.

If unsafe food is identified, the FSA does alert consumers by publishing product recall information notices (PRINs), and these alerts provide information on the business concerned. Similarly, the FSA proactively informs consumers of successful prosecutions and investigation outcomes that could also affect a business’s FHRS rating which is made publicly available to consumers.

Question 7

Do the FSA and Board feel that the Food Hygiene Rating Scheme (FHRS) launched in 2010, previously known as “Scores on the Doors Scheme on Hygiene in Food Businesses” should be made mandatory? This was first consulted on in 2008 and would partly help in England to drive up hygiene standards and therefore have some impact on reducing foodborne illness. Consumers in the rest of the UK (where it is mandatory) benefit from, making an informed choice etc. The National Audit Office report of 12th June 2019 also recommended making it mandatory. When is it planned to introduce legislation to do so?

Answer 7

We have long supported extending the statutory scheme to England. Our three-year Corporate Plan 2023-26 lays out our ambition to work toward primary legislation to make display of Food Hygiene Ratings mandatory in England.

A mandatory scheme in England would require new primary legislation and cross-Government support, so the decision on whether to consult on proposals and legislate is dependent on Government priorities and timetabling. We are committed to bringing forward the appropriate legislation when an opportunity arises. Realistically, there is unlikely to be any prospect of this in the current term of parliament.

In the meantime, we continue to work with our local authority partners to maintain and improve public awareness of the impact and benefits of the Food Hygiene Rating Scheme, which remains a highly successful public health initiative. We continue to run regular awareness-raising campaigns and hold regular meetings with businesses and local authorities to encourage further display while we await a change in legislation.

Display rates are increasing in England, despite the lack of legislation. Our annual audit of display for 2023 indicates that, in England, just over two-thirds (69%) of businesses were displaying a food hygiene rating. This is a continuation of a steady upwards trend in rates of display by businesses in England since 2017, when 55% of businesses displayed a sticker.

Question 8

Have the FSA and the Board considered ending their relationship with their service provider at the next contract end date for Official Meat Control services in meat plants throughout England and Wales due to the shortage of vets which has been ongoing since at least 2018? This could adversely effect Foodborne disease and has demonstrated the service provider is in no better position to overcome this problem than the FSA are. There has also been an increase in the service provider’s contract payments. Does the board agree that the FSA require both short and long term sustainable plans to overcome these problems? In the short term, this will most probably lead to an increase in pay to attract suitable candidates. Longer term there will be need for training of vets with a comprehensive package to retain their services for working in an unpleasant environment.

Answer 8

The FSA is currently in the process of retendering its contracts for the provision of meat inspector and official veterinarian resources to deliver Official Controls in meat plants. An important part of the strategy for this procurement exercise is to attract bids from as many providers as possible in order to try to build resilience in the market. The new contracts will come into effect in April 2025. We continue to work with our current Service Delivery Partner to improve levels of retention for official veterinarians and maintain the pipeline of new people coming into the profession.

Despite the challenges faced over recent years with the availability of veterinary resources to work in the delivery of Official Controls in meat, there have been no incidents of a meat business being unable to operate due to the absence or shortage of an Official Veterinarian. This shortage of veterinary resources across the public health sector however is a recognised problem. We highlighted this in our annual report on food standards last year and the FSA CEO gave evidence on this to the Efra Committee hearing on 12 March 2024.

Recent changes to the Home Office immigration policy, which increase minimum salaries for overseas workers applying for skilled worker visas in the UK, risk exacerbating the problem of veterinary shortages. The FSA continues to work across government, veterinary professional bodies, and other stakeholders to build longer term strategies to address these issues.

Questions on the Precision Breeding – Response to Public Consultation and Next Steps paper (FSA 24/03/05)

Questions 9-13 are from Steven Jacobs, Business Development Manager, Organic Farmers & Growers CI

Question 9

Will the FSA board acknowledge that in order to safeguard supply chains, ensure market confidence, and protect the public interest then food business operators who would potentially come into contact with products containing Precision Bred Organisms will require sufficiently detailed, and timely reporting of, information that will ensure they can put into practice full traceability when asked to do so in the event of food fraud suspicion in general and more specifically under organic food regulations?

Without a way of identifying a Precision Bred Organism (PBO), through analysis or supply chain traceability, it will be almost impossible to identify where they are. Without PBO identification organic operators at any point in the food or feed supply chain will be unable to comply with the organic regulations in England, Scotland, Wales or in Northern Ireland.

Answer 9

The existing requirements for traceability in General Food Law (Assimilated Regulation 178/2002) will be sufficient for facilitating the traceability of PBOs in the food and feed supply chain for food safety purposes. Information on PBOs authorised for use in food and feed will be published on the FSA's public register. This register will also be complemented by Defra's register of confirmed PBOs, national listing and industry led initiatives including the British Society of Plant Breeder's (BSPB) plant variety register.

General Food Law traceability requires businesses in the supply chain to have in place systems and procedures that facilitate the traceability of food and feed products and identify other businesses to which their products have been supplied. The transparency provided through various public registers will ensure that PBOs entering the food and feed supply chain can be identified at the first step in the chain. Businesses looking to establish PBO free supply chains will be able to use this transparency (alongside statutory traceability requirements) to require businesses that they are supplied by to be PBO free.

Policy responsibility for non-safety related traceability information (e.g. providing information on production method along the food / feed supply chain) in relation to England rests with Defra. The concerns raised by organic operators have been relayed to Defra who, in addition to non-safety related aspects of traceability, have overall policy responsibility for organic food and feed standards.

Question 10

Would FSA Board members agree that the detail required for food and feed ingredients that may contain PBOs will need to be fully traceable for organic food business?

Can the board accept that a level of detail, such as is the case with existing GMO legislation, would help to ensure PBOs are visible to food and feed operators all along the supply chain, including storage, distribution and retail?

We would offer the example of the publicly available register currently in operation for GMO plant varieties in the EU. Main register webpage and two examples - Interrogate with Maize here and here.

Answer 10

The FSA public register of PBOs authorised for use in food and feed will provide a similar purpose for PBOs as the EU GMO register does for GMOs, to provide information to businesses to aid traceability. This register will be complemented by Defra's register of confirmed PBOs, national listing and industry led initiatives including the British Society of Plant Breeder's (BSPB) plant variety register.

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Question 11

In response to questions submitted by Steven Jacobs (on behalf of OF&G) to the FSA Board meeting March 2023 the Board made the following statement:

"The FSA Board is aware of the concerns of stakeholders including stakeholders representing the organic sector. We will continue to consult with stakeholders as the policy develops and as we learn more about the kinds of precision bred products that may come to market in future.

"Organic farming policy sits within Defra's remit and FSA policy officials have discussed the concerns raised in your questions to the FSA Board with their counterparts at Defra.

"The Government is not amending the organic regulations as a consequence of this Act and as such, precision bred crops will still be regulated as GMOs for the purposes of the organic regulations. This means that precision bred crops cannot be classed as organic."

Our question today is directly related to sale and distribution of organic food products under UK organic food regulations:

On what legal basis will the FSA refer in order to maintain protection with regard to organic businesses who are processing, distributing and
selling organic food to British shoppers?

a. Note - Under UK law Organic products must not be processed with foodstuffs containing genetically modified (GMO) ingredients.

b. Defra have stated that under UK law all PBOs are to be classed as GMOs with regard to UK organic regulations.

Answer 11

The FSA will continue to refer to existing regulations as also referred to by Defra. We note that the Government is not amending the organic regulations as a consequence of this Act and as such, precision bred crops will still be regulated as GMOs for the purposes of the organic regulations. This means that precision bred crops cannot be classed as organic.

The Organic Products Regulations 2009 already provide provisions to ensure compliance with organic requirements, including the prohibition of the use of GMOs (and by extension, PBOs) in the organic supply chain. These regulations also allow enforcement officers to defer sanctions to other parties, should the offence be due to the fault of another person (for example, failing to disclose the presence of PBOs in the supply chain).

PBOs being used in organic food would not directly be considered a relevant breach under the Precision Breeding Regulations. The presence of PBOs in organic food would instead be dealt with through existing regulations in the same way as the presence of GMOs in organic food is dealt with.

Question 12

Will the board accept that the FSA and Defra are both responsible for food safety, and are both responsible for negative economic impacts arising when businesses operating across various parts of food and feed supply chains are found to be in breach of regulations beyond what is required under general food safety legislative frameworks?

Answer 12

The FSA has a statutory remit to protect public health from risks which may arise in connection with the consumption of food and to protect the interests of consumers in relation to food. This remit is underpinned by the Food Standards Act 1999, which established the Food Standards Agency.

Whilst Defra is also responsible for protection of consumer interests, their responsibility does not extend to food safety. Defra is responsible for the integrity of the organic sector and food information / labelling for consumers in England where not related to safety.

We have considered a wide range of impacts of the proposed regulatory framework for PBOs as detailed in the consultation. These impacts, whether positive or negative, have been considered by the FSA alongside other relevant factors and evidence in arriving at our conclusions.

Question 13

What legal routes would be open to victims of food crime stemming from accidental or deliberately fraudulent placement of product containing GMOs on any UK markets, particularly if this happens under the guise of light-touch PBO (triage 1 as an example)?

Answer 13

Powers in the Precision Breeding Regulations will be used to tackle relevant breaches of those regulations in connection with the marketing of PBOs in food and feed. This will ensure local authorities can take necessary steps to withdraw any unauthorised PBOs that are marketed for

food and feed use, or where authorised PBOs are marketed in contravention of any conditions or limitations imposed on the PBO.

Questions 15-21 are from Pat Thomas, Director, Beyond GM

Question 15

FSA has stated that PBOs do not require traceability beyond what is mandated in General Food Law (Summary of Stakeholder Responses 7.1). This has implications for imported PBOs. Having rejected the conclusions of its own literature review - that analytical methods for the detection of PBOs should be developed in order to facilitate traceability - what measures has the FSA put in place to identify and trace illegal use and import of unauthorised PBO organisms and the food/feed containing these organisms as ingredients?

Answer 15

All PBOs must be authorised for use in food and feed before being placed on the market in England. The enforcement provisions outlined in the Precision Breeding Regulations will be applicable to PBO imports as well as domestic products. These enforcement provisions will be available to both inland local authorities and port health authorities at border control posts in addition to existing powers of enforcement across food law.

The Food and Feed Law Codes of Practice (and associated guidance) already provide enforcement authorities with guidance on carrying out functions of enforcement. This will be further supplemented by additional guidance specific to the Precision Breeding Regulations for enforcement authorities in England. We also plan to produce guidance for?local authorities and port health authorities in Wales and District Councils in Northern Ireland on the application of existing GMO regulations to PBOs.

Goods imported directly into Wales or Scotland would need to comply with relevant legislation in those countries where GMO regulations will continue to apply to PB food/feed. Imports directly into Northern Ireland must meet EU rules. If a breach occurs in Wales, Northern Ireland and Scotland, enforcement authorities can take action on PBOs that do not have a GMO authorisation that applies in those countries. Therefore, these nations will continue to impose GMO controls on any third country imports of PBOs.

The FSA independently reviews new evidence that becomes available that is relevant to food and feed safety. In the case of analytical methods for the detection of PBOs, we stated in our response to the literature review that we would welcome further research in this area. Where further research is conducted, we will proactively review this evidence and consider its relevance in relation to facilitating traceability.

Question 16

The Genetic Technology Act allows developers to define for themselves which information is commercially sensitive and, as a result, will be withheld from the register. Beyond personal information about the developer “commercially sensitive” is not defined. 1) How does the FSA define “commercially sensitive”? “2) With regard to the FSA register, how will FSA handle conflicts with Defra if information relevant to the safety of the product is withheld by the developer and will FSA or Defra be taking the lead on such decisions?

Answer 16

The Precision Breeding Regulations will allow applicants to request confidentiality of certain information on the grounds of commercial sensitivity. All requests must be justified by the applicant and the FSA will make decisions on whether confidentiality can be granted. This does not mean that they can withhold safety information from us as the regulator. Limits on information disclosure on the basis of commercial sensitivity only refers to information that is put in the public domain.

Commercially sensitive information has not been explicitly defined but would generally cover information that may affect an applicant's ability to work competitively as a business. Applicants would need to be able to demonstrate that this would be the case to be granted confidentiality. Non-commercially sensitive information that is relevant to the safe use of the PBO in food and feed would not be exempt from disclosure. This is in line with the definition of commercial interests in Article 43 of the Freedom of Information Act 2000 and guidance issued by the Information Commissioner's Office (ICO).

The FSA Board has previously agreed the level of information that is required for the register of PBOs authorised for use in food and feed. Applicants will not be able to request confidentiality of this information.

Question 17

The Board Paper (Annex B, 1.3) suggests that consumer response to the consultation was low compared to the Defra consultation. FSA further suggests that consumer responses "may not be representative of the wider population."

1) Please state the evidence on which you are basing this statement.

2) Beyond sharing news about the consultation with the business and precision breeding sector, and the specialist press associated with these, what steps did FSA take to ensure consumers/citizens were aware of the consultation?

3) Please list the mainstream outlets where the consultation was publicised in order to encourage a good consumer response.

4) How does the total number of respondents and consumer/citizen respondents for this consultation compare with other FSA public consultations?

Answer 17

The FSA sent the consultation to 35,654 individuals who subscribe to FSA alerts on consultations on 8 November 2023. The total number of responses received from consumers was 242, and we conclude that the remaining individuals did not feel strongly enough to be compelled to respond.

Defra's consultation on the regulation of genetic technologies in January 2023 received 6,440 responses. We surmise that consumers were far more likely to engage on the overarching intention of the Act than the FSA's policy proposals for the new regulatory framework on PBOs for use in food and feed.

The FSA uses a range of mechanisms for spreading awareness of each consultation. We signposted the forthcoming precision breeding consultation during our Board meeting in September 2023. At the time of the launch, we published a news story that was picked up by trade media outlets, as well some industry publications including The Grocer and Food Safety News. In the case of specific policy issues such as this, wider 'consumer media' generally will not run it which is why we also use social media. This consultation was promoted on our LinkedIn page which currently has 120,602 followers (as of 5 April 2024) and is the largest of our social

media channels.

The FSA consults on a wide range of issues which receive differing levels of engagement from stakeholders and consumers. Generally, FSA consultations receive a smaller number of responses for specific policy issues and, where consultation subjects are broader, the number of responses is higher. For example, an FSA consultation held in Summer 2022 covering transitional arrangements for edible insects in Great Britain received a total of 315 responses. In other cases, such as our May 2023 consultation on proposals for the authorisation of 12 feed additives for use in animal feed (which only received seven responses with no responses from consumers), engagement has been much lower.

However, we would like to note that these examples are not a direct comparison of both consultations, and number of responses (and demographics of respondents) will differ depending on the matter that is being consulted on.

Question 18

With regard to citizen responses, there is an error in your reporting of the number of respondents to the Defra consultation. In the Board Paper (Annex B, 1.3) FSA states “By comparison, Defra’s consultation on the regulation of genetic technologies in January 2021 received a total of 6440 responses, including 3083 responses from individuals.” In fact, the 3083 figure does not represent individuals who responded but the total number of responses via Citizen Space. This total breaks down as follows: Individuals = 2750; businesses= 198; nongovernmental organisations = 100; academia = 24; public sector bodies = 11).

A further 3347 respondents used the email platform which Defra made available (and these were removed from the final analysis). Will you correct this error in your report to the Board?

Answer 18

We acknowledge the error regarding the reporting of responses to Defra’s public consultation. Paragraph 1.3 of Annex B to the Board Paper states that there were 3,083 responses from individuals to the 2021 Defra consultation on the Regulation of Genetic Technologies. This figure, from Defra’s Summary of Responses, relates in fact to the total number of responses received via Defra’s Citizen Space online platform.

In its summary, Defra indicates that 2750 of these were from individuals. Defra also received responses from individuals via e-mail. Whereas the numbers have not been broken down in Defra’s summary, it can be surmised that over 3000 responses will have been submitted in this way meaning that that over 5750 responses to the Defra consultation were from individuals. This represents over 90% of the 6440 total responses received to that consultation.

Whilst the Board Paper itself cannot be edited, the questions submitted for the 20 March 2024 Board meeting and the FSA’s responses, including this response, are published on the relevant FSA Board meeting page and will serve as a correction.

Question 19

In several places in the Summary of Stakeholder Responses (1.5, 2.6, 5.22, 7.19, 9.22, 10.4, Annex D), the FSA states that non-safety related consumer labelling is out of scope or outside of its remit. However food safety is not the FSA’s only remit. The FSA must also ensure that food/feed is not marketed in a way that misleads consumers. Will FSA publish evidence of the independent considerations it has made and any advice it has given to Defra on what steps should be taken to ensure that, in the absence of labelling to identify food/feed containing PBOs,

these products will not mislead consumers?

Answer 19

Our independent considerations with respect to consumer information have been covered in successive Board papers in 2023 and 2024, as well as within our public consultation. The Board has actively discussed the views of consumers throughout the development of our proposals and recognises the importance of these views. This was a key focus of the Board's discussion and associated Board paper at the March 2023 Board meeting.

Whilst our remit covers the protection of consumer interests, the Food Compositional Standards and Labelling provisional Common Framework outlines formal responsibilities for matters related to non-safety labelling. In the case of England, this policy area is within the remit of Defra.

The power to decide on the mandatory labelling of PBOs for non-safety related purposes sits with the Secretary of State for Defra. FSA officials have however engaged with Defra officials and Minsters to make them aware of the views of consumers on this subject and a summary of all responses to the consultation has been provided to Defra officials.

The issue of mandatory labelling was a feature of debates in both houses of Parliament during the passage of the Act. In both houses, amendments to require mandatory labelling of PBOs for information purposes failed to gain sufficient support and the Act was written into statute without a provision for mandatory labelling. It is therefore reasonable to surmise that it is not within the will of Parliament to mandate labelling of PBOs in food and feed for information purposes.

Question 20

The FSA consultation document repeats the ACNFP's claims that there is "no evidence that PBOs are intrinsically more hazardous than TBOs" (8.8) and referred respondents to the ACNFP statements on this. However, none of the ACNFP's three statements on the regulatory process and the safety of PBOs make reference to the studies and/or source material that informs this conclusion.

Respondents, therefore, had no way of checking the validity of this claim. ACNFP claims for the safety of precision bred organisms, as referenced in the consultation pack (p5, ref 3), refer to comments made in a meeting and have not, in spite of repeated requests from stakeholders such as ourselves, been supported by the publication of any credible evidence. Will FSA please publish this information forthwith – or provide an explanation as to why this information is being withheld?

Answer 20

The Advisory Committee on Novel Foods and Processes (ACNFP) is an independent Scientific Advisory Committee (SAC). The Committee is composed of members from a range of scientific disciplines who provide insight, advice and the technical knowledge needed to evaluate the safety of precision breeding. The conclusions reached by the Committee are supported by the cumulative knowledge and experience of the Committee's specialists and scientists.

Based on their review of case studies (published in the ACNFP Statement July 2023, Annex A) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs are intrinsically more hazardous than traditionally bred organisms; they concluded that it was the alteration in trait that could lead to phenotypes of concern regarding the safety of the food or feed, rather than specifically the technology used to achieve the trait.

It is common for individuals who have developed expert levels of knowledge of a subject matter to have associations with industry and to participate in an advisory or expert capacity in other areas including government committees, publicly funded research etc. since they hold the required level of knowledge in reasonably niche subject areas. This is not limited to science or the FSA's independent scientific communities. Expert knowledge in genomics is not widely accessible and the FSA follows the government guidelines in the management of any conflicts of interest. In this way, we are able to obtain the required level of expertise as a source of information when developing policy. Our policy development derives from multiple sources of information, including scientific advice, scientific research, and public consultation.

We consider the independent advice provided by the ACNFP on precision breeding to be the best available scientific advice. ACNFP meeting agendas, papers, minutes and reports are published in a timely manner.

Question 21

Responses to the FSA consultation show high levels of consumer opposition to the deregulation of PBOs. Some of these are related to science and safety but others are social, ethical and values-led in nature. The FSA Board takes advice on scientific matters from the ACNFP and its subcommittee.

1) Does the Board also take advice on social issues in relation to PBOs from its Advisory Committee for Social Science (ACSS) and is this advice published in the same way as the ACNFP advice? The published response to the consultation from the Royal Society of Biology, for example, suggests that RSB has had an opportunity to feed into ACSS processes and states that the ACSS has "carefully considered this in its advice to the Board". In our engagement with the FSA, we have never been given the opportunity to feed into ACSS processes.

2) Can the FSA please list the organisations that have been invited to feed into ACSS considerations of PBOs in the food/feed system.

3) Is ACSS advice to the Board publicly available? If so, please provide links to this advice; if not, will FSA undertake to immediately publish all advice to the board from the ACSS on social, ethical and values-led issues around PBOs – or explain why this information is withheld?

Answer 21

The ACSS helped guide the FSA research on consumer views of precision breeding by providing advice on the research design and providing peer review. This research captured consumer views around the risk and benefits of precision breeding, and the FSA Board was briefed on key findings. This research is publicly available.

The ACSS did not provide separate advice to the Board on social and ethical consumer concerns on precision breeding. The FSA Board was, however, invited to discuss our most recent research project on consumer perceptions of precision breeding at the March 2023 FSA Board meeting. Whilst this research was subject to independent peer review by the ACSS, it was not presented to the Board as ACSS advice. This report was based on the views of consumers provided through surveys and workshops and was not influenced by evidence or advice provided by external stakeholders.

In RSB's consultation response, they highlighted that they previously responded to Defra's 2021 consultation on gene editing and that they "were pleased to see that the FSA Advisory Committee for Social Science has carefully considered them in its advice to the Board". The ACSS did not actively consider the response, but the conclusions drawn out by RSB are broadly supported by the findings of our consumer research.

The primary role of the ACSS is to provide expert strategic advice to the FSA on its application of the social sciences. In comparison the main role of the ACNFP is to review the safety assessments of applications for novel and traditional foods under UK legislation and the safety assessment of food and feed products of genetic technologies under UK legislation.

Question 22 - Patricia Walters, Private individual

The majority of respondents to the GMO/PBO consultation expressed disagreement with the FSA's proposals and clearly expressed a preference that precision bred organisms should be labelled and traceable through the food/feed system. The consultation report has set this opposition aside as largely irrelevant to government and by extension FSA policy (Board Paper 4.2, 4.3, Annex B 1.7, 2.3 and Summary of Responses 1.8, 3.11, 3.18, 3.19, 5.11, 5.41, 7.14 and all statistical tables).

The framing and tone used throughout the report is dismissive of the views of the majority of respondents in favour of the minority view.

Given that the FSA is meant to act independently and serve the interests of the public, are Board members comfortable with the report's characterisation of the majority public view and the way conclusions have been constructed around it?

Answer 22

The views of consumers are important to the Board and have been actively discussed throughout the development of the FSA's proposals, including at the March 2024 Board meeting, where Board members were invited to discuss the responses to the consultation.

Board members were responsive to the concerns raised by consumers but also highlighted that the Precision Breeding Act has been debated by and passed through both Houses of Parliament. These comments reflected the Chairs opening comments which outlined that the Act was subject to robust discussion and challenge at the Bill stage through parliamentary debate. The Chair added that Parliament has decided that it is going to introduce PBOs, and it is not for the FSA to oppose this. Our role is to establish a regulatory framework so that PBOs placed on the market are safe to eat.

The Board also asked that officials continue to consider how the FSA, working with other government departments, can support the concerns of consumers and organics businesses in relation to traceability and choice.

FSA officials will continue to work across Government to ensure the new framework is implemented in a way that protects consumers from harm.

Questions 23-29 are from Claire Robinson, Co-Director, GMWatch

Question 23

In its response to the public consultation, the FSA says it relies on "the best and most recent scientific evidence" and that it obtains this from the ACNFP, which some respondents, including GMWatch, have pointed out is compromised by conflicts of interest with the GMO industry.

The FSA says that inquiries regarding the recruitment process for ACNFP should be addressed to that body because it is "independent" of the FSA. However, the FSA has chosen to rely on the ACNFP for its scientific advice and the FSA itself claims to be "independent". This would appear to any reasonable person to mean that the FSA is free to choose which advice it relies on.

Therefore is not the FSA responsible for relying on non-independent and conflicted advice? For evidence of ACFFP's conflicts of interest, see this and this peer-reviewed analysis.

Answer 23

The ACNFP is an independent Scientific Advisory Committee (SAC) provides scientific insight, advice and the technical knowledge needed to evaluate the safety of PBOs for use in food and feed. It is established under Article 5(3) the Food Standards Act 1999. Members are recruited in line with the Code of Practice for Scientific Advisory Committees (CoPSAC). The ACNFP Code of Practice requires all members to provide clear declarations of interests which are then made publicly available on the ACNFP website. The Code of Practice outlines how conflicts of interests are managed within meetings of the Committee.

We consider the independent advice provided by the ACNFP on precision breeding to be the best available scientific advice. ACNFP meeting agendas, papers, minutes and reports are published in a timely manner and open to scrutiny.

The FSA strives to be an open and transparent organisation. We want to hear the views and perspectives from all those with an interest in food including academia, industry, civil society groups and members of the public.??This is reflected in the range of viewpoints amongst members on the Scientific Advisory Committees. Recruiting people to our Advisory Committees who have experience and insights from across the food system, including as individual citizens, is essential in helping the FSA deliver its mission to keep food safe. We have no evidence to suggest that any bias from any committee member has influenced the work of the FSA.

Question 24

The FSA has been shown to be compromised by conflicts of interest on its Boards, Committees, and Councils. Does the FSA argue that it is not responsible for the makeup of its own Boards, Committees, and Councils? Given that makeup, how does it justify its claim to independence and serving the public interest?

Answer 24

The Food Standards Act 1999 safeguards our political independence and ensures we are accountable to Parliament. It sets out our main goal to protect public health in relation to food. It gives us the power to act in the consumer's interest at any stage in the food production and supply chain.

The Act also establishes how Board members are appointed and how advisory committees are established. In the case of FSA Board members, all appointments are ultimately made by UK Ministers. Appointments to SACs are made by the Chair.

Our Board works to the Cabinet Office Code of Conduct for Board members of Public Bodies and FSA Code of Conduct. Likewise, the ACNFP work accordingly to the Good Practice Guidelines for Scientific Advisory Committees.

Question 25

The FSA refers people with concerns about the conflicts of interest of the ACNFP to the Code of Practice for Scientific Advisory Committees and Councils: CoPSAC 2021. However, this code does not prevent people with conflicts of interest with industry serving on Scientific Advisory Committees like the ACNFP. It merely requires that people with conflicts of interest declare them.

How does the FSA reconcile its claims of "independence" and as serving the public interest with its adherence to this flawed code of practice?

What steps has the FSA taken to ensure that it can genuinely claim to be independent in spite of the inadequacy of the code of practice?

Answer 25

As covered in our answer to question 24, The Food Standards Act 1999 safeguards our political independence. The statutory provisions in the Act are supported by FSA and UK Government Guidance, which together ensure our advisory committees adhere to best practice on matters of conflicts of interest.

CoPSAC 2021 was established following public consultation and provides guidance on the establishment, management and conduct of committees. The guidelines require that members with conflicts of interest declare them, the rules also require members to withdraw from discussion on matters in which there may be an existing conflict of interest.

The ACNFP also publishes its own Code of Practice which outlines how the Committee should function, including in relation to managing conflicts of interest.

The ACNFP maintains a register of interests (including financial and non-financial interests) which is made available for the public to uphold transparency on potential conflicts. Where an interest is declared in a meeting, this is logged in the meeting minutes along with the resulting action. Minutes of all meetings are published on the ACNFP website.

The Advisory Assessment Panel requires that all candidates for appointment declare any relevant interests and have no conflicts of interest that would call into question their ability to perform the role. All potential conflicts of interest and how they might be managed are discussed with potential members at interview.

Question 26

Huw D. Jones has a history of conflicts of interest with industry, as well as being a longstanding lobbyist for GMO deregulation. He serves on ACRE and the ACNFP, with the latter body advising the UK Food Standards Agency and Food Standards Scotland on GM foods. This double role is a problem because it works against the independence of both committees, suggesting that they could be working in lock-step with each other. It also means that in his role on one committee, he could be sitting in judgement on a decision made in the other committee – an example of "marking your own homework".

How does the FSA justify relying on the advice of this person while at the same time claiming to be independent and serving the public interest?

Answer 26

The Advisory Committee on Releases to the Environment (ACRE) and the Advisory Committee on Novel Foods and Processes (ACNFP) Sub-Committee on Products of Genetic Technology (PGT) have different terms of reference as laid down by the respective legislation. ACRE, 8 members, focuses on the potential environmental risks associated with releases of genetically modified organisms, whilst FSA supported committees (ACNFP and sub-committee), 26 members, address the evidence associated with potential risks for food safety. The responsibilities of the two committees are distinct and they are not asked to comment on the decisions made by the other committee.

However, given the commonality in the wider science it is beneficial for the two committees to be aware of each other's work. The FSA has specifically ensured a member of ACRE sits on both the ACNFP and its Sub-Committee on Products of Genetic Technology. Members of Secretariat and policy officials from Defra and the FSA also attend both advisory committees. We therefore do not agree that sitting on two Government science committees is inappropriate. Members of both committees are independently appointed based on identified expertise, skills and experience.

The FSA have a clear code of conduct in place for declarations of interest and these are carefully scrutinised. In applying best practice, all appointments made are based on merit and equal opportunities, with independent assessment, openness and transparency of process as set out in the Code of Practice for Scientific Advisory Committees and Councils (2021). As such, all ACNFP Members complete a declaration of interests statement which can be found on their profiles on the ACNFP website. At the beginning of each meeting, all Members are asked to declare any potential conflicts of interest for the items under discussion according to the FSA advisory committee good practice guidance. A Member declaring a conflict of interest does not participate in the conversation or leaves the room while the conversation takes place; this is recorded in the minutes of the meeting.

All of our committee members are required to follow these processes. No specific interests have been raised for the member in question for his work as a member of the ACNFP. We therefore do not agree with the interpretation that the committee member in question has conflicts of interest in relation to his committee work for the FSA.

The FSA strives to be an open and transparent organisation. We want to hear the views and perspectives from all those with an interest in food including academia, industry, civil society groups and members of the public.??This is reflected in the range of viewpoints amongst members on the Scientific Advisory Committees. Recruiting people to our Advisory Committees who have experience and insights from across the food system, including as individual citizens, is essential in helping the FSA deliver its mission to keep food safe. There is no evidence to suggest that any bias from any committee member has influenced the work of the FSA.

We keep our approach to managing potential conflicts of interest up to date, and in line with all relevant government guidance. We will also continue to strive to ensure that decisions are made with consumer safety front and centre of our thinking and to be transparent in our decision-making.

Question 27

In its consultation pack, the FSA cites the ACNFP as saying there is "no evidence that PBOs are intrinsically more hazardous than TBOs".

However, the ACNFP has nowhere provided the evidence supporting this statement and our attempts to obtain it from the FSA have drawn a blank. If the ACNFP means there is no evidence that GM PBOs are intrinsically more hazardous than TBOs because scientists have not looked at this issue, then this is not evidence of safety, but a case of ignorance: "absence of evidence is not evidence of absence [of risk]".

Does the FSA agree that in the interests of evidence-based policy, the ACNFP and the FSA must either publish the studies that show that GM PBOs are as safe as TBOs, or they must honestly state that the safety/risk profile of GM PBOs is not known and that they are basing their policy on assumptions and belief?

Answer 27

The ACNFP is an independent Scientific Advisory Committee (SAC) which operates to the required standards of openness and transparency as laid down in relevant guidance. These experts provide scientific insight, advice and the technical knowledge needed to evaluate the safety of PBOs for use in food and feed. The conclusions reached by the Committee are supported by the cumulative knowledge and experience of the Committee's specialists and scientists.

We consider the advice provided by ACNFP on precision breeding to be the best scientific advice available to us through existing and longstanding arrangements for the provision of independent scientific advice. ACNFP meeting agendas, papers, minutes and reports are published in a timely manner, and this will continue to be the case for all meetings where precision breeding has been and will be discussed.

It is not possible to scientifically prove that PBOs are no more harmful that their traditionally bred counterparts; however, based on their review of case studies (published in the ACNFP Statement July 2023, Annex A) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs (as confirmed by the Advisory Committee on Releases to the Environment, ACRE) are intrinsically more hazardous than traditionally bred organisms. Instead, they concluded that it was the alteration in trait that could lead to phenotypes of concern regarding the safety of the food or feed, rather than specifically the technology used to achieve the trait. The consultation responses did not provide specific evidence to contradict this conclusion.

Question 28

If the FSA is independent of government, why does it state that it cannot impose labelling on GM PBOs because the government doesn't want it? Note that the Genetic Technology Act does not forbid labelling.

Answer 28

The FSA has no power to lay its own legislation and cannot impose labelling.

Our independent considerations with respect to consumer information have been covered in successive Board papers in 2023 and 2024, as well as within our public consultation. The Board has actively discussed the views of consumers throughout the development of our proposals and recognises the importance of these views. This was a key focus of the Board's discussion and associated Board paper at the March 2023 Board meeting.

Whilst our remit covers the protection of consumer interests, the Food Compositional Standards and Labelling provisional Common Framework outlines formal responsibilities for matters related to non-safety labelling. In the case of England, this policy area is within the remit of Defra.

The power to decide on the mandatory labelling of PBOs for non-safety related purposes therefore formally sits with the Secretary of State. The Chair and FSA officials have however engaged with Defra Minsters and officials to make them aware of the views of consumers on this subject.

The issue of mandatory labelling was a feature of debates in both houses of Parliament during the passage of the Act. In both houses, amendments to require mandatory labelling of PBOs for information purposes failed to gain sufficient support and the Act was written into statute without a provision for mandatory labelling. It is therefore reasonable to surmise that it is not within the will of Parliament to mandate labelling of PBOs in food and feed for information purposes.

Question 29

Most people who responded to the FSA's consultation disagreed with the deregulation proposals and said they wanted labelling and traceability throughout the food/feed supply chains. The FSA portrays these people – which represent the majority of responses – as opposing the government's and FSA's intentions and "opposing the use of modern biotechnologies in general" and on this basis, dismisses their views as irrelevant.

Yet it does not symmetrically apply the same standard to the opposite (minority) point of view – in favour of the government's and FSA's proposals. And the minority point of view is the one that the FSA is determined to follow.

This is an insulting, anti-democratic, and unscientific response to a public consultation. It is equivalent to asking the public for their views on airport expansion and then dismissing all those who oppose it, on the grounds that the government wants airport expansion.

The FSA's response is also inaccurate and misleading. There is no evidence to suggest that the respondents who want GMO labelling and traceability oppose "the use of modern biotechnologies in general"; the consultation was not designed to ascertain the existence of such a generalised opposition. Our experience is that people's attitudes are more nuanced. For example, GMWatch supports the use of the modern biotechnology of marker assisted selection (unencumbered by patents) in combination with conventional breeding. Similarly, many people who oppose agricultural GMOs are in favour of the use of modern biotechnology for certain medical applications; and some people who support certain agricultural uses of GM still want labelling and traceability.

Given the above, will the FSA amend its report to:

i) clarify why it fails to apply symmetrical evaluation standards to both points of view (in favour of and against the government's/FSA's proposals)

ii) recognise the nuances of public attitudes to GMOs and their regulation, as well as the limitations of the conclusions that can be drawn from the responses to the consultation (opposition to "the use of modern biotechnologies in general" was not surveyed)?

Answer 29

We agree with your statement “There is no evidence to suggest that the respondents who want GMO labelling and traceability oppose "the use of modern biotechnologies in general"; the consultation was not designed to ascertain the existence of such a generalised opposition. Our research has shown us that people's attitudes are more nuanced.”

In our summary of responses, we stated that “The majority of responses that did not support the intentions of the Act opposed the use of modern biotechnologies in general, citing reasons including the potential harm to the environment and the impacts on biodiversity, as well as the potential safety risks caused by unintended consequences of genetic modification (GM)”. The general opposition towards modern biotechnology referred to here is in the context of food, feed and agricultural uses, not wider industries (for example, healthcare). In the context of the consultation and the reasons cited for the opposition, we feel this point is sufficiently implicit so as to not mislead and reflective of the general sentiment of these respondents, although we accept your comment that this could have been made clearer.

As set out in in paras 1.9 and 3.18-19 of our response to the consultation, we did not use a numerical statistical analysis of the responses or weighting of individuals vs organisations (para 3.5) but instead considered the more detailed written free text comments in developing our response.

We disagree that this approach dismisses any views. We clearly acknowledged the overall balance of responses, but also ensured that all the main themes expressed were identified and duly considered. This is important in a consultation which was not designed to provide responses from a representative sample.

Many respondents took the opportunity to provide detailed qualitative answers directly in relation to the questions asked as well as more broad answers relevant to the wider policy. We conducted a thematic analysis of these responses to appropriately summarise the views expressed by all respondents. Our conclusions are based on unbiased consideration of all responses; however, we consider it relevant context to highlight the broader views of stakeholders in relation to the Act, which has been democratically written into law following parliamentary debates.

Questions 30 - 44 are from Leonie Nimmo, Executive Director, GM Freeze

Question 30

The Food Standards Agency (FSA) will be aware that in February the European Parliament voted to require labelling and traceability of organisms developed using ‘New Genomic Techniques’ (NGTs). Should the UK persist with plans for no labelling or traceability of ‘Precision Bred Organisms’ (PBOs), this is likely to lead to non-tariff trade barriers.

The Government’s Impact Assessment of the Genetic Technology (Precision Breeding) Bill states: “Most likely, new trade barriers would come in the form of checks and certification requirements on UK food exports entering the EU’s single market. This would not only affect products exported to the EU which contain PB plant material, but also those in the same product categories which do not.”

This acknowledgement that all food and feed trade exports with the EU could be subject to non-tariff barriers is not reflected in the FSA’s plans or documentation. Indeed, the board papers for this meeting ‘Response to Public Consultation and Next Steps’ do not mention Europe once.

What is the FSA doing to ensure that the livelihoods of British farmers and food producers will be protected in the face of burdensome non-tariff trade barriers that result from the FSA’s proposals?

Answer 30

The international trade of precision bred food and feed is primarily a matter for Defra; however, we recognise the potential impact of precision breeding on UK exports and therefore we have conducted extensive engagement with stakeholders involved in supply chains to better understand the impacts. Many of these stakeholders also responded to our consultation. We have also adopted a best practice approach to consider how our framework correlates with the regulatory frameworks of third countries. Generally, most countries – including the EU – are converging on a common direction of travel, although there will always be a degree of unavoidable divergence in approaches.

Businesses will need to ensure food exported from the UK to other countries/blocs continues to meet the rules of those countries/blocs. We will continue to work with Defra to aid understanding of stakeholder perspectives with regard to matters where UK food exports could be impacted.

The EU remains a close trading partner with the UK and we have been monitoring the progress of the European Commission’s proposal for the regulation of plants produced from New Genomic Techniques. This situation is ongoing and any final agreement on the proposals will be contingent on trilogue negotiations between the European Parliament, the Council and the Commission. These negotiations cannot happen until the Council agree a negotiation mandate.

We regularly monitor UK-EU regulatory divergence to consider the impact of divergent decision making on the UK food and feed market and we will continue to observe these developments.

Question 31

The FSA's 'Response to Public Consultation and Next Steps' states that it does not plan to revisit or reverse its decision not to develop analytical methods for the detection of precision bred products. Has it taken into account the European Parliament's votes on labelling and traceability, as well as the fact that the fact that the European Union is actively funding the development of detection strategies for NGTs, for example, via the Darwin project? The UK will fall behind scientific advances in this area if it fails to invest in detection strategies, and this is likely to create significant disadvantages in the event of future non-tariff trade barriers.

Answer 31

The FSA's 'Response to Public Consultation and Next Steps' states that it does not plan to revisit or reverse its decision not to develop analytical methods for the detection of precision bred products. Has it taken into account the European Parliament's votes on labelling and traceability, as well as the fact that the fact that the European Union is actively funding the development of detection strategies for NGTs, for example, via the Darwin project? The UK will fall behind scientific advances in this area if it fails to invest in detection strategies, and this is likely to create significant disadvantages in the event of future non-tariff trade barriers.

In our response to LGC Ltd.'s Literature review on analytical methods for the detection of precision bred products, we concluded that whilst we did not plan to take forward any of the recommendations in the report to aid ongoing policy development on precision breeding, we welcomed further research in this area to ensure we have the most up to date scientific information available when reviewing policy and/or developing new policies related to genetic technologies.

The FSA is science and evidence led. We regularly conduct horizon scanning and independently review new evidence that becomes available that is relevant to food and feed safety. In the case of detection, we will continue to monitor new developments in this area as necessary regardless of where in the world this research is conducted.

The consensus is that currently there are no methods that provide unequivocal detection of PBOs. If this changes, we will review how these methods can be deployed.

It is also worth noting that the scope of the EU's proposals for plants produced from NGTs is wider than the scope of the Precision Breeding Act, and therefore detection of NGTs (particularly those determined to be category 2 NGTs) is not directly comparable to the detection of PBOs.

Question 32

In the Government's 2022 report on 'Statistics of scientific procedures on living animals' it is stated that "policies and legislation that influence the number and type of procedures are the responsibility of different government departments". Specifically, that food safety legislation is the FSA's responsibility.

a. Has the FSA estimated how the proposed legislative framework will impact the number of procedures performed for the purpose of the creation and breeding of genetically altered animals?

b. Will the framework lead to an increase in the number of experimental animal procedures in the UK, year on year? Will the bespoke safety testing conducted or commissioned by the FSA involve

animal testing, and are developers likely to use animal testing to generate safety data?

Any mention of animal testing is absent from the ‘Response to Public Consultation and Next Steps’ and the ‘Summary of Responses’, despite it having been raised in the consultation. Please clarify.

Answer 32

Before businesses can apply for an authorisation for the use of a precision bred animal in food and feed, they will have to secure a precision bred confirmation from the Secretary of State. This will not be possible until further secondary legislation is brought forward in relation to animal welfare. We therefore do not expect to receive any applications to authorise any precision bred animals for use in food and feed for some time.

PB animals will initially fall under the auspices of the Animals in Scientific Procedures Act 1986 (ASPA). This requires that animals are only ever used in science where there are no scientifically satisfactory alternatives, where the number of animals used is the minimum needed to achieve the scientific benefit, and where the potential harm to animals is limited to that needed to achieve the scientific benefit. In addition, ASPA contains a list of pre-defined purposes for which animals may be used. This is in essence an ethical consideration, and projects that do not meet these standards will not be awarded a licence to generate a precision bred animal.

Bespoke safety testing aims to avoid animal testing wherever possible. Safety data requirements will be set out in the implementation of the technical guidance. The FSA intends to publish the technical guidance in draft form over the summer with the final draft expected to be agreed and published in the autumn. Any requirements for animal testing would need to be considered in the context of the three R principles outlined as replacement, reduction and refinement.

Question 33

The ‘Summary of stakeholder responses’ reasserts that safety information for a particular population group can be required as appropriate.

How does the FSA intend to honour this pledge when there will be no way to identify PBOs, which may become mixed with non-‘PBOs’?

Furthermore, safety labelling appears on all packaging, not just on products sold to consumers with particular health conditions. Therefore, how is it possible to do this whilst also not label ‘PBOs’?

Answer 33

Existing food legislation requires food to be appropriately labelled with safety information such as allergen labelling including “may contain” information. These requirements apply to all food products regardless of production method, including precision breeding.

The regulatory approach proposed by the FSA allows us to identify potential safety risks associated with PBOs. Following this assessment, the FSA is able to recommend or require that the appropriate measures are taken to control risks and uphold consumer safety. For the majority of products meeting this criteria, this will involve referring to existing such as Regulation No. 1169/2011, the Food Information to Consumers (FIC) Regulation. Furthermore, the FSA is able to impose further limitations and conditions of use on products, including PBOs, if necessary to ensure that consumers are sufficiently and properly informed.

In the case of a safety risk, like an allergen, where supply chains are not segregated the requirement of existing food law would be to ensure that products are labelled with “may contain” information pertaining to the possible presence of an ingredient that may have safety concerns for some people.

Question 34

Who would bear the cost in the event of a safety-related product recall, given that – with no labelling or traceability - all products in a product category would need to be recalled, not just the ‘PBO’ ones?

Answer 34

If there is a problem with a PBO food product (as with any food product) that means it should not be sold, then it may be 'withdrawn' (taken off the shelves) or 'recalled' (when customers are asked to return the product).

The FSA issues Product Withdrawal Information Notices and Product Recall Information Notices to let consumers and local authorities know about problems associated with food. In some cases, a 'Food Alert for Action' is issued. This provides local authorities with details of specific action to be taken on behalf of consumers.

As with all food products, not just PBOs, food businesses are responsible for recalling products that are unsafe and bear the cost of any recall. Therefore, most businesses will consider the potential costs of product recall procedures and the infrastructure that can be put in place to limit widespread recalls. This can include but is not limited to record keeping such as batch numbers and production dates. Additionally, food hygiene law requires businesses manufacturing food to have a Hazard Analysis and Critical Control Point (HACCP) plan in place, which will enable them to identify and control risks which may lead to a product recall.

If necessary, authorities may also issue a costs notice requiring a person to pay the costs incurred by an authority in relation to issuing an enforcement notice, up to the time of its issue.

Question 35

If there is no traceability or labelling, how will it be possible to identify gene edited products that undergo a significant production step in Wales or Scotland, in order for them to subsequently be authorised and labelled?

Answer 35

For any food and feed supply (including international trade) the supplier must ensure that the products they deal with meet the requirements of the customer, including the legal requirements of the market into which they are selling. This can be achieved through commercial contracts specifying supply chain controls, supported by documentation and audit without the need for additional traceability requirements and, in this instance, would be supported by the FSA’s Public Register of PBOs authorised for use as food/feed.

The issues of the UK Internal Market Act are being considered separately with other relevant government departments including the Department for Business and Trade which has overall policy responsibility in this area. The FSA will produce guidance for enforcement authorities in England and for those in Wales and Northern Ireland where existing enforcement provisions including those in legislation regulating GMOs (which will remain unchanged in those countries) will continue to be used.

Question 36

The ‘Response to Public Consultation and Next Steps’ and the ‘Summary of Responses’ make no mention of conditions of use being attached to Tier 2 ‘PBOs’, as mentioned in the consultation. Is this still a prospect? If so, how would these be maintained or monitored, given the absence of labelling or traceability?

Answer 36

For Tier 2 PBOs, the additional risk assessment and consideration of any other legitimate factors is designed to identify any risks so that conditions of authorisation can be put in place prior to placement on the market where necessary (such as mandatory safety labelling for certain categories of consumers with allergies or food intolerances).

Conditions of use recommended as part of risk management would be enforceable under the enforcement powers established by the Precision Breeding Regulations. Enforcement authorities will also be provided with guidance to assist with the execution of these powers.

Question 37

Will consumers be able to link the PBO products that they buy with entries on the register?

Answer 37

The FSA’s register of authorised PBOs for use in food and feed will be complemented by Defra’s register of confirmed PBOs, national listing and industry led initiatives including the British Society of Plant Breeder’s (BSPB) plant variety register. This will ensure there will be sufficient and useful information to consumers and allow businesses to provide this information to consumers, should they consider there to be a need to provide these details.

The FSA will establish an enhanced register that will go further than the basic information required by industry and enforcement officers and will include information requested by consumers for authorised PBOs for use in food and feed. At a minimum this will include:

- name of the PBO and the Authorisation holder
- purpose of the edit and date of authorisation
- any conditions of authorisation (e.g. any mandatory product-level information that should be provided)
- a unique reference number (URN) for each authorised PBO (this could both assist search functionality and enable businesses to include this URN on commercial documentation, should they wish to do so)
- a link to the relevant entry on the Defra register confirming PBO status and details of any bespoke safety assessment

The FSA’s public register will not be a product level based register as this would limit accessibility and would be difficult to keep up to date. Therefore, this approach could undermine the provision of reliable information, which would be counterproductive to the aim of our public register.

Question 38

The ‘Summary of Responses’ states “there is no justification or need to explicitly distinguish between PBOs authorised via Tier 1 and Tier 2 on the public register” on the basis that the organisms “have the same regulatory status”. However, PBOs from the two tiers have different risk profiles.

Is it the FSA's position that consumers and other interested parties have no right to know this information, or is it rather the case that the FSA is following the wishes of developers in this regard? If the FSA refuses to publish which tier the organisms have been authorised under, will it be impossible in future for the public to know what proportion of PBOs fall under the different tiers?

Answer 38

The FSA has developed a tiered approach to enable increased scrutiny of PBOs that have traits where potential safety risks are not fully understood. These PBOs will undergo a safety assessment to ensure that any risks are understood and can be managed, for example, with safety labelling. All PBOs that are authorised will be considered safe for use as food and feed irrespective of which route to authorisation was taken.

The FSA is committed to transparency and to ensuring that consumers and other interested parties can access information on all authorised PBOs including details of any safety assessments that have been conducted. This information will be on a public register of PBO authorisations and will be available on the FSA website. It follows that where information on a safety assessment is available against a PBO on the register, that PBO will have gone through the Tier 2 regulatory route to authorisation. Should a person wish to establish the proportion of PBOs that fall under each route to authorisation, they could quite easily identify those PBOs with additional safety assessment information and those without as submissions under the Tier 2 and Tier 1 regulatory routes respectively.

Question 39

What evidence has the ACNFP assessed in order to decide that there is 'no evidence that PBOs are intrinsically more hazardous than TBOs'?

Answer 39

The ACNFP is an independent Scientific Advisory Committee (SAC) provides scientific insight, advice and the technical knowledge needed to evaluate the safety of PBOs for use in food and feed. The conclusions reached by the Committee are supported by the cumulative knowledge and experience of the Committee's specialists and scientists.

We consider the advice provided by ACNFP on precision breeding to be the best scientific advice available to us through existing and longstanding arrangements for the provision of independent scientific advice. ACNFP meeting agendas, papers, minutes and reports are published in a timely manner, and this will continue to be the case for all meetings where precision breeding has been and will be discussed.

It is not possible to scientifically prove that there evidence that PBOs are no more harmful that their traditionally bred counterparts; however, based on their review of case studies (published in the ACNFP Statement July 2023, Annex A) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs (as confirmed by the Advisory Committee on Releases to the Environment, ACRE) are intrinsically more hazardous than traditionally bred organisms. Instead, they concluded that it was the alteration in trait that could lead to phenotypes of concern regarding the safety of the food or feed, rather than specifically the technology used to achieve the trait. The consultation responses did not provide specific evidence to contradict this conclusion.

Question 40

How is shifting the costs of segregation onto producers and distributers who choose not to use 'PBOs' compatible with the polluter pays principle, as outlined in the Government's 'Environmental principles policy statement'?

Answer 40

The FSA has committed to the implementation of Section 26 (3) (b) (iii) of The Genetic Technology (Precision Breeding Act 2023) meaning that for a PBO to be recommended for authorisation, the FSA must be satisfied that its production for use as food or feed will not have adverse effects on the environment.

The FSA has not received any scientific evidence that indicates that the environmental impact of PBOs differs from food or feed produced through traditional breeding practices. The use and maximum residual levels of pesticides and herbicides is regulated by the Health and Safety Executive and will continue to apply to crop farming irrespective of whether the organisms have been traditionally bred or precision bred. There is evidence to indicate that certain precision bred organisms could reduce the use of chemical pollutants and carbon emissions in crop farming and distribution and applications for PBOs that may bring environmental benefits will be welcomed.

The 'polluter pays' principle "is applicable where there is evidence of, or potential for, environmental harm, or a negative environmental effect; and the prevention of that harm is not possible, or proportionate". It does not apply to indemnify certain food businesses from paying the costs of segregating produce because they wish to offer an alternative to consumers.

The FSA has carefully considered the Environmental Principles Duty since it came into effect on 1st November 2023 and has done so during the development of the PBO regulatory framework.

Question 41

The FSA has avoided reference to or consulting on patents in its work on 'PBOs,' although these have formed a significant aspect of negotiations in Europe on NGTs. Does this mean that patents and intellectual property are outside of the FSA's remit, or outside of its competence? What information can the FSA provide on the patent regimes that will be in place with the new legislative framework?

Answer 41

This is not a matter for the FSA. This was debated in Parliament during the passage of the Act, where several amendments were tabled to probe the Government's position on the patentability of PBOs. No amendments were made to the Act to prevent the patenting of PBOs, and UK patent law does not specifically exclude patents from being granted on precision bred plants and animals.

Developers of PBO plants will be able to apply for plant breeder's rights which prevent unauthorised persons from marketing a protected variety but allow other breeders to use it in their own breeding programme to develop new varieties. Developers may also apply for a patent, but this will only be granted if patent examiners assess that the variety meets the criteria for utility, novelty and non-obviousness set out in patent law.

Question 42

How is it possible to maintain principles of non-discrimination in trade if a product can be imported into England and then sold in Wales or Scotland, but not imported into Wales or Scotland?

Answer 42

Parts 1 to 3 of the UK Internal Market Act (UKIMA) establish the market access principles of mutual recognition and non-discrimination across the four nations of the UK. Briefly, the mutual recognition principle ensures that, without further requirements, a product that has been legally produced in, or imported into, and can be legally sold in one part of the UK, can be sold in any other part of the UK, or that a service that can be legally provided in one part of the UK can be provided in another part of the UK. The non-discrimination principle ensures that goods or services coming from other parts of the UK are not directly or indirectly discriminated against (in favour of local goods or services).

Article 11 of General Food Law requires that food which is imported into Great Britain (GB) for placing on the market shall comply with the requirements of food law, or if there is a specific agreement between GB and the exporting country, then the imported foods must follow agreed requirements. In order for the product to be authorised and placed on the market, the product will need to meet the relevant domestic law.

For England, PBOs must be compliant with the requirements under the Precision Breeding Act in order to be placed on the market. Industry and enforcement authorities must already ensure compliance with existing legislation in order that PB products produced in other countries cannot currently enter the UK market where they are not authorised as GMOs and labelled as such. Goods imported directly into Wales and Scotland would need to comply with relevant legislation in which Genetically Modified Organism (GMO) regulations will continue to apply to PB food/feed.

Question 43

The ‘‘Response to Public Consultation and Next Steps’ states: “Our analysis has not identified any reason to revisit the fundamental decisions made by the FSA Board in September 2023.” Given the level of public opposition to the FSA’s plans made apparent in the consultation, what if anything would have warranted a change in approach?

Answer 43

As stated in the consultation, the FSA has worked in partnership with Defra since before their 2021 consultation on the regulation of genetic technologies. We routinely engaged with a wide network of stakeholders as the Bill (now the Act) progressed through Parliament and throughout the development of our proposals. The proposals we put forward in the consultation were drawn up with consideration of the wide range of views expressed by these stakeholders, alongside evidence gathered via other routes such as the views of consumers and the advice of the ACNFP.

We did receive views from consultation respondents that objected to the planned implementation of the new regulatory framework; the arguments presented were generally in opposition to the overarching principles of the Act or to the absence of production method labelling, rather than to the specific components of the regulatory framework that were set out in the consultation, such as the register, or the tiered routes to authorisation.

We have acknowledged the level of public opposition registered through consultation responses in our summary of responses and in the Board paper that was discussed by the board on 20 March 2024. Board members actively considered what more could be done across Governments to address these concerns, including traceability.

We did not receive arguments or suggestions that required us to change the specific proposals. The objections we received were mostly aligned to the opposition views we had heard in other more informal engagements (such as stakeholder events and workshops) and FSA

commissioned research (such as research into consumer perceptions). These arguments had been thoroughly considered in developing the proposals and discussed by the FSA Board at various FSA public board meetings in 2022 and 2023.

Changes to the policy would have been warranted if new evidence was provided that suggested the proposals would not deliver the FSA and UK Government policy objectives for precision breeding or provided a demonstrably more effective way to do so. For the FSA, the former would include new evidence that the proposals were, for example, not sufficient to protect food or feed safety. Since we did not receive any new evidence to this effect that had not already been considered, or proposals for an alternative approach that would also meet the regulatory requirements, we concluded that a fundamental change in approach was not warranted.

Question 44

The ‘‘Response to Public Consultation and Next Steps’ states that the Board has provided a steer that the new system should be responsive to future scientific developments and agile enough to keep pace with both innovation and evidence of safety. Does the Board accept that the FSA’s decision not to invest in detection techniques will have a detrimental impact on its ability to be agile and responsive to future scientific developments?

Answer 44

In our response to LGC Ltd.’s Literature review on analytical methods for the detection of precision bred products, we concluded that whilst we did not plan to take forward any of the recommendations in the report to aid ongoing policy development on precision breeding, we welcomed further research in this area to ensure we have the most up to date scientific information available when reviewing policy and/or developing new policies related to genetic technologies.

The FSA is science and evidence led. We continually conduct horizon scanning and independently review new evidence that becomes available which is relevant to food and feed safety. In the case of detection, while the consensus is that currently there are no methods that provide unequivocal detection of PBOs, we welcome further research in this area. Where further research is conducted, we will proactively review this evidence and consider its relevance in relation to facilitating traceability.

[Question 14 is not included here as it does not relate to a paper on the agenda for this meeting.]

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