18 November 2023

Professor Susan Jebb
Chair
Food Standards Agency
Clive House
70 Petty France
London
SW1H 9EX

Dear Susan,

**RE: FSA Consultation on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed.**

We write regarding the above consultation, as concerned stakeholders, professionals and experts in our respective fields.

The radical changes being considered to the regulation of genetically modified food and feed in the marketplace will have far reaching and multiple impacts along the food chain. This is a serious and important debate and attempts to inform and elicit public opinion must be grounded in transparency and truthfulness.

Having carefully reviewed the consultation pack, we conclude that this consultation falls below an acceptable standard and in particular is not being conducted in accordance with HM Government Consultation Principles, the relevant sections of which are reproduced in italics below.

Specifically:

**A. Consultations should be clear and concise**
*Use plain English and avoid acronyms. Be clear what questions you are asking and limit the number of questions to those that are necessary. Make them easy to understand and easy to answer. Avoid lengthy documents when possible and consider merging those on related topics.*

The consultation pack document is both lengthy and full of acronyms (PBO, TBO, ACNFP, UKIMA, CJEU, DHSC, FSS, ACRE, URN, IA, EHO, LA, TSO, PHA, SOC) which many stakeholders will be unfamiliar with.

Whilst there is a glossary at the end of the document (which in a critical case is inaccurate – see below), this does not encompass all these acronyms and does little to inform the reader about the interrelationships between them and their significance in the process, debate and controversies over the legislation and the FSA's proposal.

Likewise, references to General Food Law, the Food Safety Act 1990 and the Agriculture Act 1970, require a specialist knowledge of these laws and their interrelatedness in order to answer fully and in an informed manner.

The information provided on the Genetic Technology Act and the accompanying government documents – and the controversies surrounding some of these, such as the Defra Impact Assessment, which was rated as "not fit for purpose" by the Regulatory Policy Committee – have been simplified to a misleading degree and are inadequate for anyone not already immersed in the subject to properly assess the FSA plans.

The number and nature of the questions asked seem designed to facilitate a predetermined outcome rather than being a genuine attempt to elicit considered responses.

**B. Consultations should have a purpose**
*Do not consult for the sake of it. Ask departmental lawyers whether you have a legal duty to consult. Take consultation responses into account when taking policy forward. Consult about policies or implementation plans when the development of the policies or plans is at a formative stage. Do not ask questions about issues on which you already have a final view.*

What is the purpose of this consultation? At the September board meeting, FSA board members voted through the package of measures on which you are currently consulting. It is clear FSA has formed a final view – and, indeed, Defra has formed a final view – on the proposals included in this consultation. You are, therefore, asking questions about policy and proposals that are unlikely to be changed or acted upon.

**C. Consultations should be informative**
*Give enough information to ensure that those consulted understand the issues and can give informed responses. Include validated impact assessments of the costs and benefits of the options being considered when possible; this might be required where proposals have an impact on business or the voluntary sector.*

The consultation document contains multiple inaccuracies which make it impossible for anyone using this as their primary source of information to give an informed response. This document misleads in the following ways:

- In claiming that there is no scientific evidence that PBOs are unsafe (7.11, 8.8), the document misrepresents an absence of evidence as if it provided evidence of safety. The fact is, PBOs are too new, too novel and too insufficiently studied to have any reliable evidence on which to base any claim of safety. Further, the Advisory Committee on Novel Foods and Processes' (ACNFP) claims for the safety of precision bred organisms, as referenced in the consultation (p5, ref 3), refer to comments made in a meeting and have not, in spite of repeated request from stakeholders, been supported by the publication of any credible evidence.

- Claims that the ACNFP is a provider of independent scientific advice (7.18, 8.4, 8.7) are false. ACNFP members are chosen by the FSA. Out of a membership of 22 individuals, 14 have declared commercial conflicts of interest, 2 declared none, while 6 have institutional conflicts of interest even though they have declared no commercial interests of their own. There are also 3 'Associate Members' all of whom have declared commercial conflicts of interest. Out of a membership of 9 individuals on the ACNFP's subcommittee on products of genetic technologies, 6 have declared commercial conflicts of interest, 1 declared none, while 2 have institutional conflicts of interest but declared none on their own behalf. To portray the ANCFP and its Subcommittee as 'independent' is seriously misleading.

- It misrepresents the conclusions of the FSA's own research into labelling and the public register (8.49). While it is true that respondents thought a register was a good idea, this

came with an important caveat. Most said they would have no reason to use the register unless there was labelling. Around 8 in 10 of those surveyed by FSA felt that labelling was important. In addition, the consultation document is vague about the nature of the FSA public register – the shape of which is still unclear, but which appears to be merely a mirror of selected information from the proposed Defra public register.

- The conclusion of the FSA's commissioned literature review on detection of PBOs is misrepresented (8.57). It is untrue to say the review determined that detection was not possible. The broad conclusions of the review were that detection was not only possible but desirable and necessary for enforcement. It further concluded that detection methods should be developed and expanded to cover existing as well as emerging genetic technologies in the food system. The report, written by eminent researchers, notes: "*Current scientific opinion supports that modern molecular biology techniques (i.e., quantitative real-time Polymerase Chain Reaction (qPCR), digital PCR (dPCR) and Next Generation Sequencing (NGS)) have the technical capability to detect small alterations in an organism's genome, given specific prerequisites of a priori information on the DNA sequence of interest and of the associated flanking regions. These techniques also provide the best infra-structure for developing potential approaches for detection of PBOs. Should sufficient information be known regarding a sequence alteration and confidence can be attributed to this being specific to a PBO line, then detection, identification and quantification can potentially be achieved*." This throws FSA's rejection of these recommendations (8.58) into a questionable light.

- FSA has relied on a discredited Defra impact assessment as a basis for judging the impacts of its proposed changes (11.13, 11.25). The Regulatory Policy Committee opinion was that the Defra impact assessment was "weak" and "not fit for purpose". Defra has thus far failed to honour its promise to deliver a reworked impact assessment.

- FSA's failure to perform a full impact assessment (11.1) has led to misleading claims that only biotech plant breeders and local authorities will be affected by the new regulations. The consultation discourages respondents from talking about labelling (7.11) – but in terms of potential impacts, labelling, traceability and enforcement are closely connected in the food system. Removal of labelling and traceability, and offloading full responsibility for these onto businesses through suggestions of voluntary schemes (7.13, 8.67) will, for example, widely impact non-GMO, organic, artisanal and natural food businesses. It will push up the costs of producing these foods – something that could lead to the closure of smaller businesses that cannot afford to implement those measures. Lack of labelling on feed means farmers who wish to avoid PBO feed will be unable to do so, which may compromise the quality of their produce and damage their reputations.

- The lack of a full impact assessment means the consultation document fails to account for the full potential costs of enforcement. FSA itself does not bear these costs. Indeed FSA and Defra have made it clear that businesses will be expected to bear these costs. It is, therefore, a potentially serious financial impact for businesses if the blanket presumption of safety is wrong and the presence of, or contamination with, PBOs leads to health, safety or environmental problems.

- There is also a cost to consumers. Having pushed the responsibility off onto food businesses and third-party certifiers, there will likely be increased costs passed on to consumers who wish to avoid PBOs – a group that potentially comprises 8 out of 10 individuals in the UK.

- The consultation document wrongly asserts that organic producers have a “choice” on whether they wish to avoid PBOs or not (11.26). FSA knows full well that PBOs will be regulated as GMOs in the organic regulations. This is a legal requirement not a “choice”.

- In the consultation document itself (5.1, 8.11, 8.18, 8.55, glossary p38), as well as the recommended video in your precision breeding guidance for consumers, FSA has persisted in portraying precision breeding as significantly different from genetic modification and similar to traditional breeding. This is scientifically indefensible and misleading. The Genetic Technology Act defines precision breeding as genetic modification (a product of precision breeding is a product of “modern biotechnology” as defined by the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443)) and while The Act differentiates the required regulatory oversight for so called precision-bred organisms, this does not change the fundamental definition. In addition, EU Law also defines gene editing (precision breeding) as a genetic modification technology. Precision breeding can and does, either intentionally or unintentionally, result in the insertion of foreign genetic material into the genome of the gene-edited organism. Moreover, inadequate screening means that inadvertently introduced foreign DNA is often not removed from the gene-edited organism destined for the market. At no point in FSA’s information material or in the policy statements is this made clear.

**E. Consultations should last for a proportionate amount of time**
*Judge the length of the consultation on the basis of legal advice and taking into account the nature and impact of the proposal. Consulting for too long will unnecessarily delay policy development. Consulting too quickly will not give enough time for consideration and will reduce the quality of responses.*

**G. Consultations should take account of the groups being consulted**
*Consult stakeholders in a way that suits them. Charities may need more time to respond than businesses, for example. When the consultation spans all or part of a holiday period, consider how this may affect consultation and take appropriate mitigating action, such as prior discussion with key interested parties*

We believe that 8 weeks is not long enough to respond to this consultation and that the gold standard of 12 weeks should apply. Further, the consultation takes place over the Christmas, Hanukkah, Kwanzaa and New Year holiday period and therefore there may be 2-3 weeks when relevant stakeholders may simply not have the capacity or focus to respond. The stakeholder groups whom FSA wishes to reach via this consultation are consumers, businesses, third party certifiers and farmers, all of whom are very busy during the Christmas period. For some businesses this is the most hectic and important time of year in terms of annual income. In addition, the first week in January is traditionally consumed by the long-established annual Oxford Farming Conference and the Oxford Real Farming Conference, which farmers, growers and other stakeholders will be preparing for over this period. You risk losing input from these sectors because of the poor timing of the consultation. If input from these sectors is not important to FSA, then this begs our earlier question: what is the purpose of the consultation?

**H. Consultations should be agreed before publication**
*Seek collective agreement before publishing a written consultation, particularly when consulting on new policy proposals. Consultations should be published on gov.uk.*

Whilst FSA has consulted with stakeholders throughout the year, none of the feedback from stakeholders has been incorporated into the final proposals. In meetings with FSA, we have

requested several times that the consultation should be the product of collective agreement between FSA and stakeholders. We – and others we know of – requested access to the draft consultation in order to provide feedback. We were not given this opportunity.

These are serious breaches which have resulted in a consultation that is misleading, factually incorrect and deficient in several areas. As such, it does not accord with either HM Government Consultation Principles or the FSA's responsibilities and stated goal of being transparent and maintaining consumer confidence in the food system.

It is our belief that the consultation and its accompanying document is too flawed to be the basis of reliable public participation. We, therefore, request that you withdraw and postpone the consultation until these issues can be corrected and resolved.

Please ensure that this letter is circulated to the whole of the FSA board.

We await your response.

Sincerely,

Pat Thomas
Director
Beyond GM/A Bigger Conversation

The Kindersley Family
Founders
Sheepdrove Organic Farm

Rob Haward
Managing Director
Riverford Organic Farmers

Claire Robinson
Co-Director
GMWatch

Clare Marriage
Chief Executive Officer
Doves Farm Foods

Steven Jacobs
Business Development Manager
Organic Farmers and Growers

Shane Holland
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Technical Manager, Product Certification Schemes
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Mark Spencer MP, Minister of State, Food, Farming and Fisheries
Stephen Gibson, Chair Regulatory Policy Committee
Simon Case, Cabinet Secretary
Alex Chisholm, Cabinet Office Permanent Secretary