



**Beyond GM response to
Food Standards Agency consultation on proposals for a new framework
in England for the regulation of precision bred organisms used
for food and animal feed**

Beyond GM is a UK-based civil society organisation. Its aim is to raise the level of the discussion around genetic engineering and alternative approaches in food and farming to make it more thoughtful and inclusive. To this end we undertake a range of activities from public-facing engagements and publications to more structured and formal events aimed at deep-dive discussions.

We also run a parallel initiative, A Bigger Conversation, which brings together scientists, academics, ethicists, social scientists, legal experts, farmers and growers, retailers and others representing diverse perspectives, to feed into equitable, constructive discourse about the future use and regulation of emerging technologies, including genetic engineering, in food, farming and nature. These initiatives stem from and inform our broad and whole systems perspective on the place and appropriateness of technologies in farming and food production.

This document is our response to the above consultation, its answers follow the format of the online consultation document and we are happy for it to be a matter of public record.

We believe this current consultation process breaches [Cabinet Office Consultation Principles](#) in multiple ways. These concerns are detailed in a [joint complaint](#) to the FSA – signed by ourselves, Doves Farm, Riverford Organic Farmers, Sheepdrove Organic Farm, Slow Food in the UK, the Organic Farmers & Growers, GMWatch, Food Chain ID and Professors Erik Millstone and Michael Antoniou. At the time of writing, this complaint is still under consideration by the FSA.

Amongst other things, this complaint highlighted the truncated period of time for the consultation, over an extended holiday period, and the lack of a full impact assessment which we believe not only breaches Cabinet Office Principles but fails significantly to meet the FSA's main objective, according to the [Food Standards Act of 1999](#), 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.”

In addition, we wish to make it clear that we have serious concerns about the FSA stakeholder engagement process leading up to this consultation. In our view the FSA has pursued a partial and biased approach characterised by the promulgation of misleading and erroneous information and a tick-box engagement process unresponsive to converse views. These concerns, which we have articulated to the FSA on several occasions, stretch back to early discussions about the government's

intention to change its policy on GMOs and the Defra public consultation in 2021. They have never been fully addressed.

Introductory remarks

We accept that genetic technologies in agriculture and food production are here and that they might one day prove to have a justified place and value. But in all cases these novel technologies must be properly assessed and regulated.

The whole of our advocacy around the Genetic Technology Act is focused on the fact that current legislative proposals are inadequate. The Act is based on highly contested science, unclear language and on a presumption of equivalence between normal foods and gene edited/precision bred foods – which has never been investigated nor proven.

It is also predicated on exaggerated assertions of what gene editing might one day achieve such as [increased yield](#) or [climate change mitigation](#), rather than careful, independent research and the application of foresight, which is a more rational method than speculative prediction, for anticipating plausible future developments and avoiding negative outcomes.

Whilst assertion and speculation has become an acceptable way for a government to promote its policies, it is certainly not acceptable for an agency charged with independent guardianship of citizen and consumer interests.

The FSA claims to “[act independently and transparently, led by science and evidence](#)”. As a ‘Non-Ministerial Departmental Body’ accountable to Parliament it could be argued that there are obvious limits on the Agency’s independence. Nevertheless, it should not, in our view, have accepted Defra’s assertions of the underpinning science, the business case and the viability of its regulatory proposals as fact, without making its own independent and transparent assessment from its perspective of consumer protection and confidence. The FSA could, and in our view should, have taken into account the conclusions of the Regulatory Policy Committee (RPC) that the Bill, which eventually became law, was “not fit for purpose” (see detail Q6 below).

It could, and in our view should, have fully, transparently and openly, considered and assessed the contrary science view alongside the, so far incomplete and unpublished scientific opinions of the Advisory Committee on Novel Foods and Processes (ACNFP) and the evidence provided to Defra by the Advisory Committee on Releases to the Environment (ACRE), of which the RPC noted:

“... much of the evidence regarding risk discussed in the IA, is drawn from interested parties, or based on scientific trials, that do not replicate real-world conditions (including farmers’ behaviour). Such a narrative could, in turn, impede research, development and evaluation of an important new technology. The Department should have considered independent evaluations of the safety and environmental impact of using CRISPR technology in agriculture and food.”

Not doing this has resulted in an insubstantial triage process which allows FSA to appear as if it is living up to its remit whilst at the same time quietly allowing novel, untested food ingredients and

products created using a new, extreme and disruptive technology into the food system without sufficient evidence of safety, without proof of benefit, without any mechanism for testing or tracing and as a result without any effective means of enforcement and, of course, without labelling.

The way in which the FSA has dealt with the issue of labelling and used misleading terminology for the technology in its published material is arguably the most significant failure to meet its policy objectives.

For instance, the consultation document makes reference to labelling and in particular to the FSA's own consumer research but in suggesting that consumers are positive about a public register in lieu of labelling, it utterly fails to represent the findings of that research truthfully.

In [July 2021](#) a first wave of FSA research revealed that:

“Most consumers felt labelling should always inform the consumer of the presence of GE ingredients using the full term ‘genome edited.’”

In [March 2023](#) a second wave of consumer research showed that:

“Workshop participants felt very strongly that precision bred products should be labelled as precision bred. While existing mandatory labelling would inform consumers of any changes to the characteristics of the product, participants felt that this would not be sufficient on its own. They argued that being able to identify precision bred products via labelling is critical for transparency, and therefore to consumer choice and public trust.”

It further found that:

“Survey respondents agreed, with nearly four in five (77%) saying it would be important when buying a food item to know if it had been precision bred, and nearly half (45%) saying it would be ‘very’ important. Only one in six (15%) say knowing this would not be important.”

These results are especially significant given that in both the FSA's 2021 research on [Consumer perceptions of genome edited food](#), its 2022 [Survey of public attitudes towards precision breeding](#) and its 2023 research on [Consumer perceptions of precision breeding](#), the FSA's explanations and the information material provided to participants repeatedly misrepresented the process and products of genome editing and precision breeding as being something that ‘could occur naturally’. The notable fact that there was significant consumer pushback on these misrepresentations has been ignored by the FSA.

We note that the FSA website still contains misleading references to genome editing/precision breeding as being equivalent to what could occur naturally:

- [FSA response to Literature review on analytical methods for the detection of precision bred products](#), September 2023

- [FSA 22-09-04 – The Genetic Technology \(Precision Breeding\) Bill](#), September 2022
- [FSA 22-06-08 – The Genetic Technology \(Precision Breeding\) Bill](#), May 2022
- [Board meeting update paper](#) 15 September 2021

Even before the Genetic Technology Act was signed into law, the FSA would have known that so-called precision bred organisms are – scientifically and legally – GMOs by the definitions used in the Act. In addition, as the pages noted above highlight, FSA briefing materials for its Board Members and members of the public, focus on only one type of gene technology – SDN 1, or ‘simple’ gene editing – whereas the Act itself reduces and in some cases removes regulation and oversight from a wide range of genetic modification methods including the use of foreign DNA.

We note also that the consultation appears to be mainly focussed on plant-based foods/feed. However, the Genetic Technology Act also deregulates a vast range of genetically modified precision bred animals belonging to the taxonomic group Metazoa. Not giving respondents specific information to consider or space to comment on the potential risks – to food safety, to the environment and to the animals themselves – posed by precision bred animal products, or the potential trade implications, should UK regulations on PBO animals diverge from those of international trading partners, is a serious omission. Given FSA’s refusal to challenge Defra on the substance or science of the Act, reassurances that it will “work with Defra to ensure that their Animal Welfare Declaration and our authorisation process together give consumers the reassurance they desire” (8.24) are not very reassuring.

There will, inevitably, be those who are not concerned about eating the products of genetic engineering. However, in addition to the FSA’s own research, a YouGov poll by [Beyond GM](#), and research into gene edited farm animals by the [Nuffield Council on Bioethics](#), is consistent in suggesting that around 8 in 10 people in the United Kingdom do not want unregulated, unlabelled genetically modified foods to be sold in the UK.

Ignoring this is the polar opposite of the FSA’s objectives, restated in its [Food You Can Trust 2022-2027 strategy](#), which defines the Agency’s overall role to provide food that is safe, food that is what it says it is and food that is healthier and more sustainable.

THE QUESTIONS

Pre-Market Authorisation Process – Trige and two-tiered system

Question 1 – Tier 1 PBOs: Developers will apply the ACNFP criteria to determine tier and notify the FSA of the PBO status. Tier 1 notification is acknowledged by the FSA. When the authorisation decision is taken by the Secretary of State, the FSA will communicate this to the developer and, if the decision is to authorise the PBO for food/feed, place it on the public register.

We ***strongly disagree*** with the FSA using a two-tiered approach, as presented in these proposals, for the pre-market authorisation of precision bred organisms used in food and feed.

We ***strongly disagree*** that the proposal for Tier 1 notifications meets the FSA’s policy objectives in paragraph 7.9 of the consultation document.

We also ***strongly disagree*** that the proposal for Tier 1 applications is feasible – presuming that by ‘feasible’ the FSA means transparent, effective and thorough.

Our main objections to the two-tiered system are threefold:

1) PBOs are GMOs. The way in which some of them may legitimately differ from old style GMOs and might therefore be regulated differently is unclear at this time.

In the consultation document (5.1, 8.11, 8.18, 8.55, glossary p38), as well as the recommended video in the [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. Precision breeding is a marketing term, not a scientific discipline, and these new GMOs may well carry the same risks, uncertainties and novel challenges of older style GMOs.

The consultation document repeats the ACNFP’s claims that there is “*no evidence that PBOs are intrinsically more hazardous than TBOs*” (8.8) and refers 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, have 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.

Such pronouncements are based on an incorrect premise – that an absence of evidence of harm constitutes 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 claims of safety. [Scientific evidence](#) of unintended, or off-target, effects of gene editing does exist however and scientists have emphasised the need for further research before blanket claims of safety can be made.

The proposals make much of the need for “proportionate regulation”, yet proportionate is not defined – critically not in terms of scale, depth or time – or described (see more Q2 below). The ACNFP (and ACRE) have made assertions for which it has not produced or published any scientific or

regulatory justification. Neither has it produced any published critique of the scientific evidence that raises the question of risk from these technologies.

We do not, therefore, believe the proposals meet the FSA's policy objective of transparent, proportionate regulation.

2) The two-tiered proposal is little more than a piece of regulatory play-acting

In reality the two-tiered proposal barely differentiate between the Tier 1 and Tier 2 organisms. Ultimately, both can enter the food and feed chain without meaningful assessment, labelling or traceability. Further, without full risk assessment how can the FSA – or anyone else – judge whether the proposed regulations are proportional to the magnitude of the risks.

In a recent assessment of deregulatory proposals in the EU, which mirror the broad permissions in current UK regulation, researchers from the [German Federal Agency for Nature Conservation](#) concluded that 94% of gene edited (precision bred/new genomic technique) products would fall into the fully deregulated category 1 (similar to FSA's Tier 1 category, which requires no evidence of safety, health or environmental impact – and will require no labelling or traceability). The system will effectively be meaningless – giving an illusion of assessment and regulation, where little to none is actually taking place.

This begs the question: Who does the regulation serve? FSA claims that the two-tiered proposal is on advice from the ACNFP which, the consultation document claims, is a provider of independent scientific advice (7.18, 8.4, 8.7). This is 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.

The lack of independence of ACNFP and its sub-committee means that where there is doubt, the benefit of that doubt will always be for the developer, rather than for precaution and safety. This, combined with the opaque nature of its decision making, does not align with the FSA's policy objective to "*provide consumers with assurance via the new regulatory regime and maintain confidence in the food system*" (7.9).

3) The FSA is neglecting its regulatory duties by allowing developers to self-certify

The only benefit of this approach is to the developers who are being allowed to self-certify the status of their precision bred organism. This proposed self-certification process includes no mandatory checks and is therefore insufficient to ensure that developers are not making incorrect or inaccurate claims about their products.

Once again, the claim that Tier 1 organisms do not warrant bespoke risk assessments is based on the mistaken premise of absence of evidence of harm being the same as evidence of safety (“*there is not currently any evidence suggesting PBOs pose any more risk than their traditionally bred counterparts and do not warrant bespoke risk assessments*”) (8.18). All PBO organisms should be subject to a full GMO risk assessment.

Question 2 – Tier 2 PBOs: These would be subject to an application to the FSA, similar to other regulated products. Developers would apply the ACNFP criteria to determine tier. Developers with PBOs for use in food and feed falling within Tier 2 would be required to submit an application with the accompanying data described in ACNFP’s Model 1. Applications would be subject to a bespoke risk assessment and risk management process. When the authorisation decision is taken by the Secretary of State, the FSA will communicate this to the developer and, if the decision is to authorise the PBO for food/feed, place it on the public register.

While we ***agree*** that the FSA should be conducting bespoke risk assessments for Tier 2 PBOs prior to them being authorised for use in food/feed, we find the ACNFP’s criteria to determine Tiers 1 and 2 to be vague and subjective. It seems clear from the consultation pack document that the necessary elements of both Model 1 and Model 2 proposals are not finalised. It is unclear what the “*sliding scale of possible evidence requirements*” (8.13) is or how this might be applied.

Further, while the proposals say it will be up to the FSA board to determine where on the sliding scale a particular PBO could sit, and what kind of “proportionate” information will be required, the consultation document offers little in the way of a definition of the concept of “proportionate” other than the ACNFP’s notion that “*policy making should be proportionate to the extent and nature of any risk identified*” (hyperlink, 8.12).

However since PBOs are self-certified as safe by developers as part of the notification process for both Defra and FSA, safety is assumed rather than empirically demonstrated. None of the information required for Tier 2 organisms challenges this presumption and therefore we ***strongly disagree*** that the proposal for Tier 2 applications meets the FSA’s policy objectives in paragraph 7.9 of the consultation document.

We also ***strongly disagree*** that the proposal for Tier 2 applications is feasible – again, presuming that by ‘feasible’ the FSA means transparent, effective and thorough.

As discussed above, the two-tiered system is not proportionate to the possible risk of PBOs. With only a very small percentage of PBOs estimated to fall within this category (around [6%](#)), the bespoke risk assessment will have a negligible impact. This tier, therefore, seems to be a meaningless, hollow attempt to reassure consumers rather than a functional regulatory proposal. All PBOs should be subject to at least the same requirements as currently apply for a full GMO risk assessment.

In addition we have concerns about the way both models disregard the novel nature of PBOs.

From its [first statement on precision bred organisms](#) the ACNFP has put forward the opinion that PBOs should not fall within the scope of the existing [Novel Foods regulation](#). However, precision breeding is a laboratory-based process that intervenes at the level of the genome in a way that does not occur in nature, does intentionally modify molecular structure and does not have a well-defined or described history of “safe use”. Neither the ACNFP nor the FSA have provided any regulatory or scientific evidence to justify the removal of PBOs from novel food regulation, nor have they been open to any questions on the matter.

We are left to suppose that the ACNFP takes the view that precision breeding does not give rise to what the Novel Foods regulation describes as “*significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances*”. If so, this contradicts some of the stated purpose of “precision breeding”, e.g. to change a plant’s metabolism and/or nutritional value; it also flies in the face of mounting research evidence of the possibility of the creation or increase in “undesirable substances”.

In the light of this, we believe that every new precision bred organism – even if it displays phenotypic similarity to currently consumed foods – should, by default, be considered a new food, produced from a new process and should fall under the category of ‘novel’, defined as:

“any food that was not used for human consumption to a significant degree within the United Kingdom (UK) or the European Union (EU) before 15 May 1997. This means that the foods don’t have a ‘history of consumption’.”

Novel PBOs should not be allowed onto the market until the novel food process has been completed and the safety of the organism determined by a full risk assessment.

The proposed triage system seems inadequate for this purpose. We say “seems inadequate” because the proposals are lacking in any meaningful detail. In addition to the absence of any transparent assessment criteria and reporting, the vague way in which the determination of novelty (8.10, 8.55) is treated in the proposed triage process (How will this be determined? By whom? and On what basis?) and the conflation of novel foods with organic and country of origin designations in the consultation information pack (8.64) is misleading.

This consultation, therefore, seeks a passive and uninformed acceptance of the removal of PBOs from the novel foods assessment without giving respondents the information, in the form of a full impact assessment, from which to make an informed judgement.

We are aware of proposals and believe the FSA [anticipates a change in novel food regulations](#), which remain under discussion and are not likely to come into force for some years (the FSA website anticipates [Q3 24/25](#)). This proposed change in novel foods regulations is unlikely to be known or understood by most respondents to this consultation. In any case, if such changes are part of the ACNFP and FSA considerations regarding PBOs then it should have been made clear and explained as part of this consultation.

Public Register

Question 3 – The Act makes provision for the FSA to establish and maintain a public register which will provide details of PBOs authorised for use in food/feed.

We ***agree*** with the proposal to establish and maintain a public register which will provide details of PBOs authorised for use in food/feed. However, we ***strongly disagree*** that the proposal for a public register alone meets the FSA's policy objectives in paragraph 7.9 of the consultation document and we are, further, concerned that information in the consultation document (8.49) deliberately misrepresents the conclusions of the FSA's own research into labelling (see our Introductory remarks above) and the public register. 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.

In our view labelling should be mandatory but we are aware that this can be achieved by different regulatory routes. It is a significant failure on the part of the FSA that this has not been considered under its remit of ensuring consumer confidence especially as FSA research consistently showed that labelling is a highly important issue for consumers. There is a question of whether and how voluntary labelling schemes might develop and work. The role of a public register would be crucial to any such schemes. Again, it is a significant failure of the FSA not to have considered this and brought forward proposals as to how both mandatory and voluntary labelling would relate to a public register and vice versa.

We have two categories of comment on the proposed public register:

1) A public register is no substitute for product labelling

A public register on its own is not enough to ensure transparency for PBOs. It does not adequately inform consumers of the nature of the food they may be buying. Without product labelling there is no reason for consumers to consult the register. This was the finding of the FSA consumer surveys (which, as we have said, appear to have been deliberately, cynically misrepresented in this consultation pack document).

We firmly believe that any proposed register should be additional to, not instead of, labelling and should support labelling by providing clear and easily understandable information on the specific genetic modification(s), potential health or environmental risks, and any ethical or religious concerns associated with the modification(s) of the food/feed that contain the particular GM-PBO ingredient.

We urge the FSA to actively lobby ministers for existing powers under the Food Safety Act 1990 to be used to require labelling and full disclosure requirements for precision bred food.

Without labelling, businesses will find it difficult to avoid PBOs in their food supply and farmers will not be able to choose what they feed their animals.

2) The proposed FSA public register is severely lacking

The consultation document is vague about the nature of the FSA public register, but there appears to be little difference between the proposed Defra public register and the proposed FSA public register. Rather the FSA register appears to be a 'lite' version of the Defra register (as prescribed in the [Genetic Technology Act 2023](#), section 18) and therefore is not a source of independent information for consumers, but a source of government propaganda. Further, the provision for what information will be contained in the Defra register is vague, bureaucratic and may not help consumers and other end users identify PBOs they may wish to avoid.

Given that the proposed register could have a spectrum of end-users, including consumers, farmers and businesses, it should be comprehensive and user-friendly. From the perspective of these end users, the most important elements of a hypothetical comprehensive register for PBO foods/feed would be:

Accessibility: The register should be easily accessible to users and easy to navigate, and download in a readily-searchable format. Users should be able to search for the information they need quickly and easily in one place and be able to navigate the register and interpret the information in it without needing specialised knowledge, language or expertise.

Relevance: The register should provide information that is relevant to the needs and concerns of users (not favouring one user group over another). For example, if a PBO is known by different names in different products, that information should be included. The nature and purpose of the genetic change in the food/feed item should also be made clear.

Accuracy: Consumers may depend on the information in the register to make informed decisions, so it is crucial that the data is trustworthy and reliable and that the information provided in the register is accurate and comprehensive.

Timeliness: Related to accuracy, the register should be updated regularly to ensure that the information is current and relevant. If data are missing or the register contains out-of-date information, it is not useful to those trying to make informed choices.

Transparency: The register should be transparent about how its data is collected and what sources of information are used. If, for instance, the sole source of information about the product is its developer, this should be stated clearly. Links to information on potential conflicts of interests within committees/subcommittees that have made judgements on the safety or benefits of a particular ingredient would also be helpful.

Independence: Ideally any register should be unambiguously independent and not influenced by the interests of any particular group or industry. This is important to ensure that the information provided is objective and unbiased. This point relates to Transparency above.

Acknowledgement of uncertainty: Importantly, given the fast-moving nature of research into gene editing, a public register of GM-PBO foods/feed should include acknowledgement of scientific,

health, and environmental uncertainties. This is because genetic engineering is a rapidly evolving field and there are environmental and health uncertainties associated with PBO foods that are not yet fully understood or recognised.

The inclusion of scientific, health and environmental uncertainties in a public register on GM-PBO food and feed can also promote transparency and accountability. By acknowledging and disclosing uncertainties, the register can help to build trust and credibility and help consumers make informed decisions based on the best available evidence – as well as the absence of evidence where further research is needed.

Traceability

Question 4 – In relation to traceability the proposal is that no requirements beyond the existing traceability provisions in General Food Law which apply to all food and feed are necessary.

We ***strongly disagree*** that the proposal to use existing provisions in General Food Law for traceability meets the FSA's policy objectives in paragraph 7.9 of the consultation document.

Consumer concerns in relation to [provenance and systems of production](#), as well as systems of distribution (the 'food chain'), are increasing and the issue of GMOs – including PBOs – is of particular concern. From this perspective, the traceability provisions in general food law – 'one-up, one-down' – are inadequate in an increasingly long and complex food chain. With one-up, one-down, traceability can be easily lost in commodity products that are blended (e.g. milk from multiple farms in a dairy) or dissected and mixed through the supply chain (e.g. animals for meat production).

Furthermore, during product recall and food safety investigations, auditing via a one-up, one-down trail of records is likely to be inadequate where, for instance, a PBO were to cause widespread allergic reactions or toxic effects.

We are not wholly against an audit trail approach. Despite examples such as the 2013 horse meat scandal there is evidence that audit trails are effective – but are far more so when supported by appropriate analytical methods.

Contrary to the claims in the consultation document, the broad conclusions of FSA's commissioned [Literature review on analytical methods for the detection of precision bred products](#) 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 government 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 the FSA's rejection of the report's recommendations to invest in R&D to develop, validate and utilise suitable analytical methods into a questionable light.

The potential costs of not having end-to-end traceability for genetically modified products in the food system could be significant for the government, for the farming and food industries and their insurers, and for consumers, as well as for the environment. The earliest to be adversely affected will be farmers and food producers committed to non-GM and organic production, who may be at risk of losing their certification and incurring reputational damage if their products are found to be contaminated with precision bred organisms or ingredients.

Different countries may also operate different standards for gene-edited food/feed and there are adverse trade implications of regulatory divergences. Without adequate traceability, it can be difficult to ensure that products meet those requirements.

While proponents argue that gene-edited crops are the same as those that could be created by traditional breeding, this is patently not true. Gene editing, as we have previously remarked, like all genetic engineering, is a wholly lab-based process that results in novel organisms which have never before been grown or consumed. Without a traceability system in place, it will be difficult to ensure accurate, trustworthy labelling and the tracking and tracing of PBOs. The proposed policy is very likely to create confusion and undermine consumer trust in the FSA, and in the safety of the foods they consume.

While there are currently no PBO products on the market in the UK, historical incidents where lack of transparency has caused financial loss are well known:

Contamination and unintended consequences – Without robust traceability, it will be very difficult to prevent and trace contamination of non-genetically engineered crops or the unanticipated and unintended consequences of genetic engineering technology.

In 2006, for example, a field trial of genetically engineered rice in the United States resulted in contamination of the commercial rice supply, leading to a significant loss of export sales to countries that did not allow genetically engineered rice. The overall [cost to the industry](#), estimated at \$1.2 billion, included losses of up to \$253 million from food-product recalls in Europe, US export losses of \$254 million in the 2006/07 crop year and projected future export losses of \$445 million.

A major concern with all genetically engineered foods, including PBOs, is the potential to raise the level of food allergens in a given product. Food allergen recalls are on the rise and a significant cost to businesses. As the [FSA's own research](#) has noted, these have a profound effect on the UK

economy including food hypersensitivity-related hospitalisations costing approximately £80 million a year. For major retailers the [cost of a recall](#) due to cross-contamination or the presence of unwanted allergens can be on average £1 million per recall.

More recently, the contamination of tomato ketchup products with levels of the [mycotoxin Alternariol \(AOH\)](#), point to potential future contamination issues with some gene edited produce. AOH can get into tomato products when overripe or even mouldy fruits are processed. Mushrooms, [apples](#) and potatoes are also prone to contamination with AOH during long periods of storage and new types of gene-edited non-browning produce such as mushrooms, apples and potatoes can actually mask produce that is damaged, overripe or past its best.

AOH has been widely reported in the scientific literature to exert [estrogenic effects](#) (see also [here](#)) as well as to induce different types of DNA damage, including single-strand breaks (SSB), double-strand breaks (DSB) and [oxidative DNA damage](#) via the generation of reactive oxygen species. Gene edited non-browning produce could exacerbate the problem of AOH contamination and, without regulation and traceability, prove to be a source of significant future public health risk.

Legal and regulatory compliance – Without traceability, it can be difficult to ensure legal and regulatory compliance for genetically modified products. In 2000, America's corn farmers faced a sudden collapse of international and domestic demand for all varieties of US corn. Prices fell considerably when genetically modified [StarLink corn](#) was detected in taco shells by a private laboratory. StarLink had been approved for commercial use by APHIS, though limited to animal feed by the Environmental Protection Agency. Japan temporarily halted imports of US corn. It was estimated that the short-term cost to farmers was \$500 million. A class action suit was settled for \$110 million against the manufacturer of StarLink.

Enforcement (England)

Question 5 – As part of the proposed regulatory framework for food/feed from PBOs, the FSA is proposing enforcement powers and tools for Local Authorities and Port Health Authorities (“enforcement authorities”) in England. The Act does not allow for criminal sanctions beyond those available in existing food/feed law which may be used in respect of food/feed consisting or containing PBOs where appropriate.

During the 20th September 2023 FSA board meeting, board member and Chartered Trading Standards Practitioner Mark Rolf noted: *“If I were designing a system where I wanted to ensure there would be no enforcement, this is what I would design”*. This grave concern was ignored and enforcement – which is inevitably linked to transparency and labelling – appears to be the least developed and at the same time most necessary aspect of the FSA’s current proposals.

We ***strongly disagree*** that the proposed enforcement regime meets the FSA’s policy objectives in paragraph 7.9 of the consultation document.

We ***strongly disagree*** that the elements of the proposed enforcement regime are practical and deliverable.

We also **strongly disagree** that this proposal meets our needs as stakeholders.

The proposals are essentially the maintenance of the status quo, since it is already the duty of Local Authorities and Port Health Authorities to enforce existing GMO regulations. However, it will be impossible for those authorities to do their job if the products are not labelled and if traceability is limited to insufficient one-up, one-down documentation. The FSA's proposal amounts to abdicating responsibility rather than dealing with the challenges of new GMOs in the food system.

We envisage that detection, and consequently effective enforcement, may require a transitional period during which more than one method may need to be used. New detection methods for gene-edited organisms are being created and refined at a rapid pace. However, in the absence of a single set of definitive tests, a transparent audit trail combined with labelling could allow enforcement officers to trace precision bred organisms through the system.

The lack of a thorough impact assessment means the consultation document fails to account for the full potential costs of enforcement. FSA itself would not bear those 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 turns out to have been wrong and if the presence of, or contamination with, PBOs leads to adverse health or environmental problems.

There would also be costs to consumers. Having pushed the responsibility onto food businesses and third-party certifiers, there will likely be increased costs that will be passed on to those consumers who wish to avoid PBOs.

Assessment of Impact

Question 6 – We have carried out an assessment of the impact arising from our proposals.

The consultation pack (11.1) states clearly that the FSA has NOT carried out a full impact assessment and therefore the whole basis of the questions in this section is false.

In lieu of a full impact assessment the FSA has relied upon the information in the Defra Impact Assessment which was published with the draft Genetic Technology Bill. [This Impact Assessment was found to be “not fit for purpose” by the Regulatory Policy Committee \(RPC\)](#). Defra has thus far failed to honour its promise to deliver a reworked impact assessment.

In relying on Defra's flawed and contested Impact Assessment, the FSA is further embedding the errors and inadequacies of that assessment into the regulatory system. Specifically:

- It has not adequately considered and discussed the full range of potential impacts arising from the creation of a new sub-category of non-GMO
- It has not sufficiently considered and discussed the full range of impacts upon small and medium sized businesses

- It needs to explain more clearly how the introduction of a new sub-category will not undermine the policy intention of reduced regulatory burden
- It needs to include greater discussion of the impacts arising from labelling and traceability, to distinguish better the two regulatory options considered
- It needs to revisit the assumptions relating to the devolved administrations (DAs) and what impact this will have on the number of trials across the various scenarios
- It needs a detailed assessment of the competition, innovation, consumer and environmental impacts

What little work the FSA has done presumes that only plant breeding businesses and Local Authorities are impacted, and even then only minimally so by the few hours it will take one person to read the new regulations.

We believe the failure to carry out a full impact assessment is a serious omission, which makes it impossible for respondents to answer this question in a full and informed manner. Any responses based on the information in the consultation will be incomplete. Furthermore, making regulations based on an incomplete understanding of the impacts of deregulation and the creation of a new category of genetically modified organisms, may have significant adverse legal and financial consequences across the food and feed supply chain.

Therefore:

No – we do not agree with the assumptions and estimates used to calculate one-off familiarisation costs to businesses.

No – we do not agree with the narrowness of the few impacts that the FSA has identified within this consultation.

Yes – we are aware of impacts of the proposed new regulatory framework that the FSA has not included in this consultation.

No – We do not agree with the wider impacts included in this consultation.

Other groups of which we are aware that will be impacted by this regulation are:

- 1) Non-GMO, organic, artisanal and natural food businesses** – the consultation document says that “*organic food and feed firms could be disproportionately impacted should they choose to continue to supply non-PBO food/feed*” (11.26). This is a misrepresentation, since Defra has confirmed that organic standards *must* continue to treat PBOs as GMOs – it is not a choice but [a legal requirement](#). The FSA proposals will incur significant costs to the organic sector, and indeed other non-GMO sectors, as they will be responsible for ensuring their supply chain is free of PBOs without adequate support or information (such as may be provided by adequate traceability and labelling). Those costs need to be estimated and accounted for.

- 2) **Food processors** – It is likely that many food processors will need to implement a non-PBO supply chain, with associated infrastructure, to meet business and consumer demand for non-PBO products. In many cases this will add a third stream alongside organic and non-organic. It will increase the costs of production – something that could lead to the closure of smaller businesses that cannot afford to implement those measures, thereby increasing concentration of power and control in the hands of larger multinational businesses.
- 3) **Retailers** – As well as familiarisation with the legislation, retailers will likely have significant impacts as they work to ensure that some of their supply chain (e.g. own brand foods) remains PBO-free. In addition, the risk to these businesses in the case of recalls is very high.
- 4) **Farmers** – 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.
- 5) **Consumers** – Ultimately, all of these extra costs will get pushed down the chain to consumers, meaning the cost of food is likely to increase.

Concern about FSA resources

The proposals set out in the Consultation envisage FSA staff taking over key parts of the triage process. It is not clear what type of staff this refers to but given the complexity of the technology, its fast-developing nature, the detailed information required to make any sound evaluation of applications and the current lack of clear criteria we anticipate that this is beyond the current level of staffing. In the absence of any relevant detail in the proposals, we are concerned that what is really envisaged is little more than a simple box ticking exercise which will be wholly inadequate and will further undermine the credibility of the technology and consumer confidence.

It almost goes without saying that ensuring effective compliance and enforcement is important for regulations, it's important for a well-functioning society and trust in government and its agencies. It is a key element in safeguarding health and safety in protecting the environment.

Effective compliance can only be achieved if regulations are realistic and adequate. In order for enforcement activities to deliver their expected results they need to be properly resourced. These are two major stumbling blocks since the legislation into which these regulations will be written is neither realistic nor adequate nor is it scientifically sound.

From our discussions with the FSA and what we have read in the background documents, it seems that work in this area is straining the Agency's resources and could continue to do so in the future. We are, therefore, uncertain whether FSA will have the resources required to ensure the proper regulation, traceability, compliance and enforcement for so-called precision bred GMOs in the food system.

Date: 03/01/2024