Organic Farmers & Growers CIC (OF&G) is the largest certifier of organic land in the United Kingdom.

Founded fifty years ago as a marketing cooperative for organic farmers OF&G went on to become the first body to receive government approval for an organic inspection and certification scheme in the UK.

This document is our response to the 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.

We consent to this response being made public.

As an Organic Control Body our role is to ensure that the Organic standards[1] are carried out on organic farms and in food businesses across the UK, and to offer support and guidance for businesses who are making the switch to organic.

We certify the complete food supply chain from primary production, feed and seed to processed product including storage, warehousing, distribution and retail.

From our offices just outside Shrewsbury in Shropshire, we provide services to organic businesses across Great Britain and Northern Ireland, the Isle of Man and the Channel Islands.

[1] Organic standards; Retained Regulation (EC) No. 834/2007, (EC) No. 889/2008, (EC) No. 1235/2008 and Organic Products Regulation 2009.

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We have considered all of the information supplied by the Food Standards Agency and must state that we strongly disagree with the current set of proposals.

The FSA proposals cannot ensure compliance and in their current form would be unable to secure supply chain integrity and therefore will be insufficient to ensure health and environmental safety where PBO plants or products derived thereof are released into the environment or placed on to the UK market.

We firmly believe that the current proposals should be rejected or extensively revised.

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We have conferred with highly regarded scientists who have long experience in genetics and must conclude that it is scientifically incorrect to assume that the risks to health or the environment from PBO plants are generally lower compared to transgenic plants. Therefore, in both cases (transgenic plants and PBO plants), the risks to health, the environment and biodiversity must be assessed with far more rigour than is currently being proposed.

The science of genetic engineering is evolving and there is now a body of evidence building that shows that while some approaches can lead to powerful and rapid genetic alterations, they can also lead to vastly different changes than originally intended.

Tools such as CRISPR/Cas have the potential and capacity to alter gene sequences (genotype), and thus gene function and plant characteristics (phenotype) in a way that is unlikely to occur in conventional breeding, regardless of whether these are intended or unintended changes. Earlier genetic engineering methods involve the transfer of genes across individual plant or species boundaries to achieve new traits (transgenic plants).

Today, however, genetic editing makes it possible to change the characteristics of a species to an extent that would be impossible, or at the very least unlikely, using conventional breeding, even without the insertion of additional genes.

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The information in the proposal on traceability does not provide sufficient detail and as such is not sufficient to the stated objectives. It is a serious misapprehension to suggest that there is no scientific evidence that PBOs are intrinsically more hazardous than traditionally bred organisms'.

The example of antimicrobial resistance in genetically engineered dehorned cattle in the US shows just one of the dangers the UK food system would be facing with an unfettered proliferation of this technology:

FDA finds unintended antibiotic resistance genes in 'gene-edited' dehorned cattle.

'The inadvertently introduced bacterial sequences were found close to the editing site. Of the two antibiotic resistance genes found by FDA, one confers Neomycin/Kanamycin resistance and the other Ampicillin resistance.

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The presence of the previously undetected antibiotic resistance genes in gene-edited cattle raises issues of biosafety given that there is a strong global push to limit the spread of genes conferring antibiotic resistance. This is because every cell of the gene-edited cattle with the polled locus will also contain the resistance genes, allowing them to easily be transferred to bacteria.'

https://theecologist.org/2019/aug/21/antibiotic-resistance-gene-edited-cattle

We believe, therefore, that there is a clear need for regulatory frameworks to reflect the robustness required in order to protect businesses and the buying public.

Due to such well-founded reservations, we would suggest to the FSA Board and FSA staff that self-certification while potentially useful when there are far less severe dangers evident would be wholly inappropriate at any stage with regard to genetically engineered products such as 'Precision Bred Organisms'.

The risk of safety breaches appears not to be properly recognised in the current FSA proposals.

We would add that a monitoring programme will be essential, or any evaluation will be incoherent and lacking sufficient detail and lacking sufficient rigour.

Compliance of prospective operators would require assessment by desktop review but must also require regular checks through a thorough inspection regime supported by industry-wide cooperation, with PBO and non-PBO operators, and will require periodic site visits and the implementation of a much more realistic risk-based approach given the evidence outlined below.

Transparency throughout the supply chain must be assured. Without such assurance three issues are most likely to arise -

1. Extreme increase in the risk of food fraud
2. Loss of confidence in the marketplace
3. Severe economic damage to businesses, including those directly involved in PBO manufacture and those who are entirely removed from such but who would sustain interruption of supply.

Our experience of operating a regulated inspection and certification scheme across the UK and our experience of working with international partners we would strongly urge the FSA Board and officers to revise their proposals.

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We strongly disagree with the conclusion on the effectiveness of the triage approach as described in the consultation pack. The two-tier process is not sufficient and cannot protect the public and is highly likely to cause a massive destabilisation of UK food and drink markets.

The Triage process would unfairly penalise businesses and members of the public who do not wish to choose PBO ingredients. Such a situation is an error of governance and is wholly unacceptable, and we would ask that the Board please reconsider.

We believe that the FSA proposals for a public register are insubstantial. In order to effectively track and trace PBO events FSA and Trading Standards officers would need far more detail. Sequencing is the logical testing solution, however, stable isotope ratio analysis could also be used. If reference samples are collected at harvest these could be used to check origin of PBO products further downstream. We would see this as an option but less preferable.

Not enough information is provided as to what measures will be taken beyond a desk-based exercise to ensure those business submitting information to the register are doing so accurately, and therefore the FSA would likely fail in the policy objective to deliver a proportionate, transparent, regulatory system.

We would draw the Board's attention to point 9.1 -

> 9.1 The Act applies to England only. However, under UKIMA market access principles, food/feed from PBOs which have a marketing authorisation in relation to England which has been produced in, or imported into, England could also be sold lawfully in Wales and Scotland. This would be the case even if the PBOs were not authorised for use in food and feed under existing GMO legislation relating to those countries which would continue to apply.

And to point 11 -

> **Benefits**
> 11.11 By reducing regulatory burdens, the new regulatory framework can help simplify and streamline the process by which food businesses can bring PBOs to the market. Food businesses are also able to innovate and bring new products derived from genetic technologies to market. However, at this stage of the assessment it has not been possible to quantify the benefits, as the industry would be in its infancy – not knowing the type, volume and value of products being brought to market.

These statements fail to take account of UK organic regulations which are underpinned by legal obligations effective across the UK, including the Devolved Administrations.

We would point to the realistic potential for highly negative economic impacts following breaches occurring under the PBO framework, unintended or otherwise, on commercial practices under the organic regulations in Northern Ireland where EU

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organic regulations are in force under agreements including the Northern Ireland Protocol, the Trade and Cooperation Agreement, and the Windsor Framework.

We are all aware that agreements with the European Union in this area have been extremely difficult to achieve and to maintain.

We would ask that the Board have this section reviewed and amended to properly ensure that provisions are in place in Northern Ireland to ensure any such breaches are effectively handled.

We would propose the imposition of significant penalties on the businesses who are found to be in breach, and that a fund is set up to compensate any operator who suffers any loss of commercial operation as a result of PBO framework breaches.

We would kindly ask the Board to note that legally mandated organic regulations cover everything from seed to shelf. A breach of organic regulations could result in loss of organic certificates and in the case of a product manufacturer could require they ensure the removal of products from retail and wholesale outlets. In the case of a farmer or grower it could mean that land would lose organic status and would then be subject to a minimum two-year organic conversion process.

Any of these negative outcomes would come at potentially a very high cost to those businesses affected but would also potentially have a severe and dramatic impact on confidence across the marketplace, not only with organic food and drink but also for emerging PBO markets where due to the understandable nervousness in engaging with new approaches early confidence building takes time and therefore must show effective penalty measures from the very start.

We would also point to the fact that the governments of Wales and Scotland rejected the Genetic Technology Act and have withheld legislative consent and instead reaffirmed their positions that the fallback position must be to the precautionary principle.

Rather than adding undue pressure to an already tense state of play we would urge the Board to help us in maintaining confidence and collaboration across all of the nations of the British Isles.

We ask that the Board acknowledge the expertise of ourselves and of others in this area.

OF&G were the first body to be approved by the UK government to operate an organic inspection and certification scheme. We have several decades of experience in the operations of such regimes, we fully appreciate the commercial pressures at play.

We therefore strongly urge the Board to acknowledge that the current set of proposals need revising to strengthen areas that are weak, and that there is a much greater provision of detail to give clarity where so far there is simply not enough.

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Without addressing the concerns we have listed above we believe attempts to gain transparency will be ineffective and that enforcement would fail and could give rise to a decrease in food safety and an increase in food fraud.

We have been involved in a number of workshops and consultative meetings around the Genetic Technology Act but to date we have yet to see sufficient action from Defra or from the FSA to fully acknowledge the risks to people and business who would suffer great economic hardship following a breach of compliance.

Our experience with auditing processes and operational practice in a commercial reality leads us to conclude that the FSA assessment of impact is not realistic and must be reviewed.

We strongly disagree with the conclusions and believe the one-off costs as set out do not reflect the potential from negative impacts resulting from PBO manufacture, especially where a product is the result of both PBO and non-PBO approaches, as could be the case with plant and animal breeding.

It is clear that there has been a great deal of work to bring the Genetic Technology Act to the legislature. We now ask the FSA Board to pause, to soberly reflect and not to rush into allowing PBO product placement with the current set of criteria and Triage process. We believe that these are not fit for purpose. Such as the Regulatory Policy Committee adjudicated of the last Defra Impact Assessment.

The following are extracts from the RPC report [2] —

Equivalent Annual Net Direct Cost to Business (EANDCB) — Identification of impact(s)

The Department has not sufficiently considered and discussed what additional impacts may arise as a result of the creation of a new category. The creation of the PBO [Precision Bred Organism] category would mean that businesses, research firms and other interested parties, would have three distinct classifications to be aware of and use, as opposed to simply two (i.e. GMO and non-GMO) as is currently the case.

This will add further complexity to the market and potentially lead [to] further costs, such as additional transitional costs to establish new systems, as well as those for new processes to handle this new category.

In particular the IA needs to have considered whether:

- *this will create potential burdens and risks for businesses, and farmers, in cases where an organism turns out not to qualify for this new category or, leads to adverse effects that could be said not to be plausible from traditionally bred organisms;*
- *activities for organisms and businesses in the new category are the same as those in the 'traditional' or unregulated category; and*
- *the category does not create new markets, where different organisations have significant power, or where existing organisations gain or lose significant market power.*

Cost-benefit analysis - Assumptions, risk and uncertainty

The IA uses a range of assumptions that are now given appropriate justification and are supported by evidence. The IA notes that "Whilst this legislative change will only take effect in

[2] https://www.gov.uk/government/publications/the-genetic-technologies-precision-breeding-techniques-bill-rpc-opinion

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England, the mutual recognition element of the United Kingdom Internal Market (UKIM) Act means that products entering the market in England would also be marketable in both Scotland and Wales. Thus, there would be no tangible barrier to PBOs entering the market across GB. However, in the unlikely event that this does become a barrier to market, we have captured the Net Present Value of such a scenario in our overall "low estimate" with 0 trials per year." However, the Department needs to address whether this is an accurate assumption to be made and whether the Bill may create an internal market barrier, e.g., given that PBOs will still be able to be sold in the English market, it does not seem reasonable to treat this as '0 trials'.

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In summary, based on the quality of Defra's evidence the judgement of the Regulatory Policy Committee is that the Impact Assessment for the Genetic Technology (Precision Breeding) Bill 'is not fit for purpose'.

OF&G's opinion is that while we can discuss the science, and debate the rhetoric, however, we must find a way to do so with transparency and with honesty.

In a letter to the organic sector [3]farming minister Mark Spencer promised a revised Impact Assessment when the then Bill was enacted. However, this has not come to pass, and we have very serious concerns that at this stage these details are being overlooked at a time when much more scrutiny is essential.

OF&G believes that strong regulation in food systems is essential. Our experience of adhering to a strong regulatory framework comes from the audits we administer for our licensees and from our own annual audit undertaken by the United Kingdom Accreditation Service.

We would, therefore, see no reason why others should not have to comply with an equally stringent set of standards to protect integrity in food supply chains.

This will protect food producers, the science community and the environment by making clear guidelines and safeguards that are proven to foster a responsible approach to both the scientific and commercial aspects to food safety and environmental protection.

[3] https://ofgorganic.org/docs/letter-mspencer-po2022-19033.pdf

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Citizens must be given sufficient agency when attempting to decide which foodstuffs they wish to consume.

There is an urgent need for a much more serious approach to consultation on issues of coexistence for farmers and growers not using GM technologies than we have seen to date.

We must have engagement from industry and from government and government agencies on liability for any damage from contamination resulting from the use of genetically altered materials such as PBOs.

With the evolving science showing that climate and ecological crises are already having profoundly negative effects on the systems that support food production it is vital to acknowledge that banking on unproven techniques cannot be considered a responsible approach.

When the government's consultation on the Genetic Technology Bill was announced OF&G called for more funding for research in organic whole system methodologies before any move to embrace unproven technologies.

Farmers face huge challenges from increasingly erratic weather patterns and a diminishing biological diversity in our countryside. And they still must be economically viable to be able to manage land and produce consistent quantities of good quality food.

We want all parts of the food system to adhere to the same level of stringent regulation that our licensees achieve year-on-year. We want to see full support for established farming systems and fail safes in place for all systems to enable a truly sustainable growth.

We do not believe that human food systems of the future can continue to fight with nature as they have for preceding decades.

We look forward to working with colleagues across food and farming sectors and across government and non-governmental bodies to engage all the experience and insight built over time with diligent and responsible innovative experimentation and practice.

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