

Comments by GMWatch (with technical advice from molecular geneticist Dr Michael Antoniou) on the Genetic Technology (Precision Breeding) Bill, application and authorisation process, and public register, in preparation for stakeholder meeting with the UK FSA on 20 April 2023.

11 April 2023

Lack of complete traceability and labelling

The bill lacks provision for mandatory risk assessment, traceability and labelling – three rights that the public currently has regarding GMOs and that will be removed with this bill.

Risk assessment format is being drafted by the ACNFP but is likely to be inadequate (see section below). Traceability that includes the consumer and on-package labelling is planned to be scrapped. This is in spite of a Yougov poll showing that a large majority of citizens want all GMOs, including those deregulated by the bill, risk assessed and labelled¹; the FSA's own research produced similar findings.²

Traceability must include the consumer/farmer/end user in the form of a consumer-facing label. Anything less poses dangers to consumers and the environment in case something goes wrong – for example, a consumer allergic reaction, a problem with animal health stemming from the feed, or an environmental issue.

The Bill provides for a public register (clause 18) which includes all “precision bred organisms” (PBOs) released into the environment and/or the food and feed supply. This will assist traceability *up to a certain point*.

However, (i) it is not clear how much information will be available on the register about the PBO and how the information will be accessed; and (ii) **the intention is to exclude the consumer from the knowledge that an organism is a PBO. Traceability will stop before the consumer is reached!**

This seems intentionally deceptive. And it seriously impedes traceability – if, for example, a consumer has an allergic or toxic response to a “precision bred” GM tomato, **unless it is labelled as a GMO**, the consumer is not even going to report it, because “a tomato is just a tomato”.

The FSA says, “Just as with any other food, PB food may have specific safety labelling for particular consumer groups where this is necessary, for example, information on allergens for consumers with food hypersensitivities”.³ Since there are increasing numbers of people who are allergic to an increasing number of foods (we personally

¹ <https://beyond-gm.org/yougov-poll-uk-citizens-demand-robust-regulation-of-gmos/>

² <https://www.gmwatch.org/en/106-news/latest-news/20194>

³ <https://www.food.gov.uk/board-papers/the-genetic-technology-precision-breeding-bill-consumer-information-traceability-and-developing-other-elements-of-the-new>

know “pan-allergic” and “multi-allergic” people, and they can be allergic to the most unexpected foods), we propose that all “PB” food must be labelled as potentially allergenic and it must be specified that this is due to its GMO status.

The FSA says, “It will be important that PB food and feed can be identified in the Welsh, Scottish and Northern Ireland markets... Mandatory labelling to distinguish PB food could facilitate domestic enforcement and determine whether products would be suitable for export to a certain extent.”⁴

We agree with these statements. It seems clear that mandatory PB labelling would keep accountability where it belongs – with the producer – and satisfies the requirements of Wales, Scotland, and N. Ireland.

The FSA says of the public register of PBOs, “The register will be of importance to consumers, but it may have been interpreted by some as a key vehicle for providing information to consumers. While it would be a public resource accessible to all including consumers, industry and enforcement authorities, which will provide information on PBOs authorised for use as food/feed, there are limitations to its use for providing information specifically for consumers.”

Which information will be absent from the register and thereby exclude the public from being informed about which foods are PB?

Voluntary PB-free labelling scheme is discriminatory

Regarding a positive mandatory PB label, the FSA says, “Providing this additional verification and assurance for all PB food would add extra cost to the whole PB food market, making it less affordable, reducing the incentives for food businesses to innovate and bring new products to market, and reducing potential benefits.”⁵

The FSA envisages the possibility of a voluntary “PB-free” labelling scheme, to “avoid the costs of labelling and assurance being applied to all PB food”.

The FSA is keen to protect the PB sector from additional costs resulting from labelling, yet it seems unconcerned about – and has not assessed – the costs of a lack of mandatory labelling to those organic and non-GMO/conventional farming and food sectors who wish to avoid “PB food”. This is discriminatory.

The FSA wrongly assumes safety of PBOs without an evidence base

The FSA says, “There is no evidence that PB products will be less safe than conventionally bred products”.⁶ However, there is hardly any risk research using suitable

⁴ <https://www.food.gov.uk/board-papers/the-genetic-technology-precision-breeding-bill-consumer-information-traceability-and-developing-other-elements-of-the-new#section-2-traceability>

⁵ <https://www.food.gov.uk/board-papers/the-genetic-technology-precision-breeding-bill-consumer-information-traceability-and-developing-other-elements-of-the-new#section-2-traceability>

⁶ <https://www.food.gov.uk/board-papers/the-genetic-technology-precision-breeding-bill-consumer-information-traceability-and-developing-other-elements-of-the-new>

analyses (whole genome sequencing, “omics” molecular profiling, and/or long-term animal feeding trials) that could lead to a conclusion that PBOs are as safe as conventionally bred products. Absence of evidence is not evidence of absence (of an adverse effect).

However, there is plenty of evidence of the unintended, wide-scale (genome-wide) DNA damage stemming from the gene editing process as a whole (plant tissue culture, plant cell transformation, off-target/on-target effects from the gene editing tool) that will inevitably lead to alterations in gene expression patterns, which could lead to biochemical/compositional changes. Based on this, there are plenty of warnings from scientists that this could lead to risks to health (production of novel toxins and allergens) and/or the environment.⁷ The FSA appears to ignore this evidence and these warnings.

Unscientific nature of the bill puts massive responsibility onto the FSA to ensure food safety

The Bill unscientifically dismisses crucial genetic elements that could make the difference between safety or serious risk from the GMO – namely the gene copy number of the feature; its epigenetic status; and its location in the genome.

It is a long-established fact in the field of molecular biology that copy number, location in the genome and epigenetic status markedly influence, and indeed determine the function of natural and genetic elements introduced through any GM process, including gene editing. Yet the Bill instructs regulators to ignore these features in deciding whether an organism is a PBO and can therefore escape detailed scrutiny.⁸

In this context, it is extraordinarily irresponsible and scientifically unjustifiable to tell regulators they must **not** look at these features in forming a judgement about the status of a GMO.

We propose that the FSA finds a way to take into account these crucial features and to assess their implications. Otherwise it cannot fulfil its role of ensuring the safety of the food supply.

Problems with the draft risk assessment guidelines

Currently these are only published in outline draft form and in meeting minutes. According to our understanding, the plan for risk assessment is:

- DEFRA/ACRE decides what is a PBO. Then FSA/ACNFP (possibly moving to FSA staff later) does the risk assessment for food and feed.

⁷ For example, see references here <https://gmwatch.org/en/news/archive/2019/19223> and these papers: <https://doi.org/10.1186/s12302-020-00361-2> and <https://www.mdpi.com/2223-7747/10/11/2259>

⁸ For a detailed scientific discussion of this feature of the bill, see: https://www.gmwatch.org/files/robinson_antoniou_genetic_technologies_bill_response_update150622-1.pdf

- Two-tiered risk assessment is planned, with only those PBOs that trigger concerns progressing to Tier 2.⁹
- ACNFP expects most PBOs to be handled at Tier 1.¹⁰
- Triage questions¹¹ will be asked to determine which PBOs progress to Tier 2, focusing on novelty, composition, and “other safety concerns”.

Regarding the triage questions:

- Novelty is defined as a case whereby “a PBO will be generated by precision breeding of a progenitor that has not been consumed to a significant degree in the UK or EU”. However, this ignores the fact that it is not just the identity of the progenitor that matters – risks can occur from disrupting genes within an organism in so-called SDN-1 applications¹² and these are different from the risks posed by conventionally bred or mutagenesis bred organisms.¹³
- Regarding composition, which, as ACNFP states,¹⁴ “could affect nutrition, toxicity, or allergenicity”, ACNFP says, “Understanding the genetic changes made during the development of a PBO is essential in determining its safety. Knowledge of the resultant phenotypes and altered traits is important to allow identification of potential for food and feed safety risks to increase or decrease. This allows assessment of intended (anticipated) changes that may be nutritionally disadvantageous for the consumer, as well as any potentially significant changes to the toxicity and allergenicity of food or feed made from the organism.”

However, ACNFP does not specify how the genetic changes will be screened/analysed. Long-read whole genome sequencing is necessary in order to spot both the intended and the unintended changes from the genetic manipulation process. Yet ACRE has made clear that in screening GMOs to see if they qualify for being PBOs, **it will only be considering intended genomic changes** – “ACRE would focus on the intended genomic change introduced by PB [precision breeding], and therefore would only request information on the intended use and on the genetic change(s)”.¹⁵ The ACNFP states, “Additional minimum information could be requested on a case-by-case basis”, but it’s not clear what would trigger such requests.

- It is not acceptable and is highly risky to only consider intended genetic changes. Several different types of unintended DNA damage (e.g. large insertions/deletions, large rearrangements including chromothripsis, and creation of new gene sequences leading to novel mRNA and mutant protein production) inevitably accumulate at both the intended edit site (on-target) and at off-target sites from the different elements and stages of the plant gene editing process – tissue culture, cell transformation, inappropriate action of the gene editing tool and DNA repair process. These

⁹ <https://acnfp.food.gov.uk/StatementofACNFPonPBOs-January2023>

¹⁰ <https://acnfp.food.gov.uk/Minutesofthe2ndMeetingheldonthe8thofAugust2022>

¹¹ <https://acnfp.food.gov.uk/StatementofACNFPonPBOs-January2023>

¹² <https://www.mdpi.com/2223-7747/10/11/2259>

¹³ <https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full>

¹⁴ <https://acnfp.food.gov.uk/StatementofACNFPonPBOs-January2023>

¹⁵ <https://acnfp.food.gov.uk/Minutesofthe4thMeetingheldonthe21stofNovember2022>

unintended genetic (and epigenetic) changes will result in unpredictable alterations in gene expression patterns leading to altered biochemistry, which could include production of novel toxins and allergens. Thus this spectrum of unintended changes can make the difference between a safe organism and one that poses serious risks (see above-cited studies on unintended outcomes of gene editing¹⁶). If the ACNFP were true to the scientific discoveries of the large-scale unintended DNA damage that accompanies the gene editing process, then it would demand that multi-omics molecular profiling methods be used as a first step in identifying the compositional consequences (with potential implications for health and the environment) of this procedure.

- Regarding “Knowledge of the resultant phenotypes” – it is not specified what this means or how the knowledge would be obtained. It is not enough to eyeball the resultant phenotypes to see if they look and grow OK. “Omics” molecular profiling is needed – proteomics and metabolomics – to check for potential toxins and allergens.
- ACNFP says, “In all cases the risk of elevating existing allergens would be left to the developer to monitor.... it is currently very difficult to predict the emergence of new allergens or new triggers of allergic reaction; the possibility of organisms currently not identified as being allergenic, becoming allergenic as a result of editing would result in substantial remaining risk.”¹⁷

It is not acceptable to leave it to the developer to monitor for allergens. Regarding the difficulty of predicting new allergens, ACNFP is correct in its assessment and seems concerned, but no solution is suggested. A mitigating step would be to require on-package labelling of the final product, to alert the consumer to the potential of unidentified allergens being present. This would also protect the GMO developer sector, as any “damage” from a single problematic GMO would be able to be confined to that GMO and not drag in the entire sector.

- Stacking: ACNFP says, “The stacking of different PB events was discussed for the first time. ACRE and Defra representatives confirmed that all progeny of a PBO would automatically acquire the status of PBO, and it was assumed that the progeny of two different, confirmed PBOs would not need to receive further confirmation of PBO status... Members discussed whether stacking PB modifications, each previously authorised individually, could introduce new risks; this issue will be further reviewed in future workshops.”

Stacking of “PB events” will increase the risk of combined effects, so ACRE/Defra is not justified in automatically granting PBO status to all progeny of a PBO regardless of the type and number of “PB” genetic modifications they have been subjected to. Again, the FSA will unfortunately be left in the position of trying to ensure the safety of GMOs that have been wrongly and deceptively classified as PBOs by ACRE/Defra.

¹⁶ <https://www.mdpi.com/2223-7747/10/11/2259>; <https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full>

¹⁷ <https://acnfp.food.gov.uk/Minutesofthe4thMeetingheldonthe21stofNovember2022>