GM Freeze report:
Problems with the proposed regulatory framework for new-style GMOs under the Conservative government

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Background

The 2023 Genetic Technology (Precision Breeding) Act (hereafter the Act) created a new legal category for a subset of genetically modified organisms (GMOs) that were named "Precision Bred Organisms" (PBOs).* These are defined in the Act as those that "could have resulted from traditional processes," but with changes to the genome having been made using "modern biotechnology". This includes some but not all applications of gene editing. The Act paved the way for the removal of existing GMO regulations over these plants, animals and other organisms such as microbes. However, as of August 2024, much is yet to be determined as the rules will be laid out in secondary legislation named Statutory Instruments (SIs). When the 2024 general election was called, the Department for Food and Rural Affairs (DEFRA) and the Food Standards Agency (FSA) were working on these.

The draft SIs have not been published; however, the public have been informed of the substantive elements,[1] and stakeholders have had sight of some of the proposed text.[2] Sufficient information has been disclosed to provide a clear understanding of the secondary legislation that was due to be laid before Parliament under the former Conservative government.

This report outlines a number of problems with the proposed regulatory framework. It accompanies a briefing which provides recommendations to the new government. The change of power in Westminster has created an opportunity to avert the consequences of reckless deregulation. The Labour government should to act responsibly and with due consideration of the country's international legal obligations and environmental, health and socioeconomic risks, as highlighted below.

Problems with the proposed regulations under the former government

1. Traceability provisions would not meet the intentions of the Act

The Genetic Technology (Precision Breeding) Act includes a provision for secondary legislation to "impose requirements for the purpose of securing traceability in relation to food or feed produced from precision bred organisms that is placed on the market in England." Traceability is defined as "the ability to trace and follow the organism and the food or feed through all stages of production, processing and distribution."[3]

However, the only traceability requirements proposed by the FSA are for traders to be able to identify their suppliers and customers, and disclose this information to authorities if asked.[4] At the FSA's March 2024 Board meeting, Dr. James Cooper, Deputy Director of Food Policy, explained to GM Freeze that the FSA's proposals involve tracing to all *potential* sources. There could be multiple potential sources depending on the product and whether it was traded on commodity markets.

* In this document the term PBO is used, however, it is noted that this is not a scientifically meaningful classification but rather a political construct that is not recognised by other jurisdictions, including within the United Kingdom.

Likewise, it would not be possible to trace the exact products that contained a PBO, only those that *potentially* contained it. [5] Such retrospective tracking would appear to fail to meet the intentions of the Act, which implies that traceability should be proactive and occur from the point of production through the food system.

Furthermore, under general food law: "Food or feed… shall be adequately labelled or identified to facilitate its traceability."[6] In order for PBOs to be traceable they would need to be labelled throughout the supply chain, which has not been proposed by DEFRA and the FSA.

In the event of a safety-related product recall of a PBO, or the revocation of a Precision Bred Confirmation (PBC) by DEFRA,[7] this lack of traceability could result in losses which would impact all potential suppliers and distributors of a product, whether 'precision bred' or not. For example, where a PBO wheat was on the market and mixed with other wheat, all wheat that potentially contained the PBO would need to be removed from sale in the event of a safety issue or PBC revocation. Such an occurrence could have country-wide ramifications.

2. Trade problems: Devolved nations

a) Internal Markets Act conflicting with sovereignty of devolved nations

The Act only applies to England, but it was the Conservative government's position that PBO products placed on the market in England would be saleable in Scotland and Wales as a result of the Internal Market (UKIM) Act.

The Scottish Government has said that it is "wholly opposed to the imposition of the Internal Market Act, and will not accept any constraint on the exercise of its devolved powers to set standards within devolved policy areas."[8] It has described a clause in the Act which allows secondary legislation to amend it (clause 42) as a "constitutional impingement which represents an erosion of devolved competence,"[9] and informed the UK government that failure to label will obstruct the enforcement of devolved powers to regulate in this area.[10]

The Welsh government did not agree to a Legislative Consent Memorandum regarding the then-Bill in January 2023.[11] It has said that it wants to protect Welsh consumers' right to choose PBOs, and highlighted problems in relation to monitoring and the enforcement of Welsh regulations as a result of lack of labelling or traceability. It has also raised the issue of increased barriers to trade for Welsh businesses.[12]

b) "Significant production step": regulatory problems and trade advantage

A further complication is that the UKIM Act only applies to the product as it is first put on the market. Therefore, if PBOs undergo a "significant production step" in Wales or Scotland they would fall under the existing GMO legislation there. However, if there is no segregation or labelling of PBOs, it would not be possible to identify those products sold from England that would need to be labelled post-processing, for example, PBO wheat that is sold into Scotland and processed into bread there. This situation would make it almost impossible for the devolved nations to uphold their legal responsibilities with regard to their own regulations.

Furthermore, this situation creates the potential for raw materials that undergo a manufacturing process in England to be placed on the market in devolved nations unlabelled, but if the same raw materials were processed in the devolved nations they would be regulated as GMOs. This would create a disincentive for value-added production processes to occur in devolved nations, and therefore a trade advantage for England.

c) Conflicts with existing trade agreements

Products identified as PBOs could not be imported from third countries and put on the market in Wales or Scotland without falling under GMO regulations. However, they could be imported into England and then sold into Wales and Scotland without falling under GMO regulations. This undermines the principles of non-discrimination in global trade, and may place the devolved nations in an untenable situation regarding their existing trade agreements.

3. Trade problems: Europe

In February the European Parliament voted to require labelling and traceability of products from New Genomic Techniques (NGTs). This is a similar categorisation to PBOs in that it includes gene editing. NGTs are, however, scientifically defined, unlike PBOs in the UK. It is expected that many PBOs on the market in the UK would fall within the NGT category in Europe and vice versa.

Different labelling and traceability requirements for PBOs in the UK and NGTs in Europe could spell disaster for *all* British agricultural producers. For British products to be placed on the market in Europe, customs officials would need to differentiate between PBOs and Traditionally Bred Organisms. Without labels, this would require the development of a system which DEFRA has predicted would involve "checks and certification requirements", though may in future also include testing.[13] DEFRA's Impact Assessment of the Genetic Technology (Precision Breeding) Act states:

> "This would not only affect products exported to the EU which contain PB plant material, but also those in the same product categories which do not. Typically, non-tariff measures (NTMs) such as these would increase the costs of production for UK food exporters through delays and additional paperwork. The scale of the impact of these costs depends on the total value of the crop related food exports affected. The value of these exports is currently estimated to be worth around £8.56bn a year (2016-2020)."[14]

The Impact Assessment does not appear to include the value of the trade in animals, rather, it is solely an estimation based on "crop-related" products. As animals are included in the Act, this appears to be a significant omission. The Regulatory Policy Committee has judged the Impact Assessment to not be fit for purpose.[15]

If £8.56 billion worth of trade a year was subject to non-tariff barriers, this would have a huge impact on British producers, with effects also felt by the wider economy and workers that depend on this trade. Nevertheless, government agencies have failed to publicly address the potential

impact of the European Parliament vote. When questioned in March 2024 as to whether any risk analysis had been conducted on this, the Food Standards Agency failed to answer.[16]

- ### Misreporting Europe

In March 2024 the trade association for UK retailers, the British Retail Consortium, had on its website the document 'Precision Breeding Summary". This reported on the European Parliament vote, but falsely indicated that of two categories of NGT plants, only the riskier Category 2 would be subject to mandatory labelling. It indicated that only the seeds of Category 1 plants would be labelled – not the plants or products made from them. The document has now been put behind a paywall.[17]

The BRC is not the only place to have misrepresented the situation in Europe. At a Westminster Food & Nutrition Forum (WFNF) policy conference in June 2024, the lawyer Katrina Anderson outlined the legal issues around bringing PBOs to market as food. She also suggested that just one tier of NGT plants would be labelled in Europe.

4. Trade problems: International

Internationally, trade regimes differ with regard to products from newer forms of genetic modification, such as genome editing. If the UK fails to segregate PBOs it is unclear how British products for which there are PBO varieties could be traded with countries that require additional controls for such products.

This also applies to supplies to commodity markets, which function on the basis that products are homogeneous. Wheat is of particular concern given the importance of the crop[18] and the fact that wheat developed using new genetic technology is under development in the UK.[19]

5. Undermines organic sector's legal responsibly to maintain segregation

In its Consultation Pack on the proposed regulatory framework, the FSA failed to recognise the organic sector's legal responsibility to maintain supply chains that are free from PBO materials, suggesting it is a matter of choice for producers:

> "Traditional breeders and organic food and feed firms could be disproportionately impacted should they choose to continue to supply non-PBO food/feed. They are likely to face higher costs in trying to guarantee their products are non-PBO."

Organic producers, traders and retailers are required by law to exclude PBOs at farm level, through supply chains to consumers. Without a requirement to identify and trace them, excluding them will be costly, difficult and is likely to mean that organic operators are unfairly prevented from using products and ingredients that they are currently permitted to use. This will unfairly impact organic operators and may lead to reduced availability of some organic products. Any additional costs to exclude these new-style GMOs will be passed on to consumers of organic and traditionally-bred produce, thus making such produce more expensive and potentially not economically viable. The

FSA's approach to this is concerning, particularly given the significance of the organic sector to the British retail market.

6. Goes against consumer choice on labelling

The secondary legislation as it was being devised under the former government would not have required the labelling of PBOs in supply chains or at the point of sale. This would make it impossible for retailers and suppliers to meet the wishes of their customers with regard to PBOs.

Consultations have repeatedly shown that consumers overwhelmingly want labelling. In July 2021 the FSA found that "most participants strongly felt that labelling should always tell consumers if there are genome edited ingredients in the product, because transparency is crucial to enable consumers to choose for themselves, and to build consumer trust in genome edited foods."[20]

Respondents to a DEFRA consultation in 2021 "raised concerns about accountability and transparency, including the importance of consumer choice, and favoured product labelling to indicate whether a product is derived from gene-editing."[21] In November 2022 a YouGov Poll found that 79% of people thought that precision bred crops, animals and foods should be clearly labelled on the food package.[22] Of the survey respondents to the FSA's March 2023 consultation, nearly four in five (77%) said it would be important when buying a food item to know if it had been precision bred, and nearly half (45%) said it would be 'very' important. Only one in six (15%) said knowing this would not be important.[23]

Opposition to unlabelled new-style GMOs is also apparent in Europe. A number of European retailers, including SPAR, Germany's REWE group and Austria's Hofer, have stated in an open letter:

> "We want to continue to give… consumers full freedom of choice. To ensure this, EU regulations must guarantee full traceability and labeling of NGTs throughout the supply chain to ensure the continued existence of NGT-free and organic agriculture and food production."[24]

The FSA has stated that the former government "has been clear that there are no plans to require labelling of products to indicate they have been produced using PB techniques."[25] It noted that there are no provisions for labelling in the Act. However, there are also no provisions for *not* labelling in the Act. If the FSA and DEFRA stand by the decision not to label, the question arises as to why the public were consulted on this issue in the first place - government guidelines state that consultations should take place when there is scope to influence policy.[26]

In September 2022 the Advisory Committee on Novel Foods and Processes (ACNFP) held a workshop on PBOs. The report of the workshop states:

> "Lay representatives, supported by several other Members, highlighted the importance of understanding public perceptions and ensuring consumer confidence in this new technology.

> The work of the FSA in dialogue with stakeholders and consumers to inform policy decisions was noted and deemed extremely important for the acceptance of the approach for PBOs."[27]

This recognition appears to have been disregarded.

7. Failure to address the likely impact on animal tests

According to the most recent government Home Office statistics of scientific procedures using animals, "policies and legislation that influence the number and type of [scientific] procedures are the responsibility of different government departments".[28] Precision breeding is stated to be DEFRA's responsibility, whilst food safety is stated to be the FSA's responsibility.

When asked in March 2024 whether it had assessed the likely impact of its proposed legislative framework for PBOs on the number and type of scientific procedures on animals (both for experimental purposes and for the creation of PB animals), the FSA failed to answer.[29]

The FSA stated that PB animals will initially fall under the auspices of the Animals in Scientific Procedures Act 1986, which "requires that animals are only ever used in science where there are no scientifically satisfactory alternatives". If PBOs could have been produced using traditional breeding methods – as per the definition of PBOs in the Act - the application to authorise a PB animal should include a justification for not using traditional breeding.

8. Ethical issues in the development of PB animals

Concerns have been raised regarding whether it is appropriate to regulate the creation and breeding of PB animals in the same way as PB crops, given the additional ethical and welfare issues that should be considered, and the necessity for risk minimisation and a social licence for the use of PB technologies in this area.[30]

The scope of the Act is so broad that it may apply to wild, companion and sporting animals. There has been no indication that the purposes of developing a PB animal will need to meet any ethical criteria, which is of concern. Furthermore, the regulatory framework as it has been disclosed to date does not adequately address the welfare of PBO animals and their progeny and how this will be monitored.

9. Environmental risks and international obligations

The proposed process for the legal release of PBOs (as managed by DEFRA) does not include any environmental risk assessment or risk management, despite there being a provision addressing potential adverse environmental impacts in the Act.

The UK is a party to the Cartagena Protocol on Biosafety, a legally binding international agreement that addresses the risks posed by Living Modified Organisms (LMOs) to the world's biological diversity, with consideration also given to risks to human health.[31] The explanatory notes to the

Genetic Technology (Precision Breeding) Bill state: "The UK Government considers that the Cartagena Protocol does not apply to organisms produced using modern biotechnologies if those organisms could have occurred naturally or been produced by traditional methods."[32]

The former government's dismissal of the Protocol on the basis of something that has not been adequately or scientifically defined, and is therefore not provable, is a dereliction of the country's international obligations. Furthermore, taking a unilateral position on the issue is inappropriate given the focus of the Protocol on the transboundary movement of LMOs and the international impacts of their release.

The new government should commission and publish legal advice regarding the applicability of the Cartagena Protocol to the environmental release and transboundary movement of PBOs. Due regard should be given to key issues in the Protocol, including:

a) The cross-border movement of LMOs.

- A failure to require that PBOs are identified (labelled) prior to them being traded across borders could undermine the foundations of the Protocol.

b) Risk assessment and management.

- Failure to require case-by-case environmental risk assessment could be in contravention of the Protocol.

c) Public awareness, education and participation.

- The former government's conceptual framing of PBOs as organisms that "could have" been produced through traditional processes may be incompatible with its obligations under the Protocol to educate about LMOs that are a product of modern biotechnology.
- Failure to incorporate into the regulatory framework the public's strong preference for on-product labelling could be in contravention of the requirement for public participation as outlined in the Protocol.

The UK is also a signatory to the Aarhus Convention, which enshrines the right of citizens to have access to environmental information and participate in environmental decision-making.[33] Given the direction of travel for the deregulation of PBOs – including a failure to require that they are identifiable at farm level - the commitment of the previous government to this Convention is questionable.

10. Failure to adequately define 'Precision Bred' and subcategories of

Dr Michael Edenborough QC highlighted problems with the government's definition of PBOs when he addressed the Public Bill committee of the Houses of Parliament prior to the Genetic Technology (Precision Breeding) Bill becoming an Act on 30 June 2022.[34]

He referred to the Bill's definition of PBOs – those that "could have resulted from traditional processes" – as "staggeringly imprecise". He stated that PBOs had been defined "in a cascading

way" with "uncertainty built upon uncertainty," and in the event of legal proceedings to interpret the regulation, a raft of expert evidence would be required for each point of the cascade. Dr. Edenborough also highlighted the problematic nature of the "King Henry" clause (clause 42), which allows the Act to be modified by secondary legislation with little parliamentary scrutiny.

During the same hearing Daniel Zeichner MP questioned whether transgenesis, herbicide tolerant plants, and pesticide resistant insects would be permitted within the scope of the Act as a result of the way that PBOs had been defined. He stated that these raised wider issues.

The fact that PBOs have not been clearly scientifically defined to date means that no tests have been defined that are capable of determining an organisms' PB status. It will be up to developers to classify their products in line with their own definition of a PBO.

From the publicly available information to date, the SIs do nothing to clarify definitions, but rather introduce two subcategories (tiers) for which there will apparently be no clear scientific definitions either.

11. Self-classification of PBO and tier status by developers

DEFRA and the FSA intended to create two tiers of PBOs that will mean the difference between a virtually unregulated and a lightly regulated product.

Tier 1 PBOs will be those categorised by developers as low risk and will be subject to a notification rather than an authorisation procedure. Information provided to the FSA will be descriptive, and applicants will need to state that no changes have been made that are "likely" to cause problems.[35] The FSA will not assess any data. Applications may be subject to an audit check; however, the FSA expects to audit a low percentage of notifications.[36]

Tier 2 PBOs will be categorised by developers as requiring further consideration. The FSA will conduct a "safety assessment process", but this will not include any actual testing. It will involve an assessment of the data provided by the developer, which will not include the results of studies that demonstrate the composition, toxicity and allergenicity of the PBOs, but rather the *predicted impacts* of the changes on composition and allergenicity. It would appear that no information on unintended genetic changes will be considered. Furthermore, the FSA will apparently not specify the type of data that must be provided, so the agency's regulators will be working with an inadequate understanding of the PBO concerned and any risks it may present.

With no scientific definition of the two tiers, and no data or proof required for tier classification, there would appear to be flexibility for companies to select which tier their products fall under. Such a system is open to abuse. This is of particular concern given the complete absence of a safety assessment of Tier 1 products. There will be a big incentive for businesses to use the Tier 1 route to market; indeed, the FSA expects more Tier 1 applications.[37]

12. No independent safety testing

The FSA's proposals for the approval process of PBOs do not include any independent safety testing.[38] All tests will be conducted by developers and there are no requirements in the proposals for specific tests that could provide important safety information, or demonstrate to an acceptable level of probability that the PBO is equivalent to an organism that could occur through traditional processes.

An example of a procedure that could provide important safety information is long-read whole genome sequencing, which can give accurate information about unintended as well as intended genetic changes. Other "omics" molecular analyses, such as those of transcriptomes, proteomes and metabolomes, can give crucial information relevant to safety, such as about compositional changes (quantitative as well as qualitative) that may affect toxicity or allergenicity. It is unclear whether government agencies have considered the use of such analysis.

13. Inadequate approach to unintended genetic changes

The Act and accompanying proposed SIs do not require long-read whole genome sequencing or systematic monitoring for, and reporting of, unintended genetic changes to genomes ("off-target effects" and "unintended on-target effects" at the intended edit site) through to food and feed authorisations. Gene editing in human and animal cells has been found to have significant unintended consequences.[39]

The draft SIs state that in order to obtain a marketing notice, developers must provide descriptions of unintended genetic changes and the approach used to remove these, "where this was undertaken". However, the proposals do not specify which analyses developers must do in order to look for unintended changes, and they also do not require developers to remove unintended genetic changes or investigate their effects.

After a PB confirmation has been issued, the process of authorising a PBO for food or feed shifts to the FSA. The provisions in relation to unintended genetic changes will apparently not filter through to the FSA. The obligations on developers are almost exclusively focused on the changes to genomes that they *intend* to make. They will be required to provide information on measures taken to minimise the potential for unintended genetic changes, but not whether or not such changes *have* taken place.[40] As previously stated, the food and feed tier categorisation system will apparently not include the consideration of off-target or unintended on-target effects.

14. No development of analytical detection methods

The FSA commissioned LGC (formerly the Laboratory of the Government Chemist) to conduct a literature review on analytical methods for the detection of PB products, which was published in September 2023. The report made a set of recommendations that would enable the development of PBO detection methods. The recommendations included a review of the PBOs for which authorisation was requested, "to monitor… and actively assess the extent of the genetic variability

and mutations".[41] This would inform decisions regarding the type and complexity of detection methods that would need to be developed. The FSA, however, have decided not to take forward any of the recommendations in the report.[42]

The fact that the FSA and DEFRA will not be collecting the information that is necessary to develop analytical detection methods of PBOs is alarming. It is also of concern that the FSA did not reconsider this position in light of the European Parliament's votes on labelling and traceability. Moreover, the European Union is actively funding the development of detection strategies.[43] The UK will fall behind scientific advances in this area if it fails to invest in detection methods, and this is likely to create significant disadvantages in the event of future non-tariff trade barriers.

It should be noted that, under the older regulation for GMOs, developers must supply to regulators as a condition of marketing the genetic sequence details of the changes made, a detection method, and sample (reference) materials of the GMO in question. These elements of the older regulation could be required for PBOs as well, saving considerable public funds and making the work of regulators far easier.

15. Lack of post-market monitoring

The draft regulations indicate that there will be no post-market monitoring of PB plants. This is a major weakness in the regulatory framework which will mean that the risks of this new technology will not be adequately monitored and assessed.

Regarding post-market monitoring of precision bred animals and their progeny, this will be established to some extent. However, it would seem that there remain undecided variables[44] and therefore it is not possible to ascertain how robust the approach would be. Penny Hawkins of the RSPCA emphasised the importance of monitoring PB animals and their progeny during her evidence to the Public Bill committee.[45]

16. Allergen labelling and conditions of use

An expert opinion on the risks of new GM plants published by the French National Agency for Food, Environmental and Occupational Health Safety (ANSES), and supported by other governmental agencies such as the German Agency for Nature Conservation, states that potential risks of NGTs include those "linked to unexpected changes in the composition of the plant, which could give rise to nutritional, allergenicity or toxicity problems."[46]

The FSA has provided at best incoherent and at worst misleading information with regard to allergen labelling and conditions of use for PBOs. It has stated that, for particular population groups such as hypersensitive consumers or people with certain health conditions, safety information in relation to PBOs can be required as appropriate.[47] It has also stated that it is able to impose conditions of use on PBO products, which could include "mandatory safety labelling for certain categories of consumers with allergies or food intolerances". [48]

The implication is that PBOs will be labelled if required. However, at the FSA's March Board meeting, Dr. James Cooper informed GM Freeze that PBOs are the same as conventionally bred organisms. So if there was a requirement to label an allergen - for example, cabbages – then all cabbages would need to be labelled whether PB or traditionally bred.[49]

Further questioning of the FSA has not clarified the situation; rather, there still appears to be the prospect of the PB nature of an ingredient being labelled. An email sent by the FSA to GM Freeze in May 2024 stated: "the FSA can add a requirement that specific information on the precision bred nature of the PB ingredient must be supplied along the chain to facilitate safety labelling at the point of sale."[50]

17. Problems with patents

The Act is silent on the issue of intellectual property and it would seem that the proposed SIs will also not address this. Given that patents have become a major barrier for the EU adopting new regulations on NGTs,[51] it is remarkable that the British government has failed to address this issue at all.

The UK is a signatory to the European Patent Convention, which is governed by the rules of the European Patent Office. Under the terms of this convention, biological production processes and plants and animals exclusively obtained by them are not patentable. However, GMOs, as organisms produced via technical processes, are patentable. If PBOs are to be patented, it would be under paradoxical conditions that they would need to be organisms that could have occurred by traditional breeding but due to patent regulations were not obtained through traditional breeding. This throws up an irregularity between the definition of PBOs being end-product specific, whilst their patentability will arise from the technical process by which they are produced.

Experience in Europe has shown that patents on organisms developed using genetic modification can stifle innovations in traditional plant breeding, for example, if a trait is patented that is achievable through the use of both methods.[52,53] Patents can also lead to economic hardship for food producers.[54]

In recognition of the problematic nature of patenting organisms, the European Parliament has proposed a ban on patents for NGT plants.[55] It is an issue now causing a deadlock in the European Council.[56] Should the ban survive the forthcoming machinations of the European legislative process, it could influence the European Patent Office and the rules by which the UK must abide, [57] which in turn may impact the economic incentives for PBO development.

18. Inadequate assessment of impacts

DEFRA and the FSA have failed to meet their obligations with regard to assessing the impacts of the Act and proposed secondary legislation. The Regulatory Policy Committee rated DEFRA's Impact Assessment of the Act (then Bill) not fit for purpose,[58] whilst the FSA stated that it had not conducted a full impact assessment because it had estimated that the impacts would be below the

minimum threshold of +/- £10 million. How it made this assessment without conducting an impact assessment is unclear.

19. Wild species, trees and microorganisms

During the Public Bill committee hearing on 30 June 2022, Penny Hawkins of the RSPCA raised the prospect of the Act being applicable to wild species. This was a concern echoed by Professor Sarah Hartley, who noted that it could have applications in conservation and environmental management, but there had been no engagement of stakeholders in this respect.[59]

The genetic modification of trees is of particular concern given their long life cycle, number of species they interact with and ability to spread pollen and seeds over long distances. Their lifespan means that it is impossible to fully assess the long terms risks they may pose to forest ecosystems as well as local communities and indigenous people.[60]

Microorganisms such as soil microbes are also within the scope of the Act, but there are limitations of our knowledge in this area and our ability to predict or control outcomes. Issues of particular concern include the impossibility of containment, horizontal gene transfer, unintended impacts on species of plants and insects due to changes in microbiomes, and novel pathogens.[61]

20. Emerging technologies and future proofing

During the Public Bill committee hearing, Lawrence Woodward OBE pointed out that the scope of the Bill was so wide as to encompass a range of technologies that will be on the cards in the future, with varied and potentially serious risk profiles, yet it lacked the assessment and consultation processes to deal with them.

Powerful emerging technologies could have major impacts on the environment and society. These technologies include, but may not be limited to, gene drives, RNA "gene-silencing" sprays, the genetic alteration of microorganisms, and genetic modification combined with Artificial Intelligence. The Act could enable the deployment of such technologies without public engagement or parliamentary scrutiny. The new government must ensure that such technologies are developed with transparency, regulatory oversight and public awareness.

Conclusion and recommendations

The regulatory framework for PBOs as it was being devised by the former government was not fit for purpose. The government and government agencies dismissed the country's international obligations; ignored the wishes of consumers; and failed to adequately address health and environmental risks or socio-economic impacts.

Government agencies were in the process of devising a regulatory framework which was open to abuse by companies; these would be required to provide very limited information on their products

before they became legally marketable. No environmental impact assessments would be required, virtually no checks would be required of food and feed products that were self-declared by developers to be low risk and no independent safety testing would be conducted of higher-risk organisms. Serious questions remain over how PB animals would be regulated and what provisions would be put in place around animal welfare and scientific procedures involving animals.

Many of the existing problems could be addressed by mandatory labelling and traceability. This would mean that the regulations meet consumer demands for labelling, the organic market's legal requirement of co-existence, and the provisions of the Genetic Technology (Precision Breeding) Act with regard to traceability. It would also mean that, should more evidence emerge regarding increased allergenicity or unexpected toxicity of certain PBOs, safety labelling of this class of organisms would be possible in future.

Labelling and traceability would avert the potentially severe economic impacts of the UK having a divergent regulatory system from that which will be implemented in Europe and internationally. It would also allow the continued supply of traditionally bred agricultural products to commodity markets destined for international trade. It would allow the Welsh and Scottish parliaments to meet their existing legal and trade obligations, as well as facilitate the potential for devolved decision-making in this area. The cost of segregation throughout supply chains would fall on those producing the PBOs and therefore the 'true cost' would be appropriately apportioned.

Labelling and traceability would substantially ease the legal uncertainties that currently exist around the Genetic Technology (Precision Breeding) Act, creating a more predictable and potentially less volatile investment environment.

A full set of recommendations are available in the briefing 'Creating a robust regulatory framework for new-style GMOs,' prepared by GM Freeze, August 2024.

All references accessed 1st – 21st August 2024

[1] For example, in: 'Consultation pack on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed', FSA, 8th November 2023. Available from: https://www.food.gov.uk/our-work/consultation-pack-on-proposals-for-a-new-framework-in-england-for-the-regulation-of-precision-bred-organisms-used-for-food-and, and 'FSA Board Meeting - March 2024: Agenda and Papers, Questions to the Board'. Available from: https://www.food.gov.uk/board-papers/fsa-board-meeting-march-2024-agenda-and-papers'.

[2] Via an online presentation from DEFRA and the FSA on 21st May. 'Update on precision breeding legislation', DEFRA, Powerpoint presentation, created 24th May 2024.

[3] Genetic Technology (Precision Breeding) Act 2023. Available from: https://www.legislation.gov.uk/ukpga/2023/6/pdfs/ukpga_20230006_en.pdf

[4] See 'Consultation pack on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed', FSA, 8th November 2023, available from: https://www.food.gov.uk/our-work/consultation-pack-on-proposals-for-a-new-framework-in-england-for-the-regulation-of-precision-bred-organisms-used-for-food-and

[5] Interview with GM Freeze Executive Director Leonie Nimmo at the March 2024 FSA Board meeting. Information clarified by email, sent 27th March 2024.

[6] 'Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down

procedures in matters of food safety,' amended 1st October 2023. Available from: https://www.legislation.gov.uk/eur/2002/178/2023-10-01

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