GeneWatch UK response to the Department of Farming and Rural Affairs (Defra) consultation on the Plant Varieties and Seeds Framework for 'Precision Bred' Plant Varieties

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GeneWatch UK is a not-for-profit organisation which aims to ensure that genetic science and technologies are used in the public interest. We are responding to this consultation[1] as an organisation with more than 25 years' experience of working on the issues associated with the open release of Genetically Modified Organisms (GMOs).

We note that, although the Genetic Technology (Precision Breeding) Act 2023[2] (referred to in this response as 'the Act') redefines some GMOs (principally those created using gene/genome editing techniques) as 'precision bred organisms' (PBOs), these remain regulated as GMOs in many countries, including within England's closest markets, the European Union (EU), Northern Ireland, and (except to the extent the UK Internal Market Act applies), in Scotland and Wales. There will therefore be significant negative impacts on trade due to deregulating so-called 'precision bred' plants, which will contaminate food and feed and lead to refusal of entry of numerous products (food, feed, forestry, ornamentals) to many markets. In addition, gene editing technologies are not 'precise' and gene edited organisms can pose risks to human and animal health and the environment (due to both intentional and unintentional genetic changes). Full health and environmental risk assessments, and traceability and labelling throughout the food chain are therefore essential. Whilst GeneWatch UK is aware that these issues cannot be fully addressed solely through the Plant Varieties and Seed Framework, this framework must nevertheless include sufficient safeguards to (i) minimise the harm to food and farming businesses, which could suffer serious economic losses due to contamination with 'precision bred' varieties; and (ii) meet legal obligations to protect human and animal health and the environment.

In summary: GeneWatch supports the proposed measures for a 'Precision Variety List' and for mandatory labelling of seeds and plant reproductive material. However, these measures are necessary but not sufficient to prevent serious economic losses and protect human and animal health and the environment.

RESPONSE TO CONSULTATION QUESTIONS

Section 1: About GeneWatch UK

GeneWatch UK is a non-governmental organisation, registered as a not-for-profit company in England, working UK-wide in the field of public oversight of genetic science and technologies. We will provide a contact name and email when we send this response.

[Note: Section 2 of the consultation document provides information only]

Section 3: Precision Bred Plant Variety List for England

Yes: GeneWatch UK agrees that a 'Precision Bred Plant Variety List' should be established for England, and this should (at minimum) require evidence that the variety meets the legal requirements to be classified as a 'precision bred organism' (PBO), as confirmed by Defra; that its precision-bred status must be maintained in order for it to remain on the variety list; and that the list should be public. However, whilst this is necessary, it is not sufficient. In addition, before becoming an approved variety: (i) plants that could potentially enter the food/feed chain should also require a 'precision bred marketing authorisation'; (ii) the tests required to establish that a

variety is Distinct, sufficiently Uniform and Stable (DUS) and has satisfactory Value for Cultivation and Use (VCU) need to be expanded. These additional safeguards are necessary to limit adverse impacts on businesses, and to meet legal obligations to protect food/feed safety and the environment. The rationale and evidence for these additional requirements is provided in more detail below.

First, we note that the questions in this section wrongly refer only to impacts on "your business". This potentially excludes responses from members of the public, consumer groups and NGOs, and implies that people without a food or farming business have no interest in the integrity of the food chain, food prices, or potential negative impacts on human or animal health and the environment. This is wrong. In addition, GeneWatch UK has evidence regarding the potential negative impacts on other businesses (not our own). For this reason, we have chosen not to use the online form to respond to this consultation.

Although some countries are deregulating, or considering deregulating, some plants produced using gene editing techniques, such steps are not universal and definitions differ (so that at least some PBO plant products will continue to be regulated as GMOs elsewhere). In addition, many countries (including EU countries) do not allow (and are not expected to allow) PBOs in organic food, and also have 'GMO-free' product lines which are labelled for consumers. This means there is considerable potential for significant damage to export markets if food and feed containing PBOs cannot be identified and traced. The creation of a 'Precision Variety List' is a minimum requirement to limit the risk of contamination and loss of markets. The need for full traceability and labelling, and more detail on the potential costs of contamination, is given in the response to Section 5, below. In this Section, we highlight some additional measures that could reduce the risks of adverse health and environmental effects. Full health and environmental risk assessments are necessary to prevent adverse effects on human and animal health and the environment. However, within the context of the Act, additional measures can still be taken (and are essential) to reduce the potential for expensive product recalls and/or the loss of whole markets if the PBO products cannot be recalled (due to lack of labelling and traceability, discussed in response to Section 5).

The Act requires persons releasing PB plants to obtain a 'precision bred confirmation', and the proposal in this consultation correctly requires evidence of this before approving a variety. However, it is important to note that PB plants may pose risks beyond those posed by conventional varieties, which are not assessed in the process of obtaining the 'precision bred confirmation'.

Firstly, to protect food safety, before becoming an approved variety plants that could potentially enter the food/feed chain should also require a 'precision bred marketing authorisation'. Marketing of food and feed produced from precision bred organisms requires authorisation, according to the Act. This is because food safety issues could arise, as acknowledged by the Food Standards Agency (FSA), which will undertake a (limited) food and feed safety assessment for at least some PBOs, and will issue a 'precision bred marketing authorisation'.[3] It is not logical to approve a variety before this authorisation, as unauthorised PBOs may pose risks to human or animal health and may be impossible to recall should they contaminate the food chain. This would lead to major costs for businesses (described in more detail in the response to Section 5), as well as potentially posing risks to human and animal health. Failure to require a marketing authorisation before approving a variety would also undermine wider legal obligations to protect food safety.

Secondly, before a PB plant becomes an approved variety the tests required to establish that a variety is Distinct, sufficiently Uniform and Stable (DUS) and has satisfactory Value for Cultivation and Use (VCU) need to be expanded. In relation to PB food/feed, the Act requires that "*the production of any such food or feed will not have adverse effects on the*

environment" (26(3)(b)). The draft regulations allow the Secretary of State to issue a food and feed marketing authorisation if it appears to the Secretary of State that "*the production of any such food or feed in place of other food or feed that it might reasonably be expected to replace would not have adverse effects on the environment*". The UK also has legal obligations under the Convention on Biological Diversity's Cartagena Protocol on Biosafety, which seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology.[4]

Examples of adverse environmental and health impacts can be illustrated by reference to existing GM crops with comparable traits. They include:

Biosafety issues

Pathogens are likely to evolve in response to gene edited resistance in a plant or animal, so that the plant or animal is no longer resistant to disease. In the process, the pathogen may become more virulent or more transmissible, with potentially devastating consequences. For example, GM papaya genetically engineered to be resistant to the Papaya ringspot virus (PRSV) is grown commercially in the USA (Hawaii), but when grown in China it lost PRSV-resistance and a new variant of PRSV evolved.[5] Disease-resistance is a major area of research in plants that may be categorised as 'precision bred': for example, in England research is taking place on blight- and virus-resistant potatoes and on virus-resistant sugar beet. Many of the technical problems encountered by researchers working on transgenic GM plants are likely to be the same for gene edited GM plants: these include a tendency for genetically engineered disease resistance to compromise the yield or quality of the crop; resistance to one type of pathogen to confer susceptibility to another type; potential negative side effects on beneficial microbes (for example, fungi interacting with the plant or microbes in the gut of feeding animals); and a loss of disease resistance, due to pathogens evolving over time.[6] Conventional breeding, in some cases using Market Assisted Selection (MAS), is a more effective way to achieve durable and broad-spectrum resistance, while employment of a single resistance gene and adaption of the pathogen often leads to resistance breakdown in a short period.[7] Disease resistance is therefore an example where a small change in a single gene can be more risky than the multiple mechanisms of resistance in conventionally bred plants. Although, currently, the Act is only being applied to plants, it also deregulates PB animals: hence it is worth noting that research on bird-flu resistant chickens has already led to the evolution of bird-flu more likely to infect humans, in a laboratory in Scotland. [8,9]

Development of resistant weeds and pests

Herbicide-tolerant (HT) GM crops have been genetically engineered so they can be blanket-sprayed with the associated herbicides, with the aim of killing weeds whilst the crop still grows. Herbicide-tolerant GM crops cause environmental harm due to blanket spraying of these crops with weedkillers and the development of resistant weeds, has led to increased spraying of multiple herbicides. Environmental harm includes the direct impacts of herbicides on sensitive species, such as frogs and bees, and indirect impacts due to habitat loss for important species, such as the iconic Monarch butterfly in the USA.[10] Insecticide resistant GM crops (also known as Bt crops), are genetically engineered to produce toxins, intended to kill pests. There are now major problems with resistant pests, as well as increases in secondary pests.[11,12] Commercial interests favour the development of traits that are the most profitable, i.e., crops that are herbicide-tolerant so they survive blanket-spraying with the associated weedkiller (both seeds and weedkiller can be patented and sold by the same agrichemical company). Much research on gene edited crops (which may be classified as PB crops) is now focused on developing gene-edited herbicide-tolerant crops to avoid the regulations applied to GM crops.[13,14,15,16,17,18] In England, trials of Qualifying Higher Plants (QHPs) listed on the Defra website, include one for the plant *Camelina sativa*, described as 'precision bred', with resistance to ALS herbicides.[19] Because of the known adverse environmental impacts, herbicide-tolerant PB plants will not be able to be marketed in the EU without additional assessment (this is discussed further in the response to Section 5).

Other potential adverse effects on human, animal and/or plant health

GM plants, including PB plants, are not 'ingredients' but living organisms that interact with their environment. This leads to numerous potential risks (the examples here are not exhaustive). For example, one problem with attempts to genetically engineer enhanced iron and zinc content in plants is that such plants may also accumulate toxic metals such as cadmium if they are planted in contaminated soils.[20] In some cases, crops with increased nutrients may also attract pests.[21,22] Bayer's (formerly Pairwise's) gene edited salad mustard leaf variety, involves the deletion of a compound that confers the bitter taste from the mustard leaves. However, this also plays a role in plant defence[23], and is thought to confer important health benefits including anti-inflammatory, antioxidant and chemoprotective effects[24]. Changing plant nutrients could also have adverse effects on biodiversity.[25]

Effects of unintentional genetic changes

Gene editing involves cutting the DNA in plant or animal cells and relying on the cell's own mechanisms to repair the cut whilst introducing changes in the DNA. This process suffers from a variety of problems, including errors in where the DNA is cut (so-called 'off-target effects') and in how the cell repairs itself ('on-target' effects).[26,27,28] These unintended genetic changes could lead to unintended risks, such as the creation of new toxins or allergens.

Most of these adverse effects will not be captured by the proposed requirements for PBOs to have a 'precision bred' authorisation and (in some cases) a marketing authorisation. Therefore, to the extent that this is possible, and legally required, these risks must be considered within the varieties assessment. This is particularly important for biosafety issues, since the evolution of new pathogens in response to supposedly disease-resistant varieties could pose a major threat, and the Animal and Plant Health Agency (APHA), which will approve PB varieties, is the lead agency responsible for dealing with biosafety threats. In addition, one of the aims of the Plant Varieties and Seeds Act 1964 is "*preventing the spread of plant disease by means of seeds*".

[Note: Section 4 of the consultation document contains information only]

Section 5: Labelling of seed and other plant reproductive material produced using precision breeding technologies

GeneWatch UK supports the proposal for the mandatory inclusion of precision bred status on labels for seed and other plant reproductive material to identify them as precision bred. This is essential in order to protect trade and reduce the risk of contamination of the food/feed chain with so-called 'precision bred' varieties, that cannot lawfully be cultivated or processed in Scotland and Wales, or exported to Northern Ireland, or many other countries (including EU countries), or sold as organic products. However, whilst this is necessary, it is not sufficient. Full labelling and traceability, as well as measures to prevent contamination, is also essential for the same reasons. More details and evidence are provided below.

Most of the Act applies only to England. Nevertheless, 'precision bred' plants or animals or food and feed derived from them, could be lawfully marketed in Scotland and Wales as a result of the United Kingdom Internal Market Act 2020, which (controversially) would prevent these countries from refusing them.[29] However, since so-called PBOs legally remain GMOs in Scotland, Wales and Northern Ireland, there will be a need to identify them to prevent further processing (which would be unlawful).[30] Without labelling and traceability, it is hard to see how this requirement can be met. The situation is particularly difficult in Northern Ireland, where the Windsor Protocol applies.

In the EU, a highly contentious process has begun to consider deregulating some gene edited plants, which are referred to as plants developed using New Genomic Techniques (NGTs). The European Commission's Proposal[31] and the European Council's negotiating

position[32] have now both been published. So-called 'trialogue' negotiations between the Council, Commission and the European Parliament may follow. The Commission, Council and European Parliament all agree that all deregulated gene edited seeds and reproductive material must be labelled and plants developed using NGTs are not allowed in organic production. In addition, herbicide-tolerant plants are excluded from the proposed most highly deregulated category (known as NGT1): this means they are subject to the additional authorisation, traceability, labelling and monitoring requirements specified for category 2 NGT plants. The European Parliament's position supports mandatory labelling for all NGT plants (both the NGT1 and NGT2 categories). [33,34] In addition, the issue of patents on NGT plants remains highly controversial. The EU definition of NGT plants is different from the definition of 'precision bred' plants in England. This means that, even if deregulation of some gene edited plants occurs in the EU:

1. Plants destined for organic markets (and voluntarily-labelled 'GM-free' markets) will still need to be protected from contamination, in both the UK and EU;
2. Some 'precision bred' plants in England will not meet the criteria for NGT1 plants in the EU (e.g., because they are herbicide tolerant, or because of different definitions for the NGT1 category and the 'precision bred' category), and therefore will require additional steps (risk assessments, labelling) before being allowed on the EU market;
3. Labelling of seeds and reproductive material is a minimum requirement for the EU market and, during negotiations, this may be extended to require labelling throughout the food/feed and marketing chain;
4. Additional requirements may still be negotiated, particularly in relation to patenting.

Currently, manufacturers of GMOs in the UK or the EU are required to provide a unique identifier (UI) and a validated testing method for all GMOs, so that testing can be undertaken, e.g., of food and feed products, shipments, crops in farmers' fields, or to monitor GMOs in the environment. In contrast, the Genomic Technologies (Precision Breeding) Act does not include a requirement for validated testing methods for deregulated GMOs (so-called 'precision-bred organisms', PBOs).

This has major implications for international trade. For example, if a gene-edited tomato were to be released into the environment, or enter the food chain, in England, it would appear on the planned register of precision bred organisms (PBOs). However, without any traceability and labelling requirements, and with no validated test, <u>all</u> countries which require such organisms to be regulated could refuse <u>all</u> imports of food containing tomatoes from the UK, because food containing the unregulated product would not be identifiable. Thus, all food containing tomatoes as an ingredient could be blocked from the entire EU market. Tomatoes are just an example, because gene editing could be applied to any plant or animal to create a 'precision bred organism' (PBO). Deregulated PBOs could contaminate a very wide range of products and render them unfit for export, for example:

- Food crops, such as potatoes, wheat, salads and vegetables;
- Processed foods and drinks containing any of the above ingredients;
- Trees and forestry products;
- Ornamental flowers and horticultural products.

If PBOs in any of these categories are released without any traceability and labelling requirements, and with no validated test, all countries which require such organisms to be regulated could refuse all imports of food or feed containing such ingredients from the UK, because food or feed containing the unregulated product may not be identifiable. Trade in organic products could also cease, since these are required to be free of GMOs. If relevant products are developed, contamination of traded products (leading to bans on exports) could also occur with any non-food gene edited products that are deregulated as PBOs (e.g., non-food crops intended for use in biofuels; trees from which nuts or pollen can spread widely). This could also lead to bans on trade.

PBOs that enter the food chain or the environment in England might also be imported from elsewhere. Because the Act gives the Secretary of State very limited powers to reject products that are classed as PBOs, any plant, animal or associated product that meets the PBO criteria could be imported to England without any traceability or labelling requirements (except, as proposed in this consultation, on seeds or reproductive material). The import of such products would have the same effect of contaminating UK food supplies and exports as home-grown products would.

Costs to food and agricultural businesses could be substantial. Past contamination incidents give some clues as to the scale of the potential costs. However, it should be borne in mind that GMO legislation meant this contamination was traceable and identifiable. In contrast, contamination with PB plants might lead to all products containing certain crops from being rejected at borders or by retailers, since it may not be possible to know where the contamination is. Examples of contamination costs for GMOs are included in Section 3.4.2. (Consequences of GM contamination) of the GeneWatch UK report 'Time for the end of GM/GE herbicide tolerant crops?'. Measures seeking to prevent contamination also carry costs: examples are included in Section 3.4.1 (Preventing GM contamination) of the same report.

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