The Genetic Technology (Precision Breeding) Bill:

Briefing for Committee Stage

GeneWatch UK

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The Genetic Technology (Precision Breeding) Bill[1] contains proposals to deregulate some Genetically Modified Organisms (GMOs) in England, so that they:

(i) no longer require environmental risk assessments before release into the environment, or any monitoring afterwards;

(ii) are not required to be labelled for consumers when they enter the food chain as food or feed.

These exempt GMOs are referred to as 'precision-bred organisms' in the Bill.

The Bill allows regulations to be developed for those exempt GMOs used to produce food and feed (such as GM crops or farm animals). These regulations may or may not provide traceability for exempt GMOs intended to enter the food chain and may or may not require adverse effects of those GMOs used in food production on human and animal health and the environment to be avoided. Other exempt GM organisms (such as forestry trees, pets or wild animals, including insects) will not be required to have any environmental risk assessment before open release into the environment, and there is no provision to stop, destroy or clean-up such releases if anything goes wrong.

Significant negative impacts on trade are likely if exempt GMOs are released into the environment, as there is no agreed international definition of a 'precision bred organism'. If exempt GMOs are not traceable, and manufacturers are not required to publish a validated test for each GMO that is released, **all countries which require such organisms to be regulated could refuse all imports of food or other products that might be contaminated with the exempt GMO**.

This briefing outlines the major concerns about the Bill. More background information is available in GeneWatch UK's submission to the Defra consultation.[2]

What is being deregulated?

The deregulation applies to all plants (not just crops), including **algae, wild plants and trees**, and to all animals with a body made up of multiple cells, including **pets, farmed and wild animals**, some of which are highly mobile (e.g. **fish and insects**). GM micro-organisms such as viruses and bacteria are not deregulated. (These definitions are in article 2 of the Bill).

The deregulation applies to GM plants and animals created using newer techniques such as gene editing, and does not apply to older GM techniques where the gene from another species is inserted randomly. However, contrary to the claims made in much of the

accompanying material, **there is no explicit requirement in the Bill that deregulated GMOs do not contain DNA from other organisms, or that there are no unintended changes**.

Article 1(2) defines Precision Bred Organisms (PBOs) as GMOs with changes to their DNA which "could have" resulted from 'natural transformation' or from 'traditional processes', which are defined to include 'induced mutagenesis' or 'spontaneous mutation' (Article 1(7). **In theory, this means that any of the chemical letters (C, A, G and T) which make up an organism's DNA (its 'genome') could be removed or changed** (mutated)**,** including multiple changes at different places in its genome. Article 1(5) allows multiple copies of the same stretch of DNA to be inserted (this is its 'copy number'), which often means that a protein produced in a plant or animal can be produced at much higher levels than it occurs naturally. This Article also allows the epigenetic status of a gene to be changed (which can also alter gene expression, i.e. protein levels) as well as its location in the genome. **Article 1(6) allows foreign DNA to be inserted provided it does not result in a functional protein**.

The proposed content of the Notification Scheme form on page 69 of the Impact Assessment requires some evidence that genetic changes are similar to those found naturally in the same or similar species, and that the developer has looked for unintended changes.[3] It is unclear why these requirements are not part of the Bill (which does not explicitly restrict genetic changes to those found in the same or similar species, or require any evidence regarding unintended changes). Unintended changes are common in gene edited organisms.[4,5,6,7]

Where could exempt GMOs end up?

The proposed deregulation applies only to exempt GMOs released in England, including on land and in the sea (the territorial sea adjacent to England and the continental shelf, Article 47(4)). However, **this would not prevent exempt GMOs - including crops, trees, insects or fish, for example - being released where they could cross into Scotland, Wales or Northern Ireland. Living GMOs could also travel outside the UK if they are highly mobile or difficult to contain (e.g. insects, fish, pollen, nuts or seeds**).

Most of the Bill applies only to England. However, the Explanatory Notes to the Bill (paragraphs 14 to 17) state that **'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 would prevent these countries from refusing them.[8] Because **validated tests, traceability and labelling are not required by the Bill** (although in some cases, some of these requirements could be introduced by regulations, as discussed below) **it may not be possible to prevent the spread of exempt GMOs in the environment and food chain**.

This has major implications for trade, because there is no international definition of a 'precision bred organism', or agreement on which, if any, gene edited organisms should be deregulated. For example, **if a gene-edited tomato is released without any traceability 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. The same applies to exempt

GM organisms not marketed as food (such as exempt GM insects, fish or trees) which could be released with no risk assessment or traceability under the proposals in the Bill, but which might inadvertently contaminate the food chain. A theoretical example of such a product would be the future development of a gene-edited pesticide-resistant bee (something which does not exist, but which has been discussed).[9]

Even for GMOs which do not enter the food chain, there are important international obligations regarding the environment. The UK is a Party to the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity, which includes requirements for living modified organisms (LMOs, which are living GMOs), including risk assessments and notifications when living GMOs are deliberately or unintentionally moved across borders.[10] The Explanatory Notes to the Bill state (paragraph 12): "*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*". However, **the Government's interpretation of the definition in the Cartagena Protocol is not correct**.[11] This means it risks breaching the requirements of the Protocol.

The developer is not required to provide a test to identify the organism

Currently, manufacturers of GMOs 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 products, shipments, crops in farmers' fields, or to monitor GMOs in the environment.

The Bill does not include any requirement for validated testing methods for deregulated GMOs and the Impact Assessment (page 4) claims savings for the lack of "Identification and Validated Testing Methods" of £230 per application.[12]

One of the arguments developers of gene edited organisms have made is that it is difficult to test for them. However, in reality tests can be developed for gene edited organisms and such tests are routinely used to check for errors and select the desired edits during the research and development process.[13,14,15]

It is possible that a requirement for validated tests could be introduced via regulations which will specify the required information for a release notice (Article 4(2)) or a marketing notice (Article 6(3)), but currently this has not been specified. Validated tests might also be required (via regulations that do not yet exist) only for the subset of exempted GMOs that require a food and feed authorisation (i.e., food and feed produced from 'precision bred organisms', Part 3) or that require an animal marketing authorisation (i.e. vertebrates, Articles 10 to 13). However, this would not cover all exempt GMOs, e.g. many gene edited trees or insects.

The failure of the Bill to require developers to provide validated tests for those GMOs that will be deregulated means it will be hard to monitor where they are in the food chain or in the environment, or to take action if anything goes wrong.

Limited (and maybe no) environmental risk assessments

The face of the Bill includes a statement from the Secretary of State that "*the Bill will not have the effect of reducing the level of environmental protection provided for by any existing environmental law*". This is incorrect. Under current GMO law, an environmental risk assessment is required for all open releases of GMOs, and this is subject to public consultation. 'Environmental risk assessment' means the "*evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed*", when GMOs are released into the environment. GMO law also includes environmental monitoring requirements.

The Bill (Article 17) includes the possibility that environmental risk assessments "may" be introduced in some circumstances (when the deregulated GMO is imported or acquired), but not when these organisms are released into the environment. The Explanatory Notes to the Bill (page 15) clarify that these risk assessments will only apply to deregulated GMOs when they are in "contained use" (in laboratories, vats, or cages, for example), in order for the current regulations on contained use of GMOs to continue to apply.

For open releases into the environment, the Bill states that notification requirements for exempted GMOs are limited to stating that the organism is 'precision bred', or, if the release is for marketing purposes, receiving a 'precision bred confirmation' from the Secretary of State, that the GM organism is exempted (i.e., it meets the definition of a 'Precision Bred Organism' in the Bill) (Articles 6 to 9). As part of this process, the Secretary of State takes the advice of the advisory body ACRE (the Advisory Committee on Releases to the Environment, Article 22). The Secretary of State must issue the 'precision bred confirmation' "*if satisfied that the organism is precision bred*". This is sufficient to meet the requirements of the Bill, unless the exempt GMO also requires a food and feed marketing authorisation (Part 3) or is a vertebrate animal which also requires a 'precision bred animal marketing authorisation' (based on animal welfare considerations, Articles 10 to 13).

Food and feed produced from exempted GMOs may or may not have to meet additional requirements (in Part 3 of the Bill), including that "*the production of any such food or feed will not have adverse effects on the environment*" (Article 26(3)9b)). However, these regulations do not yet exist and the wording of the Bill means that, ultimately, it remains possible that they may not include any environmental requirements.

The Impact Assessment for the Bill (Section 7) describes only claimed potential benefits from the commercial cultivation of exempted GM crops. This consists of speculative and unsubstantiated claims and ignores any risks. For example, herbicide-tolerant gene edited crops are a major area of research, which could lead to exempted GM organisms.[16] According to industry figures 88% of (transgenic) GM crops grown commercially in 2019 were herbicide tolerant (HT) GM crops.[17] These GM crops – first introduced by Monsanto (now owned by Bayer) as RoundUp Ready soya – are genetically engineered to be resistant to one or more weedkillers (including glyphosate - brandname RoundUp, glufosinate, 2,4-D, and dicamba), and are patented and sold by major transnational companies which benefit from the sale of the GM seeds and pesticides. These GM crops are blanket sprayed with the associated weedkillers, causing an increase in the use of herbicides, major environmental

harms (e.g., to butterflies and frogs), and extensive problems with resistant weeds.[18,19,20,21,22,23,24,25,26,27,28,29,30,31] If herbicide-tolerant gene edited crops were to be developed they could be exempt from any environmental risk assessments under the provisions in the Bill.

No environmental risk assessments at all are planned for open releases of exempted GM organisms which are not used to produce food and feed, such as forest trees, pets or insects, for example. It is possible that a requirement for environmental risk assessments could be introduced via regulations which will specify the required information for a release notice (Article 4(2)) or a marketing notice (Article 6(3)), but currently this has not been specified. In any case, any information contained in such a risk assessment (even if required) would not provide grounds for refusal of a 'precision bred confirmation' and thus could not prevent the marketing of exempt GMOs not used in food or feed production.

There are no environmental monitoring requirements mentioned in the Bill, and, as noted above, a validated testing method is not required by the Bill, unless it is introduced later under regulations, as part of the required information requirements.

Potential environmental risks from releasing exempted GM organisms other than crops (such as farm animals, wild mammals or birds, trees, insects or fish) are not mentioned at all in the Impact Assessment, or in any other materials related to the Bill. This does not mean that there are no such risks. For example, the risk that a virus evolves to overcome genetically engineered resistance in a GM animal (perhaps becoming more transmissible or virulent), or that some animals become infected but not sick (potentially increasing the transmission of disease) are required to be considered in current risk assessments for GM disease-resistant animals.[32,33] However, for non-food applications, and perhaps also for applications in food and feed (depending on the future regulations), there will no longer be any requirement for such risks to be assessed before exempt GMOs are released into the environment, either in experiments or on a commercial scale.

Limited food safety assessments, with no labelling and potentially no traceability

Part 3 of the Bill covers food and feed produced from exempted GMOs. This specifies that **regulations may or may not make provision for regulating the placing on the market in England of food and feed produced from exempted GMOs** (Article 26(1). **Such regulations may or may not mean that a food and feed marketing authorisation is required, including measures to ensure traceability in the food chain** (Article 26(2)). **If traceability is not required this has major implications for farmers, food manufacturers and retailers, who would no longer be able to supply markets which require GMOs to be authorised, or products to be GM-free (including organic markets).** This problem could arise as soon as a particular crop (e.g. a gene edited potato) were given a 'release notice' or a 'marketing notice' as suppliers would no longer be able to guarantee that any products containing potatoes were GM-free. **In addition, products could not be recalled if anything went wrong**.

As noted above, this has major implications for trade. For example, if a deregulated 'precision bred organism' (e.g. a food crop, such as tomato, potato, wheat, or milk, meat or eggs from a gene edited animal) is released without any traceability requirements, and with no validated test, **all countries which require such organisms to be regulated could refuse all imports of food containing such ingredients from the UK, because food containing the unregulated product may not be identifiable**. Trade in organic products could also cease, since these are required to be free of GMOs.

In addition**, the Bill does not require food and feed containing exempted GMOs to be labelled for consumers**. Even if regulations make exempt GM food and feed traceable, the Bill does not require it to be labelled, or provide any mechanisms through which this could be done. This means that consumers would be denied a choice about what food they eat and could lose trust in the food chain.

Limited grounds for recall

The Secretary of State has the power to revoke a 'precision bred confirmation' if s/he is no longer satisfied that the organism is 'precision bred' (Article 9). This would mean that the GMO is no longer exempt from existing GMO regulations. In addition, the Secretary of State can suspend or revoke an authorisation for marketing some exempted GM animals (vertebrates, i.e. animals with a backbone, according to Article 11) on animal health and welfare grounds (Article 15). **Regulations may or may not allow food or feed marketing applications to be varied, cancelled or revoked, perhaps on health or environmental grounds (although this is not specified)** (Article 26(4)). However, **there are no powers in the Bill to stop releases of exempted GM organisms which are not used to produce food or feed (e.g. some exempted GM trees or insects, wild animals or pets) on health, safety or environmental grounds**.

Contamination of traded products (leading to bans on exports) could occur with non-food gene edited products that are deregulated under the Bill (e.g. breeding material such as sperm for racing horses, insects that pollinate crops, trees from which nuts or pollen can spread widely). **This could also lead to bans on trade.**

Information for the consumers, farmers, the food industry and the general public

The Bill creates a register to contain information about release and marketing notices for exempted GMOs (Article 18). However, **much of the information in the register could be kept commercially confidential, apart from**:

- the name of the person giving the notice;
- the release notice and/or marketing notice;
- **required information yet to be defined** under regulations (Article 4(3) and/or 6(2));
- a general description of the organism.

Regulations may or may not also provide for further information to be provided in a food and feed marketing authorisations register (but only for exempt GMOs used in food and feed production). Similarly, regulations will specify the required information for relevant

animals (vertebrates) which require a 'precision bred animal marketing authorisation' (Article 11(5)(b)). Since the "required information" for notices and authorisations has not been specified, it is unclear what this will include. For example, **the Bill does not currently require a validated test to be supplied**, as noted above.

Liability and remediation

A release notice must specify one or more persons, or descriptions of person, in relation to the release (Article 4(2). However, **it is not clear to what extent the persons named in the release notice will be liable for any harm to markets, human or animal health, or to the environment.**

If any food or feed contains GM organisms which have not been regulated as GMOs and are not approved for marketing in other countries, this could have major impacts on international trade. In the past, with transgenic GM crops, major costs have been incurred by farmers and food producers in countries where GM crops are grown when products contaminated with unapproved GMOs are found in the food chain, not approved for export, or turned back at ports. Because GM crops can contaminate non-GM crops (e.g. through seed mixing) this can mean that even farmers that do not grow them intentionally can lose access to non-GM and organic markets if their fields or seeds become contaminated. If traceability of food and feed is not required via regulations, the whole market could be affected because it may not be possible to verify the presence or absence of the exempt GMO. **The same could apply to GM animals (e.g. farm animals, rare breeds, dogs and horses) if sperm from exempt GM animals ends up on the market (this happened with cloned cows in the past).**

Similarly, major environmental damage could occur if exempt GM organisms become invasive, for example, or introduce unexpected allergens into the food chain.

There are no provisions in the Bill to require destruction of released exempted GMOs, even if a confirmation or authorisation is revoked, or to require clean-up of contaminated land, air or watercourses.

Conclusion

Defra's own public consultation from September 2021 found that most individuals (88 per cent) and businesses (64 per cent) supported continuing to regulate gene edited organisms as GMOs.[34]

Gene edited organisms should continue to be treated as genetically modified organisms (as currently defined in law). The protection of human health and the environment requires:

- health and environmental risk assessments prior to any open release and/or commercialisation (whether for food or feed or other purposes), and environmental monitoring plans, including the public availability of validated tests;
- opportunities for public consultation throughout the approvals process;

- traceability and labelling of gene edited foods and ingredients, so that consumers have a choice whether or not to eat them, and products can be removed from the food chain if anything goes wrong;
- environmental and economic liability measures to make the manufacturers of gene edited organisms responsible for any environmental and economic harm.

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