DEFRA Consultation

The regulation of genetic technologies

Consultation response from the Agriculture and Horticulture Development Board (AHDB)

15 March 2021

Section 2 – Part 1: the regulation of GMOs which could have been developed using traditional breeding methods

This part of this consultation addresses the regulation of GMOs produced by gene editing (GE), or other genetic technologies, but which could have been developed using traditional breeding methods.

1. Currently, organisms developed using genetic technologies such as GE are regulated as genetically modified organisms (GMOs) even if their genetic change(s) could have been produced through traditional breeding. Do you agree with this?

~~Yes – they should continue to be regulated as a GMO~~
No – they should not continue to be regulated as a GMO

Please explain your answer, providing specific evidence where appropriate. This may include suggestions for an alternative regulatory approach.

No – They should not continue to be regulated as GMO.

Where animals or plants developed using GE technology either mimic naturally-occurring genetic variation, or contain genetic variation which could have been obtained by conventional crossing and/or selection, a simpler, scientifically-credible approach is more appropriate than the regulation currently applied for GMO. It is crucially important to appreciate that the conventional breeding techniques currently used can result in new genetic variations that are not always intended or predictable (e.g. new mutations). In addition, natural populations (e.g. of weed species) can contain considerably more genetic variation than is likely to be introduced by GE technologies which allow extremely targeted genetic changes to be made through selection. Any new legislation to regulate the use of GE should be proportionate to the scale of genetic change involved, but in particular should not make the use of existing non-GE/non-GM breeding techniques impossible or more onerous to conduct.

GE not only opens the opportunity to accelerate the development of crops and livestock of potential value to farmers and consumers in the UK, but also has the potential to reduce the reliance on imported food and livestock feed.

Examples of the application of GE which showcase some of those opportunities are; a) It has been demonstrated that pigs with a deletion of a specific gene exon are resistant to the highly pathogenic Porcine Reproductive and Respiratory Virus (PRRS)[1]; b) The ability to impart disease-resistant and

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[1] Deletion of CD163 Exon 7 Confers Resistance to Highly Pathogenic Porcine Reproductive and Respiratory Viruses on Pigs - PubMed (nih.gov))
[2] CRISPR technology is revolutionizing the improvement of tomato and other fruit crops | Horticulture Research (nature.com)
[3] Genomic and phenotypic analyses of six offspring of a genome-edited hornless bull | Nature Biotechnology
[4] Simultaneous editing of three homoeoalleles in hexaploid bread wheat confers heritable resistance to powdery mildew - PubMed (nih.gov)
[5] Reduced Enzymatic Browning in Potato Tubers by Specific Editing of a Polyphenol Oxidase Gene via Ribonucleoprotein Complexes Delivery of the CRISPR/Cas9 System (nih.gov)
[6] Frontiers | CRISPR/Cas9 Gene Editing of Gluten in Wheat to Reduce Gluten Content and Exposure—Reviewing Methods to Screen for Coeliac Safety | Nutrition (frontiersin.org)
[7] https://www.researchgate.net/publication/284232532_Applications_of_Genome_Editing_in_Insects

environment-adaptive fruit crops, as well as improvement of fruit quality[2]; c) Improve animals' welfare by breeding animals that do not have horns[3]; d) Limiting pesticide usage through new heritable broad-spectrum resistance to powdery mildew in bread wheat[4]; e) Reducing food wastage by developing potato varieties with reduced enzymatic browning in tubers, by the specific editing of a single member of the StPPO gene family[5], f) Gene editing of gluten in wheat to reduce gluten content and exposure[6]. In addition we note that gene drive techniques to manage GE insect populations may also provide new opportunities[7].

Nonetheless, all technologies that can increase the efficiency of crop and livestock production and provide potential economic, welfare, environmental or consumer benefits should be fully appraised and evaluated. Assessment of both the potential benefits and risks of a technology should feature in the evaluation, with the objective of reaching scientifically-informed and evidence-based outcomes. The safety of consumers, animal welfare, and avoidance of environmental damage must be paramount in the appraisal of all technologies, including GE. However, it is important that a clear distinction is made between the perceived theoretical hazards that generically applying GE technology may involve, with the actual risks associated with the use of an individual product produced using GE technology.

We are also strongly supportive of initiatives which will encourage both publicly and privately funded research on GE in crops and livestock for UK use and enable their evaluation under commercial conditions.

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2. Do organisms produced by GE or other genetic technologies pose a similar, lesser or greater risk of harm to human health or the environment compared with their traditionally bred counterparts as a result of how they were produced?

[Similar] ~~[Lesser] [Greater]~~

Please provide evidence to support your response including details of the genetic technology, the specific risks and why they do or do not differ. Please also state which applications/areas your answer relates to (for example: does it apply to the cultivation of crop plants, breeding of farmed animals, human food, animal feed, human and veterinary medicines, other applications/ areas).

Where the organisms produced by GE mimics naturally occurring genetic variation which could be obtained by conventional crossing and/or selection, we judge that the risk of the organism to human health or environment to be similar. We acknowledge that any alteration of the animal or plant genome may affect its ecosystem, but this is irrespective of how the changes to the genome occurred as these can occur by conventional breeding and selection or GE/GMO technologies. This therefore implies that changes created by GE are not by default inherently more risky than those introduced by conventional breeding, particularly as the targeted nature of gene editing is likely to result in fewer, potentially undesirable, associated changes to the genome than some existing approaches. For this reason, we judge the risk to crops, farmed livestock, and animal and human food sources be similar.

For example, the risk of the development of ‘super weeds’ as a result of the introduction of genetically engineered herbicide tolerant crops is often cited as an example of the environmental risks associated

with genetic engineering. However, the introduction of herbicide resistance into crop species has been achieved through both transgenic methods (e.g. ROUNDUP READY® and Xtend® technology) and through conventional breeding. (e.g. CONVISO® SMART and Clearfield® technology). The development of herbicide resistance in weeds is widespread wherever herbicides are used[2] and is not reliant on the introduction of herbicide-resistant crops. Indeed the first case of a glyphosate-resistant weed species occurred before the introduction of glyphosate resistant crops[3]. Thus, 'superweed' development is a consequence of inappropriate herbicide use, not the use of genetically engineered herbicide resistant crops and the risks of herbicide resistant crops is not dependant on the technology used to introduce the resistance.

We recognise that legislation covering any technologies (new or old) requires amendments from time-to-time to adapt to changing circumstances or new knowledge. In future, the application of GE may therefore pose a lesser, or greater risk, which should be reflected in future legislation.

3. Are there any non-safety issues to consider (e.g. impacts on trade, consumer choice, intellectual property, regulatory, animal welfare or others), if organisms produced by GE or other genetic technologies, which could have been produced naturally or through traditional breeding methods, were not regulated as GMOs?

[Yes/~~No~~]

Please provide evidence to support your response and expand on what these non-safety issues are.

In principle, given that crop or livestock produced by GE represents an organism which could have been produced using conventional crossing and/or selection, and therefore are indistinguishable on a genome level, we objectively see no technical reason why any additional non-safety issues need to be considered.

From an intellectual property standpoint, because DNA is a "product of nature" and nothing new is created by the application of GE, there is no protectable intellectual property, so patents should not be granted for any organism produced using GE technology. Existing plant breeders' rights already provide protection over new plant varieties, and we would expect crops produced by GE to be covered by the existing legislation. For livestock, we accept that investment in novel application of GE may attract protection through other means (e.g. trade secrecy or branding).

We also recognise that there are individuals and organisations who actively oppose the use of GE technology on grounds of principle or belief. Recent history suggests that those with a commercial interest in the marketing of GE crop or livestock, as well as the scientific community, have not found it easy to convince the public at large (in Europe at least) that GE will provide significant benefits with no change in risk. It is therefore important that active and well-informed dialogue continues between the scientific community, government, food industry representatives and the public at large, including non-governmental organisations. For example, some opponents of GE have argued that introducing disease resistance into animals through GE will allow higher stocking densities and so potentially reduces animal welfare standards. However, there is no reason why the regulation of GE-derived

[2] Heap, I. The International Herbicide-Resistant Weed Database. www.weedscience.org/Home.aspx

[3] Heap, I, Duke, S O (2018). Overview of glyphosate-resistant weeds worldwide. *Pest Management Science* **74**(5):1040-1049.

animals should override animal welfare legislation, and any changes that have potential welfare impacts should be bound by the existing welfare legislation, which may require maximum stocking densities.

For trade, each country may take a view on the use of GE and whether or not they permit imports from countries actively using GE, and under what circumstances. In the absence of regulatory harmony, some countries will have the ability to use GE, while others will not, which could result in global trade disruptions. We recommend that the UK review the international regulatory environment in key trading partners, and where appropriate adopt similar standards. For these reasons, we support that as part of this consultation, such impacts on commercial/global trade are fully considered.

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4. What criteria should be used to determine whether an organism produced by gene editing or another genetic technology, could have been produced by traditional breeding or not?

Please provide evidence to support your response

The main element in determining whether an organism could have been produced by traditional breeding needs to be an assessment of the technology used to make the genetic change. A pre-requisite for deeming whether a change could have been generated by traditional breeding should be that it derives from a technique that does not introduce genetic material (DNA or RNA) from any organism unless that introduction could have been made using currently accepted methods in plant and animal breeding. Furthermore, to be defined as GE, and thus be exempt from regulation as GM, the technique used should produce precise and repeatable edits without unexpected off-site genome alterations caused by the technique. This assessment should be made based on robust peer review of the scientific evidence.

It should be recognised however, that any new legislation to regulate the use of GE should not make the use of existing techniques impossible or more onerous to conduct. For example, crop breeding also makes use of a variety of techniques to acquire desirable characteristics.

Only if the technology meets the criteria above, should organisms be considered as produced by GE, and be considered traditional breeding. The “general release” of the organisms themselves would then fall outside of any GM regulation, and should be considered based on a risk assessment clearly documenting details of the exact edits made and a description of the effect of the edits on the organism’s phenotype. The risk assessment, should take account of the benefits and drawbacks, including those relating to animal health and welfare, the environment and productivity. Additional recording may be required where traceability is deemed necessary.

We consider combining genomes of organisms that cannot be combined using existing breeding techniques to be classed as GMO, and therefore are not deemed to be the result of GE.

Section 3 – Part 2: Questions on broad reform of legislation governing organisms produced using genetic technologies

This part of the consultation is designed to start the process of evidence gathering to inform how Defra should reform its approach to regulating novel organisms in the longer term. There are two questions that focus on areas where views and evidence would be welcome.

These questions do not apply to the use of genetic technologies in contained use conditions (e.g. in laboratories) or to the use of genetic technologies in humans (e.g. gene editing of human embryos).

1. There are a number of existing, non-GM regulations that control the use of organisms and/or products derived from them. The GMO legislation applies additional controls when the organism or product has been developed using particular technologies.

Do you think existing, non-GM legislation is sufficient to deal with all organisms irrespective of the way that they were produced or is additional legislation needed? Please indicate in the table whether, **yes,** the existing non-GMO legislation is sufficient, or **no,** existing non-GMO legislation is insufficient and additional governance measures (regulatory or non-regulatory) are needed.

Please answer Y/N for each of the following sectors/activities:

Sector / activity	**Yes (sufficient governance)**	**No (insufficient governance)**
a) cultivation of crop plants NO		
b) breeding farmed animals NO		
c) human food NO		
d) animal feed NO		
e) human and veterinary medicines N/A		
f) other sectors/activities N/A		

Please provide evidence to support your response

No, we do not believe that non-GM legislation is sufficient to deal with organisms produced using GM technology.

We consider combining genomes of organisms that cannot be combined using existing breeding techniques to be classed as GMO, and therefore require additional legislation to the existing non-GMO legislation.

2. Where you have answered **no** (existing, non-GMO legislation is insufficient to deal with organisms produced by genetic technologies), please describe what additional regulatory or non-regulatory measures you think are required to address this insufficiency, including any changes you think need to be made to existing non-GMO legislation. Please explain how any additional measures you identify should be triggered (for example: novelty, risk, other factors).

Please provide evidence to support your response

Assessment of both the potential benefits and risks of the GM application should feature in case-by-case evaluations, with the objective of reaching scientifically-informed and evidence-based outcomes. We consider that the safety of consumers, animal welfare and avoidance of environmental damage must be paramount in the appraisal of all technologies, conventional, GE or GMO.

The introduction of new technology into agriculture can create unforeseen (though usually solvable) issues, and as part of the introduction of GE animals or plants there should be a process of monitoring and, if necessary, verification to determine and track any detrimental off-target changes as is already done with conventional pesticides for example.

We are however concerned that the political and regulatory climate in the EU has slowed the development of GM/GE crops and livestock of potential value to farmers, consumers and the environment in the UK, as well as access of UK farmers to imported sources of livestock feed. The regulatory processes should be simplified to avoid problems of this kind in future without compromising environmental or consumer safety.

We are strongly supportive of initiatives which will encourage both publicly and privately funded research on GM crops for UK use and enable their field evaluation under commercial conditions.