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Secondary Legislation Scrutiny Committee

Statutory Instrument for Affirmative procedure: The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022

Summary

- We ask members of the Secondary Legislation Scrutiny Committee to **support this Statutory Instrument which distinguishes gene editing from genetic modification.**
- The legislation will enable plant scientists in England to carry out more field trial research of gene edited crops, at reduced cost to the UK taxpayer and with less bureaucracy.
- Gene editing allows scientists and breeders to develop plants with a range of benefits such as improved nutritional quality, disease resistance and climate resilience.
- Traditional methods to introduce traits to crops through conventional breeding can take 8-15 years. Gene editing significantly speeds up this process, as it avoids the need for several years of backcrossing to remove and restore genes unnecessarily added or lost through traditional breeding.
- The Norwich Research Park is home to world leading research establishments such as the John Innes Centre, the Earlham Institute, The Sainsbury Laboratory, the Quadram Institute and we are all working on plant gene-editing.
- We believe that the full benefits of gene editing will only be realised if crops developed this way are able to reach consumers. We therefore urge the Government to bring forward progressive and proportionate and science-based regulations to allow gene edited products to be brought safely to market and provide consumer confidence.

Background

DEFRA has used powers in the Environmental Protection Act 1990 to lay a Statutory Instrument to amend the Genetically Modified Organisms (Deliberate Release) Regulations 2002 in England.

This change will allow plant scientists in England to carry out field trial research to test the benefits and field performance of gene edited crops that could have been developed through traditional breeding methods, without requiring the same regulatory burdens of risk assessments and consents that GMO field trials require.

This secondary legislation will allow two important exemptions from requirements in the Environment Protection Act 1990 which are expensive, disproportionately restrictive and not appropriate for gene edited organisms: risk assessment for environmental damage, and restriction against acquiring or releasing the organism beyond the trial site. These requirements are more appropriate for genetically modified organisms where a crop could not have been developed through traditional methods.

This change will bring England into line with the approach taken by most other countries outside the EU, many of which are compatible with the internationally recognised Cartagena Protocol. Note that the SI covers gene edited crops **in research and development only**;

commercial cultivation of gene edited plants, and any food or animal feed products derived from them, would still currently need to be authorised in accordance with existing GMO rules.

Even after this secondary legislation is passed, new crop varieties will continue to go through years of extensive field evaluation in the UK before reaching the recommended lists, so the plant breeding sector will continue to be well equipped to monitor new varieties, as they do today with traditionally bred crop varieties.

What is gene editing?

Traditional plant breeding selects for genetic variation (or changes/ mutations in DNA sequence that occur in each generation), thereby developing a crop variety that has a beneficial change that results from that mutation. Gene editing is a technique that allows scientists to make specific edits to DNA sequences in a targeted way – **without introducing any new genetic sequence**. Specific genes can be removed (deleted) or changed (mutated) by making changes at known target locations in the genome. It provides an effective pathway for introducing desired characteristics (traits) and for removing undesirable traits without introducing "foreign" DNA (genes originating from other species).

Organisms developed using gene editing technologies will contain small changes to their existing DNA which are identical to the types of changes that could occur spontaneously in nature or that are induced using traditional breeding technologies such as mutation breeding. The seeds, plants and food from gene-edited plants are indistinguishable from the seeds, plants and food provided to us by conventional breeding techniques.

Gene editing can be achieved using several different tools. CRISPR-Cas9 is the most well-known gene editing tool, particularly after its discovery and application to gene editing won the Nobel Prize in 2020, but other technologies are also used. The products closest to market in the UK are soybeans with healthier oil profiles, tomatoes with enhanced flavour qualities, non-browning apples, potatoes, and mushrooms, and plants that lack antinutrients (compounds that interfere with the absorption of nutrients).

Why is gene editing quicker than traditional breeding?

Gene editing will be particularly useful in crops with multiple copies of each genome such as wheat. Wheat has three copies of each genome and mutations in all three copies are often needed to cause greatest benefits. Using traditional breeding, it takes over 10 years to breed wheat varieties which contain mutations into all three genomes as each copy often needs to be mutated separately. Gene editing techniques could generate UK wheat varieties with mutations in all three copies in a fraction of the time (2-4 years).

Why are changes to gene editing regulation needed?

Currently in the UK, crops produced by gene editing are unnecessarily over-regulated, in the same way as Genetically Modified Organisms (GMOs). However, where gene editing is used to produce a trait in an organism that could have been achieved using conventional breeding methods, the risk is the same regardless of whether it was made through gene editing or traditional breeding methods. The traits introduced are identical and therefore the risks are the same. **Gene editing therefore carries no more safety risk than other conventional breeding methods.**

The current regulatory regime requires unnecessary additional expense and regulatory burdens for researchers wishing to trial these crops. Researchers have to spend much of their time preparing dossiers of information in application, publicly advertising proposed trials, conducting in-trial and post-trial monitoring, and commissioning costly security requirements, all for crops that are identical to traditionally-bred crops. We believe this to be a waste of tax-payers money and a drag on the UK's ability to identify and deploy new innovations in the areas of climate change and nutrition.

We estimate that the time and costs associated with these extra regulatory activities total over £200,000 per field trial. This can make research in this area unaffordable for small start-up companies and not-for-profit organisations. **For UKRI funded research, these associated costs can no longer be justified to the public purse.**

Maintaining the regulatory processes that the UK transposed from EU regulation essentially puts our research at a disadvantage in comparison to most countries outside the EU. As British farmers look to a new future post-Brexit, gene-editing will help to modernise the agriculture and food industry and reinvigorate investment in safe, nutritious, and profitable food production.

Benefits of gene editing

1. **Environmental Benefits**
   Genetic solutions can help reduce the need for chemical inputs in agriculture. Developing new crop varieties with favourable characteristics (such as increased resistance to pests and diseases and less reliance on pesticides and fertilizers) and bringing them to market sooner, we have an opportunity to reduce our chemical inputs in agriculture and use less water and land. A regulatory regime which supports the development of environmentally-sensitive crop traits and encourages farmers to change their practices accordingly, would be a significant step in moving towards lower-input agriculture in the UK.

2. **Health and Nutrition Consumer Traits**
   A growing world-population, decreasing areas of arable land and the growth in demand for plant-rich diets poses challenges around key micronutrients for human health. Gene editing allows us to improve specific qualities such as the accumulation of higher levels of vitamins and minerals which are found in low levels in many crops, or to improve oil and carbohydrate profiles, delivering foods that benefit consumers and reduce the burden on healthcare providers. Gene editing offers the potential to develop innovation in a wider range of plants for consumers.

3. **Climate resilience**
   Increased temperatures and changes to rainfall are already impacting harvests and yields in the UK, as well as around the globe. Gene editing can be used to develop crops which are more tolerant to heat, drought and salt and better able to withstand changing climates.

4. **Accelerating innovation**
   The traditional methods that plant breeders use to introduce traits can take 8-15 years. Gene editing techniques can significantly speed up the crop breeding process to just a few years, bringing about essential scientific development much sooner and at a much lower cost of investment.

5. **Putting the UK back at the forefront of crop research and stimulating industry**
   In the early 1990s, the UK was considered a global leader in crop biotechnology, but seed and breeding companies moved their advanced breeding activities to outside the EU, put off by the additional cost and time for product development as a result of the regulation. By

allowing research findings to progress through to field evaluation at a much faster pace, this regulatory change in England will provide greater opportunity for smaller companies and start-ups to get involved in this area. This will increase innovation across the sector and diversify the market, helping put the UK at the forefront of crop science.

6. **Gene editing as a research tool**
   Gene editing is not just used to create new crop varieties; it is also a useful research tool for understanding the role of genes within plants, helping us map genes, and understand how genetic changes affect plant properties.

Call to Action

The science research institutes based on the Norwich Research Park are developing the plants and food products of the future using gene editing. **We urge members of the Secondary Legislation Scrutiny Committee to support this Statutory Instrument.**

The full benefits of gene editing technology and research will only be realised if crops and products developed this way are able to reach consumers, either in the UK or in external markets.

We are calling for the Government to follow this secondary legislation by bringing forward further proposals for new regulations at the earliest opportunity, to allow the commercial availability of gene edited plants in the UK.

Progressive and proportionate regulations, based on scientific evidence of safety will provide consumer confidence in gene edited plants. Investment in plant science depends on the Government ensuring the commercial potential for this important research.

Some examples of research on gene-editing at the Norwich Research Park include:

- The John Innes Centre is using gene editing to map genes in wheat and brassicas such as oilseed rape, to increase resilience to climate change and develop new varieties.
- The Quadram Institute is working with gene edited wheat with an increased amount slowly-digested and resistant starches which reduce the elevated blood glucose levels and insulin response to refined carbohydrates.
- The Sainsbury Laboratory have used gene editing to create mildew resistant tomatoes which, if deployed, would dramatically reduce the use of fungicides.
- Tropic Biosciences are using gene-editing to boost the resilience of current banana varieties to the deadly *Fusarium* wilt disease.

Further information on these examples or full case studies can be provided.

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