

3 February 2022



The Clerk
Joint Committee on Statutory Instruments
House of Commons
London
SW1A 0AA

Dear Madam/Sir,

REF: Draft Statutory Instrument, 2022 No. 0000, The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022, laid before both Houses 20 January 2022.

We are writing to draw your attention to concerns around the above Instrument.

We have recently written to the Secondary Legislation Scrutiny Committee and believe that some of the concerns raised with that group are also relevant to your terms of reference, specifically:

That there appears to be doubt about whether there is power to make it or that it appears to make an unusual or unexpected use of the power to make

The Instrument uses secondary legislation to create a subset (as it is referred to in the Impact Assessment) of genetically modified organisms (GMOs) that “*could have occurred naturally or through traditional breeding*”. This subset is entirely theoretical and is not defined or recognised in current scientific literature, in UK regulations (*e.g.*, EPA 1990 and 2002 and 2019 amendments), in international definitions (*e.g.*, Cartagena Protocol) or the regulations of many other countries. This is a fundamental change in the law that should be debated as part of the process of primary legislation and not slipped through via statutory instrument.

During the Defra public consultation many important stakeholders objected to Defra’s contention that there are GMOs that “*could have occurred naturally or through traditional breeding*”.

- The [Royal Society](#), for instance, calls it “*problematic*” and notes that “*the challenge for the interpretation of ‘could have been produced by traditional breeding’ is that genome editing enables both highly precise changes ... and specific combinations of genetic changes that are highly unlikely to have been achieved using traditional breeding.*”
- The FSA’s [Advisory Committee on Novel Foods and Processes \(ACNFP\)](#) said that it is “*too simplistic with regards to the science*” and that it is “*first necessary to have clarity on what constitutes traditional breeding*”. On the question of risk, it notes that it would “*not be possible to say categorically that any modification made via genome editing will present a similar risk to a product from traditional breeding unless it was clearly demonstrated that an equivalent outcome had been achieved*”.

Many others [raised the same concerns](#). In addition:

- Defra's Advisory Committee on Releases in the Environment (ACRE), in its [advice to Defra](#), stated that it will remain “*necessary for regulators to assess whether or not genetic changes introduced by these technologies could have arisen naturally and/or through traditional breeding*”.

Yet no such assessment is required by the Instrument.

We would argue that, given the controversy around these issues, this is an unusual, unexpected and in the end unscientific use of the powers granted by the parent act.

The Instrument seeks to amend the Genetically Modified Organisms (Deliberate Release) Regulations 2002 and through that the Environmental Protection Act 1990.

We believe the amendment, as proposed, is at odds with the parent act. The intention of the Environmental Protection Act 1990 is to protect the environment whereas the entire rationale behind this amendment is to stimulate investment. From that perspective the only impact assessment that has been performed focuses on potential impacts on a narrow range of businesses.

However, the environmental risks from allowing trials in open fields in England and the “*removal of requirements for trial applications, in-trial monitoring, post-trial monitoring, and security measures*” are potentially quite high. A proposal for the unrestricted and deliberate release of genetically engineered organisms into the environment, therefore, must be considered against a full environmental impact assessment.

The Impact Assessment states that the purpose of the SI is to encourage “*inward investment*” and therefore stimulate “*an increase in research activities and field trials*” in the UK

But the government has not modelled the extent or the amount of increase that it is anticipating – nor the environmental impact of that increase in open field activity – and yet it is known that environmental risks of the release of genetically engineered organisms [increase with scale](#) and therefore must be considered in any impact modelling.

The Impact Assessment does not consider the negative impact on other businesses such as organic farmers and growers and those conventional farmers who choose not to farm or sell GMOs, including a potential reduction in land value from being adjacent to GMO fields. Since the proposed register does not include details of the location of the field trials/environmental releases there is a possibility of creating suspicion and mistrust within communities and between neighbours, which has also not been considered.

It does not consider the impact of escape into the food chain and what this might cost in terms of lost revenue and reputational damage.

When it was discovered that GM wheat, not authorised for market, had spread from field trials into the US food system, the EU instigated tests of incoming shipments of US wheat vowing to block any imports found to be contaminated, Japan cancelled a tender for US western white wheat and other important Asian markets *e.g.*, South Korea, China, the Philippines and Taiwan threatened to suspend imports.

That its drafting appears to be defective

There are inconsistencies, resulting in incoherence, in the language and definitions used between the Statutory Instrument, the Explanatory Memorandum and the Impact Assessment.

In some instances, the term “*could have occurred naturally*” is used, in others that term is dropped or de-emphasised, leaving only the term “*could have been achieved through traditional breeding*”, and in some instances these are used together. There is, therefore, a lack of clarity on what the Instrument is actually focussing on.

The instrument fails to define what “*could have occurred naturally*” means and by what standard this will be judged. Whilst methods of traditional breeding are set out in 5(2) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002, as noted by the Royal Society above, there needs to be greater clarity on how and, critically in our view, over what time scale, genetic changes deemed to be the same as those that “*could have been achieved through traditional breeding*” could have occurred.

In addition, the Instrument and the Explanatory Memorandum fail to deal with the fact that most crop research so far reported in the literature and currently underway uses a mixture of methods: some use genome editing, which may qualify for exemption, some use only ‘old style’ and non-exempt GM techniques and some use gene-editing tools delivered via ‘old style’ GM techniques – alongside and in support of each other. As such, the Instrument creates a hugely inconsistent environment which researchers will find hard to navigate and which will not be easy to explain to the public or those tasked with following and upholding the law.

The Instrument and Explanatory Memorandum also fail to set out any clear guidance on the management of research sites and, in particular, whether researchers have to take any precautions to prevent gene flow (through for example rotation, buffer rows or crops and subsequent cropping), or how to handle or dispose of trial crops to prevent them reaching the supply chain. This lack of clarity may well result in very different protocols being used by different researchers and the creation of an unlevel playing field and/or hesitancy, which undermines the goal of the Instrument.

This Instrument is being promoted as having limited scope; for instance, the Explanatory Memorandum talks about removing “*unnecessary burdens on the research of GM plants*”. However, the Instrument itself seeks to remove restrictions in “***all cases and circumstances** in which a person intends to release a qualifying higher plant, other than those in relation to the marketing of such qualifying higher plants*”. [our emphasis]

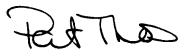
This clause is open to widespread interpretation and abuse. It opens the door for anyone – not just *bona fide* researchers such as Rothamsted and the John Innes Centre who have experience and protocols in place – to develop, import and plant any qualifying gene-edited plant for non-marketing purposes e.g., demonstration fields, educational field labs or multiplication for e.g., experimental seed stocks. The Impact Assessment does not consider the consequences of these scenarios.

Whatever view one takes of the merits or otherwise of agricultural genetic engineering technologies, it is unarguable that the process of change as well as the proposed changes themselves should be as clear and coherent as possible.

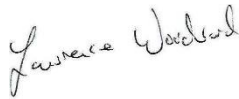
We believe this Instrument fails on multiple levels. It includes significant and far-reaching changes in definitions that are imprecise and at odds with scientific and legal definitions used in other parts of the UK, the EU and other countries.

We hope you will carefully consider the important points we have raised and address these deficiencies.

Yours Sincerely,



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