

26 January 2022



The Lord Hodgson of Astley Abbotts, CBE
Secondary Legislation Scrutiny Committee
House of Lords
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Dear Lord Hodgson,

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 as a civil society group active in the area of agricultural genetic technologies in the UK to raise important concerns and considerations about the above Instrument.

We believe that the Instrument is unworkable from a policy point of view, that it is based on highly contested science, that it ignores the majority of responses to Defra's public consultation on the issue and that it may not, ultimately, achieve its intentions.

The Instrument seeks to remove requirements for risk assessment and consent for field trials by creating an exemption (for purposes other than marketing) for what it refers to as "*qualifying higher plants*".

This exemption is based on a new subclass of genetically modified plants:

- a) that could have occurred naturally, or;
- b) that could have been made using one or more of the techniques [*"traditional breeding"*] set out in regulation 5(2)

However, neither the Instrument nor its Explanatory Memorandum provides a basis on which to justify creating a new subclass of exempted organisms. In addition, this subclass of genetically modified organisms 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.

The definition of a GMO is not a minor theoretical point but a foundational concept in the regulation of agricultural genetic technologies and we therefore believe that the regulatory change presented in this Instrument is problematic and should be considered by your Committee for the following reasons:

THIS IS A POLITICALLY AND LEGALLY IMPORTANT ISSUE THAT GIVES RISE TO ISSUES OF PUBLIC POLICY LIKELY TO BE OF INTEREST TO THE HOUSE

It has long been the government's stated policy, prior to and especially following Brexit, to change the way agricultural genetic technologies are regulated in order to, in its view, reduce regulatory

burden and encourage innovation in research, farming and associated sectors. A major component of this is to make significant amendments to regulations relating to genome editing technologies and subsequently those governing GMOs (Genetically Modified Organisms) in general, including so-called 'old style' GMOs.

This Instrument has been brought forward as a first and limited step in the process. However, its provisions – which we argue are ill thought-through – include 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.

Its implementation would constitute a dramatic shift in policy and regulation that is complex and comprises multiple connected (and in some areas disputed) issues of science and technology, practical implementation, marketing and retail issues, public opinion and trust.

That this is a matter of public policy that concerns a significant body of citizen and civil society opinion is borne out by the volume of responses to Defra's 2021 Public Consultation on the Regulation of Genetic Technologies. It is clear that this Instrument has ignored the views expressed in that consultation (see below), the vast majority of which favour continued regulation of gene editing. This raises doubts as to its political and policy credibility.

As such it is not only inadequate on its own terms, but it also alters significantly existing primary legislation, preempts parliamentary scrutiny of important future legislation and will widely be viewed in public opinion as a device to avoid much-needed inclusive public debate on an issue that matters deeply to many individuals and businesses.

Whatever view one takes of the merits or otherwise of agricultural genetic engineering technologies, it is unarguable that the process of change should be as clear and coherent as possible – especially when it comes to policy and regulation.

THE INSTRUMENT IS INAPPROPRIATE IN VIEW OF CHANGED CIRCUMSTANCES SINCE THE ENACTMENT OF THE PARENT ACT

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

There is no doubt that the rapid development of genetic engineering techniques in farming and food – in particular genome editing – require a review and changes to existing regulation. This is widely recognised and such reviews and changes are being considered and taking place throughout the world – including in the EU.

At present a range of definitions and regulatory approaches are under consideration. In some cases, they are being enacted with so little international agreement as to resemble a regulatory 'Wild West'.

The creation of a special English category of GMOs that "*could have occurred naturally or through traditional breeding*" only adds to the confusion.

This hypothetical new category of GM plants has no standing in current science or regulation – even amongst those who support regulatory change.

Even if rapid developments and changes in this technology require major and significant review and regulatory amendments to the parent act (or possibly new legislation), or alterations to risk assessment guidance documents, this piecemeal, maverick approach is inappropriate.

THE INSTRUMENT MAY IMPERFECTLY ACHIEVE ITS POLICY OBJECTIVES

The creation of a new category of GM plants is an action not raised in Defra's consultation nor, based on our recent in-depth [review](#) of available submissions, has it been suggested by any respondents, either pro- or anti-regulatory change.

It is therefore reasonable to conclude that the impacts and consequences of the Instrument have not been fully considered and are likely to give rise to issues which obstruct achieving its policy objectives.

The Instrument seeks to exclude GMOs that "*could have occurred naturally*" or through traditional breeding techniques as defined in 5(2) of the current regulation. Whilst it will achieve that objective, as it is framed the Instrument creates other issues and difficulties for researchers and developers due to its lack of clarity, coherence and criteria.

Under these new requirements, for example, applicants are under no obligation to justify what "*could have occurred naturally*" means, nor are they required to say on what basis they believe that their GMO "*could have been produced through traditional breeding*" and over what timescale.

This is problematic for several reasons:

- It creates a *de facto* 'honour system' (relying on GMO developers to self-declare whether their product is a GMO or not) which is not appropriate for the deliberate environmental release of any kind of GMO.
- It is clear from the responses made by the research community to Defra's public consultation that there is no scientific consensus as to what these terms mean. In the absence of clarity it is possible that different researchers will interpret those terms differently.
- It is universally accepted that gene editing is a genetic modification process – indeed this Instrument accepts this. But the suggestion that there is a "[genetically modified lite](#)" – a subclass of GMO that "*could have occurred naturally*" is not grounded in science and raises inevitable – and unaddressed – questions, such as, how closely related does the source plant have to be for the resulting GMO to qualify as natural and/or non-transgenic?
- This is especially critical because most crop research so far reported in the literature and which is 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, thereby risking trust.

The Instrument and Explanatory Memorandum fail to set out any 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. Finally, the lack of clarity poses problems for public communication and trust which the research community has been working hard to improve.

The Explanatory Memorandum also 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”. We are concerned about what “all cases and circumstances” means in practice and how this might be interpreted and/or abused.

THE EXPLANATORY MATERIAL LAID IN SUPPORT OF THE INSTRUMENT PROVIDES INSUFFICIENT INFORMATION TO GAIN A CLEAR UNDERSTANDING ABOUT THE INSTRUMENT’S POLICY OBJECTIVE AND INTENDED IMPLEMENTATION

The Instrument (and indeed the public consultation process from which it has emerged) presents a particularly grievous example not just of poor quality information, but also of information that appears to be deliberately misleading.

The Explanatory Memorandum fails to provide sufficient information about the process of gene editing, the scientific basis for creating a new category of “*higher qualifying plants*” that “*could have occurred naturally or through traditional breeding*”, or about the impact of this Instrument. It makes no mention of the serious conflicts between achieving the Instrument’s short-term objectives and the potential longer-term problems and practicalities of implementation as outlined above.

In seeking to define a new subclass of GMO that “*could have occurred naturally or through traditional breeding*”, the Instrument parallels the errors, omissions and unfounded claims of the [briefing materials](#) for the public consultation and the [consultation document](#) itself.

It also fails to acknowledge that responses to Defra’s 2021 Public Consultation on the Regulation of Genetic Technologies, as detailed our recent report [Filling in the Blanks – What Defra Didn’t Say](#) revealed a large degree of scepticism amongst relevant bodies, specialists and experts that Defra’s terminology “*could have occurred naturally or through traditional breeding*” could form the basis of scientifically sound regulation:

- The Institute of Food Science & Technology (IFST), for instance, called it “*overly simplistic*”.
- The Microbiology Society said it was “*purely philosophical*”
- The Nuffield Council on Bioethics were “*not convinced that this is either the most proper or most popular framing*”.
- The Royal Society called it “*problematic*” and noted how rare the phenomenon of a so-called ‘natural’ GMO is.
- The Royal Society of Biology said it provided “*no clear criteria*” and further noted that “*no clarity can be achieved using this principle*” and “*we would not recommend using it as the basis for regulation*”.

- 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"*.
- Wildlife and Countryside Link suggest there is *"no conclusive evidence"* that organisms created using gene editing could have been achieved through traditional breeding.
- The Conservative Animal Welfare Foundation found *"no basis"* for Defra's claims, bluntly noting that *"The entire purpose of expanding the use of gene editing in animals is to create animals that do not occur naturally."*
- The Organic Research Centre says Defra's premise is *"unproven in theory and should not be the basis for changing regulations or removing protections"*.

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.

These views call into question Defra's entire argument and the basis upon which it proposes to deregulate some GMOs.

No impact assessment

The Explanatory Memorandum fails to provide sufficient information in the form of an impact assessment. At the time of writing, the Regulatory Triage Assessment referred to in the memorandum has not been made publicly available.

Without this, it is difficult to justify the claim that there is no significant risk either to business or to the environment.

Further, it is not clear at all from the memorandum which businesses it presumes will be unaffected. Organic and those who chose not to farm or sell GMOs could be substantially impacted.

The Explanatory Memorandum states that it is *"the characteristics of the end-product that determines its risk to human health and the environment – not how they were made"*. This is in line with ACRE's advice that unintended and off-target impacts of genome editing likely pose few potential safety issues as they *"can usually be removed by segregation in subsequent breeding steps"*.

However, allowing open field trials with no controls, no safety assessments and no protocols for separation and capture of plant material means that this segregation will not occur until after material might have escaped into the wider environment and/or into the food chain.

The possible extent and impact of this could be considerable even with applications limited to research sites. There is no information as to whether this has been assessed.

INADEQUACIES IN THE CONSULTATION PROCESS RELATING TO THIS INSTRUMENT

Soon after the Public Consultation on the Regulation of Genetic Technologies was launched our organisation lodged a [complaint](#) with Defra and the Cabinet Office that the consultation was not being conducted in line with the [Cabinet Office Consultation Principles](#).

Our complaint notes that:

- The Consultation did not conform to Parts A and E of the Principles. It was not easy to understand or answer, was not accessible, was not targeted and did not encourage responses.
- The consultation did not conform to Part B of the Principles. It was consulting about issues on which the government has already largely formed a final view.
- The consultation did not conform to Part C of the Principles. The information provided was prejudicial rather than informative and understandable and did not include any validated cost/benefit/impact assessment.

We also expressed concerns that consultation came across as biased and lacking in thought and planning.

We are aware that we are not the only ones who complained about the process. In our view it is not possible to create coherent public policy out of such a flawed process.

Defra's report on the consultation in the Explanatory Memorandum misrepresents science responses

In the Explanatory Memorandum Defra states: *"The consultation received no scientific evidence indicating that gene edited organisms should be regulated as GMOs;"* This is simply untrue. Responses from all sides of the spectrum gave scientific perspectives – backed up by evidence – that gene edited organisms should continue to be regulated as GMOs.

It is true, as the Explanatory Memorandum states, that *"a number of responses expressed the view that GMOs are demonstrably different to the products of gene editing"*. It is also true that many respondents expressed, and provided evidence, for the opposite view.

However, what the Explanatory Memorandum fails to reveal is the extent to which scientific opinion on all sides of the spectrum questioned and criticised the scientific basis of Defra's proposals (as outlined above) – proposals which have now been carried forward into this Instrument.

Defra's report on the consultation in the Explanatory Memorandum misrepresents public views

In addition, we would also like to express deep concern that, in its haste and determination to push regulatory changes through, Defra is misleading parliament and others about the outcome of the public consultation.

The Explanatory Memorandum says:

"A proportion of public sector bodies (55%) and academic institutions (58%) did not support continuing to regulate products of gene editing as GMOs, where the resulting genetic changes are similar to those found naturally in organisms of the same species, or in very similar species that could be combined by traditional breeding. Most individuals (88%) and businesses (64%) supported

continuing to regulate the products of gene editing as GMOs. Non-governmental organisations (NGOs) were evenly split on this topic."

But stated this way these figures are disingenuous. Public sector bodies and academic institutions, for instance, made up only around 1% of the responses, whereas individuals accounted for 89% of respondents.

In fact, 85% of the responses included in [Defra's official analysis](#) indicated no support for the deregulation of gene edited organisms. It is important to note that this figure represents the final analysis AFTER Defra removed what it called 'campaign' or 'template' responses from its analysis.

There is no real appetite amongst the public, business, civil society, public sector bodies or academic institutions for deregulation and this has implications for policy and practice.

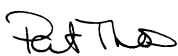
THE INSTRUMENT APPEARS TO DEAL INAPPROPRIATELY WITH DEFICIENCIES IN RETAINED EU LAW

EU law on this issue is currently being reviewed and it is clear that there is support for change to deal with genome editing technologies as they develop. Such a major change in the law requires a transparent, informed and equitable debate as it touches on all aspects of food, farming and indeed science and public trust.

This Instrument does not deal appropriately with perceived or real deficiencies in retained EU Law. Whatever the merits, or otherwise, of genome editing technologies, primary legislation, not a Statutory Instrument, is the place to deal with such a fundamental and far-reaching redefinition. This is especially so here, where this ill-considered and incoherent regulatory change may well damage the development of better, more efficient and more effective public-supported policy.

We hope you will carefully consider the important points we have raised and we look forward to your response.

Yours sincerely,



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