**EXPLANATORY MEMORANDUM TO**

# THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (AMENDMENT) (ENGLAND) REGULATIONS 2022

**2022 No. 347**

## 1. Introduction

1.1 This explanatory memorandum has been prepared by Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

## 2. Purpose of the instrument

2.1 The purpose of this instrument is to remove the need to submit a risk assessment and seek consent from the Secretary of State before they can release, for non-marketing purposes, genetically modified (GM) plants that could have been produced by traditional breeding. Instead, a notice must be given to the Secretary of State with certain prescribed information.

## 3. Matters of special interest to Parliament

***Matters of special interest to the Joint Committee on Statutory Instruments***

3.1 None.

## 4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England.

## 5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Agriculture, Fisheries and Food, Rt Hon Jo Churchill MP, has made the following statement regarding Human Rights:

"In my view the provisions of the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 are compatible with the Convention rights."

## 6. Legislative Context

6.1 This instrument is being made in exercise of powers conferred by sections 108, 111 and 122 of the Environmental Protection Act 1990.

6.2 It amends the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443).

## 7. Policy background

***What is being done and why?***

7.1 In July 2018 a CJEU case (Confederation Paysanne (C-528/16)) confirmed that in EU law all organisms produced by biotechnology are Genetically Modified Organisms (GMO) and that they need to be regulated as such, even if they cannot be distinguished from organisms occurring naturally or produced by traditional breeding methods. This means that the current regulatory regime places unnecessary burdens on the research of

GM plants, which pose the same risk as those that could have been produced by traditional breeding methods. The UK Government disagreed with this view and intervened in the case to present a different view based on scientific evidence and to argue that the regulatory regime should be proportionate to risk.

7.2 The UK Government's view is that where genetic alterations and combinations are of the type that are selected for in traditional breeding, the environmental release of these plants should not be regulated in the same way as the environmental release of Genetically Modified Organisms (GMOs). This is because it is the characteristics of the end-product that determines its risk to human health and the environment – not how they were made.

7.3 Now that the UK has left the EU, ministers wish to amend the legislation in England to allow GM plants that could have occurred naturally or through traditional methods for release for non-marketing purposes. This will enable our bioscience sector to further test the benefits and safety of the new products, without the burden of unnecessary regulatory processes.

***Explanations***

*What did any law do before the changes to be made by this instrument?*

7.4 The current regime places disproportionate regulatory burdens on the research of the subset of GM plants which could have been produced by traditional breeding methods. The current GMO legislation requires that each GM organism is assessed and authorised on a case-by-case basis before it can be used. This involves a risk assessment, a public consultation, and the publication of details of when and where its research trial will take place.

*Why is it being changed?*

7.5 Under the current provisions, anyone wanting to release any GMOs into the environment has to carry out a risk assessment and seek consent from the Secretary of State. We believe this to be an unnecessary burden on the research and development of GM plants with genetic changes that could have occurred naturally or by any of the techniques used in traditional breeding as listed in regulation 5(2) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002. These changes will only apply to plants and not to animals as animals that are being trialled in research and are regulated by The Genetically Modified Organisms (Contained Use) Regulations 2014 (S.I. 2014/1663).

*What will it now do?*

7.6 In practice, this instrument will require any individual or organisation intending to release a qualifying higher plant (GM plants with genetic changes that could have occurred naturally or by any of the techniques used in traditional breeding as listed in 5(2) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 into the environment to submit a notice to the Secretary of State. This notice will need to be submitted to Defra before the seed / other propagating plant material is placed into the ground for germination / onward growth. The notice will be published on the public register Genetically modified organisms: applications and decisions - GOV.UK (www.gov.uk).

## 8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act

## 9. Consolidation

9.1 These Regulations are not being consolidated.

## 10. Consultation outcome

10.1 Defra held a public consultation from 7 January to 17 March 2021, to gather views on the regulation of genetic technologies in England. The consultation had two parts:

*(i)* Whether the products of genetic technologies should continue to be regulated as genetically modified organisms (GMOs), if they could have been produced by traditional breeding methods.

*(ii)* Longer-term reform of legislation governing organisms produced using genetic technologies.

10.2 The proposed regulatory change to the definition of GEOs would only apply in England, however views from individuals and organisations based elsewhere in the UK, or outside the UK, were also welcomed. The consultation was hosted on the government consultation portal, Citizen Space. Responses could also be made by email or submitted to a postal address. In total, 6440 consultation responses were received via an online platform (Citizen Space), email and post. Responses were treated equally regardless of respondent type (i.e., responses were not weighted).

10.3 The consultation received no scientific evidence indicating that gene edited organisms should be regulated as GMOs; and a number of responses expressed the view that GMOs are demonstrably different to the products of gene editing. 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.

10.4 A full summary of responses can be found at Genetic technologies regulation: government response - GOV.UK (www.gov.uk).

## 11. Guidance

11.1 No guidance has been produced for this SI.

## 12. Impact

12.1 There is no, or no significant, impact on business, charities, or voluntary bodies.

12.2 There is no, or no significant impact on the public sector as a result of this instrument.

12.3 A full Impact Assessment has not been prepared for this instrument because it is a deregulatory measure with a low level of impact per business. A Regulatory Triage Assessment has been conducted. Easing the regulatory burden for research and development purposes involving qualifying GM plants will have a positive impact on

investment and will drive innovation, whilst generating wider spill over benefits into the UK economy from this increased investment.

## 13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 The approach taken is a deregulatory measure and it will reduce the overall cost to business, therefore it has not been necessary to take any action to assist small businesses.

## 14. Monitoring & review

14.1 Defra will monitor and review the impact of the instrument as part of its standard policymaking procedures and ensure that the provisions are adhered to.

14.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, the Parliamentary Under Secretary of State for Agriculture, Fisheries and Food, Rt Hon Jo Churchill MP, has made the following statement "It is not appropriate to include a statutory review clause in this instrument as it is not expected to have a significant annualised net impact on business".

## 15. Contact

15.1 Oana-Diana Georgescu at the Department for Environment, Food and Rural Affairs, email: oana-diana.georgescu@defra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Tim Mordan, Deputy Director for Genetic Resources and GM, at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

15.3 Jo Churchill MP, at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.