EXPLANATORY MEMORANDUM TO

THE GENETICALLY MODIFIED ORGANISMS (DELIBERATE RELEASE) (AMENDMENT) (ENGLAND) REGULATIONS 2019

2019 No. 1252

1. Introduction

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

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The purpose of the Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 ("this instrument") is to implement, in relation to England, Commission Directive (EU) 2018/350 amending Directive 2001/18/EC of the European Parliament and of the Council. This instrument achieves this by amending the Genetically Modified Organisms (Deliberate Release) Regulations 2002 ("the 2002 Regulations").

2.2 The Directive makes more detailed provision in respect of the environmental risk assessments which must be made before the release of Genetically Modified Organisms. There is a particular emphasis on the information which must be provided before the release of Genetically Modified Higher Plants. Applicants for consent to release these organisms have provided this information since 2010. There is no change in policy; releases will still require prior approval from the Secretary of State.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Defra regrets that it has not been possible to give the usual 21 days' notice before this instrument takes effect. Our intention was to lay this instrument on the 5th September. Regrettably we were not able to do so.

3.2 The date by which we are legally obliged to transpose Directive 2018/350 is 29th September 2019. The Government's policy is to ensure full compliance with EU legal requirements, including the transposition of EU legislation. If the Directive is not transposed on time there is a risk of infraction by the European Commission, and a risk of domestic challenge. We are, in part, reliant on using powers under section 2(2) of the European Communities Act 1972 to make this SI, and these will no longer be available following exit from the EU on 31st October 2019.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.3 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

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 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 This instrument amends the 2002 Regulations, and is made under section 2(2) of the European Communities Act 1972 and section 111 of the Environmental Protection Act 1990. The 2002 Regulations give effect, in relation to England, to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (2001/18/EC). The 2002 Regulations, amongst other things, set out the procedures to follow when seeking consent from the Secretary of State to trial or market GMOs. The 2002 Regulations provide a framework for the harmonised marketing of safe products produced from GMOs, and ensure that only safe GMOs are released. Any approval for the release of a GMO is conditional upon it passing a science-based assessment of its potential impact on human health and the environment.

6.2 The amendments to the 2002 Regulations made by this instrument are required to implement amendments to Directive 2001/18/EC made by Commission Directive (EU) 2018/350. Commission Directive (EU) 2018/350 updates four of the technical Annexes in Directive 2001/18/EC. The amendments to the annexes align them with technical guidance that was published by the European Food Safety Authority (EFSA) in 2010. The amendment relates to the methodology of the environmental risk assessment, its structure, content, and level of detail.

7. Policy background

What is being done and why?

7.1 No changes are being made to policy.

7.2 Following a request from the EU Commission in 2010, the EFSA produced non-statutory guidance which added detail to the established principles for environmental risk assessments (e.r.a.) in applications to release and market genetically modified plants as set out in Directive 2001/18/EC. Commission Directive (EU) 2018/350 amends Directive 2001/18/EC by aligning it with the EFSA's guidance. The alignment in particular adds more detail on the information that should be included in applications to market genetically modified plants. The requirement to provide this information in support of an application has no practical impact for an applicant's e.r.a. as it has been supplied in applications for the last 9 years.

7.3 In practice, most applications to market GM plants are submitted under alternative legislation (Regulation (EC) No. 1829/2003 on genetically modified food and feed) because it allows applicants to seek authorisation to import, cultivate and use genetically modified plants for food and feed under one process. The EU has already adopted Commission Implementing Regulation (EU) No. 503/2013 on applications

made under Regulation (EC) No. 1829/2003, and Commission Directive (EU) 2018/350 aligns to that Regulation. As outlined above, the EFSA has applied the requirements in relation to all applications to release and market genetically modified plants since 2010.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 None. The Department for Environment, Food and Rural Affairs does not intend to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 The Food Standards Agency was consulted in accordance with section 126(5) of the Environmental Protection Act 1990 together with interested parties, such as: umbrella industry organisations representing companies active in agricultural bio-technology; establishments interested in research in GMOs; and relevant Non-Government Organisations were engaged about the proposed changes to the instrument. As there is no change in policy for interested parties to comment upon, or shape, engagement was for information only.

10.2 The Devolved Administrations were consulted during the development of this instrument and are content.

11. Guidance

11.1 There is no associated guidance.

12. Impact

12.1 There is no impact on business, charities or voluntary bodies because there is no change in policy, and the requirements in the instrument have been in place (on a non-statutory basis) since 2010.

12.2 There is no significant impact on the public sector beyond minimal administrative input to amend application forms.

12.3 An Impact Assessment has not been prepared for this instrument because there is expected to be no additional impact on business. There is no change in policy, and the requirements in the instrument have been in place, on a non-statutory basis, since 2010.

13. Regulating small business

13.1 This instrument applies to activities that are undertaken by small businesses. No impacts on small businesses are foreseen as a result of this instrument. There is no change in policy, and the requirements in the instrument have been in place, on a non-statutory basis, since 2010.

14. Monitoring & review

14.1 A statutory review clause is included in this instrument.

15. Contact

15.1 Ivy Wellman at the Department for Environment, Food and Rural Affairs, Telephone: 020 8026 3287 or email: ivy.wellman@defra.gov.uk, can be contacted with any queries regarding the instrument.

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

15.3 George Eustice MP, Minister of State for Agriculture, Fisheries and Food at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.