EXPLANATORY MEMORANDUM TO

THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (EU EXIT) REGULATIONS 2018

AND

THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (ENGLAND) (EU EXIT) REGULATIONS 2018

NOS. [XXXX]

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 Act.

1.2 This memorandum contains information for the Committees on the UK's exit from the European Union.

2. Purpose of the instrument

2.1 The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 and The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2018 are being made under section 8(1) of the European Union (Withdrawal) Act 2018 to amend retained EU legislation and existing United Kingdom legislation. These instruments ensure that EU and UK legislation establishing the regime that controls and enforces the movement, release and marketing of genetically modified organisms will continue to be operable when the UK leaves the European Union.

2.2 Explanations

What did any relevant EU law do before exit day?

Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms sets out the procedures to follow, and the format for information to be submitted prior to a genetically modified organism being released into the environment, i.e., cultivated or marketed. It provides a framework for the harmonised marketing of safe products produced from genetically modified organisms. Applications to import genetically modified organisms into, and trade within the EU are approved collectively by all EU Member States. The Directive provides discretionary provisions which allow Member States, or devolved governments within Member States, to decide against the cultivation of genetically modified crops in their territory. The process ensures that only safe genetically modified organisms are released. Any approval for the cultivation, or marketing, of a genetically modified organism is conditional upon it passing a science-based assessment of its potential impact on human health and the environment.

The Directive is implemented in the constituent nations of the UK by:

- The Genetically Modified Organisms (Deliberate Release) Regulations 2002
- The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002

- The Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002
- The Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.

The following directly applicable EU legislation also forms part of the existing regime in the UK.

Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms regulates the export of genetically modified organisms from the EU to third (non-EU) countries. The basic requirement is for the country intending to export a genetically modified organism for the first time to gain the approval of the receiving country before it is exported. The Regulation implements the requirements of the Cartagena Biosafety Protocol to the United Nations Convention on Biological Diversity (to which both the EU and UK are each a Party).

Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms requires Member States to ensure that authorised genetically modified organisms are labelled and traceable at all stages of their being placed on the market.

Commission Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms requires applicants for marketing approval of genetically modified organisms under Directive 2001/18 to specify a unique identifier code for the GMO in question, and sets a specified format and method for assigning each code. Regulations 1830/2003 and 1946/2003 also require the application of unique identifiers.

There are further implementing regulations in the UK, as follows:

Commission Decision 94/730/EC sets out special procedures that may be followed for applications to undertake certain types of trials of genetically modified plants.

Council Decision 2002/812/EC specifies a standard format for summarising applications for consent to market genetically modified organisms.

Council Decision 2002/813/EC specifies a standard format for summarising applications for consent for trials of genetically modified organisms.

Council Decision 2003/701/EC specifies a standard format for consent holders to report on the monitoring and/ or outcome of trials with genetically modified organisms conducted under deliberate release legislation.

Council Decision 2009/770/EC specifies the format of the post-marketing monitoring report that holders of consents to market genetically modified organisms are required to complete.

Council Decision 2016/321 prohibits the cultivation of 'MON810' maize, which has EU approval for commercial use, in Member States, or parts of Member States, that chose to opt-out of its cultivation.

The Directive and the Regulations have been implemented in the UK by domestic legislation, and the Council Decisions apply in the UK. Marketing consents granted at the EU-level do not require further, national-level authorisations.

Why is it being changed?

The minor and technical changes made by the instruments are necessary to ensure that retained EU legislation and the domestic EU legislation enforcing it continues to operate effectively. The changes made to ensure that they operate effectively include amending references to the EU, EU institutions and EU administrative processes to UK equivalents; updating legal references to refer to relevant UK legislation; and retaining the requirement for the government to report.

What will it now do?

The instruments will ensure that the legislation described above will operate effectively in the UK after we leave the EU.

Existing processes for reaching decisions will be maintained at a national level. For example, the release and/ or marketing of genetically modified organisms will continue to need prior authorisation; approval to release, or market, a genetically modified organism will only be granted if a science-based assessment indicates that the safety of human health or the environment will not be compromised. Each administration of the UK will continue to be able to make its own decisions about the release of genetically modified organisms in its territory.

Regarding the UK's international obligations under the Cartagena Biosafety Protocol, the instruments will enable the UK to enforce its obligations under the Protocol that companies notify the country of import, and gain their approval for the movement of the genetically modified organism, before export takes place.

Amendments are also being made to ensure that there is the same level of transparency around trials and marketing of genetically modified organisms, and that the public continues to have access to information in a format with which they are already familiar. As consents to market genetically modified organisms are made at the EU-level, and so apply in the UK as a Member State, we are ensuring that those authorisations remain valid from the day of exit from the EU.

3. Matters of special interest to Parliament

3.1 The instruments are being laid in draft for sifting pursuant to the European Union (Withdrawal) Act 2018.

3.2 As the instruments are 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 The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 is the United Kingdom. The territorial extent of The Genetically

Modified Organisms (Amendment) (England) (EU Exit) Regulations 2018 is England and Wales.

4.2 The territorial application of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 is the United Kingdom. The territorial application of The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations is England.

5. European Convention on Human Rights

5.1 As both of the instruments are subject to negative resolution procedure and do not amend primary legislation no statement is required.

6. Legislative Context

6.1 The UK is leaving the European Union. EU and domestic legislation will continue to apply after the UK leaves the EU. The relevant EU legislation will become retained EU law by virtue of the European Union (Withdrawal) Act 2018. The retained EU legislation will not work in the UK without the amendments made by the instruments.

7. Policy background

What is being done and why?

7.1 No change is being made to policy. These instruments provide the continued ability to ensure environmental protection in the UK when it leaves the EU. For example, decisions to market genetically modified organisms are currently taken at the EU level. On exit from the EU, the decisions will be made by each of the territories of the UK. The decisions will be based on the terms that mirror those in the EU. As there is no change in policy, there is no impact on businesses.

7.2 Additionally there are further substantive corrections which are not included in these instruments but will instead will be contained within a separate instrument to be made under affirmative procedure. These corrections will transfer powers from the European Commission to the Secretary of State, to:

- make regulations for the adaptation of a system of unique identifiers;
- develop technical guidance on sampling and testing;
- establish or amend thresholds below which products containing adventitious or technically unavoidable traces of GMOs need not be labelled as such.

7.3 The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 apply to decisions on the release and marketing of genetically modified organisms which are a transferred matter for Northern Ireland under the Northern Ireland Act 1998. The UK Government remains committed to restoring devolution in Northern Ireland. This is particularly important in the context of EU exit where we want devolved Ministers to take the necessary actions to prepare Northern Ireland for exit. We have been considering how to ensure a functioning statute book across the UK, including Northern Ireland, for exit day in the absence of the Northern Ireland Executive. With exit day less than one year away, and in the continued absence of a Northern Ireland Executive, the window to prepare Northern Ireland's statute book for exit is narrowing. UK Government Ministers have, therefore, decided that in the interest of legal certainty in Northern Ireland, the UK Government will take through

the necessary legislation at Westminster for Northern Ireland, in close consultation with the Northern Ireland departments.

7.4 Decisions on the release and marketing of genetically modified organisms are a devolved matter in Scotland and Wales, and a transferred matter in Northern Ireland. It has been agreed that the Secretary of State will be empowered to make regulations with regard to this for the United Kingdom with the consent of the Devolved Administrations.

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

8.1 These instruments are being made using the power in section 8(1) of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

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 purpose of the instruments is solely to enable the current legislative and policy framework to remain unchanged by the withdrawal of the United Kingdom from the European Union. Interested parties such as umbrella industry organisations representing companies active in agricultural bio-technology; establishments interested in research in genetically modified organisms; Non-Government Organisations; and a selection of environmental campaigning communities were engaged, and proposed changes to instruments were shared with them.

10.2 Devolved administrations were engaged in the development of The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 and are content with the instrument.

11. Guidance

11.1 There is no associated guidance.

12. Impact

12.1 There is expected to be no significant impact on business, charities or voluntary bodies as the SIs simply roll over the EU legislative regime governing the release of GMOs.

12.2 There is likely to be no significant impact on the public sector.

12.3 Regulatory decisions on marketing GMOs are currently made at an EU level, with approval granted only if a risk assessment shows human health and the environment will not be affected. These decisions will now be made domestically and the completion of risk assessments may involve some small labour costs to the public sector. These are not expected to be significant.

12.4 An Impact Assessment has not been prepared for these instruments because there is expected to be minimal impact on business as the SIs relate to the maintenance of existing regulatory standards.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses. No significant impacts on small businesses is foreseen as a result of these instruments.

14. Monitoring & review

14.1 As these instruments are made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Renaud Wilson at the Department of Environment, Food and Rural Affairs, Telephone: 020 8026 3932 or email: Renaud.Wilson@defra.gsi.gov.uk can be contacted with any queries regarding the instruments.

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

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

Annex 1

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/ESIC
Appropriate-Ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 77	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal	Sub-paragraphs (3) and (7)	Ministers of the Crown	Set out the 'good reasons' for creating a

offences	of paragraph 28, Schedule 7	exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Sifting statement(s)

1.1 The Minister of State for Agriculture, Fisheries and Food, George Eustice MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In my view The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 and The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2018 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)."

1.2 This is the case because these instruments address only technical deficiencies in retained EU law and EU derived domestic legislation that will arise from withdrawal.

2. Appropriateness statement

2.1 The Minister of State for Agriculture, Fisheries and Food, George Eustice MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In my view The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 and The Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2018 do no more than is appropriate".

2.2 This is the case because these instruments address only technical deficiencies in retained EU law and EU derived domestic legislation that will arise from withdrawal.

3. Good reasons

3.1 The Minister of State for Agriculture, Fisheries and Food, George Eustice MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In my view there are good reasons for the provisions in these instruments, and I have concluded they are a reasonable course of action".

3.2 These instruments will allow the continued safeguarding of human health and the environment from the potential risks of the release, marketing or movement of genetically modified organisms; and that continuity will provide assurances for the public and industry alike.

4. Equalities

4.1 The Minister of State for Agriculture, Fisheries and Food, George Eustice MP, has made the following statement

> "These instruments do not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts."

4.2 The Minister of State for Agriculture, Fisheries and Food, George Eustice MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In relation to these instruments, I, George Eustice, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

5. Explanations

5.1 The explanations statement has been made in section 2 of the main body of the explanatory memorandum.