EXPLANATORY MEMORANDUM TO

THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (EU EXIT) REGULATIONS 2020

2020 No. 1421

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department for Environment, Food and Rural Affairs ("Defra") and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument is being made under sections 8(1) and 8C of the European Union (Withdrawal) Act 2018 (c.16) to amend retained EU legislation and existing United Kingdom legislation. The amendments are being made to ensure the retained EU legislation (and existing United Kingdom legislation which changes it) and existing United Kingdom legislation establishing the regime that controls and enforces the movement, release and marketing of genetically modified organisms ("GMOs") will continue to be operable in Great Britain (GB). These amendments are needed because of the inclusion of EU legislation related to GMOs in Annex 2 to the Protocol on Ireland/Northern Ireland to the withdrawal agreement ("the Protocol"),

Explanations

What did any relevant EU law do before exit day?

2.2 EU legislation (together with UK implementing legislation) established the regime that controls and enforces the deliberate release of GMOs and products produced from them into the environment.

2.3 '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 GMO being released into the environment, i.e., cultivated or marketed. It provides a framework for the marketing of safe products produced from GMOs. Applications to import GMOs 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 GMOs are released. Any approval for the cultivation, or marketing, of a GMO is conditional upon it passing a science-based assessment of its potential impact on human health and the environment.

The Directive is implemented in each of the 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.

2.4 The following directly applicable EU legislation also forms part of the existing regulatory regime in the United Kingdom:

i. '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 GMOs are labelled and traceable at all stages of them being placed on the market. It establishes the system for assigning unique identifiers to GMOs;

ii. 'Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms' regulates the export of GMOs from the EU to third (non-EU) countries. The basic requirement is for the country intending to export a GMO 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 both Parties);

iii. '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 GMOs under Directive 2001/18/EC to specify a unique identifier code for the specific GMO and sets a specified format and method for assigning each code. Regulations 1830/2003 and 1946/2003 also require the application of unique identifiers.

2.5 There are further implementing Regulations in the United Kingdom as follows:

i. Council Decision 2002/812/EC specifies a standard format for summarising applications for consent to market GMOs;

ii. Commission Regulation (EC) No 65/2004 establishes a system for the development and assignment of unique identifiers for GMOs;

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

2.6 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?

2.7 Prior to exit day, various secondary legislation made minor and technical changes to ensure that retained EU legislation and domestic UK legislation enforcing it would continue to work effectively. References to the EU, EU institutions and EU administrative processes were changed to UK equivalents and legal references updated to refer to the relevant UK legislation. Since those pieces of secondary legislation were made, the UK and the EU adopted the Withdrawal Agreement

including the Protocol. EU legislation on GMOs mentioned above (together with legislation made under it) is included in Annex 2 to the Protocol as follows:

i. Regulation (EC) No 1830/2003;
ii. Regulation (EC) No 1946/2003;
iii. Part C of Directive 2001/18/EC.

2.8 The inclusion of this EU legislation in Annex 2 to the Protocol means further changes are needed to ensure that the UK's obligations under the Protocol are given effect and that retained EU legislation and domestic legislation enforcing it in Great Britain will continue to work effectively. Changes need to be made to references to the UK, UK institutions and UK administrative processes and UK legislation to refer to GB equivalents.

2.9 For this purpose, this instrument amends:

i. the Genetically Modified Organisms (Amendment) (England) (EU Exit) Regulations 2019 (S.I. 2019/88);
ii. the Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/90);
iii. the Food and Farming (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/759);
iv. the Environment, Food and Rural Affairs (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/778);

2.10 A further minor amendment is also needed to revoke a provision in one piece of retained EU legislation, which was transferred into UK law, which will have no practical application in Great Britain after the end of the implementation period ("IP").

What will it now do?

2.11 These changes will ensure that the legislation described above works effectively in Great Britain or England (as the case may be) after the end of the IP, as well as ensuring that the Protocol is implemented. Each Administration of GB will continue to be able to make its own decisions about the release of GMOs in its territory. The existing processes for each Administration reaching its own decisions at national level will continue as now. This includes decisions on the marketing of GMOs, as well as approval for release or marketing.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see section 24 of the European Union (Withdrawal) Act 2018 and the territorial application of this instrument is not limited by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the United Kingdom.

4.2 The territorial application of this instrument is the United Kingdom.

4.3 The retained EU law is incorporated into domestic law under section 3 of the European Union (Withdrawal) Act 2018 save insofar as it applies to Northern Ireland for the purposes of the Protocol. Accordingly, the amendments made by this instrument will be of no practical application in Northern Ireland as the Protocol instead applies the EU law provisions in Northern Ireland.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State, Victoria Prentis MP, has made the following statement regarding Human Rights:

"In my view the provisions of the Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is being made under sections 8(1) and 8C of the European Union (Withdrawal) Act 2018 ("the 2018 Act") to amend retained EU legislation and existing UK legislation (including legislation previously made under the 2018 Act) relating to the control and movement, release and marketing of GMOs. These amendments are needed to implement the Protocol in the Withdrawal Agreement.

6.2 EU Exit SIs made in 2019 ensured that legislation enforcing the movement, release and marketing of GMOs continued to be operable when the UK left the European Union.

6.3 EU Exit SIs now need to be revisited to ensure that they remain operable after the end of the IP, and to ensure that the Protocol is correctly implemented.

7. Policy background

What is being done and why?

7.1 There is no change in policy.

7.2 The EU established a legal framework governing the movement and marketing of GMOs. UK legislation was put in place to implement the EU legislation in the UK at the appropriate time. EU Exit SIs were made in 2019 to ensure that EU legislation was transferred into UK law when the UK left the EU.

7.3 This instrument makes various amendments to EU Exit SIs which are needed to implement the Protocol.

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

8.1 This instrument is being made using the powers in sections 8 and 8C of the 2018 Act to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the UK from the European Union and to deal with matters arising out of the Protocol. 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 in connection with the provision being made in exercise of the power in section 8 of the 2018 Act.

9. Consolidation

9.1 None. Defra does not intend to consolidate relevant legislation.

10. Consultation outcome

10.1 This instrument was not subject to consultation because its purpose is solely to implement the Protocol, as well as to ensure the retained EU legislation, as it applies in Great Britain, can function. There are no changes to the current policy framework.

10.2 Defra has engaged with all UK Devolved Administrations during the development of the instrument. Defra also engaged with parties with an interest in GMOs, such as umbrella industry organisations representing companies active in agricultural bio-technology; establishments interested in research in GMOs; Non-Government Organisations; and a selection of environmental campaigning communities.

11. Guidance

11.1 Guidance is not being provided in relation to this instrument.

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.

12.3 An Impact Assessment has not been prepared for this instrument because its purpose is to maintain existing regulatory standards and so there is expected to be minimal impact on business.

13. Regulating small business

13.1 This instrument applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses because no impact is expected on small businesses.

14. Monitoring & review

14.1 As this instrument is made under the 2018 Act, no review clause is required.

15. Contact

15.1 Ivy Wellman at Defra Telephone: 020 8026 3287 or email: ivy.wellman@defra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Lucy Foster at Defra, Telephone: 020 8026 3584 or email: lucy.foster@defra.gov.uk can confirm that this Explanatory Memorandum meets the required standard.

15.3 Victoria Prentis MP at the Department of Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

Annex

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/Sifting Committees
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 7	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 offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
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.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

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

1. Appropriateness statement

1.1 The Parliamentary Under Secretary of State, Victoria Prentis 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 2020 do no more than is appropriate".

1.2 This is the case because the instrument provides for the continued effective functioning of the policy regimes described in section 2.1 of this Explanatory Memorandum and removes references to provisions of EU law which have no practical effect in Great Britain.

2. Good reasons

2.1 The Parliamentary Under Secretary of State, Victoria Prentis 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 this instrument, and I have concluded they are a reasonable course of action".

2.2 These are that without this instrument deficiencies would remain in retained EU law as it applies in Great Britain.

3. Equalities

3.1 The Parliamentary Under Secretary of State, Victoria Prentis MP, has made the following statement(s):

"The instrument does 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."

3.2 The Parliamentary Under Secretary of State, Victoria Prentis MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Victoria Prentis, MP, 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."

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this Explanatory Memorandum.