

**Explanatory Memorandum to the Genetically Modified Organisms
(Deliberate Release and Transboundary Movement) (Miscellaneous
Amendments) (Wales) (EU Exit) Regulations 2019**

This Explanatory Memorandum has been prepared by the Plant Health and Environment Protection Branch within the Economy, Skills and Natural Resources Department and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1

Minister/Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019.

I have made the statements required by the European Union (Withdrawal) Act 2018. These statements can be found in Part 2 of the annex to this memorandum.

Lesley Griffiths
Minister for Environment, Energy and Rural Affairs
27 February 2019

PART 1

1. Description

- 1.1 This instrument makes minor and technical changes to ensure the above legislation is operable in a UK-only context.
- 1.2 This instrument comes into force on “exit day”, which section 20(1) of the European Union (Withdrawal) Act 2018 defines as 29 March 2019 at 11.00pm.
- 1.3 The instrument makes no policy changes to the way the existing legislation operates. All changes make only the technical drafting fixes required to maintain continuity of approach after EU-exit.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

- 2.1 This instrument is being made using the powers conferred by paragraph 1(1) of Schedule 2 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 (c.16) (the “2018 Act”) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.
- 2.2 It also (in exercise of the powers conferred by the European Communities Act 1972 (c.68)) makes amendments to the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 to include references to EEA states and Switzerland where appropriate.
- 2.3 As set out in the Ministerial statement in Annex 2 of this Explanatory Memorandum it is proposed that the instrument be subject to the negative procedure. The instrument makes minor and technical changes and as such should be subject to annulment.
- 2.4 The CLA Committee considered a draft of these regulations on 18 February 2019, and agreed that the negative procedure is appropriate for these regulations. A copy of the published CLA report can be accessed via the following link:
<http://www.assembly.wales/laid%20documents/cr-ld12192/cr-ld12192-e.pdf>

3. Legislative background

- 3.1 This instrument is being made using the power in Part 1 of Schedule 2 to 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 for Environment, Energy and Rural Affairs, Lesley Griffiths has made the

relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

4. Purpose and intended effect of the legislation

What did any relevant EU law do before exit day?

4.1 This instrument amends our existing implementation of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMOs and repealing Council Directive 90/220/EEC (“the Deliberate Release Directive”) which specifies a framework of controls on the release of GMOs. Proposed releases require prior authorisation and this is subject to the GMO in question passing a science-based assessment of its potential impact on human health and the environment. Decisions on whether to approve GMO trial releases are delegated to Member States and regions within Member States. In the UK GMO trial decisions are devolved. Decisions on the release of GMOs for commercial marketing are taken collectively at EU level. In the specific case of GMO seeds for cultivation, the Directive provides discretionary provisions which allow Member States, or devolved Governments with Member States, to block the cultivation of EU-approved seeds in their territory.

4.2 The Directive is implemented in Wales by:

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

This instrument also amends our domestic implementation of Regulation (EC) No. 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, as implemented in Wales by the Genetically Modified Organisms (Transboundary Movements) (Wales) Regulations 2005, which regulates the export of GMOs from the EU to third (non-EU) countries. The key requirement is for the planned first export of a GMO intended for environmental release to be notified to the receiving country to obtain its approval before shipment. The regulation implements requirements of the Cartagena Biosafety Protocol to the United Nations Convention on Biological Diversity (to which the EU and UK are each a Party).

Why is it being changed?

4.3 This instrument applies to policy areas which are a transferred matter for Welsh Ministers under the Government of Wales Act 1998. No change is being made to policy. This instrument provides the continued ability to ensure environmental protection in the UK when it leaves the EU.

4.4 The amendments can be broadly categorised as:

- Removing references to provisions being ‘in accordance with EU legislation’ and other references to EU law or obligations, and instead referring to retained EU law or obligations;
- Copying out definitions within the regulations themselves, instead of referring to definitions that sit within EU Directives, or specifying that references should be to specific ‘versions’ of pieces of EU legislation;
- Updating references to other sets of legislation that will be changed following EU exit or where an update was required anyway due to the reference being to an out of date piece of legislation;
- Changing references from ‘Member State level’ to ‘any law of any part of the UK’; and
- Modifying the provision which requires Welsh Ministers to notify ‘other EU Member States’ about transboundary environmental impacts to reflect Wales’ new status outside of the EU.

What will it now do?

4.5 The instrument 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. The release 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. Wales intends to follow England, Northern Ireland and Scotland’s approach on the release of GMO’s.

5. Consultation

5.1 No formal consultations were carried out in respect of the instrument as its purpose is to resolve operability issues in order to preserve and protect the existing policy regime- it will not introduce any new policy.

6. Regulatory Impact Assessment (RIA)

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

6.2 There is no, or no significant, impact on the public sector.

6.3 The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations. The instrument simply maintains existing laws in a way that works for Wales once the UK leaves the EU. No substantive policy changes will be brought in through this legislation.

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 of the Welsh Ministers under the 2018 Act. The table also sets out those statements that may be required of Ministers of the Crown under the 2018 Act, which the Welsh Ministers have committed to also provide when required. The required statements can be found in Part 2 of this annex.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(7) and 4(3), Schedule 7 <i>Paragraph 3(7) (anticipated to be a requirement on Welsh Ministers in Standing Orders)</i>	The Welsh Ministers exercising powers in Part 1 of Schedule 2 to make a Negative SI Paragraph 3(7) applies to Ministers of the Crown, but Welsh Ministers have committed to make the same statement	A statement to explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation of the CLA Committee (as sifting committee)
Appropriateness	Sub-paragraph (2) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when 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	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	A statement to explain the good reasons for making the instrument and that what is being done is a reasonable course of action.

		Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	<p>A statement to explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them.</p> <p>A statement that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.</p>
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	A statement to 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	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	A statement setting out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved	A statement to explain why it is appropriate to create such a sub-delegated power.

		<p>Authority.</p> <p>Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2 or paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority</p>	
Urgency	Sub-paragraph (2) and (8) of paragraph 7, Schedule 7	Welsh Ministers exercising powers in Part 1 of Schedule 2 but using the urgent procedure in paragraph 7 of Schedule 7	A statement that the Welsh Ministers are of the opinion that it is necessary to make the SI using the urgent procedure and the reasons for that opinion.

Part 2

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

1. Sifting statement(s)

The Minister for Environment, Energy and Rural Affairs, Lesley Griffiths has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 should be subject to annulment in pursuance of a resolution of the National Assembly for Wales (i.e. the negative procedure)”. This is the case because the changes being made are technical in nature and make no substantive changes to how the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 and the Genetically Modified Organisms (Transboundary Movements) (Wales) Regulations 2005 operate.

2. Appropriateness statement

The Minister for Environment, Energy and Rural Affairs, Lesley Griffiths, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the Genetically Modified Organisms (Deliberate Release and Transboundary Movements) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 does no more than is appropriate”. This is the case because all changes being made are solely in order to address deficiencies arising from EU Exit”.

3. Good reasons

The Minister for Environment, Energy and Rural Affairs, Lesley Griffiths, 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”. This is because the provisions ensure that protections provided by The Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 and The Genetically Modified Organisms (Transboundary Movements) (Wales) Regulations 2005 continue to be operable after the UK leaves the European Union.

4. Equalities

- 4.1 The Minister for Environment, Energy and Rural Affairs, Lesley Griffiths, 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.

- 4.2 The Minister for Environment, Energy and Rural Affairs, Lesley Griffiths, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In relation to the instrument, I, Lesley Griffiths, 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”.

- 4.3 Little or no impact on equalities is expected.

5. Explanations

- 5.1 The explanations statement has been made in paragraph 4 (Purpose & intended effect of the legislation) of the main body of this explanatory memorandum.

6. Criminal offences

Not applicable/required.

7. Legislative sub-delegation

Not applicable/required.

8. Urgency

Not applicable/required.