

Explanatory Memorandum to the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) 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) (No. 2) Regulations 2019.

Lesley Griffiths

Minister for Environment, Energy and Rural Affairs

18 November 2019

PART 1

1. Description

- 1.1 This instrument makes technical changes to ensure the above legislation is operable after exit day.
- 1.2 Regulations 1 and 4 of this instrument come into force “immediately before exit day” and regulations 2 and 3 come into force on “exit day”. Section 20(1) of the European Union (Withdrawal) Act 2018 currently defines as 11.00pm on 31 January.
- 1.3 All changes essentially provide 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 As set out in the Ministerial statement in Annex 2 of this Explanatory Memorandum it is proposed that the instrument be subject to the draft affirmative procedure.
- 2.3 The Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (“the Principal Regulations”) were laid on 5 February 2019 and will be revoked and remade, in part, by this amending statutory instrument.
- 2.4 The Constitutional and Legislative Affairs Committee (CLAC) reported on the Principal Regulations on 13 March 2019 and raised a number of technical points. Their report made a number of technical points:
<http://www.assembly.wales/laid%20documents/cr-ld12445/cr-ld12445-e.pdf>
- 2.5 The Welsh Government responded to CLAC’s report on 25 March 2019 addressing each of the technical matters raised by CLAC. In that response, the Welsh Government accepted that many of the issues raised by CLAC necessitated amendments to the Principal Regulations. This statutory instrument makes those amendments.

3. Legislative background

3.1 This instrument is being made using the powers paragraph 1(1) of Schedule 2 and paragraph 21 of Schedule 7 to 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 commitments made by the Welsh Ministers, 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 the obligations and procedures derived from 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. That Directive has already been transposed into domestic law but the transposing domestic instrument requires changes to be operable post-Brexit. Proposed releases of GMOs 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. 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 Deliberate Release Directive provides discretionary provisions which allow Member States, or devolved Governments within Member States, to block the cultivation of EU-approved seeds in their territory.

4.2 The Deliberate Release Directive is implemented in Wales by:

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

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 2002 Regulations 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 devolved matters. This instrument provides the continued ability to ensure environmental protection in Wales when the UK leaves the EU.
- 4.4 As set out in paragraph 2.6, this amending statutory instrument provides for amendments to the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019, to reflect certain technical points raised by CLAC. The amendments are described below.
- 4.5 CLAC queried why the definition of “pre-exit approved product” did not include products approved under the Food and Feed Regulation before exit day. Regulation 2(2) addresses this deficiency.
- 4.6 CLAC identified that provisions within the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019, appeared to remove the 10 year cap for the marketing of GMOs.
- 4.7 Regulation 2(10) (4) ensures that the 10 year cap for the marketing of GMOs is maintained post exit from the EU.
- 4.8 CLAC noted the amending provision for Regulation 24(1) (e) of the 2002 Regulations, which replaces this provision with a new provision. Regulation 24(1) (d) deals with the Welsh Ministers’ duties to notify an applicant of their decision. The original 24(1) (e) dealt with action following that decision. However, the new 24(1) (e) requires the Welsh Ministers to take into account certain matters in taking their decision. The committee concluded that new Regulation 24(1) (e) should precede Regulation 24(1)(d), not follow it.
- 4.9 Regulation 2(9) has been amended so as to address this issue.
- 4.10 CLAC highlighted that the duty on Welsh Ministers to publish additional information in the public register concerning GMOs lacked any deadline.
- 4.11 Regulation 2(17) of the 2019 addresses this technical point.
- 4.12 CLAC noted that the reference to the Food and Feed Regulation in Regulation 2 of the 2002 Regulations is treated differently from the references to the “Deliberate Release Directive”, and the “First Simplified Procedure”.
- 4.13 This amending statutory instrument revokes the amendments to the definition made by 2019/379 as that definition is amended by a separate SI (the Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019, which transpose Directive 2018/350) . Regulation 17 of the Rural Affairs, Environment, Fisheries and Food (Miscellaneous Amendments and Revocations) (Wales) Regulations is revoked by Regulations 4(3).

- 4.14 The effect of these Regulations is to avoid any amendment to the definition of the “First Simplified Procedure” under the 2002 Regulations.
- 4.15 Other, more minor amendments to cross references have been made in response to CLAC’s report.

Points raised by CLAC that did not require an amendment for inclusion within this amending statutory instrument

- 4.16 Regulations 2(2)(b) and (c) – “approved product” and “pre-exit product. CLAC noted that the Food and Feed Regulation gave the function of authorising products for marketing to the European Commission, assisted by an EU Committee, and on the basis of a scientific opinion from the European Food Safety Authority (“EFSA”).
- 4.17 CLAC questioned whether the Commission will be able to continue giving authorisations that are recognised in the UK, including in Wales under the Food and Feed Regulation. They pointed out that this would be consistent with the overall intention of the EUWA, to maintain continuity, as far as practicable and for the time being, between pre- and post-Brexit law derived from the EU. CLAC identified the political significance in continuing to recognise marketing certificates for food and feed products made of, or including, genetically-modified ingredients, issued by an EU body. However, CLAC questioned whether there was a need to ensure that, post-Brexit, consents for cultivation of GMOs granted by the Commission should be excluded from the scope of the 2002 Regulations.
- 4.18 The Welsh Government has subsequently confirmed that the food and feed regulation will be amended before it is incorporated into domestic law (see the Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019/705). As a result of those amendments, the EU Commission will have no role in approving the marketing or cultivation of genetically modified organisms after the UK leaves the European Union. Therefore, there is no need to exclude from the ambit of “approved product” any post-exit consents to cultivate since no such consents can exist.
- 4.19 Regulation 2(13) – register in relation to application to market GMO. Regulation 2(13) amends regulation 35 of the 2002 Regulations by inserting an obligation to include particulars detailed under a new paragraph (3A) within the register required by section 122 of the Environmental Protection Act 1990. CLAC suggested it would be beneficial to set out where equivalent obligations on the EU Commission arose under the law as it currently stands. The Welsh Government can confirm that those obligations arise under Articles 24 and 13(h) of the 2001/18EC Directive.
- 4.20 For completeness, one issue regarding the new regulation 35(7) should be addressed. That provision requires certain information to be placed on the register but, unlike in other cases dealt with by regulation 35, no time limit is specified for the fulfilment of that obligation. This is in contrast to the position under the current

regulations. The reason for this change is that the new 35(7) is very different in character from the current provision bearing that number.

- 4.21 The current 35(7) requires consents to market granted by other EU member states to be placed on the register. Regulation 36(8) requires this to be done within 14 days of the information being received. Whilst the UK is a member of the EU this is entirely appropriate.
- 4.22 The new 35(7) imposes an obligation to place on the register consents to market granted by EU member states prior to exit day. Due to the obligation of the current 35(7) almost all such consents should already have been placed on the register in any event. This requirement is aimed at all consents granted prior to exit day – as without an enduring obligation to maintain the requirement for these consents to be on the register, they could simply be removed. The two categories below are the two most likely scenarios of where a consent might not already be on the register. But the requirement also covers consents that, for some reason (including administrative error) were not placed on the register.
- (1) Those consents only received by Welsh Ministers less than 14 days before exit day.
 - (2) Those consents which are granted prior to exit day but which are not been received by Welsh Ministers until after exit day.

The current provisions do not cover such consents.

- 4.23 For the above reasons, the new 35(7) is substantially different to the current provision. It is not a requirement that attaches to future consents but rather to an unknown number of existing consents, including those already placed on the register. In these circumstances the Welsh Government does not consider it necessary to impose a requirement that the material be put on the register within a certain time. Rather, the default position that the obligation must be fulfilled within a reasonable time will apply. The requirement arises immediately at exit day and then applies on an enduring basis. The requirement should be satisfied immediately as all pre-exit consents should already be on the register.
- 4.24 The Welsh Government notes that the equivalent England only SI contains provisions which produce an identical effect.

What will it now do?

- 4.25 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. The four administrations within the United Kingdom intend to pursue a common approach to procedures governing the release and

management of GMOs. Wales therefore intends to align its procedures for achieving these aims with those of England, Northern Ireland and Scotland.

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.

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
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. Welsh Ministers have committed to make the same statement when 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.
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	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. A statement that the Minister has

		committed to make the same statement when exercising powers in Schedule 2	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	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 18(1), 9 and paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority. 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	A statement to explain why it is appropriate to create such a sub-delegated power.

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.
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Part 2

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

1. Statement under paragraph 7(2) of Schedule 7 to the European Union (Withdrawal) Act 2018

This is not required.

2. Appropriateness statement

2.1 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:

2.2 “In my view the Genetically Modified Organisms (Deliberate Release and Transboundary Movements) (Miscellaneous Amendments) (Wales) (EU Exit) (No.2) 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

3.1 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:

3.2 “In my view there are good reasons for the provisions in this instrument, and I have concluded its provisions represent 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

This is not required.