

SL(5)454 – The Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) Regulations 2019

Background and Purpose

These Regulations amend the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (“the 2002 Regulations”) and the Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (“the 2019 Regulations”).

Regulations 3 to 8 of these Regulations amend the 2002 Regulations. The 2002 Regulations implement Directive 2001/18/EC relating to the deliberate release of genetically modified organisms (“the 2001 Directive”). These amendments are necessary to implement Commission Directive (EU) 2018/350 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms (“the 2018 Directive”).

Regulation 3 amends the definition of the 2001 Directive to reflect the amendments made to it by the 2018 Directive.

The amendments made by regulations 4 to 7 relate to the information to be contained in applications for consent to release genetically modified higher plants in relation to trials. They also make provision in relation to the information to be included in applications for consent to release genetically modified higher plants for commercial purposes. These changes are necessary owing to the substitution, by the 2018 Directive, of Annexes III and IIIB to the 2001 Directive.

Regulation 8 makes minor changes to Schedule 3 to the 2002 Regulations.

Regulation 9 amends the 2019 Regulations which come into force on exit day and will amend Schedule 3 to the 2002 Regulations. The purpose of the amendment is to omit a provision which regulation 8 of these Regulations will render redundant.

Procedure

Negative.

Technical Scrutiny

The following 4 technical points are identified for reporting under Standing Order 21.2 in respect of this instrument.

1. Standing Order 21.2(vi) that its drafting appears to be defective or it fails to fulfil statutory requirements

The transposition deadline of 29 September 2019 for the 2018 Directive has been missed. The Explanatory Memorandum states that an earlier decision was taken collectively by the UK Administrations not to transpose the 2018 Directive as part of preparations to exit the EU on 29 March 2019. However, following the extension of the EU Exit date to 31 October 2019, the UK administrations have agreed to transpose the 2018 Directive but this decision was taken with only a short timeframe to transpose. We



ask the Welsh Government whether it has been in correspondence with the European Commission regarding the late implementation of the 2018 Directive.

2. Standing Order 21.2(vi) that its drafting appears to be defective or it fails to fulfil statutory requirements

In regulation 7, which inserts Schedule 1A into the 2002 Regulations, new paragraph 15(c) contains a cross-reference to paragraph 14(f). We believe the cross-reference should be to paragraph 14(g), not paragraph 14(f).

3. Standing Order 21.2(vi) that its drafting appears to be defective or it fails to fulfil statutory requirements

- i. Section B.4(f) of Annex III B I of the 2001 Directive (which is inserted by the Annex to the 2018 Directive) requires the following information in relation to the release of genetically modified higher plants:

"Description of the methods and procedures to:

- (i) avoid or minimise the spread of the GMHPs beyond the site of release;*
- (ii) protect the site from intrusion by unauthorised individuals;*
- (iii) prevent other organisms from entering the site or minimise such entries."*

These Regulations do not appear to include a corresponding requirement, Schedule 1 of the 2002 Regulations only requires information on *"methods and procedures to protect the site"*. We ask why the text of the 2018 Directive quoted above has not been reflected in the Regulations?

- ii. In regulation 7 (which inserts Schedule 1A into the 2002 Regulations) new paragraph 18(c) requires information on *"experimental design including statistical analysis"* to be provided in an application for consent to market genetically modified higher plants. The 2018 Directive provides the following:

"Experimental design and statistical analysis of data from field trials for comparative analysis:

- (i) Description of field studies design*
- (ii) Description of relevant aspect of the receiving environments*
- (iii) Statistical analysis."*

We ask why the text of the 2018 Directive quoted above has not been reflected in the Regulations?

4. Standing Order (vii) that there appear to be inconsistencies between the meaning of its English and Welsh texts

- i. In regulation 6(13) the definition of *"plant species"* is:

"(a) wild and weedy relatives, or
(b) crops."



In the Welsh version of the Regulations the word "or" ("neu") is missing.

- ii. In regulation 7 of the Welsh language version, which inserts Schedule 1A into the 2002 Regulations, new paragraph 3(e) should be 3(dd).
- iii. In regulation 7, which inserts Schedule 1A into the 2002 Regulations, new paragraph 13 requires a "*description of the trait or traits and characteristics of the genetically modified plant which have been introduced or modified*". Both "traits" and "characteristics" translate as "nodweddion". We appreciate the difficulty of translating these provisions, but we ask the Welsh Government whether it is satisfied that both the English and the Welsh texts properly implement the relevant parts of the 2018 Directive.
- iv. In regulation 7, which inserts Schedule 1A into the 2002 Regulations, new paragraph 22(a) requires an applicant for consent to market genetically modified higher plants to provide information on "*the adverse effects arising*" in relation to certain scenario. The Welsh language version reads "*the adverse environmental effects arising*" ("*effeithiau amgylcheddol andwyol sy'n deillio o hynny*"). This inconsistency does have an effect on the meaning of the provision as the Regulations differentiate between adverse effects on the environment and on human and animal health.

The same inconsistency occurs in new paragraph 24(a)(i) with the wording "*adverse effect arising*".

Merits Scrutiny

No merits points are identified for reporting under Standing Order 21.3 in respect of this instrument.

Implications arising from exiting the European Union

These Regulations implement EU obligations in relation to the deliberate release of genetically modified organisms, and therefore the Regulations will form part of retained EU law after exit day.

Government Response

A government response is required.

Committee Consideration

The Committee considered the instrument at its meeting on 21 October 2019 and reports to the Assembly in line with the reporting points above and also to highlight issues as a result of the UK exiting the EU.

