
EXPLANATORY NOTE

(This note is not part of the Regulations)

Regulations 3 to 8 of these Regulations amend the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 ([S.I. 2002/3188 \(W. 304\)](#)) (“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 (O.J. No L 67, 9.3.2018, p. 30) (“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 (amendments to regulation 12 of, and Schedule 1 to, the 2002 Regulations by regulations 4 and 6 respectively). 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 (amendments to regulation 17 of, and the insertion of Schedule 1A to, the 2002 Regulations by regulations 5 and 7 respectively). 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 Genetically Modified Organisms (Deliberate Release and Transboundary Movement) (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 ([S.I. 2019/379 \(W. 94\)](#)) 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 in [S.I. 2019/379](#) which regulation 8 of these regulations will render redundant.

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.