

Explanatory Memorandum to the Genetically Modified Organisms (Deliberate Release) (Amendment) (Wales) 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'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) (Amendment) (Wales) Regulations 2019.

Lesley Griffiths

Minister for Environment, Energy and Rural Affairs

8 October 2019

1. Description

These Regulations implement, in relation to Wales, Commission Directive (EU) 2018/350 amending Directive 2001/18/EC of the European Parliament and of the Council. These Regulations achieve this by amending the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (S.I. 2002/3188) (W. 304) (the 2002 Regulations).

Directive (EU) 2018/350 makes more detailed provision in respect of the environmental risk assessments, which must be made before the release of Genetically Modified Organisms (GMOs). There is a particular emphasis on the information, which must be provided before the release of Genetically Modified Higher Plants. There is no change of policy in this area.

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

The transposition deadline for Directive (EU) 2018/350 was 29 September 2019 and this deadline has been missed. An earlier decision was taken collectively by the UK Administrations not to transpose Directive 2018/350 as part of preparations to exit the EU on 29 March 2019. However, following the extension to the EU Exit date to 31 October 2019, the UK administrations have agreed to transpose Directive 2018/350 but this decision was taken with only a short timeframe to transpose.

3. Legislative background

These Regulations are made in exercise of the powers conferred on Welsh Ministers by section 2(2) of the European Communities Act 1972 and section 111(4) and (11) of the Environmental Protection Act 1990 (the 1990 Act).

The National Assembly for Wales was designated under the European Communities (Designation) (No. 4) Order 2003 (SI 2003/2901) in relation to measures relating to the control and regulation of the deliberate release, placing on the market and transboundary movement of genetically modified organisms. By virtue of paragraphs 28(1) and 30 of Schedule 11 to the Government of Wales Act 2006 (the 2006 Act), these functions were transferred to the Welsh Ministers.

The functions of the Secretary of State under the provisions of the 1990 Act were transferred to the National Assembly for Wales under Article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672). By virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006 these functions were then further transferred to the Welsh Ministers.

These Regulations amend the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 (the 2002 Regulations), which give effect, in relation to Wales, to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms. The 2002 Regulations, amongst other things, set out the procedures to follow when seeking consent from the Welsh Ministers to trial or market GMOs. The 2002 Regulations provide a framework for the harmonised marketing of safe products produced from GMOs, and ensure that only safe GMOs are released. Any approval

for the release of a GMO is conditional upon it passing a science-based assessment of its potential impact on human health and the environment.

The amendments to the 2002 Regulations made by these Regulations are required to implement amendments to Directive 2001/18/EC made by Commission Directive (EU) 2018/350. Commission Directive (EU) 2018/350 updates four of the technical Annexes in Directive 2001/18/EC. The amendments to the annexes align them with technical guidance that was published by the European Food Safety Authority (EFSA) in 2010. The amendments relate to the methodology of the environmental risk assessment, its structure, content, and level of detail.

These Regulations are being made under the negative resolution procedure.

4. Purpose & intended effect of the legislation

No changes are being made to policy.

Following a request from the EU Commission in 2010, the European Food Safety Authority (EFSA) produced non-statutory guidance, which added detail to the established principles for environmental risk assessments (ERA) in applications to release and market genetically modified plants, as set out in Directive 2001/18/EC. Commission Directive (EU) 2018/350 amends Directive 2001/18/EC by aligning it with the EFSA's guidance. The alignment, in particular, adds more detail on the information that should be included in applications to market genetically modified plants. The requirement to provide this information in support of an application has no practical impact for an applicant's ERA as it has been supplied in applications for the last 9 years.

In practice, most applications to market GM plants are submitted under alternative legislation (Regulation (EC) No. 1829/2003 on genetically modified food and feed) because that legislation allows applicants to seek authorisation to import, cultivate and use genetically modified plants for food and feed under one process. The EU has already adopted Commission Implementing Regulation (EU) No. 503/2013 on applications made under Regulation (EC) No. 1829/2003, and Commission Directive (EU) 2018/350 aligns to that Regulation. The EFSA has applied the requirements set out in the 2018 Directive in relation to all applications to release and market genetically modified plants since 2010.

5. Consultation

The Food Standards Agency (FSA) Wales was consulted in accordance with section 126(5) of the Environmental Protection Act 1990, about the proposed changes to the 2002 Regulations as a consequence of implementing Commission Directive (EU) 2018/350. In their response to the consultation, the FSA Wales recognised these Regulations do not represent a change in policy and are content for the amendments to be made.

6. Regulatory Impact Assessment

There is no significant impact on the public sector beyond minimal administrative input to amend application forms.

An Impact Assessment has not been prepared for these Regulations because there is expected to be no additional impact on business. There is no change in policy, and the requirement to provide the stated information in support of an application has no practical impact for an applicant's ERA as it has been supplied on a non-statutory basis in applications for the last nine years. There is no impact on the statutory duties or on the statutory partners as set out in the Government of Wales Act 2006.