EXPLANATORY MEMORANDUM TO

The Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations (Northern Ireland) 2019

2019 No. 223

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department of Agriculture, Environment and Rural Affairs to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under Section 2 (2) of the European Communities Act 1972 and Article 8 of the Genetically Modified Organisms (Northern Ireland) Order 1991 and is subject to the negative resolution procedure.

2. Purpose

2.1. The purpose of these Regulations is to implement, in relation to Northern Ireland, 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) Regulations (Northern Ireland) 2003 (the 2003 Regulations).

2.2. 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 particular emphasis on the information which must be provided before the release of Genetically Modified Higher Plants. Applications for consent to release these organisms have provided this information since 2010. There is no change in policy; releases will still require prior approval from the Department of Agriculture, Environment and Rural Affairs.

2.3. Similar domestic legislation has been introduced in England, Scotland and Wales.

3. Background

3.1. This instrument amends the 2003 Regulations, and is made under section 2(2) of the European Communities Act 1972 and Article 8 of the Genetically Modified Organisms (Northern Ireland) Order 1991. The 2003 Regulations give effect, in relation to Northern Ireland, to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (2001/18/EC). The 2003 Regulations, amongst other things, set out the procedures to follow when seeking consent from the Department of Agriculture, Environment and Rural Affairs to trial or market GMOs. The 2003 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.

3.2. The amendments to the 2003 Regulations made by this instrument 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 amendment relates to the methodology of the environmental risk assessment, its structure, content, and level of detail.

3.3. No changes are being made to policy.

3.4. Following a request from the EU Commission in 2010, the EFSA produced nonstatutory guidance which added detail to the established principles for environmental risk assessments (e.r.a.) 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 e.r.a. as it has been supplied in applications for the last 9 years.

3.5. In practice, most applications to market Genetically Modified plants are submitted under alternative legislation (Regulation (EC) No. 1829/2003 on genetically modified food and feed) because it 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. As outlined above, the EFSA has applied the requirements in relation to all applications to release and market genetically modified plants since 2010.

4. Consultation

4.1. DAERA consulted with the Food Standards Agency, as required by Article 22(5) of the Genetically Modified Organisms (Northern Ireland) Order 1991. As there is no change in policy for interested parties to comment upon, or shape, engagement was for information only.

5. Equality Impact

5.1. There are no equality impact implications arising from the Regulations.

6. Regulatory Impact

6.1. There are no regulatory impact implications arising from the Regulations.

7. Financial Implications

7.1. There are no additional costs on UK business arising from the Regulations.

8. Section 24 of the Northern Ireland Act 1998

8.1. The Regulations do not contravene Section 24 of the Northern Ireland Act 1998.

9. EU Implications

9.1. Under EU law, the UK as a Member State (MS) is obliged to implement the Directive. There is therefore a genuine risk of infraction for further delay on introducing legislation to meet EU obligations on the Release of Genetically Modified Organisms.

10. Parity or Replicatory Measure

10.1. The Regulations will ensure parity with legislation being introduced by the other UK administrations and achieve a consistent approach, especially in relation to the authorisation of the release into the environment of Genetically Modified Organisms.

11. Additional Information

11.1. None.