

## **POLICY NOTE**

### **The Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019**

**S.S.I. 2019/57**

The above instrument (“the instrument”) was made in exercise of the powers conferred by section 2(2) of the European Communities Act 1972, paragraph 1(1) and (3) of schedule 2, and paragraph 21 of schedule 7 of the European Union (Withdrawal) Act 2018, and all other relevant powers. The instrument is subject to negative procedure.

#### **Purpose of the instrument**

To fix deficiencies (arising from the withdrawal of the United Kingdom from the European Union) in Scots law about genetically modified organisms, and make other minor changes.

#### **Policy Objectives**

The instrument will ensure that, on exit day, two Scottish statutory instruments continue to be operable after EU exit. These are, the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (“the 2002 Regulations”) and the Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005. It also makes, before exit day, a few changes to the 2002 Regulations to clarify and adjust some provisions.

#### **Explanation of the law being amended by the regulations**

##### The 2002 Regulations

The 2002 Regulations implement, for Scotland, Directive 2001/18/EC (“the Directive”) on the deliberate release into the environment of genetically modified organisms (“GMOs”) which aims to protect human health and the environment in relation to the placing of GMOs on the market and the deliberate release of GMOs into the environment for research purposes. But the consenting requirements of this regime do not apply in relation to certain exempt GMOs which are authorised under other equivalent EU regimes, such as those for GM food and feed, human and veterinary medicines, and the contained use of GM microorganisms.

Before placing on the market GMOs (as or in products), a person must obtain consent from the competent authority of the EU member State where the GMOs are to be placed on the market for the first time. Where a product has consent to be placed on the market and is marketed in accordance with that consent (including for any use permitted by that consent), then no other additional consents are needed for the GMOs to be used for that permitted purpose. If a person doesn’t have consent to market the GMOs, wants instead to release them for other purposes (such as field trials), the person must apply for consent to the competent authority of the EU member State within whose territory the release is to take place. In Scotland, the Scottish Ministers are the competent authority. Accordingly, consents are required both to market GMOs, and also to release them for other purposes (e.g. field trials).

### Consents to market GMOs

Consents to market GMOs may include some GM crops (including for commercial growing in any part of the EU, albeit the marketing of GM food and feed is authorised under a different EU regime), the import and movement of GM seed in the EU, and the import and movement of certain GMOs not covered by other EU regimes (such as GM cut flowers) in the EU. Unlike consents to release (see below), although the competent authority is responsible for granting consents for marketing release applications it has received, it can only do so after the application has been assessed and determined at EU level.

### Consents to release GMOs for other purposes, including research

Research trials can be field trials of GM crops or medical trials of GM vaccines or drugs. Consents for research trials only apply in the country receiving the application. The competent authority will arrange for the application to be assessed by a scientific committee. In the UK, this is the Advisory Committee on Releases to the Environment (ACRE). The competent authority will arrange a public consultation and, after considering the advice of the scientific committee and any representations from public bodies and/or the general public, will decide whether or not to grant consent. The competent authority is responsible for notifying the applicant of its decision (and, if the decision is to reject the application, their reasoning) and publishing their decision in the interests of transparency.

### Cultivation opt out

Subject to a “safeguard clause”, EU member States may not prohibit, restrict or impede the placing on the market of EU approved GMOs. However, during the approvals process of a given GMO, a member State may demand that the geographical scope of the consent is adjusted to the effect that all or part of the territory of that member State is excluded from GM cultivation - this is also known as the GM cultivation “opt out”. In the event that the applicant refuses to adjust the scope as so demanded, or if no such demand is made within the prescribed timeframe, a member State may still adopt measures restricting or prohibiting cultivation in their territory provided that the grounds for doing so comply with EU law, are reasoned, proportionate and non-discriminatory. The grounds also must not conflict with the environment risk assessment carried out in accordance with the Directive.

### Other regulations

The Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005 make provision for the enforcement of Regulation (EC) No. 1946/2003 on the transboundary movements of GMOs.

### **Reasons for and effect of the proposed change or changes on retained EU law**

The instrument makes provision, on exit day, to address deficiencies (arising from the withdrawal of the UK from the EU) in the 2002 Regulations and in the Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005. In particular, it fixes provisions which refer to the EU or EU institutions, and those that refer to EU member states or their competent authorities. Where appropriate, it also substitutes references to EU law, with references to retained EU law. In doing so, rather than modify the application of certain Annexes to the Directive, the text of some Annexes are replicated (with the necessary

modifications) in new schedules of the 2002 Regulations. Part 2 of the amending SSI also clarifies and adjusts some provisions of the 2002 Regulations before exit day.

### **Statements required by European Union (Withdrawal) Act 2018**

#### **Statement that in their opinion Scottish Ministers consider that the regulations do no more than is appropriate**

The Minister for Rural Affairs and the Natural Environment has made the following statement: “In my view the Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019 do no more than is appropriate.”.

#### **Statement as to why the Scottish Ministers consider that there are good reasons for the regulations and that this is a reasonable course of action**

The Minister for Rural Affairs and the Natural Environment has made the following statement: “In my view there are good reasons for the provisions in this instrument, and I consider that they are a reasonable course of action. This is because the amendments made by it; will prevent, remedy or mitigate deficiencies arising from the withdrawal of the UK from the EU; are minor and technical in nature; and are not intended to make any significant change to the policy outcomes delivered by the legislation that it amends.”.

#### **Statement as to whether the SSI amends, repeals or revokes any provision of equalities legislation, and, if it does, an explanation of that amendment, repeal or revocation**

The Minister for Rural Affairs and the Natural Environment has made the following statement: “In my view the Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019 do 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.”.

#### **Statement that Scottish Ministers have, in preparing the regulations, 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**

The Minister for Rural Affairs and the Natural Environment has made the following statement: “In my view, in preparing the Genetically Modified Organisms (EU Exit) (Scotland) (Amendment) Regulations 2019, the Scottish Ministers 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.”.

### **Additional information provided for EU Exit instruments in terms of the protocol agreed between the Scottish Government and the Scottish Parliament**

#### **Statement that Scottish Ministers have, in preparing the regulations, had due regard to the guidance principles on the environment and animal welfare**

The Minister for Rural Affairs and the Natural Environment has made the following statement: “In my view, in preparing the the Genetically Modified Organisms (EU Exit)

(Scotland) (Amendment) Regulations 2019, the Scottish Ministers have had due regard to the guidance principles on the environment and animal welfare.”.

**Statement explaining the effect (if any) of the regulations on rights and duties relating to employment and health and safety and matters relating to consumer protection (so far as is within devolved competence)**

The Minister for Rural Affairs and the Natural Environment has made the following statement: “In my view, the instrument has no effect on rights and duties relating to employment and health and safety matters relating to consumer protection (so far as is within devolved competence).”.

**An indication of how the regulations should be categorised in relation to the significance of the change proposed**

The change proposed is considered to be of low significance. The amendments made by the instrument will prevent, remedy or mitigate deficiencies arising from the withdrawal of the UK from the EU, are minor and technical in nature, and are not intended to make any significant change to the policy outcomes delivered by the legislation that it amends.

**Statement setting out the Scottish Ministers’ reasons for their choice of procedure**

It is considered that the instrument ought to be subject to negative procedure as the changes made by it to prevent, remedy or mitigate deficiencies arising from the withdrawal of the UK from the EU are minor and technical in nature, and are not intended to make any significant change to the policy outcomes delivered by the legislation that it amends.

**Consultation**

No consultation was conducted as no change in policy is intended as a result of the amendments.

**Impact Assessments**

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

**Financial Effects**

The Minister for Rural Affairs and the Natural Environment confirms that no Business and Regulatory Impact Assessment (BRIA) is necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Scottish Government  
Agriculture and Rural Economy Directorate

6 February 2019