13 November 2018

Dear Edward,

THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (EU EXIT) REGULATIONS 2018

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to the exercise of powers by UK Ministers under the European Union (Withdrawal) Act 2018 in relation to proposals within the legislative competence of the Scottish Parliament.

As you know, Mike Russell wrote to the Conveners of the Finance & Constitution and Delegated Powers and Legislative Reform Committees on 11 September setting out the Scottish Government's views on EU withdrawal. That letter also said that we must respond to the UK Government's preparations for a No-Deal scenario as best we can, despite the inevitable widespread damage and disruption that would cause. It is our unwelcome responsibility to ensure that devolved law continues to function on and after EU withdrawal.

I attach a notification which sets out the details of the SI which the UK Government propose to make and the reasons why I am content that Scottish devolved matters are to be included in these SIs. This is one of a series of such notifications that we and other Ministerial colleagues will be sending to Parliamentary Committees over the coming weeks.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

I look forward to hearing from you within 28 days from the date of this letter.

MAIRI GOUGEON

Scottish Ministers, special advisers and the Permanent Secretary are covered by the terms of the Lobbying (Scotland) Act 2016. See www.lobbying.scot

St Andrew’s House, Regent Road, Edinburgh EH1 3DG
www.gov.scot
The Genetically Modified Organisms (Amendment) (EU) (Exit) Regulations 2018

Notification to the Scottish Parliament

Name of the instrument and summary of proposal

The Genetically Modified Organisms (Amendment) (EU Exit) Regulations 2018 (the "EU Exit SI") is proposed to be made under section 8(1) of the European Union (Withdrawal) Act 2018, and also section 2(2) of the European Communities Act 1972, to amend some domestic law relating to genetically modified organisms and some associated retained EU law. This instrument is to ensure that EU and UK legislation establishing the regime that controls the release and marketing of genetically modified organisms (GMOs) will continue to be operable when the UK leaves the European Union (EU).

Explanation of law that the proposals amend

Food and feed generally originates from plants and animals grown and bred by humans for several thousand years. Over time, those plants and animals with the most desirable characteristics were chosen for breeding the next generations of food and feed. In the last 30 or so decades, it has become possible to modify the genetic make-up of living cells and organisms using modern biotechnology. The genetic material is modified artificially to give it a new property (e.g. a plant's resistance to a disease, insect or drought, a plant's tolerance to a herbicide, improving a food's quality or nutritional value, increased yield). Such organisms are called "genetically modified organisms" (GMOs). Food and feed which contain or consist of such GMOs, or are produced from GMOs, are called "genetically modified (GM) food or feed".

Domestic law on GMOs is mostly derived EU GMO legislation which aims to:

- Protect human and animal health and the environment by introducing a safety assessment of the highest possible standards at EU level before any GMO is placed on the market.
- Put in place harmonised procedures for risk assessment and authorisation of GMOs that are efficient, time-limited and transparent.
- Ensure clear labelling of GMOs placed on the market in order to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice.
- Ensure the traceability of GMOs placed on the market.

Summary of the proposals

This notification covers proposals to fix deficiencies arising from EU Exit in the following GMO legislation which extends to, and applies in, Scotland:

- The Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996
These domestic Regulations supplement provision in Part VI (genetically modified organisms) of the Environmental Protection Act 1990, which restricts the import and acquisition of GMOs. Amendments to these regulations are proposed to update out-of-date references to legislation that has been superseded. No changes are being made to policy.

- **Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.**
  This EU Regulation is directly applicable in Scotland. It requires authorised GM products to be traced and labelled at all stages of their being placed on the market. The Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004 make further provision for enforcement.

  Amendments to these regulations are proposed to remove and/or replace references to EU institutions, other member states etc that will be no longer applicable after EU exit and, where relevant, replace these with suitable UK/devolved authority references. In addition, it is proposed to amend/update references to other legislation where that has since been superseded and for references to Community legislation, substitute “retained EU law”.

- **Regulation (EC) 1946/2003 on transboundary movements of GMOs.**
  This EU Regulation is directly applicable in Scotland. It regulates the export of GMOs from the EU to third (non-EU) countries. The key requirement is for the planned first export of a GMO intended for environmental release to be notified to the receiving country to obtain its approval before shipment. The Regulation implements the requirements of the Cartagena Biosafety Protocol to the United Nations Convention on Biological Diversity (to which the UK is a Party). The Genetically Modified Organisms (Transboundary Movement) (Scotland) Regulations 2005 make further provision for enforcement.

  Amendments to these regulations are proposed to remove and/or replace references to EU institutions, other member states etc that will be no longer applicable after EU exit and, where relevant, replace these with suitable UK/devolved authority references. In addition, it is proposed to amend/update references to other legislation where that has since been superseded and, for references to Community legislation, substitute “retained EU law”.

- **Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs.**
  This EU Regulation is directly applicable in Scotland. It requires applicants for GMO marketing approval under Directive 2001/18 and Regulation 1829/2003 (relating to GMOs in food and feed) to specify a unique identifier code for the GMO in question, and sets a specified format and method for assigning each code. Regulations 1830/2003 and 1946/2003 also require unique identifiers.

  Amendments to these regulations are proposed to remove and/or replace references to EU institutions, other member states etc that will be no longer applicable after EU exit and, where relevant, replace these with suitable
UK/devolved authority references. In addition, it is proposed to amend/update references to other legislation where that has since been superseded.

The notification also covers proposals to fix deficiencies arising from EU Exit in the following related EU Decisions which extend to, and apply in, Scotland:

- **Decision 94/730/EC** which sets out simplified procedures that may apply for applications for consent to undertake GM plant trials.
- **Decision 2002/812/EC** specifies a standard format for summarising applications for consent to market GMOs.
- **Decision 2002/813/EC** specifies a standard format for summarising applications for consent to undertake GMO trials.
- **Decision 2003/701/EC** specifies a standard format for consent holders to report on the monitoring and/or outcome of authorised GMO trials.
- **Decision 2004/204/EC** specifies the information that must be included in applications to market genetically modified organisms under Directive 2001/18, and which the Commission makes publicly available.
- **Decision 2009/770/EC** specifies the format of the post-marketing monitoring report that holders of GMO marketing consents are required to complete.
- **Decision 2016/321** prohibits the cultivation of MON810 maize in Member States, or parts of Member States, that chose to opt-out of its cultivation.

Technical amendments are proposed to all of the above to ensure these Decisions will still apply after EU Exit e.g. we propose to remove and/or replace references to EU institutions, other member states etc that will be no longer applicable after EU exit and, where relevant, replace these with suitable UK/devolved authority references. In addition, it is proposed to amend/update references to other legislation where that has since been superseded and, for references to Community legislation, substitute “retained EU law”.

**Why is the change necessary?**

The changes are necessary to ensure that retained EU legislation and the domestic EU legislation enforcing it continues to operate effectively. This includes amending references to the EU, EU institutions and EU administrative processes to UK equivalents; updating legal references to refer to relevant UK legislation; and retaining the requirement for the government to report.

We are continuing to liaise with Defra and the DAs over the final version of the SI and there may yet be some minor technical changes made to the it.

**Scottish Government categorisation of significance of proposals**

Category A. The provisions are making minor technical changes to preserve the functioning of the regulations.
Scottish Ministers agree that the changes constitute a pragmatic approach to addressing deficiencies in the GMO regulatory regimes arising from EU Exit, and ensure continued effective operation of those regimes, including continued high levels of protection for human health and the environment.

Where the UK SIs make provision for exercise of functions – including functions of making regulations - they do so in a manner consistent with the devolution settlement as discussed below, in particular conferring functions either on the Secretary of State acting with the consent of the Scottish Ministers or on the Scottish Ministers directly.

**Impact on devolved areas**

There is expected to be no significant impact on business, charities or voluntary bodies as the SI simply rolls over the EU legislative regime. There is likely to be no significant impact on the public sector.

**Stakeholder engagement/consultation**

We are in regular contact with all our stakeholders regarding the move towards leaving the EU. However, these measures are aimed solely at preserving the functioning of the regulations as they are at present and we have not undertaken any focussed engagement on this basis. We have not undertaken any formal consultation.

**Have Scottish Ministers had regard to the guiding principles on animal welfare and the environment?**

The directly applicable legislation which will be rolled over post-exit and the related implementation/enforcement legislation have already been made with the guiding principles on animal welfare and the environment in mind. The proposed fixes in the EU Exit SI adhere to the spirit of the underlying EU regime – no significant policy changes are proposed.

**Any other impact assessments?**

An Impact Assessment has not been prepared for this instrument because there is expected to be minimal impact on business as the SI relates to the maintenance of existing regulatory standards – and does not infer any policy changes. We have discussed with the UK Government and on this basis, they have assessed there is not a requirement to undertake an impact assessment on this SI.

**Future Governance**

We currently have a Memorandum of Understanding with Defra which may require to be amended/updated in light of Brexit and which we plan to review in due course.

More generally, later this year, Scottish Ministers will consult on the governance gaps that will be created once the UK leaves the EU, with a view to bringing proposals back to the Scottish Parliament on medium and long term governance arrangements once the future relationship is clear. This will include proposals for future monitoring and enforcement.
Summary of reasons for Scottish Ministers’ proposing to consent to UK Ministers legislation

The Scottish Ministers propose to consent to UK SI to fix deficiencies in the GMO related domestic and EU legislation listed above. The approach set out in the UK SIs is realistic, achievable and minimises immediate disruption. It ensures continuity of current arrangements for stakeholders, Governments and regulators and ensures continued protection of human health and the environment.

The Scottish Ministers believe that the changes proposed in the regulations are necessary insofar as falling within devolved competence to secure continuation of effective regulatory regimes. The approach respects the devolution settlement and in the current circumstances where there are UK SIs and/or retained EU law in relation to GMOs which extends to or applies in Scotland and there is a need to prepare for a ‘no deal’ exit from the EU, the Scottish Ministers consider that it is appropriate for the EU Exit SI to also fix this legislation for devolved purposes.

Intended laying date

15 November 2018

Does the Scottish Parliament have 28 days to scrutinise Scottish Minister’s proposal to consent?

Yes

Information about any time dependency associated with the proposal

As the provisions are making small, minor technical changes to preserve the functioning of the regulations, there is no time dependency associated with the proposals.

Any significant financial implications

As the provisions are making small, minor technical changes to preserve the functioning of the regulations, there are no significant financial implications associated with the proposals.