

Business and Regulatory Impact Assessment

**The Genetically Modified
Organisms (Deliberate Release
etc) (Miscellaneous Amendments)
(Scotland) Regulations 2016**

**(amending SSI 2002 No.541 and
transposing EU Directive 2015/412)**

January 2019

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Title of Proposal

The Genetically Modified Organisms (Deliberate Release etc) (Miscellaneous Amendments) (Scotland) Regulations 2016 (amending SSI 2002 No.541 and transposing EU Directive 2015/412)

Purpose and intended effect

- **Background**

EU Directive 2015/412 amends Directive 2001/18/EC as regards the possibility for Member States (MS) to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. The Scottish Government has long been opposed to the cultivation of GM crops in the open environment in order to protect the clean, green status/reputation of Scotland's £14 billion food and drink sector. SG, along with around two thirds of the EU, has already taken advantage of transitional rules in the amending Directive to opt out of growing one EU approved GM maize variety and a number of others where EU approval is currently pending. Currently there are no GM crops grown in Scotland.

Prior to the amending Directive, MS' that did not wish to grow EU approved GM crops only recourse was to take out a "safeguard action". MS would have to provide scientific evidence, other than that already considered in the EU risk assessment, that the GM crop was a risk to human and/or animal health or to the environment. Non-scientific factors e.g. socio-economic factors were not admissible in MS decisions not to cultivate EU approved GM crops.

- **Objective**

To transpose the new provisions in the amending Directive so that Scotland can, if it wishes, opt out of cultivating future EU approved GM crops.

Note: the original intention was for all UK countries to transpose the new provisions in parallel. However, following the EU referendum result, England, Wales and Northern Ireland put their transposition plans on hold (although it now (Dec 2018) looks as though Wales and NI may also transpose). Scotland's position is different as SG is still exploring all avenues to maintain its links with the EU. However, in any event, we expect there to be a transition period after EU Exit during which time we may wish to use these provisions.

- **Rationale for Government intervention**

Use of the new powers in the amending Directive is discretionary. There is no transposition deadline and, coupled with the discretionary nature of the new powers, no **requirement** to transpose.

However, the EU powers cannot be implemented fully and transparently without transposition into domestic law. The powers are essential for SG to deliver its manifesto commitment to continue its opt out of the cultivation of GM crops for the lifetime of the current Parliament.

SG supports the general principle of Member States having more national discretion in relation to EU decisions – it would therefore not be appropriate to forego transposition of the discretionary powers available in this case.

This proposal contributes to the objectives of the [National Performance Framework](#) and Purpose:

- We live in a Scotland that is the most attractive place for doing business in Europe
- We value and enjoy our built and natural environment and protect it and enhance it for future generations
- We reduce the local and global environmental impact of our consumption and production

Consultation

Within Government

- SGLD (Scottish Government Legal Directorate – Rural Affairs Division)
- SASA (Science and Advice for Scottish Agriculture)
- RESAS (Rural Science and Analysis Unit)
- RPID (Rural Payments and Inspections Directorate)
- Natural Heritage Management Policy
- Food Standards Scotland

Public Consultation

A BRIA accompanied a 12 week consultation which was issued 1 November 2016 and closed on 24 January 2017. Consultation was by way of a notice on the SG GM Website and a link was circulated to relevant stakeholders. No informal consultation has taken place.

We received 6 responses to the consultation – 4 from environmental NGOs and 2 from members of the public. All those that responded to the consultation were supportive of SG's plans to transpose the EU Directive.

Business

Prior to/during the consultation, SG held one-to-one conversations with a cross section of the sectors/groups affected (see below). We planned for around 6 – 12 individuals or organisation representatives to be interviewed, in order for SG to establish what impact the proposed amendments to the legislation will have on their business or those of their members.

Options

Two options have been considered – (i) transpose the Directive, or (ii) do not transpose the Directive. Option (i) is preferred because there is a risk the SG would not be able to fulfil its manifesto commitment to opt out of cultivating future EU approved GM crops during the current Parliament. In addition, regardless of whether current or future Scottish Governments decide to use the new powers or not, it is considered best practice to transpose EU Directives.

Sectors and groups affected

- Farming
- Retail sector

- Consumer groups
- Research institutes/trials companies

Benefits

- **Option 1:** Gives SG the option to use the opt out provisions in future, in line with current SG GM policy. Maintains status quo as currently there are no GM crops grown in Scotland.
- **Option 2:** Could argue that in light of EU exit decision, transposition is no longer necessary (this is the view taken by England, Wales and NI). But, SG would not have full powers to support its policy position if there were to be a new application to the EU for cultivation of a GM crop.

Costs

It is difficult to estimate what the effect would be of either allowing to be grown or preventing the cultivation of GM crops. There are too many variables involved to attempt a precise, quantitative analysis. For these reasons it is not proposed to undertake a full, detailed assessment of the potential costs and benefits of using/not using the transposed EU powers. Instead, the following general analysis is considered appropriate.

At present there are six different types of GM crop seed in the pipeline for EU cultivation approval, including one (known as MON 810) for which an existing authorisation is up for renewal (it is these that SG used transitional arrangements to opt out of growing). They are all different varieties of GM maize, which is not a major crop in the UK and particularly not in Scotland due to unfavourable climatic conditions here. In addition, all bar one of these maize varieties are designed to resist insect pests that are not a problem here. This point is illustrated by the situation with MON 810 pest-resistant GM maize. Although approved by the EU in 1998, the seed has not been marketed to UK farmers in recognition that it would have no special utility for them.

However, we have to consider the potential for new applications being made for EU approval of GM crops which would be of potential interest to Scottish farmers. It is not clear when this might happen. Currently it takes five years on average to complete the EU risk assessment process for applications.

The potential impact of either growing or banning a particular GM crop would depend on what type of crop it is e.g. potato, oil seed rape etc; the trait e.g. pest/disease resistance, improved nutritional quality, nitrogen-use efficiency etc; and suitability for Scottish growing conditions. As previously mentioned, it is not possible to say with any certainty what types of GM crop will come forward that would be potentially useful for Scottish farmers. This, in itself, makes it difficult to produce a detailed estimate of possible costs and benefits. That said, some evidence is available which gives a broad indication of the scale of the impact that might be involved:

A 2014 meta-analysis of data available from GM crop impact studies (available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111629>) concluded that, on average, GM crop adoption has increased yields and farmer profits by 22% and 68% respectively, and reduced pesticide use by 37%.

The Potato Council has estimated that controlling potato blight with chemical fungicides costs producers in Great Britain between £39m (with low disease pressure) and £72m (high disease pressure) per annum. GM blight resistant potatoes have been commercialised in the USA and are the subject of research trials in England. If Scottish farmers were able to grow such potatoes then in principle they could forego the disease control costs indicated by the Potato Council, although this would likely be offset in part by the normally higher purchase price of GM seeds.

It should also be pointed out that, despite evidence of higher yields and lower input costs of growing GM crops, there are also potential marketing benefits from Scotland positioning itself as GM crop free. For example, at present, three quarters of Scottish seed potato exports – worth some £60 million per year – require specific confirmation that the products are non-GM. So, allowing GM potatoes or other GM crops to be grown in Scotland could have a hugely damaging economic impact on this important sector.

There is an argument that Scotland cannot compete globally in terms of scale and therefore benefits from producing high quality niche products. Food and drink is one of Scotland's booming sectors which is witnessing continued growth in domestic and export markets. It generated a record turnover of £14.3 billion in 2013, and a Bank of Scotland report "Fresh Opportunities and Growth" forecasts an average turnover growth of 19 per cent by 2020, with many businesses highlighting the importance of Scottish provenance.

Scottish Firms Impact Test

In total we contacted 24 businesses asking them to take part in a Business Regulatory Impact Assessment (BRIA) interview. Following a lengthy process where some contacts either didn't respond or said they were unwilling to take part, 6 interviews were conducted. **For details of the interview questions asked see ANNEX.** To summarise:

Representatives from the following organisations were interviewed:

- SRUC (Scotland's Rural College)
- Scottish Agronomy Ltd
- Scotland Food and Drink
- SCIMAC (Supply Chain Initiative on Modified Agricultural Crops)
- British Society of Plant Breeders
- DLF Seeds Ltd, Broxburn

Some interviewees were more familiar with the GM regulations and the amending Directive than others. The interviews began by providing some context, where necessary, before embarking on the questions.

Most interviewees said that transposition of the Directive would have little or no impact on their business, in the short-term. One mentioned that there were currently no GM crops available that were relevant for Scottish growing conditions. Some spoke of potential positives i.e. if Scotland were to build a strong reputation as a GM-free country and therefore appeal to a particular market.

All interviewees had concerns about the longer term if the Scottish Government decided to use the provisions to opt out of future GM crops that had commercial benefits for Scottish growers. Some held stronger views than others. In general, interviewees said that Scottish farmers, suppliers, consumers and others in the industry would be, or could be, disadvantaged. They talked about the use of the powers potentially limiting opportunities, limiting market choice, making the industry less competitive and adding to costs (of seed and end products) etc.

Some said it could adversely impact upon Scotland as a place to do research and development. Scotland could be seen as anti-innovation and thereby less likely to attract investment in research.

While not a resounding endorsement of the Scottish Government's position on GM cultivation, these views do not alter the objective or rationale for transposing the EU Directive. The objective is, "To transpose the new provisions in the amending Directive so that Scotland can, if it wishes, opt out of cultivating future EU approved GM crops." In other words, use of the powers to opt out is discretionary, not mandatory.

The rationale includes, "SG supports the general principle of Member States having more national discretion in relation to EU decisions – it would therefore not be appropriate to forego transposition of the discretionary powers available in this case." It is considered best practice to transpose EU Directives.

Legal Aid Impact Test

The Scottish Legal Aid Board have confirmed that they do not foresee any impact on the legal aid fund.

Enforcement, sanctions and monitoring

The SSI will be enforced by SG GM inspectorate on behalf of Scottish Ministers. It is intended to create a new type of prohibition notice (a stop notice) under the Environmental Protection Act 1990 and insert a new penalty level which falls within the penalty limitations in section 2(2) of the European Communities Act. These are:

- (a) on summary conviction, to a fine not exceeding level 5 (£5,000) on the standard scale or to imprisonment for a term not exceeding three months, or to both; or
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding 2 years or both.

Criminal Justice Division, the Crown Office and Disclosure Scotland have all been consulted as appropriate and are content.

Implementation and delivery plan

Use of the powers is discretionary so no implementation/delivery plan is required.

- **Post-implementation review**
N/A.

Summary and recommendation

Option 1 is recommended because:

- it meets SG policy on GM crops and maintains the status quo.
- transposing EU Directive is also good practice.
- stakeholders and businesses are, in the main, on board
- as stated, while it is difficult to estimate the effect on costs of either growing or not growing GM crops, due to the number of variables involved and insufficient evidence, the provisions themselves are discretionary giving Scottish Ministers the necessary powers to opt out of GM crops if they so choose.

• Summary costs and benefits table

Option	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1	N/A – see above	
2		
3		
4		

Declaration and publication

The Cabinet Secretary or Minister responsible for the policy (or the Chief Executive of non departmental public bodies and other agencies if appropriate) is required to sign off all BRIAs prior to publication. Use appropriate text from choices below:

• Sign-off for Final BRIAs:

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed: Mairi Gougeon

Date: 03/01/2019

Minister's name – Mairi Gougeon

Minister's title – Minister for Rural Affairs and the Natural Environment

Scottish Government Contact point: Helen Stanley, Ext 49503

ANNEX

General Questions

- 1. What overall impact will transposing the EU Directive into national legislation have on your business?**
- 2. Will this measure benefit your business?**
- 3. If so, in what ways will it benefit your business?**
- 4. Will this measure impose additional costs/burdens on your business?**
- 5. Do you think this measure will adversely impact certain sectors, if so which?**
- 6. Do you think this measure will adversely impact on certain markets, if so, which?**
- 7. How do you think this measure will impact on the wider industry?**

Competition and Markets Authority Questions

- 8. Will the measure directly or indirectly limit the number or range of suppliers?**
- 9. Will the measure limit the ability of suppliers to compete?**
- 10. Will the measure limit suppliers' incentives to compete vigorously?**
- 11. Will the measure limit choices and information available to consumers?**



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Any enquiries regarding this publication should be sent to us at
The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

ISBN: 978-1-78781-520-9 (web only)

Published by The Scottish Government, January 2019

Produced for The Scottish Government by APS Group Scotland, 21 Tennant Street, Edinburgh EH6 5NA
PPDAS521146 (01/19)

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