

TRANSPOSITION NOTE

The Genetically Modified Organisms (Deliberate Release etc.) (Miscellaneous Amendments) (Scotland) Regulations 2019 (“the amending Regulations”) amend the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002 (“the principal Regulations”) to make fresh and supplementary provision to transpose and implement, for Scotland, Directive (EU) 2015/412¹ amending Part D to Directive 2001/18/EC² in relation to the cultivation of genetically modified organisms (GMOs).

In particular, the amending Regulations introduce provisions in the principal Regulations for the inclusion of limits to the geographical scope of consents to market GMOs granted under Directive 2001/18/EC and authorisations to market GMOs for food use or for food granted under Regulation (EC) No 1829/2003 (the Food and Feed Regulation) in respect of the cultivation of those GMOs if so demanded either by the Scottish Ministers or another Member State. They also introduce appropriate investigatory powers, offences and penalties to enforce those limits on the geographical scope of the consent / authorisation.

The amending Regulations also give proper effect to Article 4(5) of Directive 2001/18/EC enabling the Scottish Ministers to take measures necessary to ensure compliance with that Directive introducing appropriate investigatory powers, offences and penalties for marketing GMOs without a consent or non-compliance with the conditions of a consent.

There are also provisions in the amending Regulations which update out of date references in the principal Regulations, the Environmental Protection Act 1990³ (“the 1990 Act”) and the Amendment of the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996. These are not included in the transposition table.

The amendments made by Directive (EU) 2015/412 to Directive 2001/18/EC are transposed as follows:-

Amending regulation	Principal Regulations	Article transposed	Subject
Regulation 8(d)	Inserts regulation 24(7), (8), (9), (10) and (11)	Article 26b(1), (2), (5) and (6)(a) of Directive 2001/18/EC	The amending regulation amends the principal Regulations, to the effect that when making decisions on applications for consent to market GMOs under Part C of Directive 2001/18, the Scottish Ministers must include a limit on the geographic scope for cultivation of GMOs

¹ OJ L 68 13.3.2015, p. 1

² OJ L 106 17.4.2001, p. 1

³ 1990, ch. 43

			corresponding to any demand made by either the Scottish Ministers or another member State. It also permits the variation of a Scottish consent to reintegrate all or part of Scotland or all or part of the territory of another member State.
Regulation 9	Inserts regulation 26(5), (6), (7) and (8)	Article 26b(1), (2), (5) and (6) of Directive 2001/18/EC	The amending regulation amends the principal Regulations as above but in respect of applications for renewals of consent to market.
Regulation 10	Inserts regulations 26A and 26B	Article 26b(1) and (5) of Directive 2001/18/EC	Regulation 26A permits the Scottish Ministers to demand that all or part of Scotland is excluded from an application (specified therein) (i) received by the Scottish Ministers, (ii) received by another administration in the UK or else (ii) otherwise made by another member State, for a consent or authorisation to place on the market a GMO under Part C of Directive 2001/18 or the Food and Feed Regulation, or a renewal of such a consent/authorisation. Regulation 26B allows the Scottish Ministers to request that Scotland be reintegrated into a consent (including a renewed consent) or authorisation) from which it is excluded under regulation 26A.
Regulation 11	Inserts regulation 29A and 29B	Article 26b(3), (4) and (7) and Article 26c(4) of Directive 2001/18/EC	Regulation 29A provides the Scottish Ministers with the power to restrict the cultivation of a GMO in Scotland where they did not make a demand under regulation 26A or where the applicant for consent (under Directive 2001/18) or authorisation (under the Food and Feed Regulation) did not

			<p>agree to a such a demand. There are specified grounds on which the Scottish Ministers can exercise the power (regulation 29(6)). The effect of exercising the power is that:</p> <p>(i) in respect of a consent issued by the Scottish Ministers (under Part C of Directive 2001/18), they may include a condition in the consent limiting the geographical scope as regards cultivation.</p> <p>(ii) in respect of an approved product (as defined in regulation 2 of the principal Regulations), suspend the effect of any consent under Part C of 2001/18 to market the GMO in so far as it relates to cultivation of it in Scotland.</p> <p>(iii) in respect of an authorisation (under the Food and Feed Regulation) suspend the effect of any authorisation to market the GMO in so far as it relates to cultivation of it in Scotland.</p> <p>Regulation 29B allows the Scottish Ministers to vary any of the above in respect to such consents/authorisations.</p>
Regulation 12	Inserts regulation 30A	Article 4(5) of Directive 2001/18/EC	This introduces 'stop notices', a mechanism for Scottish Ministers to prohibit the continuing release or marketing of or cultivating of a GMO.
Regulation 14	Inserts Part VIA – regulations 32A, 32B and 32C	Article 4(5) of Directive 2001/18/EC	The amending regulation provides for the powers of inspectors to investigate, offences for non-compliance and penalties after conviction for non-compliance with a stop notice. This is to fully transpose the requirement at Article 4(5) of the

			Directive 2001/18 to ensure that in the event of an unauthorised release of a GMO necessary measures are taken to terminate the release (Part B) or placing on the market (Part C) of the GMO and initiate remedial action.
Regulation16	Amends Schedule 2, Part 1 and Part 2	Annex II, Annex IIIB and Annex IV, Section A of Directive 2001/18/EC as required by Article 2(1) of Directive (EU) 2018/350	This regulation updates and strengthen the environmental risk assessment of genetically modified organisms, in particular concerning the assessment of long term environmental effects.

Scottish Government
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