
EXPLANATORY NOTE

(This note is not part of the Regulations)

These 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) 2015/412 as regards the possibility for the member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68 13.3.2015, p.1.), which amends Part D (final provisions) of [Directive 2001/18/EC](#) on the deliberate release into the environment of genetically modified organisms (OJ L 106 17.4.2001, p.1) (“the Deliberate Release Directive”).

Regulations 10 and 11 amend regulations 24 and 26 of the principal Regulations for the inclusion of limits to the geographical scope of a consent to market a GMO (including renewals of consent) issued by the Scottish Ministers in respect of cultivation of the GMO to exclude all or part of Scotland where demanded either by the Scottish Ministers or by another member State. There are also provisions therein to vary or remove such limits if required.

Regulation 12 introduces new regulations 26A and 26B into the principal Regulations. Regulation 26A permits the Scottish Ministers to demand of an applicant that all or part of Scotland is excluded from an application made to them, to a competent authority of another part of the UK or to another member State for consent to place on the market a GMO under Part C (placing on the market of GMOs as or in products) of the Deliberate Release Directive (including a renewal of such a consent) or for an authorisation to market genetically modified food or feed under Council Regulation ([EC](#)) [1829/2003](#) on genetically modified food and feed (OJ L 268, 18.10.2003, p.1) (“the Food and Feed Regulation”). Regulation 26B allows the Scottish Ministers to request reintegration of all or part of Scotland into a consent, renewed consent or authorisation.

Regulation 13 introduces new regulations 29A and 29B into the principal Regulations. These provide the Scottish Ministers with the power to restrict consent (including a renewed consent) granted by them or otherwise under the Deliberate Release Directive or authorisation granted by a competent authority under the Food and Feed Regulation where a demand in terms of regulation 26A has not been sought or where an applicant has refused to agree with a demand made under that regulation within 30 days, and where there is a compelling ground to do so.

These Regulations also give effect to Article 4(5) of the Deliberate Release Directive enabling the Scottish Ministers to take measures to ensure compliance with that Directive by introducing investigatory powers, offences and penalties for non-compliance with consents to release or market a GMO granted under Part B or Part C of the Deliberate Release Directive. It also ensures that the Scottish Ministers can take measures to ensure compliance where they have demanded (under regulation 26A) or adopted measures (under regulation 29A) to limit the cultivation of GMOs in Scotland.

In particular, regulation 14 introduces regulation 30A into the principal Regulations which introduces ‘stop notices’. This is a mechanism for the Scottish Ministers to prohibit the continuing release or marketing of or cultivation of a GMO. Regulation 16 thereafter provides the investigatory powers, offences and penalties for non-compliance by introducing Part VIA into the principal Regulations.

Regulation 18 updates schedule 2 of the principal Regulations in order to update and strengthen the environmental risk assessment of genetically modified organisms, in particular concerning the assessment of long term environmental effects.

Draft Legislation: *This is a draft item of legislation. This draft has since been made as a Scottish Statutory Instrument: The Genetically Modified Organisms (Deliberate Release etc.) (Miscellaneous Amendments) (Scotland) Regulations 2019 No. 86*

There are also provisions in these Regulations which update references to other legislation, or remove obsolete provisions, in the principal Regulations (regulations 3(b) to (g), 5, 6, 7(b) and (e), 9, 10(b) and (c), and 17), in the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 (regulations 20 to 22), in the Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004 (regulation 23), and in the Genetically Modified Organisms (Transboundary Movements) (Scotland) Regulations 2005 (regulation 24).